6–6–03 Friday
Vol. 68 No. 109 June 6, 2003

Pages 33831–34260

Federal Register

The **FEDERAL REGISTER** 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.

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 http://www.archives.gov/federal__register/.

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** 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 it includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward.

GPO Access users can choose to retrieve online **Federal Register** documents as TEXT (ASCII text, graphics omitted), PDF (Adobe Portable Document Format, including full text and all graphics), or SUMMARY (abbreviated text) files. Users should carefully check retrieved material to ensure that documents were properly downloaded.

On the World Wide Web, connect to the **Federal Register** at http://www.access.gpo.gov/nara. Those without World Wide Web access can also connect with a local WAIS client, by Telnet to swais.access.gpo.gov, or by dialing (202) 512–1661 with a computer and modem. When using Telnet or modem, type swais, then log in as guest with no password.

For more information about GPO Access, contact the GPO Access User Support Team by E-mail at gpoaccess@gpo.gov; by fax at (202) 512–1262; or call (202) 512–1530 or 1–888–293–6498 (toll free) between 7 a.m. and 5 p.m. Eastern time, Monday–Friday, except Federal holidays.

The annual subscription price for the **Federal Register** paper edition is $699, or $764 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 $264. Six month subscriptions are available for one-half the annual rate. The charge for individual copies in paper form is $10.00 for each issue, or $10.00 for each group of pages as actually bound; or $2.00 for each issue in microfiche form. All prices include regular domestic postage and handling. International customers please add 25% for foreign handling. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard or Discover. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.

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: 68 FR 12345.

Printed on recycled paper.

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**

What's NEW!

Federal Register Table of Contents via e-mail

Subscribe to FEDREGTOC, to receive the **Federal Register** Table of Contents in your e-mail every day.

If you get the HTML version, you can click directly to any document in the issue.

To subscribe, go to **http://listserv.access.gpo.gov** and select:

Online mailing list archives
FEDREGTOC-L
Join or leave the list

Then follow the instructions.

Contents

Federal Register

Vol. 68, No. 109

Friday, June 6, 2003

Separate Parts In This Issue

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.

Rules and Regulations

Federal Register
Vol. 68, No. 109
Friday, June 6, 2003

GENERAL ACCOUNTING OFFICE

4 CFR Part 81

Public Availability of General Accounting Office Records

AGENCY: General Accounting Office.

ACTION: Final rule.

SUMMARY: This rule amends General Accounting Office (GAO) regulations regarding the pubic availability and disclosure of GAO records. The amendments are necessary in order for the GAO to voluntarily adopt certain procedural principles of the Electronic Freedom of Information Act Amendments of 1996. Specifically, the amendments make it clear that the public may request and obtain electronic records under the regulations. Further, they inform the public that GAO published documents may easily be obtained from GAO's Internet Web site. Other minor changes and ''housekeeping'' amendments are made to clarify current policy and to correct titles, addresses, telephone numbers, and the hours of operation of the GAO public reading facility, which is located in the Law Library at the GAO Building. The overall effect of the amendments is for GAO to generally take less time in processing information requests.

DATES: Effective on June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Jeffrey Forman (Assistant General Counsel), 202–512–9763 or 617–788–0546; e-mail: *formanj@gao.gov*.

SUPPLEMENTARY INFORMATION: Over thirty years ago, Congress established a policy of openness toward public disclosure of government information by enacting the Freedom of Information Act (FOIA) (5 U.S.C. 522). Under FOIA, any member of the public may request access to information within control of a federal executive branch agency. GAO is a legislative agency and is, therefore, not subject to the FOIA. Nevertheless, GAO has voluntarily adopted an information disclosure policy that includes many of the procedural principles contained in FOIA. GAO also is not subject to the Electronic Freedom of Information Act Amendments of 1996 (E–FOIA), Public Law 104–231, which amended FOIA to provide greater public access to information maintained in an electronic format. This final rule amends GAO regulations addressing the public availability of GAO records by adopting practices similar to E–FOIA procedures.

GAO adopts only certain procedural features of the FOIA and E–FOIA, as opposed to adopting substantive law. Application of the FOIA and the E–FOIA to the GAO is not to be inferred (4 CFR 81.1). This rule is published as a final rule without notice or an opportunity for comment. The Administrative Procedures Act (APA), 5 U.S.C. 551 *et seq.*, does not apply to GAO. GAO voluntarily follows key principles set forth in the APA, like it voluntarily follows many of the procedural principles set forth in FOIA. Since this rule is procedural in nature, rather than substantive, it is consistent with the principles of the APA for GAO to issue it as a final rule without providing notice and an opportunity for public comment. This has been GAO's past practice as GAO has amended part 81 on previous occasions without soliciting public comment. (See for example 53 FR 50913 (Dec. 19, 1988), 49 FR 38527 (Oct. 1, 1984), and 46 FR 47053 (Sept. 24, 1981).)

Other changes to GAO's records disclosure regulations are made to reflect current GAO policy, practices, and procedures, including but not limited to organizational changes, which resulted in new titles, addresses, telephone numbers, and hours of operation that relate to GAO processing requests for GAO records and documents.

In accordance with the spirit of E–FOIA, a new provision is added to section 81.1 informing the public that GAO publications (testimonies, reports, decisions, and listings of publications) are now expressly included within the scope of the regulations to the extent that the public may readily obtain copies of them from the GAO Web site, *http://www.gao.gov* or from the U.S. General Accounting Office, 441 G Street NW., Room LM, Washington, DC 20548. The address for writing and the telephone numbers for calling GAO to obtain copies of GAO published documents are moved from section 81.2 to section 81.1 for consistency to have all pertinent information for obtaining published documents provided in the same section.

Section 81.2 is updated by correcting the title of the GAO official who has the authority and responsibility for administering the GAO records disclosure program, including issuing necessary supplemental rules and regulations. Paragraph (b) of section 81.3 revises the definition of the term ''records'' to expressly include electronically created or maintained materials. The language is amended to state in plain language that only existing records and records under GAO control are covered.

Recognizing that some requests may have more urgency than others, paragraph (f) is added to § 81.3 to provide a definition of ''compelling need'' for purposes of determining whether to honor requests for expedited processing. Section 81.4 revisions provide requesters with the correct name and address for sending to GAO requests for documents that have not been published. The GAO Internet home page address is also provided so requesters may submit their requests electronically.

Under § 81.4 as it is amended, GAO will respond to a requester by acknowledging or honoring the request within 20 days of receipt. In light of this procedure, the requirement that GAO promptly honor requests when no valid objection exists for withholding the records is no longer necessary and is therefore eliminated. Expedited requests where a requester provides GAO with a certified statement demonstrating a compelling need will be processed before other requests. A 60-day time limit for requesting an administrative appeal of a denial of a request is established. Section 81.5, concerning records originating outside GAO and records involving work in progress, is not changed.

Revisions to section 81.6 clarify and set out in greater detail current GAO policy and practice regarding records exempt from disclosure. In this regard, paragraph (l) is divided into two paragraphs, (l) and (m). Other revisions to section 81.6 reflect changes to

organizational structure by correcting the title of the GAO official with discretion to release exempt records from the Director of Policy to the Chief Quality Officer. The GAO fee schedule set out in section 81.7 is updated to reflect current costs associated with processing requests. Other revisions inform requesters of the recent change in the title of the official responsible for deciding whether a fee should be waived or reduced. Changes to section 81.8 delineate that the GAO's public reading facility is maintained in the GAO Law Library, and its location and hours of operation. The hours of operation for public use of the Law Library are changed to 8:30 a.m. to 4 p.m. GAO's public reading facility was previously open to the public from 8:30 a.m. to 5 p.m. It continues to be closed on Saturdays, Sundays, and holidays.

List of Subjects in 4 CFR Part 81

Administrative practice and procedure, Archives and records, Computer technology, Electronic products, Freedom of information.

■ For the reasons set forth in the preamble, GAO amends Title 4, Chapter I, Subchapter F of the Code of Federal Regulations by revising part 81 to read as follows:

PART 81—PUBLIC AVAILABILITY OF GENERAL ACCOUNTING OFFICE RECORDS

Sec.

Authority: 31 U.S.C. 711.

§ 81.1 Purpose and scope of part.

(a) This part implements the policy of the U.S. General Accounting Office (GAO) with respect to the public availability of GAO records. While GAO is not subject to the Freedom of Information Act (5 U.S.C. 552), GAO's disclosure policy follows the spirit of the act consistent with its duties and functions and responsibility to the Congress. Application of this act to GAO is not to be inferred from the provisions of these regulations.

(b) GAO published testimonies, reports, and decisions or listings of publications are included within the scope of this part to the extent that they may be obtained from the GAO Web site, *http://www.gao.gov,* or from the U.S. General Accounting Office, 441 G Street NW., Room LM, Washington, DC 20548, or phone 202–512–6000, FAX 202–512–6061, TDD 202–512–2537. [Please note that this address is for published GAO documents only, other records requests should be sent to the address provided in section 81.4(a).]

§ 81.2 Administration.

The Chief Quality Officer administers this part and may promulgate such supplemental rules or regulations as may be necessary.

§ 81.3 Definitions.

As used in this part:

(a) *Identifiable* means a reasonably specific description of a particular record sought, such as the date of the record, subject matter, agency or person involved, etc., which will permit location or retrieval of the record.

(b) *Records* includes all books, papers, manuals, maps, photographs, reports, and other documentary materials, regardless of physical form or characteristics, including electronically created or maintained materials, under the control of GAO in pursuance of law or in connection with the transaction of public business. As used in this part, the term ''records'' is limited to an existing record under GAO's control and does not include compiling or procuring records, library or museum material made, acquired, or preserved solely for reference or exhibition purposes, or extra copies of documents preserved only for convenience of reference.

(c) *Records available to the public* means records which may be examined or copied or of which copies may be obtained, in accordance with this part, by the public or representatives of the press regardless of interest and without specific justification.

(d) *Disclose* or *disclosure* means making available for examination or copying, or furnishing a copy.

(e) *Person* includes an individual, partnership, corporation, association, or public or private organization other than a Federal agency.

(f) *Compelling need* means that a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual, or the records are needed urgently, with respect to a request made by a person primarily engaged in disseminating information, for the requester to inform the public concerning actual or alleged Federal Government activity.

§ 81.4 Requests for identifiable records.

(a) A request to inspect or obtain a copy of an identifiable record of GAO must be submitted in writing to the Chief Quality Officer, U.S. General Accounting Office, 441 G Street, NW., Washington, DC 20548. Requests may also be made via a link from GAO's Internet Home page at *http://www.gao.gov.* Requests also may be emailed to *recordsrequest@gao.gov.* The Chief Quality Officer will either acknowledge or honor the request within 20 days of receipt.

(b) The Chief Quality Officer will honor requests for expedited processing before all other requests in cases in which the person requesting the records demonstrates a compelling need. A demonstration of compelling need shall be made by a statement certified by the requester to be true and correct to the best of the requester's knowledge and belief.

(c) In the event of an objection or doubt as to the propriety of providing the requester with a copy of the record sought, every effort will be made to resolve such problems as quickly as possible, including consultation with appropriate GAO elements. If it is determined that the record should be withheld, the Chief Quality Officer shall inform the requester in writing that the request has been denied, shall identify the material withheld, and shall explain the basis for the denial.

(d) A person whose request is denied in whole or part may administratively appeal the denial within 60 days after the date of the denial by submitting a letter to the Comptroller General of the United States at the address listed in paragraph (a) of this section, explaining why the denial of the request was unwarranted.

§ 81.5 Records originating outside GAO, or records involving work in progress.

(a) It is the policy of GAO not to provide records from its files that originate in another agency or nonfederal organization to persons who may not be entitled to obtain the records from the originator. In such instances, requesters will be referred to the person or organization that originated the records.

(b) In order to avoid disruption of work in progress, and in the interests of fairness to those who might be adversely affected by the release of information which has not been fully reviewed to assure its accuracy and completeness, it is the policy of GAO not to provide records which are part of ongoing reviews or other current projects. In response to such requests, GAO will inform the requester of the estimated completion date of the review or project so that the requester may then ask for the records. At that time, the records

may be released unless exempt from disclosure under § 81.6.

§ 81.6 Records which may be exempt from disclosure.

The public disclosure of GAO records contemplated by this part does not apply to records, or parts thereof, within any of the categories listed below. Unless precluded by law, the Chief Quality Officer may nevertheless release records within these categories.

(a) Congressional correspondence and other records relating to work performed in response to a congressional request (unless authorized by the congressional requester), and congressional contact memoranda.

(b) Records specifically required by an Executive Order to be kept secret in the interest of national defense or foreign policy. An example of this category is a record classified under Executive Order 12958, Classified National Security Information.

(c) Records related solely to the internal personnel rules and practices of an agency. This category includes, in addition to internal matters of personnel administration, internal rules and practices which cannot be disclosed without prejudice to the effective performance of an agency function. Examples within the purview of this exemption are guidelines and procedures for auditors, investigators, or examiners, and records concerning an agency's security practices or procedures.

(d) Records specifically exempted from disclosure by statute provided that such statute:

(1) Requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or

(2) Establishes particular criteria for withholding or refers to particular types of matters to be withheld.

(e) Records containing trade secrets and commercial or financial information obtained from a person that are privileged or confidential. This exemption may include, but is not limited to, business sales statistics, inventories, customer lists, scientific or manufacturing processes or development information.

(f) Personnel and medical files and similar files the disclosure of which could constitute a clearly unwarranted invasion of personal privacy. This exemption excludes from disclosure all personnel and medical files, and all private or personal information contained in other files, which, if disclosed to the public, would amount to a clearly unwarranted invasion of the privacy of any person. An example of such other files within the exemption would be files compiled to evaluate candidates for security clearance.

(g) Records and information compiled for law enforcement purposes.

(h) Records having information contained in or related to examination, operation, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions.

(i) Records containing geological and geophysical information and data (including maps) concerning wells.

(j) Inter-agency or intra-agency memoranda, letters, or other materials that are part of the deliberative process. For example, this exemption includes internal communications such as GAO or other agency draft reports, and those portions of internal drafts, memoranda and workpapers containing opinions, recommendations, advice, or evaluative remarks of GAO employees. This exemption seeks to avoid the inhibiting of internal communications, and the premature disclosure of documents which would be detrimental to an agency decision making.

(k) Records in addition to those described in paragraph (j) of this section containing information customarily subject to protection as privileged in a court or other proceedings, such as information protected by the doctor-patient, attorney-work product, or lawyer-client privilege.

(l) Records GAO has obligated itself not to disclose, including but not limited to, records for which GAO officials have made a pledge of confidentiality, and records the release of which would adversely impact significant property interests or negatively affect public safety.

(m) Unsolicited records containing information submitted by any person to GAO in confidence. An example of records covered by this exemption would be information obtained by the GAO Office of General Counsel (GAO FraudNET).

§ 81.7 Fees and charges.

(a) No fee or charge will be made for:

(1) Records provided under this part when the direct costs involve less than one hour of search time and 50 pages of photocopying.

(2) Staff-hours spent in resolving any legal or policy questions pertaining to the request.

(3) Copies of records, including those certified as true copies, furnished for official use to a federal government officer or employee.

(4) Copies of pertinent records furnished to a party having a direct and immediate interest in a matter pending before GAO, when necessary or desirable to the performance of a GAO function.

(b) The fees and charges described below will be assessed for the direct costs of search, review, and reproduction of records available to the public under this part.

(1) The cost for reproduction per page shall be 20 cents.

(2) The cost for a certification of authenticity shall be $10 for each certificate.

(3) Manual search and review for records by office personnel will be assessed at $12, $25, or $45 per hour, depending on the rate of pay of the individual actually conducting the search or review, and the complexity of the search.

(4) Other direct costs related to the request may be charged for such items as computer searches.

(5) Except as noted immediately below, requesters generally will be charged only for document duplication. However, there may be times when a search charge will be added, for example, if records are not described with enough specificity to enable them to be located within one hour. Requesters seeking records for commercial use will be charged for document duplication, search, and review costs. Additionally, representatives of the news media, in support of a news gathering or dissemination function, and education or noncommercial scientific institutions not seeking records for commercial use will be charged only for document duplication, unless such request requires extraordinary search or review.

(c) GAO shall notify the requester if an advance deposit is required.

(d) Fees and charges shall be paid by check or money order payable to the U.S. General Accounting Office.

(e) The Chief Quality Officer may waive or reduce the fees under this section upon a determination that disclosure of the records requested is in the public interest, is likely to contribute significantly to public understanding of the operations or activities of the government, and is not primarily in the commercial interest of the requester. Persons seeking a waiver or fee reduction may be required to submit a statement setting forth the intended purpose for which the records are requested, indicate how disclosure will primarily benefit the public and, in appropriate cases, explain why the volume of records requested is necessary. Determinations pursuant to this paragraph are solely within the discretion of GAO.

§ 81.8 Public reading facility.

GAO maintains a public reading facility in the Law Library at the General Accounting Office Building, 441 G Street, NW., Washington, DC. The facility shall be open to the public from 8:30 a.m. to 4 p.m. except Saturday, Sundays, and holidays.

Anthony H. Gamboa,

General Counsel, General Accounting Office.

[FR Doc. 03–14304 Filed 6–5–03; 8:45 am]

BILLING CODE 1610–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM256, Special Conditions No. 25–236–SC]

Special Conditions: Raytheon Model HS.125 Series 700A and 700B Airplanes; High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for Raytheon Model HS.125 Series 700A and 700B airplanes modified by Raytheon Aircraft Services, Inc. These modified airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. The modification incorporates the installation of a Rockwell Collins AFD 2000 Electronic Flight Instrument System (EFIS) that performs critical functions. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for the protection of this system from the effects of high-intensity radiated fields (HIRF). These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that provided by the existing airworthiness standards.

DATES: The effective date of these special conditions is May 22, 2003. Comments must be received on or before July 7, 2003.

ADDRESSES: Comments on these special conditions may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attn: Rules Docket (ANM 113), Docket No. NM256, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; or delivered in duplicate to the Transport Airplane Directorate at the above address. All comments must be marked: Docket No. NM256.

FOR FURTHER INFORMATION CONTACT: Connie Beane, FAA, Standardization Branch, ANM–113, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; telephone (425) 227–2796; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA has determined that notice and opportunity for public comment in accordance with 14 CFR 11.38 are unnecessary, because the FAA has provided previous opportunities to comment on substantially identical special conditions and has fully considered and addressed all the substantive comments received. Based on a review of the comment history and the comment resolution, the FAA is satisfied that new comments are unlikely. The FAA, therefore, finds that good cause exists for making these special conditions effective upon issuance.

However, the FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning these special conditions. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m., and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we received.

If you want the FAA to acknowledge receipt of your comments on these special conditions, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On September 23, 2002, Raytheon Aircraft Services, Inc., 1115 Paul Wilkins Road, San Antonio, Texas 78216, applied for a supplemental type certificate (STC) to modify Raytheon Model HS.125 Series 700A and 700B airplanes. These models are currently approved under Type Certificate No. A3EU. The HS.125 Series 700A and 700B airplanes are two flightcrew, two-engine airplanes, each with a maximum takeoff weight of 25,500 lbs. The modification incorporates the installation of a Rockwell Collins AFD 2000 EFIS. This equipment will replace the equipment originally installed in these airplanes which presents the required flight information in the form of analog displays. The avionics/electronics and electrical system to be installed has the potential to be vulnerable to high-intensity radiated fields (HIRF) external to the airplane.

Type Certification Basis

Under the provisions of 14 CFR 21.101, Amendment 21–69, effective September 16, 1991, Raytheon Aircraft Services, Inc. must show that the modified Model HS.125 Series 700A and 700B airplanes, as modified, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A3EU, or the applicable regulations in effect on the date of application for the change. Subsequent changes have been made to § 21.101 as part of Amendment 21–77, but those changes do not become effective until June 10, 2003. The regulations incorporated by reference in the type certificate are commonly referred to as the ''original type certification basis.''

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, part 25, as amended) do not contain adequate or appropriate safety standards for the Model HS.125 Series 700A and 700B airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Raytheon Model HS.125 Series 700A and 700B airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

Special conditions, as defined in 14 CFR 11.19, are issued in accordance with § 11.38 and become part of the type certification basis in accordance with § 21.101(b)(2), Amendment 21–69, effective September 16, 1991.

Special conditions are initially applicable to the model for which they are issued. Should Raytheon Aircraft Services, Inc. apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate A3EU to incorporate the same or similar novel or unusual design feature, these special conditions would also apply to the other model under the provisions of § 21.101(a)(1), Amendment 21–69, effective September 16, 1991.

Novel or Unusual Design Features

As noted earlier, the Raytheon Model HS.125 Series 700A and 700B airplanes modified by Raytheon Aircraft Services, Inc. will incorporate an EFIS that will perform critical functions. This system may be vulnerable to high-intensity radiated fields external to the airplane. The current airworthiness standards of part 25 do not contain adequate or appropriate safety standards for the protection of this equipment from the adverse effects of HIRF. Accordingly, this system is considered to be a novel or unusual design feature.

Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive avionics/electronics and electrical systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for the Raytheon Model HS.125 Series 700A and 700B airplanes modified by Raytheon Aircraft Services, Inc. These special conditions require that new avionic/electronic and electrical systems that perform critical functions be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters and the advent of space and satellite communications coupled with electronic command and control of the airplane, the immunity of critical digital avionic/electronic and electrical systems to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraph 1 or 2 below:

1. A minimum threat of 100 volts rms (root-mean-square) per meter electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the field strengths indicated in the following table for the frequency ranges indicated. Both peak and average field strength components from the table are to be demonstrated.

Frequency	Field strength (volts per meter)	
	Peak	Average
10 kHz–100 kHz	50	50
100 kHz–500 kHz	50	50
500 kHz–2 MHz	50	50
2 MHz–30 MHz	100	100
30 MHz–70 MHz	50	50
70 MHz–100 MHz	50	50
100 MHz–200 MHz	100	100
200 MHz–400 MHz	100	100
400 MHz–700 MHz	700	50
700 MHz–1 GHz	700	100
1 GHz–2 GHz	2000	200
2 GHz–4 GHz	3000	200
4 GHz–6 GHz	3000	200
6 GHz–8 GHz	1000	200
8 GHz–12 GHz	3000	300
12 GHz–18 GHz	2000	200
18 GHz–40 GHz	600	200

The field strengths are expressed in terms of peak of the root-mean-square (rms) over the complete modulation period.

The threat levels identified above are the result of an FAA review of existing studies on the subject of HIRF, in light of the ongoing work of the Electromagnetic Effects Harmonization Working Group of the Aviation Rulemaking Advisory Committee.

Applicability

As discussed above, these special conditions are applicable to Raytheon Model HS.125 Series 700A and 700B airplanes modified by Raytheon Aircraft Services, Inc. Should Raytheon Aircraft Services, Inc. apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate A3EU to incorporate the same or similar novel or unusual design feature, these special conditions would apply to that model as well as under the provisions of § 21.101(a)(1), Amendment 21–69, effective September 16, 1991.

Conclusion

This action affects only certain novel or unusual design features on the Raytheon Model HS.125 Series 700A and 700B airplanes modified by Raytheon Aircraft Services, Inc. It is not a rule of general applicability and affects only the applicant which applied

to the FAA for approval of these features on the airplane.

The FAA has determined that notice and opportunity for public comment in accordance with 14 CFR 11.38 are unnecessary, because the FAA has provided previous opportunities to comment on substantially identical special conditions and has fully considered and addressed all the substantive comments received. Based on a review of the comment history and the comment resolution, the FAA is satisfied that new comments are unlikely. The FAA, therefore, finds that good cause exists for making these special conditions effective upon issuance.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and record keeping requirements.

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the supplemental type certification basis for the Raytheon Model HS.125 Series 700A and 700B airplanes modified by Raytheon Aircraft Services, Inc.

1. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high intensity radiated fields.

2. For the purpose of these special conditions, the following definition applies: *Critical Functions:* Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on May 22, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–14336 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM255; Special Conditions No. 25–03–04–SC]

Special Conditions: Bombardier Model BD–100–1A10 Airplane; Automatic Takeoff Thrust Control System

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Bombardier Model BD–100–1A10 airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is associated with an Automatic Takeoff Thrust Control System (ATTCS). The applicable airworthiness regulations do not contain adequate or appropriate safety standards for approach climb performance using an ATTCS. These special conditions contain the additional safety standards the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is May 28, 2003.

Comments must be received on or before July 7, 2003.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attention: Rules Docket (ANM–113), Docket No. NM255, 1601 Lind Avenue SW., Renton, Washington 98055–4056; or delivered in duplicate to the Transport Airplane Directorate at that address. You must mark your comments: Docket No. NM255. Comments may be inspected in the Rules Docket at that address on weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Larry Reising, FAA, Propulsion/Mechanical Systems Branch, Transport Airplane Directorate, Aircraft Certification Office, ANM–112, 1601 Lind Avenue SW., Renton, Washington, telephone (425) 227–2683; fax (425) 227–2683.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice and opportunity for prior public comment hereon are impracticable, because those procedures would significantly delay issuance of the approval design and thus delivery of the affected aircraft. In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA, therefore, finds that good cause exists for making these special conditions effective upon issuance.

Comments Invited

The FAA has determined that notice and opportunity for public comment in accordance with 14 CFR 11.38 are unnecessary, because the FAA has provided previous opportunities to comment on substantially identical special conditions and has fully considered and addressed all the substantive comments received. Based on a review of the comment history and the comment resolution, the FAA is satisfied that new comments are unlikely. The FAA, therefore, finds that good cause exists for making these special conditions effective upon issuance.

However, the FAA invites interested persons to participate in this rulemaking by submitting written comments, data, and views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive as well as a report summarizing each substantive public contact with the FAA personnel concerning these proposed special conditions. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this notice between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change the special conditions based on the comments we receive.

If you want the FAA to acknowledge receipt of your comments on these special conditions, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On March 26, 1999, Bombardier Aerospace submitted an application to

Transport Canada for type certification of the Bombardier Model BD–100–1A10. On June 28, 1999, Transport Canada made application on behalf of Bombardier for type certification of the Model BD–100–1A10 by the FAA. The Bombardier Model BD–100–1A10 will be type certificated in Canada and in the United States. The Model BD–100–1A10 is a medium-sized transport category airplane, powered by two Allied Signal high bypass turbofan engines mounted on the aft fuselage. Each engine can deliver up to 6,500 pounds of thrust at takeoff. The airplane will be capable of operating with two flight crewmembers and up to 16 passengers.

The Bombardier Model BD–100–1A10 airplane will incorporate an unusual design feature to show compliance with the approach climb requirements of § 25.121(d) (''Climb: One-engine-inoperative''). This design feature is the Automatic Takeoff Thrust Control System (ATTCS). Appendix I to Title 14, Code of Federal Regulations (CFR), part 25, limits the application of performance credit for ATTCS to takeoff. Since the airworthiness regulations do not contain appropriate safety standards for approach climb performance using ATTCS, special conditions are required to ensure a level of safety equivalent to that established in the regulations.

Type Certification Basis

Under the provisions of § 21.17, Bombardier must show that Bombardier Model BD–100–1A10 meets the applicable provisions of 14 CFR part 25, effective February 1, 1965, including amendments 25–1 through 25–98.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, part 25, as amended) do not contain adequate or appropriate safety standards for the Bombardier Model BD–100–1A10 airplane because of novel or unusual design features, special conditions are prescribed under the provisions of § 21.16.

The certification basis also may include later amendments to part 25 that are not relevant to these special conditions. In addition, the certification basis for the Bombardier Model BD–100–1A10 airplane includes the following:

- 14 CFR part 34, effective September 10, 1990, including amendment 34, effective February 3, 1999, and
- 14 CFR part 36, effective December 1, 1969, including amendments 36–1 through 36–23 or through 36–24, as elected by the applicant.

These special conditions form an additional part of the type certification basis. The certification basis also may include other special conditions that are not relevant to these specific special conditions.

If the Administrator finds that the applicable airworthiness regulations (in this case, part 25) do not contain adequate or appropriate safety standards for the Bombardier Model because of a novel or unusual design feature, the FAA may prescribe special conditions under the provisions of § 21.16 (''Special conditions''). The special conditions become part of the type certification basis in accordance with § 21.101(b)(2) (''Designation of applicable regulations'').

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Novel or Unusual Design Features

As stated previously, the Bombardier Model BD–100–1A10 airplane will incorporate an unusual design feature—ATTCS—to show compliance with the approach climb requirements of § 25.121(d). This airplane is powered by two Allied Signal turbofan engines mounted on the aft fuselage and equipped with Full Authority Digital Engine Controls (FADEC) that, in part, protect against exceeding engine limits.

The airplane also incorporates a non-moving throttle system that functions by placing the throttle levers in detents for the takeoff and climb phases of flight or for a go-around; this throttle system allows the FADEC to schedule the power setting, based on the phase of flight. With the ATTCS and associated systems functioning as designed, all applicable requirements of part 25 will be met without requiring any action by the flight crew to increase power.

Automatic takeoff power control on the Bombardier Model BD–100–1A10 airplane involves uptrimming the operating engine to maximum takeoff power. This action will be controlled by the FADEC. At takeoff, when the power levers are set to the Takeoff Go-Around (TOGA) detent, if there are no FADEC fault or failure messages displayed, the system is armed, and ATTCS uptrim will occur without any further action by the crew if an engine fails. During a go-around, the uptrim is automatically armed.

For a go-around, the thrust levers are placed in the TOGA detent. The value of TOGA for the current ambient conditions will be calculated and set by the FADEC. If an engine fails, the ATTCS will change the power reference on the operating engine to achieve the maximum go-around power for the ambient conditions. The propulsive thrust used to determine compliance with the approach climb requirements of § 25.121(d) is limited to the lesser of (i) the thrust provided by the ATTCS system, and (ii) 111 percent of the thrust resulting from the initial thrust setting with the ATTCS system failing to perform its uptrim function and without action by the crew to reset thrust. This requirement serves to limit the performance effects of an ATTCS system failure and ensures that all-engines-operating go-around performance is not significantly degraded.

The engine operating limits (turbine temperature and N1) for TOGA are set and displayed to the pilot when that rating is selected. These limits are set in such a way that the engine redline limits are not exceeded when an ATTCS is engaged. When the maximum takeoff power rating is selected or triggered, the engine limits are reset automatically to reflect the uptrimmed engine redline limits.

The system is armed during all phases of the flight. The power levers will continue to function normally if the ATTCS should fail. Maximum takeoff/go-around power is available if the pilot elects to push the power levers past the takeoff/go-around power detent into the overtravel range.

Operations of all systems and equipment will be designed to function within the engine power range. Thrust increase from the initial to the maximum approved takeoff/go-around power level will be free of hazardous engine response characteristics.

The ATTCS function, as described above, is part of the powerplant control system. The ATTCS is always armed whenever power levers are above the idle detent. The system is verified before each flight via the FADEC built-in test feature. When the ATTCS is triggered following an engine failure, an ''APR'' message will appear on the engine display.

The FADEC installed on the Bombardier Model BD–100–1A10 airplane will ensure that inherent flight characteristics of the airplane do provide adequate warning, if an engine failure occurs during takeoff. The natural yawing tendency of the airplane, coupled with flashing master warning and master caution lights, will provide

the pilot with a clear indication of any engine failure during takeoff.

The part 25 standards for ATTCS, contained in § 25.904 (Automatic takeoff thrust control system (ATTCS)'') and Appendix I, specifically restrict performance credit for ATTCS to takeoff. Expanding the scope of the standards to include other phases of flight, such as go-around, was considered at the time the standards were issued, but flight crew workload issues precluded further consideration. As stated in the preamble to amendment 25–62:

> In regard to ATTCS credit for approach climb and go-around maneuvers, current regulations preclude a higher thrust for the approach climb [§ 25.121(d)] than for the landing climb (§ 25.119). The workload required for the flightcrew to monitor and select from multiple in-flight thrust settings in the event of an engine failure during a critical point in the approach, landing, or go-around operations is excessive. Therefore, the FAA does not agree that the scope of the amendment should be changed to include the use of ATTCS for anything except the takeoff phase.'' (Refer to 52 FR 43153, November 9, 1987.)

The ATTCS incorporated on the Bombardier Model BD–100–1A10 airplane allows the pilot to use the same power setting procedure during a go-around, regardless of whether or not an engine fails. In either case, the pilot obtains go-around power by moving the throttles into the forward (takeoff/go-around) throttle detent. Since the ATTCS is permanently armed, it will function automatically following an engine failure, and advance the remaining engine to the ATTCS thrust level. Therefore, this design adequately addresses the pilot workload concerns identified in the preamble to amendment 25–62.

Accordingly, these special conditions will require a showing of compliance with those provisions of § 25.904 and Appendix I that are applicable to the approach climb and go-around maneuvers.

The definition of a critical time interval for the approach climb case, during which time it must be extremely improbable to violate a flight path based on the gradient requirement of § 25.121(d), is of primary importance. That gradient requirement implies a minimum one-engine-inoperative flight path capability with the airplane in the approach configuration. The engine may have been inoperative before initiating the go-around, or it may become inoperative during the go-around. The definition of the critical time interval must consider both possibilities.

Applicability

As discussed above, these special conditions are applicable to the Bombardier Model BD–100–1A10 airplane. Should Bombardier apply later for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well under the provisions of § 21.101(a)(1), Amendment 21–69, effective September 16, 1991.

Conclusion

This action affects only certain novel or unusual design features on the Bombardier Model BD–100–1A10 airplane. It is not a rule of general applicability and affects only the applicant that applied to the FAA for approval of these features on the airplane.

The substance of these special conditions has been subjected to the notice and public comment process in several prior instances, and has been derived without substantive change from those special conditions previously issued. It is unlikely that prior public comment on this action would result in a significant change from the substance contained in this document. For this reason, and because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Bombardier Model BD–100–1A10 airplane.

1. *General.* An Automatic Takeoff Thrust Control System (ATTCS) is defined as the entire automatic system, including all devices, both mechanical and electrical that sense engine failure, transmit signals, actuate fuel controls or power levers, or increase engine power by other means on operating engines to achieve scheduled thrust or power increases and furnish cockpit information on system operation.

2. *ATTCS.* The engine power control system that automatically resets the power or thrust on the operating engine (following engine failure during the approach for landing) must comply with the following requirements stated in paragraphs 2.a, 2.b, and 2.c:

a. *Performance and System Reliability Requirements.*

(1) The probability analysis must include consideration of ATTCS failure occurring after the time at which the flightcrew last verifies that the ATTCS is in a condition to operate until the beginning of the critical time interval.

(2) The propulsive thrust obtained from the operating engine after failure of the critical engine during a go-around used to show compliance with the one-engine-inoperative climb requirements of § 25.12(d) may not be greater than the lesser of:

(i) The actual propulsive thrust resulting from the initial setting of power or thrust controls with the ATTCS system functioning; or

(ii) 111 percent of the propulsive thrust resulting from the initial setting of power or thrust controls with the ATTCS system failing to reset thrust or power and without any action by the crew to reset thrust or power.

b. *Thrust or Power Setting.*

(1) The initial thrust or power setting on each engine at the beginning of the takeoff roll or go-around may not be less than any of the following:

(i) That required to permit normal operation of all safety-related systems and equipment dependent upon engine thrust or power lever position; and

(ii) That shown to be free of hazardous engine response characteristics and not to result in any unsafe aircraft operating or handling characteristics when thrust or power is increased from the initial takeoff or go-around thrust or power to the maximum approved takeoff thrust or power.

(2) For approval of an ATTCS system for go-around, the thrust or power setting procedure must be the same for go-arounds initiated with all engines operating as for go-arounds initiated with one engine inoperative.

c. *Powerplant Controls.* In addition to the requirements of § 25.1141, no single failure or malfunction, or probable combination thereof, of the ATTCS, including associated systems, may cause the failure of any powerplant function necessary for safety. The ATTCS must be designed to:

(1) Apply thrust or power on the operating engine(s), following any one engine failure during takeoff or go-around, to achieve the maximum

approved takeoff thrust or power without exceeding engine operating limits; and

(2) Provide a means to verify to the flightcrew before takeoff and before beginning an approach for landing that the ATTCS is in a condition to operate.

3. *Critical Time Interval.* The definition of the Critical Time Interval in appendix I, § I25.2(b) shall be expanded to include the following:

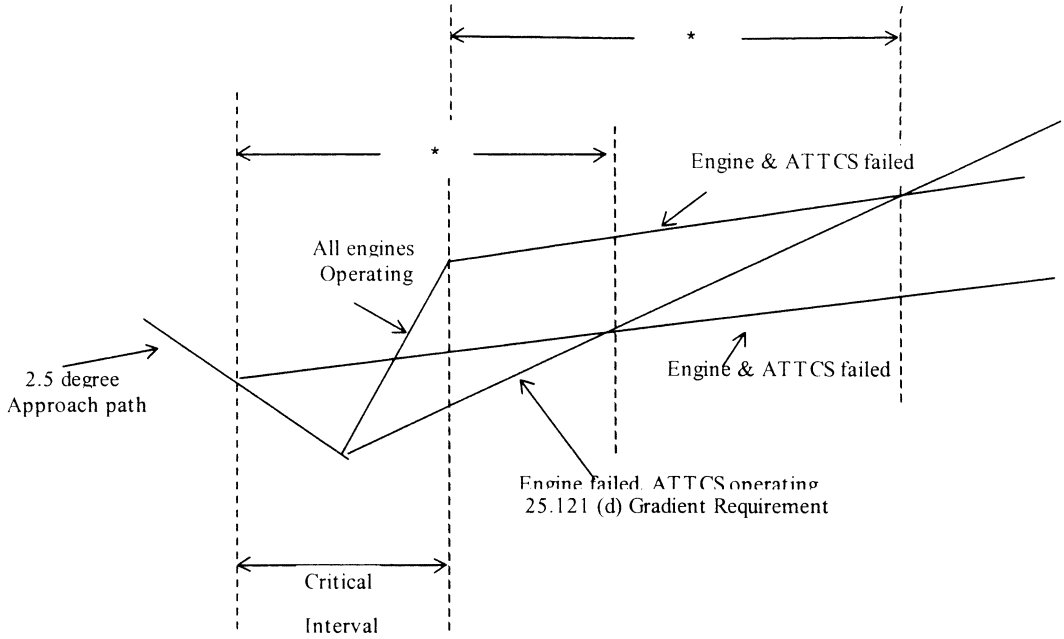
a. When conducting an approach for landing using ATTCS, the critical time interval is defined as follows:

(1) The critical time interval begins at a point on a 2.5 degree approach glide path from which, assuming a simultaneous engine and ATTCS failure, the resulting approach climb flight path intersects a flight path originating at a later point on the same approach path corresponding to the part 25 one-engine-inoperative approach climb gradient. The period of time from the point of simultaneous engine and ATTCS failure to the intersection of these flight paths must be no shorter than the time interval used in evaluating the critical time interval for takeoff beginning from the point of simultaneous engine and ATTCS failure and ending upon reaching a height of 400 feet.

(2) The critical time interval ends at the point on a minimum performance, all-engines-operating go-around flight path from which, assuming a simultaneous engine and ATTCS failure, the resulting minimum approach climb flight path intersects a flight path corresponding to the part 25 minimum one-engine-inoperative approach climb gradient. The all-engines-operating go-around flight path and the part 25 one-engine-inoperative approach climb gradient flight path originate from a common point on a 2.5 degree approach path. The period of time from the point of simultaneous engine and ATTCS failure to the intersection of these flight paths must be no shorter than the time interval used in evaluating the critical time interval for the takeoff beginning from the point of simultaneous engine and ATTCS failure and ending upon reaching a height of 400 feet.

b. The critical time interval must be determined at the altitude resulting in the longest critical time interval for which one-engine-inoperative approach climb performance data are presented in the Airplane Flight Manual (AFM).

c. The critical time interval is illustrated in the following figure:



* The engine and ATTCS failed time interval must be no shorter than the time interval from the point of simultaneous engine and ATTCS failure to a height of 400 feet used to comply with 125.2(b) for ATTCS use during takeoff.

Issued in Renton, Washington, on May 28, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–14337 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–CE–53–AD; Amendment 39–13176; AD 2003–11–17]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Models PC–12 and PC–12/45 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain Pilatus Aircraft Ltd. (Pilatus) Models PC–12 and PC–12/45 airplanes. This AD requires you to inspect the front and rear surfaces of the pressure dome for damage and cracks, and, if necessary, accomplish repairs. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Switzerland. The actions specified by this AD are intended to detect and correct damage and cracks to the pressure dome, which could lead to rapid decompression.

DATES: This AD becomes effective on July 28, 2003.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of July 28, 2003.

ADDRESSES: You may get the service information referenced in this AD from Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; telephone: +41 41 619 63 19; facsimile: +41 41 619 6224; or from Pilatus Business Aircraft Ltd., Product Support Department, 11755 Airport Way, Broomfield, Colorado 80021; telephone: (303) 465–9099; facsimile: (303) 465–6040. You may view this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2002–CE–53–AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

What Events Have Caused This AD?

The Federal Office for Civil Aviation (FOCA), which is the airworthiness authority for Switzerland, recently notified FAA that an unsafe condition may exist on certain Pilatus Models PC–12 and PC–12/45 airplanes. The FOCA reports that drill and/or rivet tool damage could have occurred in areas around the edges of the rear pressure dome during assembly of the Models PC–12 and PC–12/45 airplanes.

Pilatus has received 19 reports of damaged pressure domes. The reported damage included nicks and scratches. This type of damage could also occur on the forward surface of the pressure dome.

Has FAA Taken Any Action to This Point?

We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Pilatus Models PC–12 and PC–12/45 airplanes. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on January 14, 2003 (68 FR 1802). The NPRM proposed to require you to inspect the front and rear surfaces of the pressure dome for damage and cracks, and, if necessary, accomplish repairs.

What Is the Potential Impact if FAA Took No Action?

The damage to the pressure dome could result in cracks in the pressure dome and lead to rapid decompression.

Was the Public Invited To Comment?

The FAA encouraged interested persons to participate in the making of this amendment. The following presents the comment received on the proposal and FAA's response to the comment:

Comment Issue: How To Obtain a Repair Scheme Is Unclear

What Is the Commenter's Concern?

The commenter states that the current wording in the proposed AD is incorrect and implies that the repair scheme will come from FAA. Additionally, the commenter states that the repair scheme will come from the manufacturer; FAA will provide approval of the repair.

What Is FAA's Response to the Concern?

We do not concur that the current wording of the proposed AD is incorrect. Since the service information, which is referenced in the proposed AD, does not address repairs for this type of damage, FAA has to individually approve each repair as needed. This gives the manufacturer the option to develop other generic repair procedures, which were not developed at the time of the NPRM, for this type of damage and submit them to FAA for approval. Therefore, we have not changed the final rule AD based on this comment.

FAA's Determination

What Is FAA's Final Determination on This Issue?

We carefully reviewed all available information related to the subject presented above and determined that air safety and the public interest require the adoption of the rule as proposed except for the changes discussed above and minor editorial questions. We have determined that these changes and minor corrections:

—Provide the intent that was proposed in the NPRM for correcting the unsafe condition; and

—Do not add any additional burden upon the public than was already proposed in the NPRM.

Cost Impact

How Many Airplanes Does This AD Impact?

We estimate that this AD affects 280 airplanes in the U.S. registry.

What Is the Cost Impact of This AD on Owners/Operators of the Affected Airplanes?

We estimate the following costs to accomplish the inspection:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
8 workhours × $60 per hour = $480	No parts required	$480	$480 × 280 = $134,400.

We estimate the following costs to accomplish any necessary repairs that would be required based on the results of the inspection. We have no way of determining the number of airplanes that may need such repair:

Labor cost	Parts cost	Total cost per airplane
16 workhours × $60 per hour = $960	No parts required	$960.

Compliance Time of This AD

What Will Be the Compliance Time of This AD?

The compliance time of this AD is within 90 days after the effective date of this AD, unless already accomplished.

Why Is the Compliance Time Presented in Calendar Time Instead of Hours Time-in-Service (TIS)?

Failure of the pressure dome is only unsafe during airplane operation. However, this unsafe condition is not a result of the number of times the airplane is operated. The chance of this situation occurring is the same for an airplane with 10 hours TIS as it would be for as airplane with 500 hours TIS. For this reason, FAA has determined that a compliance based on calendar time will be utilized in this AD in order to assure that the unsafe condition is addressed on all airplanes in a reasonable time period.

Regulatory Impact

Does This AD Impact Various Entities?

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

Does This AD Involve a Significant Rule or Regulatory Action?

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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. FAA amends § 39.13 by adding a new AD to read as follows:

2003–11–17 Pilatus Aircraft Company Ltd.: Amendment 39–13176; Docket No. 2002–CE–53–AD.

(a) *What airplanes are affected by this AD?* This AD affects Models PC–12 and PC–12/45 airplanes, that are certificated in any category, with the following serial numbers: 101 through 380, 382 through 385, 387 through 395, 398 through 406, 408, 409, 413, 415, and 417.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct damage and cracks to the pressure dome, which could lead to rapid decompression.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
(1) Inspect the pressure dome for nick/scratch damage.	Within the next 90 days after July 28, 2003 (the effective date of this AD), unless already accomplished.	In accordance with Pilatus Aircraft Ltd. PC–12 Service Bulletin No. 53–003, Revision 1, dated July 26, 2002, and the applicable maintenance manual.
(2) If during the inspection required by paragraph (d)(1) of this AD, type ''A'' or ''B'' nick/scratch damage (as specified in the service information) is found, accomplish repairs.	Prior to further flight after the inspection in which the type ''A'' or ''B'' nick/scratch damage is found.	In accordance with Pilatus Aircraft Ltd. PC–12 Service Bulletin No. 53–003, Revision 1, dated July 26, 2002, and the applicable maintenance manual.
(3) If any nick or scratch is found that is more than 0.008 inches (0.2 millimeter) during the inspection required in paragraph (d)(1) of this AD, then you have type ''C'' damage and you must: (i) Use a 10X magnified visual inspection to inspect for cracks. (ii) You may fly the airplane pressurized with type ''C'' damage for 90 days or 600 takeoff/landings after the type ''C'' damage is found, whichever occurs first. (iii) After the 90 days or 600 takeoff/landings (whichever occurs first), to fly pressurized, you must do one of the following:	Inspect for cracks prior to further flight and every 10 hours TIS thereafter. Obtain an FAA approval before further flight, if cracks are found. An FAA approval is required to fly pressurized beyond 90 days or 600 landings/takeoffs, whichever occurs first, from the date of the type ''C'' damage finding.	In accordance with Pilatus Aircraft Ltd. PC–12 Service Bulletin No. 53–003, Revision 1, dated July 26, 2002, and the applicable maintenance manual.

Actions	Compliance	Procedures
(A) Incorporate an FAA-approved repair scheme obtained from the manufacturer; or (B) Fly the airplane ''unpressurized only'' and continue to inspect for cracks every 10 hours TIS. (iv) If any crack is found during an inspection required by paragraph (d)(3), the airplane may not be utilized until an FAA-approved repair scheme (obtained from the manufacturer) is incorporated.		

Note 1: As earlier specified in this AD, flight is not permitted if crack damage is found.

Note 2: As earlier specified in this AD, FAA approval is required to fly pressurized beyond 90 days or 600 takeoffs/landings, whichever occurs first, from date of repair for type ''C'' damage.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Standards Office Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Standards Office Manager.

Note 3: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Pilatus Aircraft Ltd. PC–12 Service Bulletin No. 53–003, Revision 1, dated July 26, 2002. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You may get copies from Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; telephone: +41 41 619 63 19; facsimile: +41 41 619 6224; or from Pilatus Business Aircraft Ltd., Product Support Department, 11755 Airport Way, Broomfield, Colorado 80021; telephone: (303) 465–9099; facsimile: (303) 465–6040. You may view copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in Swiss AD Number HB 2002–608, dated November 1, 2002.

(i) *When does this amendment become effective?* This amendment becomes effective on July 28, 2003.

Issued in Kansas City, Missouri, on May 27, 2003.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13793 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–102–AD; Amendment 39–13184; AD 2003–11–24]

RIN 2120–AA64

Airworthiness Directives; Dornier Model 328–100 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to all Dornier Model 328–100 series airplanes. This action requires installation of retainers instead of washers in the upper and lower torsion bars of the rudder tab. This action is necessary to prevent a spring tab torsion bar from slipping through its retaining adapters, which could result in a loose spring tab; the loss of both tension springs could allow the spring tab to flutter and result in reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective June 23, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 23, 2003.

Comments for inclusion in the Rules Docket must be received on or before July 7, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2003–NM–102–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-iarcomment@faa.gov.* Comments sent via the Internet must contain ''Docket No. 2003–NM–102–AD'' in the subject line and need not be submitted in triplicate. Comments sent via fax or the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in this AD may be obtained from FAIRCHILD DORNIER, DORNIER Luftfahrt GmbH, P.O. Box 1103, D–82230 Wessling, Germany. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

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 Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for Germany, recently notified the FAA that an unsafe condition may exist on all Dornier Model 328–100 series airplanes. The LBA advises that, on an affected airplane, a lower torsion spring was found to be loose and an upper torsion spring had migrated. The torsion spring system is part of the rudder tab control and comprises two torsion springs and adapters. The design of the torsion spring and structure adapters could result in a poor fit, allowing the spring to slip through the adapters. Loss of both tension springs, if not corrected, could allow the spring tab to flutter and result in reduced controllability of the airplane.

Explanation of Relevant Service Information

Dornier has issued Service Bulletin SB–328–27–298, Revision 1, dated November 21, 2002, which describes procedures for installation of a retainer instead of a washer in the upper and lower torsion bars of the rudder tab. Accomplishment of the action specified in the service bulletin is intended to adequately address the identified unsafe condition. The LBA classified this service bulletin as mandatory and issued German airworthiness directive 2003–104, dated April 3, 2003, to ensure the continued airworthiness of these airplanes in Germany.

FAA's Conclusions

This airplane model is manufactured in Germany and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the LBA has kept the FAA informed of the situation described above. The FAA has examined the findings of the LBA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to prevent a spring tab torsion bar from slipping through its retaining adaptors, which could result in a loose spring tab; the loss of both tension springs could allow the spring tab to flutter and result in reduced controllability of the airplane. This AD requires installation of a retainer instead of a washer in the upper and lower torsion bars of the rudder tab. The actions are required to be accomplished in accordance with the service bulletin described previously.

Changes to 14 CFR Part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material will no longer be included in each individual AD; however, the office authorized to approve AMOCs will be defined in each individual AD.

Determination of Rule's Effective Date

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the AD is being requested.
- Include justification (*e.g.,* reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2003–NM–102–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding the following new airworthiness directive:

2003–11–24 Dornier Luftfahrt GMBH: Amendment 39–13184. Docket 2003–NM–102–AD.

Applicability: Model 328–100 series airplanes, certificated in any category, as listed in Dornier Service Bulletin SB–328–27–298, Revision 1, dated November 21, 2002.

Compliance: Required as indicated, unless accomplished previously.

To prevent a spring tab torsion bar from slipping through its retaining adaptors, which could result in a loose spring tab; and to further prevent the loss of both tension springs, which could allow the spring tab to flutter and result in reduced controllability of the airplane, accomplish the following:

Retainer Installation

(a) Within 2 months after the effective date of this AD: Install a retainer instead of a washer in the upper and the lower torsion bars of the rudder, in accordance with Dornier Service Bulletin SB–328–27–298, Revision 1, dated November 21, 2002. Installation of a retainer before the effective date of this AD in accordance with Dornier Service Bulletin SB–328–27–298, dated March 26, 1999, is acceptable for compliance with the requirements of this paragraph.

Alternative Methods of Compliance

(b) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(c) Unless otherwise specified in this AD, the actions shall be done in accordance with Dornier Service Bulletin SB–328–27–298, Revision 1, dated November 21, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Fairchild Dornier, Dornier Luftfahrt GmbH, P.O. Box 1103, D–82230 Wessling, Germany. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

Note: The subject of this AD is addressed in German airworthiness directive 2003–104, dated April 3, 2003.

Effective Date

(d) This amendment becomes effective on June 23, 2003.

Issued in Renton, Washington, on May 29, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13974 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NE–47–AD; Amendment 39–13177; AD 2003–11–18]

RIN 2120–AA64

Airworthiness Directives; Pratt and Whitney PW4000 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), that is applicable to Pratt and Whitney (PW) model 4000 series turbofan engines. That AD currently requires interim actions to address engine takeoff power loss events until the high-pressure-compressor (HPC) case is redesigned and available for incorporation on the PW4000 engines. This amendment requires the same actions as that AD, adds on-wing Testing–21 to engines installed on Boeing 747 and MD–11 airplanes, and adds the requirement to install a new Ring Case Configuration (RCC) rear HPC on engines installed in the Boeing fleet as terminating action to the requirements of this AD. This amendment is prompted by the development of an RCC rear HPC for PW4000 series turbofan engines installed in the Boeing fleet. The actions specified by this AD are intended to prevent engine takeoff power losses due to HPC surge.

DATES: Effective July 7, 2003. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 7, 2003.

The incorporation by reference of certain other publications, as listed in the regulations, were approved previously by the Director of the Federal Register as of January 17, 2002 (67 FR 1, January 2, 2002), and November 12, 2002 (67 FR 65484, October 25, 2002).

ADDRESSES: The service information referenced in this AD may be obtained from Pratt & Whitney, 400 Main St., East Hartford, CT 06108, telephone (860) 565–6600; fax (860) 565–4503. This information may be examined, by appointment, at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Diane Cook, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7133; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 2002–21–10, Amendment 39–12916 (67 FR 65484, October 25, 2002), which is applicable to PW model 4000 series turbofan engines was published in the **Federal Register** on April 7, 2003, (68 FR 16736). That action proposed to require interim actions to address engine takeoff power loss events until the HPC case is redesigned and available for incorporation on the PW4000 engines. That action also proposed to add on-wing Testing–21 to engines installed on Boeing 747 and MD–11 airplanes, and add the requirement to install a new RCC rear HPC on engines installed in the Boeing fleet as terminating action to the requirements of this AD.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Embedded Engine Configuration

One commenter states that proposed paragraph (u)(1)(ii) embeds an engine configuration that is not listed in Table 1 of the proposed AD and requires operators to replace the rear hook regardless of whether or not it is worn beyond serviceable limits. In addition, the commenter states that it is an undue burden on the operators to track and maintain an additional build configuration not previously tracked.

The FAA does not agree. For engines installed on Boeing airplanes, after the effective date of this AD, any time a Segmented Case Configuration (SCC) HPC module is disassembled to a level that separates the HPC rear case assembly from the HPC module at the H flange, the RCC rear HPC must be incorporated making the replacement of the rear hook a non-issue. After May 31, 2006, any SCC HPC engine installed on

Boeing airplanes must have incorporated a Haynes material HPC inner case rear hook. This requirement maintains the appropriate safety level and the intent of the fleet management plan to reduce the risk of a group 3 surge event. The FAA does not agree that tracking SCC engines with a Haynes material HPC inner case rear hook as well as RCC HPC engines imposes an undue burden on operators.

Service Bulletin Updated

One commenter notes that proposed paragraphs (j)(5), (m), (o)(1), (t)(1), (u), (u)(3), and Table (9) reference service bulletin (SB) PW4ENG 72–755, dated February 28, 2003, however the subject SB has been updated to Revision 1, dated April 8, 2003.

The FAA agrees. Since the issuance of the proposed rule, Revision 1 to SB PW4ENG 72–755 was issued on April 8, 2003, to correct various typographical errors, and Revision 2 was issued on May 23, 2003, to change the part number of two brackets due to interference concerns. The FAA has reviewed the data and concurs with these minor changes to the SB. The final rule incorporates SB PW4ENG 72–755, Revision 2, dated May 23, 2003.

Alternate Shroud Repair

Two commenters state that proposed paragraph (m) defines a minimum build standard for Boeing 747 and 767 airplanes that requires an HPC module to incorporate the requirements of SB PW4ENG 72–755. One of the requirements of that SB changes the abradable sealing surface material for the stage 5, 6, and 7 shrouds from felt metal (PWA 24–1) to plasma spray (PWA279), and states that this work should be done by a PW repair facility. The commenters note that Chromalloy Georgia has an FAA-approved procedure for repairing these shrouds with plasma spray and request that the FAA include the alternate Chromalloy Georgia process in the Additional Service Information section of the AD, and in paragraphs (m), (u) and (u)(3).

The FAA does not agree. The AD mandates the incorporation of the RCC HPC into the module in accordance with SB PW4ENG 72–755 and mandates any concurrent requirements of SB PW4ENG 72–755. The other provisions of SB PW4ENG 72–755 may be done by any method, technique, and practice that is either prescribed in the current manufacturer's maintenance manual or Instructions for Continued Airworthiness or is acceptable to the administrator. Thus, the final rule requires only that after the effective date of that AD, the RCC rear HPC must have a plasma spray abradable sealing surface, but does not mandate how that surface must be applied. In this instance, the Chromalloy Georgia procedures numbers 96 CGT 073–08 and 96 CGT 085–05 are acceptable methods for applying plasma spray abradable material for this shroud repair.

Accuracy of Economic Analysis

Two commenters question the accuracy of the economic analysis. These commenters suggest that the NPRM's economic analysis understated the required parts cost of approximately $119,500 per engine.

The FAA does not agree. The NPRM's economic analysis reflects the average incremental cost of incorporating the RCC per engine during a heavy maintenance HPC compressor shop visit. This is based on the cost of the RCC hardware including the valve and harness changes, and deducts the cost of the SCC overhaul. While the actual cost for an engine may be higher or lower than the $119,500, based on variations between the worldwide overhaul facilities to perform a SCC HPC overhaul and variations of work done in-house by the operator, the FAA believes its use of an average cost fairly estimates the economic burden of this AD.

Typographical Error

Three commenters note a typographical error in proposed Table 1, item 9 (Configuration I), where Service Bulletin ''PW4ENG 72–55'' should read ''PW4ENG 72–755''.

The FAA agrees, and has changed the final rule accordingly.

Clarifications

One commenter notes that in proposed paragraph (c) (1) the text of CSN limits should be revised to read ''CSN or CST limits'', to eliminate any possible confusion.

The FAA agrees and has changed the final rule accordingly.

One commenter suggests a wording change to proposed paragraph (e)(3) and (e)(4) from ''remove from service'', to ''remove from service or perform on-wing Testing-21''. The commenter states that this change would highlight that on-wing Testing-21 is an option.

The FAA agrees and has changed the final rule accordingly.

Service Bulletin 72–749

One commenter requests that proposed paragraph (u)(2)(ii) include a reference to PW SB PW4ENG 72–749, Revision 1, dated January 8, 2003, since this SB incorporates the Haynes material HPC inner case rear hook and HPC inner case mid hook.

The FAA agrees and has added a reference to PW SB PW4ENG 72–749, dated June 2002, and Revision 1 of that SB, dated January 8, 2003, as additional methods of compliance to this paragraph as well as paragraph (u)(1)(ii) of the final rule.

Requirements Too Restrictive

Two commenters state that proposed paragraph (o)(2) is too restrictive and will result in numerous requests for alternative methods of compliance (AMOC). The commenters gave examples when the flange between ''A'' and ''T'' can be separated, without disturbing the gas path. These commenters request that the FAA remove the requirement for Testing-21 on engines that, during a shop visit, have a flange separation without disturbing the gas path hardware.

The FAA agrees. Paragraph (o)(2) of the final rule has been changed to be less restrictive for engines in the shop that have had a flange separation between ''A'' and ''T'' flanges by removing the Testing-21 requirement if, the engine is reassembled with the gas path-related components remaining in the as-removed condition.

Remove Reference to Service Document

One commenter states that in paragraph (l)(2)(i) of the proposed rule, the PW Clean, Inspect, and Repair (CIR) Manual 51A357, Section 72–35–68, Inspection/Check-04, Indexes 8–11, dated September 15, 2001, or dated March 15, 2002, should have only used the March 15, 2002 date.

The FAA does not agree. The final rule retains the September 15, 2001, reference and adds CIR 72–35–68 Insp/Chk-04, Indexes 8–11, dated December 15, 2002, as an additional method to inspect the HPC mid hook and rear hook of the HPC inner case for wear.

Table 1 Serial Number Errors

One commenter states that proposed Table 1 has serial number errors in the configuration designator ''G'' where the table identifies the Phase 3, 1st Run Subpopulation Engines by model and serial numbers. The serial numbers for the PW4052, PW4056, PW4060, PW4060A, PW4060C, and PW4062 rating are incorrect. The commenter states that the correct serial numbers should be SN 727732 through SN 728000 inclusive and SN 729001 through SN 729010 inclusive.

The FAA agrees and has changed the final rule accordingly.

Configuration Designator G Description

One commenter states that the description for configuration designator G in Table 1 of the proposed rule, should be more specific with respect to the Haynes material, and should reference PW4ENG 72–714, dated June 27, 2000; or Revision 1, dated November 8, 2001; or Chromalloy Florida Repair procedure 00CFL–039–0 dated December 27, 2000.

The FAA does not agree. Configuration G engines, listed by serial number, are first run Phase 3 engines produced without Haynes material in the HPC inner case rear hook. Since these engines specifically do not have Haynes material HPC inner case rear hooks, the FAA does not believe it is necessary to list out the PW SBs or Chromalloy Florida Repair procedure. However the wording in the description has been changed for clarification.

Include Future Revisions of Documents

One commenter requests that the FAA consider the practice of referencing a document with a specified control date, inclusive of future revisions in an effort to eliminate the errors to NPRMs and the need to request AMOCs when the referenced material is subsequently revised.

The FAA does not agree. The FAA cannot incorporate by reference a document before that document has been published. Therefore, since each revision to a SB is considered a separate document for purposes of incorporation by reference, it is not legally possible for the FAA to approve future revisions before they are published. The FAA will continue to use the AMOC process to approve a later revision of an SB or other service documents incorporated by reference in an AD as an AMOC to the original SB.

Use Compressor Age to Control Ring Case Configuration Incorporation

One commenter feels it would be more appropriate for the AD to control RCC incorporation based on compressor age, as opposed to a specified date based on forecasted aircraft utilization.

The FAA does not agree. The compliance dates within the final rule use the current average airplane and engine utilization rates for the total fleet. If an operator has a utilization rate outside of this average, the operator can use the AMOC process to seek relief. The risk accumulation of the operator's fleet would be evaluated against the risk model predictions of the total fleet.

Add Terminating Action for Engines Installed on Airbus Fleet

One commenter suggests that this final rule include the incorporation of the RCC rear HPC as terminating action for engines installed on the Airbus fleet.

The FAA does not agree. The FAA is currently evaluating proposals for terminating actions for Airbus and McDonnell Douglas fleets. Once those proposals are found to meet the airworthiness standards for both engines and transport category aircraft, the FAA will incorporate those terminating actions into this AD. The FAA believes, however, that the current rule should be revised now in order to maintain the desired level of safety based on the fleet-wide risk analysis.

Request to Add PW4062A Model to Applicability

One commenter states that the applicability section of the proposal does not include the PW4062A model engine. Since this engine is currently used on the Boeing 747–400F airplane and is subject to takeoff power losses due to HPC surges, this commenter requests that this model be included in the applicability section.

The FAA does not agree. The PW4062A engine model is intentionally not added to the applicability section of this AD. The amended Type Certificate adding the PW4062A model included as part of the PW4062A design the interim measures applied to other engine models to address this known high power surge issue. Those measures appear in the Limitation Section of Chapter 5 in the PW4062A Engine Manual. The terminating action for PW4062A model engines installed on Boeing aircraft, the installation of a ring case compressor (RCC), will be addressed in a separate AD that applies to the PW4062A model. The FAA will consider adding the PW4062A engine model to this AD in the future once terminating action is developed and approved for the Airbus and McDonnell Douglas fleets.

Minimum Build Requirements Inadvertently Omitted

One commenter notes that proposed paragraph (m) does not include the minimum build HPT/HPC mismatch requirement, or the incorporation of SB PW4ENG 72–514, both previously mandated for the SCC HPC engines installed on Boeing airplanes. This commenter points out that it is feasible to have a SCC HPC engine enter the shop, have no work done to the HPC, and be returned to a Boeing airplane. This commenter questions whether these omissions were an oversight.

The FAA agrees that these omissions were an oversight. While the HPC/HPT mismatch or SB PW4ENG 72–514 minimum build standard requirements are not required for RCC HPC engines, the FAA intended that these two requirements form part of the minimum build standard for all SCC HPC engines, regardless of whether the engine is installed on Boeing, Airbus or MD–11 airplanes. Therefore, the FAA revised paragraph (m) of the final rule to include these two requirements for the SCC HPC engines installed on the Boeing fleet.

AD Compliance Considered More Restrictive Than PW SB Compliance

One commenter states that the compliance of proposed paragraph (m), which requires the ring case incorporation when the HPC module is disassembled to a level that separates the HPC rear case assembly from the HPC module at the H flange, is more restrictive than the PW SBs compliance category 6. This commenter requests that paragraph (m) define the compliance to be the same as a PW SB compliance category 6.

The FAA agrees. It was intended that the compliance for paragraph (m) of the AD be equivalent to a PW SB compliance category 6. Therefore, for clarification, the FAA has added the word ''fully'', to paragraphs (m) and (u) of the final rule, to clarify that a fully separated H flange from the HPC module is the same as PW SB compliance category 6.

Request for Drawdown Time

One commenter requests that the FAA allow one or two months of drawdown time from the effective date of the AD, for RCC incorporation. The commenter asks that the FAA consider that some operators may not be ready to do the incorporation by the time the AD is in effect.

The FAA does not agree. The final rule will not be effective until 30 days after publication, providing adequate time to prepare to comply with this AD.

Request for Reduced Test Interval

One commenter asks the FAA to consider as an addition to proposed paragraph (u)(2)(i) to allow two SCC HPC engines on an airplane after January 31, 2007, provided that the Testing-21 interval be reduced in half, to 400 hours-since-last-test. The commenter suggests that the reduced interval can account for an additional SCC HPC engine installation.

The FAA does not agree. Proposing two SCC HPC engines on-wing after January 31, 2007, with a Testing-21

interval reduction by half, results in a dual engine group 3 surge risk greater than the FAA proposal. Since the commenter's proposal does not have an equivalent risk to the requirement of proposed (u)(2)(i), the FAA has not made this change.

Additional Clarification

In addition, the FAA has added clarification to proposed paragraph (f) to ensure that the intent of this AD is, after the effective date, to allow only new Airbus operators to apply the initial categorization criteria of proposed paragraphs (f)(1) through (f)(9). Those operators who have complied with paragraph (f) in accordance with the current AD, AD 2002–21–10, should not re-apply paragraphs (f)(1) through (f)(9) of the final rule after the effective date of this AD.

Revised or Added Service Documents

Since the issuance of the NPRM, service documents PW SB PW4ENG 72–714, Revision 2, dated February 28, 2003; PW SB PW4ENG 72–749, Revision 1, dated January 8, 2003; PW SB PW4ENG 72–755, Revision 2, dated May 23, 2003; PW CIR PN51357, Section 72–35–68, Inspection/Check-04, Index 8–11, dated December 15, 2002, and PW4000 EM 50A605, 71–00–00, Testing 21, dated June 15, 2003, and, have been issued as revisions to service documents referenced in the proposed rule. The FAA has reviewed and approved these documents, has added them to the appropriate compliance paragraphs as additional methods of compliance, and has added them to the list of documents that have been incorporated by reference.

Removal of a Service Document

The manufacturer has submitted data which supports removing from the final rule CIR 51A357, Section 72–35–68, Repair-16, which is an HPC inner rear case mid hook Greek Ascoloy weld repair. Currently, the existing AD allows the repair of the HPC inner mid hook using either Greek Ascoloy or Haynes material. Service Bulletin PW4ENG 72–749 replaces both the HPC inner rear case mid hook and inner case rear hook with hooks made of Haynes material. There is evidence that indicates that the best configuration for a SCC HPC inner rear case is to have Haynes material mid and rear hooks. The FAA has reviewed the data, and based on the incorporation of the RCC HPC modules, believes this configuration has low impact on the fleet. Therefore, proposed paragraph (l)(2)(i) has been revised to remove CIR 51A357, Section 72–35–68, Repair-16.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Regulatory Analysis

This final rule does not have federalism implications, as defined in Executive Order 13132, because it 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. Accordingly, the FAA has not consulted with state authorities prior to publication of this final rule.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under 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. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 removing Amendment 39–12916 (67 FR 65484, October 25, 2002) and by adding a new airworthiness directive, Amendment 39–13177, to read as follows:

2003–11–18 Pratt & Whitney: Amendment 39–13177. Docket No. 2000–NE–47–AD. Supersedes AD 2002–21–10, Amendment 39–12916.

Applicability: This airworthiness directive (AD) is applicable to Pratt & Whitney (PW) model PW4050, PW4052, PW4056, PW4060, PW4060A, PW4060C, PW4062, PW4152, PW4156, PW4156A, PW4158, PW4160, PW4460, PW4462, and PW4650 turbofan engines. These engines are installed on, but not limited to, certain models of Airbus Industrie A300, Airbus Industrie A310, Boeing 747, Boeing 767, and McDonnell Douglas MD–11 series airplanes.

Note 1: This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (w) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Compliance with this AD is required as indicated, unless already done.

To prevent engine takeoff power losses due to high-pressure-compressor (HPC) surges, do the following:

(a) When complying with this AD, determine the configuration of each engine on each airplane using the following Table 1:

TABLE 1.—ENGINE CONFIGURATION LISTING

Configuration	Configuration designator	Description
(1) Phase 1 without high pressure turbine (HPT) 1st turbine vane cut back stator (1TVCB).	A	Engines that did not incorporate the Phase 3 configuration at the time they were originally manufactured, or have not been converted to Phase 3 configuration; and have not incorporated HPT 1TVCB using any Revision of service bulletin (SB) PW4ENG 72–514.

TABLE 1.—ENGINE CONFIGURATION LISTING—Continued

Configuration	Configuration designator	Description
(2) Phase 1 with 1TVCB	B	Same as Configuration A except that HPT 1TVCB has been incorporated using any Revision of SB PW4ENG 72–514.
(3) Phase 3, 2nd Run	C	Engines that incorporated the Phase 3 configuration at the time they were originally manufactured, or have been converted to the Phase 3 configuration during service; and that have had at least one HPC overhaul since new.
(4) Phase 3, 1st Run	D	Same as Configuration C except that the engine has not had an HPC overhaul since new, except those engines that are defined as Configuration Designator G.
(5) HPC Cutback Stator Configuration Engines	E	Engines that currently incorporate any Revision of SBs PW4ENG 72–706, PW4ENG 72–704, or PW4ENG 72–711.
(6) Engines that have passed Testing-21	F	Engines which have successfully passed Testing-21 performed in accordance with paragraph (i) or (j) of this AD. Once an engine has passed a Testing-21, it will remain a Configuration F engine until the HPC is overhauled, or is replaced with a new or overhauled HPC.
(7) Phase 3, 1st Run Subpopulation Engines. These engines are identified by model and serial numbers (SNs) as follows:. PW4152: SN 724942 through SN 724944 inclusive; PW4158: SN 728518 through SN 728533 inclusive; PW4052, PW4056, PW4060, PW4060A, PW4060C, PW4062: SN 727732 through SN 728000 inclusive and SN 729001 through SN 729010 inclusive; PW4460, PW4462: SN 733813 through SN 733840 inclusive.	G	Engines that incorporated the Phase 3 configuration and did not incorporate Haynes material HPC inner case rear hook at the time they were originally manufactured, that were built from August 29, 1997 up to the incorporation of the HPC inner rear case with Haynes material rear hook at the original engine manufacturer and have not had an HPC overhaul since new.
(8) Engines from Configuration G that have passed Testing-21.	H	Engines that have successfully passed Testing-21 performed in accordance with paragraph (i) or (j) of this AD. Once an engine has passed a Testing-21, it will remain a Configuration H engine until the HPC is overhauled, or is replaced with a new or overhauled HPC.
(9) Engines installed on Boeing airplanes with a build standard that incorporates a ring case configuration (RCC) rear HPC.	I	Engines that have incorporated PW SB PW4ENG 72–755, Revision 2, dated May 23, 2003, or have been manufactured with an RCC rear HPC.

Configuration E Engines Installed on Boeing 747, 767, and MD–11 Airplanes

(b) For Configuration E engines, do the following:

(1) Before further flight, limit the number of engines with Configuration E as described in Table 1 of this AD, to one on each airplane.

(2) Remove all engines with Configuration E from service before accumulating 1,300 cycles-since-new (CSN) or cycles-since-conversion (CSC) to Configuration E, whichever is later.

Configuration G and H Engines Installed on Boeing 747, 767, MD–11, and Airbus A300 and A310 Airplanes

(c) For Configuration G and H engines installed on Boeing 747, 767, MD–11, and Airbus A300 and A310 airplanes, except as provided in paragraph (b) of this AD:

(1) Before further flight, remove from service engines that exceed the CSN or cycles-since-Testing-21 (CST) limits listed in the following Table 2. Thereafter, ensure that no Configuration G or H engines exceed the HPC CSN or CST limits listed in Table 2 of this AD.

TABLE 2.—CONFIGURATION G AND H LIMITS

Configuration designator	B747 PW4056	B767 PW4052	B767 PW4056	B767 PW4060 PW4060A PW4060C PW4062	MD–11 PW4460 PW4462	A300/310 PW4152 PW4156A PW4158
G	1,700 CSN 600 CST	3,000 CSN 600 CST	2,100 CSN 600 CST	1,350 CSN 600 CST	1,150 CSN 600 CST	2,800 CSN 600 CST
H						

(2) Prior to return to service and installed on Boeing 747 and 767 airplanes, Configuration G and H engines must meet the requirements of paragraph (j) of this AD.

(3) Prior to return to service and installed on Airbus or McDonnell Douglas airplanes, Configuration G or H engines must meet the requirements of paragraph (i) of this AD.

Engines Installed on Boeing 767 and MD–11 Airplanes

(d) For engines installed on Boeing 767 and MD–11 airplanes, except as provided in paragraph (b) and (c) of this AD:

(1) Before further flight, limit the number of engines that exceed the HPC CSN, HPC cycles-since-overhaul (CSO), or HPC CST limits in Table 3 of this AD, to no more than one engine per airplane. Thereafter, ensure that no more than one engine per airplane

exceeds the HPC CSN, CSO, or CST limit in Table 3 of this AD.

(2) Prior to return to service and installed on MD–11 airplanes, engines must meet the requirements of paragraph (i) of this AD.

(3) Prior to return to service and installed on Boeing 767 airplanes, engines must meet the requirements of paragraph (j) of this AD.

Engines Installed on Boeing 747 Airplanes

(e) Except as provided in paragraph (b) and (c) of this AD, before further flight, and thereafter, manage the engine configurations installed on Boeing 747 airplanes as follows:

(1) Limit the number of Configuration A, B, C, or E engines that exceed the HPC CSN or HPC CSO limits listed in Table 3 of this AD, to not more than one engine per airplane. Table 3 follows:

TABLE 3.—ENGINE LIMITS FOR BOEING AIRPLANES

Configuration designator	B747 PW4056	B767 PW4052	B767 PW4056	B767 PW4060 PW4060A PW4060C PW4062	MD–11 PW4460 PW4462
A	1,400 CSN or CSO	3,000 CSN or CSO	1,600 CSN or CSO	900 CSN or CSO	800 CSN or CSO
B	2,100 CSN or CSO	4,400 CSN or CSO	2,800 CSN or CSO	2,000 CSN or CSO	1,200 CSN or CSO
C	2,100 CSO	4,400 CSO	2,800 CSO	2,000 CSO	1,300 CSO
D	2,600 CSN	4,400 CSN	3,000 CSN	2,200 CSN	2,000 CSN
E	750 CSN or CSO	750 CSN or CSO	750 CSN or CSO	750 CSN or CSO	750 CSN or CSO
F	800 CST	800 CST	800 CST	800 CST	800 CST

(2) The single Configuration A, B, C, or E engine per airplane that exceeds the HPC CSN or CSO limits listed in Table 3 of this AD, must be limited to 2,600 HPC CSN or CSO for Configuration A, B, or C engines, or 1,300 HPC CSN or CSC to Configuration E, whichever is later, for Configuration E engines.

(3) Remove from service or perform on-wing Testing-21 in accordance with paragraph (j)(3) for Configuration D engines, before accumulating 2,600 CSN.

(4) Remove from service or perform on-wing Testing-21 in accordance with paragraph (j)(3) for Configuration F engines, before accumulating 800 CST.

(5) Prior to return to service and installed on Boeing airplanes, Configuration A, B, C, D, and F engines must meet the requirements of paragraph (j) of this AD.

Engines Installed on Airbus A300 and A310 Airplanes

(f) For Airbus operators that began operation of their A300 fleet after the effective date of this AD, use paragraphs (f)(1) through (f)(9) to determine which Airbus A300 PW4158 engine category 1, 2, or 3 limits of the following Table 4 of this AD apply to your engine fleet. For Airbus operators that have been in operation before the effective date of this AD, use your PW4158 engine category classification previously determined for your fleet and continue to apply the A300 PW 4158 Category limits in Table 4 of this AD, to your fleet.

TABLE 4.—ENGINE LIMITS FOR AIRBUS AIRPLANES

Configuration designator	A300 PW4158 Category 1, and A310 PW4156 and PW4156A	A300 PW4158 Category 2, and A310 PW4152	A300 PW4158 Category 3
A	900 CSN or CSO	1,850 CSN or CSO	500 CSN or CSO
B	2,200 CSN or CSO	4,400 CSN or CSO	1,600 CSN or CSO
C	2,200 CSO	4,400 CSO	1,600 CSO
D	4,400 CSN	4,400 CSN	4,400 CSN
E	Not Applicable	Not Applicable	Not Applicable
F	800 CST	800 CST	800 CST

(1) Determine the number of Group 3 takeoff surges experienced by engines in your fleet before April 13, 2001. Count surge events for engines that had an HPC overhaul and incorporated either SB PW 4ENG 72–484 or SB PW4ENG 72–575 at the time of overhaul. Do not count surge events for engines that did not have the HPC overhauled (*i.e.* 1st run engine) or had the HPC overhauled but did not incorporate either SB PW4ENG 72–484 or SB PW4ENG 72–575. See paragraph (v)(5) of this AD for a definition of a Group 3 takeoff surge.

(2) Determine the number of cumulative HPC CSO accrued by engines in your fleet before April 13, 2001. Count HPC CSO for engines that had an HPC overhaul and incorporated either SB PW4ENG 72–484 or SB PW4ENG 72–575 at the time of overhaul. Do not count HPC CSO accrued on your engines while operating outside your fleet.

(3) Calculate the surge rate by dividing the number of Group 3 takeoff surges determined in paragraph (f)(1) of this AD, by the number of cumulative HPC CSO determined in paragraph (f)(2) of this AD, and then multiply by 1,000.

(4) If the surge rate calculated in paragraph (f)(3) of this AD is less than 0.005, go to paragraph (f)(5) of this AD. If the surge rate calculated in paragraph (f)(3) of this AD is greater than or equal to 0.005, go to paragraph (f)(6) of this AD.

(5) If the cumulative HPC CSO determined in paragraph (f)(2) of this AD is greater than or equal to 200,000 cycles, use A300 PW4158 Category 2 limits of Table 4 of this AD. If less than 200,000 cycles, go to paragraph (f)(7) of this AD.

(6) If the surge rate calculated in paragraph (f)(3) of this AD is greater than 0.035, use A300 PW 4158 Category 3 limits of Table 4 of this AD. If less than or equal to 0.035, go to paragraph (f)(7) of this AD.

(7) Determine the percent of takeoffs with greater than a 1.45 Takeoff engine pressure ratio (EPR) data for engines operating in your fleet. Count takeoffs from a random sample of at least 700 airplane takeoffs that has occurred over at least a 3-month time period, for a period beginning no earlier than 23 months prior to the effective date of this AD. See paragraph (v)(6) of this AD for definition of Takeoff EPR data.

(8) If there is insufficient data to satisfy the criteria of paragraph (f)(7) of this AD, use A300 PW4158 Category 3 limits of Table 4 of this AD.

(9) If the percentage of takeoffs with greater than a 1.45 Takeoff EPR data determined in paragraph (f)(7) of this AD is greater than 31%, use A300 PW 4158 Category 3 limits listed in Table 4 of this AD. If the percentage of takeoffs with greater than a 1.45 Takeoff EPR data determined in paragraph (f)(7) of this AD is less than or equal to 31%, use A300 PW 4158 Category 1 limits listed in Table 4 of this AD.

(g) For engines installed on Airbus A300 or A310 airplanes, except as provided in paragraph (c) of this AD, before further flight, limit the number of engines that exceed the

CSN, CSO, or CST limits listed in Table 4 of this AD, to no more than one engine per airplane. Thereafter, ensure that no more than one engine per airplane exceeds the HPC CSN, CSO, or CST limits listed in Table 4 of this AD. See paragraph (i) of this AD for return to service requirements.

(h) For Airbus A300 PW4158 engine operators, except those operators whose engine fleets are determined to be Category 3 classification based on surge rate in accordance with paragraph (f)(6) of this AD, re-evaluate your fleet category within 6 months from the last evaluation, and thereafter, at intervals not to exceed 6 months, using the following criteria:

(1) For operators whose engine fleets are initially classified as Category 1 or 3 in accordance with paragraph (f) of this AD, determine the percent of takeoffs with greater than a 1.45 Takeoff EPR data for engines operating in your fleet. Count takeoffs from a sample of at least 200 takeoffs that occurred over the most recent six month time period since the last categorization was determined, or the total number of takeoffs accumulated over 6 months if less than 200 takeoffs. See paragraph (v)(6) of this AD for definition of takeoff EPR data.

(i) If there is insufficient data to satisfy the criteria of paragraph (h)(1) of this AD, use A300 PW4158 Category 3 limits listed in Table 4 of this AD.

(ii) If the percentage of takeoffs with greater than a 1.45 Takeoff EPR data determined in paragraph (h)(1) of this AD is greater than 31%, use A300 PW4158 Category 3 limits listed in Table 4 of this AD.

(iii) If the percentage of takeoffs with greater than a 1.45 Takeoff EPR data determined in paragraph (h)(1) of this AD is less than or equal to 31%, use A300 PW4158 Category 1 limits listed in Table 4 of this AD.

(2) For operators whose engine fleets are initially classified as Category 2 in accordance with paragraph (f) of this AD, determine the percent of takeoffs with greater than a 1.45 Takeoff EPR data for engines operating in your fleet. Count takeoffs from a sample of at least 200 takeoffs that occurred over the most recent six month time period since the last categorization was determined, or the total number of takeoffs accumulated over 6 months if less than 200 takeoffs. See paragraph (v)(6) of this AD for definition of takeoff EPR data.

(i) If there is insufficient data to satisfy the criteria of paragraph (h)(2) of this AD, use A300 PW4158 Category 3 limits listed in Table 4 of this AD.

(ii) If the percentage of takeoffs with greater than a 1.45 Takeoff EPR data determined in paragraph (h)(2) of this AD is greater than 37%, use A300 PW4158 Category 3 limits listed in Table 4 of this AD.

(iii) If the percentage of takeoffs with greater than a 1.45 Takeoff EPR data determined in paragraph (h)(2) of this AD is greater than or equal to 21% and less than or equal to 37%, use A300 PW4158 Category 1 limits listed in Table 4 of this AD.

(iv) If the percentage of takeoffs with greater than a 1.45 Takeoff EPR data determined in paragraph (h)(2) of this AD is less than 21%, use A300 PW4158 Category 2 limits listed in Table 4 of this AD.

Return to Service Requirements for Engines To Be Installed on Airbus or McDonnell Douglas Airplanes

(i) Engines removed from service in accordance with paragraph (c), (d), or (g) of this AD may be returned to service and installed on Airbus or McDonnell Douglas airplanes under the following conditions:

(1) After passing a cool-engine fuel spike stability test (Testing-21) that has been done in accordance with one of the following PW4000 Engine Manuals (EM) as applicable, except for engines configured with Configuration E, or engines that have experienced a Group 3 takeoff surge:

(i) PW4000 EM 50A443, 71–00–00, TESTING–21, dated March 15, 2002.

(ii) PW4000 EM 50A822, 71–00–00, TESTING–21, dated March 15, 2002.

(2) Engines tested before the effective date of this AD, in accordance with PW4000 EM 50A443, 71–00–00, Testing-21, dated November 14, 2001; or PW4000 EM 50A822, 71–00–00, TESTING–21, dated November 14, 2001; or PW4000 EM 50A443, Temporary Revision No. 71–0026, dated November 14, 2001; or PW4000 EM 50A822, Temporary Revision No. 71–0018, dated November 14, 2001; or PW Internal Engineering Notice (IEN) 96KC973D, dated October 12, 2001, meet the requirements of TESTING–21; or

(3) After passing an on-wing Testing-21 on PW4460 and PW4462 engines installed on the MD–11 airplanes that has been done in accordance with Major IEN 02KCW13H, dated December 9, 2002 or done prior to the approval of Major IEN 02KCW13H, dated December 9, 2002 in accordance with Minor IEN 02KCW13F, dated October 14, 2002 except for engines configured with Configuration E, or engines that have experienced a Group 3 takeoff surge; or

(4) The engine HPC was replaced with an HPC that is new from production with no time in service; or

(5) The engine HPC has been overhauled, or the engine HPC replaced with an overhauled HPC with zero cycles since overhaul; or

(6) An engine that is either below or exceeds the limits of Table 3 or Table 4 of this AD may be removed and installed on another airplane without Testing-21, as long as the requirements of paragraph (c), (d), or (g) of this AD are met at the time of engine installation.

Return to Service Requirements for Engines To Be Installed on Boeing 747 or 767 Airplanes

(j) Engines removed from service in accordance with paragraph (c), (d), or (e) of this AD may be returned to service and installed on Boeing airplanes under the following conditions:

(1) After passing a cool-engine fuel spike stability test (Testing-21) that has been done in accordance with PW4000 EM 50A605, 71–00–00, Testing-21, dated June 15, 2003, except for engines configured with Configuration E, or engines that have experienced a Group 3 takeoff surge; or

(2) Engines tested before the effective date of this AD, in accordance with PW4000 EM 50A605, 71–00–00, Testing-21, dated March 15, 2002; or PW IEN 96KC973D, dated October 12, 2001; or PW4000 EM 50A605, Temporary Revision No. 71–0035, dated November 14, 2001 meet the requirements of Testing-21; or

(3) For PW4056 engines installed on Boeing 747 airplane, after successfully completing on-wing Testing-21 in accordance with Major IEN 02KCW13E, dated November 21, 2002 or if done prior to the approval of Major IEN 02KCW13E dated November 21, 2002 in accordance with Minor IENs 02KCW13, dated October 14, 2002, 02KCW13A, dated October 14, 2002, 02KCW13C, dated July 25, 2002, or 02KCW13D, July 29, 2002 except for engines configured with Configuration E, or engines that have experienced a Group 3 takeoff surge; or

(4) An engine that is either below or exceeds the limits of Table 3 or Table 4 of this AD may be removed and installed on another airplane without Testing-21, as long as the requirements of paragraph (c), (d), or (e) of this AD are met at the time of engine installation.

(5) Engine has incorporated the RCC rear HPC in accordance with PW SB PW4ENG 72–755, Revision 2, dated May 23, 2003. Completing this SB changes the engine configuration to Configuration I.

Phase 0 or Phase 1, FB2T or FB2B Fan Blade Configurations

(k) For Configuration A, B, C, D, E, F, G, and H engines with Phase 0 or Phase 1, FB2T or FB2B fan blade configurations complying with the requirements of AD 2001–09–05, (66 FR 22908, May 5, 2001), AD 2001–09–10, (66 FR 21853, May 2, 2001), or AD 2001–01–10, (66 FR 6449, January 22, 2001), do the following:

(1) Operators complying with the ADs listed in paragraph (k) of this AD using the weight restriction compliance method, must perform Testing-21 in accordance with paragraph (i) or (j) of this AD whenever any quantity of fan blades are replaced with new fan blades, overhauled fan blades, or with fan blades having the leading edges recontoured after the effective date of this AD, if during the shop visit the HPC is not overhauled and separation of a major engine flange, located between ''A'' flange and ''T'' flange, does not occur.

(2) If an operator changes from the weight restriction compliance method to the fan blade leading edge recontouring method after the effective date of this AD, testing-21 in accordance with paragraph (i) or (j) of this AD is required each time fan blade leading edge recontouring is done, if the fan blades accumulate more than 450 cycles since new or since fan blade overhaul, or since the last time the fan blade leading edges were recontoured.

Minimum Build Standard For Engines Installed on Airbus and McDonnell Douglas Airplanes

(l) Use the following minimum build standards for engines to be returned to service and installed on Airbus and McDonnell Douglas airplanes:

(1) After the effective date of this AD, do not install an engine with HPC and HPT modules where the CSO of the HPC is 1,500

cycles or greater than the CSN or CSO of the HPT.

(2) For any engine that undergoes an HPC overhaul after the effective date of this AD:

(i) Inspect the HPC mid hook and rear hook of the HPC inner case for wear in accordance with PW Clean, Inspect and Repair (CIR) Manual PN 51A357, Section 72–35–68 Inspection/Check-04, Indexes 8–11, dated December 15, 2002, or March 15, 2002, or September 15, 2001. If the HPC rear hook is worn beyond serviceable limits, replace the HPC inner case rear hook with an improved durability hook in accordance with PW SB PW4ENG 72–714, Revision 1, dated November 8, 2001, or Revision 2, dated February 28, 2003; or Chromalloy Florida Repair Procedure 00 CFL–039–0, dated December 27, 2000. If the HPC inner case mid hook is worn beyond serviceable limits, repair the HPC inner case mid hook in accordance with PW SB PW4ENG 72–749, dated June 17, 2002, or Revision 1, dated January 8, 2003; or Chromalloy Florida Repair Procedure 02 CFL–024–0, dated September 15, 2002.

(ii) After the effective date of this AD, any engine that undergoes an HPC overhaul may not be returned to service unless it meets the build standard of PW SB PW4ENG 72–484, PW4ENG 72–486, PW4ENG 72–514, and PW4ENG 72–575. Engines that incorporate the Phase 3 configuration already meet the build standard defined by PW SB PW4ENG 72–514.

(3) After the effective date of this AD, any engine that undergoes separation of the HPC and HPT modules must not be installed on an airplane unless it meets the build standard of PW SB PW4ENG 72–514. Engines that incorporate the Phase 3 configuration already meet the build standard defined by PW SB PW4ENG 72–514.

Minimum Build Standard for Engines Installed on Boeing 747 and 767 Airplanes

(m) For engines to be returned to service and installed on Boeing 747 and 767 airplanes, after the effective date of this AD:

(1) Any SCC HPC module that is disassembled to a level that fully separates the HPC rear case assembly at H flange from the HPC module may not be returned to service unless the RCC rear HPC is incorporated in accordance with PW SB PW4ENG 72–755, Revision 2, dated May 23, 2003. Any SCC HPC module that is not disassembled in accordance with (m)(1), must meet the following minimum build standard:

(i) Do not install an engine with HPC and HPT modules where the CSO of the HPC is 1,500 cycles or more than the CSN or CSO of the HPT.

(ii) Any engine that undergoes separation of the HPC and HPT modules must not be installed on an airplane unless it meets the build standard defined by PW SB PW4ENG 72–514. Engines that incorporate the Phase 3 configuration meet the build standard defined by PW SB PW4ENG 72–514.

Stability Testing Requirements for Engines To Be Installed on Airbus or McDonnell Douglas Airplanes

(n) For engines to be installed on Airbus or McDonnell Douglas airplanes, after the effective date of this AD, Testing-21 must be performed in accordance with paragraph (i) of this AD, before an engine can be returned to service after having undergone maintenance in the shop, except under any of the following conditions:

(1) The engine HPC was overhauled, or replaced with an overhauled HPC with zero cycles since overhaul; or the engine HPC was replaced with an HPC that is new from production with no time in service, or

(2) Engine maintenance intended to maintain the airworthiness of the engine between planned shop visits, that requires separation of a major engine flange located between ''A'' flange and ''T'' flange, that results in the engine being reassembled with all gas path-related components remaining in the as-removed condition, or

(3) Engines with an HPC having zero CSN or CSO, or engines that successfully passed Testing-21 with zero CST; and are split at Flange E for transportation reasons as specified in the applicable Storage/Transport section of the applicable Engine Manual.

Stability Testing Requirements for Engines To Be Installed on Boeing 747 or 767 Airplanes

(o) For engines to be installed on Boeing 747 or 767 airplanes, after the effective date of this AD, Testing-21 must be performed in accordance with paragraph (j) of this AD, before an engine can be returned to service after having undergone maintenance in the shop, except under any of the following conditions:

(1) Engine HPC has incorporated the RCC rear HPC in accordance with PW SB PW4ENG 72–755, Revision 2, dated May 23, 2003. Completing this SB changes the engine configuration to Configuration I; or

(2) Engine maintenance intended to maintain the airworthiness of the engine between planned shop visits, that requires separation of a major engine flange located between ''A'' flange and ''T'' flange, that results in the engine being reassembled with all gas path-related components remaining in the as-removed condition; or

(3) Engines that successfully passed Testing-21 with zero CST, and are split at Flange E for transportation reasons as specified in the applicable Storage/Transport section of the applicable EM.

Thrust Rating Changes, Installation Changes, and Engine Transfers

(p) When a thrust rating change has been made by using the Electronic Engine Control (EEC) programming plug, or an installation change has been made during an HPC overhaul, use the lowest cyclic limit of Table 3 or Table 4 of this AD, associated with any engine thrust rating change or with any installation change made during this period. See paragraph (v)(2) for definition of HPC overhaul period.

(q) When a PW4158 engine is transferred to another PW4158 engine operator whose engine fleet has a different category, use the lowest cyclic limit in Table 4 of this AD that was used or will be used during the affected HPC overhaul period.

(r) When a PW4158 engine operator whose engine fleet changes category in accordance with paragraph (h) of this AD, use the lowest cyclic limits in Table 4 of this AD that were used or will be used during the affected HPC overhaul period.

(s) Engines with an HPC having zero CSN or CSO at the time of thrust rating change, or installation change, or engine transfer between PW4158 engine operators, or subsequent change in operator engine fleet category in accordance with paragraph (h) of this AD in the direction of lower to higher Table 4 limits, are exempt from the lowest cyclic limit requirement in paragraphs (p), (q), and (r) of this AD.

Engines That Surge

(t) For engines that experience a surge, and after troubleshooting procedures are completed for airplane-level surge during forward or reverse thrust, do the following:

(1) For engines that experience a Group 3 takeoff surge, remove the engine from service before further flight and for engines that will be installed on Airbus or McDonnell Douglas airplanes, perform an HPC overhaul; or for engines that will be installed on Boeing airplanes, incorporate the RRC rear HPC in accordance with PW SB PW4ENG 72–755, Revision 2, dated May 23, 2003.

(2) For any engine that experiences a forward or reverse thrust surge at EPR's greater than 1.25 that is not a Group 3 takeoff surge, do the following:

(i) For Configuration A, B, C, D, F, G, and H engines, remove engine from service within 25 CIS or before further flight if airplane-level troubleshooting procedures require immediate engine removal, and perform Testing-21 in accordance with paragraph (i) or (j) of this AD, as applicable.

(ii) For Configuration E engines, remove engine from service within 25 CIS or before further flight if airplane-level troubleshooting procedures require immediate engine removal.

(3) Paragraphs (t)(1) and (t)(2) are not applicable to engines that incorporate the RCC rear HPC in accordance with PW SB PW4ENG 72–755, Revision 2, dated May 23, 2003.

Terminating Action for Boeing Airplanes

(u) For Boeing operators with PW4000 engines installed on Boeing 747 or Boeing 767 airplanes, modify the engine HPC assembly by incorporating the RCC rear HPC in accordance with PW SB PW4ENG 72–755, Revision 2, dated May 23, 2003 as follows:

(1) For engines installed on Boeing 767 airplanes, manage the engine configuration installed on the airplanes in your fleet as follows:

(i) By May 31, 2006 and thereafter, ensure that at least one Configuration I engine is installed on the airplane.

(ii) After May 31, 2006, the non-Configuration I engine (SCC HPC module) installed on the airplane must have incorporated the Haynes material in the HPC inner case rear hook during the original engine build or during an HPC overhaul in accordance with PW4ENG 72–714, Revision 1, dated November 8, 2001, or Revision 2, dated February 28, 2003; or SB PW4ENG 72–749, dated June 17, 2002, or Revision 1, dated January 8, 2003; or Chromalloy Florida

Repair procedure 00CFL–039–0, dated December 27, 2000.

(2) For engines installed on Boeing 747 airplanes, manage the engine configuration installed on the airplanes in your fleet as follows:

(i) By January 31, 2007 and thereafter, ensure that no more than one non-Configuration I engine is installed on the airplane.

(ii) After January 31, 2007, the non-Configuration I engine installed on the airplane must have incorporated the Haynes-material in the HPC inner case rear hook during the original build or during an HPC overhaul in accordance with SB PW4ENG 72–714, dated June 27, 2000, or Revision 1, dated November 8, 2001, or Revision 2, dated February 28, 2003; or SB PW4ENG 72–749, dated June 17, 2002, or Revision 1, dated January 8, 2003; or Chromalloy Florida Repair procedure 00CFL–039–0, dated December 27, 2000.

(3) Prior to June 30, 2009 or whenever the HPC module is disassembled to a level that fully separates the HPC rear case assembly at H flange from the HPC module, whichever occurs first, incorporate the RCC rear HPC in accordance with PW SB PW4ENG 72–755, Revision 2, dated May 23, 2003. Engines incorporating the RCC rear HPC are Configuration I engines. See paragraph (v)(7) for definition of HPC rear case assembly.

(4) Incorporation of the RCC rear HPC constitutes terminating action to the Testing-21 requirements as specified in paragraph (o) of this AD, and engine stagger limit requirements as specified in paragraphs (c), (d), and (e) of this AD for engines installed on Boeing airplanes.

Note 2: Terminating action to this AD for engines installed on Airbus and McDonnell Douglas airplanes is pending RCC rear HPC certification to 14 CFR part 25. Once approved, this AD will be superseded to add terminating action requirements for the Airbus and McDonnell Douglas fleets.

Definitions

(v) For the purposes of this AD, the following definitions apply:

(1) An HPC overhaul is defined as restoration of the HPC stages 5 through 15 blade tip clearances to the limits specified in the applicable fits and clearances section of the engine manual.

(2) An HPC overhaul period is defined as the time period between HPC overhauls.

(3) An HPT overhaul is defined as restoration of the HPT stage 1 and 2 blade tip clearances to the limits specified in the applicable fits and clearances section of the engine manual.

(4) A Phase 3 engine is identified by a (–3) suffix after the engine model number on the data plate if incorporated at original manufacture, or a ''CN'' suffix after the engine serial number if the engine was converted using PW SBs PW4ENG 72–490, PW4ENG 72–504, or PW4ENG 72–572 after original manufacture.

(5) A Group 3 takeoff surge is defined as the occurrence of any of the following engine symptoms that usually occur in combination during an attempted airplane takeoff operation (either at reduced, derated or full rated takeoff power setting) after takeoff power set, which can be attributed to no specific and correctable fault condition after completing airplane-level surge during forward thrust troubleshooting procedures:

(i) Engine noises, including rumblings and loud ''bang(s).''

(ii) Unstable engine parameters (EPR, N1, N2, and fuel flow) at a fixed thrust setting.

(iii) Exhaust gas temperature (EGT) increase.

(iv) Flames from the inlet, the exhaust, or both.

(6) Takeoff EPR data is defined as Maximum Takeoff EPR if takeoff with Takeoff-Go-Around (TOGA) is selected or Flex Takeoff EPR if takeoff with Flex Takeoff (FLXTO) is selected. Maximum Takeoff EPR or Flex Takeoff EPR may be recorded using any of the following methods:

(i) Manually recorded by the flight crew read from the Takeoff EPR power management table during flight preparation (see Aircraft Flight Manual (AFM) chapter 5.02.00 and 6.02.01, or Flight Crew Operation Manual (FCOM) chapter 2.09.20) and then adjusted by adding 0.010 to the EPR value recorded; or

(ii) Automatically recorded during Takeoff at 0.18 Mach Number (Mn) (between 0.15 and 0.20 Mn is acceptable) using an aircraft automatic data recording system and then adjusted by subtracting 0.010 from the EPR value recorded; or

(iii) Automatically recorded during takeoff at maximum EGT, which typically occurs at 0.25–0.30 Mn, using an aircraft automatic data recording system.

(7) HPC rear case assembly is defined as the HPC rear case with heat shields and other minor detail parts installed within the HPC rear case, but not including the HPC rear segmented stators.

Alternative Methods of Compliance

(w) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the ECO.

Special Flight Permits and Testing-21 Reports

(x) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be done. Within 60 days of test date, report the results of the cool-engine fuel spike stability assessment tests (Testing-21) and on-wing Testing-21 to the ANE–142 Branch Manager, Engine Certification Office, 12 New England Executive Park, Burlington, MA 01803–5299, or by electronic mail to *9-ane-surge-ad-reporting@faa.gov.* Reporting requirements have been approved by the Office of Management and Budget and assigned OMB control number 2120–0056. Be sure to include the following information:

(1) Engine serial number.

(2) Engine configuration designation per Table 1 of this AD.

(3) Date of the cool-engine fuel spike stability test or on-wing Testing-21, as applicable.

(4) HPC Serial Number, and HPC time and cycles-since-new and since-compressor-overhaul at the time of the test.

(5) Results of the test (Pass or Fail).

Documents That Have Been Incorporated By Reference

(y) The actions must be done in accordance with the following Pratt and Whitney (PW) service bulletin (SB), Internal Engineering Notice (IEN), Temporary Revisions, (TR's), Clean, Inspection, and Repair Manual (CIR) repair procedures, engine manual (EM) sections, and Chromalloy Florida Repair Procedure:

Document No.	Pages	Revision	Date
PW SB PW4ENG72–714	1–2	1	Nov. 8, 2001.
	3	Original	Jun. 27, 2000.
	4	1	Nov. 8, 2001.
	5–12	Original	Jun. 27, 2000.
Total pages: 12			
PW SB PW4ENG72–714	All	2	Feb. 28, 2003.
Total pages: 14			
PW SB PW4ENG72–749	All	Original	Jun. 17, 2002.
Total pages: 14			
PW SB PW4ENG72–749	1	1	Jan. 8, 2003.
	2–4	Original	Jun. 17, 2002.
	5–7	1	Jan. 8, 2003.
	8	Original	Jun. 17, 2002.
	9–10	1	Jan. 8, 2003.

Document No.	Pages	Revision	Date
	11	Original	Jun. 17, 2002.
	12–14	1	Jan. 8, 2003.
Total pages: 14			
PW SB PW4ENG72–755	1	2	May 23, 2003.
	2–37	1	Apr. 8, 2003.
	38–39	2	May 23, 2003.
	40–54	1	Apr. 8, 2003.
	55	2	May 23, 2003.
	56–152	1	Apr. 8, 2003.
	153	2	May 23, 2003.
	154–166	1	Apr. 8, 2003.
	167–171	2	May 23, 2003.
	172–179	1	Apr. 8, 2003.
	180–183	2	May 23, 2003.
	184–195	1	Apr. 8, 2003.
	196	2	May 23, 2003.
	197–233	1	Apr. 8, 2003.
	234	2	May 23, 2003.
	235–287	1	Apr. 8, 2003.
Total pages: 287			
PW IEN 96KC973D	All	Original	Oct. 12, 2001.
Total pages: 19			
PW TR 71–0018	All	Original	Nov. 14, 2001.
Total pages: 24			
PW TR 71–0026	All	Original	Nov. 14, 2001.
Total pages: 24			
PW TR 71–0035	All	Original	Nov. 14, 2001.
Total pages: 24			
PW CIR 51A357, Section 72–35–68, Inspection/Check-04, Indexes 8–11.	All	Original	Sep. 15, 2001.
Total pages: 5			
PW CIR 51A357, Section 72–35–68, Inspection/Check-04, Indexes 8–11.	All	N/A	Mar. 15, 2002.
Total pages: 5			
PW CIR 51A357, Section 72–35–68, Inspection/Check-04, Indexes 8–11.	All	N/A	Dec. 15, 2002.
Total pages: 10			
PW4000 EM 50A443, 71–00–00, TESTING–21	All	Original	Mar. 15, 2002.
Total pages: 20			
PW4000 EM 50A605, 71–00–00, TESTING–21	All	Original	Mar. 15, 2002.
Total pages: 20			
PW4000 EM 50A605, 71–00–00, TESTING–21	1–7	Original	Mar. 15, 2002.
	8–25	N/A	Jun. 15, 2003.
Total pages: 25			
PW4000 EM 50A822, 71–00–00, TESTING–21	All	Original	Mar. 15, 2002.
Total pages: 20			
Chromalloy Florida Repair Procedure, 00 CFL–039–0			
Summary	1–3	Original	Dec. 27, 2000.
Insp/chk-01	801	Original	Dec. 27, 2000.
Repair-01	901–903	Original	Dec. 27, 2000.
Total pages: 7			
Chromalloy Florida Repair Procedure, 02 CFL–024–0			
Summary	1–5	Original	Sep. 15, 2002.
Inspection	801–802	Original	Sep. 15, 2002.
Repair	901–906	Original	Sep. 15, 2002.
Total pages: 13			

The incorporation by reference of IEN 96KC973D, dated October 12, 2001; TR 71–0018, TR 71–0026, and TR 71–0035, all dated November 14, 2001; and CIR 51A357, Section 72–35–68, Inspection/Check-04, Indexes 8–11, dated September 15, 2001 was approved by the Director of the Federal Register as of January 17, 2002 (67 FR 1, January 2, 2002). The incorporation by reference of SB PW4ENG 72–714, Revision 1, dated November 8, 2001, SB PW4ENG 72–749, dated June 17, 2002; EM 50A443, Section 71–00–00, Testing-21, EM 50A822, Section 71–00–00, Testing-21, EM 50A605, and Section 71–00–00, Testing-21, all dated March 15, 2002; Chromalloy Florida Repair Procedure, 00 CFL–039–0, dated December 27, 2000; and Chromalloy Florida Repair Procedure, 02 CFL–024–0, dated September 15, 2002; was approved by the Director of the Federal Register as of November 12, 2002 (67 FR 65484, October 25, 2002). The incorporation by reference of SB PW4ENG 72–714, Revision 2, February 28, 2003, SB PW4ENG 72–755, Revision 2, dated May 23, 2003; SB PW4ENG 72–749, Revision 1, dated January 8, 2003; SB PW4ENG 72–714, Revision 2, dated February 28, 2003; CIR 51A357, Section 72–35–68, Inspection/Check-04, Indexes 8–11, dated March 15, 2002; and dated December 15, 2002; and EM 50A605, Section 71–00–00, Testing-21, dated June 15, 2003, was approved by the Director of the Federal Register on June 23, 2003, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. PW document copies may be obtained from Pratt and Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–6600; fax (860) 565–4503. Chromalloy Florida document copies may be obtained from Chromalloy Florida, 630 Anchors St., NW., Walton Beach, FL 32548; telephone (850) 244–7684; fax (850) 244–6322. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(z) This amendment becomes effective on July 7, 2003.

Issued in Burlington, Massachusetts, on May 28, 2003.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 03–13782 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NE–12–AD; Amendment 39–13168; AD 2003–11–09]

RIN 2120–AA64

Airworthiness Directives; Turbomeca Turmo IV A and IV C Series Turboshaft Engines; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to Airworthiness Directive (AD) 2003–11–09 applicable to Turbomeca Turmo IV A and IV C series turboshaft engines that was published in the **Federal Register** on May 29, 2003 (68 FR 31970). The engine model in the regulatory section, under applicability, is incorrect. This document corrects that model. In all other respects, the original document remains the same.

EFFECTIVE DATE: July 3, 2003.

FOR FURTHER INFORMATION CONTACT: Antonio Cancelliere, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7751; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A final rule AD, FR Doc. 03–13115 applicable to Turbomeca Turmo IV A and IV C series turboshaft engines, was published in the **Federal Register** on May 29, 2003 (68 FR 31970). The following correction is needed:

§ 39.13 [Corrected]

■ On page 31970, in the third column, in the regulatory section, under applicability, in the first paragraph, in the fifth line, ''FA 330–PUMA'' is corrected to read ''SA 330–PUMA''.

Issued in Burlington, MA, on June 2, 2003.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 03–14275 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–311–AD; Amendment 39–13179; AD 2003–11–20]

RIN 2120–AA64

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

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Bombardier Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, that currently requires repetitive lubrication of the slide shaft of the input plunger of the brake control valve assembly. This amendment adds requirements for modifying the brake control valve assembly, which terminates the repetitive lubrications required by the existing AD. This amendment also adds subsequent repetitive lubrications of the valve utilizing the grease fittings installed during the modification. This amendment is prompted by reports of temporary loss of braking action upon landing. The actions specified by this AD are intended to prevent temporary loss of braking action due to the freezing of moisture on the input plunger of the brake control valve during steep descent.

DATES: Effective July 11, 2003.

The incorporation by reference of Bombardier Service Bulletin 601R–32–017, dated November 9, 1993, as listed in the regulations, is approved by the Director of the Federal Register as of July 11, 2003.

The incorporation by reference of Canadair Regional Jet Alert Service Bulletin S.B.A601R–32–016, dated October 14, 1993, as listed in the regulations, was approved previously by the Director of the Federal Register as of February 4, 1994 (59 FR 2952, January 20, 1994).

ADDRESSES: The service information referenced in this AD may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office (ACO), 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Parrillo, Aerospace Engineer, Systems and Flight Test Branch, ANE–172, FAA, New York ACO, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7505; fax (516) 568–2716.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 93–21–04, amendment 39–8801 (59 FR 2952, January 20, 1994), which is applicable to certain Bombardier Model CL–600–2B19 (Regional Jet series 100) series airplanes, was published in the **Federal Register** on January 13, 2003 (68 FR 1566). The action proposed to require repetitive lubrication of the slide shaft of the input plunger of the brake control valve assembly; modification of the brake control valve assembly, which would terminate the repetitive lubrications required by the existing AD; and subsequent repetitive lubrications of the valve utilizing the grease fittings that are installed during the modification.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request To Revise Identification of Regional Jet Series 100

One commenter requests that the proposed AD be revised to either remove the reference to ''Regional Jet Series 100'' in association with the affected airplanes throughout the document or add a reference to series 440 airplanes. The commenter explains that the proposed AD applies to Model CL–600–2B19 airplanes. The type certificate data sheet (TCDS) identifies the affected airplane model as ''CL–600–2B19 (Regional Jet Series 100 & 440).'' The commenter suggests that the references to this airplane model should be revised to reflect both the 100 and 440 series.

The FAA concurs with the request. After the proposed AD was issued, the TCDS was revised to incorporate this change. The final rule has been revised accordingly to correctly identify the affected airplanes where appropriate.

Request To Incorporate AD Actions Into the Maintenance Program

Paragraph (c) of the proposed AD proposed to require repetitive

lubrication of the brake control valve in accordance with Bombardier Service Bulletin 601R–32–017. One commenter requests that the proposed AD be revised to instead require incorporation of the lubrication task (task 32–43–06–05 of the CL–600–2B19 Maintenance Requirements Manual (MRM)) into the approved maintenance program. The commenter asserts that the lubrication task, if incorporated into the MRM, would be considered a routine task subject to normal maintenance program development and escalation. The commenter adds that incorporating the task into the MRM would terminate the repetitive lubrication requirements specified in the proposed AD.

The FAA does not concur with the request. An AD's requirements are mandated for all affected airplanes, but the applicable section of the MRM (Part 1, CSP A–053) is not approved by the FAA (although it is ''accepted''). Consequently, the FAA does not control revisions to Part 1 of the MRM. If a task were to be subsequently altered or deleted, the intent of the AD would then become nullified. However, under the provisions of 14 CFR 39.19 and paragraph (d)(1) of this AD, an operator may request approval of an alternative method of compliance (AMOC) to allow use of a particular task card for this AD. However, the AMOC granted would require adherence to a particular revision of the task card; use of any subsequent revisions would require a new AMOC request and approval to enable the cognizant ACO to determine that the intent of the AD requirement has not been altered. No change to the final rule is necessary regarding this issue.

Clarification of Requirements

Certain portions of the preamble and paragraph (b) of this final rule have been revised to clarify that the modification includes applying grease to the grease fittings that are installed during the modification.

The repetitive lubrication interval was clarified in paragraph (c) of this final rule. Whereas the proposed AD specified that the lubrication be done ''at intervals of 1,500 flight hours,'' this final rule will require that the lubrication be done ''at intervals not to exceed 1,500 flight hours.''

Paragraph (d)(2) has been revised in this final rule to clarify that AMOCs approved previously in accordance with AD 93–21–04 are approved as alternative methods of compliance with paragraph (a) of this AD only.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Changes to 14 CFR Part 39/Effect on the AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. Because we have now included this material in part 39, we no longer need to include it in each individual AD; however, the office authorized to approve AMOCs is identified in paragraph (d)(1) of this AD.

Cost Impact

The FAA estimates that 2 airplanes of U.S. registry are affected by AD 93–21–04. The actions that are currently required by that AD take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required actions is estimated to be $60 per airplane.

Approximately 194 airplanes of U.S. registry will be affected by this AD.

The modification required by this AD will take approximately 4 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts will cost approximately $3,812 per airplane. Based on these figures, the cost impact of the modification on U.S. operators is estimated to be $786,088, or $4,052 per airplane.

The lubrication of the brake control valve required by this AD will take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of this action on U.S. operators is estimated to be $11,640, or $60 per airplane, per lubrication.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 removing amendment 39–8801 (59 FR 2952, January 20, 1994), and by adding a new airworthiness directive (AD), amendment 39–13179, to read as follows:

2003–11–20 Bombardier, Inc. (Formerly Canadair): Amendment 39–13179. Docket 2000–NM–311–AD. Supersedes AD 93–21–04, Amendment 39–8801.

Applicability: Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent temporary loss of braking action due to the freezing of moisture on the input plunger of the brake control valve during steep descent, accomplish the following:

Requirements of AD 93–21–04

Lubrications

(a) Within 3 days after February 4, 1994 (the effective date of AD 93–21–04, amendment 39–8801), and thereafter at intervals not to exceed 3 days, lubricate, with grease, the sliding shaft of the input plunger of the brake control valve assembly, per Canadair Regional Jet Alert Service Bulletin S.B.A601R–32–016, dated October 14, 1993, until modification of the brake control valve, as required by paragraph (b) of this AD, is accomplished.

New Actions Required by This AD

Modification

(b) Within 12 months after the effective date of this AD: Modify the brake control valve assembly by accomplishing all the actions (including the application of grease to the grease fittings) specified in Bombardier Service Bulletin 601R–32–017, dated November 9, 1993, per the service bulletin. Such modification terminates the repetitive lubrications of the sliding shaft of the input plunger of the brake control valve assembly required by paragraph (a) of this AD.

Repetitive Lubrications

(c) Within 1,500 flight hours after doing the modification required by paragraph (b) of this AD, and thereafter at intervals not to exceed 1,500 flight hours, lubricate with grease the brake control valve per paragraph 2.B.(18) of the Accomplishment Instructions of Bombardier Service Bulletin 601R–32–017, dated November 9, 1993.

Alternative Methods of Compliance

(d)(1) In accordance with 14 CFR 39.19, the Manager, New York Aircraft Certification Office (ACO), FAA, is authorized to approve alternative methods of compliance for this AD.

(2) Alternative methods of compliance, approved previously in accordance with AD 93–21–04, amendment 39–8801, are approved as alternative methods of compliance with paragraph (a) of this AD.

Incorporation by Reference

(e) The actions shall be done in accordance with Canadair Regional Jet Alert Service Bulletin S.B.A601R–32–016, dated October 14, 1993; and Bombardier Service Bulletin 601R–32–017, dated November 9, 1993; as applicable.

(1) The incorporation by reference of Bombardier Service Bulletin 601R–32–017, dated November 9, 1993, is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Canadair Regional Jet Alert Service Bulletin S.B.A601R–32–016, dated October 14, 1993, was approved previously by the Director of the Federal Register as of February 4, 1994 (59 FR 2952, January 20, 1994).

(3) Copies of these service bulletins may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office (ACO), 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 1: The subject of this AD is addressed in Canadian airworthiness directive CF–93–26R2, dated January 18, 1994.

Effective Date

(f) This amendment becomes effective on July 11, 2003.

Issued in Renton, Washington, on May 28, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13975 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Acepromazine Maleate Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the use of acepromazine maleate injectable solution in dogs, cats, and horses as a tranquilizer.

DATES: This rule is effective June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed ANADA 200–319 that provides for use of Acepromazine Maleate (acepromazine maleate) Injection as a tranquilizer. Phoenix Scientific's Acepromazine Maleate Injection is approved as a generic copy of Fort Dodge Animal Health's PROMACE Injectable approved under NADA 015–030. The ANADA is approved as of March 25, 2003, and the regulations are amended in 21 CFR 522.23 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subject in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.23 [Amended]

■ 2. Section 522.23 *Acepromazine maleate injection* is amended in paragraph (b), introductory text, by removing ''No. 000856'' and by adding in its place ''Nos. 000856 and 059130''.

Dated: May 27, 2003.

Steven F. Sundlof,

Center for Veterinary Medicine.

[FR Doc. 03–14348 Filed 6–5–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9060]

RIN 1545–BB91

Disclosure of Return Information to the Department of Agriculture

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains regulations that incorporate and clarify the phrase ''return information reflected on returns'' in conformance with the terms of section 6103(j)(5) of the Internal Revenue Code (Code). These temporary regulations also remove certain items of return information that the IRS currently discloses, but the Department of Agriculture no longer needs, for conducting the census of agriculture. The text of the temporary regulations serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective Date.* These regulations are effective on June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Christine Irwin at (202) 622–4570 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

These temporary regulations incorporate the phrase ''return information reflected on returns'' into § 301.6103(j)(5)–1 in conformance with the statutory language that describes the type of return information that the IRS may disclose to the Department of Agriculture under section 6103(j)(5) of the Code. These temporary regulations are consistent with a recent clarification of the same phrase (*i.e.*, return information reflected on returns) in § 301.6103(j)(1)–1, involving the disclosure of return information to the Bureau of the Census. *See* 68 FR 2691.

Also, currently § 301.6103(j)(5)–1 provides an itemized description of the return information authorized for disclosure in conjunction with the census of agriculture. These temporary regulations remove certain items of return information currently listed in § 301.6103(j)(5)–1 that the Department of Agriculture no longer needs in conjunction with the census of agriculture.

Explanation of Provisions

These temporary regulations adopt the phrase ''return information reflected on returns'' in lieu of the phrase ''return information'' that currently appears in § 301.6103(j)(5)–1. (The phrase ''return information reflected on returns'' encompasses the phrase ''return information reflected thereon'' in section 6103(j)(5) of the Code.) These temporary regulations clarify the phrase ''return information reflected on returns'' by explaining that the phrase includes, but is not limited to, information on returns, information derived from processing such returns, and information derived from other sources for the purposes of establishing and maintaining taxpayer information relating to returns. The phrase includes information derived from returns, monthly corrections of, and additions to, taxpayer information contained in IRS databases (*e.g.*, taxpayer address and name changes) that are obtained from other sources, and computer codes the IRS derives from returns and/or tax forms and integrates within taxpayer data bases.

On March 4, 2003 and March 17, 2003, the Department of Agriculture's National Agriculture Statistics Service (NASS) notified the IRS that certain items of return information that are currently listed in § 301.6103(j)(5)–1 are no longer needed in conjunction with the census of agriculture. Specifically, the Department of Agriculture no longer needs the following items currently extracted from IRS forms: (1) From Form 1040, Schedule F (Profit or Loss from Farming): sales of livestock and produce raised; (2) From Form 1120 series: Parent corporation Employer Identification Number, and related Name and Principal Business Activity (PBA) code for entities with agricultural activity; and (3) From Form 851 (Affiliations Schedule): subsidiary taxpayer identity information, annual accounting period, subsidiary PBA code, parent taxpayer identity information, parent PBA code, Master File Tax Code, Document Locator Number, and cycle posted. As a result, these items of return information currently listed in § 301.6103(j)(5)–1 will be removed by this document.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because no preceding notice of proposed rulemaking is required for this temporary regulation, the provisions of the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply. Pursuant to section 7805(f) of the Code, the IRS will submit this Treasury decision to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Christine Irwin, Office of the Associate Chief Counsel, Procedure & Administration (Disclosure & Privacy Law Division).

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR part 301 is amended as follows:

PART PART 301—PROCEDURE AND ADMINISTRATION

■ **1.** The authority citation for part 301 is amended by removing the entry for ''Section 301.6103(j)(5)–1'' and adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ Section 301.6103(j)(5)–1T also issued under 26 U.S.C. 6103(j)(5). * * *

§ 301.6103(j)(5)–1 [Removed]

■ **2.** Section 301.6103(j)(5)–1 is removed.

■ **3.** Section 301.6103(j)(5)–1T is added to read as follows:

§ 301.6103(j)(5)–1T Disclosures of return information reflected on returns to officers and employees of the Department of Agriculture for conducting the census of agriculture (temporary).

(a) *General rule.* Pursuant to the provisions of section 6103(j)(5) of the Internal Revenue Code and subject to the requirements of paragraph (c) of this section, officers or employees of the Internal Revenue Service will disclose return information reflected on returns to officers and employees of the Department of Agriculture to the extent, and for such purposes, as may be provided by paragraph (b) of this section. ''Return information reflected on returns'' includes, but is not limited to, information on returns, information derived from processing such returns, and information derived from other sources for the purposes of establishing

and maintaining taxpayer information relating to returns.

(b) *Disclosure of return information reflected on returns to officers and employees of the Department of Agriculture.* (1) Officers or employees of the Internal Revenue Service will disclose the following return information reflected on returns in this paragraph (b) for individuals, partnerships and corporations with agricultural activity, as determined generally by industry code classification or the filing of returns for such activity, to officers and employees of the Department of Agriculture for purposes of, but only to the extent necessary in, structuring, preparing, and conducting, as authorized by chapter 55 of title 7, United States Code, the census of agriculture.

(2) From Form 1040 (Schedule F)—

(i) Taxpayer identity information (as defined in section 6103(b)(6) of the Internal Revenue Code);
(ii) Spouse's Social Security Number;
(iii) Annual accounting period;
(iv) Principal Business Activity (PBA) code;
(v) Taxable cooperative distributions;
(vi) Income from custom hire and machine work;
(vii) Gross income;
(viii) Master File Tax (MFT) code;
(ix) Document Locator Number (DLN);
(x) Cycle posted;
(xi) Final return indicator;
(xii) Part year return indicator; and
(xiii) Taxpayer telephone number.

(3) From Form 943—

(i) Taxpayer identity information;
(ii) Annual accounting period;
(iii) Total wages subject to Medicare taxes;
(iv) MFT code;
(v) DLN;
(vi) Cycle posted;
(vii) Final return indicator; and
(viii) Part year return indicator.

(4) From Form 1120 series—

(i) Taxpayer identity information;
(ii) Annual accounting period;
(iii) Gross receipts less returns and allowances;
(iv) PBA code;
(v) MFT Code;
(vi) DLN;
(vii) Cycle posted;
(viii) Final return indicator;
(ix) Part year return indicator; and
(x) Consolidated return indicator.

(5) From Form 1065 series—

(i) Taxpayer identity information;
(ii) Annual accounting period;
(iii) PBA code;
(iv) Gross receipts less returns and allowances;
(v) Net farm profit (loss);
(vi) MFT code;
(vii) DLN;
(viii) Cycle posted;
(ix) Final return indicator; and
(x) Part year return indicator.

(c) *Procedures and Restrictions.* (1) Disclosure of return information reflected on returns by officers or employees of the Internal Revenue Service as provided by paragraph (b) of this section will be made only upon written request designating, by name and title, the officers and employees of the Department of Agriculture to whom such disclosure is authorized, to the Commissioner of Internal Revenue by the Secretary of Agriculture and describing—

(i) The particular return information reflected on returns for disclosure;

(ii) The taxable period or date to which such return information reflected on returns relates; and

(iii) The particular purpose for the requested return information reflected on returns.

(2)(i) No such officer or employee to whom the Internal Revenue Service discloses return information reflected on returns pursuant to the provisions of paragraph (b) of this section shall disclose such information to any person, other than the taxpayer to whom such return information reflected on returns relates or other officers or employees of the Department of Agriculture whose duties or responsibilities require such disclosure for a purpose described in paragraph (b) of this section, except in a form that cannot be associated with, or otherwise identify, directly or indirectly, a particular taxpayer.

(ii) If the Internal Revenue Service determines that the Department of Agriculture, or any officer or employee thereof, has failed to, or does not, satisfy the requirements of section 6103(p)(4) of the Internal Revenue Code or regulations or published procedures thereunder, the Internal Revenue Service may take such actions as are deemed necessary to ensure that such requirements are or shall be satisfied, including suspension of disclosures of return information reflected on returns otherwise authorized by section 6103(j)(5) and paragraph (b) of this section, until the Internal Revenue Service determines that such requirements have been or will be satisfied.

(d) *Effective date.* This section is applicable on June 6, 2003.

David A. Mader,

Assistant Deputy Commissioner of Internal Revenue.

Approved: May 12, 2003.

Pamela F. Olson,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 03–14205 Filed 6–5–03; 8:45 am]

BILLING CODE 4830–01–P

POSTAL SERVICE

39 CFR Part 111

Hazardous Materials: Domestic Mail Manual Revisions for Division 6.2 Infectious Substances and Other Related Changes

ACTION: Final rule.

SUMMARY: In this final rule, the Postal Service adopts revisions to the mailing standards in *Domestic Mail Manual* (DMM) C023 related to the requirements and packaging standards for mailable types of Division 6.2 infectious substances. These DMM revisions adopt many of the regulatory and packaging changes for infectious substances that the U.S. Department of Transportation (DOT) made to Title 49 Code of Federal Regulations (49 CFR) in the **Federal Register** final rule published on August 14, 2002 (67 FR 53117–53144) and the subsequent change published on August 27, 2002 (67 FR 54967). As adopted by the Postal Service, these DMM revisions will provide a greater level of safety for handling and transporting mailable infectious substances in the mailstream. These changes will also facilitate domestic and international air transportation by aligning the Postal Service mailing standards with the current international standards for the transport of hazardous materials.

Other minor changes and clarifications are also adopted to the hazardous materials mailing standards in DMM C021, C023, C024, C050, and F010 to improve clarity and reduce misunderstandings; to ensure the packaging integrity of mailable hazardous materials during Postal Service handling; and to provide a greater level of safety for Postal Service employees and the public.

EFFECTIVE DATE: June 12, 2003. However, mailers using a business reply mail format for diagnostic (clinical) specimen mailpieces or a merchandise return service format for sharps waste or regulated medical waste mailpieces, are

provided with a phase-in period through January 1, 2004.

FOR FURTHER INFORMATION CONTACT: Jane Stefaniak (703) 292–3548, Mailing Standards, United States Postal Service.

SUPPLEMENTARY INFORMATION: On December 19, 2002, the Postal Service published a proposed rule in the **Federal Register** (67 FR 77726–77737) that proposed revisions to the standards in DMM C023 for mailing Division 6.2 infectious substances. The proposal was initiated to align the Postal Service standards with the DOT Federal regulations in 49 CFR and to make other minor changes and clarifications to the related mailing standards in DMM C021, C023, C024, C050, and F010.

Part A of this document provides background information on why the Postal Service needs to adopt these changes. Part B identifies and responds to the comments received by the Postal Service on the proposed rule. Part C summarizes the changes adopted by the Postal Service in this final rule. The actual changes to the DMM appear at the end of this final rule.

Part A—Background Information

The carriage of U.S. mail by the United States Postal Service (Postal Service) is regulated by Title 39 Code of Federal Regulations (39 CFR). Unlike commercial carriers, the Postal Service is not subject to the Federal regulations of the U.S. Department of Transportation (DOT) in Title 49 Code of Federal Regulations (49 CFR). The Postal Service is, however, subject to the legal restrictions in Title 18 United States Code 1716 (18 U.S.C. 1716) which prohibits the mailing of * * *'' all disease germs, or scabs, and all other natural or artificial articles, compositions, or material which may kill or injure another, or injure the mails or other property''* * * if that matter is outwardly or of its own force dangerous to life, health, or property. Accordingly, for legal and safety reasons, the mailing standards for hazardous materials in the Domestic Mail Manual (DMM) not only closely adhere to the DOT regulations in 49 CFR, but also include many additional limitations and prohibitions.

In many instances, the Postal Service standards are more restrictive than the DOT requirements that apply to shipments being transported in domestic commerce. As an example, commercial shippers are permitted under the DOT regulations in 49 CFR to send certain types of flammable materials via air transportation. In contrast, the Postal Service prohibits the mailing of all flammable materials via air transportation.

Under Postal Service mailing standards, most hazardous materials are nonmailable. With few exceptions, the Postal Service generally limits the mailing of hazardous materials to only those materials that can be reclassified as an ORM–D material under the DOT Federal regulations in 49 CFR 173.144 and that can be renamed with the proper shipping name of ''Consumer Commodity.'' Additionally, mailable hazardous materials must meet the Postal Service quantity and packaging requirements, which in many instances are more restrictive than the DOT requirements in 49 CFR. Of all regulated hazardous materials, ORM–D materials present the lowest level of risk during handling and transportation.

Over the past few years, the Postal Service has encountered increasing difficulties with the commercial carriers who are contracted to provide air transportation services for the carriage of U.S. mail. Many carriers have refused to transport mailpieces containing mailable hazardous materials. In some instances, an air carrier has established a corporate policy not to carry hazardous materials. In other cases, an air carrier has refused to carry a specific type of hazardous material (*e.g.*, diagnostic specimens) because Postal Service packaging standards, which met Federal standards, did not meet the international standards followed by the air carrier industry.

To ensure an acceptable level of safety and to facilitate domestic and international transportation, the Postal Service is adopting some of the regulatory and packaging changes for Division 6.2 infectious substances that DOT adopted as revisions to 49 CFR in the **Federal Register** (67 FR 53117–53144 and 67 FR 54967). The DOT changes are consistent with the current international standards found in the *Technical Instructions for the Safe Transport of Dangerous Goods* published by the International Civil Aviation Organization (ICAO).

It should also be noted that many of the DOT Federal regulations in 49 CFR involve requirements for the transport of hazardous materials that have moderate, high, or very high risk levels and that are shipped in very large quantities (exceeding 70 pounds in weight). Such hazardous materials are not permitted in the U.S. mail due to the legal restrictions in 18 U.S.C. 1716, concerns for employee and public safety, and Postal Service size and weight limitations. Accordingly, the Postal Service is adopting only the DOT regulations for Division 6.2 infectious substances that apply to materials that can be safely handled in the U.S. mail. As an example, the Postal Service will not adopt the new DOT bulk packaging options for regulated medical waste because under DOT regulations in 49 CFR, a bulk packaging is defined as a receptacle that has a capacity greater than 450L (119 gallons) for liquid materials or a net mass greater than 400 kg (882 pounds) for solid materials. As established by law, the maximum size and weight limits per mailpiece are 70 pounds and 108 inches in combined length and girth (130 inches for Parcel Post). A bulk packaging receptacle as defined by DOT is nonmailable in the U.S. mail because it exceeds the maximum size and weight limits for mailing and it also would pose an unacceptable risk level during Postal Service transport and handling.

Part B—Comments on the Proposed Rule

On December 19, 2002, the Postal Service published a proposed rule in the **Federal Register** (67 FR 77726–77737) that provided information on the revisions to the mailing standards in the DMM that the Postal Service proposed to adopt. The Postal Service solicited comments on the proposed rule from members of the general public and responses were received from nine parties. The parties represented: four authorized sharps mailers; three commercial medical laboratories that process diagnostic (clinical) specimens received through the mail; one institute comprised of two separate trade associations that represented members involved in private waste services and manufacturing businesses; and one law firm representing a group of manufacturers of healthcare products.

The comments received generally fell into one of the following four categories: comments on the proposed effective date; comments on the proposed rules for diagnostic (clinical) specimens; comments on the proposed rules for mailable types of regulated medical waste and sharps waste; and comments in support of the Postal Service proposed rule. A summary of the comments grouped by category is detailed in items 1 through 4.

1. Comments Related to the Effective Date of the Final Rule

Four commenters, including three of the sharps mailers and the institute, opposed the Postal Service proposal of an effective date of April 30, 2003. Two of the sharps mailers requested an effective date of six months after the date of the final rule, while the other two commenters requested an effective date of one year after the date of the final rule. All commenters felt that a

delayed effective date was needed to allow them and their clients a sufficient amount of time in which to use up preexisting packaging that is already in circulation. The Postal Service agrees that a phase-in period is needed and in this final rule has adopted an effective date of June 12, 2003, with a phase-in period through January 1, 2004. This phase-in period will allow for mailer implementation of the new packaging requirements for diagnostic (clinical) specimen mailpieces using a business reply mail format and regulated medical waste or sharps waste mailpieces using a merchandise return service format.

2. Comments Related to the Proposed Changes Affecting Diagnostic (Clinical) Specimens

Four commenters, including the three medical laboratories and the law firm, submitted comments related to the proposed requirements for clinical specimens.

Two of the medical labs and the law firm all maintained that the Postal Service proposal to require placement of the biohazard symbol on the primary container of a Risk Group 1, 2 or 3 diagnostic (clinical) specimen was impractical. They noted that mailers would incur added costs to place the symbol on the primary container. One commenter also noted that under the Federal requirements issued by the U.S. Department of Occupational Health and Safety Administration (OSHA), the biohazard symbol is required to appear on the secondary container. For these reasons, in this final rule the Postal Service has changed the placement requirement for the biohazard symbol on Risk Group 1, 2, and 3 specimens. For mailable types of Risk Group 1, 2, and 3 specimens, the biohazard symbol is required to appear on the secondary packaging, except in the instance where the secondary packaging also serves as the outer shipping container for a Risk Group 1 specimen. In that instance, then the biohazard symbol must appear on the inner packaging or on the primary container. The biohazard symbol must not appear on the outer shipping container of a mailable Risk Group 1, 2, or 3 specimen.

One of the medical labs opposed the Postal Service proposal to include diagnostic (clinical) specimens in the description of Division 6.2 materials in DMM C023.8.1 because they felt it could be confusing to most mailers. The text in DMM C023.8.1 is intended to generally identify the items that are described under the category of Division 6.2, some of which are regulated as infectious substances, and some of which are not. The definition of a Division 6.2 material (infectious substance) is defined in DMM C023.8.2a, and that definition very closely mirrors the definition adopted by DOT in 49 CFR. The Postal Service does not feel that the general explanation in DMM C023.8.1 is confusing or misleading, but has made some minor changes to the text in the final rule for the purpose of clarity.

The same medical lab also asked whether it was the intent of the Postal Service to mirror the risk group classifications adopted by DOT. The answer is yes. The Postal Service believes this intent was clearly stated in the proposed rule, and it is also restated in Part C of this final rule. This commenter also asked whether the Postal Service classified all diagnostic (clinical) specimens collected for insurance purposes or through drug testing programs as Risk Group 1 materials. The Postal Service cannot make such a determination. In the proposed rule and in this final rule, the Postal Service has placed the responsibility for the proper determination of the Risk Group on the sender (*i.e.* generally the health care professional or individual who collects the specimen) as stated in DMM C023.8.2f. The Postal Service position on this point is in alignment with the stance DOT adopted in 49 CFR. The Postal Service suggests that packaging distributors include information to inform the collector of the specimen that the packaging may only be used to send Risk Group 1 specimens and that different packaging with stricter requirements must be used to send Risk Group 2, 3, or 4 specimens.

Another one of the medical labs that provided comments requested that the Postal Service clarify what materials are acceptable for a primary and secondary container holding a dry specimen. They also asked the Postal Service to clarify what would constitute a ''securely sealed'' primary receptacle in DMM C023.8.10b. Unlike the DOT regulations, the Postal Service proposed packaging requirements for dry clinical specimens since these types of specimens are routinely sent through the U.S. mail. Dry specimens often include materials such as saliva swabs, dried blood spots, and fecal smears. In the final rule, the Postal Service has made a few minor changes to the text for packaging a dry specimen in order to clarify the requirements. The Postal Service believes these changes are sufficient.

3. Comments Related to the Proposed Changes Affecting Regulated Medical Waste and Sharps Waste

Five parties, including the four sharps mailers and the institute, submitted comments related to the proposed changes affecting the mailing of regulated medical waste and sharps waste. For Postal Service purposes, regulated medical waste is defined in DMM C023.8.2e and sharps waste is defined in DMM C023.8.2g.

All four sharps mailers opposed the Postal Service proposal to limit the capacity of a sharps primary receptacle to a maximum of 3 gallons. Two commenters requested a limit of 5 gallons, one requested a limit of 11 gallons, and the other specified no maximum limit. Over the past few years, the Postal Service has experienced instances in which mailpieces containing sharps waste and having a 5-gallon primary receptacle have been found broken open in the mailstream. Although the number of incidents is small, the Postal Service believes that when properly designed and packaged prior to mailing, no approved sharps container should break open while in the mailstream. It was for this reason, and to ensure the safety of postal employees who handle these mailpieces, that the Postal Service proposed the new design requirement. The Postal Service does not agree with the commenters that a primary receptacle used to collect sharps (and designed for return via the U.S. mail) needs to be larger than 3 gallons in capacity. Most sharps container systems previously approved by the Postal Service have a primary receptacle with a capacity of less than 1 gallon. Primary receptacles having a capacity of 3 gallons or greater are not generally used to collect sharps waste for mail-back purposes, rather they are used to collect other types of nonsharps waste. Accordingly, the Postal Service will adopt a 3-gallon limit for a primary receptacle used to collect sharps waste as defined in DMM C023.8.2g and a 5-gallon limit for a primary receptacle used to collect regulated medical waste as defined in DMM C023.8.2e.

One sharps mailer opposed the Postal Service proposal to change the requirements for the secondary container for regulated medical waste and sharps waste packaging systems. The same sharps mailer also opposed the Postal Service proposal to prohibit easy-fold bottoms on outer shipping containers if they are not reinforced with a water-resistant tape. The commenter felt that the previous Postal Service requirement which allowed a

secondary container to consist of a 3 mil plastic bag with a reinforced fiberboard sleeve (open on the top and bottom) was sufficient. They also felt that requiring a reinforced bottom on the outer shipping container was unnecessary and would increase their production costs. The Postal Service feels these changes are necessary for safety reasons. At least two incidents have occurred in which the bottom of an auto-fold style outer shipping container gave way during postal handling causing the bagged primary receptacle to slide out of the reinforced sleeve and through the bottom of the outer shipping container. In this situation, the only level of protection from the primary container was the 3 mil plastic bag, which increased the safety risk to postal employees. For this reason, the Postal Service adopts the packaging change for regulated medical waste and sharps waste mailpieces that requires the secondary container be completely enclosed in a watertight container or containment system. The secondary container may consist of more than one component. If one of the components is a plastic bag, it must be at least 3 mil thick and be used in conjunction with a strong and securely sealed fiberboard box. A plastic bag by itself will not meet the requirement for a secondary container. The Postal Service also adopts the packaging change for regulated medical waste and sharps waste mailpieces to require that the bottom of the outer shipping container and all joints and flaps be securely taped, glued, or stitched to maintain the integrity of the container. When tape or glue is used to secure an outer shipping container, the material must be water-resistant.

One sharps mailer and the institute commented that the Postal Service proposed definition of ''regulated medical waste'' should also include sharps. Both felt that the Postal Service should not maintain a separate category for sharps waste since DOT had no such distinction. One commenter further stated that if sharps waste were included in the definition of regulated medical waste, then the Postal Service would only need one set of packaging requirements and mailers would not have to use different marking requirements for mailpieces containing regulated medical waste and sharps waste. The Postal Service does not agree with those arguments. Since the Postal Service began allowing medical waste in the mail more than ten years ago, there has been, and continues to be, a great deal of concern involving the potential dangers associated with sharps waste should package failure occur during postal handling. The Postal Service has experienced a few instances in which a used syringe was found protruding from a sharps waste mailpiece that was not properly packaged prior to mailing. For this reason, the Postal Service will continue to maintain separate categories for sharps waste and other mailable types of regulated medical waste. This distinction will include separate requirements for the primary receptacles and different marking requirements for the outer shipping container. The Postal Service does not feel this will present a hardship on mailers since many already design and market their waste container systems for specific uses. It can also be noted that healthcare professionals generally do not mix sharps waste in the same containers used to collect other nonsharps medical waste.

Although not proposed by the Postal Service, one sharps waste mailer recommended the Postal Service require that sharps container systems be tested by ''certified'' labs, rather than by independent labs, as already permitted in DMM C023.8.7d. The Postal Service has not noted any significant problems with the use of independent labs, and therefore, sees no reason to adopt this recommendation. The problems associated with package failure of sharps waste container systems appear to be caused by container system design or the improper assembly of the container system by the end user prior to mailing.

The institute recommended that the Postal Service establish a ''performance-based'' standard for packaging rather than adopt new requirements for sealing the outer shipping container. The institute further suggested that the Postal Service allow a manufacturer or distributor to prove that their packaging material is safe when placed in the mail. We believe the commenter misinterpreted our intent and might not be aware of the preexisting requirements for package testing. The Postal Service has always required that packaging systems for sharps waste be tested by an independent testing facility using several of the tests detailed in 49 CFR part 178. Because the Postal Service has not experienced any significant problems with the test reports provided by the independent testing facilities, we do not feel there is a need to change the previously existing requirements for package testing. Additionally and as stated previously, the Postal Service will adopt new securing requirements for the outer shipping container to further reduce the potential for package failure during postal processing. The adoption of this requirement is directly related to specific instances of package failure that have occurred during postal handling.

The institute also recommended the that Postal Service require the assembly instruction sheet for each sharps container system also include a customer service telephone number for the end user to call if they need assistance or find a component part is missing. Although the Postal Service did not include this requirement in the proposed rule, it will adopt a variation of it in this final rule. The adopted text will require that each assembly sheet for a sharp waste or regulated medical waste container system list a customer service telephone number or provide specific information on where such a telephone number is located elsewhere on the container system. The Postal Service does not feel this will present a hardship for mailers, since many already display a customer service phone number on their assembly instruction sheets. The adoption of this requirement will help provide one more support level to the third-party end user who is being relied on to properly assemble the container system before depositing it into the mail. Proper assembly of a sharps container system prior to mailing is critical to ensuring it will be safely handled and transported without deterioration or package failure.

The institute further recommended that the Postal Service discontinue the use of the term ''waste manifest'' in the requirements that apply to the mailing of sharps waste and replace the term with ''shipping paper.'' The Postal Service did not propose this change and feels it is unnecessary. The text in DMM C023.8.7c(3) states that the waste manifest serves as the shipping paper. In addition, such a change could pose a hardship for regulated medical waste and sharps waste mailers who presently identify this document as a waste manifest, by causing them to incur the cost for redesigning and replacing the documents.

4. Comments Supporting the Proposed Changes

Seven of the commenters, including three sharps mailers, two medical labs, the institute, and the law firm, submitted comments that supported some of the requirements in the Postal Service proposed rule. Those comments are summarized in this section.

Two of the sharps mailers stated that they did not oppose the Postal Service proposal to limit the maximum weight of a mailpiece containing regulated medical waste or sharps waste to 25 pounds. Another further stated that, in

general, they supported the Postal Service proposed rule.

One medical lab stated they were pleased with the Postal Service changes that would improve packaging integrity and they supported them. The commenter further stated that they approved of the text in DMM C023.8.10a that included the phrase ''* * * for drug testing programs or for insurance purposes * * *'' within the definition of the term diagnostic (clinical) specimen. The commenter stated that the slightly stricter packaging requirements would help to ensure their receipt of safely packaged specimens.

Three commenters, including one medical lab, the institute, and the law firm, supported the Postal Service effort to align the mailing standards with the DOT regulations in 49 CFR. These commenters felt that harmonization of the packaging requirements among all agencies and regulators would be a positive benefit for all mailers and shippers.

The institute also stated that they recognized and supported the continued role of the Postal Service in providing mailing options for senders of infectious substances and mail-back systems.

One medical lab stated they appreciated the Postal Service proposal to provide specific packaging requirements for dry specimens. They further noted they supported the development of mailing standards that benefit both the industry and the Postal Service.

Part C—Summary of Changes

In this final rule, the Postal Service adopts the following changes to the mailing standards in DMM C023.8.0 for Division 6.2 infectious substances:

- New classification criteria for Division 6.2 infectious substances based on the defining criteria developed by the World Health Organization (WHO) and consistent with the DOT Federal regulations in 49 CFR for domestic transport and the International Civil Aviation Organization (ICAO) technical instructions for international transport.
- New DOT packaging requirements that are applicable to the mailable types of Division 6.2 materials and consistent with the ICAO technical instructions. For safety reasons, in some instances the Postal Service volume limits are lower than the DOT limits.
- New DOT Federal requirements that regulate diagnostic (clinical) specimens in Risk Groups 2, 3, or 4 as hazardous materials.
- New DOT Federal requirements that do not regulate certain Risk Group 1 materials, including diagnostic (clinical) specimens, as hazardous materials.
- Revisions and modifications in the DOT Federal regulations related to the definitions of Division 6.2 materials and clarification of the use of the biohazard symbol on regulated and nonregulated material.

In addition, the Postal Service is adopting a few minor clarifications and changes to the hazardous materials standards in DMM C023 and certain related standards in DMM C021, C023, C024, C050, and F010. These changes will improve clarity in the standards and reduce misunderstandings. They will also improve packaging integrity for mailable types of regulated medical waste and sharps waste, and provide a greater level of safety during handling for both Postal Service employees and the public. These changes include:

- Minor revisions to the text in DMM C021 to improve clarity.
- Minor clarifications to the definitions in DMM C023.1.1 including added text in the definition for ''air transportation requirements'' to note that the Postal Service does not guarantee air transportation service for any class of mail. Air transportation service is usually provided for First-Class Mail®, Priority Mail®, and Express Mail® destined to zones 5 through 8; however, air transportation service is dependent on the ability of the Postal Service to procure an air carrier.
- Standardization of the terminology used in DMM C023 for identifying the different components required for the proper packaging of mailable hazardous materials.
- Expansion of the requirements in DMM C023.8.0 to establish that mailable types of regulated medical waste are subject to the same authorization requirements as sharps waste.
- Clarifications and minor changes to the requirements in DMM C023.8.0 for regulated medical waste and sharps waste containers to enhance the accuracy of the regulations and reduce misunderstanding of the standards. In addition, the Postal Service adopts additional limitations for regulated medical waste and sharps waste containers to ensure packaging integrity during Postal Service handling and to provide a greater level of safety for Postal Service employees and the public.
- Standardization of the maximum weight limit in DMM C023 for several different types of mailable hazardous materials as 25 pounds or less. This change affects nonflammable compressed gases, matches, regulated medical waste, sharps waste, and nonspillable wet batteries.
- Reinstatement of former DMM C024.18.0 (DMM Issue 56) with revised text to clarify the mailability of odd-shaped items in paper envelopes and to support the restrictions for harmful matter in DMM C021. Additional clarifying text is also added to DMM C050.2.2d.
- Revisions to DMM F010 that prohibit the use of the ancillary service endorsement ''Change Service Requested'' on Priority Mail, First-Class Mail, Standard Mail, and Package Services mail containing mailable hazardous materials under DMM C023. Also, a revision to require a return or forwarding endorsement on Standard Mail containing mailable hazardous materials.

These changes are effective June 12, 2003. However, mailers are provided with a phase-in period through January 1, 2004, for implementation of the new packaging requirements for diagnostic specimen mailpieces using a business reply mail format and medical waste mailpieces (including sharps waste) using a merchandise return service format. This time period will allow mailers to exhaust any existing packaging stock already in circulation.

The Postal Service believes that the adoption of the changes in this final rule will help to ensure an acceptable level of security and safety during Postal Service handling for the limited types and quantities of hazardous materials that are permitted in the U.S. mail.

Based on the proposed rule, and after careful consideration of the comments received, as described above, the Postal Service adopts the following changes to the Domestic Mail Manual, which are incorporated by reference in the Code of Federal Regulations. See 39 CFR part 111:

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 414, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

■ 2. Revise the following sections of the *Domestic Mail Manual* (DMM) as follows:

Domestic Mail Manual (DMM)

* * * * *

C Characteristics and Content

C000 General Information

* * * * *

C020 Restricted or Nonmailable Articles and Substances

C021 Articles and Substances Generally

* * * * *

2.0 NONMAILABLE ARTICLES AND SUBSTANCES—GENERAL

2.1 Basic Information

[Delete the last two sentences of 2.1 and insert the following text to read as follows:]

* * *The mailability standards that apply to perishable, hazardous, and restricted matter are detailed in C022, C023, and C024, respectively. Publication 52, *Hazardous, Restricted, and Perishable Mail*, contains additional clarification and further describes the conditions of preparation and packaging under which the USPS accepts for mailing potentially harmful matter that is otherwise nonmailable. Publication 52 also contains detailed information on the mailability of specific hazardous materials.

* * * * *

3.0 INJURIOUS AND HARMFUL ARTICLES

3.1 General

Except as provided in this document, any article, composition, or material is nonmailable if it can kill or injure another or injure the mail or other property. Harmful matter includes but is not limited to:

* * * * *

[Revise item b to read as follows:]

b. All poisonous animals except scorpions mailed for medical research purposes or for the manufacture of antivenom; all poisonous insects; all poisonous reptiles; and all types of snakes, turtles, and spiders.

* * * * *

3.2 Hazardous Materials

[Revise the first sentence to read as follows:]

Harmful matter also includes regulated hazardous materials as defined in C023 that are likely to harm USPS employees or to destroy, deface, or otherwise damage mail or postal equipment.* * *

4.0 MARKING

* * * * *

4.2 Addressing

[Revise 4.2 to read as follows:]

For any matter mailed under the provisions in C020, the recipient's name and address must be affixed or applied directly to the mailpiece using a material or method that is not water-soluble and not easily smeared or rubbed off. Except for diagnostic specimen mailpieces using a business reply mail format and nonregulated materials, a return address that includes the sender's name and address must appear on all matter mailed under C020. The return address, when required, must be applied using a material or method that is not water-soluble and not easily smeared or rubbed off.

4.3 Warning Label

[Revise the last sentence in 4.3 to read as follows:]

* * *See C023 for the warning label requirements that apply to the mailing of hazardous materials.

* * * * *

C023 Hazardous Materials

Summary

[Revise the Summary to read as follows:]

C023 describes the general standards, restrictions, and prohibitions that apply to the mailability of hazardous materials.

1.0 GENERAL

1.1 Definitions

The following conditions apply:

[Revise the last sentence in item a to read as follows:]

a. * * *In international commerce, hazardous materials are known as dangerous goods.

[At the end of item b, add a new sentence to read as follows:]

b. * * *Almost all limited quantity materials are nonmailable.

[At the end of item c, add a new sentence to read as follows:]

c. * * *ORM–D materials having the proper shipping name of ''consumer commodity'' are mailable subject to USPS quantity and packaging standards.

* * * * *

[Revise items e and f to read as follows:]

e. *Air transportation requirements*, for the purposes of C023 only, apply to all mailable hazardous materials sent at the First-Class Mail, Priority Mail, or Express Mail rates. All mailable hazardous materials sent at those rates must meet the requirements that apply to air transportation. Mailable hazardous materials sent at any of those rates may or may not be transported via air depending on the distance between the point of origination and the point of destination, and the ability of the USPS to obtain an air carrier between those points.

f. *Surface transportation requirements*, for the purposes of C023 only, apply to all mailable hazardous materials sent at the Standard Mail or Package Services rates. All mailable hazardous materials sent at the Standard Mail or Package Services rates must meet the requirements that apply to surface transportation.

* * * * *

[Revise item h to read as follows:]

h. *Secondary container* is the packaging component into which the primary receptacle(s) and any required absorbent and cushioning material is securely placed. The packaging of certain mailable hazardous materials does not require the use of a secondary container.

[Revise item i to read as follows:]

i. *Outer shipping container* is the exterior packaging component into which a primary receptacle, along with any required absorbent and cushioning material, and the secondary container (if required) are securely placed. The outer shipping container bears the addressing information along with all required markings.

1.2 U.S. Department of Transportation

[Revise 1.2 to read as follows:]

The U.S. Department of Transportation (DOT) regulates the surface and air carriage of hazardous materials within the United States via any means of transportation. The DOT regulations for the transport of hazardous materials are codified in Title 49, *Code of Federal Regulations* (49 CFR) 100–185. USPS mailing standards for hazardous materials generally adhere to 49 CFR, but also include many additional limitations and prohibitions.

[Renumber current 1.3 through 1.9 as new 1.4 through 1.10 and insert new 1.3 to read as follows:]

1.3 USPS Standards

The USPS standards generally restrict the mailing of hazardous materials to ORM–D materials with the proper shipping name of ''consumer commodity'' that meet USPS quantity limitations and packaging requirements. The few non-ORM–D materials permitted to be mailed are subject to the standards in C023. Detailed information on the mailability of specific hazardous materials is contained in Publication 52, *Hazardous, Restricted, and Perishable Mail.*

1.4 Hazard Class

* * * * *

[Renumber ''Exhibit 1.3 DOT Hazard Classes and Mailability Summary'' as ''Exhibit 1.4 DOT Hazard Classes and Mailability Summary.'']

* * * * *

1.6 Mailability Rulings

[In the first sentence, change ''package'' to ''mailpiece.'']

1.7 Warning Labels

[Change ''division 6.2 materials under 8.3'' to ''Division 6.2 materials under 8.5'' and ''as required in 1.7'' to ''as required in 1.8''.]

1.8 Package Markings

[Delete the last sentence in 1.8 and insert two new sentences to read as follows:]

* * *The designation ''ORM–D'' or ''ORM–D AIR'', as required, must be placed within a rectangle that is approximately 6.3 mm (¼ inch) larger on each side than the designation. Mailable ORM–D materials sent as Standard Mail or Package Services must also be marked on the address side as ''Surface Only'' or ''Surface Mail Only.''

1.9 Shipping Papers

[Revise 1.9 to read as follows:]

A shipper's declaration for dangerous goods (*i.e.*, shipping paper) prepared under 49 CFR 172.200 through 172.205 is required for certain types of hazardous materials when mailed. The shipping paper must be completed and signed in triplicate by the mailer. It must be affixed to the outside of the mailpiece within an envelope or similar carrier that can be easily opened and resealed to allow viewing of the document. Shipping papers are required as follows:

a. *Air transportation requirements.* Except for nonregulated materials sent under 8.3 or 8.10 and diagnostic specimens sent under 8.6, mailpieces containing mailable hazardous materials sent at the First-Class Mail, Priority Mail, or Express Mail rates must include a shipping paper.

b. *Surface transportation requirements.* Except for nonregulated materials sent under 8.3 or 8.10 and mailable ORM–D materials, mailpieces containing mailable hazardous materials sent at the Standard Mail or Package Services rates must include a shipping paper.

1.10 Air Transportation Prohibitions

[Revise the first two sentences in 1.10 to read as follows (the remainder of 1.10 is unchanged):]

All mailable hazardous materials sent at the First-Class Mail, Priority Mail, or Express Mail rates must meet the requirements for air transportation. The following types of hazardous materials that are prohibited from carriage on air transportation must not be sent at the First-Class Mail, Priority Mail, or Express Mail rates:

* * * * *

2.0 EXPLOSIVES (HAZARD CLASS 1)

2.1 Definition

[In the second sentence, change ''Exhibit 1.3'' to ''Exhibit 1.4''.]

2.2 Mailability

[In the second sentence, change ''division 1.4'' to ''Division 1.4S.'']

3.0 GASES (HAZARD CLASS 2)

3.1 Definition

[In item b, change ''division 2.1 or 2.3'' to ''Division 2.1 or 2.3''.]

3.2 Mailability

[In the second, third, and fourth sentences, change ''division'' to ''Division.'']

3.3 Container

[Revise 3.3 to read as follows:]

An other-than-metal primary receptacle containing a mailable gas may be acceptable if the water capacity of the primary receptacle is 4 fluid ounces (7.22 cubic inches) or less per mailpiece and the primary receptacle meets 49 CFR requirements. Mailable nonflammable and flammable compressed gases are acceptable in metal primary receptacles that have a water capacity up to 33.8 fluid ounces (1 liter or 61.0 cubic inches), depending on their internal pressure. A DOT 2P container must be used as the primary receptacle if the internal pressure is from 140 to 160 psig at 130°F (55°C). A DOT 2Q container must be used as the primary receptacle if the pressure is from 161 to 180 psig at 130°F (55°C). A container with an internal pressure over 180 psig at 130°F (55°C) is prohibited from mailing. Mailable flammable compressed gases are restricted to 33.8 fluid ounces (1 liter) per mailpiece. Mailable nonflammable compressed gases are permitted in individual 33.8 fluid ounce (1 liter) containers that must be securely packed within an outer shipping container. Each mailpiece must not exceed a total weight of 25 pounds.

3.4 Marking

[In the first sentence, change ''Surface Mail Only'' to ''''Surface Only'' or ''Surface Mail Only.'''']

4.0 FLAMMABLE AND COMBUSTIBLE LIQUIDS (HAZARD CLASS 3)

* * * * *

4.2 Flammable Liquid Mailability

[In items a and b, change ''secondary packaging'' to ''secondary container''; change ''outer packaging'' to ''outer shipping container''; and change ''Surface Mail Only'' to ''''Surface Only'' or ''Surface Mail Only.'''']

4.3 Combustible Liquid Mailability

[In items a and b, change ''secondary packaging'' to ''secondary container''; change ''outer packaging'' to ''outer shipping container''; and change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

[Revise item c to read as follows:]

c. For air or surface transportation, if the flashpoint is above 200°F (93°C) the material is not regulated as a hazardous material. Such nonregulated materials must be properly and securely packaged to prevent leakage under the general packaging requirements in C010.

4.4 Cigarette Lighters

[In the second sentence, change ''division 2.1'' to ''Division 2.1''.]

[In item c, change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

5.0 FLAMMABLE SOLIDS (HAZARD CLASS 4)

* * * * *

5.2 Mailability

[Change ''outer packaging'' to ''outer shipping container'' and change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

5.3 Matches

* * * * *

[Revise items c and d to read as follows:]

c. They are tightly packed in a securely sealed primary receptacle to prevent any shifting or movement that could cause accidental ignition by rubbing against adjoining items. The primary receptacle(s) is placed securely within an outer shipping container made of fiberboard, wood, or other equivalent material.

Multiple primary receptacles may be placed in a single outer shipping container. The address side of the mailpiece must be marked ''Surface Only'' or ''Surface Mail Only'', and ''Book Matches'', ''Strike-on-Card Matches'', or ''Card Matches'', as appropriate. A shipping paper is not required.

d. The gross weight of each mailpiece is not more than 25 pounds.

6.0 OXIDIZING SUBSTANCES, ORGANIC PEROXIDES (HAZARD CLASS 5)

* * * * *

6.2 Mailability

[Revise 6.2 to read as follows:]

Oxidizing substances and organic peroxides are prohibited in international mail. For domestic mail, a material that can qualify as an ORM–D material is permitted via air or surface transportation. Liquid materials must be enclosed within a primary receptacle having a capacity of 1 pint or less; the primary receptacle(s) must be surrounded by absorbent cushioning material and held within a leak-resistant secondary container that is packed within a strong outer shipping container. Solid materials must be contained within a primary receptacle having a weight capacity of 1 pound or less; the primary receptacle(s) must be surrounded with cushioning material and packed within a strong outer shipping container. Each mailpiece may not exceed a total weight of 25 pounds. The address side of each mailpiece must be plainly and durably marked with ''ORM–D AIR'' or ''ORM–D,'' as applicable, immediately following or below the proper shipping name. A mailable Class 5 material sent via surface transportation must be marked ''Surface Mail'' or ''Surface Mail Only'' on the address side. A mailable material sent via air transportation must bear a shipper's declaration for dangerous goods.

7.0 TOXIC SUBSTANCES (HAZARD CLASS 6, DIVISION 6.1)

7.1 Definitions

[In the first sentence, change ''division 6.1'' to ''Division 6.1''.]

7.2 Mailability

[In the second sentence, change ''division 6.1'' to ''Division 6.1''.]

7.3 Authorized Parties

[In the first sentence, change ''division 6.1'' to ''Division 6.1''.]

7.4 Packaging and Marking

[In item a, change ''inner receptacle(s)'' to ''primary receptacle(s)''; change ''secondary packaging'' to ''secondary container''; change ''outer packaging'' to ''outer shipping container''; and change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

[In item b, change ''secondary leakproof (for liquids) or siftproof (for solids) packaging'' to ''leakproof (for liquids) or siftproof (for solids) secondary container''; change ''secondary packaging'' to ''secondary container''; change ''outer packaging'' to ''outer shipping container''; and change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

* * * * *

8.0 INFECTIOUS SUBSTANCES (HAZARD CLASS 6, DIVISION 6.2)

[Revise 8.0 to read as follows:]

8.1 General

The materials covered under Division 6.2 include infectious substances (*i.e.*, etiologic agents), biological products, cultures and stocks, diagnostic (clinical) specimens, regulated medical waste, sharps waste, toxins, and used health care products. Division 6.2 materials are not permitted in international mail or domestic mail, except when they are intended for medical or veterinary use, research, or laboratory certification related to the public health; and only when such materials are properly prepared for mailing to withstand shocks, pressure changes, and other conditions related to ordinary handling in transit. Mailable Division 6.2 materials sent as international mail must meet the standards in *International Mail Manual* 135. For domestic mail, mailable Division 6.2 materials must meet the applicable standards in 8.0. Unless otherwise noted, all mailable Division 6.2 materials in Risk Groups 2, 3, or 4 must be prepared to meet the requirements for air transportation.

8.2 Definitions

The terms used in the standards for Division 6.2 materials are defined as follows:

a. *Division 6.2 (infectious substance)* means a material known to contain or suspected of containing a pathogen. A pathogen is a virus or microorganism (including its viruses, plasmids, or other genetic elements, if any) or a proteinaceous infectious particle (prion) that has the potential to cause disease in humans or animals. A Division 6.2 material must be assigned to a risk group as defined in 8.2f. Assignment to a risk group is based on the known medical condition and history of the source patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgment concerning individual circumstances of the source patient or animal. Infectious substances are subject to applicable requirements in 42 CFR part 72 (Interstate Shipment of Etiologic Agents).

b. *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product used in the prevention, diagnosis, treatment, or cure of diseases in humans or animals. A biological product includes a material manufactured and distributed in accordance with one of the following provisions: 9 CFR part 102 (Licenses for Biological Products); 9 CFR part 103 (Experimental Products, Distribution, and Evaluation of Biological Products Prior to Licensing); 9 CFR part 104 (Permits for Biological Products); 21 CFR part 312 (Investigational New Drug Application); 21 CFR part 314 (Applications for FDA Approval to Market a New Drug); 21 CFR part 600–680 (Biologics); or 21 CFR part 812 (Investigational Device Exemptions). A biological product known to contain or suspected of containing a pathogen in Risk Group 2, 3, or 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate, unless otherwise excepted by standard.

c. *Cultures and stocks* means a material prepared and maintained for growth and storage and containing a Risk Group 2, 3, or 4 infectious substance.

d. *Diagnostic (clinical) specimen* means any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected animals. A diagnostic specimen is not assigned a UN identification number unless the source patient or animal has or may have a serious human or animal disease from a Risk Group 4 pathogen, in which case it must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate. Assignment to UN 2814 or UN 2900 is based on known medical condition and history of the patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgment concerning individual circumstances of the source patient or animal.

e. *Regulated medical waste,* for USPS purposes, means a soft waste material (other than a sharp) known to contain or suspected of containing an infectious substance in Risk Group 2 or 3 and generated in the diagnosis, treatment, or immunization of human beings or animals; research on the diagnosis, treatment, or immunization of human beings or animals; or the production or testing of biological products. Soft medical waste includes items such as

used rubber gloves, swabs, gauze, tongue depressors, etc. Regulated medical waste classified in Risk Group 4 is nonmailable.

f. *Risk group* means a ranking of a microorganism's ability to cause injury through disease. A risk group is defined by criteria developed by the World Health Organization (WHO) that are based on the severity of the disease caused by the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventive agents and treatment. There is no relationship between a risk group and a DOT packing group. Assignment to a risk group is based on the known medical condition and history of the source patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgment concerning individual circumstances of the source patient or animal. The sender is responsible for accurately ranking a mailable material within the correct risk group. Exhibit 8.2f details the criteria for each risk group according to the level of risk.

Exhibit 8.2f Risk Group Criteria

Risk group	Pathogen	Risk to individuals	Risk to community
4	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.	High	High.
3	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available.	High	Low.
2	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited.	Moderate	Low.
1	A microorganism that is unlikely to cause human or animal disease. A material containing only such microorganisms is not subject to regulation as a hazardous material, but it is subject to the packaging requirements in 8.10, unless otherwise noted in 8.0.	None or Very Low.	None or Very Low.

g. *Sharps,* for USPS purposes, means any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and that is also capable of cutting or penetrating skin or a packaging material. Sharps include used medical waste such as needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires. Sharps waste classified in Risk Group 4 is nonmailable.

h. *Toxin* means a Division 6.1 material from a plant, animal, or bacterial source. A toxin containing an infectious substance or a toxin contained in an infectious substance must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

i. *Used health care product* means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the definition of a diagnostic specimen, biological product, regulated medical waste, or sharps waste, is contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation. A used health care product classified in Risk Group 4 is nonmailable.

8.3 Nonregulated Materials

The following materials are not subject to regulation as Division 6.2 hazardous materials and are mailable when the packaging requirements in 8.10 are met:

a. A diagnostic (clinical) specimen known to contain or suspected of containing a microorganism in Risk Group 1, or that does not contain a pathogen. Also, a diagnostic specimen in which the pathogen has been neutralized or inactivated so that exposure to it cannot cause disease.

b. A biological product known to contain or suspected of containing a microorganism in Risk Group 1, or that does not contain a pathogen. Also any biological product, including an experimental product or component of a product, subject to Federal approval, permit, or licensing requirements, such as those required by the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) or the U.S. Department of Agriculture (USDA).

c. Blood collected for blood transfusion or the preparation of blood products; blood products; tissues intended for use in surgical procedures; and human cell, tissues, and cellular and tissue-based products regulated under authority of the Public Health Service Act and/or the Food, Drug, and Cosmetic Act. Also, blood collected for blood transfusion or the preparation of blood products and sent for testing as part of the collection process, except where the person collecting the blood has reason to believe it contains a pathogen in Risk Group 2 or 3, in which case the test sample must be packaged under 8.6.

d. A material, including a Division 6.2 waste, that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance in Risk Group 2, 3, or 4.

e. Forensic material in Risk Group 1 transported on behalf of a U.S. government, state, local, or Indian tribal government agency.

f. Environmental microbiological samples, such as samples of dust from a ventilation system or mold from a wallboard, collected to evaluate occupational and residential exposure risks.

8.4 Packaging—General

All materials mailable under the provisions in 8.0 must be properly packaged. Exhibit 8.4a lists the specific reference in 8.0 under which each type of mailable material must be packaged.

Exhibit 8.4A Packaging References for Materials Mailable Under 8.0

Material	Risk group			
	1	2	3	4
Blood for Transfusion	8.10	8.6	8.6	nm
Biological Product	8.10	8.5	8.5	8.5
Culture or Stock	8.10	8.5	8.5	8.5
Diagnostic Specimen	8.10	8.6	8.6	8.5
Division 6.2 (Infectious Substance)	8.10	8.5	8.5	8.5
Forensic Material	8.10	8.9	8.9	8.5
Regulated Medical Waste	8.7	8.7	8.7	nm
Sharps Waste	8.7	8.7	8.7	nm
Toxin (Division 6.2)	8.10	8.5	8.5	8.5
Treated Medical Waste	8.10	n/a	n/a	n/a
Used Health Care Product	8.8	8.8	8.8	nm

nm—nonmailable.
n/a—not applicable.

8.5 Packaging of Division 6.2 Infectious Substances

Division 6.2 materials include infectious substances (etiologic agents), biological products, cultures or stocks, and toxins known or suspected to contain a Risk Group 2, 3, or 4 pathogen. It also includes diagnostic specimens known or suspected to contain a Risk Group 4 pathogen. The packaging of Division 6.2 infectious substances is subject to these standards:

a. All Division 6.2 materials must meet the packaging requirements in 49 CFR 173.196. Either the primary receptacle or the secondary container must be capable of withstanding, without leakage, an internal pressure that produces a pressure differential of not less than 0.95 bar, 14 psi (95 kPa), and temperatures in the range of −40°F to 131°F (−40°C to 55°C) as required by 49 CFR 173.196.

b. The material must be packaged in a securely sealed and watertight primary receptacle (test tube, vial, etc.) that is enclosed in another watertight and durable secondary container that is securely sealed. Several primary receptacles may be enclosed in the secondary container if there is adequate cushioning material between them to prevent breakage during normal handling, and if the total volume of the material in all enclosed primary receptacles does not exceed 50 ml for liquids or 50 g for solids. The primary receptacle(s) and the secondary container must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

c. The space between the primary receptacle(s) and the secondary container at the top, bottom, and sides must contain enough absorbent material to take up the entire contents of the primary receptacle(s) in case of breakage or leakage.

d. The primary receptacle(s) and the secondary container must be securely enclosed in an outer shipping container constructed of fiberboard or other equivalent material. No external surface of the outer shipping container may be less than 3.9 inches (100 mm) as required by 49 CFR 173.196. An itemized list of the contents of the primary receptacle(s) must be enclosed between the secondary container and the outer shipping container.

e. Each mailpiece must be designed and constructed so that, if it were subject to the environmental and test conditions in 49 CFR 178.609, there would be no release of the contents to the environment and no significant reduction in the effectiveness of the packaging.

f. All mailpieces sent under 8.5 must be sent First-Class Mail or Priority Mail and must be marked on the address side with the proper shipping name and UN number of the material (*e.g.*, ''UN 2814, Infectious Substances, Affecting Humans'' or ''UN 2900, Infectious Substances, Affecting Animals''). Each mailpiece must bear a DOT Class 6 label for infectious substances (etiologic agents), proper UN package specification markings, and orientation markings. A shipping paper is required. Any mailpiece classified as a Risk Group 4 material and that contains any of the select agents or toxins listed in 42 CFR 73.4 or 73.5 must meet all requirements in 42 CFR 72 and must also be sent using Registered Mail service.

g. Articles that include dry ice as a refrigerant for the infectious substance must meet the requirements in 49 CFR 173.196(b)(2)(ii).

8.6 Packaging for Diagnostic Specimens in Risk Group 2 or 3

A diagnostic (clinical) specimen known or suspected to contain a Risk Group 4 pathogen must be packaged under 8.5. A diagnostic specimen classified in Risk Group 1 must be packaged under 8.10. A diagnostic specimen classified in Risk Group 2 or 3 and that meets the definition in 8.2d must be sent as First-Class Mail, Priority Mail, or Express Mail. Such materials must be packaged in a triple packaging, consisting of a primary receptacle, secondary container, and outer shipping container, subject to the following specific requirements:

a. *Liquid Diagnostic (Clinical) Specimens.*

(1) The specimen must be contained in a leakproof and securely sealed primary receptacle. A single primary receptacle may not contain more than 500 ml of a specimen. Multiple primary receptacles are permitted in a single mailpiece if the mailpiece does not contain more than 4,000 ml. The primary receptacle(s) must be surrounded with sufficient cushioning material to withstand shock and pressure changes and with absorbent material capable of taking up the entire liquid contents should the primary receptacle(s) leak.

(2) The primary receptacle(s) and the absorbent material must be securely packed within a secondary container in such a way that, under normal conditions of transport, the primary receptacle cannot break, be punctured, or leak its contents into the secondary container.

(3) The secondary container must be leakproof, securely sealed, and placed within a strong outer shipping container having suitable cushioning material such that any leakage of the contents does not impair the protective properties of the cushioning material or the outer shipping container. The secondary container must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

(4) The primary receptacle(s) or the secondary container must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 0.95 bar, 14 psi (95 kPA). The completed mailpiece must be capable of successfully passing

the drop test in 49 CFR 178.603 at a drop height of at least 1.2 meters (3.9 feet). The address side of the outer shipping container must be clearly and durably marked ''Diagnostic Specimen.'' A shipping paper is not required.

b. *Solid (or Dried) Diagnostic Specimens.*

(1) The primary receptacle must be siftproof with a capacity of not more than 500 g (1.1 pounds).

(2) If several fragile primary receptacles are placed in a single secondary container, they must be individually wrapped or separated with sufficient cushioning material to prevent contact between them. The secondary container must be siftproof to contain the contents should the primary receptacle(s) leak. The secondary container must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

(3) The outer shipping container may not exceed 4 kg (8.8 pounds) capacity. The outer shipping container must be clearly and durably marked ''Diagnostic Specimen.'' A shipping paper is not required.

8.7 Sharps Waste and Other Mailable Regulated Medical Waste

Regulated medical waste and sharps waste known to contain or suspected of containing an infectious substance in Risk Group 4 are nonmailable. Regulated medical waste and sharps waste as defined in 8.2e and 8.2g, respectively, and classified in Risk Group 1, 2, or 3 are permitted for mailing only using merchandise return service (see S923) with First-Class Mail or Priority Mail, subject to the following requirements:

a. *Authorization.* Each distributor or manufacturer of a complete regulated medical waste or sharps waste mailing container system (including all component parts required to safely mail such waste to a storage or disposal facility) must obtain authorization from the USPS prior to mailing. Before applying for authorization, each type of mailing container system must be tested and certified under the standards in 8.7d by an independent testing facility. The manufacturer or distributor in whose name the authorization is being sought must submit a written request to the manager, Mailing Standards, USPS Headquarters (see G043 for address). The request for authorization must contain the following:

(1) An irrevocable $50,000 surety bond or letter of credit as proof of sufficient financial responsibility to cover disposal costs if the manufacturer (or distributor) ceases doing business before all its waste container systems are disposed of or to cover cleanup costs if spills occur while the containers are in USPS possession. The surety bond or letter of credit must be issued in the name of the manufacturer or distributor seeking the authorization and must name the USPS as the beneficiary or obligee, as appropriate.

(2) Address of the headquarters or general business office of the distributor or manufacturer seeking the authorization.

(3) Address of each disposal and storage site.

(4) List of all types of mailing container systems to be covered by the request, a complete sample of each mailing container system, and proof of package testing certifications performed by the independent testing facility that subjected the packaging materials to the testing requirements in 8.7d.

(5) Copy of the proposed waste manifest (*i.e.*, shipping paper) to be used with each mailing container system.

(6) 24-hour toll free telephone number for emergencies.

(7) List of the types of waste to be mailed for disposal in each mailing container system.

(8) Copy of the merchandise return service label to be used with each mailing container system.

b. *Packaging.* Regulated medical waste and sharps waste in Risk Group 4 are nonmailable. A waste material treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance in Risk Group 2, 3, or 4, must be packaged under 8.10. The packaging for regulated medical waste and sharps waste in Risk Group 1, 2, or 3 is subject to these standards:

(1) Regulated medical waste and sharps waste meeting the definitions in 8.2e and 8.2g, respectively, must be collected in a rigid, securely sealed, and leakproof primary receptacle. For sharps waste, the primary receptacle must also be puncture-resistant and may not have a maximum capacity that exceeds 3 gallons in volume. For regulated medical waste, the primary receptacle may not have a maximum capacity that exceeds 5 gallons in volume. Each primary receptacle may not contain more than 50 ml (1.66 ounces) of residual waste liquid. Each primary receptacle must display the international biohazard symbol shown in Exhibit 8.7c(2). Each primary receptacle must maintain its integrity when exposed to temperatures between 0° and 120°F.

(2) The primary receptacle must be packaged within a watertight secondary container or containment system. The secondary container may consist of more than one component. If one of the components is a plastic bag, it must be at least 3 mil in thickness and be used in conjunction with a strong fiberboard box. A plastic bag by itself does not meet the requirement for a secondary container. Several primary receptacles may be enclosed in a secondary container. The primary receptacle(s) must fit securely and snugly within the secondary container to prevent breakage during ordinary processing.

(3) The secondary container must be enclosed in a strong outer shipping container constructed of 200-pound grade corrugated fiberboard. The joints and flaps of the outer shipping container must be securely taped, glued, or stitched to maintain the integrity of the container. When tape or glue is used to secure an outer shipping container, the material must be water-resistant. Fiberboard boxes with interlock bottom flaps (*i.e.*, easy-fold) are not permitted as outer shipping containers unless reinforced with water-resistant tape. The secondary container must fit securely and snugly within the outer shipping container to prevent breakage during ordinary processing.

(4) There must be enough material within a watertight barrier to absorb and retain three times the total liquid allowed within the primary receptacle (150 ml per primary receptacle) in case of leakage.

(5) Each mailpiece must not weigh more than 25 pounds.

(6) In each mailing container system, the authorized manufacturer or distributor must include a step-by-step instruction sheet that clearly details the proper sequence and method of container system assembly prior to mailing to prevent package failure during transport due to improper assembly. The instruction sheet must also include a customer service telephone number, or provide specific information on where such a telephone number is located elsewhere on the container system, for third-party end users to contact if they have assembly questions or find a component part is missing.

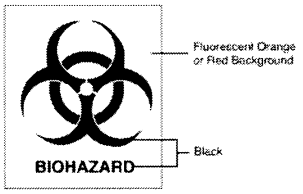
c. *Mailpiece Labeling, Marking, and Documentation.* Regulated medical waste and sharps waste must meet the following requirements:

(1) Each primary receptacle and outer shipping container must bear a label, which cannot be detached intact, showing: (a) The company name of the manufacturer or the distributor to which the mailing authorization is issued; (b) the USPS Authorization Number, and; (c) the container ID number (or unique model number) signifying that the

packaging material is certified and that the manufacturer or distributor obtained the authorization required by 8.7a.

(2) The primary receptacle(s) and the outer shipping container must bear the international biohazard symbol in black with either a fluorescent orange or fluorescent red background as shown in Exhibit 8.7c(2).

Exhibit 8.7c(2) **International Biohazard Symbol**



(3) Each mailpiece must have a four-part waste manifest, which also serves as the shipping paper. The manifest must be affixed to the outside of the mailpiece in an envelope or similar carrier that can be easily opened and resealed to allow review of the document. The manifest must comply with all applicable requirements imposed by the laws of the state from which the container system is mailed. At a minimum, the information in Exhibit 8.7c(3) must be on the manifest.

Exhibit 8.7c(3)
Manifest for Regulated Medical Waste and Sharps Waste Containers

1. Generator (Mailer):

a. Name.
b. Complete address (not a Post Office box).
c. Telephone number.
d. Description of contents of mailing container. ''Regulated Medical Waste'' or ''Regulated Medical Waste—Sharps'' is required as appropriate.
e. Date container was mailed.
f. State permit number of approved facility in which contents are to be disposed of.

2. Destination Facility (Disposal Site)

Complete address (not a Post Office box).

3. Generator's (Mailer's) Certification

The following certification statement must be printed on manifest: ''I certify that this container has been approved for the mailing of [insert either ''regulated medical waste'' or ''sharps waste,'' as appropriate], has been prepared for mailing in accordance with the directions for that purpose, and does not contain excess liquid or nonmailable material in violation of the applicable Postal Service regulations. I AM AWARE THAT FULL RESPONSIBILITY RESTS WITH THE GENERATOR (MAILER) FOR ANY VIOLATION OF 18 USC 1716 WHICH MAY RESULT FROM PLACING IMPROPERLY PACKAGED ITEMS IN THE MAIL. I also certify that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packed, marked, and labeled, and in proper condition for carriage by air according to the national governmental regulations.''
This statement must be followed by printed or typewritten name of generator (mailer), signature of generator, and date signed.

4. Destination Facility (Storage or Disposal Site)

The following certification statement of receipt, treatment, and disposal must be printed on manifest: ''I certify that the contents of this container have been received, treated, and disposed of in accordance with all local, state, and federal regulations.''
This statement must be followed by printed or typewritten name of an authorized recipient at destination facility, signature of authorized recipient, and date signed.

5. Transporter Intermediate Handler Other Than the Postal Service (If Different From Destination Facility)

a. Name.
b. Complete address (not a Post Office box).
c. Printed or typewritten name of transporter or intermediate handler.
d. Signature of transporter or intermediate handler and date signed.

6. Serialized Waste Manifests

Each waste manifest or mail disposal service shipping record must be serialized using a unique numbering system for identification purposes.

7. Comment Area

Each manifest must contain an area designated for entering comments or noting discrepancies.

8. Completion and Distribution of Waste Manifest
Each manifest must contain instructions for properly completing the four-part form. Copies of the form must be distributed as follows: a. One copy must be kept by generator (mailer). b. One copy must be kept by transporter or intermediate handler for 90 days. c. One copy must be kept by destination facility for 90 days. d. One copy must be mailed to generator by destination facility.
9. Emergency Telephone Number
Each manifest must bear the following statement with appropriate information: ''IN CASE OF EMERGENCY, OR THE DISCOVERY OF DAMAGE OR LEAKAGE, CALL 1–800–###–####.''

(4) The outer shipping container must bear a properly prepared merchandise return service label (see S923). The merchandise return service permit must be held in the same name as that of the authorized medical waste mailer.

(5) The outer shipping container must be marked on two opposite side walls with the package orientation marking in 49 CFR 173.312 to identify the proper upright position of the mailpiece during handling.

(6) Mailpieces containing regulated medical waste or sharps waste must be marked on the address side with the correct UN number and proper shipping name (*e.g.*, ''Regulated Medical Waste, UN 3291'' or ''Regulated Medical Waste—Sharps, UN 3291'').

d. *Package Testing.* Testing must be performed by an independent testing facility on one sample of each type of mailing container system to prove compliance with 8.7a. The sample mailing container system must withstand the tests in 49 CFR 178.604 (leakproof test), 178.606 (stacking test), 178.608 (vibration standard), and 178.609(e), (f), and (h) (test requirements for packaging for infectious substances). In addition, the absorbent material must withstand an absorbency test that satisfies the requirements in 8.7b(4). The test results must show that if every container system prepared for mailing were to be subject to the environmental and test conditions in 49 CFR, there would be no release of the contents to the environment and no significant reduction in the effectiveness of the packaging. Periodic retesting must be performed whenever a change is made to the design of the container system or every 24 months, whichever occurs first.

8.8 Packaging of Used Health Care Products

A used health care product known or suspected to contain a Risk Group 4 pathogen is nonmailable. A used health care product meeting the definition in 8.2i, classified in Risk Group 1, 2, or 3, and being returned to the manufacturer or manufacturer's designee is mailable as First-Class Mail, Priority Mail, or Express Mail subject to the following packaging requirements:

a. Each used health care product must be drained of liquid to the extent possible and placed in a watertight primary receptacle designed and constructed to ensure that it remains intact under normal conditions of transport. For a used health care product capable of cutting or penetrating skin or packaging material, the primary receptacle must be capable of retaining the product without puncture of the packaging under normal conditions of transport. The primary receptacle must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

b. Each primary receptacle must be placed inside a watertight secondary container designed and constructed to ensure that it remains intact under normal conditions of transport. The secondary container must also be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

c. The secondary container must be placed inside an outer shipping container with sufficient cushioning material to prevent movement between the secondary container and the outer shipping container. An itemized list of the contents of the primary receptacle and information concerning possible contamination with a Division 6.2 material, including its possible location on the product, must be placed between the secondary container and the outer shipping container. A shipping paper and a content marking on the outer shipping container are not required.

8.9 Packaging of Forensic Material in Risk Groups 2 and 3

Forensic material in Risk Group 1 sent on behalf of a U.S. government, state, local, or Indian tribal government agency must be packaged under 8.10. Forensic material known or suspected to contain a Risk Group 4 infectious substance must be packaged under 8.5. Forensic material known or suspected to contain a Risk Group 2 or 3 pathogen is mailable as First-Class Mail, Priority Mail, or Express Mail when packaged in a triple packaging, consisting of a primary receptacle, secondary container, and outer shipping container as follows:

a. The forensic material must be held within a securely sealed primary receptacle. The primary receptacle must be surrounded by sufficient absorbent material (for liquids) and cushioning material to protect the primary container from breakage. The absorbent material must be capable of taking up the entire liquid contents of the primary receptacle in case of leakage. The primary receptacle must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

b. The primary receptacle and the absorbent and cushioning material must be enclosed in a watertight and securely sealed secondary container. The secondary container must also display the international biohazard symbol as shown in Exhibit 8.7c(2).

c. The secondary container must be firmly and snugly packed within a strong outer shipping container that is securely sealed. A shipping paper and a content marking on the outer shipping container are not required.

8.10 Packaging for Risk Group 1 Materials

Division 6.2 materials in Risk Group 1 are not subject to regulation as hazardous materials (see 8.3), but when presented for mailing they must be properly packaged. Regulated medical waste, sharps waste, and used health care products classified in Risk Group 1 must be packaged and mailed under the applicable requirements in 8.7 or 8.8. All other Risk Group 1 materials are mailable as First-Class Mail, Priority Mail, Express Mail, or Package Services. Such materials must be held within a securely sealed primary receptacle. The primary receptacle must be surrounded by sufficient absorbent material (for liquids) and cushioning material to protect the primary receptacle from breakage. The absorbent material must be capable of taking up the entire liquid contents of the primary receptacle in case of leakage. Either the primary receptacle or the inner packaging must be marked with the international

biohazard symbol as shown in Exhibit 8.7c(2). The primary receptacle and the absorbent and cushioning material must be snugly enclosed in a strong outer shipping container that is securely sealed. A shipping paper and a content marking on the outer shipping container are not required. Risk Group 1 diagnostic specimens and biological products are subject to the following packaging standards:

a. *Liquid Diagnostic (Clinical) Specimens and Biological Products.* A diagnostic (clinical) specimen in Risk Group 4 or a biological product in Risk Group 2, 3, or 4 must be packaged under 8.5. A diagnostic specimen in Risk Group 2 or 3 must be packaged under 8.6. The packaging of a diagnostic specimen in Risk Group 1 (*e.g.*, a urine specimen or blood specimen used in drug-testing programs or for insurance purposes) or a biological product (*e.g.*, polio vaccine) in Risk Group 1 is subject to the following standards:

(1) *Not Exceeding 50 ml.* A diagnostic specimen or biological product consisting of 50 ml or less per mailpiece must be packaged in a securely sealed primary receptacle. Two or more primary receptacles whose combined volume does not exceed 50 ml may be enclosed within a single mailpiece. Sufficient absorbent material and cushioning material to withstand shock and pressure changes must surround the primary receptacle(s), or be otherwise configured to take up the entire liquid contents in case of leakage. The primary receptacle(s) and the absorbent cushioning must be enclosed in a secondary container having a leakproof barrier that can prevent failure of the secondary container if the primary receptacle(s) should leak during transport. The secondary container must be securely sealed and it may serve as the outer shipping container provided it has sufficient strength to withstand ordinary postal processing. The secondary container must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2), except when the secondary packaging also serves as the outer shipping container. In that case, the biohazard symbol must appear either on the inner packaging or on the primary container. A shipping paper and a content marking on the outer shipping container are not required.

(2) *Exceeding 50 ml.* A clinical specimen or biological product that exceeds 50 ml must be packaged in a securely sealed primary receptacle. A single primary receptacle must not contain more than 500 ml of specimen. Two or more primary receptacles whose combined volume does not exceed 500 ml may be enclosed in a single secondary container. Sufficient absorbent material and cushioning material to withstand shock and pressure changes must surround the primary receptacle(s), or be otherwise configured to take up the entire liquid contents in case of leakage. The primary receptacle(s) and the absorbent cushioning must be enclosed in a secondary container having a leakproof barrier that can prevent failure of the secondary container if the primary receptacle(s) should leak during transport. The secondary container cannot serve as the outer shipping container. The secondary container must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2). The secondary container must be securely and snugly enclosed in a fiberboard box or container of equivalent strength that serves as the outer shipping container. The maximum amount of a specimen that may be enclosed in a single mailpiece must not exceed 4,000 ml. A shipping paper and a content marking on the outer shipping container are not required.

b. *Solid (or Dried) Specimens.* A solid or dry specimen, such as a saliva swab, blood spot, or fecal smear in Risk Group 1 must be completely dried prior to placing it in or on a secure primary receptacle. Cushioning material to withstand shock and pressure changes is only required if the dry specimen is held in a breakable primary receptacle. When required, the cushioning material must surround the primary receptacle to prevent breakage or damage to the primary receptacle. The primary receptacle (and cushioning material, if required) must be enclosed in a secondary container having a leakproof barrier that can prevent failure of the secondary container if the primary receptacle breaks during shipment. The secondary container must be securely sealed and it may serve as the outer shipping container provided it has sufficient strength to withstand ordinary postal processing. The secondary container must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2), except when the secondary packaging also serves as the outer shipping container. In that case, the biohazard symbol must appear either on the inner packaging or on the primary container. A shipping paper and a content marking on the outer shipping container are not required.

9.0 RADIOACTIVE MATERIALS (HAZARD CLASS 7)

[Change ''Publication 52, Acceptance of Hazardous, Restricted, or Perishable Matter'' to ''Publication 52, Hazardous, Restricted, or Perishable Mail.'']

10.0 CORROSIVES (HAZARD CLASS 8)

* * * * *

10.2 Mailability

[In item a, change ''secondary packagings'' to ''secondary containers''; change ''secondary packaging'' to ''secondary container''; and change ''outer packaging'' to ''outer shipping container''.]

[In item b, change ''secondary packaging'' to ''secondary container'' and change ''outer packaging'' to ''outer shipping container''.]

10.3 Marking

[In the first sentence, change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

10.4 Nonspillable Wet Electric Storage Batteries

* * * * *

[Revise item a to read as follows:]

a. The nonspillable battery must be protected from short circuits, surrounded with sufficient cushioning material, and securely packaged in a strong fiberboard box that serves as the outer shipping container.

[In item b, change ''outer packaging'' to ''outer shipping container''.]

* * * * *

[In item d, change ''50 pounds'' to ''25 pounds.'']

11.0 MISCELLANEOUS HAZARDOUS MATERIALS (HAZARD CLASS 9)

11.1 Definition

[In the second sentence, remove ''magnetized materials,''.]

* * * * *

11.3 Marking

[In the first sentence, change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

11.4 Dry Ice

[In item a, change the heading ''Air Transportation'' to ''Air Transportation Requirements.'']

[In item b, change the heading ''Surface Transportation'' to ''Surface Transportation Requirements''. Also change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

* * * * *

[Renumber current 11.5 as new 12.0 to read as follows:]

12.0 OTHER REGULATED MATERIALS—MAGNETIZED MATERIALS

[Change the introductory paragraph in new 12.0 to read as follows (the remainder of new 12.0 is unchanged):]

A magnetized material is not classified within any of the nine hazard classes. Such material is regulated as a hazardous material only if offered for carriage on air transportation and when it has a magnetic field strength capable of causing the deviation of aircraft instruments. Regulated magnetized materials are mailable subject to the following limitations:

a. Definition.

[In the second sentence in item a, change ''a hazard class 9 material'' to ''a hazardous material.'']

b. Mailability.

[In the third sentence in item b, change ''Publication 52'' to ''Publication 52, Hazardous, Restricted, and Perishable Mail.'']

* * * * *

C024 Other Restricted or Nonmailable Matter

* * * * *

[Renumber current 18.0 and 19.0 as new 19.0 and 20.0, and insert new 18.0 to read as follows:]

18.0 ODD-SHAPED ITEMS IN PAPER ENVELOPES

Pens, pencils, key rings, bottle caps, and other similar odd-shaped items are not permitted in letter-size or flat-size paper envelopes unless they are wrapped within the other contents of the envelope to streamline the shape of the mailpiece and prevent damage during postal processing. If an odd-shaped item is not properly wrapped, it could burst through the envelope and cause injury to employees and damage to USPS processing equipment. Odd-shaped items that are properly wrapped within paper envelopes and sent at the First-Class Mail or Standard Mail nonautomation rates may be subject to the nonmachinable surcharge under E130 or E620, as applicable. Certain types of odd-shaped items, when properly wrapped, are permitted as automation rate letter-size mail subject to the standards in C810. Flat-size automation rate mail is subject to the uniform thickness requirement in C820.

* * * * *

C050 Mail Processing Categories

* * * * *

2.0 LETTER-SIZE MAIL

* * * * *

2.2 Nonmachinable Criteria

A letter-size piece is nonmachinable if it has one or more of the following characteristics (see C010.1.3 to determine the length, height, top, and bottom of a mailpiece):

* * * * *

[Revise item d by adding a reference to C024.18.0 to read as follows:]

d. Contains items such as pens, pencils, or loose keys or coins that cause the thickness of the mailpiece to be uneven (see C024.18.0).

* * * * *

F Forwarding and Related Services

F000 Basic Services

F010 Basic Information

* * * * *

5.0 CLASS TREATMENT FOR ANCILLARY SERVICES

5.1 First-Class Mail and Priority Mail

* * * * *

[Revise item e to read as follows:]

e. ''Change Service Requested'' is not permitted for the following:

(1) Priority Mail, other than Priority Mail containing perishable matter under C022 (except for live animals).

(2) First-Class Mail or Priority Mail containing hazardous materials under C023.

(3) First-Class Mail or Priority Mail with a special service other than Delivery Confirmation or Signature Confirmation.

Exhibit 5.1 Treatment of Undeliverable First-Class Mail and Priority Mail

[Revise the listing for ''Change Service Requested'' to read as follows:]

Mailer endorsement	USPS treatment of UAA pieces
*	* * * * * * *
''Change Service Requested'' [2].	Option 1 [2] In all cases (regardless of whether a change-of-address order is on file): Separate notice of new address or reason for nondelivery provided (in either case, address correction fee charged); piece disposed of by USPS. Option 2 [2] If no change-of-address order on file: Piece disposed of by USPS; separate notice of reason for nondelivery provided (address correction fee charged). If change-of-address order on file: Months 1 through 12: piece forwarded (no charge); separate notice of new address provided (address correction fee charged). Months 13 through 18: piece disposed of by USPS; separate notice of new address provided (address correction fee charged). After month 18: piece disposed of by USPS; separate notice of reason for nondelivery provided (address correction fee charged). Restrictions (for Options 1 and 2): The following restrictions apply: (1) This endorsement is limited to use on valid mailpieces bearing a proper ACS participant code and only for: (a) Priority Mail containing perishable matter (other than live animals) and the marking ''Perishable'' and; (b) First-Class Mail (excluding hazardous materials). (2) Delivery Confirmation and Signature Confirmation are the only special services permitted with this endorsement.
*	* * * * * * *

* * * * *

[Revise the text of footnote 2 to read as follows:]

2. Valid only for ACS participating pieces (subject to F030) other than pieces containing hazardous materials.

* * * * *

5.3 Standard Mail

* * * * *

[Reletter current items c through j as new items d though k, and add new item c to read as follows:]

c. The endorsement ''Change Service Requested'' is not permitted for Standard Mail containing hazardous materials under C023. Standard Mail containing hazardous materials must bear the endorsement ''Address Service Requested,'' ''Forwarding Service Requested,'' or ''Return Service Requested.''

* * * * *

Exhibit 5.3a Treatment of Undeliverable Standard Mail

[Revise the listings for ''No endorsement'', ''Address Service Requested'', and ''Change Service Requested'' to read as follows:]

Mailer endorsement	USPS treatment of UAA pieces
No endorsment [1]	In all cases: Piece disposed of by USPS. Restrictions: Standard Mail containing hazardous materials must bear a permissible endorsement (see 5.3e).
''Address Service Requested'' [2].	* * * * *
*	* * * * * * *
''Change Service Requested'' [1,3].	In all cases: Separate notice of new address or reason for nondelivery provided (in either case, address correction fee charged); piece disposed of by USPS. Restrictions: The following restrictions apply: (1) Delivery Confirmation is the only special service permitted with this endorsement. (2) This endorsement is not permitted for Standard Mail containing hazardous materials.

[Renumber footnote 1 as 2, and add new footnotes 1 and 3, to read as follows:]

1. Not valid for pieces containing hazardous materials.

2. Valid for all pieces, including Address Change Service (ACS) participating pieces.

3. Not valid for pieces containing hazardous materials. Valid for all other pieces, including ACS participating pieces.

* * * * *

5.4 Package Services

* * * * *

[Reletter current items c through e as new items d through f, and add new item c to read as follows:]

c. The endorsement ''Change Service Requested'' is not permitted for Package Services mail containing hazardous materials under C023.

* * * * *

Exhibit 5.4 Treatment of Undeliverable Package Services Mail

[Revise the listing for ''Change Service Requested'' to read as follows:]

Mailer endorsement	USPS treatment of UAA pieces
*	* * * * * * *
''Change Service Requested'' [2].	In all cases: Separate notice of new address or reason for nondelivery provided (in either case, address correction fee charged); piece disposed of by USPS. Restrictions: The following restrictions apply: (1) Delivery Confirmation and Signature Confirmation are the only special services permitted with this endorsement. (2) This endorsement is not permitted for Package Services Mail containing hazardous materials.

* * * * *

[Add new footnote 2 to read as follows:]

2. Not valid for pieces containing hazardous materials. Valid for all other pieces, including ACS participating pieces.

* * * * *

An appropriate amendment to 39 CFR part 111 to reflect these changes will be published.

Neva Watson,

Attorney, Legislative.

[FR Doc. 03–14185 Filed 6–5–03; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NC 97–200319b; FRL–7498–1]

Approval and Promulgation of Implementation Plans; North Carolina: Approval of Revisions to the Visible Emissions Regulation Within the North Carolina State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On April 16, 2001, the North Carolina Department of Environment and Natural Resources submitted revisions to the North Carolina State Implementation Plan (SIP). Addressed in this rulemaking is a revision to rule 15 NCAC 2D .0521. The purpose of this revision is to make the revised regulations consistent with the requirements of the Clean Air Act as amended in 1990. The EPA is approving the revision.

DATES: This direct final rule is effective August 5, 2003, without further notice, unless EPA receives adverse comment by July 7, 2003. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: All comments should be addressed to: Randy Terry at the EPA, Region 4 Air Planning Branch, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.

Copies of the State submittal(s) are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 4, Air Planning Branch, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Randy Terry, 404/562–9032.

North Carolina Department of Environment and Natural Resources, 512 North Salisbury Street, Raleigh, North Carolina 27604.

FOR FURTHER INFORMATION CONTACT: Randy B. Terry at 404/562–9032, or by electronic mail at *terry.randy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On April 16, 2001, the North Carolina Department of Environment and Natural Resources submitted a revision to the North Carolina State Implementation Plan (SIP) modifying rule 15A NCAC 2D .0521 Visible Emissions. These revisions include an exemption to this rule for engine maintenance and testing controls where visible emissions controls are infeasible.

Additionally, rule .0521 is being amended to establish an equitable reasonable procedure for sources using continuous opacity monitors (COM) to show compliance with the visible emission standard. This amendment is designed to provide sources using COMs the same opportunity to comply with the visible emissions rule as sources that do not use COM devices. Under the previous rule, the opacity is violated if two six minute averages exceed the standard in one hour or if five six-minute averages exceed the standard in 24 hours. Under the new amendment, sources with COMs are allowed to exceed the current opacity limit for up to .8 percent of the total operating hours without violating the visible emissions rule. Exceedances of the opacity limit greater than .8 percent of the total operating hours will be considered a violation of this rule.

In a letter dated March 29, 2002, EPA provided comments to North Carolina explaining the additional requirements that must be met in order for EPA to approve this rule. These requirements included the submittal of a worst case demonstration proving that such an exemption would not violate the National Ambient Air Quality Standards. On July 10, 2002, North Carolina submitted this demonstration to EPA. After a detailed review of this demonstration, EPA finds that North Carolina's amendments to rule .0521 Visible Emissions are approveable.

In addition to the revision being addressed within this notice, several other revisions were contained in this submittal and approved in 67 FR 51527. The additional revisions included the adoption of rules 15 NCAC 2Q .0316 and .0317, and the amending of rules .0109, .0803 and .0805 through .0808.

II. Final Action

EPA is approving the aforementioned changes to the SIP because the revisions are consistent with Clean Air Act and EPA regulatory requirements. The EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective August 5, 2003, without further notice unless the Agency receives adverse comments by July 7, 2003.

If the EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on August 5, 2003, and no further action will be taken on the proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

III. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this 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 action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this 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 approves 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 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 approves 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 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 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.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate,

the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 5, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Dated: April 30, 2003.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

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

PART 52—[AMENDED]

■ 1. The authority for citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart II—North Carolina

■ 2. In the table in § 52.1770(c), table 1 is amended under subchapter 2D by revising the entry for ''.0521 Cotrol of Visible Emissions'' to read as follows:

§ 52.1770 Identification of plan.

* * * * *

(c) * * *

TABLE 1.—EPA APPROVED NORTH CAROLINA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
Subchapter 2D	**Air Pollution Control Requirements**			
* *	*	*	* *	*
Section .0500	Emission Control Standards.			
* *	*	*	* *	*
Sect. .0521	Control of Visible Emissions	4/01/01	6/06/03 [Insert citation of publication].	
* *	*	*	* *	*

* * * * *

[FR Doc. 03–12024 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WI–113–7343; FRL–7508–4]

Approval and Promulgation of Implementation Plans; Wisconsin; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to an adverse comment, the EPA is withdrawing the direct final rule providing new compliance options for sources subject to Wisconsin rules that limit emissions of nitrogen oxides (NO_X) from large electricity generating units in the Milwaukee-Racine ozone non-attainment area. In the direct final rule published on April 10, 2003 (68 FR 17551), we stated that if we receive any adverse comments by May 12, 2003, the rule would be withdrawn and not take effect. EPA subsequently received adverse comments. EPA will address the comments received in a subsequent final action based upon the proposed action also published on April 10, 2003 (68 FR 17576). EPA will not institute a second comment period on this action.

DATES: The direct final rule is withdrawn as of June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Alexis Cain, Environmental Scientist, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, Telephone: (312) 886–6524.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxide.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: May 22, 2003.

Steven Rothblatt,

Acting Regional Administrator, Region 5.

PART 52—[AMENDED]

■ Accordingly, the addition of 40 CFR 52.2570(c)(108) is withdrawn as of June 6, 2003.

[FR Doc. 03–14188 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MA–088–7216C; A–1–FRL–7509–2]

State of Massachusetts; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: On April 8, 2003, EPA published a proposed rule (68 FR 17002) and a direct final rule (68 FR 16959) conditionally approving revisions to section 310 CMR 7.06 entitled ''Visible Emissions'' as a State Implementation Plan (SIP) revision for the Commonwealth of Massachusetts. In the direct final rule published on April 8, 2003, we stated that if we received adverse comment by May 8, 2003, the rule would be withdrawn and not take effect. EPA subsequently received adverse comments, and thus EPA is withdrawing the final rule. EPA will address the comments received in a subsequent final action based upon the proposed action also published on April 8, 2003 (68 FR 17002). EPA will not institute a second comment period on this action.

DATES: This withdrawal of the direct final action is made as of June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Jeffrey S. Butensky, Environmental Planner, (617) 918–1665; *butensky.jeff@epa.gov.*

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: May 28, 2003.

Ira W. Leighton,

Acting Regional Administrator, EPA New England.

[FR Doc. 03–14189 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0002; FRL–7308–1]

Thymol and Eucalyptus Oil; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited exemptions from the requirement of a tolerance for residues of thymol and eucalyptus oil on honey and honeycomb. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of these pesticides in beehives. This regulation eliminates the need to establish a maximum permissible level for residues of thymol and eucalyptus oil in or on honey and honeycomb. These time-limited exemptions from the requirement of a tolerance for residues of the thymol and eucalyptus oil will expire and are revoked on June 30, 2005.

DATES: This regulation is effective June 6, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0002, must be received on or before August 5, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: madden.barbara@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a Federal or State government agency involved in administration of environmental quality programs. Potentially affected entities may include, but are not limited to:

•Federal or State Government Entity, (NAICS 9241), i.e., Departments of Agriculture, Environment, etc.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0002. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml__00/Title__40/40cfr180__00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing time-limited exemptions from the requirement of a tolerance for residues of thymol and eucalyptus oil in or on honey and honeycomb. These time-limited exemptions from the requirement of a tolerance for residues of the thymol and eucalyptus oil will expire and are revoked on June 30, 2005. EPA will publish a document in the **Federal Register** to remove the revoked exemptions from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide

chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Thymol and Eucalyptus Oil on Honey and Honeycomb and FFDCA Tolerances

The varroa mite is an ectoparasite of honey bees. It was first detected in the continental United States in Maryland in 1979, and found in Florida and Wisconsin by 1987. Currently, it is the most important pest of honey bee colonies. The mites feed on the hemolymph of the developing bee larva, pupa, and adult bees. Dead or dying newly emerged bees have malformed wings, legs, abdomens, and thoraces. Recent anecdotal evidence suggests that bee viruses and varroa mites are closely linked. The mites have been shown to activate some of these viruses; causing virus outbreaks that ultimately lead to colony mortality.

Fluvalinate is currently registered for the control of varroa mites; however, populations of varroa mites have developed resistance to fluvalinate. Varroa mite resistance to fluvalinate has been well documented by the United States Department of Agriculture (USDA), Agricultural Research Service (ARS). According to USDA, ARS many hives treated with fluvalinate have resulted in wholesale colony losses. Due to the destructive nature of this pest coupled with the importance of honey bees (for honey production and pollination of numerous agricultural crops) to the U.S. economy, it is imperative that alternative means of controlling the varroa mite be developed.

The Agency has authorized the use of coumaphos in beehives to control varroa mites under section 18 of FIFRA since 1999 in up to 46 states. During the 2001 use season there were limited reports of mites resistant to coumaphos in Maine and Florida. Resistance to coumaphos in Florida was confirmed by the USDA's Texas Bee Lab in December of 2001. In Maine, bees are primarily imported during the growing season from Florida. South Carolina has indicated that the beekeeping industry is migratory in nature, especially in the coastal region of the state and subject to the introduction of coumaphos resistant mites from Florida. Therefore, the states have requested use of the unregistered product ApiLife VAR, containing thymol and eucalyptus oil to control mites resistant to coumaphos. EPA has authorized under FIFRA section 18 the use of thymol and eucalyptus oil in beehives for control of varroa mites in Maine, Minnesota, Mississippi, Utah, Indiana, and South Carolina. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of thymol and eucalyptus oil in or on honey and honeycomb. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary exemptions from the requirement of a tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these exemptions without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these exemptions from the requirement of a tolerance will expire and are revoked on June 30, 2005, under section 408(l)(5) of the FFDCA, residues of the pesticide in the tolerance remaining in or on honey and honeycomb after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these exemptions earlier if any experience with, scientific data on, or other relevant information on these pesticides indicate that the residues are not safe.

Because these exemptions from the requirement of a tolerance are being approved under emergency conditions, EPA has not made any decisions about whether thymol and eucalyptus oil meets EPA's registration requirements for use on honey and honeycomb or whether permanent exemptions for this use would be appropriate. Under these circumstances, EPA does not believe that these exemptions from the requirement of a tolerance serve as a basis for registrations of thymol and eucalyptus oil by a State for special local needs under FIFRA section 24(c). Nor do these exemptions serve as the basis for any State other than Maine and South Carolina to use these pesticides in beehives under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for thymol and eucalyptus oil, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety for Thymol

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of thymol and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for exemptions from the requirement of a tolerance for residues of thymol in or on honey and honeycomb. EPA's assessment of the dietary exposures and risks associated with establishing these exemptions from the requirement of a tolerance follows.

A. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by thymol is discussed in this unit.

The EPA has not received nor does it have available any guideline studies on the mammalian toxicity of thymol. Thymol is found naturally occurring in

thyme herb (e.g., *Thymus vulgaris, T. zygis*). Thyme herb is used as a food seasoning ingredient, and is generally recognized as a safe (GRAS) natural seasoning by the Food and Drug Administration (FDA) (21 CFR 182.10). Thyme oil also is recognized as a GRAS essential oil by FDA (21 CFR 182.20).

In September of 1993, the EPA issued a Reregistration Eligibility Decision (RED) for thymol. At that time the Agency concluded that thymol is an active ingredient that should be considered for a broad waiver of generic data requirements. This conclusion was based on the following information:

Thymol is a component of many non-pesticidal consumer products currently marketed in the United States. Thymol is listed as a food additive by the Food and Drug Administration (21 CFR 172.515; synthetic flavoring substances and adjuvants). Thymol is rapidly degraded in the environment to elemental constituents by normal biological, physical, and/or chemical processes that can be reasonably expected to exist where the pesticide is applied.... The phenols of thymol are considered GRAS as set forth in 21 CFR 172.515 (synthetic flavoring substances and adjuvants)....

Thymol toxicity data reported available literature cite acute oral LD_{50} values as 980 milligrams/kilogram (mg/kg) and 880 mg/kg for the rat and guinea pig, respectively (Sax, 1984). The acute oral toxicity reported for the rat and guinea pig, respectively corresponds to Toxicity Category III. The Material Safety Data Sheet (MSDS) for the manufacture of technical grade thymol cites human health effects as irritating when exposed by inhalation, dermal or eye contact. The MSDS also estimates a human ingestion LD_{50} at 2 grams of the synthetic thymol. Based upon an estimated thymol dermal toxicity LD_{50} of greater than 2,000 mg/kg, the dermal toxicity would be Toxicity Category III. (Refer to pages 6 and 7 of the RED)

A summary of the submitted information on thymol toxicity allows for the statements that the acute oral LD_{50} in the rat is 980 mg/kg and in the mouse is 640 to 1,800 mg/kg. Thymol is corrosive to the rabbit eye and skin, and is not reported as a dermal sensitizer in the guinea pig. Thymol is readily absorbed from the gastrointestinal tract and is essentially excreted in the urine as a glucuronate and sulfate conjugate of the parent compound. Dosing of rats with thymol in the feed at 667 mg/kg body weight/day (highest dose tested) for 19 weeks did not produce any harmful effects. Thymol is not mutagenic in Salmonella, but gives statistically significant positive results in an Unscheduled DNA synthesis and Sister Chromatid Exchange tests, and in a cell transformation test with Syrian hamster embryonic cells. Multiple malformations are noted when thymol is injected into the air bubble or yolk sac of embryonic chickens.

B. Exposure Assessment

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure*—i. *Food*. Thymol is found naturally occurring in thyme herb (e.g., *Thymus vulgaris, T. zygis*). Thyme herb is used as a food seasoning ingredient, and is generally recognized as a safe (GRAS) natural seasoning by FDA (21 CFR 182.10). Thyme oil also is recognized as a GRAS essential oil by FDA (21 CFR 182.20). The volatile oil component of thyme herb is about 2% to 5% content, and thyme oil is reported to contain from 30% to 75% thymol, and even up to 90%. Thymol may be safely used in foods as a synthetic flavoring substance when used in the minimum quantity to produce the intended effect (21 CFR 172.515). Levels of thymol reported in foods where it is permitted as a direct food additive have been stated as 44 ppm in ice cream, ices, etc.; 2.5 ppm to 11 ppm in non-alcoholic beverages; 9.4 ppm in candy, 5 ppm to 6.5 ppm in baked goods, and 100 ppm in chewing gum. Thymol is a natural component of lime blossom honey, where the maximum thymol content has been determined to be 0.16 mg/kg.

Studies in Europe showed that when ApiLife Var was used for 8 weeks in the autumn over 1 to 5 years the maximum thymol residue observed was 0.48 mg/kg. The average (median) residue value for thymol was 0.16 mg/kg in honey. When export and import tonnage values of honey are taken into consideration with U.S. honey production, the average yearly per capita intake of honey is about 2 pounds, roughly equivalent to 1 kg. If all the honey contained 0.5 mg/kg thymol then the per capita intake of thymol would be about 1.4 µg/day. For a 60 kg adult the chronic exposure value is about 0.022 µg/kg body weight/day. If a 60 kg adult consumed 1 kg of honey containing 0.5 mg thymol in 90 days the subchronic dietary exposure to thymol would be about 2 µg/kg body weight/day. Even if all 2 kg of the thymol-containing honey were consumed in one sitting, the acute exposure to thymol still would be as low as 83 µg.

2. *Drinking water exposure*. No drinking water exposure is expected from the pesticidal use of thymol which is confined to placement in beehives. Thymol is currently registered for use on ornamental plants, shrubs and grasses so there is some potential for exposure to water. However, thymol is a constituent of a mixture of organic compounds known to be rapidly degraded in the environment to elemental compounds by normal biological, physical and/or chemical processes. In the RED, the Agency concluded that the registered uses of thymol will result in negligible exposure of the environment and nontarget organisms (refer to page 7 of the RED). Therefore, thymol is not expected to be found in drinking water.

3. *Other non-occupational exposure*. The potential for non-dietary exposure to thymol residues for the general population, including infants and children, is unlikely because the proposed use site is limited to beehives. Thymol is a normal constituent of the human diet, as a component of thyme and thyme oil, and as a direct food additive. Therefore, while there exists a great likelihood of prior exposure for most, if not all individuals to thymol, any increased exposure due to the proposed use would be negligible. Thyme, which contains thymol, is a pesticide active ingredient for the control of aphids on ornamental plants. Thyme and thyme oil are considered minimum risk pesticides, and are exempted as active ingredients under FIFRA [40 CFR 152.25(g)].

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether thymol has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, thymol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this exemption from the requirement of a tolerance, therefore, EPA has not

assumed that thymol has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Aggregate Risks and Determination of Safety for U.S. Population, Infants and Children

The dietary exposure to residues of thymol to the U. S. population from use of ApiLife Var is not likely to add significantly to current dietary exposure to thymol. For instance, thymol has been measured in chewing gum at 100 mg/kg, in candy at 9.4 mg/kg, and in ice cream at 44 mg/kg. These values respectively are 200–, 20–, and 100–fold greater than the highest level of thymol (i.e., 0.48 mg/kg) measured in honey treated with ApiLife Var. In addition, thymol as measured in ice cream is about 300–fold higher than the average residue level of thymol (i.e., 0.16 mg/kg) in hives treated with ApiLife Var. Additionally, it is typical for language to appear on labels of honey that states ''Do not feed to infants under 1 year,'' so there likely would be no exposure of this population to residues of thymol in the honey. Older children likely have been exposed to thymol residues from consumption of candy, ice cream, and baked goods. Consumption of honey from hives treated with ApiLife Var is unlikely to significantly increase exposure to thymol. Therefore, based on the long history of use of thyme, thyme oil, and thymol in the diet with no known adverse effects, it is reasonable to conclude that no harm will result from exposure to thymol in honey from beehives treated with ApiLife Var. Accordingly, EPA finds that exempting thymol from the requirement of a tolerance will be safe.

V. Aggregate Risk Assessment and Determination of Safety for Eucalyptus Oil

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of eucalyptus oil and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for exemptions from the requirement of a tolerance for residues of eucalyptus oil in or on honey and honeycomb. EPA's assessment of the dietary exposures and risks associated with establishing these exemptions from the requirement of a tolerance follows.

A. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by eucalyptus oil is discussed in this unit.

The EPA has not received nor does it have available any guideline studies on the mammalian toxicity of eucalyptus oil. Eucalyptus oil is obtained from steam distillation of the leaves of Eucalyptus globulus and, in addition to cineole, contains triterpenes, monoterpenes, sesquiterpenes, aldehydes and ketones. Information submitted by the applicant allows for the statements that acute oral LD_{50} value for eucalyptus oil in rats is 2,480 mg/kg. Eucalyptol (1,8-cineole) which makes up 70% or more of eucalyptus oil may be safely used in foods as a synthetic flavoring substance when used in the minimum quantity to produce the intended effect (21 CFR 172.515). Eucalyptus globulus leaves also may safely be used in foods (21 CFR 172.510).

B. Exposure Assessment

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure.*—i. *Food.* Eucalyptus oil is obtained from steam distillation of the leaves of Eucalyptus globulus and, in addition to cineole, contains triterpenes, monoterpenes, sesquiterpenes, aldehydes and ketones. Levels of eucalyptus oil reported in foods where it is permitted as a direct food additive have been stated as 0.5 to 50 ppm in ice cream, ices etc.; 1.7 ppm in non-alcoholic beverages; 1.0 ppm in alcoholic beverages; 130 ppm in candy; and 76 ppm in baked goods. Cineole in foods has been reported at 0.13 ppm in non-alcoholic beverages; 0.50 ppm in ice cream, ices, etc.; 15 ppm in candy; 0.5 to 4.0 ppm in baked goods, and 190 ppm in chewing gum.

Studies in Europe showed that when ApiLife Var was used for 8 weeks in the autumn over 1 to 5 years, residues of eucalyptus oil (measured as 1,8-cineole) were less than the limit of detection, i.e., <0.01 ppm.

ii. *Drinking water exposure.* No drinking water exposure is expected from the pesticidal use of eucalyptus oil which is confined to placement in beehives. Further, there are no products registered that will result in exposure to drinking water. Therefore, eucalyptus oil is not expected to found in drinking water.

2. *Other non-occupational exposure.* The potential for non-dietary exposure to eucalyptus oil residues for the general population, including infants and children, is unlikely because the proposed use-site is limited to beehives. Eucalyptus oil is a constituent of the human diet as a direct food additive. Eucalyptus oil is used as a component of decongestant products, as an expectorant component of cough and cold products, in various oral dosage forms (e.g., lozenges and syrups), and as an inhalant in vapor baths. It is used in dermally applied products for burns, blisters, and for muscle and joint aches. It may be a component of toothpaste, soaps, detergents and toiletries. It is reported to be used internally at 0.3 to 0.6 grams/day, and externally at 5% to 20% in paraffin, jelly, or vegetable oil bases. Oil of eucalyptus has antimicrobial properties, and has been registered as an active pesticide ingredient in an herbal flea collar pet product (active ingredient is in the product at 1.00%).

3. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether eucalyptus oil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, eucalyptus oil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this exemption from the requirement of a

tolerance, therefore, EPA has not assumed that eucalyptus oil has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Aggregate Risks and Determination of Safety for U.S. Population, Infants and Children

The dietary exposure to residues of eucalyptus oil to the U.S. population from use of ApiLife Var is not likely to add significantly to current dietary exposure to eucalyptus oil. This is because no residues of eucalyptus oil were detectable (i.e., <0.01 ppm; measured as 1,8-cineole) when ApiLife was used in hives in the autumn in Europe for up to 5 years. Even if oil of eucalyptus residues were found in honey from hives treated with Apilife Var, they would have to be present at 5,000 times greater than the limit of detection to reach the level reported in ice cream (i.e., 50 mg/kg) and 170 times greater than the limit of detection to reach the level reported in non-alcoholic beverages (i.e., 1.7 mg/kg). Therefore, based on the long history of use of eucalyptus oil in the diet with no known adverse effect, coupled with the expectation of no to minimal residues from use of ApiLife Var in hives, it is reasonable to conclude that no harm will result from this pesticidal use. Accordingly, EPA finds that exempting eucalyptus oil from the requirement of a tolerance will be safe.

VI. Other Considerations

A. Analytical Enforcement Methodology

The Agency has not reviewed the method, nor its accuracy or reliability, used to previously analyze thymol and eucalyptus oil residues in honey; nor has it confirmed that prior use of ApiLife Var in European hives will give equivalent residues in hives in the United States. However, review of information submitted on a gas chromatographic method of analysis to measure thymol and eucalyptus oil in European hives, and the similarity of the European hives to U.S. hives allow for the conclusion that thymol and eucalyptus oil residues in honey from these hives will not be significantly greater, provided ApiLife Var is applied at the same rates to overwintering hives in the United States as was done previously in Europe.

The method may be requested from: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:(703) 305–6463; e-mail address: madden.barbara@epa.gov.

B. International Residue Limits

No Codex Maximum Residue Levels (MRL) are established for thymol. However, Switzerland has established an MRL of 0.8 mg/kg, apparently not from a safety finding, but rather arising from legislation that prohibits foreign odors or tastes in honey. According to the World Health Organization, thymol residues in food are safe to consumers at up to 50 mg/kg. According to European Union regulation Nr. 2377/90, thymol is in group II of the non-toxic veterinary drugs which do not require a MRL. No Codex Maximum Residue Levels (MRL) are established for eucalyptus oil.

VII. Conclusion

Therefore, time-limited exemptions from the requirement of a tolerance are established for residues of thymol and eucalyptus oil in or on honey and honeycomb.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0002 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 5, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by the docket ID number OPP–2003–0002, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes a time-limited exemption from the tolerance requirement under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, 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 in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 23, 2003.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.1240 is added to subpart D to read as follows:

§ 180.1240 Thymol; exemption from the requirement of a tolerance.

Time-limited exemptions from the requirement of a tolerance are established for residues of thymol in or on honey and honeycomb in connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. These time-limited exemptions from the requirement of a tolerance for residues of the thymol will expire and are revoked on June 30, 2005.

■ 3. Section 180.1241 is added to subpart D to read as follows:

§ 180.1241 Eucalyptus oil; exemption from the requirement of a tolerance.

Time-limited exemptions from the requirement of a tolerance are established for residues of eucalyptus oil in or on honey and honeycomb in connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. These time-limited exemptions from the requirement of a tolerance for residues of the eucalyptus oil will expire and are revoked on June 30, 2005.

[FR Doc. 03–14198 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

Fisheries of the Northeastern United States

CFR Correction

In Title 50 of the Code of Federal Regulations, Part 600 to End, revised as of October 1, 2002, § 648.21 is corrected by removing paragraph (e) appearing on page 337 and reinstating the paragraph (e) appearing on page 316 in the 2000 edition. The reinstated text reads as follows:

§ 648.21 Procedures for determining initial annual amounts.

* * * * *

(e) *Inseason adjustments.* The specifications established pursuant to this section may be adjusted by the Regional Administrator, in consultation with the MAFMC, during the fishing year by publishing notification in the Federal Register stating the reasons for such an action and providing a 30–day public comment period.

* * * * *

[FR Doc. 03–55515 Filed 6–5–03; 8:45 am]

BILLING CODE 1505–01–D

Proposed Rules

Federal Register
Vol. 68, No. 109
Friday, June 6, 2003

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 MANAGEMENT AND BUDGET

2 CFR Subtitles A and B

Office of Federal Financial Management; Government-wide Guidance for Grants and Agreements

AGENCY: Office of Federal Financial Management, Office of Management and Budget (OMB), Executive Office of the President.

ACTION: Notice of proposed relocation of policy guidance for grants and other agreements.

SUMMARY: OMB proposes two changes to the framework of Federal government policies for grants and other financial assistance and nonprocurement agreements that will make it easier for applicants and recipients to use the policies.

First, OMB proposes to publish in a single title in the Code of Federal Regulations (CFR) its guidance to Federal agencies for grants and agreements that is currently located in seven separate OMB circulars and other policy documents.

Second, OMB proposes to create in the same new title of the CFR a subtitle in which Federal agencies will co-locate their regulations for the award and administration of grants and agreements.

DATES: All comments on this proposal should be in writing, and must be received by July 7, 2003.

ADDRESSES: Due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Electronic mail comments may be submitted to: *ephillip@omb.eop.gov*. Please include ''Relocating Grant Policy'' in the subject line and the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and E-mail address in the text of the message. Comments may also be submitted via facsimile to 202–395–3952. Comments may be mailed to Elizabeth Phillips, Office of Federal Financial Management, Office of Management and Budget, Room 6025, New Executive Office Building, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Elizabeth Phillips, Office of Federal Financial Management, Office of Management and Budget, telephone 202–395–3053 (direct) or 202–395–3993 (main office) and e-mail: *ephillip@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: This **Federal Register** document seeks public comment on two proposed changes to the Federal government's policy framework for grants and agreements. As discussed in the following sections, the proposed changes provide a good foundation for future streamlining and simplification of the policy framework that may be accomplished through the implementation of the Federal Financial Assistance Management Improvement Act of 1999 (Pub. L. 106–107).

I. First Proposal: Publish OMB's Guidance in the Code of Federal Regulations

OMB's government-wide guidance for grants and other financial assistance and nonprocurement agreements currently resides in seven OMB circulars that are accessible at OMB's Internet site and two separate OMB guidance documents that are less easily found. To help make all of the guidance easier to use and more accessible for both Federal agencies and recipients of grants and agreements, OMB proposes to publish the separate documents in a single location in the CFR. Although located in the CFR, the nature and status of the OMB guidance will remain the same. The OMB guidance is directed to Federal agencies, which adopt and implement it through regulations or policy documents and require recipients to comply with the agency implementation. The OMB guidance documents are:

For administrative requirements:

- OMB Circular A–102, ''Grants and Cooperative Agreements with State and Local Governments,'' and
- OMB Circular A–110, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations.''

These two circulars provide to Federal agencies OMB's guidance related to administrative requirements for grants and agreements with different types of recipients, including States, local governments, Indian Tribal governments, institutions of higher education, hospitals, and other non-profit organizations.

For guidance related to costs:

- OMB Circular A–21, ''Principles for Determining Costs Applicable to Grants, Contracts, and Other Agreements with Educational Institutions;''
- OMB Circular A–87, ''Cost Principles for State, Local, and Indian Tribal Governments;'' and
- OMB Circular A–122, ''Cost Principles for Non-Profit Organizations.''

These three circulars provide guidance related to the costs that may be charged to Federal awards.

For audit guidance:

- OMB Circular A–133, ''Audits of States, Local Governments, and Non-Profit Organizations.''

A–133 provides guidance implementing the requirements of the Single Audit Act of 1984, as amended (31 U.S.C., Chapter 75).

For other guidance:

- OMB Circular A–89, ''Federal Domestic Assistance Program Information,'' which provides guidance to agencies for implementing the Federal Program Information Act, as amended (31 U.S.C., Chapter 61);
- OMB guidance on nonprocurement suspension and debarment, issued under Section 6 of Executive Order 12549, and last amended on June 26, 1995, at 60 FR 33036, which includes OMB guidance on drug-free workplace that is issued under the Drug-Free Work Place Act of 1988, as amended (41 U.S.C. 701 *et seq.*); and
- OMB guidance on lobbying restrictions (last amended on January 19, 1996, at 61 FR 1412), for Federal agencies' implementation of the requirements of 31 U.S.C. 1352.

A. Relationship of First Proposal to Grants Streamlining Under Pub. L. 106–107

In parallel with this proposal to relocate in the CFR the OMB circulars and guidance documents in their current form, which will make those documents available to the public in a single location, interagency work groups are developing proposals under Public Law 106–107 to streamline the award and administration of Federal grants and agreements. Public comments that OMB and Federal agencies received under Public Law 106–107 noted that the public finds the current policy framework for grants and agreements to be very confusing. The commenters cited a need to better align the various OMB circulars and guidance documents with each other to provide greater commonality in cross-cutting areas like definitions. They also identified a need to make Federal agency regulations that implement the OMB guidance more consistent with that guidance, to make it easier for applicants and recipients to understand their obligations and those of their subrecipients. Therefore, some interagency work group proposals may involve significant revision of current OMB circulars and guidance documents; for example, one group's effort to develop standard award terms and conditions may lead to future proposals to revise the OMB circular guidance on post-award administrative requirements. The proposal in this notice to provide a single CFR location for OMB guidance is a good first step that provides a foundation for any future streamlining of the policy framework. Any revision to an OMB circular or guidance document would be proposed in a **Federal Register** notice separate from this notice, with an opportunity for public comment.

B. Structure of 2 CFR To Implement the First Proposal

OMB proposes to establish a subtitle A for its guidance in Title 2 of the CFR, a title that currently is reserved and that would be redesignated ''Government-wide Grants and Agreements.'' OMB proposes to locate its current circulars and guidance documents within Chapter II of subtitle A. Chapter I would be reserved at this time, as the future location of the OMB guidance after any revisions due to the Public Law 106–107 streamlining efforts.

Subtitle A, Chapter II also will include a part with general information about 2 CFR. That part will address the purpose and scope of the title, the applicability of the various portions of the OMB guidance to different types of agreements, and the responsibilities of the OMB and Federal agencies with respect to the guidance.

II. Second Proposal: Co-Locate OMB Guidance and Related Agency Regulations

Most Federal agencies issue regulations related to some or all of OMB's government-wide guidance for grants and agreements. Because each agency's regulations currently are in its own title in the CFR, an entity that may receive awards from more than one Federal agency must read regulations in multiple locations in the CFR. To reduce this burden, an interagency working group under the Public Law 106–107 grants streamlining effort recommended that agencies co-locate their implementing regulations with the OMB guidance in Title 2 of the CFR. An applicant or recipient then could more easily find the agencies' implementing regulations, as well as the OMB guidance, in one location.

Note that this proposal entails only Federal agency regulations for nonprocurement instruments. Some portions of the OMB guidance (specifically, the cost principles in OMB Circulars A–21, A–87, and A–122, and the guidance on single audits in OMB Circular A–133) apply to both procurement and nonprocurement instruments. The Federal Acquisition Regulation (FAR) implements those portions for procurement contracts. The current proposal is to co-locate the OMB guidance with agency implementing regulations only for grants and agreements; the proposal would not relocate the implementation of the OMB guidance for procurement contracts, which will continue to be in the FAR.

To accomplish the co-location, OMB proposes to establish a second subtitle in Title 2 of the CFR. Subtitle B would be ''Federal Agency Regulations for Grants and Agreements.'' Ultimately, each Federal agency that has regulations implementing OMB's guidance will establish a chapter in Subtitle B where its regulations will appear. Each agency will be responsible for organizing the subject matter in its chapter.

III. Relative Timing of Changes Resulting From First and Second Proposals

As explained above, OMB is proposing to establish its guidance in 2 CFR in two phases. In the first phase, the circulars and guidance documents would be moved into Chapter II of the new CFR title in their current form (adapted to CFR codification). In the second phase, after any revisions due to the Public Law 106–107 streamlining effort, they would be moved into Chapter I of the new title.

The timeframe for agencies to complete their move of regulations would correspond to the second of the two phases. Once OMB establishes the guidance documents in Chapter I, with any revisions, the revised guidance would require agencies to locate their implementing regulations in 2 CFR. Agencies could elect to move existing regulations during the first phase, in parallel with OMB's relocation of current circulars and guidance, but they would not be required to do so.

IV. Summary of Proposals

In summary, OMB proposes to establish in the near term, after considering public comments received in response to this notice:

- Title 2 of the CFR, which would be entitled ''Government-wide Grants and Agreements;''
- Subtitle A of Title 2, which would be ''Government-wide Guidance for Grants and Agreements;''
- Chapter I of Subtitle A, which would be reserved;
- Chapter II of Subtitle A, which would contain all existing OMB Circulars and other guidance;
- Subchapter A of Chapter II, which would be ''General Matters'' related to Chapter II.
- Subtitle B of Title 2, which would be ''Federal Agency Regulations for Grants and Agreements,'' where Federal agencies may now choose to locate, and eventually will be required to locate, agency regulations implementing the OMB guidance on the award and administration of grants and agreements.

OMB in the longer term plans to move its guidance, with any revisions resulting from the streamlining under Pub. L. 106–107, to Chapter I of Subtitle A. During that transition, Federal agencies will establish their chapters in Subtitle B and add content to that subtitle.

V. Invitation To Comment

OMB welcomes your input on any aspect of the two proposals described in this notice. You may wish to comment on the merits of either proposal individually or the two in combination.

Joseph L. Kull,

Deputy Controller.

TABLE 1.—PROPOSED ORGANIZATION OF TITLE 2

Title 2, Government-wide Grants and Agreements
Subtitle A—Government-wide Guidance for Grants and Agreements
Chapter I—[Reserved.]
Chapter II—Office of Management and Budget Circulars and Guidance
Subchapter A—General matters
Part 1—General
Subchapter B—Circulars
Subchapter C—Other guidance documents
Subtitle B—Federal Agency Regulations for Grants and Agreements
Chapters III and following—Each Federal agency will establish a chapter under Subtitle B for its regulations on grants and agreements

[FR Doc. 03–14335 Filed 6–5–03; 8:45 am]
BILLING CODE 3110–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NE–11–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Canada Models PW118, PW120, PW120A, and PW121 Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for Pratt & Whitney Canada (PWC) models PW118, PW120, PW120A, and PW121 turboprop engines. This proposed AD would require replacing the low pressure rotor speed (NL) sensor port sealing tube and reworking or replacing the external air tube connecting the P2.5/P3 switching valve to the rear inlet case. This proposed AD is prompted by a report of an internal oil fire in the engine intercompressor case (ICC). A fire in the ICC could cause the existing tubes to disengage due to melted brazing on the tubes. Once these tubes disengage, the ICC fire then develops into an external fire within the engine nacelle cavity. The actions specified in this proposed AD are intended to prevent fire in the engine nacelle cavity, in-flight engine shutdown, and airplane damage.

DATES: We must receive any comments on this proposed AD by August 5, 2003.

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

- By mail: Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–NE–11–AD, 12 New England Executive Park, Burlington, MA 01803–5299.
- By fax: (781) 238–7055.
- By e-mail: *9-ane-adcomment@faa.gov*

You may get the service information identified in this proposed AD from Pratt & Whitney Canada, Technical Publications Department, 1000 Marie Victorin, Longueuil, Quebec J4G 1A1.

You may examine the AD docket at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Ian Dargin, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7178; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES.** Include ''AD Docket No. 2003–NE–11–AD'' in the subject line of your comments.If you want us to acknowledge receipt of your mailed comments, send us a self-addressed, stamped postcard with the docket number written on it; we will date-stamp your postcard and mail it back to you. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. If a person contacts us through a nonwritten communication, and that contact relates to a substantive part of this proposed AD, we will summarize the contact and place the summary in the docket. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You may get more information about plain language at *http://www.plainlanguage.gov.*

Examining the AD Docket

You may examine the AD Docket (including any comments and service information), by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. See **ADDRESSES** for the location.

Discussion

Transport Canada, which is the airworthiness authority for Canada, recently notified the FAA that an unsafe condition may exist on PWC models PW118, PW120, PW120A, and PW121 turboprop engines. Transport Canada advises that they have received a report of an internal oil fire in the engine ICC. An ICC fire melts the brazing on the external air tube connected to the P2.5/P3 switching valve, and on the low pressure rotor speed (NL) sensor port sealing tube, allowing both to disengage. Once these tubes disengage, the ICC fire then develops into an external fire within the engine nacelle cavity, resulting in in-flight engine shutdown and potential airplane damage.

Relevant Service Information

We have reviewed and approved the technical contents of PWC Service Bulletin (SB) No. 20914, Revision 4, dated December 14, 2001. That SB describes procedures for replacing the low pressure rotor speed (NL) sensor port sealing tube and reworking or replacing the external air tube connecting the P2.5/P3 switching valve to the rear inlet case. Transport Canada classified this SB as mandatory and issued airworthiness directive No. CF–2002–10, dated January 28, 2002, in order to ensure the airworthiness of these PWC models PW118, PW120, PW120A, and PW121 turboprop engines in Canada.

FAA's Determination and Requirements of the Proposed AD

These PWC models PW118, PW120, PW120A, and PW121 turboprop

engines, manufactured in Canada, are type-certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, Transport Canada has kept us informed of the situation described above. We have examined Transport Canada's findings, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States. Therefore, we are proposing this AD, which would require replacing the low pressure rotor speed (NL) sensor port sealing tube and reworking or replacing the external air tube connecting the P2.5/P3 switching valve to the rear inlet case. The proposed AD would require that these actions be done using the service information described previously.

Changes to 14 CFR Part 39—Effect on the Proposed AD

On July 10, 2002, we published a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's AD system. This regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

Costs of Compliance

There are approximately 1,933 PWC models PW118, PW120, PW120A, and PW121 turboprop engines of the affected design in the worldwide fleet. We estimate that 1,160 engines installed on airplanes of U.S. registry would be affected by this proposed AD. We also estimate that it would take approximately 2 work hours per installed engine to replace the parts, and that the average labor rate is $60 per work hour. Required parts would cost approximately $1,966 per engine. Based on these figures, the total replacement cost of the proposed AD to U.S. operators is estimated to be $2,419,760. We also estimate that it would take approximately 2 work hours per tube to perform the rework in lieu of tube replacement, and required parts for rework would cost approximately $197 per engine. Based on these figures, the total rework cost of the proposed AD to U.S. operators is estimated to be $367,720. PWC has informed the FAA that it may provide the parts and labor to the operators at no cost, thereby substantially reducing the cost of the proposed rule.

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. Would 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 summary of the costs to comply with this proposal and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES.** Include ''AD Docket No. 2003–NE–11–AD'' in your request.

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 Federal Aviation Administration 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:

Pratt & Whitney Canada: Docket No. 2003–NE–11–AD.

Comments Due Date

(a) The FAA must receive comments on this airworthiness directive (AD) action by August 5, 2003.

Affected ADs

(b) None.

Applicability

(c) This AD is applicable to Pratt & Whitney Canada (PWC) models PW118, PW120, PW120A, and PW121 turboprop engines. These engines are installed on, but not limited to, Empresa Brasileira de Aeronautica (EMBRAER) EMB–120RT, 120ER, and 120FC, Bombardier Inc. (formerly Dehavilland of Canada) DHC–8–100 series, and Aerospatiale ATR 42–200, –300, and –320 airplanes.

Unsafe Condition

(d) This AD was prompted by a report of an internal oil fire in the engine intercompressor case (ICC). A fire in the ICC could cause the low pressure rotor speed (NL) sensor port sealing tube and the external air tube connecting the P2.5/P3 switching valve to the rear inlet case, to disengage due to melted brazing on the tubes. Once these tubes disengage, the ICC fire then develops into an external fire within the engine nacelle cavity. The actions specified in this AD are intended to prevent fire in the engine nacelle cavities, in-flight engine shutdown, and airplane damage.

Compliance

(e) Compliance with this AD is required at the next engine shop visit, or within 90 days after the effective date of this AD, whichever occurs first, unless already done.

Low Pressure Rotor Speed (NL) Sensor Port Sealing Tube

(f) Replace the low pressure rotor speed (NL) sensor port sealing tube with an improved durability tube, in accordance with paragraphs 2.A. and 2.B., Accomplishment Instructions of PWC Service Bulletin (SB) No. 20914, Revision 4, dated December 14, 2001.

Switching Valve-to-Rear Inlet Case Sealing Air Tube Assembly

(g) Remove the switching valve-to-rear inlet case sealing air tube assembly, in accordance with paragraph 2.C., Accomplishment Instructions of PWC SB No. 20914, Revision 4, dated December 14, 2001, and do the following:

(1) Either install an improved durability switching valve-to-rear inlet case sealing air tube assembly, in accordance with paragraph 2.G., Accomplishment Instructions of PWC SB No. 20914, Revision 4, dated December 14, 2001; or

(2) Rework the switching valve-to-rear inlet case sealing air tube assembly and install tube assembly, in accordance with paragraphs 2.D., 2.F., and 2.G., Accomplishment Instructions of PWC SB No. 20914, Revision 4, dated December 14, 2001.

Alternative Methods of Compliance

(h) Alternative methods of compliance must be requested in accordance with 14 CFR part 39.19, and must be approved by the Manager, Engine Certification Office, FAA.

Material Incorporated by Reference

(i) The replacements and rework must be done in accordance with PWC SB No. 20914, Revision 4, dated December 14, 2001.

Related Information

(j) The subject of this AD is addressed in Transport Canada airworthiness directive No. CF–2002–10, dated January 28, 2002.

Issued in Burlington, Massachusetts, on May 30, 2003.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 03–14276 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–103809–03]

RIN 1545–BA56

Disclosure of Return Information to the Department of Agriculture

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: The IRS is issuing regulations to incorporate and clarify the phrase ''return information reflected on returns'' in conformance with the terms of section 6103(j)(5) of the Internal Revenue Code (Code). These temporary regulations also remove certain items of return information that the IRS currently discloses, but the Department of Agriculture no longer needs, for conducting the census of agriculture. The text of the temporary regulations published in the Rules and Regulations section of this issue of the **Federal Register** serves as the text of the proposed regulations.

DATES: Written and electronic comments and requests for a public hearing must be received by August 1, 2003.

ADDRESSES: Send submissions to: CC:PA:RU (REG–103809–03), room 5226, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered between the hours of 8 a.m. and 4 p.m. to CC:PA:RU (REG–103809–03), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the IRS Internet site at *http://www.irs.gov/regs.*

FOR FURTHER INFORMATION CONTACT: Christine Irwin at (202) 622–4570 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Procedure and Administration Regulations (26 CFR Part 301) relating to Code section 6103(j)(5). The temporary regulations contain rules relating to the disclosure of return information reflected on returns to officers and employees of the Department of Agriculture for conducting the census of agriculture.

The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

Special Analyses

It has been determined this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because no notice of proposed rulemaking is required, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the IRS will submit this notice of proposed rulemaking to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before adoption of these proposed regulations as final regulations, the IRS will consider any written (a signed original and 8 copies) or electronic comments that the IRS timely receives. The IRS and Treasury Department request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying. The IRS may schedule a public hearing if any person who timely submits written comments requests such a hearing in writing. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Christine Irwin, Office of the Associate Chief Counsel, Procedure & Administration (Disclosure & Privacy Law Division).

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 301 is proposed to be amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

■ 1. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ 2. Section 301.6103(j)(5)–1 is added to read as follows:

§ 301.6103(j)(5)–1 Disclosures of return information reflected on returns to officers and employees of the Department of Agriculture for conducting the census of agriculture.

[The text of this proposed section is the same as the text of § 301.6103(j)(5)–1T published elsewhere in this issue of the **Federal Register**.]

David A. Mader,

Assistant Deputy Commissioner of Internal Revenue.

[FR Doc. 03–14206 Filed 6–5–03; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H–049D]

RIN 1218–AC05

Controlled Negative Pressure REDON Fit Testing Protocol

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

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: OSHA is proposing to approve an additional controlled negative pressure (CNP) fit testing protocol for its Respiratory Protection Standard. The proposed protocol would affect OSHA respiratory protection standards for shipyard employment and construction. The proposed protocol is referred to as the CNP REDON fit testing protocol. Provisions contained in OSHA's current Respiratory Protection Standard allow individuals to propose additional fit testing protocols. This proposed revision is based on a new quantitative fit testing protocol submitted to OSHA for addition to the standard.

The proposed protocol requires three different test exercises followed by two

redonnings of the respirator, while the currently approved CNP protocol specifies eight test exercises, including one redonning of the respirator. In addition to amending the Respiratory Protection Standard to include the proposed protocol, this rulemaking is proposing to make several editorial and non-substantive technical revisions to this standard associated with the proposed protocol and the approved CNP protocol.

DATES: Submit written comments regarding this proposal, including comments on the information-collection determination described in section IV.C (Paperwork Reduction Act) of this notice, by the following dates:

Hard copy. Submitted (postmarked or sent) by September 4, 2003.

Facsimile and electronic transmission. Sent by September 4, 2003.

Please see the section below entitled **SUPPLEMENTARY INFORMATION** for additional information on submitting written comments.

ADDRESSES: Submit comments and attachments to comments using one of the procedures described below:

Regular mail, express delivery, hand-delivery, and messenger service. Submit three copies of written comments and attachments to the OSHA Docket Office, Docket No. H–049D, Technical Data Center, Room N–2625, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210; telephone (202) 693–2350. OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m., EST.

Please note that security-related problems may result in significant delays in receiving comments and other written materials by regular mail. Telephone the OSHA Docket Office at (202) 693–2350 for information regarding security procedures associated with delivery of materials by express delivery, hand delivery, and messenger service.

Facsimile. Transmit written comments (including attachments) consisting of 10 or fewer pages by facsimile to the OSHA Docket Office at (202) 693–1648. You must include the docket number of this notice, Docket No. H–049D, in your comments.

Electronic. You may submit comments electronically through the Internet on OSHA's Homepage at *http://*/*ecomments.osha.gov*. If you would like to submit additional studies or journal articles, you must submit three copies of them to the OSHA Docket Office at the address above. These materials must clearly identify your electronic comments by name, date, subject, and docket number so we can attach them to your comments.

All comments and submissions will be available for inspection and copying in the OSHA Docket Office at the address above. Comments and submissions posted on OSHA's web page will be available at *http://www.osha.gov*. Contact the OSHA Docket Office at (202) 693–2350 for information about materials not available on the OSHA web page and for assistance in using this web page to locate docket submissions. Because comments sent to the docket or to OSHA's web page are available for public inspection, the Agency cautions against including in these comments personal information such as social security numbers and birth dates.

FOR FURTHER INFORMATION CONTACT: For technical inquiries, contact Mr. John E. Steelnack, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2289 or facsimile (202) 693–1678. Copies of this **Federal Register** notice are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington DC 20210; telephone (202) 693–1888. For an electronic copy of this notice, go to OSHA's website (*http://www.osha.gov*), and select ''**Federal Register**,'' ''Date of Publication,'' and then ''2003.''

SUPPLEMENTARY INFORMATION:

I. Background

The Respiratory Protection Standard currently includes three (3) quantitative fit testing protocols: Generated aerosol fit testing protocol; ambient aerosol condensation nuclei counter (CNC) fit testing protocol; and controlled negative pressure (CNP) fit testing protocol. The standard specifies the procedure to be followed to add new test protocols as they are developed and validated. The criteria for determining that a fit testing protocol is valid include: (1) A test report prepared by an independent government research laboratory (*e.g.*, Lawrence Livermore National Laboratory, Los Alamos National Laboratory, the National Institute for Standards and Technology) stating that the laboratory tested the protocol and found it to be accurate and reliable; or (2) an article published in a peer-reviewed industrial hygiene journal describing the protocol and explaining how the test data support the protocol's accuracy and reliability. When a protocol meets such criteria, OSHA conducts a notice-and-comment rulemaking under Section 6(b)(7) of the Occupational Safety and Health Act of 1970. OSHA believes the CNP REDON meets these criteria as described below.

II. Summary and Explanation of the Proposal

Introduction. In his letter submitting the protocol for review, Dr. Crutchfield included copies of two peer-reviewed articles from industrial hygiene journals describing the accuracy and reliability of the CNP REDON fit testing protocol. (See Exs. 2 and 3; Section III below provides complete reference information on these articles.) In this submission, Dr. Crutchfield also described in detail the equipment and procedures required to administer the proposed protocol. According to this description, the proposed protocol is a variation of the controlled negative pressure (CNP) fit testing protocol developed by Dr. Crutchfield in the early 1990s, which OSHA approved for inclusion in Part I.C of Appendix A when the Agency developed the final Respiratory Protection Standard. The proposed protocol uses the same fit test requirements and test instrumentation specified for the CNP fit testing protocol in paragraphs (a) and (c) of Part I.C.4 of Appendix A of this standard. However, the proposed protocol includes only three test exercises followed by two redonnings of the respirator, instead of the eight test exercises and one respirator redonning required in paragraph (b) of the CNP fit testing protocol. The three tests, listed in order of administration, are normal breathing, bending over, and head shaking. The procedures for administering these three test exercises and the two respirator donnings to an employee, and for measuring respirator leakage during each test, are described below:

- *Facing forward.* In a normal standing position, without talking, the test participant shall breathe normally; then, while facing forward, he/she shall hold his/her breath for 10 seconds for test measurement.
- *Bending over.* The test participant shall bend at the waist as if he/she is going to touch his/her toes; then, while facing parallel to the floor, he/she shall hold his/her breath for 10 seconds for test measurement.
- *Head shaking.* The test participant shall shake his/her head back and forth vigorously several times while shouting for approximately three seconds; then, while facing forward, he/she shall hold his/her breath for 10 seconds for test measurement.
- *First redonning (REDON–1).* The test participant shall remove and redon the respirator mask; after redonning the

mask, he/she shall face forward and hold his/her breath for 10 seconds for test measurement.

• *Second redonning (REDON–2).* The test participant shall remove and redon the respirator mask again; after redonning the mask, he/she shall face forward and hold his/her breath for 10 seconds for test measurement.

As noted earlier, Dr. Crutchfield submitted two peer-reviewed journal articles that provided information on the accuracy and reliability of the proposed CNP REDON fit testing protocol. In the first of these articles, the most important conclusion made by the authors is that the proposed CNP REDON fit testing protocol results in substantially lower respirator fit factors overall than the most commonly used ambient aerosol (AA) fit testing protocol. Accordingly, lower fit factors indicate that the proposed protocol would detect more respirator leaks than the AA protocol, thereby providing employees with an increased margin of safety when they select respirators. The main conclusion reached by the authors in the second article is that the overall fit factors obtained from the three exercises and two redonnings required by the proposed protocol are the same as the overall fit factors found when using the eight-exercise CNP protocol described in the Respiratory Protection Standard. Therefore, compared to the eight-exercise CNP protocol, the same overall fit factors can be obtained in less time using the proposed protocol.

Peer-reviewed articles. In the first peer-reviewed article, entitled ''Effect of exercise and mask donning on measured respirator fit'' and published in *Applied Occupational and Environmental Hygiene*, Dr. Crutchfield and his colleagues tested 14 Air Force personnel who wore elastomeric full facepiece or half mask air purifying respirators while being fit tested using either AA fit testing equipment (the Portacount Plus®, manufactured by TSI, Inc., St. Paul, MN) or CNP fit testing equipment (FitTester 3000®, manufactured by Occupational Health Dyanmics, Birmingham, AL) (Ex. 2). The study participants wore their usual respirator mask for half of the tests (mask 1), and a respirator mask that was either a size larger or smaller than their usual mask for the other half of the tests (mask 2). The purpose of using the second mask was to obtain poor respirator fit (*i.e.*, to ensure respirator leakage on some of the tests). Each study participant received three fit tests per day for five consecutive days; they removed and redonned the respirator between fit tests. During a fit test, they engaged in one of two test-exercise procedures. The first procedure (procedure 1) consisted of the three test exercises described in the proposed protocol (*i.e.*, facing forward, bending over, and head shaking), with no repeated donnings. The second procedure (procedure 2) consisted of the following nine exercises (listed in order of administration): Normal breathing; deep breathing; side-to-side head turning (pausing to inhale at each extreme position); up-and-down head nodding (pausing to inhale at each extreme position); talking loudly (reading a standard passage, counting backward from 100, or reciting a memorized poem or song); grimacing (contracting the facial muscles); bending over (as if touching the toes); jogging in place; and normal breathing. Only the first AA fit test administered each day with each mask (1 and 2) used the second test-exercise procedure; the remaining AA fit tests, and all of the CNP fit tests, used the first test-exercise procedure.

The authors used the AA fit test equipment to compare fit factors for both procedures 1 and 2 under the two mask conditions. This comparison showed that, for mask 1, the log-transformed median overall fit factor obtained under procedure 1 was significantly lower than it was for procedure 2, while no significant difference was found between the procedures for mask 2. Additionally, the authors compared fit factors obtained from the two types of fit test equipment (*i.e.*, CNP and AA) under procedure 1. Accordingly, they found that the log-transformed median fit factors obtained using either type of equipment did not differ significantly among the three test exercises (*i.e.*, facing forward, bending over, and head shaking) for mask 1. However, for mask 2, the data obtained using both types of equipment showed that the bending over test exercise resulted in a significantly lower log-transformed mean fit factor than was obtained using the normal breathing test exercise.

Assessing the fit factors for procedure 2 using the AA fit test equipment, the authors found that the talking exercise resulted in a significantly lower log-transformed mean fit factor than the fit factor determined using the normal breathing exercise for mask 1; for mask 2, the log-transformed mean fit factors for both the talking and bending over exercises were significantly lower than the fit factor obtained for the normal breathing exercise. A subsequent analysis showed that the initial normal breathing exercise, as well as the bending over and the head shaking exercises, accounted for most of the fit testing failures. Finally, after collapsing the data across mask conditions and exercise procedures, the authors found that the log-transformed median fit factor for the CNP equipment was significantly lower than the log-transformed median fit factor for the AA equipment.

The authors concluded that the results obtained using the AA equipment showed that the three exercises in procedure 1 were as effective in determining poor mask fit as the nine exercises that composed procedure 2. In reaching this conclusion, they specifically discounted the talking exercise, which was assessed in this study using only the AA equipment. In doing so, they asserted that the prolonged exhalation associated with the talking exercise may increase particle migration from the lungs to the sampling probe, which would cause the probe to detect an increase in particle concentration; consequently, the talking exercise likely results in artificially low fit factors. They also concluded that CNP equipment used with the three exercises in procedure 1 detected more poorly fitting masks than AA equipment used with either exercise procedure. The authors noted as well that the study participants took substantially less time to perform the three exercises in procedure 1 than the nine exercises in procedure 2, regardless of the type of equipment used.

The second peer-reviewed article, entitled ''A faster, more rigorous protocol for fit testing emergency response respirators'' and published in *Semiconductor Safety Association Journal*, describes a study in which 511 firefighters were fit tested for the Scott Model AV–2000 self-contained breathing apparatus using CNP fit testing equipment (Ex. 3). To detect respirator leakage, the authors converted the respirator, which normally operates at positive pressure, to operate in the negative pressure mode. During fit testing, the firefighters performed one of two exercise procedures. The first exercise procedure (procedure 1), administered to 407 firefighters, consisted of the full complement of exercises described in the proposed protocol (*i.e.*, facing forward, bending over, head shaking, and two mask redonnings). The second procedure (procedure 2), administered to 104 of the firefighters, replicated the CNP test exercises listed in Part I.4(b) of Appendix A in the Respiratory Protection Standard, including (listed in order of administration): Normal breathing; deep breathing; side-to-side head turning (pausing to inhale at each extreme position); up-and-down head nodding (pausing to inhale at each

extreme position); talking (reading a standard passage, counting backward from 100, or reciting a memorized poem or song); grimacing (contracting the facial muscles); bending over (as if touching the toes); and breathing normally (remove and redon the respirator mask, then breathe normally). In addition, the authors used a short screening procedure to identify firefighters who could not pass the a complete fit testing protocol. Eighty-five (85) of the firefighters in procedure 1 (20.9%) and 30 of the firefighters in procedure 2 (28.8%) did not pass this screening test.

Comparisons among the firefighters who completed a fit testing protocol showed that the log-transformed median overall fit factor did not vary significantly between the two exercise procedures. However, after plotting the overall fit factors of the individual firefighters for the two exercises (*i.e.*, one plot for each exercise), the authors noted that the overall fit factors for procedure 1 were substantially less than the fit factors for procedure 2 at the low end of the two distributions. They interpreted this difference as indicating that the fit factors obtained using procedure 1 were more conservative (*i.e.*, lower) than the fit factors obtained for procedure 2 at lower levels of respirator fit. Based on these results, the authors concluded that the two exercise procedures resulted in similar fit factors, and that procedure 1, with three exercises and two respirator redonnings, took substantially less time to administer than procedure 2, with eight exercises (including one redonning).

Editorial and technical revisions to the Respiratory Protection Standard. In addition to proposing the CNP REDON fit testing protocol, this rulemaking is proposing to make several editorial and technical revisions to the Respiratory Protection Standard. The first editorial revision would add the proposed CNP REDON protocol to the exception already specified for the approved CNP protocol under paragraph 14(a) of Part I.A in Appendix A of the Standard. Accordingly, paragraph 14(a) would except both the approved CNP protocol and the CNP REDON protocol from the test exercises specified for the other approved fit testing protocols listed in the appendix. OSHA believes that this revision is necessary because the proposed protocol consists of a test exercise procedure that differs substantially from the procedure required for the other approved fit testing protocols.

The second editorial revision involves the introductory paragraph describing the CNP protocol under Part I.C.4 of Appendix A. The eighth sentence in this paragraph refers to the CNP instrument manufacturer as ''Dynatech Nevada.'' However, the instrument manufacturer now is Occupational Health Dynamics of Birmingham, Alabama. OSHA is proposing to revise this sentence to identify the current manufacturer of this instrument.

In an earlier comment to OSHA (Ex. 14), Dr. Crutchfield noted that test administrators use either an auditory warning device or the screen tracing currently provided on the CNP test instrument to detect participants' failure to hold their breath for the required 10-second period when measuring respirator fit. While using the screen tracing for this purpose was not part of the CNP protocol approved earlier by OSHA, the Agency believes that such a visual warning device would be useful in measuring respirator fit under both the approved CNP protocol and the proposed CNP REDON protocol. Therefore, OSHA is proposing to revise paragraph (c) of the approved CNP protocol (under Part I.A.4 of the standard) to include the screen tracing currently provided on the CNP test instrument as a visual warning device to detect non-compliance with the breath hold procedure.

In a 1998 journal article entitled ''CNP fit testing under OSHA's updated respiratory protection standard'' published in *Respiratory Protection Update,* Dr. Crutchfield indicated that OSHA's description of the CNP fit test requirements in paragraphs (a)(2) and (a)(5) of the approved CNP protocol contained several errors (Ex. 8). In this regard, the default test pressure in paragraph (a)(2) should read -15 (not -1.5) mm of water, while the breath hold requirement in paragraph (a)(5) should be 10 (not 20) seconds. Accordingly, the Agency is proposing to revise these parameters because implementing correct fit test procedures will improve the assessment of respirator fit factors using the approved CNP protocol, as well as the proposed CNP REDON protocol should the Agency approve it in a final rulemaking.

Conclusions. OSHA believes that the information submitted by Dr. Crutchfield in support of the proposed protocol meets the criteria for proposed fit testing protocols established by the Agency in Part II of Appendix A of the Respiratory Protection Standard. Therefore, the Agency concludes that the proposed protocol warrants notice-and-comment rulemaking under Section 6(b)(7) of the OSH Act, and is initiating this rulemaking to determine whether to approve the proposed protocol for inclusion in Part I of Appendix A of the standard. However, because the only difference between the proposed protocol and the existing CNP protocol in Part I.C.4 of Appendix A is the exercise procedure used during fit testing, the Agency is limiting the proposed regulatory text (see section V below) to a description of the exercise procedure, and is referring to paragraphs (a) and (c) of Part I.C.4 for information on the CNP fit test requirements and the CNP test instrument. In addition, if approved, the protocol would be an alternative to the existing quantitative fit testing protocols already listed in the Part I of Appendix A; employers would be free to select this alternative or to continue using any of the other protocols currently listed in the appendix. The Agency also believes that the proposed editorial and technical revisions to Part I of Appendix A are necessary for proper implementation of both the approved CNP protocol and the proposed CNP REDON protocol.

Issues for public comment. OSHA invites comments and data from the public regarding the accuracy and reliability of the CNP REDON protocol, as well as its effectiveness in detecting respirator leakage and its usefulness in selecting respirators that will protect employees from airborne contaminants in the workplace. Specifically, the Agency invites public comment on the following issues:

- Were the studies described in the peer-reviewed articles well controlled, and conducted according to accepted experimental design practices and principles?
- Were the results of the studies described in the peer-reviewed articles properly, fully, and fairly presented and interpreted?
- Will the proposed protocol reliably identify respirators with unacceptable fit as effectively as the quantitative fit testing protocols already listed in Part I.C of Appendix A of the Respiratory Protection Standard?
- Will the proposed protocol generate reproducible fit testing results?
- Should OSHA expand application of the proposed protocol fit test exercises to other quantitative fit tests (*e.g.*, ambient aerosol tests)?
- Will the proposed editorial and technical revisions to Part I of Appendix A improve proper implementation of the approved CNP protocol and the proposed CNP REDON protocol?

III. References

The preamble to this proposal cites the following references:

(1) Crutchfield C.D., E.O. Fairbank, and S.L. Greenstein. ''Effect of exercise

and mask donning on measured respirator fit.'' *Applied Occupational and Environmental Hygiene*, vol. 14 (no. 12), pages 827–837, 1999. (See Ex. 2.)

(2) Crutchfield, C.D., W.F. Peate, and D.W. Kautz. ''A faster, more rigorous protocol for fit testing emergency response respirators.'' *Semiconductor Safety Association Journal*,[1] vol. 13 (no. 4), pages 23–29, 1999. (See Ex. 3.)

Copies of these references are available from the OSHA's Docket Office, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, DC 20210; telephone (202) 693–2350 or facsimile (202) 693–1648.

IV. Procedural Determinations

A. Legal Considerations

Employers covered by this proposal already must comply with the fit testing requirements specified in paragraph (f) of OSHA's Respiratory Protection Standard at 29 CFR 1910.134. Accordingly, these provisions currently are protecting their employees from the significant risk that results from poorly fitting respirators. For this proposal, the Agency preliminarily determined that the new CNP fit testing protocol provides employees with protection that is comparable to the protection afforded to them by the existing fit testing provisions. In this regard, the proposal is not expected to replace existing fit testing protocols, but instead would be an alternative to them. Therefore, OSHA preliminarily finds that the proposal would not directly increase or decrease the protection afforded to employees, nor would it increase employers' compliance burdens. As demonstrated in the following section, the proposal may reduce employers' compliance burdens by decreasing the time required for fit testing respirators for employee use.

B. Preliminary Economic Analysis and Regulatory Flexibility Certification

The proposal is not a significant rulemaking under Executive Order 12866, or a ''major rule'' under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501) or Section 801 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 601). The proposal would impose no additional costs on any private or public sector entity, and does not meet any of the criteria for a significant or major rule specified by the Executive Order or relevant statutes.

The proposal offers employers an additional option to fit test their employees for respirator use. In addition to the existing CNP protocol, which would continue to be an option, the Agency would add the CNP REDON protocol as a supplemental option. According to a recent NIOSH–BLS survey of respirator use, approximately 25,000 establishments currently use the existing CNP fit testing protocol out of some 282,000 establishments requiring respirator use (Ex. 6–3, Docket H–049C). Employers would have a choice between the existing protocol consisting of eight exercises, including one redonning of the respirator, or the new protocol, which involves three exercises and two redonnings of the respirator. By providing regulatory flexibility to these employers, the proposal may reduce their costs in terms of decreasing fit testing time. In this regard, OSHA assumes that the proposed CNP REDON protocol would be adopted by some employers who use the existing CNP protocol, as well as some employers who are purchasing new or replacement equipment for administering fit tests; these employers would adopt the proposed protocol because it consists of fewer exercises than the existing CNP and ambient aerosol protocols, thereby decreasing the time and cost required for fit testing. However, the Agency believes that the proposed protocol is unlikely to be adopted by employers who currently use the ambient aerosol protocols because of the equipment and training investment they have already made to administer these protocols. Finally, the Agency proposes to include the screen tracing in the existing and proposed CNP fit testing protocols as a visual warning device to detect non-compliance with the breath hold procedure. OSHA concludes that this proposal would add no additional cost burden to employers because, as noted earlier, the manufacturer already provides this capability on the CNP test equipment. Therefore, the Agency preliminarily concludes that this proposed rulemaking would impose no additional costs on these employers. Consequently, the proposal requires no Preliminary Economic Analysis. Furthermore, because the proposal imposes no costs on employers, OSHA certifies that it would not have a significant impact on a substantial number of small businesses. Accordingly, the Agency need not prepare an Initial Regulatory Flexibility Analysis.

C. Paperwork Reduction Act

After thoroughly analyzing the proposed fit testing provisions in terms of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.* and 5 CFR part 1320), OSHA believes that these provisions would not add to the existing collection-of-information (*i.e.,* paperwork) requirements regarding fit testing employees for respirator use. The paperwork requirement specified in paragraph (m)(2) of the existing Respiratory Protection Standard at 29 CFR 1910.134 specifies that employers must document and maintain the following information on quantitative fit tests administered to employees: The name or identification of the employee tested; the type of fit test performed; the specific make, model, style, and size of respirator tested; the date of the test; and the strip chart recording or other recording of the test results. The employer must maintain this record until the next fit test is administered. However, this paperwork requirement would remain the same whether employers currently use the other fit testing protocols already listed in Part I of Appendix A of the Respiratory Protection Standard, or implement the proposed fit testing protocol instead. Therefore, use of the proposed fit testing protocol in the context of the existing fit testing protocols does not require an additional paperwork burden determination because OSHA already accounted for this burden during the final rulemaking for the Respiratory Protection Standard (*see* 63 FR 1152–1154; OMB Control Number 1218–0099).

Interested parties who wish to comment on OSHA's determination that the proposed fit testing protocol contains no additional paperwork requirements compared to the existing paperwork requirements must send their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for OSHA, Office of Management and Budget, Room 10235, 725 17th Street, NW., Washington, DC 20503. The Agency also encourages commenters to submit their comments on this paperwork determination to OSHA along with their other comments on the proposed rule.

D. Federalism

The Agency reviewed the proposal according to the most recent Executive Order on Federalism (Executive Order 13132, 64 FR 43225, August 10, 1999). This Executive Order requires that Federal agencies, to the extent possible, refrain from limiting state policy options, consult with states before taking actions that restrict their policy options, and take such actions only when clear constitutional authority exists and the problem is national in scope. The Executive Order allows Federal agencies to preempt state law

[1] Now the *Semiconductor Environmental Safety and Health Association Journal.*

only with the expressed consent of Congress. In such cases, Federal agencies must limit preemption of state law to the extent possible.

Under section 18 of the Occupational Safety and Health Act of 1970 (OSH Act), Congress expressly provides OSHA with authority to preempt state occupational safety and health standards to the extent that the Agency promulgates a Federal standard under section 6 of the OSH Act. Accordingly, section 18 of the OSH Act authorizes the Agency to preempt state promulgation and enforcement of requirements dealing with occupational safety and health issues covered by OSHA standards unless the state has an OSHA-approved occupational safety and health plan (*i.e.,* is a State-plan State). (*See Gade* v. *National Solid Wastes Management Association*, 112 S. Ct. 2374 (1992).) Therefore, with respect to states that do not have OSHA-approved plans, the Agency concludes that this proposal conforms to the preemption provisions of the OSH Act. Additionally, section 18 of the OSH Act prohibits states without approved plans from issuing citations for violations of OSHA standards; the Agency finds that the proposed rulemaking does not expand this limitation.

OSHA has authority under Executive Order 13132 to propose adding the CNP REDON fit testing protocol to its Respiratory Protection Standard at 29 CFR 1910.134 because the problems addressed by these requirements are national in scope. In this regard, the proposal offers hundreds of thousands of employers across the nation an opportunity to adopt an additional protocol to use in assessing respirator fit among their employees. Therefore, the proposal would provide employers in every state with an alternative means of complying with the fit testing requirements specified in paragraph (f) of OSHA's Respiratory Protection Standard.

Should OSHA adopt the proposed fit testing protocol in a final rulemaking, section 18(c)(2) of the OSH Act (29 U.S.C. 667(c)(2)) requires State-plan States to adopt the same protocol, or develop an alternative that is at least as effective as that protocol. However, compliance with the new fit testing protocol would only provide employers with an alternative to the existing requirements for fit testing protocols specified in its Respiratory Protection Standard; therefore, the alternative is not, itself, a mandatory standard. Accordingly, State-plan States are not obligated to adopt the final provisions that result from this rulemaking. Nevertheless, OSHA strongly encourages them to adopt the final provisions to provide compliance options to employers in their states.

E. State Plans

The Agency strongly encourages the 24 states and two territories with their own OSHA-approved occupational safety and health plans to revise their current Respiratory Protection Standard should the Agency adopt the proposed fit testing protocol based on this rulemaking. OSHA believes that such a revision would provide employers in the State-plan States with any economic benefits that may accrue from its enactment, while protecting the safety and health of employees who use respirators against airborne hazardous substances in the workplace. These states and territories are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Connecticut, New Jersey, and New York have OSHA-approved State Plans that apply to state and local government employees only.

F. Unfunded Mandates

OSHA reviewed the proposal according to the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*) and Executive Order 12875. As discussed above in section IV.B (Preliminary Economic Analysis and Regulatory Flexibility Certification) of this preamble, the Agency has made a preliminary determination that the proposal imposes no additional costs on any private or public sector entity. The substantive content of the proposal applies only to employers whose employees use respirators for protection against airborne workplace contaminants, and compliance with the proposal would be strictly optional for these employers. Accordingly, the proposal would require no additional expenditures by either public or private employers.

OSHA standards do not apply to state and local governments, except in states that have voluntarily elected to adopt a State Plan approved by the Agency. Consequently, the proposal does not meet the definition of a ''Federal intergovernmental mandate'' (*see* section 421(5) of the UMRA (2 U.S.C. 658(5)). In conclusion, the proposal does not mandate that state, local, and tribal governments adopt new, unfunded regulatory obligations.

G. Applicability of Existing Consensus Standards

When OSHA promulgated its original respirator fit testing protocols on January 8, 1998 under Appendix A of its final Respiratory Protection Standard (29 CFR 1910.134), no national consensus standards addressed these protocols. However, the American National Standards Institute (ANSI) subsequently developed a national consensus standard on fit testing protocols as an adjunct to its respiratory protection program, ANSI Z88.2–1992. ANSI approved this national consensus standard, entitled ''Respirator Fit Testing Methods,'' on June 8, 2001 as ANSI Z88.10–2001.

Paragraph 7.3 of ANSI Z88.10–2001 provides the requirements for conducting the CNP fit test, including requirements for test instrumentation and administering the fit test; these requirements are consistent with the CNP fit test requirements specified in 1998 by OSHA in Part I.C.4 of its Respiratory Protection Standard. In addition, section 9 and Table 1 of ANSI Z88.10–2001 describe the exercises required during CNP fit testing; these required exercises duplicate the exercises described in this CNP REDON proposal, except that the second respirator redonning is optional under the ANSI standard.[2] However, paragraph 9.2 of the ANSI standard specifies that one optional exercise must be included with the required exercises.

OSHA concludes that the CNP REDON fit testing protocol proposed in this rulemaking closely matches the requirements of the recent ANSI Z88.10–2001 standard. The proposed CNP REDON protocol relies on the CNP test procedures and instrumentation described in paragraphs (a) and (c) of Part I.C.4 in Appendix A of the Respiratory Protection Standard, which are similar to requirements specified in paragraph 7.3 of the ANSI standard. Any differences between these OSHA requirements and the provisions of the ANSI standard appear to be minor. In addition, the fit testing exercises in the proposed CNP REDON protocol are the same exercises in the ANSI standard when a second respirator redonning is selected as the optional exercise.

[2] Other optional exercises include deep breathing, side-to-side head movement, up-and-down head movement, stepping up and down, a second normal breathing exercise, grimacing followed by normal breathing, painter or sand-blaster movements, and other job-specific movements.

H. Review of the Proposed Standard by the Advisory Committee for Construction Safety and Health (ACCSH)

This proposal would revise Part I.C of Appendix A of OSHA's current Respiratory Protection Standard (29 CFR 1910.134) by including the CNP REDON protocol with the three fit testing protocols already approved by the Agency, and would also make several technical revisions to the approved CNP protocol. Accordingly, this proposal would revise the fit testing requirements specified by the Respiratory Protection Standard for the construction industry (see 29 CFR 1926.103).

OSHA's regulation governing the Advisory Committee on Construction Safety and Health (ACCSH) at 29 CFR 1912.3 requires the Agency to consult with the ACCSH whenever the Agency proposes a rulemaking that involves the occupational safety and health of construction employees. OSHA met with the ACCSH and described the CNP proposed rule at the ACCSH meeting on December 5, 2002. The ACCSH members had no questions or comments on this proposal at this meeting. Subsequently, OSHA distributed the proposed CNP rule to the ACCSH membership for their review prior to their next regular meeting on May 22, 2003. OSHA staff discussed the CNP proposal and answered questions from the ACCSH members during their meeting on May 22, 2003. The ACCSH then recommended that OSHA proceed with publishing the proposal.

I. Public Participation

The Agency requests members of the public to submit written comments and other information concerning this proposal. These comments may include objections to the proposal, as well as comments that endorse or support the proposed amendment set forth in this notice. OSHA welcomes such comments and information so that the record of this rulemaking will represent a balanced public response on the issues involved. (See the sections above titled **DATES** and **ADDRESSES** for information on submitting these comments and information to the Agency.) Submissions received within the specified comment period will become part of the record, and will be available for public inspection and copying in the OSHA Docket Office.

J. List of Subjects in 29 CFR Part 1910

Hazardous substances; Health; Occupational safety and health; Quantitative fit testing; Respirators; Respirator selection.

K. Authority and Signature

John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, directed the preparation of this notice. Accordingly, the Agency issues the proposed amendment under the following authorities: Sections 4, 6(b), 8(c), and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Section 107, Contract Work Hours and Safety Standards Act.

(Construction Safety Act; 40 U.S.C. 333); Section 41, Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); Secretary of Labor's Order No. 5–2002 (67 FR 65008); and 29 CFR part 1911.

Signed at Washington, DC on May 28, 2003.

John L. Henshaw,

Assistant Secretary of Labor.

V. Proposed Amendment to Standard

For the reasons stated in the preamble, the Agency proposes to amend 29 CFR part 1910 as follows:

PART 1910—[AMENDED]

Subpart I—[Amended]

1. Revise the authority citation for subpart I of part 1910 to read as follows:

Authority: Sections 4, 6 and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Section 107, Contract Work Hours and Safety Standards Act (the Construction Safety Act; 40 U.S.C. 333); Section 41, Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); and Secretary of Labor's Order Nos. 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2002 (67 FR 65008), as applicable.

Sections 29 CFR 1910.132, 1910.134, and 1910.138 also issued under 29 CFR part 1911.

Sections 29 CFR 1910.133, 1910.135, and 1910.136 also issued under 29 CFR part 1911 and 5 U.S.C. 553.

2. Appendix A to § 1910.134 is amended as follows in Part I:

A. In Section A, revise the introductory text of paragraph 14(a);

B. In Section C, paragraph 4, 8th sentence, remove the name ''Dynatech Nevada'' and add, in its place, ''Occupational Health Dynamics of Birmingham, Alabama.''

C. In Section C, paragraphs 4(a)(2) and (5) are revised.

D. In Section C, paragraph 4(c)(1) is revised.

E. In Section C, paragraph 5 is added at the end of Part I.

The revised and added text reads as follows:

§ 1910.134 Respiratory protection.

* * * * *

Appendix A to § 1910.134: Fit Testing Procedures (Mandatory)

* * * * *

Part I. OSHA—Accepted Fit Testing Protocols

A. Fit Testing Procedures—General Requirements

* * * * *

14. Test Exercises. (a) Employers shall perform the following test exercises for all fit testing methods prescribed in this appendix, except for the CNP quantitative fit testing protocol and the CNP REDON quantitative fit testing protocol. For these two protocols, employers shall ensure that the test subjects (*i.e.*, employees) perform the exercise procedure specified in Part I.C.4(b) of this appendix for the CNP quantitative fit testing protocol, or the exercise procedure described in Part I.C.5(b) of this appendix for the CNP REDON quantitative fit testing protocol. For the remaining fit testing methods, employers shall ensure that the test exercises are performed in the appropriate test environment in the following manner:

* * * * *

C. * * *

* * * * *

(a) * * *

* * * * *

(2) The CNP system default selected for test pressure shall be set at −15.0 mm (−0.58 inches) of water, and the modeled inspiratory flow rate shall be 53.8 liters per minute for performing fit tests.

* * * * *

(5) The test subject shall be trained to hold his/her breath for at least 10 seconds.

* * * * *

(c) * * *

(1) The test instrument shall have an effective audio warning device, or a visual warning device in the form of a screen tracing, that indicates when the test subject fails to hold his/her breath during the test. The test shall be terminated if the test subject fails to hold his/her breath during the test. The test subject then may be refitted and retested.

* * * * *

5. Controlled negative pressure (CNP) REDON quantitative fit testing protocol.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in paragraphs (a) and (c) of Part I.C.4 of this appendix (Controlled negative pressure (CNP) quantitative fit testing protocol), except they may use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in paragraph (b) of Part I.C.4 of this appendix.

(b) Employers shall ensure that each test subject being fit tested using this protocol follows the exercise and measurement procedures, including the order of administration, described below in Table A–1 of this appendix.

TABLE A–1.—CNP REDON QUANTITATIVE FIT TESTING PROTOCOL

Name of exercise [1]	Exercise procedure	Measurement procedure
Facing Forward	Stand and breathe normally, without talking	Face forward while holding breath for 10 seconds.
Bending Over	Bend at the waist as if going to touch his/her toes	Face parallel to the floor while holding breath for 10 seconds.
Head Shaking	For about three seconds, shake head back and forth vigorously several times while shouting.	Face forward while holding breath for 10 seconds.
REDON–1	Remove and redon the respirator mask	Face forward while holding breath for 10 seconds.
REDON–2	Remove and redon the respirator mask again	Face forward while holding breath for 10 seconds.

[1] Exercises are listed in the order in which they are to be administered.

(c) After completing the test exercises, the test administrator shall question each test subject regarding the comfort of the respirator. If the test subject states that the respirator is unacceptable, the employer shall ensure that the test administrator repeats the protocol using another respirator model.

(d) When calculating the overall fit factor for each test subject, employers shall determine the harmonic mean of the fit factors measured for each test exercise.

[FR Doc. 03–13748 Filed 6–5–03; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD13–03–013]

RIN 1625–AA00

Safety Zone; Fireworks Display, Columbia River, Astoria, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes establishing a safety zone for an annual fireworks display on the waters of the Columbia River in the vicinity of Astoria, Oregon. The Captain of the Port, Portland, Oregon, is taking this action to safeguard watercraft and their occupants from safety hazards associated with the fireworks display. Entry into this safety zone is prohibited unless authorized by the Captain of the Port.

DATES: Comments and related material must reach the Coast Guard by July 7, 2003.

ADDRESSES: You may mail comments and related material to U.S. Coast Guard MSO/Group Portland, 6767 N. Basin Ave, Portland, Oregon 97217. U.S. Coast Guard Group/MSO Portland 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 U.S. Coast Guard MSO/Group Portland, 6767 N. Basin Ave, Portland, OR 97217 between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Tad Drozdowski, at (503) 240–9370.

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 (CGD13–03–013), 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 they 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 U.S. Coast Guard Group/MSO Portland 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

The Coast Guard is establishing a safety zone regulation to allow a safe annual fireworks display. The fireworks will occur annually on the second Saturday in August. This event will result in a number of vessels congregating near the fireworks launching area. The safety zone is needed to provide for the safety of the spectators and their watercraft from the inherent safety hazards associated with the fireworks display. Without providing an adequate safety zone, the public could be exposed to falling burning debris within blast range should a catastrophic accident occur on the launching barge. This safety zone will be enforced by representatives of the Captain of the Port, Portland, Oregon. The Captain of the Port may be assisted by other federal and local agencies. The Cost Guard plans to publish a notice of implementation at least 30 days prior to the event.

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 expectation is based on the fact that the regulated area established by the rule would encompass less than one mile of the Columbia River for a period of only one hour, annually.

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 will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit a portion of the Columbia River during the one hour fireworks display. This safety zone will not have significant economic impact on a substantial number of small entities for the following reasons. This rule will be in effect for only one hour, annually, in the evening when vessel traffic is low. Traffic will be allowed to pass through the zone with the permission of the Captain of the Port or his designated representatives on scene, if safe to do so. Because the impacts of this rule are expected to be so minimal, the Coast Guard certifies under 5 U.S.C. 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601–612) that this rule will not have a significant economic impact on a substantial number of small entities.

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 (Pub. L. 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 LTJG Tad Drozdowski at (503) 240–2584.

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

We have 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.

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 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 because the safety zone would not last longer than one week in duration. A draft ''Environmental Analysis Check List'' and a draft ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES.** Comments on this section will be considered before we make the final decision on whether the rule should be categorically excluded 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 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. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5; Department of Homeland Security Delegation No. 0170.

2. Section 165.13–1316 is added to read as follows:

§ 165.1316 Safety Zone; Columbia River Astoria, Oregon

(a) *Location.* All waters of the Columbia River at Astoria, Oregon enclosed by the following points: North from the Oregon shoreline at 123°49′36″ West to 46°11′ 51″ North, thence east to 123°48′53″ West, thence south to the Oregon shoreline and finally westerly along the Oregon Shoreline to the point of origin.

(b) *Regulations.* In accordance with the general regulations § 165.23 of this part, no person or vessel may enter or remain in this zone unless authorized

by the Captain of the Port or his designated representatives.

(c) *Enforcement period.* This section will be enforced on the second Saturday of August from 9:30 p.m. (PDT) to 10:30 p.m. (PDT).

Dated: May 16, 2003.

Paul D. Jewell,

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

[FR Doc. 03–14305 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD07–03–069]

RIN 1625–AA11

Regulated Navigation Area; Port Everglades Harbor, Fort Lauderdale, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to create a regulated navigation area in Port Everglades Harbor, Fort Lauderdale, Florida to improve the security and safety of the harbor, and increase the safety of law enforcement officers and high-risk vessels in the vicinity of Port Everglades Harbor. This rule would establish a slow speed zone in the harbor to control vessel speed and allow law enforcement vessels to control vessel movement in this waterway.

DATES: Comments and related material must be received on or before July 21, 2003.

ADDRESSES: You may mail comments and related material to Commanding Officer, U.S. Coast Guard, Marine Safety Office, 100 MacArthur Causeway, Miami, Florida 33139. The Captain of the Port Miami 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 the above address between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LTJG Jennifer Sadowski, Coast Guard Marine Safety Office Miami, Waterways Management at (305) 535–8701.

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 [CGD07–03–069], 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 they reached us, please enclose a 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 Commanding Officer, Marine Safety Office Miami 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

The terrorist attacks of September 2001 killed thousands of people and heightened the need for development of various security measures throughout the seaports of the United States. The President declared national emergencies following the September 11, 2001 terrorist attacks and has continued them, specifically: The continuing national emergency with respect to terrorist attacks, at 67 FR 58317 (Sep. 13, 2002); and continuing national emergency with respect to persons who commit, threaten to commit, or support terrorism, at 67 FR 59447 (Sep. 20, 2002). The President found pursuant to law, including the Magnuson Act (50 U.S.C. 191 *et seq.*), that the security of the United States is and continues to be endangered since the terrorist attacks on the United States of September 11, 2001, and that such disturbances continue to endanger the security of the United States, at Executive Order 13,273, 67 FR 56215 (Aug. 21, 2002). Following the attacks of well-trained and clandestine terrorists, national security and intelligence officials warned that future terrorist attacks are likely.

The Captain of the Port (COTP) Miami has determined that there is an increased risk that subversive activity could be launched by vessels or persons in close proximity to Port Everglades because of the numerous high-capacity passenger vessels, vessels carrying hazardous cargo, critical infrastructure facilities including propane and petroleum processing facilities, and U.S. military vessels that utilize the port. Implementation of a port-wide slow speed regulated navigation area would greatly aid law enforcement officers in managing vessel traffic as any vessels not complying with the slow speed zone would quickly draw attention giving law enforcement more time to assess the situation and take appropriate action in protecting vessels within the port and port facilities.

On April 25, 2003, the Coast Guard issued a temporary final rule entitled ''Regulated Navigation Area; Port Everglades Harbor, Fort Lauderdale, Florida'' (68 FR 25498) creating a temporary regulated navigation area identical to this proposed rule. That temporary rule expires at 12:01 a.m. on September 1, 2003. Prior to the creation of that temporary final rule, vessels were able to enter the harbor from sea at a high rate of speed and maintain that high rate of speed in the harbor until coming within close proximity of high capacity passenger vessels, vessels carrying hazardous cargo, critical infrastructure facilities and U.S. military vessels that are often moored within an existing security zone or naval vessel protection zone. Law enforcement officers did not have sufficient time to react to vessels that failed to slow their speed prior to reaching the limits of the existing security zone or naval vessel protection zone. This regulated navigation area is necessary to protect the public, port, law enforcement officials, and waterways of the United States from potential subversive acts.

Nothing in this proposed rule would relieve vessels or operators from complying with all state and local laws in the regulated area, including manatee slow speed zones.

Discussion of Rule

The rule would require all vessels within the regulated navigation area to proceed at slow speed. Slow speed is defined as the speed at which a vessel proceeds when it is fully off plane, completely settled into the water and not creating excessive wake. This rule would minimize the potential national security hazards that could result from a vessel being permitted to transit through the harbor, in the vicinity of high capacity passenger vessels, vessels carrying hazardous cargo, critical infrastructure facilities and U.S. military vessels, at a high rate of speed and would facilitate law enforcement control of vessel movement.

The regulated navigation area would be in the vicinity of Port Everglades Harbor, Fort Lauderdale, Florida, and include all waters of the Atlantic Intracoastal Waterway and Port Everglades Harbor, from shore to shore, south of the 17th Street Bridge (at a line connecting 26° 06.04′ N, 080°07.17′ W and 26° 06.04′ N, 080°07.05′ W), north of the intersection of the Dania Cut Off Canal and the Intracoastal Waterway (latitude 26° 04.72′ N) and west of a north-south line connecting red day board #6 and green day board #7 at the entrance to Port Everglades Harbor (longitude 080° 06.30′ W).

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). The Coast Guard expects 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. The proposed regulated navigation area is narrowly tailored to protect the public, ports, and waterways of the United States. Watercraft would still be permitted to transit through the regulated navigation area but would have to proceed at slow speed.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this proposed rule would have a significant economic impact upon 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. The proposed regulated navigation area is narrowly tailored to protect the public, ports, and waterways of the United States. Watercraft would still be permitted to transit through the regulated navigation area but would be required to proceed at slow speed.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 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 proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact LTJG Jennifer Sadowski at (305) 535–8701 for assistance in understanding and participating in this rulemaking.

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 Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates 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 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 this proposed rule would 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. Although this proposed rule would not result in such an expenditure, we do discuss the effects of this proposed 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

We have 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 does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.1D, 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. A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

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.

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.

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 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. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.

2. Add a new § 165.765 to read as follows:

§ 165.765 Regulated Navigation Area; Port Everglades Harbor, Fort Lauderdale, Florida.

(a) *Location.* The following area in the vicinity of Port Everglades Harbor is a regulated navigation area: all waters of the Atlantic Intracoastal Waterway and Port Everglades Harbor, from shore to shore, south of the 17th Street Bridge (at a line connecting 26° 06.04′ N, 080°07.17’ W and 26°06.04′ N, 080°07.05′ W), north of the intersection of the Dania Cut Off Canal and the Intracoastal Waterway (latitude 26° 04.72′ N) and west of a north-south line connecting red day board #6 and green day board #7 at the entrance to Port Everglades Harbor (longitude 080° 06.30′ W).

(b) *Regulations.* Vessels entering and transiting through the regulated navigation area shall proceed at a slow speed. Nothing in this rule alleviates vessels or operators from complying with all state and local laws in the area, including manatee slow speed zones.

(c) *Definition.* As used in this section, *slow speed* means the speed at which a vessel proceeds when it is fully off plane, completely settled in the water and not creating excessive wake. Due to the different speeds at which vessels of different sizes and configurations may travel while in compliance with this definition, no specific speed is assigned to slow speed. A vessel is not proceeding at slow speed if it is:

(1) On a plane;

(2) In the process of coming up on or coming off of plane; or

(3) Creating an excessive wake.

Dated: 27 May 2003.

James S. Carmichael,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 03–14306 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[FRL–7509–6]

Advisory Committee for Regulatory Negotiation Concerning All Appropriate Inquiry; Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency, as required by the Federal Advisory Committee Act (Pub. L. 92–463), is announcing the date and location of an upcoming meeting of the Negotiated Rulemaking Committee On All Appropriate Inquiry.

DATES: A meeting of the Federal Advisory Committee on Regulatory Negotiation for All Appropriate Inquiry is scheduled for July 8 and July 9, 2003.

ADDRESSES: The meeting will take place at the Hotel Washington, 15th and Pennsylvania Avenue NW., Washington, DC 20004. The meeting is scheduled to begin at 8:30 a.m. and end at 4:30 p.m. on both days. Dates and locations of subsequent meetings will be announced in later notices.

FOR FURTHER INFORMATION CONTACT: Persons needing further information should contact Patricia Overmeyer of EPA’s Office of Brownfields Cleanup and Redevelopment, 1200 Pennsylvania Ave., NW., Mailcode 5105T, Washington, DC 20460, (202) 566–2774, or *overmeyer.patricia@epa.gov*.

SUPPLEMENTARY INFORMATION: Under the Small Business Liability Relief and Brownfields Revitalization Act, EPA is required to develop standards and practices for carrying out all appropriate inquiry. The Federal Advisory Committee meeting is for the purpose of negotiating the contents of a proposed regulation setting federal standards and practices for conducting all appropriate inquiry. At its meeting on July 8 and 9, the Committee will continue substantive deliberations on the proposed rulemaking including discussion of the criteria established by Congress in the Small Business Liability Relief and Brownfields Revitalization Act amendments to CERCLA (101)(35)(B)(iii). These criteria include:

‘‘(I) The results of an inquiry by an environmental professional.

(II) Interviews with past and present owners, operators, and occupants of the facility for the purpose of gathering information regarding the potential for contamination at the facility.

(III) Reviews of historical sources, such as chain of title documents, aerial photographs, building department records, and land use records, to determine previous uses and occupancies of the real property since the property was first developed.

(IV) Searches for recorded environmental cleanup liens against the facility that are filed under Federal, State, or local law.

(V) Reviews of Federal, State, and local government records, waste disposal records, underground storage tank records, and hazardous waste handling, generation, treatment, disposal, and spill records, concerning contamination at or near the facility.’’

All meetings of the Negotiated Rulemaking Committee are open to the public. There is no requirement for advance registration for members of the public who wish to attend or make comments at the meeting. Opportunity for the general public to address the Committee will be provided starting at 2:30 p.m. on both July 8 and July 9, 2003.

Dated: June 2, 2003.

Thomas P. Dunne,

Associate Assistant Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. 03–14322 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NC97–200319a; FRL–7497–9]

Approval and Promulgation of Implementation Plans; North Carolina: Approval of Revisions to the Visible Emissions Regulation Within the North Carolina State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve the State Implementation Plan (SIP) revision submitted by the North Carolina Department of Environment and Natural Resources for the purpose of amending rule NCAC 2D .0521 Visible Emissions. In the Final Rules Section of this **Federal Register**, the EPA is approving the North Carolina SIP revision as a direct final rule without

prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no significant, material, and adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Written comments must be received on or before July 7, 2003.

ADDRESSES: All comments should be addressed to: Randy Terry at the EPA, Region 4 Air Planning Branch, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.

Copies of the State submittal(s) are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 4, Air Planning Branch, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Randy Terry, 404/562–9032.

North Carolina Department of Environment and Natural Resources, 512 North Salisbury Street, Raleigh, North Carolina 27604.

FOR FURTHER INFORMATION CONTACT: Randy B. Terry at 404/562–9032, or by electronic mail at *terry.randy@epa.gov*.

SUPPLEMENTARY INFORMATION: For additional information *see* the direct final rule which is published in the Rules Section of this **Federal Register**.

Dated: April 30, 2003.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 03–12023 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 140–0396; FRL–7509–4]

Disapproval of State Implementation Plan Revisions, Antelope Valley Air Quality Management District, Butte County Air Quality Management District, Kern County Air Pollution Control District, Mojave Desert Air Quality Management District, and Shasta County Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to disapprove revisions to the Antelope Valley Air Quality Management District (AVAQMD), Butte County Air Quality Management District (BCAQMD), Kern County Air Pollution Control District (KCAPCD), Mojave Desert Air Quality Management District (MDAQMD), and Shasta County Air Quality Management District (SHAQMD) portions of the California State Implementation Plan (SIP) concerning excess emissions. We are proposing action on local rules that regulate these emissions under the Clean Air Act as amended in 1990 (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by July 7, 2003.

ADDRESSES: Mail comments to Andrew Steckel, Rulemaking Office Chief (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105 or e-mail to *steckel.andrew@epa.gov*.

You can inspect copies of the submitted rule revisions and EPA's technical support documents (TSDs) at our Region IX office during normal business hours. You may also see copies of the submitted rule revisions at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1001 ''I'' Street, Sacramento, CA 95814.

Antelope Valley AQMD, 43301 Division St., Ste. 206, Lancaster, CA 93535–4649.

Butte County AQMD, 2525 Dominic Drive, Suite J, Chico, CA 95928–7184.

Kern County APCD, 2700 ''M'' Street, Suite 302, Bakersfield, CA 93301–2370.

Mojave Desert AQMD, 14306 Park Avenue, Victorville, CA 92392–2310.

Shasta County AQMD, 1855 Placer Street, Ste. 101, Redding, CA 96001–1759.

Copies of the rules may also be available via the Internet at *http://www.arb.ca.gov/drdb/drdbltxt.htm*. Please be advised that this is not an EPA Web site and may not contain the same version of the rule that was submitted to EPA.

FOR FURTHER INFORMATION CONTACT: Thomas C. Canaday, EPA Region IX, (415) 947–4121.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to EPA.

Table of Contents

I. The State's Submittal

A. What Rules Did the State Submit?

Table 1 lists the rules proposed for disapproval with the date that they were adopted and submitted by the California Air Resources Board (CARB).

TABLE 1.—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted	Submitted
AVAQMD	430	Breakdown Provisions	03/17/98	02/16/99
BCAQMD	275	Reporting Procedures for Excess Emissions	02/15/96	05/10/96
KCAPCD	111	Equipment Breakdown	05/02/96	07/23/96
MDAQMD	430	Breakdown Provisions	12/21/94	01/24/95
SHAQMD	3:10	Excess Emissions	12/05/95	05/10/96

On April 23, 1999, we determined that the AVAQMD Rule 430 submittal met the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review. On July 19, 1996, we determined that the BCAQMD Rule 275 submittal and the SHAQMD Rule 3:10 submittal met the completeness criteria. On October 30, 1996, we determined that the KCAPCD Rule 111 submittal met the completeness criteria and on February

24, 1995, we determined that the MDAQMD Rule 430 submittal met the completeness criteria.

B. Are There Other Versions of These Rules?

There are no previous versions of AVAQMD Rule 430, BCAQMD Rule 275, MDAQMD Rule 430 or SHAQMD Rule 3:10 in the SIP. We approved a version of KCAPCD Rule 111 into the SIP on October 24, 1980. The Kern County Air Pollution Control District adopted a revision to the SIP-approved version on May 2, 1996, and CARB submitted it to us on July 23, 1996.

C. What Is the Purpose of the Submitted Rules?

AVAQMD Rule 430, KCAPCD Rule 111, and MDAQMD Rule 430 establish that the Air Pollution Control Officer (APCO) may, in his discretion, refrain from enforcement action against an owner or operator of any equipment which has violated a technology-based emission limitation provided that a breakdown has occurred and certain other conditions are met. BCAQMD Rule 275 and SHAQMD Rule 3:10 establish that an emergency constitutes an affirmative defense to any action brought for non-compliance with technology-based emission limits. SHAQMD Rule 3:10 also provides that excess emissions during start-up and shutdown shall not be considered a violation if the owner or operator can demonstrate that the excess emissions are unavoidable. Finally, SHAQMD Rule 3:10 states that the APCO may provide an exemption for excess emissions during start-up and shutdown in the permit for a particular source. The TSDs have more information about these rules.

II. EPA's Evaluation and Action

A. How Is EPA Evaluating the Rules?

Generally, SIP rules must be enforceable (see section 110(a) of the Act), must require Reasonably Available Control Technology (RACT) for major sources in nonattainment areas (see section 182(a)(2)(A)), and must not relax existing requirements (see sections 110(l) and 193).

Guidance and policy documents that we used to help evaluate specific enforceability and RACT requirements consistently include the following:

1. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook).

2. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).

3. ''State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup and Shutdown,'' EPA Office of Air and Radiation, and EPA Office of Enforcement and Compliance Assurance, September 20, 1999 (''Excess Emissions Policy'').

4. ''Guidelines for Including State and Local Rules in SIPs,'' EPA Region IX, December 17, 1998. These guidelines were transmitted to the California Air Resources Board in a letter dated December 23, 1998 from David P. Howekamp, Director, Air Division, EPA Region IX, to Michael Kenny, Executive Officer, California Air Resources Board.

B. Do the Rules Meet the Evaluation Criteria?

The submitted SIP revisions conflict with section 110 and part D of the Act for the following reasons:

1. AVAQMD Rule 430, KCAPCD Rule 111, and MDAQMD Rule 430 describe how the districts intend to apply their enforcement discretion in instances where facilities exceed emissions limits due to breakdown. As stated in EPA's Excess Emissions Policy, a state or EPA may exercise its enforcement discretion to refrain from taking an enforcement action where excess emissions result from sudden and unavoidable malfunctions caused by circumstances entirely beyond the control of the owner or operator. However, the September 20, 1999 policy also makes clear that EPA will not approve SIP revisions that allow a state director's decision to bar EPA's or citizens' ability to take enforcement action. Accordingly, were EPA to approve enforcement discretion rules such as these, we would do so only while making clear that such action had no effect on EPA's or citizens' enforcement prerogatives. Under these circumstances, such a SIP revision would have no effect on the SIP. For this reason EPA considers it unproductive and potentially confusing to approve these enforcement discretion rules into the SIP.

2. As stated in the Excess Emissions Policy, EPA interprets the Act to require that all periods of excess emissions are violations of the applicable emissions limitation. A SIP revision may provide an affirmative defense for excess emissions so long as a State director's decision not to take an enforcement action does not bar EPA's or citizens' ability to take enforcement action. Further, acceptable affirmative defense provisions may only apply to actions for penalties, but not to actions for injunctive relief. BCAQMD Rule 275 and SHAQMD Rule 3:10 do not limit the applicability of the affirmative defense for excess emissions during an emergency to actions for penalties, but rather apply the defense to any action brought for non-compliance with technology-based emissions limits. BCAQMD Rule 275 and SHAQMD Rule 3:10 also fail to make clear that the excess emissions are violations of the applicable emissions limitation and that a determination by the APCO not to take an enforcement action (or a finding by the APCO that an emergency exists) would not bar EPA or citizen action.

These and other rule provisions which do not meet the evaluation criteria are discussed further in the TSDs.

C. Proposed Action and Public Comment

As authorized in sections 110(k)(3) of the Act, we are proposing a disapproval of the submitted AVAQMD Rule 430, BCAQMD Rule 275, KCAPCD Rule 111, MDAQMD Rule 430 and SHAQMD Rule 3:10. These are not required SIP submittals, so this disapproval would have no sanction implications under CAA section 179 or FIP implications under CAA section 110(c).

We will accept comments from the public on the proposed disapproval for the next 30 days.

III. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled ''Regulatory Planning and Review.''

B. Paperwork Reduction Act

This rulemaking does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless 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.

This rulemaking action will not have a significant impact on a substantial number of small entities because SIP disapprovals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply disapprove for inclusion in the

SIP requirements that the State is already imposing. Therefore, because the Federal SIP disapproval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.,* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates Reform Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the disapproval action proposed does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action proposes to disapprove pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

E. Executive Order 13132, Federalism

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rulemaking action 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, as specified in Executive Order 13132, because it merely disapproves state rules implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rulemaking.

F. Executive Order 13175, Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' These proposed rule disapprovals do not have tribal implications, as specified in Executive Order 13175. They will not have substantial direct effects on tribal governments, 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. Thus, Executive Order 13175 does not apply to these rule disapprovals.

EPA specifically solicits additional comment on these proposed rule disapprovals from tribal officials.

H. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rulemaking on children, and explain why the planned action is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rulemaking is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use

This rulemaking is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compound.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: May 15, 2003.

Alexis Strauss,

Acting Regional Administrator, Region IX.

[FR Doc. 03–14320 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 146

[FRL–7509–5]

Underground Injection Control Program—Revision of Underground Injection Control Requirements for Class I Municipal Wells in Florida; Notice of Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On May 5, 2003, the Environmental Protection Agency published two notices in the **Federal Register**. The first announced the Notice of Availability (NOA) (68 FR 23673) of EPA's ''Relative Risk Assessment of Management Options for Treated Wastewater in South Florida'' and the second announced the Notice of Data Availability (NODA) (68 FR 23666) which summarizes information from the relative risk assessment and solicits public comment on how the deep well injection findings should inform the final determination on the July 7, 2000 proposed rule, Revision to the Federal Underground injection Control (UIC) requirements for Class I Municipal Wells in Florida (65 FR 42234). This notice announces two (2) public meetings on the NODA.

DATES: The meeting dates are: June 24, 2003, 6 p.m. to 9 p.m., West Palm Beach, Florida; and June 25, 2003, 6 p.m. to 9 p.m., Tampa, Florida.

ADDRESSES: For additional information see the **SUPPLEMENTARY INFORMATION** section of this **Federal Register**. The meeting locations are: Florida Department of Environmental Protection, Southeast District, Public Meeting Room, 2nd Floor, 400 N. Congress Ave., West Palm Beach, Florida 33401; and Tampa Marriott Waterside Hotel, 700 South Florida Avenue; Tampa, FL 33602.

FOR FURTHER INFORMATION CONTACT: For inquiries, and/or to access the risk assessment report, contact Nancy H. Marsh, Ground Water & UIC Section, EPA Region 4, 61 Forsyth Street, SW, Atlanta, GA 30303 (phone: (404) 562–9450; E-mail: *marsh.nancy@epa.gov*) or Howard Beard, Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency, EPA East, 1200 Pennsylvania Ave., NW., Mail Code 4606M, Washington, DC 20460 (phone: (202) 564–3874; E-mail: *beard.howard@epa.gov*) or contact the Safe Drinking Water Hotline, phone (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. Eastern daylight-saving time.

SUPPLEMENTARY INFORMATION: Comments may be given orally or in writing at the public meeting. If giving written comments please submit an original and three copies of your comments and enclosures (including any references). Comments should be limited to those issues discussed in the NODA and not the entire ''Relative Risk Assessment of Management Options for Treated Wastewater in South Florida.'' Written comments may also be mailed to Nancy H. Marsh at the address in the For Further Information Contact section. The public comment period ends July 7, 2003.

Dated: May 30, 2003.

James D. Giattina,

Director, Water Management Division, Region 4.

[FR Doc. 03–14321 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 68, No. 109
Friday, June 6, 2003

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

Animal and Plant Health Inspection Service

[Docket No. 03–043–1]

Availability of an Environmental Assessment for Field Testing Bursal Disease-Marek's Disease Vaccine

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning authorization to ship for the purpose of field testing, and then to field test, an unlicensed Bursal Disease-Marek's Disease Vaccine for use in chickens. The environmental assessment, which is based on a risk analysis prepared to assess the risks associated with the field testing of this vaccine, examines the potential effects that field testing this veterinary vaccine could have on the quality of the human environment. Based on the risk analysis, we have reached a preliminary determination that field testing this veterinary vaccine will not have a significant impact on the quality of the human environment, and that an environmental impact statement need not be prepared. We intend to authorize shipment of this vaccine for field testing following the close of the comment period for this notice unless new substantial issues bearing on the effects of this action are brought to our attention. We also intend to issue a U.S. Veterinary Biological Product license for this vaccine, provided the field test data support the conclusions of the environmental assessment and the issuance of a finding of no significant impact and the product meets all other requirements for licensing.

DATES: We will consider all comments that we receive on or before July 7, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–043–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–043–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 03–043–1'' on the subject line.

You may read the environmental assessment, the risk analysis (with confidential business information removed), and any comments that we receive in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

You may request a copy of the environmental assessment (as well as the risk analysis with confidential business information removed) by writing to Dr. Patricia L. Foley, USDA, APHIS, VS, CVB–LPD, 510 South 17th Street, Suite 104, Ames, IA 50010, or by calling (515) 232–5785. Please refer to the docket number, date, and complete title of this notice when requesting copies.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief Staff Officer, Operational Support Section, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; phone (301) 734–8245, fax (301) 734–4314. For information regarding the environmental assessment or the risk analysis, contact Dr. Patricia L. Foley, USDA, APHIS, VS, CVB–LPD, 510 South 17th Street, Suite 104, Ames, IA 50010; (515) 232–5785.

SUPPLEMENTARY INFORMATION: Under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*), a veterinary biological product must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. A field test is generally necessary to satisfy prelicensing requirements for veterinary biological products. Prior to conducting a field test on an unlicensed product, an applicant must obtain approval from the Animal and Plant Health Inspection Service (APHIS), as well as obtain APHIS' authorization to ship the product for field testing.

To determine whether to authorize shipment and grant approval for the field testing of the unlicensed product referenced in this notice, APHIS conducted a risk analysis to assess the potential effects of this product on the safety of animals, public health, and the environment. Based on the risk analysis, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: Merial Select, Inc.

Product: Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Virus, Serotype 3 Vector, Code 1A88.R0.

Field Test Locations: Georgia, North Carolina, and Texas.

The above-mentioned product is a combination Bursal Disease-Marek's Disease Vaccine prepared using serotype 3 Marek's disease virus which has been genetically modified to express a bursal disease virus antigen. The vaccine is for use in chickens as an aid in the prevention of disease caused by bursal disease virus and serotype 3 Marek's disease virus.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provision of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends

to issue a finding of no significant impact (FONSI) based on the EA and authorize shipment of the above product for the initiation of field tests following the close of the comment period for this notice.

Because the issues raised by field testing and by issuance of a license are identical, APHIS has concluded that the EA that is generated for field testing would also be applicable to the proposed licensing action. Provided that the field test data support the conclusions of the original EA and the issuance of a FONSI, APHIS does not intend to issue a separate EA and FONSI to support the issuance of the product license, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine following completion of the field test provided no adverse impacts on the human environment are identified and provided the product meets all other requirements for licensing.

Authority: 21 U.S.C. 151–159.

Done in Washington, DC, this 3rd day of June, 2003.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–14301 Filed 6–5–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 03–060–1]

Availability of an Environmental Assessment for Field Testing Feline Leukemia Vaccine, Live Canarypox Vector

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning authorization to ship for the purpose of field testing, and then to field test, an unlicensed feline leukemia vaccine for use in cats. The environmental assessment, which is based on a risk analysis prepared to assess the risks associated with the field testing of this vaccine, examines the potential effects that field testing this veterinary vaccine could have on the quality of the human environment. Based on the risk analysis, we have reached a preliminary determination that field testing this veterinary vaccine will not have a significant impact on the quality of the human environment, and that an environmental impact statement need not be prepared. We intend to authorize shipment of this vaccine for field testing following the close of the comment period for this notice unless new substantial issues bearing on the effects of this action are brought to our attention. We also intend to issue a U.S. Veterinary Biological Product license for this vaccine, provided the field test data support the conclusions of the environmental assessment and the issuance of a finding of no significant impact and the product meets all other requirements for licensing.

DATES: We will consider all comments that we receive on or before July 7, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–060–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–060–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 03–060–1'' on the subject line.

You may read the environmental assessment, the risk analysis (with confidential business information removed), and any comments that we receive in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

You may request a copy of the environmental assessment (as well as the risk analysis with confidential business information removed) by writing to Dr. Eleanor Eagly, USDA, APHIS, VS, CVB–PEL, 510 South 17th Street, Suite 104, Ames, IA 50010, or by calling (515) 232–5785. Please refer to the docket number, date, and complete title of this notice when requesting copies.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief Staff Officer, Operational Support Section, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; phone (301) 734–8245; fax (301) 734–4314. For information regarding the environmental assessment or the risk analysis, contact Dr. Eleanor Eagly, USDA, APHIS, VS, CVB–PEL, 510 South 17th Street, Suite 104, Ames, IA 50010; (515) 232–5785.

SUPPLEMENTARY INFORMATION: Under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*), a veterinary biological product must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. A field test is generally necessary to satisfy prelicensing requirements for veterinary biological products. Prior to conducting a field test on an unlicensed product, an applicant must obtain approval from the Animal and Plant Health Inspection Service (APHIS), as well as obtain APHIS' authorization to ship the product for field testing.

To determine whether to authorize shipment and grant approval for the field testing of the unlicensed product referenced in this notice, APHIS conducted a risk analysis to assess the potential effects of this product on the safety of animals, public health, and the environment. Based on the risk analysis, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: Merial Select, Inc.

Product: Feline Leukemia Vaccine, Live Canarypox Vector, Code 1555.R2.

Field Test Locations: California, Missouri, Indiana, Georgia, Florida, Virginia, Connecticut, and Pennsylvania.

The above-mentioned product is a canarypox vectored recombinant vaccine containing the genes of the feline leukemia virus. The vaccine is for use in cats as an aid in the prevention of disease caused by feline leukemia virus.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provision of NEPA (40 CFR parts 1500–1508), (3)

USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact (FONSI) based on the EA and authorize shipment of the above product for the initiation of field tests following the close of the comment period for this notice.

Because the issues raised by field testing and by issuance of a license are identical, APHIS has concluded that the EA that is generated for field testing would also be applicable to the proposed licensing action. Provided that the field test data support the conclusions of the original EA and the issuance of a FONSI, APHIS does not intend to issue a separate EA and FONSI to support the issuance of the product license, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine following completion of the field test provided no adverse impacts on the human environment are identified and provided the product meets all other requirements for licensing.

Authority: 21 U.S.C. 151–159.

Done in Washington, DC, this 3rd day of June, 2003.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–14302 Filed 6–5–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 03–019N]

Codex Alimentarius Commission: 26th Session of the Codex Alimentarius Commission (Codex)

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting, request for comments.

SUMMARY: The Office of the Under Secretary for Food Safety, United States Department of Agriculture (USDA) is sponsoring a public meeting on June 12, 2003. The purpose of this meeting is to provide information and receive public comments on agenda items that will be discussed at the Twenty-sixth Session of the Codex Alimentarius Commission which will be held in Rome, Italy from June 30 to July 7, 2003. The Under Secretary recognizes the importance of providing interested parties with information about the Codex Alimentarius Commission.

DATES: The public meeting is scheduled for Thursday, June 12, 2003, from 1 p.m. to 4 p.m.

ADDRESSES: The public meeting will be held in Room 107A, Whitten Building, U.S. Department of Agriculture (Smithsonian Metro Stop), Washington, DC 20250.

If you have comments, please send an original and two copies to: FSIS Docket Clerk, Docket 03–019N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW., Washington, DC 20250–3700. All comments submitted in response to this notice will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: F. Edward Scarbrough, Ph.D., U.S. Manager for Codex Alimentarius, Room 4861, South Building, U.S. Department of Agriculture, 14th and Independence Avenue, SW., Washington, DC 20250; Telephone (202) 205–7760.

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius Commission (Codex) was established in 1962 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization. Codex is the principal international organization for encouraging fair international trade in food and protecting the health and economic interests of consumers. 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. Codex meets biennially. The Executive Committee serves as the executive body of Codex between the biennial meetings.

The Provisional Agenda for the 26th Session of the Codex Alimentarius Commission is as follows:

Part I: Introduction
1. Adoption of the Agenda
2. Report by the Chairperson on the 49th, 50th and 52nd Sessions of the Executive Committee
3. Reports of FAO/WHO Regional Coordinating Committees

Part II: Procedural Matters
4. Amendments to the Procedural Manual
(a) Amendments to the Rules of Procedure
(b) Other amendments to the Procedural Manual

Part III: Codex Standards and Related Texts
5. Draft Standards and Related Texts at Step 8 of the Procedure (including those submitted at Step 5 with a recommendation to omit Steps 6 and 7 and those submitted at Step 5 of the Accelerated Procedure)
6. Proposed Draft Standards and Related Texts at Step 5
7. Withdrawal or revocation of existing Codex Standards and Related Texts
8. Proposals for the elaboration of new Standards and Related Texts

Part IV: Policy and General Matters
9. Risk Analysis Policies of the Codex Alimentarius Commission
10. Joint FAO/WHO Evaluation of the Codex Alimentarius and other FAO and WHO Work on Food Standards
11. FAO/WHO Trust Fund for Participation of Developing Countries in Codex Standard-Setting
12. Other Matters arising from FAO and WHO
13. Matters arising from the reports of Codex Committees and Task Forces

Part V: Programme and Budgetary Matters
14. Financial and Budgetary Matters 2002/2003 and Proposed Budget 2004/2005
15. Proposed Schedule of Codex Meetings 2003–2005

Part VI: Elections and Appointments
16. Election of Chairperson and Vice-Chairpersons and Election of Members of the Executive Committee
17. Appointment of Regional Coordinators
18. Designation of Countries for Appointing the Chairpersons of Codex Committees and Task Forces

Part VII: Other Matters
19. Other Business
20. Adoption of the Report

Public Meeting

The public meeting is scheduled on Thursday, June 12th in Room 107A, Whitten Building, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250. Attendees will hear brief descriptions of the issues and will have the opportunity to pose questions and offer comments.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and make copies of this **Federal Register** publication available through the FSIS Constituent Update. FSIS provides a weekly Constituent Update, which is communicated via Listserv, a free e-mail subscription service. In addition, the update is available on-line through the FSIS Web page located at *http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations,

Federal Register notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent Listserv consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through the Listserv and web page, FSIS is able to provide information to a much broader, more diverse audience.

For more information contact the Congressional and Public Affairs Office, at (202) 720–9113. To be added to the free e-mail subscription service (Listserv) go to the ''Constituent Update'' page on the FSIS Web site at *http://www.fsis.usda.gov/oa/update/update.htm.*

Click on the ''Subscribe to the Constituent Update Listserv'' link, then fill out and submit the form.

Done at Washington, DC on June 3, 2003.

F. Edward Scarbrough,

U.S. Manager for Codex Alimentarius.

[FR Doc. 03–14300 Filed 6–5–03; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Idaho Panhandle National Forests, Bonner County, Idaho and Pend Oreille County, Washington; Chips Ahoy Project

AGENCY: Forest Service, USDA.

ACTION: Revised Notice of Intent to prepare an Environmental Impact Statement.

SUMMARY: The USDA Forest Service published a Notice of Intent to prepare and environmental impact statement for the Chips Ahoy Project in the **Federal Register** on December 6, 2002 (Vol. 67, No. 235, pages 72635–72637). A revised Notice of Intent is being issued due to two major changes (Forest Service Handbook 1909.15 part 21.2):

1. There will be a delay of more than six months in filing the final EIS;

2. There has been a change in the project's proposed action and purpose and need.

The Priest Lake Ranger District on the Idaho Panhandle National Forests will prepare an Environmental Impact Statement on a proposal to treat forest vegetation over approximately 2,000 acres. The treatments are being proposed to restore forest communities to a more historical composition and structure and to re-introduce fire into these ecosystems. Treatments will include regeneration harvest, thinning, and underburning. A Roads Analysis Process will be completed as a part of the Environmental Impact Statement. The Roads Analysis may suggest changes in the administrative and recreation use of roads and trails in the analysis area to protect forest and watershed resources.

DATES: Comments concerning the scope of the project analysis must be received within 30 days from the date of this notice in the **Federal Register** and during the Draft Environmental Impact Statement comment period of 45 days. The Draft Environmental Impact Statement is expected in September 2003 and the Final Environmental Impact Statement is expected February 2004.

ADDRESSES: Send written comments to Chips Ahoy Project, Attn: David DelSordo, Priest Lake Ranger Station, 32203 Highway 57, Priest River, ID 83856.

FOR FURTHER INFORMATION CONTACT: David DelSordo, Project Leader, Priest Lake Ranger Station, 32203 Highway 57, Priest River, ID 83856, by calling 208–443–6809, or *ddelsordo@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The project area is located within Bonner County, Idaho, and Pend Oreille County, Washington. The project area is located approximately twenty miles north of the community of Priest River, Idaho. A past bark beetle outbreak, in combination with root diseases, other insects and diseases, and winter storm damage has left many of these stands in poor condition and with hazardous fuel loads. This Notice Of Intent reflects changes in the Purpose of the Action based on comments received over the last six months.

Purpose for Action

The purpose for this action is to improve the health, resilience, diversity, and productivity of terrestrial ecosystems by advancing species composition, forest structures, and patterns toward desired conditions; reduce fire risk in these ecosystems; and increase the amount of wet forest communities that are dominated by western white pine and western larch trees. Another purpose for the project is to help restore aquatic resources to a more healthy condition.

Proposed Action

The proposed action is separated into three categories, vegetative treatments, fuel treatments, and road treatments. The proposal is to treat forest vegetation over approximately 2,000 acres within the project area. Different types of treatments would be used depending upon the existing condition of the forest stands. These treatments include regeneration treatments on approximately half of the acreage and commercial thinning on the remaining acreage. After the tree cutting operations are complete, most of the vegetative treatment areas would be underburned to reduce the fuels, prepare the sites for reforestation, and to allow wildland fire to resume a more natural role. In order to access some of the proposed vegetative treatment areas, approximately 3.5 miles of temporary road would be constructed. These temporary roads would be recontoured following their use. Resource protection measures will be included to protect snags, soils, heritage resources, water quality, wildlife, and other resources. The arrangement and management of classified and unclassified roads and trails in the area may be changed to improve watershed quality, protect other resources, and enhance recreation opportunities. Approximately 8 miles of road are planned to be decommissioned. Construction of an alternate snowmobile use route is proposed to mitigate for planned road decommissioning.

Responsible Official

Ranotta K. McNair, Forest Supervisor, Idaho Panhandle National Forests, 3815 Schreiber Way, Ceour d'Alene, ID 83815

Nature of Decision To Be Made

The Forest Supervisor of the Idaho Panhandle National Forests will decide whether or not to implement this project, and if so, in what manner.

Scoping Process

The agency invites written comments and suggestions on the scope of the analysis. In addition to this notice, a revised proposed action letter will be sent to interested government officials, agencies, groups, and individuals on the Chips Ahoy mailing list. Please contact the Priest Lake Ranger Station at 208–443–2512 if you are interested in being added to this mailing list. No public meetings are planned at this time.

Comment Requested

This notice of intent initiates the scoping process which guides the development of the environmental impact statement. Specific written comments on the proposed action will be most helpful.

Early Notice of Importance of Public Participation in Subsequent Environmental Review

A Draft Environmental Impact Statement will be prepared for

comment. The comment period on the Draft Environmental Impact Statement will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of Draft Environmental Impact Statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions; *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the Draft Environmental Impact Statement stage but that are not raised until after completion of the Final Environmental Impact Statement may be waived or dismissed by the courts; *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningful consider them and respond to them in the Final Environmental Impact Statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the Final Environmental Impact Statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the Final Environmental Impact Statement or the merits of the alternative formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received, including the names and address of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, section 21.)

Dated: June 2, 2003.

Ranotta K. McNair,

Forest Supervisor.

[FR Doc. 03–14269 Filed 6–5–03; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Second Creek Watershed, Adams County, MS

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of a Finding of No Significant Impact.

SUMMARY: Pursuant to section 102(2) (C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Regulations (40 CFR part 1500); and the Natural Resources Conservation Service Regulations (7 CFR part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for Second Creek Watershed, Adams County, Mississippi.

FOR FURTHER INFORMATION CONTACT: Homer L. Wilkes, State Conservationist, Natural Resources Conservation Service, Suite 1321, A.H. McCoy Federal Building, 100 West Capitol Street, Jackson, Mississippi 39269, Telephone 601–965–5205.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federal assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Homer L. Wilkes, State Conservationist has determined that the preparation and review of an environmental impact statement are not needed for this project.

Second Creek Watershed, Adams County, Mississippi

Notice of a Finding of No Significant Impact

The project concerns a watershed plan to provide supplemental flood protection and reduce threat to loss of life from sudden dam failure to the residents of the Second Creek Watershed and others. The planned works of improvement consists of rehabilitating floodwater retarding structure (FWRS) No. 10B and No. 12. The notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various Federal, State, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Homer L. Wilkes. No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register**.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904—Watershed Protection and Flood Prevention and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials.)

Dated: May 15, 2003.

Homer L. Wilkes,

State Conservationist.

[FR Doc. 03–14307 Filed 6–5–03; 8:45 am]

BILLING CODE 3410–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to procurement list.

SUMMARY: This action adds to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: July 6, 2003.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, (703) 603–7740.

SUPPLEMENTARY INFORMATION: On September 13, December 27, 2002, January 31, and April 4, 2003, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (67 FR 58013, 79044, 68 FR 4985 and 16467) of proposed additions to the Procurement List. After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–

2.4. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

Accordingly, the following products and services are added to the Procurement List:

Products

Product/NSN: 2 in 1 Scrubber Squeegee M.R. 1036.

NPA: The Lighthouse for the Blind, Inc. (Seattle Lighthouse), Seattle, Washington.

Contract Activity: Defense Commissary Agency (DeCA), Ft. Lee, Virginia.

Product/NSN: Amazing Micro Mop, M.R. 1049.

NPA: The Lighthouse for the Blind, Inc. (Seattle Lighthouse), Seattle, Washington.

Contract Activity: Defense Commissary Agency (DeCA), Ft. Lee, Virginia.

Services

Service Type/Location: Janitorial/Custodial, Austin Straubel International Airport, ATCT and Base Building, Green Bay, Wisconsin.

NPA: Brown County ARC, Inc., Green Bay, Wisconsin.

Contract Activity: Federal Aviation Administration, Des Plaines, Illinois.

Service Type/Location: Janitorial/Custodial, Department of Veterans Affairs, Community Based Outpatient Clinic, Muskegon, Michigan.

NPA: Goodwill Industries of West Michigan, Inc., Muskegon, Michigan.

Contract Activity: Department of Veterans Affairs, Battle Creek, Michigan.

Service Type/Location: Janitorial/Custodial, Naval Reserve Center, La Crosse, Wisconsin.

NPA: Riverfront Activity Center, Inc., La Crosse, Wisconsin.

Contract Activity: Naval Facilities Engineering Command, Crane, Indiana.

Service Type/Location: Janitorial/Custodial, U.S. Army Reserve Center, Arlington Heights, Arlington Heights, Illinois.

NPA: Jewish Vocational Service and Employment Center, Chicago, Illinois.

Contract Activity: Headquarters, 88th Regional Support Command, Fort Snelling, Minnesota.

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 03–14339 Filed 6–5–03; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee is proposing to add to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: July 6, 2003.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments of the proposed actions. If the Committee approves the proposed additions, the entities of the Federal Government identified in the notice for each product or service will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List. Comments on this certification are invited.

Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following products and services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products

Product/NSN: Markers, Dry Erase, Chisel Tip, Set of 8, 7520–00–NIB–0661.

NPA: Dallas Lighthouse for the Blind, Inc., Dallas, Texas.

Contract Activity: Office Supplies & Paper Products Acquisition Center, New York, New York.

Services

Service Type/Location: Custodial Service, Army Corps of Engineers, Jadwin Building, Galveston, Texas.

NPA: Training, Rehabilitation, & Development Institute, Inc., San Antonio, Texas.

Contract Activity: U.S. Army Corps of Engineers, Galveston, Texas.

Service Type/Location: Janitorial/Custodial, The Dalles Dam, The Dalles, Oregon.

NPA: Hood River Sheltered Workshop, Inc., Hood River, Oregon.

Contract Activity: Army Corps of Engineers, Portland, Oregon.

Service Type/Location: Janitorial/Grounds and Related Services, Robert F. Peckham Federal Building/U.S. Courthouse, San Jose, California.

NPA: Hope Rehabilitation Services, Santa Clara, California.

Contract Activity: GSA, Public Buildings Service (9PMFC), San Francisco, California.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 03–14340 Filed 6–5–03; 8:45 am]

BILLING CODE 6353–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Arizona Advisory Subcommittee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a conference call of the Arizona Advisory Subcommittee will convene at 12 p.m. (PDT) and adjourn at 1 p.m., Tuesday, June 10, 2003. The purpose of the conference call is to discuss border violence and the four state project.

This conference call is available to the public through the following call-in number: 1–800–659–8296, access code number 17229298. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls not initiated using the provided call-in number or over wireless lines and the Commission will not refund any incurred charges. Callers will incur no charge for calls using the call-in number over land-line connections. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and access code.

To ensure that the Commission secures an appropriate number of lines for the public, persons are asked to register by contacting Philip Montez of the Western Regional Office, (213) 894–3437, by 3 p.m. on Monday, June 9, 2003.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 30, 2003.

Ivy L. Davis,

Chief, Regional Programs Coordination Unit.

[FR Doc. 03–14247 Filed 6–5–03; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Connecticut Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a conference call of the Connecticut Advisory Committee to the Commission will convene at 9:30 a.m. and adjourn at 11:30 p.m. on Thursday, June 19, 2003. The purpose of the conference call is to plan for a community forum in Bridgeport, fall 2003.

This conference call is available to the public through the following call-in number: 1–800–659–8296, Chairperson Ki-Taek Chun. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls not initiated using the supplied call-in number or over wireless lines and the Commission will not refund any incurred charges. Callers will incur no charge for calls using the call-in number over land-line connections. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and contact name.

To ensure that the Commission secures an appropriate number of lines for the public, persons are asked to register by contacting Ki-Taek Chun, Director of the Eastern Regional Office, (202) 376–7533 (TDD (202) 376–8116), by 4 p.m. on Wednesday, June 18, 2003.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 30, 2003.

Ivy L. Davis,

Chief, Regional Programs Coordination Unit.

[FR Doc. 03–14248 Filed 6–5–03; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Texas Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a conference call of the Texas Advisory Committee to the Commission will convene at 3 p.m. and adjourn at 4 p.m. (CDT) on Friday, June 13, 2003. The purpose of the conference call is to plan future projects.

This conference call is available to the public through the following call-in number: 1–800–659–8290, access code: 17153228. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls not initiated using the supplied call-in number or over wireless lines and the Commission will not refund any incurred charges. Callers will incur no charge for calls using the call-in number over land-line connections. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and access code.

To ensure that the Commission secures an appropriate number of lines for the public, persons are asked to register by contacting Philip Montez, Director of the Western Regional Office, (213) 894–3437 (TDD (213) 894–3435), by 3 p.m. on Thursday, June 10, 2003.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 19, 2003.

Ivy L. Davis,

Chief, Regional Programs Coordination Unit.

[FR Doc. 03–14249 Filed 6–5–03; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Washington State Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a conference call of the Washington State Advisory Committee will convene at 10 a.m. (PDT) and adjourn at 11:30 a.m., Wednesday, June 11, 2003. The purpose of the conference call is to plan future SAC activities.

This conference call is available to the public through the following call-in number: 1–800–659–8297, access code number 17026193. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls not initiated using the supplied call-in number or over wireless lines and the Commission will not refund any incurred charges. Callers will incur no charge for calls using the call-in number over land-line connections. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and access code.

To ensure that the Commission secures an appropriate number of lines for the public, persons are asked to register by contacting Thomas Pilla of the Western Regional Office, (213) 894–3437, by 3 p.m. on Tuesday, June 10, 2003.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 30, 2003.

Ivy L. Davis,

Chief, Regional Programs Coordination Unit.

[FR Doc. 03–14246 Filed 6–5–03; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Advance Monthly Retail Trade and Food Services Survey

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before August 5, 2003.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *DHynek@doc.gov).*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to: Scott Scheleur, U. S. Census Bureau, Room 2626–FOB 3, Washington, DC 20233–6500, (301) 763–7128.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Advance Monthly Retail Sales Survey (MARTS) provides an early indication of monthly retail sales at the United States level. MARTS also provides estimates of monthly sales of food service establishments and drinking places. The Bureau of Economic Analysis (BEA) uses the data as critical inputs to the calculation of Gross Domestic Product (GDP). Policymakers such as the Federal Reserve Board need to have the most timely estimates in order to anticipate economic trends and act accordingly. The Council of Economic Advisors (CEA) and other government agencies and businesses use the data to formulate economic policy and make decisions. These estimates have a high BEA priority because of their timeliness. There would be approximately a one month delay in the availability of these data if this survey were not conducted. Data are collected monthly from small-size, medium-size, and large-size businesses which are selected using a stratified random sampling procedure. The MARTS sample is re-selected periodically, generally at approximately two-year intervals. Small-size and medium-size retailers are requested to participate for those two years, after which they are replaced with new panel respondents. Smaller firms have less of a chance for selection due to our sampling procedure. Firms canvassed in this survey are not required to maintain additional records and carefully prepared estimates are acceptable if book figures are not available. There is no change in response burden.

II. Method of Collection

We will collect this information by mail, FAX, and telephone follow-up.

III. Data

OMB Number: 0607–0104.

Form Number: SM–44(00)A, SM–44(00)AE, SM–44(00)AS, and SM–72(00)A.

Type of Review: Regular Submission.

Affected Public: Retail Businesses.

Estimated Number of Respondents: 4,500.

Estimated time Per Response: 5 minutes.

Estimated Total Annual Burden Hours: 4,500.

Estimated Total Annual Cost: The cost to the respondent is estimated to be $98,190 based on the median hourly salary of $21.82 for accountants and auditors. (U. S. Department of Labor—Bureau of Labor Statistics—Occupational Employment Statistics 2001, where $21.82 represents the median hourly wage of the full-time wage and salary earnings of accountants and auditors) *http://www.bls.gov/oes/2001/oes_13Bu.htm*

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Section 182.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: June 1, 2003.

Madeleine Clayton,

Office of the Chief Information Officer.

[FR Doc. 03–14229 Filed 6–5–03; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-549–813]

Canned Pineapple Fruit from Thailand: Notice of Extension of Time Limit of Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: Effective Date: June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Marin Weaver at (202) 482–2336 or Monica Gallardo at (202) 482–3147, Office of AD/CVD Enforcement 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

TIME LIMITS:

Statutory Time Limits

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to complete the preliminary results within 245 days after the last day of the anniversary month of an order/finding for which a review is requested and the final results within 120 days after the date on which the preliminary results are published. However, if it is not practicable to complete the review within these time periods, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the preliminary results to a maximum of 365 days after the last day of the anniversary month of an order/finding for which a review is requested and for the final results to 180 days (or 300 days if the Department does not extend the time limit for the preliminary results) from the date of publication of the preliminary results.

Background

On August 27, 2002, the Department of Commerce (the Department) published a notice of initiation of administrative review of the antidumping duty order on canned pineapple fruit from Thailand, covering the period July 1, 2001, through June 30, 2002 (67 FR 55000). On September 25,

2002, the Department published a correction to the initiation (67 FR 60210). On March 27, 2003 the Department partially extended the preliminary results (68 FR 14941). The preliminary results are currently due no later than June 6, 2003.

Extension of Time Limit for Preliminary Results of Review

We determine that it is not practicable to complete the preliminary results of this review within the partially extended time limit for the reasons stated in our memorandum from Gary Taverman, Director, Office 5, to Holly Kuga, Acting Deputy Assistant Secretary for AD/CVD Enforcement II, dated May 29, 2003, which is on file in the Central Records Unit, Room B-099 of the main Commerce building. Therefore, the Department is further extending the time limit for completion of the preliminary results until no later than June 20, 2003. We intend to issue the final results no later than 120 days after publication of the preliminary results notice.

This extension is in accordance with section 751(a)(3)(A) of the Act.

Dated: May 30, 2003.

Holly Kuga,

Acting Deputy Assistant Secretary for for AD/CVD Enforcement II.

[FR Doc. 03–14345 Filed 6–5–03; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–839]

Certain Circular Welded Non-Alloy Steel Pipe From Korea: Notice of Extension of Time Limit for 2001–2002 Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit.

SUMMARY: The Department of Commerce is extending the time limit for the preliminary results of the current review of the antidumping duty order on certain circular welded non-alloy steel pipe from Korea. The period of review is November 1, 2001 through October 31, 2002. This extension is made pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended.

EFFECTIVE DATE: June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Scott Holland or Julie Santoboni, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1279 or (202) 482–4194, respectively.

Background

On December 26, 2002, the Department published a notice of initiation of administrative review of the antidumping duty order on certain circular welded non-alloy steel pipe from Korea, covering the period November 1, 2001, through October 31, 2002. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* (67 FR 78772). The preliminary results for this review are currently due no later than August 2, 2003.

Extension of Time Limits for Preliminary Results

Section 751(a)(3)(A) of the Act requires the Department to issue the preliminary results of an administrative review within 245 days after the last day of the anniversary month of an order for which a review is requested and a final determination within 120 days after the date on which the preliminary results are published. If it is not practicable to complete the review within the time period, section 751(a)(3)(A) of the Act allows the Department to extend these deadlines to a maximum of 365 days and 180 days, respectively.

We are currently analyzing sales and cost information provided by the three respondents in this review and are awaiting supplemental information. In addition, we plan to verify the sales and cost information provided by the respondents in accordance with 19 CFR 351.307 (b)(1)(v). Accordingly, it is not practicable to complete this review within the originally anticipated time limit (*i.e.*, August 2, 2003). Therefore, the Department of Commerce is extending the time limit for completion of the preliminary results to not later than December 1, 2003, in accordance with section 751(a)(3)(A) of the Act.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: June 3, 2003.

Jeffery May,

Deputy Assistant Secretary for AD/CVD Enforcement.

[FR Doc. 03–14347 Filed 6–5–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570–881]

Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Certain Malleable Iron Pipe Fittings From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Anya Naschak at (202) 482–6375, Ann Barnett-Dahl at (202) 482–3833, or Helen Kramer at (202) 482–0405; Antidumping and Countervailing Duty Enforcement Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

SUPPLEMENTARY INFORMATION:

Preliminary Determination:

We preliminarily determine that malleable iron pipe fittings (MPF) from the People's Republic of China (PRC) are being sold, or are likely to be sold, in the United States at less than fair value (LTFV), as provided in section 733 of the Act. The estimated margins of sales at LTFV are shown in the ''Suspension of Liquidation'' section of this notice.

Case History

This investigation was initiated on November 19, 2002, based on a petition filed by Ward Manufacturing and Anvil International (collectively, petitioners). *See Notice of Initiation of Antidumping Duty Investigation: Certain Malleable Iron Pipe Fittings From the People's Republic of China*, 67 FR 70579–81 (November 25, 2002) (*Initiation Notice*). In a letter dated January 2, 2003, the Department set aside a period for all interested parties to raise issues regarding product coverage. We received a request from Beijing Sai Lin Ke Hardware Co., Ltd (SLK) and LDR Industries, Inc. (LDR) (collectively SLK/LDR), for a scope exclusion. Petitioners had no objection to this request. *See* Memo to the File from Anya Naschak, dated April 1, 2003. No other comments were received. Since the initiation of the investigation, the following events have occurred.

On December 11, 2002, the Department requested information from the U.S. Embassy in the PRC to identify producers/exporters of the subject merchandise and received a response in December 2002. On December 23, 2002,

the United States International Trade Commission (ITC) issued its affirmative preliminary determination that there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury by reason of imports of MPF from the PRC. *See Malleable Iron Pipe Fittings from the People's Republic of China*, International Trade Commission, Investigation No. 731-TA-1021 (Preliminary), USITC Publication 3568 (ITC Preliminary Determination).

On December 16, 2002, the Department issued a letter requesting information on the quantity and value of shipments of subject merchandise to the United States during the period of investigation (POI) to the Chinese Ministry of Foreign Trade & Economic Cooperation with a letter requesting that it forward the questionnaire to all Chinese exporters of MPF who had shipments during the POI. We also sent courtesy copies of the quantity and value questionnaire to the following possible producers/exporters of subject merchandise identified in the petition and on the basis of U.S. Bureau of Customs and Border Protection (BCBP) information: Jinan Meide Casting Co., Ltd. (JMC), SLK, Langfang Pannext Pipe Fitting Co., Ltd. (LPFC), Simmons International, Ltd. (Simmons), Shantou ZhongXing Industry Co., Ltd. (formerly Shantou Zhongxing Economic & Trading Co., Ltd.) (Shantou), Shanghai Dongsheng Electric Import & Export Co., Ltd. (SDE), Brantingham Manufacturing (Brantingham), Shandong Maxwill Import and Export (Shandong), Chen Tai International Trading Co., Ltd. (CTIT), and Unique Industries (UI). On December 24, 2002, Chengde Malleable Iron General Factory (Chengde) requested to be considered a voluntary respondent in this investigation.

On December 27 and 30, 2002, the following Chinese producers/exporters of MPF submitted information on the quantity and value of their shipments of subject merchandise to the United States during the POI: JMC, SLK, Pannext Fittings Corporation (PFC) and LPFC (collectively, Pannext), and Simmons. On January 3, 2003, Chengde also submitted quantity and value information.

On January 8, 2003, we selected JMC, SLK, and Pannext as the mandatory respondents (see ''Selection of Respondents'' below). The Department issued its non-market economy (NME) antidumping questionnaire to JMC, SLK, and Pannext. In NME cases, Section A of the questionnaire requests general information concerning a company's corporate structure and business practices, the merchandise under investigation that it sells, and the manner in which it sells that merchandise in all of its markets. Section C requests a complete listing of U.S. sales. Section D requests information on the factors of production of the merchandise sold in or to the United States. Section E requests information on further manufacturing.

On January 27 and 29, 2003, Myland Industrial Co., Ltd. (Myland), and SCE Co., Ltd. (SCE), respectively requested to be considered voluntary respondents in this investigation. We received complete Section A responses from JMC, SLK, and Pannext (collectively, respondents) on January 30, 2003. We received a complete Section A response from Chengde on February 7, 2003, and from SCE on February 21, 2003. The Department received comments from petitioners on respondents' Section A questionnaire responses on February 7, 2003. On February 13, 2003, the Department issued supplemental Section A questionnaires to JMC, SLK, and Pannext. We received complete supplemental responses from JMC on February 24, 2003, from SLK on February 25, 2003, and from Pannext on March 3, 2003.

SCE and Chengde submitted their complete Sections C and D responses on February 21 and 24, 2003, respectively. JMC submitted its complete Sections C and D responses on February 24, 2003. Pannext submitted a complete Section C response on February 26, 2003, and a complete Section D response on March 3, 2003. SLK submitted its complete Sections C and D responses on March 4, 2003. Petitioners filed comments on JMC's submissions on March 5, 2003.

On March 18 and 19, 2003, the Department sent out supplemental Section C and D questionnaires to SLK, JMC, and Pannext. JMC and SLK submitted their complete supplemental responses on April 2, 2003. Pannext submitted its complete supplemental response on April 11, 2003. SLK submitted an additional supplemental response on April 14, 2003. Petitioners submitted comments on JMC's submissions on April 9, 2003. The Department sent an additional supplemental questionnaire to Pannext on April 23, 2003, and to JMC on April 25, 2003. On April 28, 2003, the Department received Pannext's complete additional supplemental response. On May 2, 2003, the Department received JMC's complete additional supplemental response. On May 7, 2003, the Department sent a letter to Pannext, JMC, and SLK, requesting that they revise certain of their data and resubmit these data electronically. The Department received a response on May 9, 2003, and May 12, 2003 from JMC, SLK, and Pannext.

On February 20, 2003, Myland filed its Section A response in a format that was inconsistent with the Department's regulation. On March 3, 2003, the Department returned Myland's Section A questionnaire response, and explained the filing requirements in detail. The Department granted Myland the opportunity to re-file its response in the proper format and extended Myland's Section A filing deadline to March 7, 2003. Myland submitted a revised Section A response on March 19, 2003. In addition, Myland submitted its Section C response on March 24, 2003, and its Section D response on March 26, 2003, which were originally due on February 28, 2003. The Department rejected Myland's Sections A, C, and D responses in accordance with 19 C.F.R. 351.302(d). Additionally, the Department informed Myland on April 14, 2003 that because Myland had not complied with the requests for information by the Department in a timely manner, they could not be considered a voluntary respondent. *See* 19 C.F.R. 351.204(d)(2); *see also* Letter from Abdelali Elouaradia to Myland Industrial Co., Ltd., dated April 14, 2003 (April 14th Letter). On April 18, 2003, Myland submitted a letter requesting to be allowed to resubmit its questionnaire responses. On May 6, 2003, the Department informed Myland that it would be unable to consider Myland's information for the reasons expressed in its April 14th Letter.

On January 29, 2003, the Department requested publicly available information for valuing the factors of production and comments on surrogate country selection. On February 28, 2003, Pannext submitted information concerning surrogate value of zinc to be used for valuing the factors of production. On March 26, 2003, SLK submitted information concerning the surrogate values of steel scrap and electricity for use in valuing the factors of production. On May 5, 2003, petitioners submitted information concerning surrogate values of steel scrap and financial ratios for use in valuing the factors of production.

On February 28, 2003, petitioners' submission alleged that there is a reasonable basis to believe or suspect critical circumstances exist with respect to the investigation of MPF from the PRC. The Department preliminarily determined that critical circumstances exist for JMC and SCE and for the PRC-wide entity, but not for Pannext, SLK, Myland, or Chengde. *See Notice of Preliminary Determination of Critical Circumstances: Certain Malleable Iron*

Pipe Fittings from the People's Republic of China, 68 FR 19779 (April 22, 2003)

On March 21, 2003, pursuant to section 733(c)(1)(B) of the Act, the Department postponed the preliminary determination of this investigation until May 28, 2003. *See Notice of Postponement of Preliminary Determination of Antidumping Duty Investigation: Certain Malleable Iron Pipe Fittings from the People's Republic of China*, 68 FR 13896 (March 21, 2003).

Postponement of the Final Determination

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. The Department's regulations, at 19 C.F.R. 351.210(e)(2), require that requests by respondents for postponement of a final determination be accompanied by a request for an extension of the provisional measures from a four-month period to not more than six months.

On May 2, 2003, JMC requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination until 135 days after the publication of the preliminary determination. Pannext and SLK submitted requests for a postponement of the Department's final determination until 135 days after the publication of the preliminary determination on May 7, 2003, and May 6, 2003, respectively. JMC also included a request to extend the provisional measures to not more than six months after the publication of the preliminary determination. *See* JMC's letter to the Department, dated May 2, 2003. Accordingly, because we have made an affirmative preliminary determination, the requesting parties account for a significant proportion of exports of the subject merchandise, and no compelling reasons exist to deny the request, we have postponed the final determination until not later than 135 days after the date of the publication of the preliminary determination, and are extending the provisional measures accordingly, in accordance with section 735(a)(2) of the Act and section 351.210(e) of the Department's Regulations.

Period of Investigation

The POI is April 1, 2002, through September 30, 2002. This period corresponds to the two most recent fiscal quarters prior to the month of the filing of the petition (*i.e.*, October 2003). See 19 C.F.R. 351.204(b)(1).

Scope of Investigation

For purposes of this investigation, the products covered are certain malleable iron pipe fittings, cast, other than grooved fittings, from the People's Republic of China. The merchandise is classified under item numbers 7307.19.90.30, 7307.19.90.60 and 7307.19.90.80 of the Harmonized Tariff Schedule (HTSUS).

Excluded from the scope of this investigation are metal compression couplings, which is imported under HTSUS number 7307.19.90.80. A metal compression coupling consists of a coupling body, two gaskets, and two compression nuts. These products range in diameter from ½ inch to 2 inches and are carried only in galvanized finish. HTSUS subheadings are provided for convenience and BCBP purposes. The written description of the scope of this proceeding is dispositive.

Selection of Respondents

Section 777A(c)(1) of the Act directs the Department to calculate individual dumping margins for each known exporter and producer of the subject merchandise. However, section 777A(c)(2) of the Act gives the Department discretion, when faced with a large number of exporters/producers, to limit its examination to a reasonable number of such companies if it is not practicable to examine all companies. Where it is not practicable to examine all known producers/exporters of subject merchandise, this provision permits the Department to investigate either: (1) a sample of exporters, producers, or types of products that is statistically valid based on the information available at the time of selection; or (2) exporters and producers accounting for the largest volume of the subject merchandise that can reasonably be examined. After consideration of the complexities expected to arise in this proceeding and the resources available to the Department, we determined that it was not practicable to examine the over 100 potential producers and/or exporters from the PRC. Instead, we found that, given our resources, we would be able to investigate three Chinese producers/exporters. The three selected mandatory respondents, JMC, SLK, and Pannext, were selected because they were the three largest exporters and because they accounted for over 60 percent of exports of the subject merchandise from the PRC during the POI, as determined by BCBP data and provided by the producers/exporters at the time we made our respondent selection. *See* Memorandum from Richard Weible to Joseph A. Spetrini Re: Selection of Respondents, January 8, 2003.

Non-Market Economy Country Status

The Department has treated the PRC as an NME country in all past antidumping investigations. *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Circular Welded Carbon-Quality Steel Pipe From the People's Republic of China*, 67 FR 36570, 36571 (May 24, 2002); and *Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Structural Steel Beams From the People's Republic of China*, 66 FR 67197, 67198–99 (December 28, 2001); and *Notice of Final Determination of Sales at Less Than Fair Value Certain: Folding Metal Tables and Chairs From the People's Republic of China*, 67 FR 20090, 20091 (April 24, 2002). A designation as an NME remains in effect until it is revoked by the Department (*see* Section 771(18)(C) of the Act). The respondents in this investigation have not requested a revocation of the PRC's NME status. We have, therefore, preliminarily determined to continue treating the PRC as an NME country.

When the Department is investigating imports from an NME, section 773(c)(1) of the Act directs us to base the normal value (NV) on the NME producer's factors of production (FOP). Section 773(c)(4) provides that when valuing FOP, the Department shall utilize FOP from a comparable market economy that is a significant producer of comparable merchandise. The sources of individual factor prices are discussed under the ''Normal Value'' section, below.

Furthermore, no interested party has requested that the MPF industry in the PRC be treated as a market-oriented industry and no information has been provided that would lead to such a determination. Therefore, we have not treated the MPF industry in the PRC as a market-oriented industry in this investigation.

Separate Rates

In proceedings involving NME countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and thus should be assessed a single antidumping duty deposit rate. It is the Department's

policy to assign all exporters of merchandise subject to investigation in an NME country this single rate, unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate. The five companies that have submitted Section A responses have provided the requested company-specific separate rates information and have stated that, for each company, there is no element of government ownership or control. All five companies have requested a separate company-specific rate.[1]

JMC reported that it is a Sino-U.S. equity joint venture between Jinan Malleable Iron Corporation and South Hudson Inc., established under Chinese law as a limited liability corporation. JMC is privately owned by individual shareholders and controlled by a board of directors. JMC states that it does not have any relationship with the central, provincial, or local governments in the PRC. JMC further states that there are no government controls on the export activities of JMC.

SLK reported that it is wholly-owned by LDR, a U.S. company, and controlled by its managers and owners. SLK stated that they have no relationship with any other producers or exporters of subject merchandise, and that there are no government controls on the export activities of SLK. SLK further states that they it is not owned or controlled by a provincial or local government. Because SLK is wholly foreign-owned, a separate rate analysis is not necessary.

Pannext reported that it is a subsidiary of Pantex Computer Inc. (PCI), a company incorporated in Texas, United States and is controlled by its two-person board of directors, one of whom is the owner of PCI, and the other is the general manager of Pannext. Pannext stated that all exports of the subject merchandise were produced by Pannext. Pannext claimed that Pannext and its affiliates have no corporate relationship with any level of the PRC government. Because Pannext is wholly foreign-owned, a separate rate analysis is not necessary.

Chengde reported that it is an employee-owned enterprise. Chengde further states that Chengde is under the direct control of its general manager who makes all business decisions, and that Chengde is independent of any national, provincial, or local government, including ministries or offices of those governments with respect to exports of the subject merchandise to the United States.

SCE reported that SCE operates in a market economy and operates beyond the jurisdiction of the NME government of the PRC. SCE states that it has no relationship with national, provincial and local governments, and that there are no controls on the export activities of SCE.

Based on these claims, we considered whether each respondent is eligible for a separate rate. The Department's separate rate test to determine whether the exporters are independent from government control is not concerned, in general, with 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, e.g., Certain Cut-to-Length Carbon Steel Plate from Ukraine: Final Determination of Sales at Less than Fair Value*, 62 FR 61754, 61757 (November 19, 1997); *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); and *Honey from the People's Republic of China: Preliminary Determination of Sales at Less than Fair Value*, 60 FR 14725, 14726 (March 20, 1995).

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 out of the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China*, 56 FR 20588 (May 6, 1991) and amplified in the *Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China*, 59 FR 22585, 22586–87 (May 2, 1994) (*Silicon Carbide*). Under 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* governmental control over export activities. *See id.*

1. 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. JMC, SLK, Pannext, SCE, and Chengde have 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'' and the ''Company Law of the People's Republic of China.'' In addition, in previous cases, the Department has analyzed the ''Company Law of the People's Republic of China'' and found that it establishes an absence of *de jure* control. *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value: Certain Partial-Extension Steel Drawer Slides with Rollers from the People's Republic of China*, 60 FR 29571, 29573 (June 5, 1995). We have no information in this proceeding that would cause us to reconsider this determination. Therefore, based on the foregoing, we have preliminarily found an absence of *de jure* control for JMC, SLK, Pannext, SCE, and Chengde.

2. Absence of *De Facto* Control

The Department typically considers four factors in evaluating whether each respondent is subject to *de facto* governmental control of its export functions: (1) whether the export prices are set by or are subject to the approval of a governmental agency; (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 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. 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 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 governmental control that would preclude the Department from assigning separate rates.

All respondents asserted the following: (1) they establish their own export prices; (2) they negotiate contracts without guidance from any governmental entities or organizations; (3) they make their own personnel decisions; and (4) they retain the proceeds of their export sales, using

[1] As noted above, Myland is not eligible for a separate rate because the Department has rejected its Section A response in accordance with 19 C.F.R. 351.302(d)

profits according to their business needs. Additionally, none of the respondents' questionnaire responses suggest pricing is coordinated among exporters. Furthermore, our analysis of the respondents' questionnaire responses reveals no other information indicating government control. Based on the information provided, we preliminary determine that there is an absence of *de facto* governmental control of the respondents' export functions. Consequently, we preliminarily determine that JMC, SLK, Pannext, Chengde, and SCE have met the criteria for the application of a separate rate.

The People's Republic of China-Wide Rate

All exporters were given the opportunity to respond to the Department's questionnaire. As explained above, we received timely Section A responses from JMC, SLK, Pannext, Chengde, and SCE.[2] Our review of U.S. import statistics from the PRC, however, reveals that JMC, SLK, Pannext, Chengde, and SCE did not account for all imports of subject merchandise into the United States from the PRC, even after adjusting for the merchandise of Chinese origin Myland said it had imported into the United States. For this reason, we preliminarily determine that some PRC exporters of MPF failed to respond to our questionnaire. Consequently, we are applying a single antidumping rate the PRC-wide rate to all other exporters in the PRC based on our presumption that those respondents who failed to demonstrate entitlement to a separate rate constitute a single enterprise under common control by the Chinese government. *See, e.g., Final Determination of Sales at Less Than Fair Value: Synthetic Indigo from the People's Republic of China*, 65 FR 25706, 25707 (May 3, 2000) (*Synthetic Indigo*). The PRC-wide rate applies to all entries of subject merchandise except for entries from JMC, SLK, Pannext, Chengde, and SCE.

Use of Facts Otherwise Available

Section 776(a) of the Act provides that, if an interested party withholds information that has been requested by the Department, fails to provide such information in a timely manner or in the form or manner requested, significantly impedes a proceeding under the antidumping statute, or provides information which cannot be verified, the Department shall use, subject to sections 782(d) and (e) of the Act, facts otherwise available in reaching the applicable determination. Pursuant to section 782(e) of the Act, the Department shall not decline to consider submitted information if that information is necessary to the determination but does not meet all of the requirements established by the Department provided that all of the following requirements are met: (1) the information is submitted by the established deadline; (2) the information can be verified; (3) the information is not so incomplete that it cannot serve as a reliable basis for reaching the applicable determination; (4) the interested party has demonstrated that it acted to the best of its ability; and (5) the information can be used without undue difficulties.

Section 776(a)(2)(B) of the Act permits the Department to use facts available when a party does not provide the Department with information by the established deadline or in the form and manner requested by the Department. In addition, section 776(b) of the Act provides that, if the Department finds that an interested party ''has failed to cooperate by not acting to the best of its ability to comply with a request for information,'' the Department may use information that is adverse to the interests of that party as facts otherwise available.

Adverse inferences are appropriate ''to ensure that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.'' *See* Statement of Administrative Action (SAA) accompanying the URAA, H.R. Doc. No. 316, 103d Cong., 2d Session at 870 (1994). Furthermore, ''affirmative evidence of bad faith on the part of the respondent is not required before the Department may make an adverse inference.'' *See Antidumping Countervailing Duties; Final Rule*, 62 FR 27296, 27340 (May 19, 1997).

PRC-Wide Rate

In the case of the single PRC enterprise, as explained above, some exporters of the single enterprise failed to respond to the Department's request for information. Pursuant to section 776(a) of the Act, in reaching our preliminary determination, we have used total adverse facts available for the PRC-wide rate because certain entities did not respond. Also, because some exporters of the single enterprise failed to respond to the Department's requests for information, the Department has found that the single enterprise failed to cooperate to the best of its ability. Therefore, pursuant to section 776(b) of the Act, the Department preliminarily finds that, in selecting from among the facts available, an adverse inference is appropriate.

An adverse inference may include reliance on information derived from the petition, the final determination in the investigation, any previous review, or any other information placed on the record. *See* section 776(b) of the Act. However, section 776(c) of the Act provides that, when the Department relies on secondary information rather than on information obtained in the course of an investigation or review, the Department shall, to the extent practicable, corroborate that information from independent sources that are reasonably at its disposal. Independent sources may include published price lists, official import statistics and customs data, and information obtained from interested parties during the particular investigation or review. *See* SAA at 870 and 19 C.F.R. 351.308(d). ''Corroborate'' means that the Department will satisfy itself that the secondary information to be used has probative value. *Id.* To corroborate secondary information, the Department will, to the extent practicable, examine the reliability and relevance of the information used. *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, from Japan; Preliminary Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews*, 61 FR 57391, 57392 (November 6, 1996).

For our preliminary determination, as adverse facts available, we have used as the PRC-wide rate the recalculated dumping margin from the petition (*see* below). In the petition, the petitioners based export price (EP) on Chinese price quotes publicly available in the United States. *See* http://www.smithcooper.com/products.htm#Malleable. For the NV calculation, the petitioners based the factors of production, as defined by section 773(c)(3) of the Act (raw materials, labor, energy, and representative capital costs), on the quantities of inputs used by the petitioners.

With regard to the EP calculation in the petition, the information relied upon in this case was based on the publicly available Chinese price quotes. Therefore, we find that the U.S. price from the petition margin is sufficiently corroborated. To corroborate the petitioners' NV calculations, we

[2] As previously stated, for the preliminary determination we have found that Myland did not respond to the Department's questionnaire in a timely manner.

compared the petitioners' factor consumption data to that data on the record of this investigation. As discussed in a separate memorandum to the file, we found that the factors consumption data in the petition were reasonable and of probative value. *See* Memorandum to the File Regarding Total Facts Available Corroboration Memorandum for the PRC-Wide Rate, dated May 28, 2003. The values for the factors of production in the petition were based on publicly available information for comparable inputs. Therefore, we find that these Indian surrogate values are sufficiently corroborated.

As a result of this calculation, the PRC-wide rate, for the preliminary determination, is 146.41 percent. Because this is a preliminary margin, the Department will consider all margins on the record at the time of the final determination for the purpose of determining the most appropriate final PRC-wide margin.

Surrogate Country

When the Department is investigating imports from an NME country, section 773(c)(1) of the Act directs it to base NV, in most circumstances, on the NME producer's factors of production, valued in a surrogate market economy country or countries considered to be appropriate by the Department. In accordance with section 773(c)(4) of the Act, the Department, in valuing the factors of production, shall utilize, to the extent possible, the prices or costs of factors of production in one or more market economy countries that are at a level of economic development comparable to the NME country and are significant producers of comparable merchandise. The sources of the surrogate factor values are discussed under the NV section below.

The Department has determined that India, Pakistan, Indonesia, Sri Lanka and the Philippines are countries comparable to the PRC in terms of economic development. *See* Memorandum from Jeffrey May to Abdelali Elouaradia: Antidumping Duty Investigation on Certain Malleable Iron Pipe Fittings from the People's Republic of China, dated January 13, 2003. Customarily, we select an appropriate surrogate based on the availability and reliability of data from these countries. For PRC cases, the primary surrogate has often been India if it is a significant producer of comparable merchandise. In this case, we have found that India is a significant producer of comparable merchandise.

We used India as the primary surrogate country and, accordingly, we have calculated NV using Indian prices to value the PRC producers' factors of production, when available and appropriate. *See* Surrogate Country Selection Memorandum to The File from Anya Naschak, Case Analyst, dated May 28, 2003, (Surrogate Country Memorandum). We have obtained and relied upon publicly available information wherever possible. *See* Factors of Production Valuation Memorandum for the Preliminary Determination to The File from Case Analysts, dated May 28, 2003 (Factor Valuation Memorandum).

In accordance with section 351.301(c)(3)(i) of the Department's regulations, for the final determination in an antidumping investigation, interested parties may submit publicly available information to value factors of production within 40 days after the date of publication of this preliminary determination.

Fair Value Comparison

To determine whether sales of MPF to the United States by JMC, SLK, and Pannext were made at less than fair value, we compared EP or constructed export price (CEP), as appropriate, and NV, as described in the ''Export Price and Constructed Export Price'' and ''Normal Value'' sections of this notice. In accordance with section 777A(d)(1)(A)(i) of the Act, we calculated weighted-average EPs or CEPs.

Export Price and Constructed Export Price

In accordance with section 772(a) of the Act, for respondent JMC we used EP because the subject merchandise was sold directly to unaffiliated customers in the United States prior to importation and because CEP was not otherwise indicated. As explained below, for respondents SLK and Pannext, we used CEP. In accordance with section 777A(d)(1)(A)(i) of the Act, we compared POI-wide weighted-average EPs or CEPs to the NVs.

We calculated EP based on prices to unaffiliated purchasers in the United States. For JMC we made deductions, where appropriate, for foreign inland freight, brokerage and handling, international freight, marine insurance, and other sales specific adjustments. *See* Proprietary Memorandum from Ann Barnett-Dahl to Abdelali Elouaradia: Preliminary Determination Analysis Memorandum for Jinan Meide Casting Co., Ltd., dated May 28, 2003 (JMC Analysis Memo). Because marine insurance was provided by an NME company, we based it on a surrogate rate from a publicly available price list for India. *See* Factor Valuation Memorandum.

SLK classified all of its sales of the subject merchandise in the United States as CEP sales in its questionnaire response. SLK made all of its U.S. sales of the subject merchandise to the first unaffiliated U.S. customer prior to importation by LDR, its U.S. affiliated reseller. We examined the facts surrounding the U.S. sales process.

LDR handled the sales of the subject merchandise in the United States during the POI. LDR conducted all sales negotiations without SLK's participation, received purchase orders from U.S. customers and sent order confirmations to these customers. LDR also issued all invoices and received payment from its U.S. customers. *See* Section A Questionnaire Response (January 29, 2003), and Section A Supplemental Questionnaire Response (February 25, 2003). Because LDR made all sales in the United States, the Department preliminarily determines that SLK's U.S. sales were made ''in the United States'' within the meaning of section 772(b) of the Act, and, thus, should be treated as CEP transactions.

We calculated weighted-average CEPs for SLK's U.S. sales made in the United States through its U.S. affiliate. We based CEP on the reported gross unit prices to unaffiliated purchasers in the United States. We made deductions, where appropriate, for discounts, rebates, marine insurance, international freight, U.S. duties, and for foreign inland freight from the plant to the port of exportation in accordance with section 772(c)(2)(A) of the Act. To calculate inland freight, we multiplied the reported distance from the plant to the port of exit by a surrogate truck freight rate from India. In accordance with section 772(d)(1) of the Act, we deducted from CEP direct and indirect selling expenses (*i.e.*, advertising and imputed credit expenses, and indirect selling expenses and inventory carrying costs) that were associated with LDR's economic activities occurring in the United States. *See* Proprietary Memorandum from Helen Kramer to Abdelali Elouaradia: Preliminary Determination Analysis Memorandum for Beijing Sai Lin Ke Hardware Co., Ltd. and LDR Industries, dated May 28, 2003 (SLK Analysis Memo).

In its questionnaire response Pannext classified all of its sales of the subject merchandise in the United States as CEP sales. All of Pannext's U.S. sales of the subject merchandise to the first unaffiliated U.S. customer during the POI were made prior to importation through PFC, a U.S.-based affiliated

reseller. We examined the facts surrounding the U.S. sales process.

The sale of subject merchandise by Pannext in the United States during the POI was handled by PFC. PFC received purchase orders from, and sent order confirmations to, U.S. customers. PFC also issued all invoices and received payment from Pannext's customers. *See* Section A Questionnaire Response (January 29, 2003), and Section A Supplemental Questionnaire Response (March 3, 2003).

Because the contracts on which Pannext's U.S. sales were based were between PFC and its unaffiliated U.S. customers, and PFC invoiced and received payment from the unaffiliated U.S. customers, the Department preliminarily determines that Pannext's U.S. sales were made ''in the United States'' within the meaning of section 772(b) of the Act, and, thus, should be treated as CEP transactions. This is consistent with *AK Steel Corp. v. United States*, 226 F.3d 1361, 1374 (Fed. Cir. 2000).

We calculated weighted-average CEPs for Pannext's U.S. sales made in the United States through its U.S. affiliate. We based CEP on the reported gross unit prices to unaffiliated purchasers in the United States. We made deductions, where appropriate, for discounts, marine insurance, international freight, U.S. duties, and for foreign inland freight from the plant to the port of exportation in accordance with section 772(c)(2)(A) of the Act. Because marine insurance was provided by an NME company, we based it on a publicly available price list for India. *See* Factor Valuation Memorandum. To calculate inland freight, we multiplied the reported distance from the plant to the port of exit by a surrogate rail rate from India. In accordance with section 772(d)(1) of the Act, we deducted from CEP direct and indirect selling expenses (*i.e.*, credit and indirect selling expenses) that were associated with Pannext's economic activities occurring in the United States. *See* Proprietary Memorandum from Anya Naschak to Abdelali Elouaradia: Preliminary Determination Analysis Memorandum for Langfang Pannext Pipe Fitting Co., Ltd. and Pannext Fittings Corporation, dated May 28, 2003 (Pannext Analysis Memo).

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine the NV using a factors-of-production methodology if: (1) the merchandise is exported from an NME country; and (2) the 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: (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 used factors of production, reported by respondents, for materials, energy, labor, by-products, and packing. *See* section 773(c)(3) of the Act.

The statute provides that in NME cases, the Department ''shall determine the normal value of the subject merchandise on the basis of the value of the factors of production utilized in producing the merchandise.'' *See* section 773(c)(1) of the Act. However, in the instant investigation, JMC, Pannext, and SLK have submitted information on the record that they do not keep records of the inputs of recycled scrap used in the manufacture of subject merchandise, which would be necessary to determine the quantity of recycled scrap used in producing one kilogram of subject merchandise as a factor of production. Further, respondents note that they do not record in the normal course of business the quantities of inputs required to produce each model of subject merchandise. Respondents note that they have reported their factors of production excluding the inputs of recycled scrap. Respondents have explained that their production line is a closed loop system, where in the ordinary course of business all scrap produced is simultaneously reintroduced into the production process. Therefore, it is the respondents' position that the Department should not include in its calculation a factor of production for recycled scrap because the offset would nullify any additional input quantity.

In an effort to determine the quantity of these inputs, the Department provided respondents with an opportunity to report recycled scrap as an input. First, the Department requested that all respondents adjust their reported factors of production by the control number (CONNUM)-specific yield loss ratios. Respondents have acted to the best of their ability to comply with this request. In their supplemental submissions, the respondents adjusted their factors of production to account for these yield loss ratios, and reported estimated yield loss ratios on a CONNUM-specific basis. However, respondents noted that they are only able to report estimated data, because these ratios are not inclusive of material lost due to spillage, slag, or evaporation in the melting process, and are based on a small number of tests, rather than on actual CONNUM-specific data.

Second, the Department requested, at least twice, that each respondent separately report the quantity of recycled scrap reintroduced into the production process in order to account for the material lost in the production process. *See e.g.*, the Department's NME Questionnaire, dated January 8, 2003, at D-1, D-6, JMC Supplemental C and D Questionnaire, dated March 19, 2003, at page 7, Pannext Supplemental Section C and D Questionnaire, dated March 19, 2003 at pages 6–7, Pannext Second Supplemental C and D Questionnaire, dated April 23, 2003, at page 4, SLK Supplemental Section C and D Questionnaire, dated March 18, 2003, at page 6, and Memorandum from Ann Barnett-Dahl to the File, dated May 19, 2003. Respondents explained that they do not keep records on reintroduced scrap, and are therefore unable to provide the Department with the quantity of these inputs. *See e.g.*, JMC's Section D Questionnaire response, dated February 24, 2003, at pages 23 25, JMC's Section D Supplemental response, dated April 2, 2003, at pages 18–19, Pannext's Section D Supplemental response, dated April 11, 2003, at pages 16–17, Pannext's Section D Second Supplemental response, dated April 28, 2003, at pages 4–5, SLK's Section D Supplemental response, dated April 14, 2003, at pages 5–6.

However, it is the Department's practice to require the reporting of all inputs in the production process in the calculation of constructed value. When a party is unable to provide the Department with the requested information, section782(c) of the Act requires a party to promptly notify the Department as to why it cannot comply with the Department's questionnaire. Section782(c) also requires parties to suggest alternative forms in which they are able to comply with the request. *See China Steel Corporation and Yieh Loong v United States*, Court No. 01–01040, Slip Op. 03–52 at 31–32 (May 14, 2003). In this investigation, the Department promptly requested that each respondent separately report the quantities of reintroduced scrap. Respondents have stated they are unable to provide the Department with the requested information, but they have not provided the Department with any alternate means of accounting for the unreported recycled scrap inputs. In lieu of an alternative provided by respondents, the Department must resort to partial facts available in the calculation of dumping margins in this case to account for the unreported input values.

Section 776(a) of the Act provides that if an interested party withholds information that has been requested by the Department, fails to provide such information in a timely manner or in the form or manner requested, significantly impedes a proceeding under the antidumping statute, or provides information which cannot be verified, the Department shall use, subject to sections 782(d) and (e) of the Act, facts otherwise available in reaching the applicable determination. Specifically, section 776(a)(2)(B) of the Act permits the Department to use facts available when a party does not provide the Department with information by the established deadline or in the form and manner requested by the Department. In addition, section 776(b) of the Act provides that, if the Department finds that an interested party ''has failed to cooperate by not acting to the best of its ability to comply with a request for information,'' the Department may use information that is adverse to the interests of that party as facts otherwise available. The purpose of applying an adverse inference is ''to ensure that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.'' *See* Statement of Administrative Action (SAA) accompanying the URAA, H.R. Doc. No. 316, 103d Cong., 2d Session at 870 (1994).

In the instant investigation, the Department is not relying on adverse facts available, as respondents have supplied the Department with CONNUM-specific yield losses as requested. However, the information currently on record does not satisfy the statute with respect to the unreported inputs in the calculation of normal value. The respondents have said that they are unable to provide the Department with this information, and have not proposed an alternative methodology through which the Department could comply with its statutory obligation to value all inputs. Therefore, for this preliminary determination, the Department must rely on partial facts available for the value of recycled scrap. In its calculation of constructed value for this preliminary determination, the Department is therefore relying on information provided by the petitioners in its calculation of the unreported inputs. In their May 15, 2003, submission to the Department, petitioners provided worksheets demonstrating the unreported factors of production for metallic inputs using petitioners', JMC's, and Pannext's data. *See* Letter from Petitioners to the Department dated May 15, 2003 (Petitioners' May 15th Letter). Petitioners calculated an adjustment factor for the unreported metallic inputs based on the total quantity of inputs of purchased scrap and recycled scrap from the Petition, adjusting for respondent's reported yield losses and by-product adjustments for one type of subject merchandise. The Department does not have sufficient information to recalculate these input adjustments for the unreported metallic inputs on a CONNUM-specific basis. Therefore, for this preliminary determination, the Department is using an average of the adjustment ratios for JMC and Pannext as calculated in Petitioners' May 15th Letter at Exhibit 4, and increasing JMC, Pannext, and SLK's reported values for purchased steel scrap by this average, 56.83%.

Additionally, in certain instances JMC and Pannext have reported their factors of production for purchased metallic inputs as less than one kilogram of input to make one kilogram of output. It is the Department's position that it is unreasonable that JMC and Pannext have documented an output weight greater than the input weight. As neutral facts available, for JMC and Pannext, when the reported metallic input to produce one kilogram of output was less than one kilogram, we have used the POI-wide average quantity for steel scrap input as reported in their response. *See e.g.*, Pannext's Section D Questionnaire Response, dated March 3, 2003, at Exhibit 7, and JMC's Section D Questionnaire Response, dated February 24, 2003, at Exhibit D-8-A. For a further analysis of the company-specific calculations, please see JMC Analysis Memo, Pannext Analysis Memo, and SLK Analysis Memo.

We valued the above input factors of production using publicly available published information as discussed in the ''Surrogate Country'' and ''Factor Valuations'' sections of this notice.

In accordance with 19 C.F.R. 351.408(c)(1), where a producer sources an input from a market economy and pays for it in market economy currency, the Department employs the actual price paid for the input to calculate the factors-based NV. *See also Lasko Metal Products v. United States*, 43 F. 3d 1442, 1445–1446 (Fed. Cir. 1994) (*Lasko*). However, though respondents JMC and Pannext reported that one of their material inputs used in the manufacture of certain types of subject merchandise were sourced from market economies and paid for in market economy currency, Pannext and JMC purchased this input from market economies that the Department considers to be potentially aberrational. The Department has determined that South Korea, Thailand, and Indonesia maintain broadly available, non-industry specific export subsidies which may benefit all exporters to all export markets. *See 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). Therefore, the Department has not used use the values of inputs from these countries from to calculate the surrogate values. *See* ''Factor Valuation'' section below.

Pannext reported a ''self-produced'' factor for water among its factors of production for inputs. We preliminarily determine to value water through use of surrogate valuation, rather than based on surrogate valuation of the factors going into the production of those inputs.

Factor Valuations

In accordance with section 773(c) of the Act, we calculated NV based on factors of production (FOP) reported by respondents for the POI. For JMC the Department has applied, as neutral facts available, an average of the FOP values reported by Pannext and SLK for the unreported input of resin coated sand used in the production of subject merchandise. A complete analysis of this issue is available in the JMC Analysis Memo. In the case of one respondent, a trading company, SLK, one of its suppliers failed to report a factor of production for resin coated sand. Therefore, for SLK the Department has applied, as neutral facts available, an average of the FOP values reported by Pannext and the values reported by the remaining four suppliers of SLK for resin coated sand. For SLK, the Department has also applied, as neutral facts available, and average of the FOP values reported by Pannext and JMC for the unreported inputs of limestone used in the production of subject merchandise. A complete analysis of this issue is available in the SLK Analysis Memo.

To calculate NV, the reported per-unit factor quantities were multiplied by publicly available Indian surrogate values (except as noted below). In selecting the surrogate values, we considered the quality, specificity, and contemporaneousness of the data. As appropriate, we adjusted input prices by including freight costs to make them delivered prices. For a detailed description of all surrogate values used for respondents, *see* Factor Valuation Memorandum.

We added to Indian import surrogate values a surrogate freight cost using the shorter of the reported distance from the domestic producer 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, 1407–1408 (Fed. Cir. 1997). For those Indian rupee values not contemporaneous with the POI, we adjusted for inflation using wholesale price indices published in the International Monetary Fund's *International Financial Statistics*.

We valued raw material inputs using the weighted-average unit import values derived from the *Monthly Statistics of the Foreign Trade of India: Volume II*, July 2002 (*Indian Import Statistics*) for the time period corresponding to the POI and, where viable contemporaneous data was not available, we have used *Monthly Statistics of the Foreign Trade of India: Volume II*, December 2001 (*2001 Import Statistics*), as used in *Non-Malleable Cast Iron Pipe Fittings from the People's Republic of China: Final Determination of Sales at Less than Fair Value*, 68 FR 7765, 7767 (February 18, 2003) (*Non-Malleable Final*), inflated to 2002 levels (*see* Factor Valuation Memorandum). For the raw material input of one input used in the production of certain types of subject merchandise purchased by Pannext and JMC from a market economy supplier, for the reasons stated above in the ''Normal Value'' section, the Department is valuing these inputs using *Indian Import Statistics*.

We valued electricity using the year 2002 Electricity Prices for Industry rate as reported by the International Energy Agency (IEA) in *Key World Energy Statistics from the IEA*. The source is the same as in *Non-Malleable Final*, but it is more contemporaneous.

We valued labor using the latest regression-based wage rate for the PRC found on Import Administration's Web page (http://ia.ita.doc.gov/wages/) as described in 19 C.F.R. 351.408(c)(3).

To value foreign inland truck freight costs, we relied upon per kilometer prices from *The Financial Express*, June 17, July 14, Sept. 1, and Oct. 6, 2002 (http://www.financialexpress.com). For JMC and Pannext we valued marine insurance based on publicly available price quotes from a marine insurance provider at http://www.rjgconsultants.com/insurance.html, and we used the actual costs of those services provided to the respondents by market economy suppliers. For JMC we valued brokerage and handling based on a publicly summarized version of the average value for brokerage and handling expenses reported in *Final Determination of Sales at Less Than Fair Value: Certain Circular Welded Carbon-Quality Steel Pipe from the People's Republic of China*, 67 FR 36570 (May 24, 2002), and accompanying Factor Valuation Memorandum.

Because the Department did not find industry-specific data to calculate selling, general and administrative (SG&A) expenses, factory overhead, and profit, we used the ''Finance of Large Public Limited Companies, 2000–01,'' a sample of 964 large public limited companies in India that were reported in the April 2002 Reserve Bank of India Bulletin, as previously used in the *Non-Malleable Final*.

For a complete analysis of surrogate values used in the preliminary determination, see the Factor Valuation Memorandum.

Verification

As provided in section 782(i)(1) of the Act, we intend to verify all company information relied upon in making our final determination.

Rate for Cooperative Producers/Exporters That Were Not Selected

For those PRC producers/exporters who responded to our separate rates questionnaire but were not selected as mandatory respondents (*i.e.*, Chengde and SCE), we have calculated a weighted-average margin based on the rates calculated for those producers/exporters that were selected as mandatory respondents. *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Freshwater Crawfish Tail Meat From the People's Republic of China*, 62 FR 41347, 41350 (August 1, 1997).

Suspension of Liquidation

In accordance with section 733(d)(2)(A) of the Act, we are directing the BCBP to suspend liquidation of all imports of subject merchandise entered, or withdrawn from warehouse, for consumption as follows: for Pannext, SLK, Myland or Chengde, we will instruct BCBP to suspend liquidation on or after the date of publication of this notice in the **Federal Register**; for JMC, SCE and companies subject to the PRC-wide rate, we will instruct BCBP to suspend liquidation on or after the date which is 90 days prior to the date of publication of this notice in the **Federal Register**, due to the Preliminary Determination of Critical Circumstances. *See Notice of Preliminary Determination of Critical Circumstances: Certain Malleable Iron Pipe Fittings from the People's Republic of China*, 68 FR 19779 (April 22, 2003). We will instruct the BCBP to require a cash deposit or the posting of a bond equal to the weighted-average amount by which the NV exceeds the EP or CEP, as indicated below. These suspension-of-liquidation instructions will remain in effect until further notice.

We determine that the following percentage weighted-average margins exist for the POI:

Manufacturer/exporter	Weighted-average margin (percent)
Jinan Meide Casting Co., Ltd	13.80
Beijing Sai Lin Ke Hardware Co., Ltd	144.43
Langfang Pannext Pipe Fitting Co., Ltd	4.96
Chengde Malleable Iron General Factory	52.50
SCE Co., Ltd	52.50
PRC-Wide Rate	146.41

The PRC-wide rate applies to all entries of the subject merchandise except for entries from JMC, SLK, Pannext, Chengde, and SCE.

International Trade Commission Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination of sales at LTFV. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether the domestic industry in the United States is materially injured, or

threatened with material injury, by reason of imports, or sales (or the likelihood of sales) for importation, of the subject merchandise.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Import Administration no later than ten days after the date of issuance of the verification reports, and rebuttal briefs, limited to issues raised in case briefs, no later than five days after the time limit for filing the case brief. *See* 19 C.F.R. 351.309(c)(1)(i); 19 C.F.R. 351.309(d)(1). A list of authorities used and an executive summary of issues should accompany any briefs submitted to the Department. This summary should be limited to five pages total, including footnotes. In accordance with section 774 of the Act, we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, any hearing will be held two days after the receipt of the rebuttal briefs at the U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, at a time and location to be determined. *See* 19 C.F.R. 351.310(d)(1). Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room 1870, within 30 days of the date of publication of this notice. *See* 19 C.F.R. 351.310(c). Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. At the hearing, each party may make an affirmative presentation only on issues raised in that party's case brief, and may make rebuttal presentations only on arguments included in that party's rebuttal brief. *See* 19 C.F.R. 351.310(c).

The Department will make its final determination no later than 135 days after the date of publication of this preliminary determination.

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act.

Dated: May 28, 2003.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 03–14343 Filed 6–5–03; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

University of North Carolina, et al.; Notice of Consolidated Decision on Applications for Duty-Free Entry of Electron Microscopes

This is a decision consolidated pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in Suite 4100W, Franklin Court Building, U.S. Department of Commerce, 1099 14th Street, NW., Washington, DC.

Docket Number: 03–018. *Applicant:* University of North Carolina at Chapel Hill, Chapel Hill, NC 27599–7295. *Instrument:* Electron Microscope, Model Tecnai G^2 12 TWIN. *Manufacturer:* FEI Company, The Netherlands. *Intended Use:* See notice at 68 FR 23979, May 6, 2003. *Order Date:* May 7, 2002.

Docket Number: 03–020. *Applicant:* Wayne State University, Detroit, MI 48202. *Instrument:* Electron Microscope, Model JEM–2010 FasTEM. Manufacturer: JEOL Ltd., Japan. *Intended Use:* See notice at 68 FR 23979, May 6, 2003. *Order Date:* December 5, 2002.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as these instruments are intended to be used, was being manufactured in the United States at the time the instruments were ordered. *Reasons:* Each foreign instrument is a conventional transmission electron microscope (CTEM) and is intended for research or scientific educational uses requiring a CTEM. We know of no CTEM, or any other instrument suited to these purposes, which was being manufactured in the United States at the time of order of each instrument.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. 03–14342 Filed 6–5–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–122–815]

Redetermination Pursuant to NAFTA Panel Remand: Pure Magnesium and Alloy Magnesium From Canada

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Redetermination Pursuant to NAFTA Panel Remand: Pure Magnesium and Alloy Magnesium From Canada.

SUMMARY: The Department of Commerce (''Commerce'') has prepared these results of redetermination pursuant to the decision of the Binational NAFTA Panel (''Panel'') in *Alloy Magnesium and Pure Magnesium from Canada,* USA–CDA–00–1904–07 (October 15, 2002) (''*Panel Decision*''). These results pertain to the Department's determination in *Alloy Magnesium and Pure Magnesium from Canada: Final Results of Full Sunset Reviews,* 65 FR 41444 (July 5, 2000) (''*Final Results*'') that the revocation of the countervailing duty order on pure magnesium and alloy magnesium would be likely to lead to the continuation or recurrence of a countervailable subsidy. The Panel remanded this sunset review to Commerce with instructions to amend its determination in this case by removing the reporting of an all others subsidy rate. The Panel affirmed Commerce's final remand determination on January 21, 2003. Accordingly, Commerce hereby amends the sunset review in this case by removing the reporting of an all others subsidy rate.

EFFECTIVE DATE: June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Joanna Schlesinger or James P. Maeder, Jr., Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–4968 or (202) 482–3330.

SUPPLEMENTARY INFORMATION:

Statute and Regulations

This review is conducted pursuant to sections 751(c) and 752 of the Act. The Department's procedures for the conduct of sunset reviews are set forth in *Procedures for Conducting Five-year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) (''*Sunset Regulations*'') and in 19 CFR part 351 (2002) in general. Guidance on

methodological or analytical issues relevant to the Department's conduct of sunset reviews is set forth in the Department's *Policy Bulletin 98:3 Policies Regarding the Conduct of Five-year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin,* 63 FR 18871 (April 16, 1998) (''*Sunset* Policy Bulletin'').

Background

The Gouvernement du Quebec (''GOQ'') and Magnesium Corporation of America (''Magcorp'') challenged certain findings made by Commerce in its *Final Results* before the Panel. On March 27, 2002, based on its findings pursuant to the GOQ and Magcorp's challenge, the Panel upheld Commerce's determination with respect to certain issues. However, the Panel remanded to Commerce this sunset review with instructions to reconsider: (i) The determination to utilize the results of the sixth review as the subsidy rate to be reported to the ITC; (ii) the basis for the all others rate; and (iii) the reasons for the failure to investigate subsidies alleged to have been received by Magnola Metallurgy, Inc. (''Magnola''). Panel Determination, USA–CDA–00–1904–07 at 31 (Mar. 27, 2002) (''*Panel Determination*''). The Panel further instructed Commerce to file its further remand determination within 45 days of the date of the order. On June 10, 2002, Commerce issued the draft remand results to the Gouvernement du Quebec (''GOQ''), Norsk Hydro Canada, Inc. (''NHCI''), and domestic interested parties.

Commerce issued the Final Results of Determination Pursuant to NAFTA Panel Remand of the Sunset Review of the Countervailing Orders on Pure and Alloy Magnesium from Canada (''Remand Determination'') on June 25, 2002. On July 15, 2002, the GOQ filed the Rule 73(2)(b) Challenge of the Determination on Remand by the Gouvernement du Quebec (''Rule 73(2)(b) Challenge''). The GOQ's Rule 73(2)(b) Challenge contends that Commerce improperly concluded that it was ''required'' to report an all others rate and that the rate selected was improper. U.S. Magnesium LLC (formerly Magcorp) [1] also filed a Rule 73(2)(b) Challenge, contesting Commerce's refusal to investigate alleged subsidies to Magnola. Commerce responded to the Rule 73(2)(b) Challenges filed by the GOQ and U.S. Magnesium on August 5, 2002.

The Panel concluded that Commerce's remand determination with respect to Magnola is supported by substantial evidence and is in accordance with law. However, the Panel remanded the matter to Commerce with instructions to amend its determination by removing the reporting of an all others subsidy rate. The Panel further instructed Commerce to file its further remand determination within 45 days of the date of the order.

Final Results of Review

While we disagree with the Panel's finding with respect to the all others rate, consistent with the Panel's instructions we hereby amend our final determination by removing the reporting of an all others subsidy rate in this case. We determine that revocation of the countervailing duty order would likely lead to continuation or recurrence of a countervailable subsidy at the following percentage weighted-average margins:

Manufacturer/producers/exporter	Weighted-Average margin (percent)
Norsk Hydro Canada Inc. (''Norsk'').	1.84

This notice serves as the only 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. Timely notification of 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 violation which is subject to sanction.

This five-year (''sunset'') review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Dated: June 2, 2003.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 03–14346 Filed 6–5–03; 8:45 am]

BILLING CODE 3510–DS–P

[1] U.S. Magnesium purchased all of the assets of Magcorp on June 24, 2002, pursuant to an auction approved by U.S. Bankruptcy Judge Robert E. Gerber of the Southern District of New York. *See* Motion for Substitution of Party, filed by U.S. Magnesium on July 15, 2002.

DEPARTMENT OF COMMERCE

International Trade Administration

[C-122–839]

Certain Softwood Lumber Products From Canada: Notice of Extension of Time Limit for the Preliminary Results of Countervailing Duty New Shipper Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: June 6, 2003.

FOR FURTHER INFORMATION CONTACT: Eric Greynolds or Gayle Longest, Office of AD/CVD Enforcement VI, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, DC 20230; telephone (202) 482–6071 or 482–3338, respectively.

SUPPLEMENTARY INFORMATION: On December 31, 2002, the Department of Commerce (the Department) initiated a new shipper review relating to the countervailing duty order on certain softwood lumber products from Canada, covering the period January 1, 2002 through December 31, 2002. *See Certain Softwood Lumber From Canada: Notice of Initiation of Antidumping Duty New Shipper Review for the Period May 22, 2002, Through October 31, 2002; Notice of Initiation of Countervailing Duty New Shipper Review for the Period January 1, 2002, Through December 31, 2002; and Rescission of Countervailing Duty Expedited Review*, January 8, 2003 (68 FR 1030). The respondent in this new shipper review is Scierie Lapointe & Roy Ltee (Lapointe & Roy). The current deadline for the preliminary results of this review is June 30, 2003. Section 751(a)(2)(B)(iv) of the Tariff Act of 1930, as amended (the Act), requires the Department to make a preliminary determination within 180 days after the date on which the new shipper review was initiated. However, when the Department determines a case is extraordinarily complicated such that it cannot complete the review within this time period, section 751(a)(2)(B)(iv) of the Act allows the Department to extend the time limit for the preliminary determination from 180 days to a maximum of 300 days.

Pursuant to section 751(a)(2)(B)(iv) of the Act, the Department has determined that this case is extraordinarily complicated given the number of programs and the complexity of the calculations used to derive the benefit from these programs. *See* Decision Memorandum from Melissa G. Skinner,

Director, Office of AD/CVD Enforcement VI, to Holly A. Kuga, Acting Deputy Assistant Secretary, dated concurrently with this notice, which is on file in the Central Records Unit, Room B-099 of the main Commerce building. Thus, in accordance with the statutory and regulatory authority cited above, the Department is extending the deadline for issuing the preliminary results of this new shipper review by 120 days to no later than October 27, 2003. We plan to issue the final results within 90 days after the date the preliminary results are issued.

This extension is in accordance with section 751(a)(2)(B)(iv) of the Act.

Dated: May 28, 2003.

Holly A. Kuga,

Acting Deputy Assistant Secretary Import Administration, Group II.

[FR Doc. 03–14344 Filed 6–5–03; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 021127290–3138–03; I.D. 033103C]

Financial Assistance for Research and Development Projects in the Gulf of Mexico and Off the U.S. South Atlantic Coastal States; Marine Fisheries Initiative (MARFIN); Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The National Marine Fisheries Service (NMFS) publishes this notice to correct an action entitled ''Notice of Solicitation for Applications'' to clarify the Eligibility Information to include ''U.S. citizens''.

DATES: We must receive your application by close of business 5 p.m. eastern daylight time on June 27, 2003. Applications received after that time will not be considered for funding. The earliest start date of awards is about 200 days after the date of publication of this notice. Applicants should consider this processing time in developing requested start dates for their applications.

ADDRESSES: You can obtain an application package from, and send your completed applications(s) to: National Marine Fisheries Service, State/Federal Liaison office, 9721 Executive Center Drive N., St. Petersburg, FL 33702. You may also obtain the application package from the MARFIN Home Page at: http://caldera.sero.nmfs.gov/grants/grants.htm

FOR FURTHER INFORMATION CONTACT: Ellie Francisco Roche, Chief, State/Federal Liaison Office at 727–570–5324.

SUPPLEMENTARY INFORMATION: The National Marine Fisheries Service (NMFS) published a notice soliciting applications for financial assistance in the **Federal Register** of May 13, 2003 (68 FR 25578), entitled ''Notice of Solicitation for Applications.'' ''U.S. citizens'' were inadvertently omitted as eligible applicants and this document makes them eligible.

Correction

''1. Eligible applicants include U.S. citizens, institutions of higher education, hospitals, other nonprofits, commercial organizations, and state, local and Indian tribal governments. Federal agencies or institutions are not eligible. Foreign governments, organizations under the jurisdiction of foreign governments and international organizations are excluded for purpose of this solicitation since the objective of the MARFIN program is to optimize research and development benefits from U.S. marine fishery resources.''

You should consult the May 13, 2003, notice for all of the other requirements for submitting an application.

Dated: June 2, 2003.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 03–14309 Filed 6–5–03; 8:45 am]

BILLING CODE 3510–22–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Request for Public Comments on Commercial Availability Petition Under the African Growth and Opportunity Act (AGOA)

June 3, 2003.

AGENCY: The Committee for the Implementation of Textile Agreements (CITA).

ACTION: Request for public comments concerning a petition for a determination that certain fabrics, for use in men's and boys' shirts, cannot be supplied by the domestic industry in commercial quantities in a timely manner under the AGOA.

SUMMARY: On June 2, 2003, the Chairman of CITA received a petition from Ryberg and Smith, L.L.P. on behalf of their clients, Consolidated Fabrics Ltd., Socota Textile Mills Ltd., New Island Clothing Ltd., Aquarelle Clothing Ltd., and Jaysix USA Inc., alleging that certain fabrics, listed below, used in the production of certain men's and boys' shirts, cannot be supplied by the domestic industry in commercial quantities in a timely manner. It requests that men's and boys' shirts of such fabrics be eligible for preferential treatment under the AGOA. CITA hereby solicits public comments on this request, in particular with regard to whether such shirting fabrics can be supplied by the domestic industry in commercial quantities in a timely manner. Comments must be submitted by June 23, 2003, to the Chairman, Committee for the Implementation of Textile Agreements, room 3001, United States Department of Commerce, 14th and Constitution Avenue, N.W. Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Janet Heinzen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-3400.

SUPPLEMENTARY INFORMATION:

Authority: Section 112(b)(5)(B) of the AGOA, Section 1 of Executive Order No. 13191 of January 17, 2001.

Background

The AGOA provides for quota- and duty-free treatment for qualifying textile and apparel products. Such treatment is generally limited to products manufactured from yarns or fabrics formed in the United States or a beneficiary country. The AGOA also authorizes quota- and duty-free treatment for apparel articles that are both cut (or knit-to-shape) and sewn or otherwise assembled in one or more AGOA beneficiary countries from fabric or yarn that is not formed in the United States, if it has been determined that such fabric or yarns cannot be supplied by the domestic industry in commercial quantities in a timely manner. In Executive Order No. 13191, the President delegated to CITA the authority to determine whether yarns or fabrics cannot be supplied by the domestic industry in commercial quantities in a timely manner under the AGOA and directed CITA to establish procedures to ensure appropriate public participation in any such determination. On March 6, 2001, CITA published procedures in the Federal Register that it will follow in considering requests. (66 FR 13502).

On June 2, 2003, the Chairman of CITA received a petition from Ryberg and Smith, L.L.P. on behalf of their clients, Consolidated Fabrics Ltd.,

Socota Textile Mills Ltd., New Island Clothing Ltd., Aquarelle Clothing Ltd., and Jaysix USA Inc., alleging that certain fabrics, listed above, cannot be supplied by the domestic industry in commercial quantities in a timely manner and requesting quota- and duty-free treatment under the AGOA for certain men's and boys' shirts that are both cut and sewn in one or more AGOA beneficiary countries from such fabrics.

CITA is soliciting public comments regarding this request, particularly with respect to whether these fabrics can be supplied by the domestic industry in commercial quantities in a timely manner. Also relevant is whether other fabrics that are supplied by the domestic industry in commercial quantities in a timely manner are substitutable for the fabrics for purposes of the intended use. Comments must be received no later than June 23, 2003. Interested persons are invited to submit six copies of such comments or information to the Chairman, Committee for the Implementation of Textile Agreements, room 3100, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, DC 20230.

If a comment alleges that these shirting fabrics can be supplied by the domestic industry in commercial quantities in a timely manner, CITA will closely review any supporting documentation, such as a signed statement by a manufacturer of the fabrics stating that it produces the fabrics that are the subject of the request, including the quantities that can be supplied and the time necessary to fill an order, as well as any relevant information regarding past production.

CITA will protect any business confidential information that is marked business confidential from disclosure to the full extent permitted by law. CITA will make available to the public non-confidential versions of the request and non-confidential versions of any public comments received with respect to a request in room 3100 in the Herbert Hoover Building, 14th and Constitution Avenue, N.W., Washington, DC 20230. Persons submitting comments on a request are encouraged to include a non-confidential version and a non-confidential summary.

Fabrics named in the request:

(a) Fabrics of subheadings 5208.21, 5208.22, 5208.29, 5208.31, 5208.32, 5208.39, 5208.41, 5208.42, 5208.49, 5208.51, 5208.52 or 5208.59, of average yarn number exceeding 135 metric;

(b) Fabrics of subheadings 5513.11 or 5513.21, not of square construction, containing more than 70 warp ends and filling picks per square centimeter, of average yarn number exceeding 135 metric;

(c) Fabrics of subheadings 5210.21 or 5210.31, not of square construction, containing more than 70 warp ends and filling picks per square centimeter, of average yarn number exceeding 135 metric;

(d) Fabrics of subheadings 5208.22 or 5208.32, not of square construction, containing more than 75 warp ends and fillings picks per square centimeter, of average yarn number exceeding 135 metric;

(e) Fabrics of subheadings 5407.81, 5407.82 or 5407.83, weighing less than 170 grams per square meter, having a dobby weave created by a dobby attachment, of average yarn number exceeding 135 metric;

(f) Fabrics of subheadings 5208.42 or 5208.49, not of square construction, containing more than 85 warp ends and filling picks per square centimeter, of average yarn number exceeding 85 metric, or exceeding 135 metric if the fabric is of oxford construction (a modified basket weave with a large filling yarn having no twist woven under and over two single, twisted warp yarns);

(g) Fabrics of subheading 5208.51, of square construction, containing more than 75 warp ends and filling picks per square centimeter, made with single yarns, of average yarn number 135 or greater metric;

(h) Fabrics of subheading 5208.41, of square construction, with a gingham pattern, containing more than 85 warp ends and filling picks per square centimeter, made with single yarns, of average yarn number 135 or greater metric, and characterized by a check effect produced by the variation in color of the yarns in the warp and filling; or

(i) Fabrics of subheading 5208.41, with the warp colored with vegetable dyes, and the filling yarns white or colored with vegetable dyes, of average yarn number greater than 65 metric.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 03–14395 Filed 6–4–03; 11:46 am]

BILLING CODE 3510–DR–S

CONSUMER PRODUCT SAFETY COMMISSION

Submission for OMB Review; Comment Request—Safety Standard for Omnidirectional Citizens Band Base Station Antennas

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: In the **Federal Register** of March 24, 2003, (68 FR 14202), the Consumer Product Safety Commission published a notice in accordance with provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) to announce the agency's intention to seek extension of approval of the collection of information required in the Safety Standard for Omnidirectional Citizens Band Base Station (16 CFR part 1204). No comments were received in response to that notice. By publication of this notice, the Commission announces that it has submitted to the Office of Management and Budget a request for extension of approval of that collection of information, without change, for three years from the date of approval.

The Safety Standard for Omnidirectional Citizens Band Base Station Antennas establishes performance requirements for omnidirectional citizens band base station antennas to reduce unreasonable risks of death and injury which may result if an antenna contacts overhead power lines while being erected or removed from its site. Certification regulations implementing the standard require manufacturers, importers, and private labelers of antennas subject to the standard to test antennas for compliance with the standard, and to maintain records of that testing.

The records of testing and other information required by the certification regulations allow the Commission to determine that antennas subject to the standard comply with its requirements. This information would also enable the Commission to obtain corrective actions if omnidirectional citizens band base station antennas failed to comply with the standard in a manner which creates a substantial risk of injury to the public.

Additional Information About the Request for Extension of Approval of a Collection of Information

Agency address: Consumer Product Safety Commission, Washington, DC 20207.

Title of information collection: Safety Standard for Omnidirectional Citizens Band Base Station Antennas, 16 CFR part 1204.

Type of Request: Extension of approval without change.

General description of respondents: Manufacturers, importers, and private labelers of omnidirectional citizens band base station antennas.

Estimated number of respondents: 5.

Estimated number of hours per respondent: 220 per year.

Estimated number of hours for all respondents: 1,100 per year.

Estimated cost of collection for all respondents: $46,552 per year.

Comments: Comments on this request for extension of approval of information collection requirements should be submitted by July 7, 2003 to (1) The Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for CPSC, Office of Management and Budget, Washington DC 20503; telephone: (202) 395–7340, and (2) the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207. Written comments may also be sent to the Office of the Secretary by facsimile at (301) 504–0127 or by e-mail at *cpsc-os@cpsc.gov.*

Copies of this request for extension of the information collection requirements and supporting documentation are available from Linda Glatz, management and program analyst, Office of Planning and Evaluation, Consumer Product Safety Commission, Washington, DC 20207; telephone: (301) 504–7671, e-mail: *lglatz@cpsc.gov.*

Dated: May 30, 2003.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 03–14228 Filed 6–5–03; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP02–562–004]

CenterPoint Energy—Mississippi River Transmission Corporation; Notice of Compliance Filing

May 30, 2003.

Take notice that on May 27, 2003, CenterPoint Energy—Mississippi River Transmission Corporation (MRT) tendered for filing in Appendix 1 attached to the filing, the information and explanations requested by the Commission in its order issued May 5, 2003 in Docket No. RP02–562–002.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with § 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: June 9, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14237 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–342–003]

MIGC, Inc.; Notice of Compliance Filing

May 30, 2003.

Take notice that on May 23, 2003, MIGC, Inc. (MIGC) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheets, to become effective May 1, 2003:

First Revised Sheet No. 30.
Sub First Revised Sheet No. 31.
Substitute First Revised Sheet No. 32.
Third Revised Sheet No. 33.
Original Sheet No. 33A.
Original Sheet No. 52B.
Fourth Revised Sheet No. 60.
Sub Original Sheet No. 60A.
Third Revised Sheet No. 61.
Fifth Revised Sheet No. 65.
Second Revised Sheet No. 66A.
Third Revised Sheet No. 69.
Substitute Third Revised Sheet No. 70.
Original Sheet No. 70A.
Second Revised Sheet No. 82.
Original Sheet No. 82A.
Fourth Revised Sheet No. 85.
First Revised Sheet No. 118.
First Revised Sheet No. 119.

MIGC asserts that the purpose of this filing is to comply with the Commission's order issued May 9, 2003, in Docket Nos. RP00–342–001 and RP00–342–002, to file actual tariff sheets reflecting certain revisions to its August 10, 2001 and September 12, 2001 filings in compliance with Order No. 637.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with § 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: June 4, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14236 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–483–000]

Northwest Pipeline Corporation; Notice of Proposed Changes in FERC Gas Tariff

May 30, 2003.

Take notice that on May 27, 2003, Northwest Pipeline Corporation (Northwest) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets, to be effective June 27, 2003.

First Revised Sheet No. 125.
First Revised Sheet No. 126.
First Revised Sheet No. 127.
First Revised Sheet No. 128.
Original Sheet No. 129.
Sheet Nos. 130 through 199.
Eighth Revised Sheet No. 363.
Eighth Revised Sheet No. 365.

Northwest states that the purpose of this filing is to revise Northwest's park and loan service under Rate Schedule PAL by adding a park point and loan point adjacent to the Jackson Prairie storage facility in Lewis County, Washington.

Northwest states that a copy of this filing has been served upon its customers and interested state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with § 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Comment Date: June 9, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14243 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–390–001]

Overthrust Pipeline Company; Notice of Tariff Filing

May 30, 2003.

Take notice that on May 23, 2003, Overthrust Pipeline Company (Overthrust) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1–A, the following tariff sheets, to be effective July 1, 2003:

Substitute Original Sheet No. 53A.
Substitute Original Sheet No. 53B.

Overthrust states that this filing proposes to amend Overthrust's May 1, 2003, tariff filing that was filed in compliance with the Commission's Order No. 587–R in Docket No. RM96–1–024, dated March 12, 2003, which incorporated the most recent Version 1.6 standards promulgated by the North American Energy Standards Board (NAESB).

Overthrust states that it was discovered that a portion of NAESB Standard 5.3.45, that was intended to be included verbatim, was inadvertently omitted from the May 1, 2003, filing. Therefore, Overthrust seeks to incorporate the omitted portion of NAESB Standard 5.3.45.

Overthrust states that a copy of this filing has been served upon its customers, the Public Service Commission of Utah and the Public Service Commission of Wyoming.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with § 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: June 4, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14239 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–482–000]

Panhandle Eastern Pipe Line Company and Panhandle Eastern Pipe Line Company, LLC; Notice of Proposed Changes in FERC Gas Tariff

May 30, 2003.

Take notice that on May 23, 2003, Panhandle Eastern Pipe Line Company (Panhandle) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the tariff sheets listed on Appendix A to the filing, to reflect a change in corporate name and corporate form.

Panhandle states that the revised tariff sheets reflect a name change that is planned to occur on June 23, 2003. Panhandle states that on June 23, 2003, it plans to convert from a corporation to a limited liability company and change its corporate name to Panhandle Eastern Pipe Line Company, LLC.

Panhandle states that a copy of this filing has been mailed to all affected customers and interested state commissions, and that copies of the revised tariff sheets will be provided upon request.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with § 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Comment Date: June 4, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14242 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Docket No. RP03–391–001; Notice of Tariff Filing

Questar Southern Trails Pipeline Company

May 30, 2003.

Take notice that on May 23, 2003, Questar Southern Trails Pipeline Company (Southern Trails) tendered for filing as part of its FERC Gas Tariff, Original Volume No.1, Substitute Original Sheet No. 64B, to be effective July 1, 2003.

Southern Trails states that this filing proposes to amend Southern Trail's May 1, 2003 tariff filing that was filed in compliance with the Commission's Order No. 587–R in Docket No. RM96–1–024, dated March 12, 2003, which incorporated the most recent Version 1.6 standards promulgated by the North American Energy Standards Board (NAESB). Southern Trails states that it was discovered that a portion of NAESB Standard 5.3.45, that was intended to be included verbatim, was inadvertently omitted from the May 1 filing. Therefore, Southern Trails seeks to incorporate the omitted portion of NAESB Standard 5.3.45.

Southern Trails states that a copy of this filing has been served upon its customers and the Public Service Commissions of Utah, New Mexico, Arizona, and California.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with § 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: June 4, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14240 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–481–000]

Transwestern Pipeline Company; Notice of Filing

May 30, 2003.

Take notice that on May 23, 2003, Transwestern Pipeline Company (Transwestern) tendered for filing a copy of an Operator Balancing Agreement between Transwestern and Unocal Keystone Gas Storage, LLC.

Transwestern states that Transwestern and Unocal Keystone Gas Storage, LLC have entered into an Operator Balancing Agreement that contains several provisions that are supplemental to the form of operator balancing agreement (OBA) set forth in Transwestern's tariff. In accordance with Section 15.5 of the General Terms and Conditions of Transwestern's tariff, Transwestern must file with the Commission any supplemental provisions contained in an OBA entered into by Transwestern that are not reflected in the form of OBA set forth in the tariff.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before the intervention and protest date as shown below. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Comment Date: June 6, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14241 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP03–369–001]

USG Pipeline Company; Notice of Errata Filing

May 30, 2003.

Take notice that on May 27, 2003, USG Pipeline Company (USGPC) tendered for filing as part of its FERC Gas Tariff, Substitute Second Revised Sheet No. 59, with an effective date of July 1, 2003.

USGPC states that the purpose of this filing is to correct an error on a tariff sheet submitted on May 1, 2003 to comply with the Commission's Order No. 587–R issued March 12, 2003, in Docket No. RM96–1–024.

USGPC states that complete copies of this filing are being provided to its sole customer, United States Gypsum Company, which receives service as certificated under part 157 of the Commission's regulations, and to interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with § 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings.

See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

Protest Date: June 9, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14238 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL03–128–000, et al.]

D.E. Shaw Plasma Power, L.L.C., et al.; Electric Rate and Corporate Filings

May 30, 2003.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. D.E. Shaw Plasma Power, L.L.C.

[Docket No. EL03–128–000]

Take notice that on May 28, 2003, D. E. Shaw Plasma Power, L.L.C. (the Petitioner) tendered for filing with the Federal Energy Regulatory Commission (Commission) a Petition for Declaratory Order Disclaiming Jurisdiction; and Request for Expedition. The Petitioner is asking the Commission for an order declaring that: (1) D.E. Shaw & Co., L.P. (DESCO LP) will not be deemed a public utility under Section 201'' of the Federal Power Act (FPA), 16 U.S.C. 824(e); (2) the license agreement between DESCO LP and D.E. Shaw & Co. Energy, L.L.C. (DESCO Energy) will not be considered a jurisdictional facility under the FPA; (3) the advisory services that DESCO Energy proposes to provide to DESCO LP will not be considered activities subject to the Commission's FPA jurisdiction; and (4) the Commission's disclaimers of jurisdiction in Paragraphs 15, 19, 20, and 23 of D.E. Shaw Plasma Power, L.L.C., 102 FERC § 61,275 dated March 7, 2003 with respect to the interests, persons, and entities referenced therein apply to the new circumstances described in the petition.

Comment Date: June 20, 2003.

2. West Georgia Generating Company, LLC

[Docket No. ER99–2186–002]

Take notice that on May 28, 2003, West Georgia Generating Company, LLC (West Georgia) tendered for filing a triennial market-power analysis in compliance with the order granting it authority to make sales at market-based rates.

Comment Date: June 18, 2003.

3. Consumers Energy Company

[Docket No. ER01–318–006]

Take notice that on May 28, 2003, Consumers Energy Company (Consumers) tendered for filing Second Sub Original Sheet No. 136 of its First Revised FERC Electric Tariff No. 6 in compliance with the May 12, 2003 Order issued in this proceeding. Consumers states that The sheet being filed is to become effective November 1, 2000.

Consumers states that copies of the filing were served upon those on the official service list in this proceeding.

Comment Date: June 18, 2003.

4. New York Independent System Operator, Inc.

[Docket No. ER03–13–004]

Take notice that on May 12, 2003, the New York Independent System Operator, Inc., (NYISO) tendered for filing a compliance filing in accordance with the Commission's April 11, 2003 Order, in Docket Nos. ER03–13–001 and 002. The NYISO has requested an effective date of May 12, 2003.

NYISO states that it has served a copy of this filing upon all parties that have executed service agreements under the NYISO's Open Access Transmission Tariff or the Services Tariff and upon the New York State Public Service Commission and to the electric utility regulatory agencies in New Jersey and Pennsylvania.

Comment Date: June 13, 2003.

5. San Diego Gas & Electric Company

[Docket No. ER03–548–002]

Take notice that on May 28, 2003, San Diego Gas & Electric Company (SDG&E), pursuant to FERC's Order issued May 8, 2003 in Docket Nos. ER03–548–000 and 001, tendered for filing its First Revised Service Agreement Nos. 9 and 11 to its FERC Electric Tariff, First Revised Volume No. 6. SDG&E states that these agreements were accepted for filing on May 8, 2003, conditioned upon SDG&E's filing of designations for both interconnection facilities agreements in compliance with Order No. 614 and section 35.9(a) of the Commission's Regulations.

SDG&E states that copies of the filing have been served on CalPeak Power and on the California Public Utilities Commission.

Comment Date: June 18, 2003.

6. Devon Power LLC, Middletown Power LLC, Montville Power LLC, Norwalk Power LLC, and NRG Power Marketing Inc.

[Docket No. ER03–563–006]

Take notice that on May 28, 2003, Devon Power LLC, Middletown Power LLC, Montville Power LLC, Norwalk Power LLC (collectively Applicants) and NRG Power Marketing Inc., tendered for filing in compliance with the Commission's Order issued April 25, 2003, the revised Cost of Service Agreements among each of the Applicants, NRG Power Marketing Inc., as agent for each Applicant, and ISO New England Inc.

Applicants state that they have provided copies of this filing to ISO–NE, the affected state regulatory authorities, counsel to the NEPOOL Participants Committee, and the NEPOOL Participants identified in their filing.

Comment Date: June 18, 2003.

7. ISO New England Inc.

[Docket No. ER03–854–001]

Take notice that on May 28, 2003, ISO New England Inc. (the ISO) tendered an Errata Filing to correct a tariff sheet contained in the May 15, 2003, filing made in Docket No. ER03–854–000. The ISO states that copies of the Errata Filing have been served upon the parties in the above-captioned proceeding.

Comment Date: June 18, 2003.

8. D.E. Shaw Plasma Trading, L.L.C.

[Docket No. ER03–879–000]

Take notice that on May 28, 2003, D. E. Shaw Plasma Trading, L.L.C. tendered for filing an application for authorization to sell energy, capacity, and ancillary services at market-based rates pursuant to section 205 of the Federal Power Act.

Comment Date: June 18, 2003.

9. D.E. Shaw & Co. Energy, L.L.C.

[Docket No. ER03–880–000]

Take notice that on May 28, 2003, D. E. Shaw & Co. Energy, L.L.C. tendered for filing an application for authorization to sell energy, capacity, and ancillary services at market-based rates pursuant to section 205 of the Federal Power Act.

Comment Date: June 18, 2003.

10. D.E. Shaw Plasma Power, L.L.C.

[Docket No. ER03–882–000]

Take notice that on May 28, 2003, D. E. Shaw Plasma Power, L.L.C., tendered for filing an application for authorization to sell energy, capacity, and ancillary services at market-based rates pursuant to section 205 of the Federal Power Act.

Comment Date: June 18, 2003.

11. Ameren Services Company

[Docket No. ER03–883–000]

Take notice that on May 28, 2003, Ameren Services Company (ASC) tendered for filing a Transmission System Interconnection Agreement and Parallel Operating Agreement between ASC and Bio-Energy Partners. ASC asserts that the purpose of the Agreement is to permit ASC to provide transmission service to Bio-Energy Partners pursuant to Ameren's Open Access Transmission Tariff.

Comment Date: June 18, 2003.

12. Nordic Marketing of Ohio, L.L.C.

[Docket No. ER03–885–000]

Take notice that on May 28, 2003, Nordic Marketing of Ohio, L.L.C. petitioned the Commission to: (1) Accept for filing its Rate Schedule FERC No. 1, which will permit it to sell electric energy and capacity to wholesale customers at market-based rates and permit transmission capacity reassignment; (2) waive 60 days' notice and allow that rate schedule to become effective 60 days after filing or the date the Commission issues an order accepting the rate schedule, whichever occurs first; and (3) grant such other waivers and blanket authorizations as have been granted to other power marketers.

Comment Date: June 18, 2003.

13. Entergy Services, Inc.

[Docket No. ER03–886–000]

Take notice that on May 28, 2003, Entergy Services, Inc., on behalf of Entergy Arkansas, Inc., tendered for filing the Thirty-second Amendment to the Power Coordination, Interchange and Transmission Service Agreement between Entergy Arkansas, Inc. and Arkansas Electric Cooperative Corporation, dated March 1, 2003. Entergy Services, Inc., states that the Thirty-second Amendment modifies Exhibit A to Appendix A of Rate Schedule No. 82.

Comment Date: June 18, 2003.

14. Nordic Marketing of Pennsylvania, L.L.C.

[Docket No. ER03–887–000]

Take notice that on May 28, 2003, Nordic Marketing of Pennsylvania, L.L.C. petitioned the Commission to: (1) Accept for filing its Rate Schedule FERC No. 1, which will permit it to sell electric energy and capacity to wholesale customers at market-based rates and permit transmission capacity reassignment; (2) waive 60 days' notice and allow that rate schedule to become effective 60 days after filing or the date the Commission issues an order accepting the rate schedule, whichever occurs first, and (3) grant such other waivers and blanket authorizations as have been granted to other power marketers.

Comment Date: June 18, 2003.

15. Nordic Marketing of Illinois, L.L.C.

[Docket No. ER03–888–000]

Take notice that on May 28, 2003, Nordic Marketing of Illinois, L.L.C. petitioned the Commission to: (1) Accept for filing its Rate Schedule FERC No. 1, which will permit it to sell electric energy and capacity to wholesale customers at market-based rates and permit transmission capacity reassignment; (2) waive 60 days' notice and allow that rate schedule to become effective 60 days after filing or the date the Commission issues an order accepting the rate schedule, whichever occurs first, and (3) grant such other waivers and blanket authorizations as have been granted to other power marketers.

Comment Date: June 18, 2003.

16. Consumers Energy Company

[Docket No. ES02–36–003]

Take notice that on May 22, 2003, Consumers Energy Company (Consumers) submitted an amendment to its original application in this proceeding, pursuant to section 204 of the Federal Power Act. This amendment seeks authorization to issue up to an additional: (1) $750 million (for a total of $1.75 billion) of long-term securities for general corporate purposes, (2) $1 billion (for a total of $1.5 billion) of long-term securities for refinancing or refunding of existing long-term securities, and (3) $1.45 billion (for a total of $2.65 billion) of long-term first mortgage bonds to be issued as security for other long-term securities.

Consumers also requests a waiver of the Commission's competitive bidding and negotiated placement requirements at 18 CFR 34.2.

Comment Date: June 20, 2003.

17. Old Dominion Electric Cooperative

[Docket No. ES03–39–000]

Take notice that on May 22, 2003, Old Dominion Electric Cooperative (Old Dominion) submitted an application pursuant to section 204 of the Federal Power Act seeking authorization to guarantee obligations in an amount not to exceed $150 million at any one time.

Old Dominion also requests a waiver from the Commission's competitive bidding and negotiated placement requirements at 18 CFR 34.2.

Comment Date: June 13, 2003.

Standard Paragraph

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 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 motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at *http://www.ferc.gov* , using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866)208–3676, or for TTY, contact (202)502–8659. Protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14332 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG03–69–000, et al.]

Gilroy Energy Center, LLC, et al.; Electric Rate and Corporate Filings

May 28, 2003.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Gilroy Energy Center, LLC

[Docket No. EG03–69–000]

Take notice that on May 23, 2003, Gilroy Energy Center, LLC (Gilroy) filed with the Federal Energy Regulatory Commission (Commission) an

application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

Gilroy, a Delaware limited liability company, proposes to acquire, own and operate 405 MW of electric generating facilities and sell the output of such facilities at wholesale. Gilroy further states that copies of the application were served upon the U.S. Securities and Exchange Commission and California Public Utilities Commission.

Comment Date: June 18, 2003.

2. Creed Energy Center, LLC

[Docket No. EG03–70–000]

Take notice that on May 23, 2003, Creed Energy Center, LLC (Creed) filed with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

Creed, a Delaware limited liability company, proposes to acquire, own and operate certain generating equipment associated with a nominally rated 45 MW natural gas-fired, simple cycle electric generating facility located in Solano County, California, and sell the output at wholesale. Creed further states that copies of the application were served upon the U.S. Securities and Exchange Commission and California Public Utilities Commission.

Comment Date: June 18, 2003.

3. Goose Haven Energy Center, LLC

[Docket No. EG03–71–000]

Take notice that on May 23, 2003, Goose Haven Energy Center, LLC (Goose Haven) filed with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

Goose Haven, a Delaware limited liability company, proposes to acquire, own and operate certain generating equipment associated with a nominally rated 45 MW natural gas-fired, simple cycle electric generating facility located in Solano County, California, and sell the output at wholesale. Goose Haven further states that copies of the application were served upon the U.S. Securities and Exchange Commission and California Public Utilities Commission.

Comment Date: June 18, 2003.

4. Carolina Power & Light Company

[Docket No. ER03–540–006]

Take notice that on May 23, 2003, Carolina Power & Light Company and Florida Power Corporation tendered for filing with the Federal Energy Regulatory Commission a revision of the compliance filings submitted on May 15 and 20, 2003 in Docket Nos. ER03–540–003 and 004. The revised compliance filing implements modifications to the credit security provisions of their Open Access Transmission Tariffs, to become effective May 14, 2003, in compliance with the Commission's May 9, 2003 Order Accepting in part and Rejecting in part Tariff Sheets as Modified (103 FERC § 61,159).

Carolina Power & Light Company states that this filing was served upon the parties to this proceeding, the North Carolina Utilities Commission, the South Carolina Public Service Commission and the Florida Public Service Commission.

Comment Date: June 13, 2003.

5. Midwest Independent Transmission System Operator, Inc.

[Docket No. ER03–869–000]

Take notice that on May 23, 2003, pursuant to Section 205 of the Federal Power Act and Section 35.12 of the Commission's regulations, the Midwest Independent Transmission System Operator, Inc. (Midwest ISO) submitted for filing a Letter Agreement which establishes a new Operating Protocol among Michigan Electric Transmission Company, LLC, Kinder Morgan Michigan, LLC and the Midwest ISO.

Midwest ISO states that a copy of this filing was sent to Michigan Electric Transmission Company, LLC and Kinder Morgan Michigan, LLC.

Comment Date: June 13, 2003.

6. Bangor Hydro-Electric Company

[Docket No. ER03–870–000]

Take notice that on May 23, 2003, Bangor Hydro-Electric Company (BHE) tendered for filing Notices of Cancellation of its FERC Electric Tariff Original Volume No. 5 (Open and Maintenance Agreement between Great Northern Paper, Inc., Great Lakes Power, Inc. (GLPI) and BHE (O&M Agreement)) effective May 16, 2003. BHE states that they also filed a Termination Agreement between GLPI and BHE addressing the applicability of the indemnification provisions of the O&M Agreement to acts occurring prior to May 16, 2003 as well as final payments due under the O&M Agreement.

BHE states that copies of the filing were served upon the parties to the Operation and Maintenance Agreement, the Maine Public Utilities Commission, and Maine Public Advocate.

Comment Date: June 13, 2003.

7. Bangor Hydro-Electric Company

[Docket No. ER03–871–000]

Take notice that on May 23, 2003, Bangor Hydro-Electric Company (BHE) filed a Construction Agreement between BHE and Brascan Energy Marketing, Inc. (BEMI) for the BHE/Great Northern Paper Company—Millinocket 115kV Interface Project, an Interconnection Agreement between BHE and Great Lakes Hydro American L.L.C. (GLHA), an Interconnection Agreement between BHE and Katahdin Paper Company, Inc., and an Undivided Ownership, Operation, and Maintenance Agreement between BHE and GLHA (collectively, the Agreements) BHE requests an effective date of May 16, 2003 for the Agreements.

Comment Date: June 13, 2003.

8. Southern Company Services, Inc.

[Docket No. ER03–872–000]

Take notice that on May 23, 2003, Southern Company Services, Inc. (SCS), acting on behalf of Georgia Power Company (GPC), filed with the Federal Energy Regulatory Commission the Interconnection Agreement between GPC and Southern Power Company dated as of May 23, 2003 for the Franklin CC Unit 3. SCS states that the Interconnection Agreement sets forth the terms and conditions for the interconnection of the Franklin CC Unit 3 to the GPC electric system.

Comment Date: June 13, 2003.

9. New York Independent System Operator, Inc.

]Docket No. ER03–873–000]

Take notice that on May 23, 2003, the New York Independent System Operator, Inc. (NYISO) filed proposed revisions to the NYISO's Market Administration and Control Area Services Tariff. NYISO states that the proposed revisions are intended to remove the requirement that the NYISO determine whether or not the Long Island reserves constraint specifically caused a unit to be committed. The NYISO has requested that the Commission make the filing effective on September 30, 2001.

The NYISO has served a copy of this filing to all parties that have executed Service Agreements under the NYISO's Open-Access Transmission Tariff or Services Tariff, the New York State Public Service Commission and to the electric utility regulatory agencies in New Jersey and Pennsylvania.

Comment Date: June 13, 2003.

Standard Paragraph

Any person desiring to intervene or to protest this filing should file with the

Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 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 motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at *http://www.ferc.gov* , using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659. Protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14232 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG03–72–000, et al.]

Whiting Clean Energy, Inc., et al.; Electric Rate and Corporate Filings

May 29, 2003.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Whiting Clean Energy, Inc.

[Docket No. EG03–72–000]

Take notice that on May 21, 2003, Whiting Leasing LLC (WL), 801 East 86th Avenue, Merrillville, Indiana 46410, filed with the Federal Energy Regulatory Commission (Commission) an Application for Determination of Exempt Wholesale Generator Status pursuant to part 365 of the Commission's Regulations and Section 32 of the Public Utility Holding Company Act, as amended (the Application).

WL states that it is an Indiana Corporation that will own and lease a gas-fired combined cycle cogeneration facility rated at approximately 525 MW capacity and that the facility will be used for the generation of electricity exclusively for sale at wholesale. WL further states that copies of this application have been served upon the Indiana Utility Regulatory Commission and the Securities and Exchange Commission.

Comment Date: June 11, 2003.

2. Phibro Inc.

[Docket No. ER95–430–024]

Take notice that on May 27, 2003, Phibro Inc., tendered for filing an updated market power analysis in compliance with the Commission's orders authorizing Phibro Inc., to engage in wholesale sales of electric power at market-based rates.

Comment Date: June 17, 2003.

3. Entergy Services, Inc.

[Docket No. ER02–1783–001]

Take notice that on May 27, 2003, Entergy Services, Inc., on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc., (collectively, the Entergy Operating Companies) tendered for filing a compliance refund report in accordance with the Commission's letter order in Docket No. ER02–1783–000 issued April 11, 2003.

Comment Date: June 17, 2003.

4. Southern California Edison Company

[Docket No. ER03–142–004]

Take notice that on May 27, 2003, Southern California Edison Company (SCE) tendered for filing revised rate sheets for its Transmission Owner Tariff (TO Tariff), FERC Electric Tariff, Second Revised Volume No. 6, and for its Existing Transmission Contracts with the city of Colton, California. SCE states that the purpose of this filing is to comply with the Federal Energy Regulatory Commission's Order On Compliance and Rehearing dated May 12, 2003,103 FERC ¶ 61,166.

SCE states that copies of this filing were served upon the Service List compiled by the Secretary in this docket.

Comment Date: June 17, 2003.

5. San Diego Gas & Electric Company

[Docket No. ER03–217–003]

Take notice that on May 27, 2003, San Diego Gas & Electric Company (SDG&E) pursuant to FERC's Order issued January 24, 2003, 102 FERC ¶ 61,063, tendered for filing Service Agreements Nos. 17 and 18 to its FERC Electric Tariff, First Revised Volume No. 6. SDG&E states that these agreements were accepted for filing on January 24, 2003, conditioned upon SDG&E's filing of designations for both interconnection agreements in compliance with Order No. 614 and Section 35.9(a) of the Commission's Regulations.

SDG&E states that copies of the filing have been served on Termoelectrica de Mexicali S. de R.L. de C.V., Termoelectrica U.S., LLC, and on the California Public Utilities Commission.

Comment Date: June 17, 2003.

6. Virginia Electric and Power Company

[Docket No. ER03–519–001]

Take notice that on May 27, 2003, Virginia Electric and Power Company, doing business as Dominion Virginia Power, tendered for filing an amendment to its February 11, 2003 filing of the revised Generator Interconnection and Operating Agreement (Interconnection Agreement) between Dominion Virginia Power and Old Dominion Electric Cooperative, Inc. (ODEC) to interconnect ODEC's Marsh Run CT Project with Dominion Virginia Power's transmission system. Dominion Virginia Power states the amendment is in response to the Commission's April 11, 2003 letter requesting additional information regarding the Interconnection Agreement.

Dominion Virginia Power states that copies of the filing were served upon ODEC and the Virginia State Corporation Commission.

Comment Date: June 17, 2003.

7. Midwest Independent Transmission System Operator, Inc.

[Docket No. ER03–787–001]

Take notice that on May 27, 2003, Midwest Independent Transmission System Operator, Inc. (Midwest ISO) submitted for filing, pursuant to Section 205 of the Federal Power Act and Section 35.12 of the Commission's regulations, an executed Interconnection and Operating Agreement among Interstate Power and Light Company, a wholly owned subsidiary of Alliant Energy and Flying Cloud Power Partners, LLC.

Midwest ISO states that a copy of this filing was sent to Interstate Power and Light Company and Flying Cloud Power Partners, LLC.

Comment Date: June 17, 2003.

8. Lamar Power Partners, LP

[Docket No. ER03–874–000]

Take notice that on May 27, 2003, Lamar Power Partners, LP tendered for filing a Notice of Cancellation pursuant to 18 CFR 35.15 in order to reflect the cancellation of its market-based rate tariff, designated as FERC Electric Tariff, Original Volume No. 1, originally accepted for filing in Docket No. ER00–1844–000.

Comment Date: June 17, 2003

9. California Independent System Operator Corporation

[Docket No. ER03–875–000]

Take notice that on May 27, 2003, the California Independent System Operator Corporation (CAISO) submitted an amendment to the CAISO Tariff (Amendment No. 52). CAISO states that Amendment No. 52 eliminates the requirement that System Resources submitting Energy bids into the CAISO Real Time Markets limit such bids to $0/MWh. The CAISO proposes that System Resources be permitted to submit bids above $0/MWh in the CAISO Real Time Markets.

CAISO states that it has served copies of Amendment No. 52 upon the Public Utilities Commission of the State of California, the California Energy Commission, the California Electricity Oversight Board, and upon all parties with effective Scheduling Coordinator Service Agreements under the CAISO Tariff. In addition, the ISO states that it is posting Amendment No. 52 on the CAISO Home Page.

Comment Date: June 17, 2003.

10. Illumina Energy Solutions, Inc.

[Docket No. ER03–876–000]

Take notice that on May 27, 2003, Illumina Energy Solutions, Inc., (Illumina) petitioned the Commission for acceptance of Illumina Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission regulations.

Comment Date: June 17, 2003.

11. Southern California Edison Company

[Docket No. ER03–877–000]

Take notice that on May 27, 2003, Southern California Edison Company (SCE) tendered for filing a Facilities Agreement under SCE's Transmission Owner Tariff (Tariff) between SCE and Southern California Public Power Authority (SCPPA).

SCE states that the Facilities Agreement specifies the terms and conditions pursuant to which SCE will engineer, design, construct, install and own the Reliability Upgrades to SCE's electrical system as a result of SCPPA's intent to construct and interconnect the Magnolia Power Project to the City of Burbank's Olive Substation and transmit a maximum of 200 MW of generation through the Los Angeles Department of Water and Power's electrical system.

SCE states that copies of this filing were served upon the Public Utilities Commission of the State of California and SCPPA.

Comment Date: June 17, 2003.

12. PJM Interconnection, L.L.C.

[Docket No. ER03–878–000]

Take notice that on May 27, 2003, PJM Interconnection, L.L.C. (PJM), submitted for filing a construction service agreement among PJM, Waymart Wind Farm L.P., and PPL Electric Utilities Corporation. PJM requests a waiver of the Commission's 60-day notice requirement to permit the requested May 12, 2003 effective date for the agreement.

PJM states that copies of this filing were served upon the parties to the agreement and the state regulatory commissions within the PJM region.

Comment Date: June 17, 2003.

13. Dominion Energy Marketing, Inc.

[Docket No. ER03–881–000]

Take notice that on May 27, 2003, Dominion Energy Marketing, Inc. (DEMI) tendered for filing with the Federal Energy Regulatory Commission (Commission) its request to amend the Western Systems Power Pool (WSPP) Agreement to include DEMI as a participant. DEMI requests that the Commission allow the amendment to the WSPP Agreement to become effective on May 27, 2003.

DEMI states that a copy of this filling has been served upon the WSPP Executive Committee Chair, WSPP Operating Committee Chair, WSPP General Counsel, and Arizona Public Service Company.

Comment Date: June 17, 2003.

14. Valero Refining Company, California

[Docket No. ER03–884–000]

Take notice that on May 27, 2003, Valero Refining Company—California, tendered for filing a Notice of Cancellation, pursuant to 18 CFR 35.15, giving notice of cancellation of its market-based electric tariff filed with the Commission and approved by letter order issued April 23, 2002.

Comment Date: June 17, 2003.

Standard Paragraph

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 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 motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at *http://www.ferc.gov*, using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659. Protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14233 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Regulations Governing Off-the-Record Communications; Public Notice

May 30, 2003.

This constitutes notice, in accordance with 18 CFR 385.2201(h), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or a prohibited off-the-record communication relevant to the merits of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance

of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such requests only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication should serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of prohibited and exempt communications recently received in the Office of the Secretary. The communications listed are grouped by docket numbers. These filings are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866)208–3676, or for TTY, contact (202)502–8659.

Docket No.	Date filed	Presenter or requester
Prohibited		
1. Project No. 2342–000	5–22–03	Keith Bonney.
Exempt		
1. CP03–75–000	5–30–03	Joanne Wachholder.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14235 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 2181–014 and 2697–014]

Northern States Power Company; Notice of Site Visit

May 30, 2003.

a. *Date and Time of Site Visit:* June 18, 2003, 1 p.m. to 5 p.m., and June 19, 2003, 8:30 a.m. to 12 p.m.

b. *Place:* We will meet at the Menomonie Project powerhouse (300 2nd Street NW., Menomonie, WI) at 1 p.m. on June 18, 2003. On June 19, 2003, we will meet at the Cedar Falls Project powerhouse (N7075 540th Street, Menomonie, WI) at 8:30 a.m.

Applicant Contact: Lloyd Everhart, Xcel Energy, (715)839–2692.

c. *FERC Contact:* John Ramer, (202)502–8969; john.ramer@ferc.gov.

d. *Purpose of the Site Visit:* Applications for new hydropower licenses for the Menomonie and Cedar Falls Projects have been filed with the Federal Energy Regulatory Commission (FERC), and the FERC staff is presently reviewing these applications. part of staff's review process is to assess the proposed projects' potential effects on environmental resources and to make recommendations to protect or enhance those resources, if needed. Staff needs complete and adequate information before they can complete their review of these applications. Therefore, the FERC staff intends to visit the Menomonie and Cedar Falls Hydropower Projects, FERC Nos. P–2181 and P–2697, respectively, to familiarize themselves with the project facilities and operations, and any resources that could be affected by licensing these projects.

e. *Proposed Schedule and Location:* We will meet at the Menomonie Project powerhouse at 1 p.m. on June 18, 2003, and first tour the powerhouse and dam facilities. We will then tour the project impoundment and stop at recreational facilities and other points of interest, completing the Menomonie Project tour by 5 p.m. On June 19, 2003, we will meet at the Cedar Falls Project powerhouse at 8:30 a.m., and first tour the powerhouse and dam facilities. This will be followed by a tour of the reservoir and points of interest around the reservoir, which will conclude by 12 p.m.

f. All local, state, and Federal agencies, Indian Tribes, and interested parties, are hereby invited to accompany FERC staff on this site visit. If you want to participate and need further information regarding schedule, location, or agenda, please contact: John Ramer at (202)502–8969, Peter Foote at (716)568–0425, or the applicant contact listed above.

Magalie R. Salas,

Secretary.

[FR Doc. 03–14234 Filed 6–5–03; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OAR–2003–0070, FRL–7509–3]

Agency Information Collection Activities: Proposed Collection; Comment Request; The SunWise School Program

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 EPA is planning to submit the following continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB): The SunWise School Program, Global Programs Division, EPA ICR No. 1904.01, expiration date: 11/30/03. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the continuing information collection as described below.

DATES: Comments must be submitted on or before August 5, 2003.

ADDRESSES: Follow the detailed instructions in **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Kristin Kenausis, Office of Atmospheric Programs, Global Programs Division, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., (6205J), Washington, DC 20460, (202) 564–2289, *kenausis.kristin@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has established a public docket for this ICR under Docket ID number OAR–2003–0070, which is available for public viewing at the Air and Radiation 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 Air and Radiation Docket is (202) 1744. 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, and according to the following detailed instructions: Submit your comments to EPA online using EDOCKET (our preferred method), by email to a-and-r-*Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Air and Radiation Docket, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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 elementary and middle school students, parents, and teachers (SIC Div. I: Group 8211).

Title: SunWise School Program; (OMB Control Number 2060–0439; EPA ICR No. 1904.01, expiring on 11/30/03).

Abstract: The goal of the SunWise School Program is to teach children and their care givers how to protect themselves from overexposure to the sun. The SunWise School Program recognizes the challenge of measuring the progress and evaluating the effectiveness of an environmental and public health education program where the ultimate goal is to reduce risk and improve public health. Therefore, the continual and careful evaluation of program effectiveness through a variety of means, including data from pre- and post-intervention surveys, tracking and monitoring of classroom activities and school policies, and advisory board meetings, is necessary to monitor progress and refine the program. Surveys to be developed and administered include: (1) Student survey to identify current sun safety knowledge and behaviors among students; (2) Parent survey to compare findings with those of their children as well as to draw comparisons with the benchmarks established in other national surveys; and (3) Teacher questionnaire for measuring their receptivity to the educational component of the Program. The data will be analyzed and results will indicate the Program's effect on participants' sun-protection attitudes and behaviors. Responses to the collection of information are voluntary. All responses to the collection of information remain anonymous and 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. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

Burden Statement: The annual public reporting and record keeping burden for this collection of information is estimated to average .5 hours per response.

Number to be surveyed annually (A)	Total hours burden (B)	Rate per hour ($) (C)	Total cost (D=B*C) (D)
3,000 Students	3,000	0	0
1,000 Teachers	500	$36.88	$18,440.00
1,000 Parents	250	20.29	5,072.50
Total (annual)	3,750	.....	23,512.50
ICR Total (3 years)	11,250	.....	70,537.50

The contractor (Boston University Medical Center) will assist EPA in data collection and analysis. EPA has contracted for a total of 400 professional hours. At an average rate of $100 per hour, the total cost for the contractor is $40,000 annually. Agency burden to manage this contract is estimated at 4 hours/month or 48 hours annually. The cost of this labor will be calculated based on a GS–12, Step 5 pay level ($44.75/hour using the salary associated with this grade and step, multiplied by a benefits factor of 1.6 [16]). Total hours (48) multiplied by $44.75 per hour amounts to a total agency labor cost of $2,196/per annum.

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: May 28, 2003.

Drusilla Hufford,

Director, Global Programs Division.

[FR Doc. 03–14323 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL–6640–8]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 260–5073 OR (202) 260–5075.

Weekly receipt of Environmental Impact Statements

Filed May 26, 2003 Through May 30, 2003

Pursuant to 40 CFR 1506.9.

EIS No. 030251, Final EIS, NPS, MT, Glacier National Park—Going-to-Sun Road Rehabilitation Plan to Protect and Preserve a National Historic Landmark, Waterton-Glacier International Peace Park, The World's First International Peace Park, A World Heritage Site, MT, Wait Period Ends: June 30, 2003, Contact: Mary Riddle (406) 888–7898. The above NPS EIS should have appeared in the 5/30/2003 **Federal Register.** The 30-day Wait Period is Calculated from 5/30/2003.

EIS No. 030252, Final EIS, AFS, IL, Natural Area Trails Project, Construction, Reconstruction, Maintenance and Designation of Trails for Hikers and Equestrian Use, Approval of Site-Specific Mitigation and/or Monitoring Standards, Shawnee National Forest, Jackson, Pope, Johnson, Union, Hardin and Saline Counties, IL, Wait Period Ends: July 7, 2003, Contact: Richard Johnson (618) 253–7114.

EIS No. 030253, Draft EIS, FHW, IL, U.S. Route 20 (FAP 301) Project, Construction from Illinois Route 84 North of Galena to Bolton Road Northwest of Freeport, NPDES Permit and U.S. Army COE Section 404 Permit, Jo Daviess and Stephenson Counties, IL Comment Period Ends: July 21, 2003, Contact: Norman R. Stoner (217) 492–4640.

EIS No. 030254, Draft Supplement, DOE, TN, GA, TX, SC, MO, Programmatic EIS—Stockpile and Management for a Modern Pit Facility (MPF) Construction and Operation, Site Location: Savannah River Site, SC; Los Alamos Site, NM; Nevada Test Site; Carlsbad Site, NM; and Pantex Site, TX and Plutonium Pit Manufacturing Capabilities Upgrading at Los Alamos National Laboratory (LANL), NM, Contact: James Rose (202) 586–5484. This document is available on the Internet at: *http://www.mpfeis.com.*

EIS No. 030255, Final EIS, MMS, AL, MS, TX, FL, LA, Eastern Gulf of Mexico Outer Continental Shelf Oil and Gas Lease Sales 189 (proposed for 2003) and 197 (proposed for 2005) Leasing Program 2002–2007, Eastern Planning Area, Counties and Parishes of TX, LA, MS, AL and FL, Wait Period Ends: July 7, 2003, Contact: Dr. Kay Marano Briggs (703) 787–1646.

EIS No. 030256, Final EIS, AFS, OR, Rimrock Ecosystem Restoration Project, To Promote Healthy and Sustainable Watershed Conditions, Implementation, Umatilla National Forest, Heppner Ranger District, Grant, Morrow and Wheeler Counties, OR, Wait Period Ends: July 7, 2003, Contact: Dave Kendrick (541) 676–9187. This document is available on the Internet at: *http://www.fs.fed.us/r6/uma/nepa/readroom.htm.*

EIS No. 030257, Draft EIS, AFS, MT, Logan Creek Ecosystem Restoration Project, To Reduce Hazardous Fuel across the Landscape, Restore or Maintain Vegetation Management, Flathead National Forest, Tally Lake Ranger District, Flathead County, MT, Comment Period Ends: July 21, 2003, Contact: Bryan Donner (406) 863–5408.

Amended Notices

EIS No. 030216, Draft EIS, FHW, OH, OH–161/37 Improvement, from OH–161(New Albany Bypass) to west of OH–161/37 Interchange with OH–16, Funding, Franklin and Licking Counties, OH, Comment Period Ends: July 18, 2003, Contact: Roger Ryder (614) 469–6896. Revision of FR notice published on 05/16/2003: Change in Contact Person Name and Telephone Number.

EIS No. 030238, Draft EIS, DOE, OR, Northeast Oregon Hatchery Program, Grande Ronde—Imnaha Spring Chinook Hatchery Modification and Modernization of Two Existing Hatchery Facilities and Construction of Three New Auxiliary Hatchery Facilities, Wallowa County, OR, Comment Period Ends: July 7, 2003, Contact: Mickey Carter (503) 230–5885. Revision of FR Notice Published on 5/23/2003: Correction of Lead Agency from DOA to DOE.

EIS No. 030247, Draft EIS, CGD, LA, Port Pelican Deepwater Port Construction and Operation, License Approval, Vermillion Lease Block 140 on the Continental Shelf in the Gulf of Mexico southwest of Freshwater City, LA, Comment Period Ends: July 15, 2003, Contact: Mark Prescott (202) 267–0225. Revision of FR notice published on 5/30/2003: Correction of Title Block 40 Should be Block 140.

Dated: June 3, 2003.

B. Katherine Biggs,

Associate Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 03–14331 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7508–5]

Office of Environmental Justice; Environmental Justice Collaborative Problem-Solving Grant Program Request for Applications (May 30, 2003–September 30, 2003)

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The purpose of this notice is to solicit applications from eligible community-based organizations in order for the U.S. Environmental Protection Agency (EPA) to provide financial assistance to those organizations through the new Environmental Justice Collaborative Problem-Solving Grant Program described in this notice. Community-based organizations who are eligible to receive financial assistance must be non-government, nonprofit organizations currently exempt from taxation under section 501 (c) (3) of the Internal Revenue Code or exempt under applicable state law, and working on or planning to work on projects to address local environmental and/or public health concerns in their communities. All awards will be made in the form of a Federal grant in the amount of $100,000.00 to be used over a three-year period.

This Request for Applications Includes the Following

Translations Available

A Spanish translation of this material is available at 1–800–952–6215. It can also be downloaded from: *http://www.epa.gov/compliance/recent/ej.html.*

I. Scope and Purpose of Request for Applications

The purpose of this notice is to solicit applications from eligible community-based organizations in order for the U.S. Environmental Protection Agency to provide financial assistance to those organizations through the new Environmental Justice Collaborative Problem-Solving Grant Program described in this notice. Community-based organizations who are eligible to receive financial assistance must be non-government, nonprofit organizations currently exempt from taxation under section 501 (c) (3) of the Internal Revenue Code or exempt under applicable state law, and working on or planning to work on projects to address local environmental and/or public health concerns in their communities. All awards will be made in the form of a Federal grant to 15 community-based organizations in the amount of $100,000.00 to be used over a three-year period.

Identification Number: CFDA 66.306.

Date of Notification: May 30, 2003.

Submission Due Date: September 30, 2003.

EPA's Office of Environmental Justice (OEJ), in coordination with the Federal Interagency Working Group on Environmental Justice (IWG), has developed an Environmental Justice Collaborative Problem-Solving Model. (See section III of this RFA for a complete description of this model.) The purpose of the Environmental Justice Collaborative Problem-Solving (CPS) Grant Program is for EPA to provide financial assistance to community-based organizations to utilize this model to address one or more environmental and/or public health issues in their communities. An underlying purpose of the Environmental Justice CPS Grant Program is to replicate lessons learned so that the Environmental Justice Collaborative Problem-Solving Model can be utilized by other, similarly situated communities seeking to address local environmental and/or public health issues.

This Request for Applications (RFA) outlines the purpose, goals, and general procedures and guidelines for applying for the Environmental Justice CPS Grants, for Fiscal Year (FY) 2003. OEJ's Environmental Justice CPS Grants seek to accomplish a strategically defined set of objectives that address one or more local environmental and/or public health issues by focusing on two key areas (*e.g.*, capacity-building of the community residents, and forming collaborative partnerships). Application instructions are provided in section V of this RFA.

Number of Grants Proposed: Fifteen (15) Environmental Justice CPS grants will be awarded for fiscal year (FY) 2003.

Applications must be date stamped by courier service or postmarked by U.S. Postal Service by 12 p.m. Eastern Time, September 30, 2003. Use the appropriate address below, depending on your method of delivery.

VIA U.S. Postal Service

U.S. Environmental Protection Agency, Office of Environmental Justice (MC 2201A), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

Attention: Linda K. Smith, Project Officer, *Phone:* (202) 564–2602.

VIA Federal Express, Airborne, United Parcel Service, or Other Courier Service

U.S. Environmental Protection Agency, Office of Environmental Justice, Ariel Rios Building South, Room 2232, 1200 Pennsylvania Ave., NW., Washington, DC 20004.

Attention: Linda K. Smith, Project Officer, *Phone:* (202) 564–2602.

Applications Sent by Fax or E-mail Will Not Be Accepted

II. Commonly Asked Questions About Environmental Justice

How Does EPA Define Environmental Justice?

EPA defines ''environmental justice'' as the fair treatment and meaningful involvement of all people regardless of race, color, national origin or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Fair treatment means that no one group of people, including racial, ethnic, or socioeconomic groups, should bear a disproportionate share of the negative environmental consequences resulting from industrial, municipal, and commercial operations or the execution of federal, state, local, and tribal environmental programs and policies. Meaningful involvement means that: (1) Potentially affected community residents have an appropriate opportunity to participate in decisions about a proposed activity that will affect their environment and/or health; (2) the public's contribution can influence the regulatory agency's decision; (3) the concerns of all participants involved will be considered in the decision-making process; and (4) the decision-makers seek out and facilitate the involvement of those potentially affected.

What Is the EPA's Commitment to Environmental Justice?

EPA Administrator Christine Todd Whitman reaffirmed the Agency's commitment to environmental justice as the ''goal to be achieved for all communities and persons across this Nation * * * when everyone, regardless of race, culture, or income, enjoys the same degree of protection from environmental and health hazards and equal access to the decision-making process to have a healthy environment in which to live, learn and work.'' In her August 9, 2001, memorandum, the Administrator directed EPA's senior managers and staff to integrate environmental justice into all EPA policies, programs, and activities. Consequently, in FY 2003, each Regional and Headquarters Office developed Environmental Justice Action Plans to transform the Administrator's words into action, with strategic goals and measurable results. Each Regional and Headquarters Office began implementing these action plans which are available at: *http://epa.gov/compliance/environmentaljustice.* Inherently strategic in nature and deemed as ''works in progress,'' these action plans represent the commitments of each office over the next 1–5 years.

Consistent with this commitment, EPA, through OEJ, will provide financial assistance to those community-based organizations who wish to engage in capacity-building initiatives, and also utilize constructive engagement and collaborative problem-solving to seek viable solutions for their community's environmental and/or public health issues. Moreover, OEJ staff members will provide hands-on technical assistance to those grantee community-based organizations throughout the duration of the grant.

What Does the OEJ Mean by Capacity-Building?

Capacity-building refers to the mechanisms a community uses which

provide the residents with the information, skills, and tools to more effectively achieve their goals. These mechanisms may lead to better documentation and assessment of an environmental and/or public health problem. Documentation and assessment mechanisms range from neighborhood surveys to the use of mapping tools through the EPA's geographic information systems. A particularly helpful tool in this regard would be the Environmental Justice Mapper which is available at: *http://www.epa.gov/compliance/whereyoulive.html.* Other capacity-building mechanisms may involve increasing the community's ability to understand the permitting process and to use legal tools to participate in the environmental decisionmaking process, such as those described in the Environmental Law Institute's ''A Citizen's Guide to Using Environmental Laws to Secure Environmental Justice.'' This publication is available at: *http://www.epa.gov/compliance/resources/publications/ej/citizen_guide_ej.pdf.*

A third type of capacity-building mechanism may involve enhancing the community's understanding and appreciation of the partnership development process, consensus building, and the use of alternative dispute resolution to address local environmental and/or public health concerns.

What Does the OEJ Mean by Constructive Engagement and Collaborative Problem-Solving?

Constructive engagement and collaborative problem-solving are essential approaches to address local environmental and/or public health concerns. A key starting point is the community's involvement in clearly formulating and articulating a goal to be accomplished (*e.g.*, establishment of a health clinic or medical screening program; or replacement of diesel buses with clean fuel buses). Constructive engagement means outreach and education to affected community residents and other stakeholders. Collaborative problem-solving requires an understanding of the need to seek other partners such as industry; federal, state and local governments; academia; and environmental organizations to address the community's environmental and/or public health concerns. It involves developing strategic partnerships, by including all organizations which can play a role in addressing the problems. Collaborative problem-solving involves a well-designed and strategic plan to sustain the partnership and to work towards addressing the local environmental and/or public health issues.

III. Description of the Environmental Justice Collaborative Problem-Solving Model

The elements of the Environmental Justice Collaborative Problem-Solving Model are discussed in detail in below. A sample of a project where the elements of the Model have been used is also provided below. The elements of the Environmental Justice Collaborative Problem-Solving Model are discussed in detail below. A sample of a project where the elements of the Model have been used is also included below. More examples of how the Model has been applied can be found on the Internet, the ''Federal Interagency Working Group on Environmental Justice Status Report, (February 2002). (*http://epa.gov/compliance/resources/publications/ej/iwg-status-02042002.pdf*), an evaluation report for six of the 2002 demonstration projects *http://www.epa.gov/evaluate/ej.htm* and, the recent 2003 List of Revitalization Projects *http://epa.gov/compliance/resources/publications/ej/iwg-2003.pdf.*

1. Issue Identification, Community Vision, and Strategic Goal Setting

Long-standing concerns in the affected community tend to surface from the efforts of one individual or a small group of individuals who are particularly active in the community. These concerns can include ''substantive issues'' such as high asthma rates, children suffering from high levels of lead poisoning, undesirable land uses, the close proximity of residences to pollution-generating facilities, the lack of parks and recreational areas, or the lack of access to health care or medical monitoring. These concerns also can include ''process issues'' such as the need to strengthen public participation, identifying leaders or leadership development, improved education of stakeholders, and trust among stakeholder groups to work together. Collaborative problem-solving stresses moving beyond merely identifying the issues to formulating viable strategies to address and resolve them. Involving the broader community in a planning process usually leads to greater clarity in the goals set, common understanding and trust, and the ability to act collectively. Strategic goals should not only address the problem but also lead to greater community capacity, viable partnerships, and leveraging of resources-institutional, technical, and financial. A key step in the goal-setting process is determining whether or not the conditions are ripe for a collaborative problem-solving process. The following list provides several important steps a community-based organization can take to identify an issue, articulate a community vision, and set strategic goals:

- Building upon existing leadership and expertise in the affected community;
- Conducting local education and outreach efforts, fact-finding and assessments;
- Involving affected community residents early in identifying concerns and crystallizing issues;
- Identifying early on potential partners from all stakeholder groups;
- Building upon a strong understanding of community history and practices;
- Building upon a clearly articulated community vision of its goals; and,
- Employing tools for involving the affected community residents in planning project activities.

2. Community Capacity Building

Capacity building refers to mechanisms which provide the community-based organizations with information, skills, and tools to more effectively achieve the community's goals. These mechanisms may involve better documentation and assessment of a problem, use of consensus building, and alternative dispute resolution. Capacity building efforts should focus on residents of the affected community as well as other stakeholders. Leadership skills in areas such as strategic thinking, management processes, and effective communications are very critical. The ability to build trust and build partnerships across stakeholder groups is one such leadership skill. Therefore, particular attention should be paid to nurturing the leadership skills of key individuals in a project. Capacity building and leadership development can be accomplished through a range of activities, from attendance at meetings, workshops, and training sessions to participation in mentoring opportunities. Several key steps toward community capacity building and to acquiring successful leadership skills could include:

- Building upon existing organizational capacity in the affected community;
- Identifying specific capacity building mechanisms which are tailored to community needs and project goals;
- Fostering capacity through training, mentoring, technical assistance, or resource support;

• Ensuring capacity building for those community representatives directly involved in the collaborative problem-solving processes; and

• Developing processes that help ensure capacity building and leadership development of community residents in the future.

3. Consensus Building and Dispute Resolution

Collaborative problem-solving encourages all parties to seek to find common ground and derive ''mutual gains'' from participating in a consensus building process. More often than not, this will lead to greater capacity to address the community's concerns and the eventual resolution of issues. Moreover, consensus building efforts often result in greater understanding and trust among different stakeholders that will lead to a greater capacity to address other issues. There also will be cases in which crystallized disputes require the use of a facilitator or mediator to help resolve such disputes. There exists a wide array of approaches within the area of dispute resolution—ranging from unassisted negotiation to arbitration—that communities can employ to best suit their needs. Several key steps a community can employ to achieve consensus building and successful dispute resolution are:

• Designing processes, both formal and informal, to help ensure fair treatment and meaningful participation of all collaborative problem-solving stakeholders;

• Instituting processes which promote the development of a common vision, and goals among all partners;

• Identifying, nurturing and promoting collaborations with win/win scenarios and the ''mutual gains'' approach;

• Promoting the use of facilitation or mediation to ensure understanding of the consensus building process; and

• Ensuring that existing or potential conflicts are resolved, where necessary, through the use of alternative dispute resolution techniques.

4. Multi-Stakeholder Partnerships, and Resource Mobilization

Building a successful partnership requires vision, clear problem identification, organizational capacity and commitment, individual leadership, use of technical resources, and, in some cases, use of a facilitator. This is an evolving process that grows with existing capacity on the part of the affected community as well as other stakeholder groups. Different stakeholder groups will require different assistance to ensure their effective participation. For example, community groups may need support in accessing government resources while industry may need education on how to work effectively and proactively with communities. Well-structured partnerships assemble the needed capacity to resolve issues. They are important vehicles for creating a broad-based framework that mobilizes the resources necessary—human, institutional, technical, legal, and financial—to address a problem. In this way, they are a critical part of a capacity building strategy. Several ways to achieve well structured multi-stakeholder collaborative partnerships include:

• Establishing dialogues which lead to possible partnerships with all relevant stakeholders/parties, which invariably include the community, business, and government;

• Ensuring clarity of goals, objectives, and common vision among all members of the partnership;

• Developing a clear, workable organizational structure and workplan to address communications and coordination needs of the collaborative partnership;

• Identifying and recruiting partners to address the resource needs of a project (*e.g.,* human, institutional, technical, legal, and financial);

• Strengthening partnerships as new issues and relationships are understood; and

• Establishing processes that allow for the inclusion of new partners as they emerge.

5. Supportive and Facilitative Role of Government

Environmental and public health government agencies can play an important role in addressing a community's concerns because the agencies are invested with the statutory authority to address those issues. They make decisions of a regulatory nature, provide technical assistance and resources, and can help ensure that all relevant stakeholders come to the table. It is important that community organizations seeking to resolve a problem formulate a clear strategy to engage government agencies at the local, state, tribal, and/or Federal levels. Securing support from environmental and public health government regulatory agencies can be accomplished by:

• Securing commitments from multiple agencies, whether Federal, state, local, or tribal government agencies, as appropriate;

• Seeking to ensure interagency and intergovernmental cooperation and coordination to address complex environmental and/or public health, housing, transportation, economic development, community revitalization, *etc.*; and

• Accessing and securing support for a specific community need that coincides with a current activity being conducted by an environmental and/or public health government agency.

6. Management and Implementation

Realizing a vision to address identified issues requires attention to three major areas: (1) Action plans; (2) management; and (3) partnership design. Plans to address these areas should be formulated and executed in ways that build upon the unique assets and challenges of specific communities and stakeholder partners. Action plans should include clear objectives, timelines, and delegation of responsibilities. Management plans should ensure proper communications, coordination, and utilization of resources. Well-formulated partnership designs should address the convening processes, the role of lead organizations, planning for regular meetings, and understanding ways to increase the capacity of partner organizations. As a result, all partners must articulate and follow through on commitments for the project to: (1) Address the identified issues thoroughly; (2) strengthen and maintain partnerships; and (3) realize the shared goals. Several ways that could accomplish a successful management plan include:

• Ensuring tangible outcomes and improvements in community conditions;

• Developing strategies tailored to the community's assets and deficits;

• Designing projects to meet the strength of partnerships, resources and the capacity of the partners;

• Producing clearly defined, well-formulated action plans;

• Identifying and building upon small successes achieved along the way;

• Ensuring clear commitments on the part of all partners; and

• Clustering and ordering tasks to promote the efficient use of time and resources.

7. Framework, Lessons Learned, and Replication of Best Practices

Key to deepening and sustaining the work is the ability to sum up progress in quantitative, qualitative, institutional, and social terms, and to incorporate lessons learned into a continuous process. Formulating a plan for evaluating one's work is an important element of success. Not only will it help the project implementation plan stay on

course, but such a plan will also allow for greater clarity of lessons learned. Lessons learned need to be shared not only with the affected community residents, but also with other communities and stakeholders so that best practices can be replicated broadly. Several key steps that should be included in developing an evaluation framework for lessons learned can consist of:

- Clearly defining measures of success of project objectives, process, outputs, institutional effects, and quality-of-life results;
- Understanding and evaluating, from different stakeholder perspectives, indicators used to measure success;
- Developing a ''template'' for successful collaborative models, based on experience in a specific community;
- Developing mechanisms to integrate the lessons into future efforts as new issues and challenges are identified; and
- Sharing, publishing, and disseminating experiences and lessons learned.

Example of a Project Where the Environmental Justice Collaborative Problem-Solving Model Is Used

An example of a community-based organization that has successfully utilized elements of the Environmental Justice Collaborative Problem-Solving Model is outlined below. CPS Project X, located in Any Town, USA, is a proactive community-based organization of 1,400 members who have taken the lead in establishing collaborative partnerships to address local environmental and/or public health issues through environmental cleanup and community revitalization initiatives. A synopsis of the CPS Project X Partnership as it relates to the Environmental Justice Collaborative Problem-Solving Model follows:

1. *Issue Identification/Vision:* A community survey confirmed concerns about public health problems associated with two abandoned toxic waste sites. The community developed a vision of environmental cleanup and community revitalization. Their goals included cleanup and redevelopment plans involving improved housing, and the need for a technology and job-training center, greenway development, and a health clinic.

2. *Community Capacity Building:* Proactive, committed, and strategic leadership provided by a champion resulted in the formation of CPS Project X, a community-based organization, and the development of the broad-based CPS Project X Partnership. Among other things, the CPS Project X Partnership educated the community on the fundamentals of brownfields redevelopment and sustainable development.

3. *Consensus Building and Dispute Resolution:* Partners have been and continue to be committed to a consensus building process that rests upon a common vision among its partners. All major stakeholders have participated in the development of a common vision for the project.

4. *Multi-Stakeholder Collaborative Partnerships:* The CPS Project X Partnership established a steering committee co-chaired by CPS Project X, the City of Any Town, and the County of All Towns, and EPA. Other partners included: local banks; State Department of Health and Environmental Control; State Economic Development Administration; the University of State; and several elected officials. These partners have brought significant resources—human, technical, and institutional—to help realize the community's goals.

5. *Supportive and Facilitative Role of Government:* Several Federal agencies have provided resources and technical assistance, including EPA; the Departments of Transportation, Housing and Urban Development, and Energy; the National Institute for Environmental Health Sciences, and the Agency for Toxic Substances and Disease Registry. Federal funding for this effort has exceeded $1.5 million.

6. *Management and Implementation:* A well-formulated partnership design, which included specific subcommittees geared to address the project goals, and a set of clear objectives have resulted in a viable workplan. Assistance in organizational management issues is being provided by an expert in nonprofit organizations. Ongoing coordination is being provided by a partnership consisting primarily of the steering committee co-chairs.

7. *Evaluation Framework/Lessons Learned:* While the CPS Project X Partnership has not developed an overall evaluation framework, some measures of success are built into discreet project components such as the Health Care Clinic Workplan, Brownfields Assessment Workplan, and the Dump Superfund Initiative Workplan. A case study of this project has been completed by EPA: another is being planned by a non-government organization.

More examples of how the Model has been applied can be found in two EPA documents, the ''Federal Interagency Working Group on Environmental Justice Status Report, (February 2002). (*http://epa.gov/compliance/resources/publications/ej/iwg-status-02042002.pdf*) and the recent 2003 List of Revitalization Projects *http://epa.gov/compliance/resources/publications/ej/iwg-2003.pdf.*

IV. Evaluation Criteria (Performance Measures) for the Collaborative Problem-Solving Grant Program

As required by 40 CFR 30.63, anticipated accomplishments must be stated. The following criteria will be used to determine the effectiveness of the Environmental Justice CPS Grant Program in meeting its anticipated objective. The overarching goal of the Environmental Justice CPS Grant Program is to build the capacity of the communities to address strategically defined local environmental and/or public health issues in a collaborative problem-solving partnership, and to create positive public health and/or environmental improvements in each of the affected communities selected for this program.

The Environmental Justice CPS Grant Program is intended to seek:

1. Improvements in the capacity of affected communities to think strategically and to work with other stakeholders; and

2. Improvements in the environmental conditions in the communities that are perceived to have an impact on the health of the residents of these affected communities.

The following criteria will be used by EPA to measure the success of the overall Environmental Justice CPS Grant Program. These criteria are for the evaluation of the grant program *as a whole.* However, each grantee must include evaluation criteria for its project at the time the application is submitted. All grant applications must reflect the following four key elements:

1. Proper documentation and assessment of the local environmental and/or public health problem.

2. Development of the appropriate partnerships, including all organizations which can play a role in addressing the problem(s).

3. Formulation of a well-designed strategic plan to sustain the partnerships and to ensure resolution of the issue(s).

4. Development of mechanisms to share lessons learned from the process.

EPA will use several measures to evaluate the success of the Environmental Justice CPS Grant Program, including, but not limited to:

- Operation and maintenance of effective collaborative partnerships are sustained throughout the period of the grant and afterwards.
- More effective oversight of the grant program by EPA is achieved with OEJ

staff members and regional staff more involved in the grants.

- Significant reduction in public health and environmental risks in affected communities is achieved.
- Significant improvement in the quality of life issues for the affected communities is achieved.
- Facilitation and/or mediation services are effectively utilized to help resolve local environmental and/or public health issues in affected communities.
- Community capacity is significantly improved for program participants.
- Outcomes or lessons learned in affected communities are transferred to other similarly situated communities.

V. Environmental Justice Collaborative Problem-Solving Grant Application Instructions

A. Who May Submit Applications and May Applicants Submit More Than One?

Any affected community-based organization with nonprofit status either demonstrated through designation by the Internal Revenue Service as a section 501(c)(3) organization or incorporated as a nonprofit under applicable state law may submit an application during the period of this solicitation. Applicants must be nonprofit, non-governmental organizations to receive these Federal funds. Universities are not eligible to apply for this grant program. Please also refer to Appendix E for Guidance on Lobbying Restrictions.

The Environmental Justice CPS Grant Program is a competitive process. EPA will consider only one application per community-based organization for any given project.

The community-based organization who applies for an Environmental Justice CPS Grant must submit one original, signed by a person authorized to receive funds for the organization, and two copies of the application (double-sided copies encouraged). Applications must be reproducible (for example, stapled once in the upper left hand corner, on white paper, and with page numbers).

B. What Activities Under the Environmental Justice CPS Grants Are Eligible for Funding?

The Environmental Justice CPS Grant Program is designed for multi-media environmental issues and/or public health concerns. For this reason, each project must include activities which are authorized by two or more of the following federal environmental statutes.

(1) *Clean Water Act, section 104(b)(3):* Conduct and promote the coordination of research, investigations, experiments, training, demonstration projects, surveys, and studies relating to the causes, extent, prevention, reduction, and elimination of water pollution.

(2) *Safe Drinking Water Act, section 1442(c)(3)(A):* Develop, expand, or carry out a program (that may combine training, education, and employment) for occupations relating to the public health aspects of providing safe drinking water.

(3) *Solid Waste Disposal Act, section 8001(a):* Conduct and promote the coordination of research, investigations, experiments, training, demonstration projects, surveys, public education programs, and studies relating to solid waste (*e.g.,* health and welfare effects of exposure to materials present in solid waste and methods to eliminate such effects).

(4) *Clean Air Act, section 103(b)(3):* Conduct research, investigations, experiments, demonstration projects, surveys, and studies related to the causes, effects (including health and welfare effects), extent, prevention, and control of air pollution.

(5) *Toxic Substances Control Act, section 10(a):* Conduct research, development, monitoring, public education, training, demonstration projects, and studies on toxic substances.

(6) *Federal Insecticide, Fungicide, and Rodenticide Act, section 20(a):* Conduct research, development, monitoring, public education, training, demonstration projects, and studies on pesticides.

(7) *Marine Protection, Research, and Sanctuaries Act, section 203:* Conduct research, investigations, experiments, training, demonstration projects, surveys, and studies relating to the minimizing or ending of ocean dumping of hazardous materials and the development of alternatives to ocean dumping.

Please Note: Applications for proposed projects that are inconsistent with the above stated EPA statutory authorities or goals of the program are ineligible for funding and will not be evaluated and ranked.

C. Have You Received Any Other Grants or Cooperative Agreements From EPA in the Last 3 Years?

Please list the grant or cooperative agreement number, title of the project, and amount of funding provided by EPA.

Please Note: Do not use the same project description for this application that was used for any prior award. To do so will disqualify your application.

D. How Much Money May Be Requested, and Are Matching Funds Required?

Costs will be determined in accordance with OMB Circular No. A–122 for nonprofit organizations. The ceiling in federal funds for individual grants is $100,000. Funds can be dispersed as needed or up to 80% of the grant award can be obtained. The remaining 20% of the grant award will be available upon the successful completion of the grant and the acceptance by EPA of the final report as detailed in the grant. Applicants are *not* required to provide matching funds.

E. Are There Any Restrictions on the Use of the Federal Funds?

Yes. EPA grant funds can only be used for the purposes set forth in the grant agreement, and must be consistent with the statutory authority for the award. Grant funds from this program cannot be used for matching funds for other federal grants, lobbying, or intervention in federal regulatory or adjudicatory proceedings. In addition, the grantee may not use these federal assistance funds to sue the federal government or any other government entity. Refer to 40 CFR 30.27, entitled ''Allowable Cost.'' The scope of Environmental Justice CPS grants may not include construction, promotional items (*e.g.,* T-shirts, buttons, hats, and furniture purchases).

F. Who Should You Call if You Have Questions About the Environmental Justice CPS Grants?

For questions concerning CPS grants, you may contact the Environmental Justice Coordinator in your region. Because this is a competitive grant program, any questions concerning the application and review process must be submitted via e-mail or fax in order to ensure fairness to all possible applicants. You can contact the Project Officer by calling direct to (202) 564–2602 or to the Toll-free number 1–800–962–6215. All questions must be sent via e-mail to *smith.linda@epa.gov* or by fax to (202) 501–1162. They will be posted on the Web site and sent via the EJ–EPA list serv.

G. What Must the Environmental Justice CPS Grant Contain?

Proposals from community-based organizations must have the following (Forms Can be Downloaded from *http://www.epa.gov/ogd/AppKit/application.htm*):

1. *Form SF 424—Application for Federal Assistance.* The official form is required for all federal grants. It requests basic information about the grantee and the proposed project.

2. *Other Forms Required.*

Budget Form SF 424A. Provides information on your budget. Budget figures/projections should support your workplan narrative.

Separate Detailed Budget. The detailed budget should include the specific components of the general categories you listed on the SF 424A (*e.g.,* personnel costs, fringe benefits, specific travel, equipment, supplies, and contractor costs, broken down by project phases).

SF 424B. Assurances—Non-Construction Programs.

Preaward Compliance Review Report.

Certification Regarding Lobbying.

Quality Assurance Statement (if a research project).

3. *A Project Workplan Narrative of the Proposal not to exceed 15 Typewritten Pages.* A workplan narrative describes the applicant's proposed project. The typed pages of the workplan must be in 12 point font, on letter-size paper (8½ x 11 inches), single-spaced, single-sided, and have 1″ margins. The project workplan narrative is one of the most important components of your application and (assuming that all other required materials are submitted) will be used as the primary basis for selection. The workplan narrative must include all of the information described in Item G below.

4. *Letter(s) of Commitment.* Your application must include letters of commitment from the other stakeholder partners/organizations identified in your application.

5. *Documentation of Nonprofit Status.* Any affected community-based organization with nonprofit status either demonstrated through designation by the Internal Revenue Service as a section 501(c)(3) organization or incorporated as a nonprofit under applicable state law may submit an application during the period of this solicitation. Applicants must be nonprofit, non-governmental organizations to receive these Federal funds. Universities are not eligible to apply for this grant program. The application must include documentation as evidence of the organization's current nonprofit status.

6. *Resumes of the Key Personnel.* The application must include resumes of the Principal Investigator or Project Manager, and two other key personnel who will be significantly involved in the project.

7. *Evaluation Criteria for How To Determine the Success of The Project (Performance Measures).*

8. *The answer to the question concerning past awards in Section V–C.*

Note: Applications that do not include *ALL* the information listed above will not be considered.

Please mark any information in the proposal that you consider confidential. EPA will follow the procedures at 40 CFR part 2 if information marked confidential is requested from the Agency under the Freedom of Information Act.

H. How Will the Applications Be Evaluated?

The applications will be evaluated by an EPA Review Panel and selected according to the following criteria. The corresponding points next to each criterion are the weights EPA will use to evaluate the applications. Please note that certain sections are given greater weight than others. Your application will be ranked based on the following evaluation criteria:

1. Clear and Concise Description of the Project (35 points)

The project workplan narrative is one of the most important components of your application and (assuming that all other required materials are submitted) will be used as the primary basis for selection. The workplan narrative must provide the following information:

a. Describe your community-based organization and its qualifications to undertake this collaborative problem-solving project. In addition, describe your qualifications as the Principal Investigator/Project Manager to undertake this project. Include whether or not your organization has received any grant/cooperative agreement from EPA in the last 3 years as described in Item V–C. above. (5)

b. Describe the community being served (*e.g.,* demographics, geographic location, community history and assets, issues of concern). Provide a discussion of the environmental and/or public health issues your project seeks to address. (5)

c. Describe the strategic goals your project seeks to accomplish. (5)

1. Describe the process your organization and your collaborating partners used to formulate these goals (*e.g.,* needs assessment, planning charettes).

2. Describe how you intend to build consensus among your partners around these goals.

3. Describe how achievement of those goals will address the issues of concern and improve the environment and/or public health of your community.

d. Describe the specific steps you have and/or will undertake to engage in constructive engagement among collaborative partners, and to establish and manage a formal collaborative problem-solving partnership, including but not limited to the following: (5)

1. Strategies used;

2. Partnership structure (*e.g.,* committee, work group, etc.);

3. Key obstacles to overcome;

4. Communications and coordination mechanisms and procedures;

5. Use of consensus building and dispute resolution techniques;

6. Decision-making process; and

7. Use of formal agreements.

e. Describe the organizations which are members of the formal collaboration, including qualifications of each organization other than the applicant; the roles of each organization; the commitments made by each organization; and the ways by which each organization will implement their commitments. (5)

f. Provide an implementation plan. Describe in chronological order the activities you and your partners will undertake to carry this project. Use of a timeline is encouraged. (5)

1. Describe your intended activities to build the capacity of your community-based organization, the impacted community, and other stakeholder partners to achieve the goals of your project. Describe how such capacity building activities will enhance the ability of partners to:

- address the strategically-defined issues; and
- undertake the collaborative problem-solving partnership.

I.

2. Provide the steps you intend to take to achieve the project's objectives and desired results. Include an analysis of the obstacles, gaps, and/or conflicts that your project will face, and discuss how your implementation strategies are designed to overcome them.

g. Describe how the project will develop and incorporate an evaluation strategy, establish and track milestones and performance measures (activities, outputs, and outcomes), and share lessons learned. Areas for evaluation may include, but are not limited to, the following: (5)

1. Improvements in the capacity of the community-based organization to form partnerships;

2. Improvements in the ability of the community-based organization to build and sustain a strong working relationship with the partners in order to resolve problems in a collaborative manner; and

3. Improvements in the environmental and/or public health conditions in the community.

2. Adherence to the Environmental Justice Collaborative Problem-Solving Model Described in Appendix D (25 points)

The following seven elements have been identified as key factors to the success of an Environmental Justice Collaborative Problem-Solving Model:

1. Issue Identification, Community Vision, and Strategic Goal Setting;
2. Community Capacity Building;
3. Consensus Building and Dispute Resolution;
4. Multi-Stakeholder Partnerships and Resource Mobilization;
5. Supportive and Facilitative Role of Government;
6. Management and Implementation; and
7. Evaluation, Lessons Learned, and Replication of Best Practices.

a. Please describe how your project utilizes the elements of a collaborative problem solving model, and how each contribute to the overall success of the project.

b. Describe how the project, either through its implementation or results, will contribute to further development of the Environmental Justice Problem-Solving Model.

3. A detailed budget which shows how the funds will be specifically used in terms of personnel, fringe benefits, travel, equipment, supplies, contractor costs, and other costs. Funds cannot be used for construction, lobbying, or litigation against the government. The budget must list proposed milestones with deadlines, and estimated costs and completion dates. (10 points)

4. An appendix which describes the qualifications of the Principal Investigator or Project Manager and explains why he/she is qualified to undertake this project. (10 points)

5. A Memorandum of Agreement signed by each representative of the collaborative partnership which identifies the roles and responsibilities of each partner. Each partner is valued at 2 points with a maximum possible total of 10. (10 points)

Please Note: A letter of support from an individual or entity does not qualify as a reflection of an agreement to participate in a collaborative partnership.

6. A set of evaluation criteria which reflect how the success of the project will be measured. These should include qualitative and quantitative measures. (10)

I. When and Where Must Applications Be Submitted?

The applicant must submit one signed original application with required attachments and two copies. Applications must be postmarked by U.S. Postal Service or date stamped by courier service by 12 p.m. Eastern Time, September 30, 2003. Use the appropriate address below, depending on your method of delivery.

Applications Sent by FAX or E-Mail Will Not Be Accepted

VIA U.S. Postal Service

U.S. Environmental Protection Agency, Office of Environmental Justice (MC 2201A), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001,

Attention: Linda K. Smith, Project Officer, Phone: (202) 564–2602.

VIA Federal Express, Airborne, United Parcel Service, or Other Courier Service

U.S. Environmental Protection Agency, Office of Environmental Justice, Ariel Rios Building South, Room 2232, 1200 Pennsylvania Ave., NW., Washington, DC 20004.

Attention: Linda K. Smith, Project Officer, *Phone:* (202) 564–2602.

Applications Sent by Fax or E-Mail Will Not Be Accepted

VI. Selection Process and Program Schedule

A. How Will Applications Be Reviewed?

A panel of EPA employees will review, evaluate, and rank the applications of potential grant recipients. Applications will be screened to ensure that they meet all eligible activities and requirements described in sections IV and V above.

B. How Will the Final Selections Be Made?

After the individual projects are reviewed and ranked, OEJ will compare the best applications and make final selections. Additional factors that OEJ will take into account include geographic and socioeconomic balance, the diverse nature of the projects, the projected use of the funds, and projects whose environment and/or public health benefits can be sustained after the grant is completed. The OEJ Director will make the final grant selections.

Please note that this is a very competitive grants program. Limited funding is available and many grant applications are expected to be received. Therefore, the Agency cannot fund all applications. If your project is not funded, a listing of other EPA grant programs may be found in the Catalog of Federal Domestic Assistance. This publication is available on the Internet at *http://www.epa.gov/compliance/recent/ej.html.*

C. How Will Applicants Be Notified?

After all applications are received, OEJ will mail acknowledgments to the applicants. Once applications have been recommended for funding, OEJ will notify the finalists. OEJ will notify those applicants in writing whose projects are not selected for funding.

D. What Is the Expected Timeframe for Reviewing and Awarding the Environmental Justice CPS Grants?

May 30, 2003—FY 2003 OEJ Collaborative Problem-Solving Grant Program Application Guidance is available and published in the **Federal Register** and on the Internet.

June 1, 2003 to September 30, 2003—Eligible grant recipients develop, complete and submit their applications.

September 30, 2003—Applications must be date stamped by courier service or postmarked by U.S. Postal Service by 12 p.m. Eastern Time, September 30, 2003.

October 1, 2003–November 3, 2003—EPA reviews and evaluates applications.

November 22, 2003–December 22, 2003—Applicants will be contacted if their application is being considered for funding.

January 1, 2004—The OEJ Director will make final recommendations for award.

January 31, 2004—OEJ will release the national announcement of the 2003 recipients.

VII. Reporting Requirements/Special Conditions

Activities must be complete and funds spent within the timeframe specified in the three-year grant award. Project start dates will depend on the grant award date. OEJ anticipates grant awards by January 1, 2004. Substantial communication between EPA and the grantee will include:

A. *Quarterly Reports*—The grant recipient's Project Manager will be required to submit quarterly reports to update OEJ on the project's progress. The reports should include, but not be limited to, information identified under the elements of the Environmental Justice Collaborative Problem-Solving Model that pertain to:

1. Specific grant activities accomplished, such as establishing an effective, collaborative partnership between the grant recipient and other stakeholders;
2. Operating and maintaining an effective collaborative partnership and problem-solving mechanism;
3. Noteworthy community capacity-building activities that took place;

4. Identifying activities that resulted in the improvement of the community's environmental and/or public health concerns;.

5. Stating how funding resources were committed; and,

6. Identifying any issues/problems encountered and the methods for resolution.

B. *Monthly Conference Calls*—Moreover, the grantee will confer on a monthly basis with the OEJ staff person identified as the technical contact. A template will be furnished on those items to be discussed. In general, every call and report will follow the evaluation criteria described in section IV.

C. *Development of Performance Measures for Grant*—As a condition to receiving Environmental Justice CPS grants, grantees are required to develop measurable outcomes to be achieved through the activities for which these grant funds were awarded. The performance measures (evaluation criteria) should focus on solid, qualitative activities related to the grantee's activities, outputs, and outcomes. These performance measures will help gather insights concerning successful implementation strategies and generate lessons learned that may be applicable to future projects under this grant program.

The success of this grant program will be entirely dependent on the work of the grantees. Therefore, EPA and the grantee will examine whether, as a result of the grantee's activities and outputs, there has been:

- Better overall environmental and/or public health protection for community residents;
- Significant improvement in the quality-of-life of community residents;
- Significant increase in the community's capacity as it relates to understanding the environmental and/or public health issues affecting the community; a better understanding of the permitting processes; a better understanding of the use of environmental laws and their implementing regulations to address environmental justice concerns; and a better understanding of alternative dispute resolution and negotiation techniques;
- Effective use of the collaborative problem-solving processes;
- Transferability of the lessons learned to other communities similarly situated; and,
- Effective community revitalization.

D. *Final Report Requirement*—All grant recipients must submit a Final Technical Report for EPA approval within ninety (90) days of the end of the project period. A draft of this report should be submitted within 60 days of the end of the project period. A Financial Status Report is also required and is described in the award agreement document. The EPA will collect, review, and disseminate those final reports which can serve as models for future projects.

E. *Change in Project Requiring Project Officer Approval*—The grant recipient is responsible for the successful completion of the project. However, any change in the Project Manager or Principal Investigator is subject to approval by the EPA Project Officer. You must immediately submit the reason for the change and the qualifications of the new Project Manager or Principal Investigator to the Project Officer in writing. This can be sent by e-mail to *smith.linda@epa.gov* or by fax to (202) 501–1162.

For further information about this Environmental Justice CPS grant program, please visit the EPA's Web site at: *http://www.epa.gov/compliance/environmentaljustice/grants/index.html* or call our hotline at 1–800–962–6215 (available in Spanish).

Dated: May 30, 2003.

Barry E. Hill,

Director, Office of Environmental Justice.

[FR Doc. 03–14324 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0164; FRL–7306–5]

Bacillus Thuringiensis VIP3A Insect Control Protein; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0164, must be received on or before July 7, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5412; e-mail address: cole.leonard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal productiom (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *EPA Docket*. EPA has established an official public docket for this action under docket ID number OPP–2003–0164. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that are available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet

under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose 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 EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0164. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP–2003–0164. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2003–0164.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP–2003–0164. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of

the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 29, 2003.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the Syngenta Seeds, Inc. petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Syngenta Seeds, Inc.

PP 3G6547

EPA has received a pesticide petition (PP 3G6547) from Syngenta Seeds, Inc., P.O. Box 12257, 3054 Cornwallis Road, Research Triangle Park, NC 27709–2257, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the pesticide *Bacillus thuringiensis* VIP3A insect control protein, as expressed in event COT102, and the genetic material necessary for its production in or on cotton.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Syngenta Seeds, Inc. has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Syngenta Seeds, Inc., and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

Syngenta has developed a new cotton line that expresses an insect control protein designated VIP3A. It has been genetically incorporated into a cotton plant product identified as *Bacillus thuringiensis* (*Bt*) VIP3A insect control protein as expressed in event COT102. VIP3A is one of a novel class of recently discovered insecticidal proteins that occur naturally in *Bacillus thuringiensis*. The VIPs (vegetative insecticidal proteins) are produced during vegetative bacterial growth.

Other than its demonstrated insecticidal activity, VIP3A is not known to have any other biological or catalytic function. Although, VIP3A protein shares no homology with known Cry proteins, extensive testing has established that VIP3A is similarly very specific in its activity, and has demonstrated toxicity only to the larvae of certain lepidopteran species, including key pests of cotton. Further, because VIP3A appears to target a different receptor than Cry proteins in sensitive species, it represents a potentially useful tool in the prevention or management of pest resistance to Cry proteins.

Upon commercial introduction, the use of transgenic VIP3A cotton plants is expected to offer an important new option in lepidopteran pest control and integrated pest management programs. Moreover, VIP3A cotton will be an attractive, biologically based alternative to the use of foliar insecticides. The use of VIP3A cotton plants is expected to offer substantial environmental and worker safety benefits associated with the reduced need for broad-spectrum insecticides. Additionally, benefits to cotton growers will likely include greater profitability, convenience and predictability in producing a high-yielding cotton crop.

VIP3A-expressing cotton plants derived from transformation event COT102 have been field tested under U. S. Department of Agriculture (USDA) notifications and in compliance with the guidelines for USDA-regulated plantings in 2000, 2001, and 2002. The overall results of those trials have indicated that cotton plants derived from event COT102 have significant and specific insecticidal activity against several lepidopteran pests including, but not limited to, *Helicoverpa zea* (cotton bollworm), *Heliothis virescens* (tobacco budworm), and *Pectinophora gossypiella* (pink bollworm)

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues. Cotton, Gossypium hirsutum*, has been genetically modified to be resistant to selected *lepidopteran* insect pests. Insect protection was accomplished by the insertion of the VIP3A(a) gene, which was cloned from *Bacillus thuringiensis* strain AB88. The identity of the active pesticidal ingredient in cotton plants derived from transformation event COT102 includes the protein VIP3A and the genetic material necessary for its production in cotton. Research has demonstrated the

specific insecticidal properties of VIP3A to certain *lepidopteran* insects in cotton as well as its lack of effects on nontarget organisms such as mammals, birds, fish, and beneficial insects.

2. *Magnitude of residue.* A determination of the magnitude of residue at harvest is not required for residues exempt from tolerances. However, the petitioner has provided data on the quantity of VIP3A protein measured in various plant parts including seeds of VIP3A cotton, as measured by enzyme linked immunosorbent assay (ELISA). Additionally, the petitioner has provided data on the quantity or presence of VIP3A protein in processed cottonseed products.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytical method is not required because this petition requests an exemption from tolerances. However, the petitioner has submitted an analytical method for detection of the VIP3A protein in cottonseed by ELISA analysis.

C. Mammalian Toxicological Profile

The VIP3A(a) gene expressed in event COT102 cotton is very similar (ca. 99% homology) to VIP3A or VIP3A--like genes that appear to occur commonly in *Bt* strains from a variety of sources. In addition, it has been determined that the VIP3A protein demonstrates insect specific toxicity and must be ingested to be active. Once in the insect gut, the VIP3A protein binds to specific receptors (different from those bound by Cry1A proteins), inserts into the membrane and forms ion-specific pores. These events disrupt the digestive processes and cause death of the insect. The lack of mammalian toxicity has been confirmed in numerous safety studies conducted in laboratory animals, which are traditional experimental surrogates for humans. These studies, summarized herein, demonstrate the lack of toxicity of the VIP3A protein following high-dose acute oral exposures to mice, rapid degradation of VIP3A upon exposure to simulated gastric fluid, and the lack of amino acid sequence similarity of the VIP3A protein to proteins known to be mammalian toxins or human allergens. It can be concluded from these studies that the VIP3A protein will be non-toxic to humans.

When proteins are toxic, they are known to act via acute mechanisms and at very low doses (Ref. 1). Therefore, when a protein demonstrates no acute oral toxicity in high-dose testing using a standard laboratory mammalian test species, this supports the determination that the protein will be non-toxic to humans and other mammals, and will not present a hazard under any realistic exposure scenario, including long-term exposures.

Studies conducted to assess the mammalian safety of VIP3A protein have demonstrated no toxicity. Four acute oral toxicity studies in mice have been completed. Three of the VIP3A test substances used were produced via microbial expression systems and one prepared by extracting protein from leaves of VIP3A event Pacha-derived corn plants. The four test substances contained VIP3A protein that differed from the VIP3A protein expressed in event COT102 by zero to two amino acids. At maximum dosage the microbially expressed test substance was administered at a level of 5,000 milligrams/kilogram (mg/kg) with an estimated acute lethal dose $(LD)_{50}$ by gavage determined to be >3,675 mg VIP3A/kg mg/kg/bwt/wt. Because toxicity was not observed at this dose, it can be concluded that the LD_{50} for pure VIP3A protein is >3,675 mg/kg body weight. The VIP3A protein in both the microbial and plant derived test substance was determined to be substantially equivalent to VIP3A produced in event COT102 derived cotton plants, as measured by biological activity, protein size, immunreactivity, mass spectral analysis of amino acid sequence, and apparent lack of post-translational modifications.

The amino acid sequence of VIP3A is not homologous to that of any known or putative allergens described in public data bases. The VIP3A protein is not derived from a known source of allergens and does not display characteristics commonly associated with allergens, including glycosylation or stability to heat and food processing. Additionally, VIP3A is susceptible to gastric digestion by pepsin and did not provoke an allergic response in an experimental atopic dog model of human food allergy.

VIP3A protein appears to be present in multiple commercial formulations of *Bacillus thuringiensis* microbial insecticides at concentrations estimated to be ca. 0.4 32 parts per million (ppm). This conclusion is based on the presence of proteins of the appropriate molecular weight and immunoreactivity (by SDS-PAGE and western blot), and quantitation by ELISA. Therefore, it is conceivable that small quantities of VIP3A protein are present in the food supply because VIP3A or a very similar protein, based on size and immunoreactivity appears to be present in currently registered insecticide products used on food crops, including fresh market produce. These commercial *Bacillus thuringiensis* products are all exempt from food and feed tolerances.

D. Aggregate Exposure

1. Dietary exposure—i. *Food.* Food products derived from cotton (refined cottonseed oil and cellulose linters fiber) are highly processed and are essentially devoid of any proteins. Moreover, no VIP3A protein was detected in refined cottonseed oil or cotton fiber produced from event COT102-derived VIP3A cotton plants. Therefore, no human dietary exposure to VIP3A protein is expected to occur via VIP3A cotton. Even if dietary exposure to VIP3A protein were to occur, data derived from bioinformatic analyses as well as direct *in vitro* and *in vivo* testing collectively indicate that the VIP3A protein is unlikely to have allergenic potential. The amino acid sequence of VIP3A is not homologous to that of any known or putative allergens described in public data bases. The VIP3A protein is not derived from a known source of allergens and does not display characteristics commonly associated with allergens, including glycosylation or stability to heat and food processing. Additionally, VIP3A is susceptible to gastric digestion by pepsin and did not provoke an allergic response in an experimental atopic dog model of human food allergy.

ii. *Drinking water.* No exposure to VIP3A and the genetic material necessary for its production in cotton via drinking water is expected. The proteins are incorporated into the plant and will not be available. However, if exposure were to occur by this route, no risk would be expected because the VIP3A protein is not toxic to mammals.

2. *Non-dietary exposure.* Non-dietary exposure is not anticipated, due to the proposed use pattern of the product. Exposure via dermal or inhalation routes is unlikely because the plant-incorporated protectant is contained within plant cells. However, if exposure were to occur by non-dietary routes, no risk would be expected because the VIP3A protein is not toxic to mammals.

E. Cumulative Exposure

Because there is no indication of mammalian toxicity to the VIP3A protein, it is reasonable to conclude that there are no cumulative effects for this plant-incorporated protectant.

F. Safety Determination

1. *U.S. population.* The lack of mammalian toxicity at high levels of exposure to the VIP3A protein

demonstrates the safety of the product at levels well above possible maximum exposure levels anticipated via consumption of processed food products produced from VIP3A cotton. Moreover, little to no human dietary exposure to VIP3A protein is expected to occur via VIP3A cotton. Due to the lack of toxicity of the VIP3A protein and its very low potential for allergenicity, dietary exposure is not anticipated to pose any harm for the U.S. population. No special safety provisions are applicable for consumption patterns or for any population sub-groups.

2. *Infants and children.* The plant-incorporated protectant active ingredient, *Bacillus thuringiensis* VIP3A insect control protein and the genetic material necessary for its production in cotton, demonstrates no mammalian toxicity. Thus, there are no threshold effects of concern and, consequently, there is no need to apply an additional margin of safety.

G. Effects on the Immune and Endocrine Systems

The safety data submitted show no adverse effects in mammals, even at very high dose levels, and support the prediction that the VIP3A protein would be non-toxic to humans. Therefore, no effects on the immune or endocrine systems are predicted. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Ref. 1). Further, the VIP3A protein is derived from a source that is not known to exert an influence on the endocrine system.

H. Existing Tolerances

There are no existing tolerances for the *Bacillus thuringiensis* VIP3A protein and the genetic material necessary for its production. Other *Bacillus thuringiensis* based pesticide products are exempt from tolerances.

I. International Tolerances

There are no existing international tolerances or exemptions from tolerance for the *Bacillus thuringiensis* VIP3A protein and the genetic material necessary for its production.

J. Reference

1. Sjoblad, R. D., J. T. McClintock and R. Engler, (1992) Toxicological Consideration for Protein Components of Biological Pesticide Products. *Regulatory toxicol Pharmacol* 15: 3-9

[FR Doc. 03–14199 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OA–2003–0005: FRL–7508–7]

Public Involvement Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of New Public Involvement Policy.

SUMMARY: The EPA is issuing its new Public Involvement Policy. The purpose of today's Notice is to advise the public and present the Policy. The new Policy provides guidance to EPA staff on effective and reasonable means to involve the public in EPA's regulatory and program implementation decisions. The core of the Policy is the recommended seven basic steps for effective public involvement, which the Agency should consider when making major decisions on rules, policies and program implementation activities. The Policy is directed internally, but EPA's partners in states, tribes or local governments may also find it to be a useful tool for them.

FOR FURTHER INFORMATION CONTACT: Patricia Bonner, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001; 202–566–2204; *bonner.patricia@epa.gov.* For printed copies, telephone 202–566–2216.

SUPPLEMENTARY INFORMATION: How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OA–2003–0005. The official public docket consists of the complete Public Involvement Policy with its appendices and addenda, public comments on the 1981 and draft 2000 Policy, the Agency's Response to Comments and the Framework for Implementing EPA's Public Involvement Policy. The official public docket is the collection of materials that is available for public viewing at the Office of Environmental Information Docket, 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.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/ or use http://www.epa.gov/publicinvolvement to access the Policy and all its attachments. Electronic versions of items in the public docket are available through EPA's electronic public docket and comment system, EPA Dockets (EDOCKET). You may use EDOCKET at *http://www.epa.gov/edocket/* to access the index listing of the contents of the official public docket and documents that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number. You may still access any of the publicly available docket materials through the EPA Docket Center.

Background

On January 19, 1981, the Environmental Protection Agency (EPA) published its first Agency-wide Public Participation Policy (46 FR 5736, Jan. 19, 1981). In November 1999, the EPA requested public comment on whether and how to change that Policy, and subsequently began a process to revise the policy and create a plan to implement it across the Agency. In December 2000, EPA released a draft revised Public Involvement Policy for public comment (65 FR 82335, Dec. 28, 2000). The comment period closed on July 31, 2001, following a two-week internet-based dialogue on ''Public Involvement in EPA Decisions,'' which included 1,144 participants from all 50 states.

Overview of EPA's New Public Involvement Policy

The Policy's core elements are the following seven basic steps for effective public involvement:

1. Plan and budget for public involvement activities.
2. Identify the interested and affected public.
3. Consider providing technical or financial assistance to the public to facilitate involvement.
4. Provide information and outreach to the public.
5. Conduct public consultation and involvement activities.
6. Review and use input, and provide feedback to the public.
7. Evaluate public involvement activities.

This Policy is meant to encourage development of new tools for public involvement and should not limit the degree or types of public involvement already in use at EPA. Agency guidance, which EPA is issuing simultaneously with this Policy, provides specific recommendations for accomplishing each of these seven steps, while also acknowledging the need for EPA officials to use discretion when

planning and implementing public involvement activities.

The Policy reflects changes over the past 22 years such as:

- New and expanded public participation techniques.
- New options for public involvement through the Internet.
- EPA's emphasis on assuring compliance.
- Increased use of partnerships and technical assistance.
- Increased public access to information.
- Increased capacity of States, Tribes and local governments to carry out delegated programs.

The Policy also reflects EPA's experience with public involvement from the national to the local level, and incorporates many ideas provided to EPA through public comments on the draft Policy. Today's Notice is limited to this brief introduction and the core policy statement. Concurrent with this Notice, EPA is also issuing the following supporting documents to facilitate and promote support the Policy's implementation:

Appendix 1—''Guidance for Implementing Public Involvement at EPA'' [*http://www.epa.gov/publicinvolvement/policy2003/guidance.pdf.*]

Appendix 2—Definitions that are integral to this Policy.

Appendix 3—Examples of EPA's Public Involvement Regulations.

Appendix 4—Federal Advisory Committees.

Addendum 1—Selected tools the Agency has developed since 1981 to assist EPA staff and regulatory partners in conducting public involvement and consultation.

Addendum 2—Summary of comments and EPA's responses.

Two additional documents may be of interest. The Agency's complete ''Response to Comments on EPA's Draft 2000 Public Involvement Policy'' is available at http://www.epa.gov/publicinvolvement/responsetocomments.pdf and the ''Framework for Implementing EPA's Public Involvement Policy'' is available at *http://www.epa.gov/publicinvolvement/framework.pdf.* (All documents referenced in the Policy are also available upon request to Public Involvement Staff, USEPA/OPEI/OEPI/PPCD Mail Code 1807T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.)

The goal of this Policy is to improve the effectiveness of EPA's public involvement activities, ensure well-informed decisions, and encourage innovative methods for involving the public. As EPA implements the Policy, the Agency plans to share its experiences with states, tribes, local governments and other partners and interested parties.

Dated: May 29, 2003.

Christine Todd Whitman,

Administrator.

EPA's Public Involvement Policy (Final May 2003)

Introduction

EPA's mission is to protect human health and the environment. To achieve that mission, EPA needs to continue to integrate, in a meaningful way, the knowledge and opinions of others into its decision-making processes. Effective public involvement can both improve the content of the Agency's decisions and enhance the deliberative process. Public involvement also promotes democracy and civic engagement, and builds public trust in government.

EPA has long been committed to public involvement. The fundamental premise of this Policy is that EPA should continue to provide for meaningful public involvement in all its programs, and consistently look for new ways to enhance public input. EPA staff and managers should seek input reflecting all points of view and should carefully consider this input when making decisions. They also should work to ensure that decision-making processes are open and accessible to all interested groups, including those with limited financial and technical resources, English proficiency, and/or past experience participating in environmental decision-making. Such openness to the public increases EPA's credibility, improves the Agency's decision-making processes, and informs its final decisions. At the same time, EPA should not accept any recommendation or proposal without careful, critical examination.

This Policy supplements, but does not amend, existing EPA regulations that prescribe specific public participation requirements applicable to EPA's activities under specific statutes, such as those found at 40 CFR part 25 ''Public Participation in Programs Under the Resource Conservation and Recovery Act, the Safe Drinking Water Act, and the Clean Water Act.'' (See 40 CFR part 25, which can be found at *http://www.epa.gov/publicinvolvement/pdf/part25.pdf.*) The public participation requirements contained in such regulations specify the minimum required level of public participation. (A partial listing of existing public participation regulatory requirements is contained in Appendix 3.) Whenever feasible, Agency officials should strive to provide increased opportunities for public involvement above and beyond the minimum regulatory requirements.

What Is Public Involvement?

The term ''public involvement'' is used in this Policy to encompass the full range of actions and processes that EPA uses to engage the public in the Agency's work, and means that the Agency considers public concerns, values, and preferences when making decisions. The term ''the public'' is used in the Policy in the broadest sense to include anyone, including both individuals and organizations, who may have an interest in an Agency decision. (See Appendix 2 for a detailed definition of ''public'' and other important terms.)

What Are the Purposes, Goals and Objectives of This Policy?

The purposes of this Policy are to:

- Improve the acceptability, efficiency, feasibility and durability of the Agency's decisions.
- Reaffirm EPA's commitment to early and meaningful public involvement.
- Ensure that EPA makes its decisions considering the interests and concerns of affected people and entities.
- Promote the use of a wide variety of techniques to create early and, when appropriate, continuing opportunities for public involvement in Agency decisions.
- Establish clear and effective guidance for conducting public involvement activities.

Effective public involvement will make it easier for the public to contribute to the Agency's decisions, build public trust, and make it more likely that those who are most concerned with and affected by Agency decisions will accept and implement them. This policy supports EPA in meeting statutory and regulatory requirements regarding public participation, particularly in environmental permitting programs and enforcement activities.

EPA goals for public involvement processes are to:

- Foster a spirit of mutual trust, confidence, and openness between the Agency and the public.
- Ensure that the public has timely, accessible and accurate information about EPA programs in a variety of formats so that people can better understand the implications of potential alternative courses of action.
- Consult with interested or affected segments of the public and take public viewpoints into consideration when making decisions.
- Learn from individuals and organizations representing various public sectors and the information they are uniquely able to provide (community values, concerns, practices, local norms, and relevant history, such as locations of past contaminant sources, potential impacts on small businesses or other sectors, industry conducted study results, etc.)
- Solicit assistance from the public in understanding potential consequences of technical issues, identifying alternatives for study, and selecting among the alternatives considered.
- Keep the public informed about significant issues and changes in proposed programs or projects.
- Foster, to the extent possible, equal and open access to the regulatory process for all interested and affected parties.
- Understand the goals and concerns of the public, and respond to them.
- Anticipate conflict and encourage early discussions of differences among affected parties.

• Promote the public's involvement in the Agency's mission of protecting human health and the environment.

• Explain to the public how its input affected the Agency's decision.

To achieve these purposes and goals, while recognizing resource constraints, Agency officials should strive to provide for, encourage, and assist public involvement in the following ways:

• Involve the public early and often throughout the decision-making process.

• Identify, communicate with and listen to affected sectors of the public (Agency officials should plan and conduct public involvement activities that provide equal opportunity for individuals and groups to be heard. Where appropriate, Agency officials should give extra encouragement and consider providing assistance to sectors, such as minority and low-income populations, small businesses, and local governments, to ensure they have full opportunity to be heard and, where possible, access to technical or financial resources to support their participation.)

• Involve members of the public in developing options and alternatives when possible and, before making decisions, seek the public's opinion on options or alternatives.

• Use public input to develop options that facilitate resolution of differing points of view.

• Make every effort to tailor public involvement programs to the complexity and potential for controversy of the issue, the segments of the public affected, the time frame for decision making and the desired outcome.

• Develop and work in partnerships with state, local and tribal governments, community groups, associations, and other organizations to enhance and promote public involvement.

When Does This Policy Apply?

This Policy applies to all EPA programs and activities. In programs or activities where the public is already meaningfully involved, EPA can use this Policy to enhance that public involvement. Where the existing level of public involvement needs to improve, this Policy provides suggestions for how to move forward. Finally, this Policy can serve as a model for building public involvement into new programs as they are developed.

The activities where conducting meaningful public involvement should particularly be considered include:

• EPA rulemaking, when the regulations are expected to be classified as Significant Actions (under the terms of Executive Order 12866).

• EPA issuance or significant modification of permits, licenses or renewals.

• Selection of plans for cleanup, remediation or restoration of hazardous waste sites or Brownfields properties.

• EPA's decision on whether to authorize, delegate or approve states or local governments to administer EPA programs consistent with the relevant regulatory requirements for each program (Note: Tribes seeking approval to administer environmental programs under EPA statutes generally also seek ''treatment in a similar manner as a state (TAS)'' status from EPA. Appropriate opportunities for public participation are contained in the relevant statutory and regulatory provisions establishing a TAS process. Consult with the Office of Regional Counsel or the Office of General Counsel, and/or the American Indian Environmental Office for assistance.)

• All other policy decisions that the Administrator, Deputy Administrator or appropriate Assistant, Regional or Associate Administrator determine warrant public participation in view of EPA's commitment to involve the public in important decisions.

• The development of significant information products (as the Office of Environmental Information has defined them in Appendix 2: Definitions).

• For activities not listed here, EPA staff may use this Policy in whole or in part to strengthen decision making.

In planning and conducting public involvement activities, Agency officials should rely on the sound use of discretion. The Policy is not a rule, is not legally enforceable, and does not confer legal rights or impose legal obligations upon any member of the public, EPA or any other agency. Resource constraints, the need for timely action and other considerations may affect the appropriate nature and extent of public involvement. For example, a compelling need for immediate action may make it appropriate to limit public involvement. In particular, the desire to reach agreement among all parties, while valuable, should not prevent the Agency from carrying out its responsibility to make decisions or take actions to preserve and protect the environment and public health.

Nevertheless, the Agency should approach all decision making with a bias in favor of significant and meaningful public involvement. Experience throughout government has shown that a lack of adequate participation or of effective means for participation can result in decisions that do not appropriately consider the interests or needs of those that will be most affected by them. Furthermore, early involvement can ultimately reduce delay, by avoiding time-consuming review, public debate or litigation. Finally, decisions based on meaningful public involvement are likely to be better in substance and stand the test of time, avoiding the need to reopen controversial issues.

Does This Policy Affect Authorized, Approved or Delegated Programs?

EPA developed this Policy for EPA staff use, but it also may be useful to States, Tribes and local governments that implement federally delegated, authorized or approved programs. EPA encourages these entities to adopt similar public involvement policies if they have not already done so. EPA intends to discuss the effectiveness of their public involvement activities during periodic meetings with States, Tribes and local governments, and will obtain their input about ways to improve EPA's activities. EPA will not use whether a State, Tribe or local government has adopted EPA's Public Involvement Policy as a criterion for the authorization, approval or delegation of programs or the award of grants. In general, recipients may use grants for continuing environmental programs and Performance Partnership Grants to fund public involvement activities to the extent that costs are allowable under OMB Circular A–87 and applicable EPA regulations. (Note: Some statutory or regulatory provisions require compliance with certain public participation requirements before EPA may approve a grant. *See* 40 CFR 25.11 and 25.12.) The grant applicant may comply with such requirements without adopting EPA's Policy.

What Are the Roles of States, Tribes and Local Governments?

State agencies, Tribes and some local governments have unique roles regarding EPA's programs and decisions:

1. State agencies, Tribes and some local governments may be co-regulators with EPA. In some cases, they implement authorized, approved or delegated Federal programs. In other cases, they run independent, but closely-related programs. In both cases they work closely with EPA as regulatory partners, and EPA will consult them as appropriate when implementing this Policy. In addition, they may have expertise that can be valuable to EPA in designing public involvement activities.

2. State agencies, Tribes and local governments also may be regulated parties when they undertake activities that are subject to Federal laws and regulations. As regulated parties, they are also members of the community of regulated stakeholders, and would benefit from the application of the Policy like other regulated parties.

3. Whether they are partners helping EPA implement a program or members of the regulated community affected by EPA regulations, state agencies, Tribes, and regional and local governments often play an active role in making recommendations on policies, rules, plans and recommendations under development, and providing input on EPA's decisions.

The role of Tribes is unique in another way. Each federally-recognized Tribal government is a sovereign entity that has an individual government-to-government relationship with the federal government. EPA should coordinate and consult meaningfully with Tribes to the greatest extent practicable for agency actions that may affect the tribes. This Policy complements EPA's efforts to consult with Tribes. See Executive Order 13175, Consultation and Coordination With Indian Tribal Governments November 6, 2000.

Consultation should be a meaningful and timely two-way exchange with Tribal officials that provides for the open sharing of information, the full expression of Tribal and EPA views, a commitment to consider Tribal views in decision making, and respect of Tribal self-government and sovereignty. The Agency should allow comment from Tribes early in the planning process and prior to making a decision. However, consultation does not imply that the Tribes or any other non-EPA entities that are consulted can stop an Agency action by withholding consent.

How Does the Policy Relate to Environmental Justice?

This Policy complements and is consistent with EPA's environmental justice efforts. ''Environmental Justice'' is the fair treatment of people of all races, cultures, and incomes, including minority and/or low-income communities and Tribes, with respect to the development, implementation, and enforcement of environmental laws and policies, and their meaningful involvement in the decision-making processes of the government. Environmental justice is achieved when everyone, regardless of race, culture or income, enjoys the same degree of protection from environmental and health hazards and equal access to the decision-making process to have a healthy environment in which to live, learn and work. This includes ensuring greater public participation in the Agency's development and implementation of its regulations and policies. (Memorandum from EPA Administrator Christine Todd Whitman, dated August 9, 2001, ''EPA's Commitment to Environmental Justice.'') (*See also,* Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, dated February 11, 1994.) Thus, ensuring meaningful public involvement advances the goals of environmental justice.

EPA's Seven Basic Steps for Effective Public Involvement

The EPA should ensure that it conducts meaningful public involvement activities and implements all public involvement provisions required by statute.

There are seven basic steps to consider when planning for public involvement. Agency officials should exercise judgment and carefully consider the particular circumstances of each situation in determining how to carry out those steps. Agency staff and managers should strive to provide the most meaningful public involvement opportunities appropriate to each situation. Agency officials should consider the issues, locations, potential environmental and human health consequences of the activities, potential for controversy, specific needs of the public and the Agency, and other circumstances when designing public involvement processes. For instance, enhanced opportunities for public involvement should be created for those situations in which there is the potential for greater environmental or human health consequences or controversy. It is important to note that the Agency needs to set priorities for its use of resources, and that budgetary constraints may affect the implementation of any of these elements.

The seven basic steps for effective public involvement in any decision or activity are:

1. Plan and budget for public involvement activities.
2. Identify the interested and affected public.
3. Consider providing technical or financial assistance to the public to facilitate involvement.
4. Provide information and outreach to the public.
5. Conduct public consultation and involvement activities.
6. Review and use input and provide feedback to the public.
7. Evaluate public involvement activities.

The recommended goals, actions and methods for each of these steps are described in Appendix 1, Guidance for Implementing Public Involvement at EPA, at *http://www.epa.gov/publicinvolvement/policy2003/guidance.pdf.*

Who Is Responsible for Managing the Application of This Policy?

Under the overall direction of the Administrator, and consistent with this policy, Assistant, Regional and Associate Administrators are responsible for ensuring that their managers and staff encourage and facilitate public involvement in programs and activities. Public involvement should be an integral part of any Agency program. Moreover, the Agency should strive to achieve public involvement that is commensurate with the potential impact of the activity. The Assistant, Regional or Associate Administrators should make certain that concerns about the adequacy of public involvement are heard and, where necessary, acted upon as resources allow. Managers should encourage and facilitate the proper training, support and counseling of staff, and, recognizing overall budgetary constraints, should plan for and provide adequate funding for training or other needs in their specific budgets. (*See* more detailed responsibilities section in Appendix 1 at *http://www.epa.gov/publicinvolvement/policy2003/guidance.pdf.*)

[FR Doc. 03–14325 Filed 6–5–03; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

May 28, 2003.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (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 the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before July 7, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all Paperwork Reduction Act comments to Judith B. Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., DC 20554 or via the Internet to *Judith-B.Herman@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at (202) 418–0214 or via the Internet at *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–1007.

Title: Streamlining and Other Revisions of Part 25 of the Commission's Rules.

Form No.: FCC Form 312, Schedule S.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 150 respondents; 971 responses.

Estimated Time Per Response: 10 hours (5 hours for outside legal assistance).

Frequency of Response: On occasion, annual, and other reporting requirements, third party disclosure requirement.

Total Annual Burden: 9,686 hours.

Total Annual Cost: $95,194,000.

Needs and Uses: On May 19, 2003, the Commission released a First Report and Order (R&O) in IB Docket Nos. 02–34 and 02–54, FCC 03–102. The Report and Order adopts two different licensing frameworks for non-geostationary orbit (NGSO)-like systems and geostationary orbit (GSO)-like systems. The R&O requires that new licensees execute a bond in the amount of $7.5 million for NGSO licensees and $5 million for GSO licensees and submit the bond to the Commission within 30 days of license grant. The bond would discourage speculative applications without deterring legitimate satellite operators. The bond only applies to *new* satellite licensees only, not replacement satellites. The Report and Order results

in faster provision of satellite services to the public, thus enabling the U.S. satellite industry to maintain its leadership rule in the world market. This collection of information is used by the Commission in carryout out its duties as required by the Communications Act and the World Trade Organization (WTO) Basic Telecom Agreement.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–14289 Filed 6–5–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 9:35 a.m. on Tuesday, June 3, 2003, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's corporate and enforcement activities.

In calling the meeting, the Board determined, on motion of Director James E. Gilleran (Director, Office of Thrift Supervision), seconded by Vice Chairman John M. Reich, concurred in by John M. Hawke, Jr. (Comptroller of the Currency), and Chairman Donald E. Powell, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no notice earlier than May 29, 2003, of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(10) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550–17th Street, NW., Washington, DC.

Dated: June 3, 2003.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 03–14485 Filed 6–4–03; 3:36 pm]

BILLING CODE 6714–01–M

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting Notice

* * * * *

Previously Announced Date & Time: Tuesday, June 3, 2003, 10 a.m., meeting closed to the public. This meeting was cancelled.

Previously Announced Date & Time: Thursday, June 5, 2003, 10 a.m. meeting open to the public. This meeting was cancelled.

Previously Announced Date & Time: Friday, June 6, 2003, 10 a.m. public hearing on public financing of presidential candidates and nominating conventions. The starting time has been changed to 9 a.m.

* * * * *

Date & Time: Tuesday, June 10, 2003, at 10 a.m.

Place: 999 E street, NW., Washington, DC.

Status: This meeting will be closed to the public.

Items To Be Discussed: Compliance matters pursuant to 2 U.S.C. 437g. Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C. Matters concerning participation in civil actions or proceedings or arbitration. Internal personnel rules and procedures or matters affecting a particular employee.

* * * * *

Date & Time: Wednesday, June 11, 2003, at 10 a.m.

Place: 999 E Steet, NW., Washington, DC (ninth floor).

Status: This hearing will be open to the public.

Matter Before the Commission: Enforcement policies and procedures.

Date & Time: Thursday, June 12, 2003 at 10 a.m.

Place: 999 E Street, NW., Washington, DC (ninth floor).

Status: This meeting will be open to the public.

Items To Be Discussed: Correction and Approval of Minutes.

Draft Advisory Opinion 2003–05: National Association of Home Builders of the United States (NAHB) by counsel, E. Mark Braden and William H. Schweitzer.

Draft Advisory Opinion 2003–10—Rory Reid and the Nevada State Democratic Party by counsel, Marc E. Elias.

Draft Advisory Opinion 2003–13—American Academy of Ophthalmologists, Inc. by Steven L. Miller, Director, OPHTHPAC.

Routine Administrative Matters.

Person to Contact for Information: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 03–14365 Filed 6–03–03; 4:23 pm]

BILLING CODE 6715–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank 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 office 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 June 20, 2003.

A. Federal Reserve Bank of Minneapolis (Richard M. Todd, Vice President and Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. Mary Jane Lindholm, Clarkfield, Minnesota; to retain control of Clarkfield Holding Company, Clarkfield, Minnesota, and thereby indirectly retain control of Farmers and Merchants State Bank of Clarkfield, Clarkfield, Minnesota.

Board of Governors of the Federal Reserve System, June 2, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–14252 Filed 6–5–03; 8:45 am]

BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

[2003–N01]

Integrated Acquisition Environment Pilot; Posting Awarded Contracts on the Worldwide Web

AGENCY: The Integrated Acquisition Environment (IAE) Program Office, GSA.

ACTION: Notice and request for comments.

SUMMARY: The Integrated Acquisition Environment (IAE) program office, which is responsible for improving Federal acquisition processes through reliance on a technology-based integrated infrastructure, is initiating a pilot to begin making Federal contracts available to the general public on the worldwide web (web). This pilot effort is intended to increase transparency in agency acquisition activities and further the Administration's global vision of a citizen-centric E-Government. The IAE program office seeks public comment to help in identifying priorities for the pilot's implementation.

DATES: Interested parties should submit comments to the Regulatory Secretariat at the address shown below on or before August 5, 2003.

ADDRESSES: Submit written comments to—General Services Administration, Regulatory Secretariat (MVA), 1800 F Street, NW., Room 4035, ATTN: Laurie Duarte, Washington, DC 20405.

Submit electronic comments via the Internet to—*Notice.2003–N01@gsa.gov.*

Please submit comments only and cite Notice 2003–N01 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: Ms. Teresa Sorrenti, Project Manager, Integrated Acquisition E-Gov Initiative, by phone at (703) 872–8610 or by e-mail at *teresa.sorrenti@gsa.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) and the IAE program office seek to promote greater transparency in Government contracting through the effective use of technology. Transparency fosters public confidence in the Government's procurement processes and the critical missions they support.

The Government has taken, and continues to take, important steps to leverage Federal information technology investments and increase transparency in ways that help Federal buyers to achieve better results. For example:

• FedBizOpps (*http://www.fedbizopps.gov*) enables vendors and other interested members of the public to easily acclimate themselves with the planned procurements of departments and agencies across the executive branch. This gateway hosts a wide variety of business documents, such as notices, solicitations, and other related acquisition information, that vendors need to bid on and negotiate contracts with agencies. The transparency FedBizOpps provides helps to reduce vendor transaction costs. This, in turn, generates competition to lower cost and improve quality in purchases for taxpayers.

• The interagency contract directory (*http://www.contractdirectory.gov*), which will be rolled out later this year, will provide general information to agencies and the public about awarded contracts that are available to satisfy the needs of other Federal agencies. Information in the directory will be made available in a standardized format to facilitate market research and help agency managers rationalize contracting efforts.

• The Federal Procurement Data System—Next Generation (FPDS–NG) will entirely transform how information about acquisition activities is captured. As this new management information system is phased in over the next two years, agencies and the public will enjoy faster and wider access to transactional information as well as real-time web-based reporting.

Several public interest groups have requested that agencies make contracts available online. These groups believe this type of transparency will facilitate constructive dialogue to promote model contracting, improve weak practices, and reduce repetitive requests under the Freedom of Information Act (FOIA) for contracts that are of particular interest to the public. While a limited amount of information about awarded contracts is available today through FPDS and FedBizOpps, Federal contracts are not routinely posted on the web.

In light of the public interest in having contracts posted and the benefits derived through improved transparency in acquisition generally, the IAE program office is initiating a project to pilot the online posting of Federal contracts. The IAE program office intends to scope the pilot in a manner that is both (1) responsive to the interests of our taxpayers, and (2) reasonable in light of potential costs and burden associated with this effort and the capabilities of technology currently employed by the Government. This scope may be modified based on the success of initial pilot efforts and future enhancements to the Government's technology infrastructure. It may also be re-scoped to include grants. Irrespective of how the pilot is structured, any proprietary information contained in a contract covered by the pilot would be redacted before posting.

The program office welcomes the public's comments in helping to identify priorities for implementing the pilot. Comments are especially welcome on the following issues:

1. *Scope and availability.* What parameters (factors) should guide the initial shape of the pilot (*e.g.*, size or type of contract; amount of competition sought; product or service purchased; awards related to specific Federal programs)? How long should contracts remain available after they have been posted?

2. *Guidance.* What, if any, type of guidance may be beneficial to ensure posting is consistent with applicable laws and regulations (*e.g.*, is there a need for guidance to address the redaction of proprietary information, the identification of contracts whose disclosure would compromise the national security, or the application of FOIA generally)?

Dated: June 3, 2003.

David A. Drabkin,

Deputy Associate Administrator, Office of Acquisition Policy.

[FR Doc. 03–14341 Filed 6–5–03; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Availability of Funds for Family Planning Male Reproductive Health Research Grants

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of Population Affairs.

ACTION: Notice; correction.

SUMMARY: The Office of Population Affairs published a notice in the **Federal Register** of April 14, 2003 announcing the availability of funds for family planning male reproductive health research grants. A correction Notice was published on May 23, 2003. There was an error in this Notice. This Notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Susan B. Moskosky, 301–594–4008.

Correction

In the **Federal Register** of May 23, 2003, in FR Doc. 03–12983, on page 28228, in the first column, second paragraph under the heading ''Correction'' correct the second sentence which reads ''Awards will range from $100,000 to $250,000 per year, inclusive of direct costs'' to read:

''Awards will range from $100,000 to $250,000 per year, inclusive of indirect costs.''

Dated: May 30, 2003.

Alma L. Golden,

Deputy Assistant Secretary for Population Affairs.

[FR Doc. 03–14245 Filed 6–5–03; 8:45 am]

BILLING CODE 4150–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03077]

Community-Based Interventions To Reduce Motor Vehicle-Related Injuries; Notice of Availability of Funds; Amendment

A notice announcing the availability of fiscal year (FY) 2003 funds for cooperative agreements for Community-Based Interventions to Reduce Motor Vehicle-Related Injuries was published in the **Federal Register** on May 19, 2003, Vol. 68, No. 69, pages 27078–27082. The notice is amended as follows:

On page 27078, Column 3, Section ''D. Funding,'' insert second paragraph ''Recipient Financial Participation: Matching funds are not required for this program.''

On page 27082, Column 2, Section ''J. Where to Obtain Additional Information,'' under contact information for Tim Groza, MPA, Project Officer, replace ''770–4676'' with ''770–488–4676''.

Dated: May 30, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–14270 Filed 6–5–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03030]

Controlling Asthma in American Cities Project Phase II-Intervention Implementation; Notice of Availability of Funds

Application Deadline: July 7, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301 and 317 of the Public Health Service Act, (42 U.S.C. 241 and 247b), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement program for the Controlling Asthma in American Cities Project (CAACP). This program addresses the ''Healthy People 2010'' focus area of Respiratory Diseases.

The purpose of the program is to build on the planning phase of CAACP (including the experience and skills gained from the pilot testing of intervention approaches) to improve overall asthma management and decrease asthma-related morbidity among children (0–18 years) in a previously defined urban population with a large and unmet asthma control need.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Environmental Health: Reduce the burden of asthma.

C. Eligible Applicants

Assistance will only be provided to currently funded recipients from CDC Program Announcement Number 01117, Controlling Asthma in American Cities Project, Phase I Planning. Refer to Attachment II for a list of currently funded recipients. All attachments referenced in this announcement are posted with the announcement on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding,'' then ''Grants and Cooperative Agreements.''

Program Announcement Number 01117 was for the two-year planning phase of this project, while this announcement is competitive among planning phase awardees for implementation of intervention activities. Program Announcement Number 01117 stated: ''Depending on the availability of funds, a new competitive announcement, limited to Phase I awardees, may be announced in the future that will implement the intervention activities.'' No other applications are solicited.

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.

D. Funding

Availability of Funds

Approximately $4 million is available in FY 2003 to fund approximately five to seven awards. It is expected that the average award will be $700,000, ranging from $500,000 to $800,000. It is expected that the awards will begin on or about September 15, 2003 and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Recipient Financial Participation

Matching funds are not required for this program.

Funding Preferences

Funding preferences may include: (1) Geographic distribution; (2) minority populations with disproportionate asthma burden; and (3) a balance of proposed intervention strategies.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient Activities, and CDC will be responsible for the activities listed under 2. CDC Activities.

1. Recipient Activities

a. Describe and implement the community asthma action plan developed during the planning period. The plan should be detailed and include time-phased intervention objectives that are tied to the asthma objectives in Healthy People 2010. The plan should be feasible from a programmatic implementation perspective and from a cost perspective. The plan should address sustainability issues (*i.e.,* the institutionalization of intervention activities), as well as encourage community capacity building and empowerment.

b. Conduct a comprehensive evaluation of the entire project using CDC's framework for program evaluation as a guide. As part of this, recipients will monitor and evaluate progress in implementing the community-based asthma action plan and measure the long-term population-based impact of the project on the health of the communities of focus.

c. Continue collaboration with broad community representation and support in implementing, modifying, evaluating, and ultimately sustaining the project.

d. Serve as a resource for other asthma control projects.

e. Document and disseminate experiences in working as a collaborative/coalition and in implementing the project interventions.

f. Formally summarize project activities, progress in reaching project objectives, and general insights/lessons every six months to local partners and to CDC.

g. Work with CDC or its contractors to package and disseminate effective

interventions developed and/or tested as part of CAACP.

h. Participate annually in a CDC-organized meeting of CAACP grantees and key stakeholders.

2. CDC Activities

a. Provide technical assistance in the development of intervention strategies, communication and policy issues, and the interpretation of the scientific literature related to asthma management and control.

b. Provide liaison among grantees and identify potential sources of information and assistance.

c. Coordinate activities among sites, when appropriate.

d. Provide leadership in development of a comprehensive evaluation plan of CAACP as a whole and provide technical assistance to all grantee sites regarding appropriate evaluation strategies and specific evaluation tools.

e. Convene meetings among grantees, collaborators, and key stakeholders to discuss findings and improve outcomes.

f. Assist with the interpretation and dissemination of interim and final project findings and lessons. This may include coordinating one or more publishable reports related to project activities/findings.

g. If applicable, assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. If applicable, the CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

F. Content

Applications

The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, Evaluation Criteria, and this Content section to develop the application content. Additional guidance/clarification is provided in Attachment III. The application will be evaluated on the criteria listed, so it is important to follow them in laying out the program plan. The narrative should be no more than 25 pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font. In addition to the application forms, the application must contain the following in this order:

1. *Table of Contents:* A table of contents that provides page numbers for each of the following sections should be included.

2. *Project Narrative:* The narrative must contain the following sections:

a. Overview of the assets, attributes, and deficiencies of the communities of focus (*i.e.*, describing the public health and community environment in which CAACP is working, including a description of any community assessments or asset mapping done in the past three years).

b. Summary of asthma-related activities and issues unique to your communities of focus that directly or indirectly impact CAACP planning and implementation activities (*i.e.*, a description of asthma-specific activities not directly funded by CAACP that have occurred or are ongoing in the communities of focus).

c. Description of project organization, staffing, active collaboration, and community support.

d. Summary of the activities of the two-year planning period.

e. Description and justification of the community-based, intervention-phase asthma action plan to be implemented over the next five years.

f. Description of the comprehensive evaluation plan including a summary of the baseline data already collected during the planning phase.

G. Submission and Deadline

Application Forms

Submit the signed original and two copies of PHS 5161–1 (OMB Number 0920–0428). Forms are available at the following Internet address: *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) at: 770–488–2700. Application forms can be mailed to you.

Submission Date, Time, and Address

The application must be received by 4 p.m. Eastern Time, July 7, 2003.

Submit the application to: Technical Information Management–PA#03030, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd., Atlanta, GA 30341–4146.

Applications may not be submitted electronically.

CDC Acknowledgement of Application Receipt

A postcard will be mailed by PGO–TIM, notifying you that CDC has received your application.

Deadline

Applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received 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, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals as stated in the purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application and shall be an element of evaluation.

A peer review group appointed by CDC may conduct site visits or reverse site visits, as a part of their review of the applications and, if conducted, will use the results of these visits as well as application content addressing the following criteria:

1. The Community-focused, Intervention-phase Asthma Action Plan (40 percent).

The aim of this plan should be to reduce the burden of asthma among children ranging from newborn to 18 years of age, throughout the pre-selected communities of focus. The plan will be evaluated on the following criteria.

a. The detail to which the plan is described.

b. The likely effectiveness of the individual intervention strategies as well as the plan as a whole. This includes the estimated efficacy of each intervention (how much it will reduce asthma morbidity and/or improve quality of life), the likely reach of each intervention (percentage of the community under 18 years of age likely to be engaged/impacted by the intervention), and the potential synergy created by the intertwining of interventions. While all are essential, the project is especially interested in determining the combined effectiveness

of interventions that together have a high degree of community reach and participation.

c. The feasibility of the plan from a program implementation perspective, and from a cost/economic perspective. Included in this should be an estimate of how long it will take to fully implement the plan, with the idea that the quicker the intervention can be implemented effectively and efficiently, the better.

d. The degree to which pilot testing, previous community experience, and/or the science of effective asthma interventions were used/are being used to create the plan and its details.

e. The degree to which the plan reflects and builds on a mature and comprehensive understanding of the assets, attributes, and deficiencies of the communities of focus including non-CAACP asthma activities completed or ongoing in these communities.

f. The degree of community participation in the plan. The following questions should be addressed: Is there documentation of community participation in the development of the plan? Does the plan encourage community capacity building and empowerment? Do community partners play a large role in the implementation period and does this empower or build capacity within the community?

g. Approach to sustainability issues. This includes a discussion of what needs to happen to make the intervention strategies sustainable after project funding is finished, how likely it is that this will occur, and what project staff and partners are doing or planning to do to make this happen.

h. The value of the community asthma action plan and the individual intervention strategies from a broader scientific and community public health perspective. In other words, are the strategies innovative and ambitious enough to stretch our understanding of asthma control and community health?

i. Ability to replicate the community asthma action plan in other cities or expand into new neighborhoods within the same city. This includes the degree to which the individual intervention strategies will likely be attractive to other communities (*i.e.*, cost-feasible, resource-feasible, and reproducible).

2. Project organization, staffing, active collaboration and community support (30 percent). Projects will be judged on the following:

a. The diversity of individuals and organizations involved in the project.

b. The competence and community leadership potential of those actively engaged and participating in the project.

c. The depth of expertise (both formal expertise and significant past hands-on experience) in all areas critical to the project's success.

d. The overall competence, leadership, and vision of the principal investigator(s) and project coordinator(s). This is based, in part, on their individual skills/experience with a community-based team approach to decision-making and problem solving.

e. The ability of project staff and collaborators to communicate openly and easily, to understand each other's roles, and to make optimal project-related decisions. This will be based, in part, on the project's organizational structure and decision-making procedures developed and practiced over the two-year planning period.

f. The commitment of the collaborating individuals and especially, organizations. This includes the degree to which project collaborators have taken ownership or plan to take ownership of the project.

g. The effort made by project staff and collaborators to involve grassroots community members and/or representatives in a meaningful way.

h. The project's effectiveness in creating community awareness and interest in asthma and the project, in particular.

i. The prospect of sustaining the collaborative partnership beyond the project period and even beyond childhood asthma as the public health focus. This includes an assessment of how the project interacts with other existing community projects and coalitions in the region.

3. Evaluation Plan (20 percent).

Projects will be judged on the following:

a. Outcome-based Evaluation Strategies. The overall evaluation plan should be designed to measure the impact of the project's activities and interventions as a whole on the targeted communities' population of children and/or teens with asthma. Evaluation strategies aimed at measuring the impact of a single, specific intervention are important but remain secondary to measuring the project's overall population-based impact. Evaluation strategies that incorporate some or all of the following outcome measures (but not necessarily limited to the following) are suggested:

(1) Hospitalization data (ideally starting a minimum of three years prior to the onset of intervention activities to allow for trend analyses, and with comparable data from outside the communities of focus for comparison).

(2) Emergency care data (as above if possible).

(3) School absenteeism (all causes in those identified as having asthma or asthma-specific absenteeism).

(4) Quality of life and/or asthma symptom surveys (if a non-biased sample can be identified and obtained).

(5) Asthma medications (*i.e.*, the ratio of rescue to controller medication prescriptions filled).

(6) Asthma care visits (*i.e.*, ratio of scheduled to unscheduled visits, or number of asthma maintenance visits per year).

(7) Changes in community empowerment and/or active participation in community health (as measured by a validated instrument in a non-biased sample of the community).

b. Comprehensive Evaluation Plan: Applicants will be judged on how well they have articulated an evaluation plan that complements the outcome-based measures described above (section H2a) and is likely to be useful in understanding and/or measuring the following: (1) The dynamics of the collaborative process, including decision making; (2) the general effectiveness of the collaborative in helping to create, implement, and sustain community interventions; (3) the relationship between the project/collaborative and the community it seeks to serve; (4) the reach of project activities in the communities of focus; (5) the effectiveness of specific intervention components; (6) the cost and resource feasibility of specific intervention components; and (7) the impacts of the project and/or collaborative on the community outside of its specific impacts on asthma.

The evaluation plan will be additionally judged on the degree to which: (1) The project's stakeholders have been identified; (2) their perspectives and evaluation needs are reflected in the plan; and (3) the evaluation plan is cost and resource feasible.

c. Baseline comprehensive evaluation data collected, organized, and/or analyzed during the two-year planning phase with an emphasis on the following: (1) The proportion of baseline data needed for the proposed comprehensive evaluation already collected and analyzed; (2) the likelihood that the baseline data not yet collected will be collected and analyzed in the near future; (3) the quality of the data and the data analysis reports already collected and/or analyzed; and (4) the adequacy of the collected or soon-to-be collected data as a baseline for the proposed comprehensive evaluation.

d. Does the application adequately address the CDC Policy requirements

regarding the inclusion of women, ethnic, and racial groups in the proposed research? These include:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for the study participants includes the process of establishing partnerships with community(s) and recognition of mutual benefits.

4. Use of the Planning Period (10 percent).

The project will be judged on how well it made use of the two-year planning period (accountability). The following planning period activities should be considered in this overall evaluation of the activities undertaken to date. (*Of note:* Planning phase activities specifically related to the organization of the collaborative aspects of the project will not be included in this section. These activities will instead be incorporated into the score for section 2. ''Project organization, staffing, active collaboration, and community support'' above).

a. The development of a well-articulated, plausible vision for the project that meets the needs of stakeholders and collaborators.

b. The degree to which planning phase goals and objectives were clearly defined, improved upon (as needed), and achieved.

c. The degree to which piloting of project ideas took place and were well focused and well designed.

d. The degree to which the project staff and partners learned from these piloting experiences (*i.e.,* were they evaluated in a way meaningful to the project).

e. The quality and usefulness of project-related materials (educational materials, training manuals, resource banks, clinical referral lists, *etc.*) created, identified, and/or organized during the planning period.

f. The degree to which the staff/collaborators acquired clearly defined skills (*i.e.*, via training) that helped or will help in the creation and/or implementation of intervention strategies.

g. The degree to which baseline assessments (*i.e.*, community health assessments, asset mapping, focus groups, key informant interviews, survey data, utilization data, etc.) and/or process evaluation (of the planning period) were effectively utilized by project staff, partners, and other community stakeholders.

h. The degree to which the planning period was useful in developing a more accurate and richer understanding of the assets, attributes, and deficiencies of the communities of focus as well as the asthma-related activities/issues in these communities (outside of CAACP).

5. Budget (not scored)

The extent to which the budget is clearly detailed, justified, and appropriate for the activities proposed.

The applicant should include costs for one person to travel to Atlanta, GA to attend the sixth National Environmental Health Conference, December 3–5, 2003. Review the CDC/NCEH Web site for additional information concerning this conference: *http://www.cdc.gov/nceh/default.htm.*

6. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? (Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.)

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as the 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. Detailed Line-Item Budget and Justification.

e. 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.

Send all reports to the Grants Management Specialist identified in the ''Where To Obtain Additional Information'' section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement as posted on the CDC Web site.

AR–1 Human Subjects Requirements

AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR–7 Executive Order 12372 Review

AR–8 Public Health System Reporting Requirements

AR–9 Paperwork Reduction Act Requirements

AR–10 Smoke-Free Workplace Requirements

AR–11 Healthy People 2010

AR–12 Lobbying Restrictions

Office of Management and Budget Clearance

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, Internet address: *http://www.cdc.gov.*

Click on ''Funding'' then ''Grants and Cooperative Agreements''.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd., Atlanta, GA 30341–4146, *Telephone:* (770) 488–2700.

For business management and budget assistance, contact: Mildred Garner, Grants Management Officer, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, *Telephone:* (770) 488–2745, *e-mail address: Mgarner@cdc.gov.*

For program technical assistance, contact: Michael Friedman, M.D., Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS E–17, Atlanta, GA 30333, *Telephone Number:* (404) 498–1028, *e-mail address: mff7@cdc.gov.*

Dated: June 2, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–14271 Filed 6–5–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Intervention Research Grants To Promote the Health of People With Disabilities, Program Announcement #03029

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Intervention Research Grants to Promote the Health of People with Disabilities, Program Announcement #03029.

Times and Dates: 9 a.m.–9:50 a.m., June 29, 2003. (Open). 9:50 a.m.–5:15 p.m., June 29,2003. (Closed). 8:30 a.m.–3 p.m., June 30, 2003. (Closed).

Place: Atlanta Airport Marriott, 4711 Best Friend Road, College Park, GA 30337, Telephone (404) 766–7900.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #03029.

Contact Person for More Information: Hani Atrash, M.D., Associate Director for Program Development, National Center on Birth Defects and Developmental Disabilities, CDC, 4770 Buford Highway, MS–F34, Atlanta, GA 30341, Telephone (770) 488–7150.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 27, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03–14272 Filed 6–5–03; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 68 FR 7118–7123, dated February 12, 2003) is amended to reorganize the National Center for Health Statistics.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the functional statement for the Division of Environmental Health Laboratory Sciences and insert the following:

Division of Laboratory Sciences (HCN8). (1) Develops and maintains a national laboratory response capability for applying state-of-the-art biomonitoring technology to improve the detection, prevention, and public health management of chemical terrorism emergencies and emergencies resulting from human exposure to toxic chemicals; (2) develops and applies biomonitoring methods for environmental chemicals that identify chemicals to which people are exposed and measures individual exposure levels; (3) applies biomonitoring measurements to determine the exposure of the general U.S. population to selected environmental chemicals, to assess the exposure of special population groups that are known or suspected to be at high-risk of excessive exposure, and study to the relationship between level of exposure and adverse health effects; (4) provides technical assistance, technology transfer, reference laboratory measurements, laboratory standardization programs, and external quality assurance to State and local public health laboratories and health officials; Federal agencies; international organizations; academic, international, and private laboratories; and professional organizations to improve laboratory science and laboratory capacity in the fields of environmental health and selected chronic diseases; (5) develops and validates advanced laboratory technology to assess nutritional and genetic risk factors for environmental disease and selected chronic diseases; and (6) collaborates with other CDC organizations; Federal, State, and local agencies; and private and professional organizations to investigate new or emerging health problems known to potentially related to exposure to environmental chemicals.

Clinical Chemistry Branch (HCN85). (1) Provides statistical consultation in areas of research, study design, analysis, reporting, and quality control development for laboratory investigations and environmental health studies to NCEH staff, other Federal agencies, State and local public health departments, and other national and international organizations; (2) provides system analysis, computer programming and interfacing, technical support, and application of computerization and other advanced technology to the resolution of laboratory problems and data analysis, management, reporting, and presentation; (3) maintains reference methods for epidemiologic studies and clinical trials which provide the basis for public health strategies to reduce morbidity and mortality due to cardiovascular disease. In this capacity, serves as the WHO Collaborating Center for Reference and Research in Blood Lipids; (4) develops, evaluates, and standardizes analytical methods for the measurement of biochemical markers for assessing disease status and risk for selected chronic diseases; (5) designs and implements collaborative programs with appropriate agencies or professional groups to effect technology transfer, improvement of proficiency and quality, and the standardization of analytical performance among health laboratories involved in clinical and epidemiologic investigations; (6) provides technical assistance and guidance to governmental agencies, professional societies, and the general clinical laboratory community on pre-analytical issues, measurement problems, study design, and reference and quality control material preparation, storage, and handling; and (7) develops, prepares, and distributes purified and biological reference materials used for standardization programs, quality control assessment, and calibration of analytical methods in research.

Emergency Response and Air Toxicants Branch (HCN88). (1) Develops and maintains analytical methods to measure, in human specimens, toxic substances that are known or potential agents for use in chemical terrorism; (2) applies these measurements in response to chemical terrorism emergencies and, as part of a coordinated Federal response, deploys a rapid response laboratory team to assist in obtaining

human specimens for analysis; (3) transfers technology, provides training, and provides technical assistance for measurement of chemical agents in human specimens to a network of laboratories that provide additional capacity for responding to chemical terrorism; (4) provides review and expert consultation to Federal, state, local and international governments and health organizations on assessing and interpreting biomonitoring measurements of chemical agents likely to be used in terrorism; (5) for toxic substances of public health concern but unlikely to be involved in chemical terrorism, transfers biomonitoring technology, provides biomonitoring training, and provides technical assistance in biomonitoring to state laboratories, including methods for analyzing both inorganic and organic toxic substances in human specimens; (6) develops and maintains analytical methods to measure organic toxic substances that contaminate air (air toxicants) in human specimens and applies these analytical methods to assess human exposures to these chemicals for many purposes, including surveillance of levels in the population, epidemiological studies, and emergency response investigations; and (7) develops and maintains analytical methods to assess human exposure to tobacco smoke and its chemical constituents and applies these methods to epidemiologic studies of tobacco smoke exposure and related disease.

Inorganic Toxicants and Nutrition Branch (HCN84). (1) Develops and maintains analytical methods to measure trace-essential and toxic elements in human specimens; (2) applies these analytical methods to assess human exposures to these chemicals for many purposes, including surveillance of levels in the population, epidemiological studies, and emergency response investigations; (3) provides training, guidance, and assistance to State and local governments, and domestic and international laboratories in the development, maintenance and technology transfer of analytical capability for measurement of trace-essential and toxic elements in specimens from humans, animals, and the environment; (4) develops and maintains analytical capability and expertise in the measurement and interpretation of physiologic levels of micronutrients such as the vitamins, essential elements, and other dietary substances or their metabolites (as biomarkers); (5) provides technical assistance to national, state, international and local investigations, surveys, and clinical studies of the nutritional status, prevalence, risk factors, and treatment of chronic diseases; and (6) develops, maintains, and distributes, as appropriate, standards, reference materials, protocols, and standardization programs to assist state, international and other laboratories in the transfer of laboratory technology and in establishing and maintaining quality control and calibration of analytical methods for essential and toxic elements, nutrients, and markers of physiologic damage.

Molecular Biology Branch (HCN87). (1) Collaborates in the development and implementation of large, population-based, genetic repositories comprising specimens from nationally representative samples of healthy people, patients, unaffected family members, or unrelated control subjects; (2) develops and evaluates laboratory methods in genetics and develops, evaluates, and standardizes auto-antibody measurements; (3) uses population-based and disease-based repositories to study genetic risk factors for disease and gene-environment interactions; (4) provides advice and technical assistance to state and local health departments, other Federal agencies, national and international organizations, and academic centers on laboratory measurements in genetics; and (5) develops, maintains, and distributes appropriate standards, reference materials, and protocols for diabetes auto-antibody measurement.

Newborn Screening Branch (HCN82). (1) Provides technical consultation and assistance concerning quality assurance and procedural issues to State Public Health laboratories, international laboratories, and manufacturers of diagnostic products involved in performing newborn screening tests; (2) develops and maintains analytical methods to measure substances in dried-blood spots (DBSs), and produces certified DBS quality control and reference materials for newborn screening tests; (3) maintains a DBS proficiency testing program for newborn screening programs worldwide for inborn errors of metabolism, hemoglobinopathies, and other newborn disorders; (4) provides technical and administrative support to public health laboratory projects for early detection of autoimmune, immuno-proliferative, and immuno-deficiency diseases; and (5) evaluates and refines emerging laboratory methods for micro- and nano-detection to public health applications and population-based screening for these immune disorders.

Organic Analytical Toxicology Branch (HCN86). (1) Develops and maintains analytical methods to measure selected synthetic and naturally occurring organic chemicals, their metabolites, and reaction products (adducts) in human specimens; (2) applies these analytical methods to assess human exposures to these chemicals for many purposes, including surveillance of levels in the population, epidemiological studies, and emergency response investigations; (3) aids in transferring these methods within Division laboratories and to state, local and other public health laboratories; (4) develops and prepares various matrix-based quality control materials for use in such analyses; and (5) provides review, expert consultation, and original scientific publications/information to Federal, state, local, and international governments and health organizations on topics related to human exposure assessment, organic analytical methodology, high technology analytical instrumentation, preparation and analysis of biological specimens, quality control procedures, laboratory safety, and medical interpretation of laboratory findings.

Dated: May 15, 2003.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03–14223 Filed 6–5–03; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Board of Scientific Advisors, June 26, 2003, 8 a.m. to June 27, 2003, 6 p.m., National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892 which was published in the **Federal Register** on May 21, 2003, 68 FR 27837.

This meeting is amended to change the closing time on 06/27/03 to 1 p.m. The meeting is open to the public.

Dated: May 29, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–14261 Filed 6–5–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Cancer Institute.

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 Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of of Committee: Board of Scientific Counselors, National Cancer Institute Subcommittee 2—Basic Sciences.

Date: July 14–15, 2003.

Time: 7 p.m. to 12:45 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Florence E. Farber, PhD, Health Scientific Administrator, Office of the Director, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 2115, Bethesda, MD 20892, (301)–496–7628, *ff6p@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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 29, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–14262 Filed 6–5–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

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 Cancer Institute Initial Review Group Subcommittee A—Cancer Centers.

Date: August 8, 2003.

Time: 7:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: David E. Maslow, PhD, Chief, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard—Room 8117, Bethesda, MD 20892–7405, (301) 496–2330.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 28, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–14265 Filed 6–5–03; 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 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 of Child Health and Human Development Special Emphasis Panel Family Management of Childhood Diabetes—Data Coordinating Centers.

Date: June 26, 2003.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Hameed Khan, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E01, Bethesda, MD 20892, (301) 435–6902, *khanh@mail.nih.gov.*

(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: May 29, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–14264 Filed 6–5–03; 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 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 Mental Health Special Emphasis Panel Somatic Treatment.

Date: June 19, 2003.

Time: 11:30 a.m. to 1:30 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: David I. Sommers, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6144, MSC 9606, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@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.

Name of Committee: National Institute of Mental Health Special Emphasis Panel Eating Disorders.

Date: July 8, 2003.

Time: 10 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: Peter J. Sheridan, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6142, MSC 9606, Bethesda, MD 20892–9606, 301–443–1513, *psherida@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel Statistics SEP.

Date: July 31, 2003.

Time: 1 p.m. to 2:30 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: Henry J. Haigler, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6150, MSC 9608, Bethesda, MD 20892–9608, 301–443–7216, *hhaigler@mail.nih.gov.*

(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: May 28, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–14266 Filed 6–5–03; 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 Grant Application Reviews.

Date: June 16, 2003.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, Willco Bldg., Room 409, 6000 Executive Blvd., Rockville, MD, (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, PhD, Scientific Review Administrator, Extramural Project Review Branch, Office of Scientific Affairs, National Institute on Alcohol Abuse and Alcoholism, 6000 Executive Blvd., Suite 409, Bethesda, MD 20892–7003, (301) 443–2926, *skandasa@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: May 28, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–14267 Filed 6–5–03; 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: Microbiology, Infectious Diseases and AIDS Initial Review Group, Acquired Immunodeficiency Syndrome Research Review Committee, AIDS Research Review Committee.

Date: June 25–26, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Roberta Binder, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, Room 2209, 6700B Rockledge Drive, Bethesda, MD 20892–7616, 301–496–2550, *rb169n@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: May 28, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–14268 Filed 6–5–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Recombinant DNA Advisory Committee.

The meeting will be open to the public, 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 inform the contact person listed below in advance of the meeting.

Name of Committee: Recombinant DNA Advisory Committee (RAC).

Date: June 18, 2003.

Open: 8:30 a.m. to 5 p.m.

Agenda: In addition to protocol review and Data Management, the NIH RAC will: Review presentations from the 2003 annual meeting of the American Society of Gene Therapy relevant to retroviral vectors; discuss the Recommendations of the United Kingdom Gene Therapy Advisory Committee and Committee of Safety of Medicine on Retroviruses; discuss future presentations to the RAC on retroviral gene transfer; and discuss an in-depth assessment regarding containment level requirements for Modified Vaccinia Ankara Pox viral vectors.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

Name of Committee: Recombinant DNA Advisory Committee (RAC).

Date: June 19, 2003.

Open: 8:30 a.m. to 12 p.m.

Agenda: A presentation on preliminary results of an NIH-funded research project on informed consent and review and discuss the RAC Informed Consent Working Group draft guidance document.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact: Stephen Rose, PhD, Executive Secretary, Recombinant DNA Advisory Committee, Office of Biotechnology Activities, Rockledge 1, Room 750, Bethesda, MD 20892, (301) 396–9839.

Information is also available on the Institute's/Center's Home page: *www4.od.nih.gov/oba*, where an agenda and any additional information for the meeting will be posted when available.

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant molecules techniques could be used, it has been determined not to be cost effective or in the pubic interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual programs listed in the Catalog of Federal Domestic Assistance are affected (Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 29, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–14263 Filed 6–5–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2003 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of funding availability for Cooperative Agreement for National Consumer and Consumer Supporter Self-Help Technical Assistance Centers.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS) announces the availability of FY 2003 funds for the grant program described below. A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, is also available at the Internet site: *http://www.fedgrants.gov.*

This notice is not a complete description of the program; potential applicants must obtain a copy of the Request for Applications (RFA), including Part I, Cooperative Agreement for National Consumer and Consumer Supporter Self-Help Technical Assistance Centers, Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application.

Funding Opportunity Title: Cooperative Agreement for National Consumer and Consumer Supporter Self-Help Technical Assistance Centers-Short Title: Self-Help Technical Assistance Centers.

Funding Opportunity Number: SM 03–008.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 520A of the Public Health Service Act, as amended and subject to the availability of funds.

Funding Instrument: CA.

Funding Opportunity Description: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS) is accepting applications for Fiscal Year (FY) 2003 cooperative agreements to support five National Consumer and Consumer Supporter Self-Help Technical Assistance (TA) Centers. The purpose of these technical assistance centers is to assist with the improvement of State and local level mental health service systems by providing consumers, as well as supporters, service providers, and the general public, with necessary skills to foster self-help/self-management approaches.

Eligible Applicants: In accordance with Congressional authorization, applications may be submitted by public or private domestic, nonprofit entities, including faith-based organizations, which meet the criteria of consumer or consumer supporter organizations as defined in the announcement. Applicant organizations must have been in operation for a minimum of one year, and key personnel supporting the grant must have been employed by the organization for at least one year.

Due Date for Applications: August 7, 2003.

Estimated Funding Available/Number of Awards: It is expected that approximately $1,865,000 will be available for 5 awards in FY 2003 for three national consumer self-help technical assistance centers and two national consumer-supporter self-help technical assistance centers. An additional $122,000 will be competitively awarded to one of the three successful national consumer self-help technical assistance centers to facilitate the Alternatives Conference. Awards may be requested for a period of 1 year. Each applicant may apply for up to $373,000 for direct and indirect costs. Applications with proposed

budgets that exceed $373,000 will be returned without review.

Is Cost Sharing Required: No.

Period of Support: 1 year.

How to Get Full Announcement and Application Materials: Complete application kits may be obtained from the SAMHSA/CMHS National Mental Health Information Center at 800–789–2647. The PHS 5161–1 application form and the full text of the funding announcement are also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov* (Click on 'Grant Opportunities').

When requesting an application kit, the applicant must specify the funding opportunity title and number for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit.

Contact for Additional Information: Risa S. Fox, M.S., Public Health Advisor, SAMHSA/CMHS, 5600 Fishers Lane, Room 11C–22, Rockville, MD 20857; (301) 443–3653; E-mail: *rfox@samhsa.gov.*

Dated: June 3, 2003.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03–14349 Filed 6–5–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No.FR–4815–N–30]

Notice of Submission of Proposed Information Collection to OMB: Public Housing Construction Report

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.

DATES: *Comments Due Date:* July 7, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2577–0027) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395–6974; E-mail *Lauren_Wittenberg@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Public Housing Construction Report.

OMB Approval Number: 2577–0027.

Form Numbers: HUD–5378.

Description of the Need for the Information and Its Proposed Use: PHAs are responsible for contract administration during project development and for the hiring of architects or other persons licensed under the State law to assist and to advise them. Contract administration includes the submission of necessary information to the PHA by that advisor to monitor the status of construction.

Respondents: State, Local or Tribal Government, business or other for-profit.

Frequency of Submission: Semi-monthly.

Reporting Burden: Number of Respondents 158, Annual Responses 24 × Hours per Response 0.25 = Burden Hours 948.

Total Estimated Burden Hours: 948.

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: May 30, 2003.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 03–14224 Filed 6–5–03; 8:45 am]

BILLING CODE 4210–72–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4815–N–31]

Notice of Submission of Proposed Information Collection to OMB: Family Self-Sufficiency Program (FSS)

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.

DATES: *Comments Due Date:* July 7, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2577–0178) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395–6974; E-mail *Lauren_Wittenberg@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as

required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also Lists the Following Information:

Title of Proposal: Family Self-Sufficiency Program (FSS).

OMB Approval Number: 2577–0178.

Form Numbers: HUD–52650, HUD–52652.

Description of the Need for the Information and its Proposed Use: The Family Self-Sufficiency Program, which was established in the National Affordable Housing Act of 1990, promotes the development of local strategies that coordinate the use of public housing assistance and assistance under the Section 8 rental certificate and voucher programs (now known as the Housing Choice Voucher Program) with public and private resources to enable eligible families to achieve economic independence and self-sufficiency. Housing agencies enter into a Contract of Participation with each eligible family that opts to participate in the program; consult with local officials to develop an Action Plan; and report annually to HUD on implementation of the FSS program. Housing agencies submit an initial program plan and report annually on progress to HUD.

Respondents: Individuals or households, public housing agencies, State or local government.

Frequency of Submission: Annually, On occasion.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting burden	750	45,800		0.8		36,500

Total Estimated Burden Hours: 36,500.

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: May 31, 2003.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 03–14225 Filed 6–5–03; 8:45 am]

BILLING CODE 4210–72–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4809–N–23]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, room 7266, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, address to Shirley Kramer, Division of Property Management, Program Support Center, HHS, room 5B–41, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for

use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register,** the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Coast Gurard:* Ms. Teresa Sheinberg, U.S. Coast Guard, Room 6109, 2100 Second St., SW., Washington, DC 20593–0001; (202) 267–6142; *Energy:* Mr. Andy Duran, Department of Energy, Office of Engineering & Construction Management, ME–90, Washington, DC 20585; (202) 586–4548; *GSA:* Mr. Brian K. Polly, Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th and F Streets, NW., Washington, DC 20405; (202) 501–0052; *Navy:* Mr. Charles C. Cocks, Director, Department of the Navy, Real Estate Policy Division, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Ave., SE., Suite 1000, Washington, DC 20374–5065; (202) 685–9200; (These are not toll-free numbers).

Dated: May 28, 2003.

John D. Garrity,

Director, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 6/6/03

Suitable/Available Properties

Buildings (by State)

California

Calexico Border Patrol Station
813 Andrade Ave.
Calexico Co: CA 92231–
Landholding Agency: GSA
Property Number: 54200320012
Status: Excess
Comment: 5600 sq. ft. main bldg., and 6845 sq. ft. parking/garage structure, need repairs
GSA Number: 9–J–CA–1539

Bell Federal Service Center
5600 Rickenbacker Road
Bell Co: Los Angeles CA 90201–
Landholding Agency: GSA
Property Number: 54200320009
Status: Excess
Comment: Correction/Republished: 9 bldgs., various sq. ft., need repair, portion occupied, restricted access, presence of asbestos/lead paint/PCBs, most recent use—warehouse/office
GSA Number: 9–G–CA–1575

Unsuitable Properties

Buildings (by State)

California

Bldg. 141MG
Naval Recreation Center
Naval Base
San Diego Co: CA
Landholding Agency: Navy
Property Number: 77200320054
Status: Excess
Reason: Extensive deterioration

Florida

8 Bldgs.
Naval Air Station
Milton Co: FL 32570–6001
Location: 1440, 1440A, 1437, 1444, 1444A, 1444G, 2927, 2886
Landholding Agency: Navy
Property Number: 77200320055
Status: Excess
Reasons: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

Hawaii

Change Room
Base Camp
Kahoolawe Co: Maui HI
Landholding Agency: Navy
Property Number: 77200320059
Status: Excess
Reasons: Not accessible by road; Within 2000 ft. of flammable or explosive material

Electric Generator Bldg.
Base Camp
Kahoolawe Co: Maui HI
Landholding Agency: Navy
Property Number: 77200320060
Status: Excess
Reasons: Not accessible by road; Within 2000 ft. of flammable or explosive material

Compressor Shed
Base Camp
Kahoolawe Co: Maui HI
Landholding Agency: Navy
Property Number: 77200320061
Status: Excess
Reasons: Not accessible by road; Within 2000 ft. of flammable or explosive material

System Shed
Base Camp
Kahoolawe Co: Maui HI
Landholding Agency: Navy
Property Number: 77200320062
Status: Excess
Reasons: Not accessible by road; Within 2000 ft. of flammable or explosive material

Idaho

Bldg. TAN 616
Idaho Natl Eng & Env Lab
Scoville Co: Butte ID 83415–
Landholding Agency: Energy
Property Number: 41200320007
Status: Excess
Reason: contamination

Illinois

Bldgs. T60, 61, 86, 87
Fermi National Accelerator Laboratory
Batavia Co: DuPage IL 60510–
Landholding Agency: Energy
Property Number: 412003290009
Status: Excess
Reason: Extensive deterioration

Maryland

Bldg. 503A
Naval Air Station
Patuxent River Co: MD
Landholding Agency: Navy
Property Number: 77200320056
Status: Excess
Reason: Extensive deterioration

Texas

6 Bldgs.
Pantex Paint
Amarillo Co: Carson TX 79120–
Location: 12–008, 12–R–008, 12–059, 12–059E, 12–059V, 12–R–059
Landholding Agency: Energy
Property Number: 41200320009
Status: Unutilized
Reasons: Within 2000 ft. of flammable or explosive material; Secured Area

Bldgs. 12–017E, 12–019E
Pantex Plant
Amarillo Co: Carson TX 79120–
Landholding Agency: Energy
Property Number: 41200320010
Status: Unutilized
Reasons: Within 2000 ft. of flammable or explosive material; Secured Area

Virginia

Bldg. NH–42
Naval Station
Norfolk Co: VA 23511–
Landholding Agency: Navy
Property Number: 77200320057
Status: Excess
Reason: Extensive deterioration

Bldgs. SP–271, SP–376
Naval Station
Norfolk Co: VA 23511–3095
Landholding Agency: Navy
Property Number: 77200320058
Status: Excess
Reason: Extensive deterioration

Bldg. CG–02
CAMSLANT
Pungo Co: Princess Anne VA
Landholding Agency: Coast Guard
Property Number: 88200320001
Status: Underutilized
Reason: Secured Area

Bldg. CG–05
CAMSLANT
Virginia Beach Co: Princess Anne VA
Landholding Agency: Coast Guard
Property Number: 88200320002
Status: Underutilized
Reason: Secured Area

[FR Doc. 03–13934 Filed 6–5–03; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

National Park Service

Native American Graves Protection and Repatriation Review Committee: Nomination Solicitation

AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: This notice is a solicitation on behalf of the Secretary of the Interior for nominations to fill three vacancies on the Native American Graves Protection and Repatriation Review Committee.

DATES: Postmark or hand-delivery deadline: August 5, 2003.

ADDRESSES: 1. Via U.S. Mail: Address nominations to Mr. John Robbins, Designated Federal Official, NAGPRA Review Committee, National Park Service, 1849 C Street NW (2253), Washington, DC 20240. Because increased security in the Washington, DC, area may delay delivery of U.S. Mail to U.S. Government offices, a copy of each mailed nomination should also be faxed to (202) 371-5197.

2. Via commercial delivery: Address nominations to Mr. John Robbins, Designated Federal Official, NAGPRA Review Committee, National Park Service, 1201 Eye Street NW, 8th floor, Washington, DC 20005.

3. Via hand delivery: Address nominations to Mr. John Robbins, Designated Federal Official, NAGPRA Review Committee, National Park Service, 1201 Eye Street NW, 8th floor, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Dr. Martha Graham, National NAGPRA, 1849 C Street NW (2253), Washington, DC 20240, telephone (202) 354-2202, e-mail martha_graham@nps.gov.

SUPPLEMENTARY INFORMATION:

General Information

1. The Review Committee was established by the Native American Graves Protection and Repatriation Act of 1990 (NAGPRA), 25 U.S.C. 3001 et seq.

2. The Review Committee is responsible for—

a. monitoring the NAGPRA inventory and identification process;

b. reviewing and making findings related to the identity or cultural affiliation of cultural items, or the return of such items;

c. facilitating the resolution of disputes;

d. compiling an inventory of culturally unidentifiable human remains and developing a process for disposition of such remains;

e. consulting with Indian tribes and Native Hawaiian organizations and museums on matters within the scope of the work of the Review Committee affecting such tribes or organizations;

f. consulting with the Secretary of the Interior in the development of regulations to carry out NAGPRA; and

g. making recommendations regarding future care of repatriated cultural items.

3. Seven members comprise the Review Committee. All members are appointed by the Secretary of the Interior. The Secretary may not appoint Federal officers or employees to the Review Committee.

a. Three members are appointed from nominations by Indian tribes, Native Hawaiian organizations, and traditional Native American religious leaders to represent the interests of Indian tribes, Native Hawaiian organizations, and traditional Native American religions. At least two of these members shall be traditional Native American religious leaders.

b. Three members are appointed from nominations submitted by national museum organizations and scientific organizations to represent the interests of such organizations.

c. One member is appointed from a list of persons proposed by all of the other members to represent the interests of the general public.

4. Appointment terms: Per the Review Committee's current charter, new members are appointed for 4-year terms and incumbent members may be reappointed for 2-year terms.

5. The Review Committee's work is completed during public meetings. The Review Committee normally meets two times per year, and each meeting is normally 2½ days. The next Review Committee meeting is tentatively scheduled in Albuquerque, NM, in November 2003.

6. Compensation: Review Committee members are compensated for their participation in Review Committee meetings.

7. Reimbursement: Review Committee members are reimbursed for travel expenses incurred in association with Review Committee meetings.

8. Additional information regarding the Review Committee, including the Review Committee's charter, meeting protocol, and dispute resolution procedures, is available on the National NAGPRA program Website, www.cr.nps.gov/nagpra (click ''Review Committee'' in the menu on the left).

Solicitation of Nominations: The Secretary of the Interior is soliciting nominations to fill three Review Committee vacancies, as follows -

1. One vacancy will be filled by a traditional Native American religious leader nominated by Indian tribes, Native Hawaiian organizations, and/or traditional Native American religious leaders.

2. Two vacancies will be filled by persons nominated by national museum organizations and scientific organizations.

Required Nomination Information: Nominations must include the following information; nominations that do not include all of the following information will be considered nonresponsive to this solicitation.

1. Nominations by tribes, or by national museum or scientific organizations: Nominations must be submitted on official tribal or organization letterhead with the original signature of the nominator, and the nominator's daytime telephone number. Nominators must be the Indian tribe official or organization leader authorized by their tribe(s) or organization(s) to submit nominations in response to this solicitation, and the nomination must include a statement that the nominator is so authorized.

2. Nominations by traditional Native American religious leaders: Nominations must include a statement that the nominator is a traditional Native American religious leader and the nominator's daytime telephone number.

3. Information about nominees: All nominations must include the following information—

a. Nominee's name, address, and daytime telephone number (required), and e-mail address (optional).

b. Nominee's resume or brief biography. The resume or biography should emphasize the nominee's NAGPRA experience.

c. Nominations of traditional Native American religious leaders must include a statement by the nominator that the nominee is a traditional Native American religious leader.

Definitions of Some Terms Used in this Notice

1. Indian tribe: Any tribe, band, nation, or other organized group or community of Indians, including any Alaska Native village (as defined in, or established pursuant to, the Alaska Native Claims Settlement Act), that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians. (25 U.S.C. 3001 (7))

2. Native Hawaiian organization: Any organization that—

a. serves and represents the interests of Native Hawaiians,—

b. has as a primary and stated purpose the provision of services to Native Hawaiians, and

c. has expertise in Native Hawaiian affairs, and

d. shall include the Office of Hawaiian Affairs and Hui Malama I Na Kupuna O Hawai'i Nei. (25 U.S.C. 3001 (11))

3. Indian tribe official: The principal leader of an Indian tribe or Native Hawaiian organization or the individual officially designated by the governing body of an Indian tribe or Native Hawaiian organization or as otherwise provided by tribal code, policy, or established procedure as responsible for matters relating to NAGPRA. (43 CFR 10.2 (b)(4))

4. Traditional Native American religious leader: A person who is recognized by members of an Indian tribe or Native Hawaiian organization as being responsible for performing cultural duties relating to the ceremonial or religious traditions of that Indian tribe or Native Hawaiian organization, or exercising a leadership role in an Indian tribe or Native Hawaiian organization based on the tribe's or organization's cultural, ceremonial, or religious practices. (43 CFR 10.2 (d)(3))

Dated: May 6, 2003.

John Robbins,

Assistant Director, Cultural Resources.

[FR Doc. 03–14313 Filed 6–5–03; 8:45 am]

BILLING CODE 4310–70–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Availability; Draft Environmental Impact Statement for a Proposed Land Exchange Between the National Park Service and the Eastern Band of Cherokee Indians at Great Smoky Mountains National Park and the Blue Ridge Parkway

AGENCY: National Park Service (NPS).

ACTION: Notice of availability of draft environmental impact statement.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, and the President's Council on Environmental Quality Regulations (40 CFR 1500–1508), as implemented by Director's Order 12, the National Park Service (NPS) announces the availability of a draft environmental impact statement (DEIS) for a proposed land exchange between the NPS and the Eastern Band of Cherokee Indians (EBCI). The Department of the Interior waived the NPS policy regarding the selection of a DEIS preferred alternative. This notice also announces the locations of public hearings for the purpose of receiving comments on the draft document.

The DEIS analyzes two action alternatives and one no-action alternative for determining the feasibility of the proposed land exchange. The two action alternatives incorporate various management prescriptions to ensure resource protection and quality visitor experience conditions. The no-action alternative would continue current management practices and policies into the future.

Under the 168-acre exchange alternative, the Ravensford site (166 acres located within Great Smokey Mountains National Park and the two acres located within the Blue Ridge Parkway) would be exchanged for the 218-acre Waterrock Knob site. The Ravensford site would become part of the Qualla Boundary and the Waterrock Knob site would become part of the Blue Ridge Parkway. The EBCI would construct a three-school complex on the Ravensford site and would retain restricted use of the entire site. Restricted use would be in the form of deed restrictions on future development and a Government to Government Conservation/Education Agreement on future conservation/educational measures for archaeological, cultural, and natural resources material.

Travel to the Big Cove Community would no longer be jurisdictionally separated from the remainder of the Qualla Boundary. This alternative would place no restriction on the use of the Waterrock Knob site by the Blue Ridge Parkway; however, with the exception of possible future development of nature trails, the site would be expected to remain in its natural state.

Under the 143-acre exchange alternative, the Ravensford site would be exchanged for the 218-acre Waterrock Knob site. This alternative would be similar to the 168-acre exchange, except 25 acres would remain within Great Smoky Mountains National Park at the Ravensford site in order to ensure that certain cultural and natural resources remain under the control of the NPS. Areas of the site not included in the proposed exchange under this alternative are open field areas to the northwest of the Big Cove Road bridge, the floodplain forest located adjacent to the Oconaluftee River, and nearly all of the wetland area located east of Big Cove Road. The open field area contains important cultural resources, while the floodplain forest and wetland are considered important natural areas. The remaining acreage of the Ravensford site would be transferred to the EBCI for development of the three-school campus. This alternative would also reconnect the EBCI jurisdictional authority along the Big Cove Road with the remaining Qualla Boundary. With respect to the Waterrock Knob site, this alternative would be identical to the 168-acre alternative.

DATES: The DEIS will be available for public review from June 13, 2003, through August 15, 2003. Public meetings will be held on July 8, 9, and 10, 2003. Representatives of the NPS will be available at the public hearings to receive comments, concerns, and other input from the public related to the DEIS. Specific information about public meetings follows:

Dates	Times	Locations
July 8	6–10 PM	2431 Center Drive, Hollingworth Auditorium, Knoxville, TN 37996.
July 9	6–10 PM	Milepost 382 Hemphill Road, Blue Ridge Parkway Folk Art Center, Asheville, NC 28803.
July 10	6–10 PM	Cherokee Elementary School, Cherokee, NC.

ADDRESSES: Comments on the DEIS may be submitted by mail to John Yancy, Associate Regional Director, Natural Resources Stewardship & Science, Atlanta Federal Center, 100 Alabama Street SW., Atlanta, GA 30303. Comments may also be submitted via toll free phone: (888) 820–3644; toll free fax: (888) 820–3643; or via email at *NPSlandexchange@saic.com.* A very limited number of printed copies of the DEIS are available upon request from the above address. A copy can also be requested on CD. The complete text and an executive summary of the DEIS is available for review or download on the Internet at *http://www.npslandexchange.com/.*

Copies of the DEIS will also be available for review at the following locations:

Anna Porter Public Library, 207 Cherokee Orchard Road, Gatlinburg, TN 37738

Blue Ridge Parkway Headquarters, 199 Hemphill Knob Road, Asheville, NC 28803
John C. Hodges Library, Government Documents, University of Tennessee, 1015 Volunteer Blvd., Knoxville, TN 37996
Great Smoky Mountains National Park, Oconaluftee Visitor Center, 1194 Newfound Gap Highway, Cherokee, NC 28719
Great Smoky Mountains National Park, 107 Park Headquarters Road, Gatlinburg, TN 37738
Great Smoky Mountains National Park, Sugarlands Visitor Center, 107 Park Headquarters Road, Gatlinburg, TN 37738
Qualla Boundary Public Library, 810 Ocquoni Road, Room 151, Cherokee, NC 28719
Ramsey Library, CPO# 1500, University of North Carolina—Asheville, NC 28804.

SUPPLEMENTARY INFORMATION: The proposed action involves the exchange of land known as the Ravensford site that is located on the North Carolina side of the Great Smoky Mountains National Park and Blue Ridge Parkway for land of equal or greater monetary value that would be consolidated within a unit of the National Park Service in North Carolina as allowed under the Land and Water Conservation Act. Congress authorized the NPS to consider the feasibility of a land between the Great Smoky Mountains National Park and Blue Ridge Parkway and the Eastern Band of the Cherokee Indians. The tribal purpose for securing this land is for new schools construction. The exchange would also reestablish the territorial jurisdiction along Big Cove Road to the Qualla Boundary (also known as the EBCI Reservation).

Under the proposed action, land that is currently part of an area between the Great Smoky Mountains National Park and Blue Ridge Parkway known as the Ravensford site would be exchanged for a 218-acre site adjacent to the Blue Ridge Parkway known as the Waterrock Knob site. In addition to the no-action alternative, two exchange alternatives were developed and are analyzed in the DEIS. Environmental impacts were analyzed in this DEIS for the following resources areas: Land use, infrastructure, air quality and noise, visual resources, geology and soils, water resources, ecological resources, cultural resources, socioeconomic, waste management, and environmental justice. Direct, indirect, and cumulative impacts along with associated mitigation measures to reduce the potential for impacts were evaluated and are described for each resource area.

Our practice is to make the public comments we receive in response to planning documents, including names and home addresses of respondents, available for public review during regular business hours. If you wish for us to withhold your name and/or address, you must state this prominently at the beginning of your comment. Anonymous comments will be included in the public record. However, the National Park Service is not legally required to consider or respond to anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

The responsible official for this environmental impact statement is William W. Schenk, Regional Director, National Park Service, Southeast Region, 100 Alabama Street SW., Atlanta, Georgia 30303.

Dated: May 6, 2003.

William W. Schenk,

Regional Director, Southeast Region.

[FR Doc. 03–14316 Filed 6–5–03; 8:45 am]

BILLING CODE 4310–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Availability of the Final General Management Plan and Final Environmental Impact Statement for Wilson's Creek National Battlefield, MO

AGENCY: National Park Service, Interior.

SUMMARY: Pursuant to section 102(2) of the National Environmental Policy Act (NEPA) of 1969, the National Park Service (NPS) announces the availability of the final general management plan and environmental impact (GMP/EIS) for Wilson's Creek National Battlefield, Missouri (WICR). This notice is being furnished as required by NEPA Regulations 40 CFR 1501.7.

DATES: The required no-action period on this final GMP/EIS will expire 30 days after the Environmental Protection Agency has published a notice of availability of the final GMP/EIS in the **Federal Register**.

ADDRESSES: Copies of the Final GMP/EIS are available from the Acting Superintendent, Wilson's Creek National Battlefield, 6424 West Farm Road 182, Republic, Missouri 65738–9514. The phone number is 417–732–2662 and the fax number is 417–732–1167.

SUPPLEMENTARY INFORMATION: The purpose of the general management plan is to set forth the basic management philosophy for WICR and to provide the strategies for addressing issues and achieving identified management objectives. The final GMP/EIS describes and analyzes the environmental impacts of two action alternatives. A no action alternative is also evaluated. The draft GMP/EIS for WICR was released to the public on June 21, 2002. The public comment period ended August 20, 2002.

Although 84 reviewers submitted written comments on the draft GMP/EIS, no substantive comments were received. Of those responding, 43, or slightly over 50 percent, expressed a preference for a particular alternative. Of that number, 36 reviewers, or nearly 90 percent, expressed their support for alternative B, Wilson's Creek Battlefield Commemoration, the preferred alternative. Many of the remaining reviewers expressed support for enhancement of the battlefield landscape, and the expanded commemoration and interpretation of the Battle of Wilson's Creek. However, many also expressed concern that future park management would eliminate or severely limit recreational opportunities. Recreational use will continue to be allowed but will be managed so as not to conflict with the core mission of the park or the primary visitor experience.

The responsible official is Mr. Ernest Quintana, Acting Midwest Regional Director, NPS.

Dated: April 18, 2003.

Ernest Quintana,

Acting Regional Director, Midwest Region.

[FR Doc. 03–14314 Filed 6–5–03; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Delaware Water Gap National Recreation Area Citizen Advisory Commission Meeting

AGENCY: National Park Service; Interior.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Delaware Water Gap National Recreation Area Citizen Advisory Commission. Notice of this meeting is required under the Federal Advisory Committee Act (Pub. L. 92–463).

Meeting Date and Time: Saturday, September 6, 2003, at 9 a.m.

ADDRESS: Foster Armstrong House, Montague NJ 07827.

The agenda will include reports from Citizen Advisory Commission members including setting dates and times for future meetings, and other topics as deemed necessary by the members. Acting Superintendent Doyle Nelson will give a report on various park issues, including an update on the park's historic leasing program. The agenda is set up to invite the public to bring issues of interest before the Commission. These issues typically include treatment of historic buildings within the recreation area, monitoring of waste water facilities outside the recreation area but empyting into the Delaware River, and wildlife management issues.

SUPPLEMENTARY INFORMATION: The Delaware Water Gap National Recreation Area Citizen Advisory Commission was established by Public Law 100–573 to advise the Secretary of the Interior and the United States Congress on matters pertaining to the management and operation of the Delaware Water Gap National Recreation Area, as well as on other matters affecting the recreation area and its surrounding communities.

FOR FURTHER INFORMATION, CONTACT: Superintendent, Delaware Water Gap National Recreation Area, Bushkill, PA 18324, 570–588–2418.

Dated: April 9, 2003.

Doyle Nelson,

Acting Superintendent.

[FR Doc. 03–14315 Filed 6–5–03; 8:45 am]

BILLING CODE 4310–MY–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before May 17, 2003. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St., NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St., NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by June 23, 2003.

Carol D. Shull,

Keeper of the National Register of Historic Places.

ILLINOIS

Pike County

Shastid, John, House, 326 East Jefferson, Pittsfield, 03000579.

MARYLAND

Baltimore Independent City

Baltimore City College, 3320 The Alameda, Baltimore (Independent City), 03000573.

MASSACHUSETTS

Norfolk County

Blue Hills Parkway, (Metropolitan Park System of Greater Boston MPS) Blue Hills Parkway, Boston, 03000574.

Quincy Shore Drive, (Metropolitan Park System of Greater Boston MPS) Quincy Shore Drive, Quincy, 03000575.

MINNESOTA

Meeker County

Pipe Lake Fort, Address Restricted, Cosmos, 03000576.

NEW YORK

New York County

69th Street Transfer Bridge, Hudson River W of the West Side Highway bet. W 66th and 70th Sts., New York, 03000577.

WISCONSIN

Dane County

American Tobacco Company Warehouses Complex, 651 W. Doty St., Madison, 03000580.

Winnebago County

Riverside Cemetery, 1901 Algoma Blvd., Oshkosh, 03000578.

WYOMING

Park County

UXU Ranch, (Dude Ranches along the Yellowstone Highway in the Shoshone National Forest) 1710 N. Fork Highway, Shoshone National Forest, Wapiti, 03000581.

[FR Doc. 03–14317 Filed 6–5–03; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before May 10, 2003.

Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by June 23, 2003.

Carol D. Shull,

Keeper of the National Register of Historic Places.

ALASKA

Juneau Borough—Census Area

Point Retreat Light Station, (Light Stations of the United States MPS), on Mansfield Peninsula at N. end of Admiralty Island near Jct. of Lynn Canal and Stephens Passage, Juneau, 03000529.

ARIZONA

Maricopa County

Robson Historic District, Roughly bounded by Country Club Dr., Robson and 2nd Sts., Mesa, 03000530.

West Second Street Historic District (Boundary Revision), Roughly bounded by Robson St., University Dr. and MacDonald St., Mesa, 03000531.

ARKANSAS

Garland County

Pleasant Street Historic District, Roughly bounded by Malvern Av., Pleasant, Church, Gulpha, Garden, Grove and Kirk Sts., Hot Springs, 03000532.

CALIFORNIA

Riverside County

Galleano Winery, 4231 Wineville Rd., Mira Loma, 03000533.

GEORGIA

Coweta County

Powell Chapel School, 620 Old Atlanta Hwy., Newnan, 03000535.

Fulton County

Berkeley Park Historic District, Roughly bounded by Bellemeade Rd., Northside Dr., Atlanta Waterworks and Howell Mill Rd., Atlanta, 03000536.

Habersham County

Pyle—Davis House, 202 Massachusetts Bvd., Demorest, 03000537.

ILLINOIS

Cook County

Produce Terminal Cold Storage Company Building, 1550 South Blue Island Av., Chicago, 03000538.

INDIANA

Carroll County

Carrollton Bridge, Carrollton Rd. across Wabash R., Delphi, 03000539.

Cinton County

Christian Ridge Historic District, roughly bounded by Prairie Cr., Young & E. Washington Sts., & Harvard Terr., Frankfort, 03000540.

Jackson County

Southern Indiana Railroad Freighthouse, 105 N. Broadway, Seymour, 03000541.

Marion County

Nicholson—Rand House, 5010 W. Southport Rd., Indianapolis, 03000542.

Montgomery County

Crawfordsville High School, (Indiana's Public Common and High Schools MPS) 201 E. Jefferson St., Crawfordsville, 03000543.

Newton County

Scott—Lucas House, 514 S. Main St., Morocco, 03000544.

Posey County

Mount Vernon Downtown Historic District, Roughly bounded by Ohio R., 6th & Walnut Sts. & College Av., Mount Vernon, 03000545.

Pulaski County

Pulaski County Bridge No.31, CR 1175 W, Medaryville, 03000546.

Scott County

Scottsburg Courthouse Square Historic District, Roughly bounded by 1st., Kerton, Railroad & Wardell Sts., Scottsburg, 03000547

Tippecanoe County

Big Four Depot, 200 N. 2nd St. Lafayette, 03000548.

MASSACHUSETTS

Worcester County

Central Street Historic District, Roughly bounded by Central, Quaker, West, Chesley, Bow, Prospect & Fletcher Sts., Millville, 03000550.

East Main—Cherry Street Historic District (Boundary Increase), Park Street, Spencer, 03000551.

Mendon Center Historic District, Roughly bounded by Main, Hastings, Maple, North, Washington & George Sts., Mendon, 03000552.

MISSISSIPPI

Amite County

Bethany Presbyterian Church, Jct. MS 48 & Perry Rd., Centreville, 03000553.

De Soto County

Robertson—Yates House, 5000 Robertson Gin Rd., Hernando, 03000554.

N. MARIANA ISLANDS

Saipan Municipality

Hachiman Jinja, Lot nos. H 300–11 & H 300–4, Kannat Taddong Papago, 03000549.

OHIO

Lucas County

Toledo Traction Company Power Station, 300 Water St., Toledo, 03000555.

SOUTH DAKOTA

Moody County

Egan Park, (Federal Relief Construction in South Dakota MPS) 2nd St., Egan, 03000556.

TEXAS

El Paso County

House at 912 Magoffin Avenue, 912 Magoffin Ave, El Paso, 03000557.

Johnson County

Joiner—Long House, 604 Prairie Av., Cleburne, 03000558.

Smith County

Azalea Residential Historic District, (Tyler, Texas MPS) Roughly bounded by S. Robinson Av., Sunnybrook Dr., Fair Ln., Old Bullard Rd., College Av., W. 4th St., Highland Av., Tyler, 03000559.

Travis County

Deep Eddy Bathing Beach, 301 Quarry St., Austin, 03000560.

VIRGINIA

Arlington County

Ashton Heights Historic District, Roughly bounded by Wilson Bvd., N. Irving St., Arlington Bvd., N. Oxford St., N. Piedmont & N. Oakland Sts., Arlington, 03000561.

Chesapeake Independent City

Centreville—Fentress Historic District, roughly bounded by Fentress Rd., Centerville Tnpk., Blue Ridge Rd., Whittamore Rd., Chesapeake, 03000562.

Oaklette Historic District, roughly bounded by Indian River Rd., Oaklette, Webster, St. Lawrence, & Seneca Sts., Chesapeake, 03000563.

Sunray Agricultural Historic District, Roughly bounded by Great Dismal Swamp & I 64, Chesapeake, 03000564.

Floyd County

Phlegar Farm, Off VA 615, Floyd, 03000565.

Frederick County

Middletown Historic District, bounded by Main St., Church St., Senseney Av., 1st, 4th, 6th & 3rd Sts., Middletown, 03000566.

Nelson County

Lovingston High School, 8445 Thomas Nelson Hwy., Lovingston, 03000567.

Newport News Independent City

Lee's Mill Earthworks, 280 Rivers Ridge Cir., Newport News, 03000568.

Northampton County

Cape Charles Light Station, (Light Stations of the United States MPS) Smith Island, Kiptopke, 03000569.

Prince George County

Prince Georges County Courthouse Historic District, 6400 Courthouse Rd., Prince George, 03000570.

Suffolk Independent City

Bay Point Farm, 1400 Sleepy Hole Rd., Suffolk, 03000571.

York County

Sessions—Pope—Sheild House, 600 Main St., Yorktown, 03000572.

To assist with the preservation of this resource, the comment period has been reduced to three (3) days:

DISTRICT OF COLUMBIA

District of Columbia

Olympia Apartments (Apartment Buildings in Washington, DC, MPS) 1368 Euclid St., NW., Washington, 03000534.

[FR Doc. 03–14318 Filed 6–5–03; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[ATF Notice No. 1; ATF O 1120.2; Docket No. 2003–39]

Delegation Order—Authority To Make Determinations on Notices of Clearances, Letters of Clearance, Letters of Denial, and Appeals of Letters of Denial Under 18 U.S.C. 843(h)

To: All ATF Offices

1. *Purpose.* This order delegates certain authorities of the Director to subordinate Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) officials to make determinations on Notices of Clearance, Letters of Clearance, Letters of Denial, and Appeals of Letters of Denial under 18 U.S.C. 843(h) for responsible persons and employee possessors listed on explosives licenses and permits.

2. *Delegation.* Under the authority vested in the Director, ATF, by Department of Justice Final Rule (AG Order No. 2650–2003) as published in the **Federal Register** on January 31, 2003, and by title 28 CFR 0.130 through 0.131, the Chief of the National Explosives Licensing Center is to make determinations relating to Notices of Clearance and Letters of Clearance, and the Chief of the Brady Operations Branch is to make determinations relating to letters of denial and appeals of letters of denial.

3. *Questions.* Questions regarding this order should be addressed to the Firearms, Explosives and Arson Services Division at (202) 927–8300.

Signed: May 5, 2003.

Bradley A. Buckles,

Director.

[FR Doc. 03–14338 Filed 6–5–03; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF LABOR

Office of Disability Employment Policy

[SGA 03–13]

Customized Employment Grants Initiative

AGENCY: Office of Disability Employment Policy, Department of Labor.

ACTION: Notice of availability of funds; solicitation for grant applications (SGA 03–13).

This notice contains all of the necessary information and forms needed to apply for grant funding. (SGA 03–13)

SUMMARY: The U.S. Department of Labor (DOL or the Department), Office of Disability Employment Policy (ODEP) announces the availability of $2.5 million to award up to five competitive grants ranging from approximately $500,000 to $750,000 for strategic planning and implementation activities designed to improve the employment and career advancement of people with disabilities through enhanced availability and provision of customized employment services through the One-Stop delivery system established under the Workforce Investment Act of 1998 (WIA) (Pub. L. 105–220, 29 U.S.C. 2801 *et seq.*).

The purpose of this Customized Employment Grant Initiative, begun by ODEP in FY'01 and continued in FY'02, is to provide funds to selected Local Workforce Investment Boards (Local Boards), or, if appropriate, the WIA grant recipient or fiscal agent for the local area on behalf of the Local Board. The Local Board will be the lead entity in a consortium/partnership of public and private entities, to build the capacity in local One-Stop Centers to provide customized employment services to those persons with disabilities who may not now be regularly targeted for services by the One-Stop Center system. Grants funded under this program will also provide a vehicle for Local Boards to systemically review their policies and practices in terms of service to persons with disabilities, and to incorporate new and innovative practices, as appropriate.

Grants are for a one-year period and may be renewed for a period of up to four additional years at varying funding levels depending upon the availability of funds and the efficacy of the project activities. *See also* Parts IV, IX.

The applicants scoring the highest when evaluated pursuant to the criteria set forth in Part VII, in conjunction with considerations by the Grant Officer delineated in Part IX of this Solicitation for Grant Application will be awarded Customized Employment Grants.

Eligibility: Eligible applicants for these grants are Local Workforce Investment Boards (Local Boards) or if appropriate, the Workforce Investment Act (WIA) (Pub. L. 105–220, 29 U.S.C. 2801 *et seq.*) grant recipient or fiscal agent for the local area on behalf of the local board under the Workforce Investment Act. The Local Board may enter into numerous partnerships with other public and private entities, consistent with the proposed activities of the grant.

DATES: Applications will be accepted commencing on June 6, 2003. The closing date for receipt of applications under this announcement is July 21, 2003. Applications must be received by 4:45 p.m. (ET) at the address below. No exceptions to the mailing and hand-delivery conditions set forth in this notice will be granted. Applications that do not meet the conditions set forth in this notice will be considered non-responsive.

ADDRESSES: Applications shall be mailed to: U.S. Department of Labor, Procurement Services Center, Attention: Cassandra Willis, Reference SGA 03–13, Room N–5416, 200 Constitution Avenue, NW., Washington, DC 20210. Telefacsimile (FAX) applications will not be accepted. Applicants are advised that mail in the Washington area may be delayed due to mail decontamination procedures.

FOR FURTHER INFORMATION CONTACT: Cassandra Willis, U.S. Department of Labor, Procurement Services Center, telephone (202) 693–4570 (this is not a toll-free number), prior to the closing deadline. Persons who are deaf or hard of hearing may contact ODEP via the Federal Relay Service, (800) 877–8339. This announcement will also be published on the Internet on ODEP's online Home Page at: *http://www2.dol.gov/odep.* Award notifications will also be published on the ODEP homepage.

SUPPLEMENTARY INFORMATION:

Part I. Delivery of Applications

1. *Late Applications.* Any application received after the exact date and time specified for receipt at the office designated in this notice will be considered non-responsive, unless it is received before awards are made and it (a) is determined that its late receipt was caused by DOL error; (b) was sent by U.S. Postal Service registered or certified mail not later than the fifth calendar day before the date specified for receipt of applications (*e.g.,* an application submitted in response to a solicitation requiring receipt of applications by the 20th of the month must have been post marked by the 15th of that month); or (c) was sent by the U.S. Postal Service Express Mail Next Day Service to addressee not later than 5 p.m. at the place of mailing two working days prior to the date specified for receipt of applications. The term ''working days'' excludes weekends and Federal holidays. ''Post marked'' means a printed, stamped or otherwise placed impression (exclusive of a postage meter machine impression) that is readily identifiable, without further action, as having been supplied or affixed on the date of mailing by an employee of the U.S. Postal Service.

2. *Withdrawal of Applications.* Applications may be withdrawn by written notice or telegram (including mail gram) received at any time before an award is made. Applications may be withdrawn in person by the applicant or by an authorized representative thereof, if the representative's identity is made known and the representative signs a receipt of the proposal.

3. *Hand-delivered proposals.* It is preferred that applications be mailed at least five days prior to the closing date. To be considered for funding, hand-delivered applications must be received by 4:45 p.m., ET, at the specified address. Failure to adhere to the above instructions will be basis for a determination of non-responsiveness. Overnight express mail from carriers other than the U.S. Postal Service will be considered hand-delivered applications and must be received by the above specified date and time.

Part II. Authority

Omnibus Appropriations Resolution, 2003, Public Law 1087; Consolidated Appropriations Act, 2001, Public Law 106–554, 29 U.S.C. 557b.

Part III. Background

The President's New Freedom Initiative is designed to increase the number of people with disabilities who enter, reenter, and remain in the workforce. It is dedicated to increasing investment in and access to assistive technologies, a quality education, and increasing the integration of Americans with disabilities into the workforce and community life. The WIA provides the infrastructure for streamlining services

and securing employment through the One-Stop delivery system.

WIA provides a system in which multiple programs and agencies (including state Vocational Rehabilitation agencies) to: (a) Form partnerships in this effort; (b) share expertise and coordinate resources; and (c) provide services to assist people in gaining and retaining employment. The One-Stop Career Centers that comprise this system are in a position to expand employment opportunities for people with disabilities, thus ensuring that the intent of the New Freedom Initiative is accomplished.

Under WIA, collaboration with multiple required partners [1] is intended to create a coordinated and streamlined system for the customer seeking employment. It is essential to involve additional state or local programs as partners with the One-Stop Center to enable people with disabilities to have increased employment opportunities and choice in employment. These additional programs include, but are not limited to, state programs for Mental Retardation and Developmental Disabilities, Medicaid, Mental Health and Transportation; State Councils for Developmental Disabilities; state assistive technology programs, Small Business Development Centers and secondary education programs. While not required partners under WIA, these programs have expertise and/or resources that can contribute to expanding employment and business opportunities for people with disabilities.

In addition, community colleges, University Centers for Excellence in Developmental Disabilities, business incubators, lending institutions, foundations, faith-based and community organizations, and other state or local programs may also be critical partners. These agencies and programs may not be informed about the potential for coordinating resources and expertise with Local Workforce Investment Boards and One-Stop Centers to increase employment, choice and wages for people with disabilities.

In addition, One-Stop Centers may elect to become employment networks under the Social Security Administration's (SSA) Ticket-to-Work and Work Incentives Improvement Act of 1999 (42 U.S.C. 1320b–19 *et seq.*) (TTW), thus making it more likely that they will require expertise in customized employment strategies to successfully facilitate employment for people with disabilities who are recipients of Supplemental Security Income (SSI) or Social Security Disability Insurance (SSDI). The TTW is providing increased employment opportunities for people with disabilities who receive SSI and/or SSDI benefits by addressing some of the major barriers encountered by these individuals as they attempt to gain or regain employment. Approximately eight million people with disabilities receive SSI and/or SSDI benefits. According to the U.S. General Accounting Office, less than one percent of these individuals leave the rolls each year as a result of paid employment. About one-third of those who do leave the SSI and/or SSDI roles typically return within three years.

The TTW program provides a variety of work incentives, including greater choices of needed employment services, the continuation of Medicare eligibility for SSDI recipients and, at the state's option, health coverage under the Medicaid program to certain workers with disabilities, either by permitting them to purchase Medicaid coverage or by extending Medicaid eligibility to them without charge. As a result, there is unprecedented opportunity for these individuals to enter, or return to the workforce.

Therefore, increasing numbers of individuals with disabilities will be approaching their local One-Stop Centers for assistance.

Many strategies exist for securing integrated, competitive employment for people with disabilities, including people who previously might have been considered ''nonfeasible'' for employment, and people who have been segregated in institutions, nursing homes, and day activity programs.

Many exemplary practices and promising strategies have emerged through decades of research and demonstration projects, and through other public and private activities promoting increased choice and self-determination for people with disabilities. These include a variety of approaches such as:

- Supported employment;
- Supported entrepreneurship;
- Individualized job development;
- Job carving and restructuring;
- Use of personal agents (including individuals with disabilities and family members);
- Development of micro-boards, micro-enterprises, cooperatives and small businesses; and
- Use of personal budgets and other forms of individualized funding that provide choice and control to the person and promote self-determination.

These and other innovations hold the promise of dramatically increasing both employment and wages for people with disabilities, in part by increasing their choices for integrated, competitive employment, business ownership, micro-enterprise development, entrepreneurship, and other employment options that were previously seldom available.

An important focus of these innovations has been on providing non-stereotypical jobs that provide increased earnings, benefits, and career advancement potential for people with significant disabilities. There is a substantial need for a sustained and coordinated initiative to build professional competency within One-Stop Centers and their partners, including service providers and employers, about the use of such customized employment strategies.

Additionally there is a need to:

(1) Effectively expand the availability of personal agents, job development expertise, and other strategies for achieving customized employment for people with disabilities;

(2) Increase the number of eligible training providers who register with the local One-Stop Career Center with expertise in providing customized employment assistance, including faith-based and community organizations that have expertise in supporting families and individuals;

(3) Provide information, technical assistance, training and strategic planning that focuses on integrating customized employment strategies into the workforce investment system;

(4) Develop ongoing linkages with employers, professional and business service organizations and trade associations and market to employers the abilities of people with disabilities to work in a variety of jobs;

(5) Coordinate all necessary employment and related supports from WIA partners and other essential programs that are not required partners under WIA; and,

(6) Research and demonstrate alternative methods of determining effective performance by the workforce investment system in terms of service to people with disabilities.

[1] Some of the required partners are adult education and literacy activities under Title II of WIA; post-secondary vocational education activities under the Carl Perkins Act (20 U.S.C. 2301 *et seq.*); vocational rehabilitation programs authorized under Title V of the Workforce Investment Act; welfare-to-work programs; veterans employment and training activities, community services block grant employment and training activities; U.S. Department of Housing and Urban Development employment and training activities; and activities authorized under Title V of the Older Americans Act (WIA sec. 121(b), 29 U.S.C.A. 2841(b), 20 CFR 662.200).

This SGA is designed to award strategic planning and implementation grants for customized employment to develop and/or expand the capacity of local workforce systems to provide meaningful and effective opportunity through One-Stops for all persons with disabilities. This SGA will lead to the development of comprehensive models of direct service delivery in the context of a One-Stop setting for individuals with disabilities with the greatest barriers to employment, many of whom have never been employed, have been limited to subsidized employment, are underemployed, or may be considered by some as unable to be employed. The Customized Employment grants will involve cutting edge approaches such as use of customized employment strategies and active involvement of essential programs of both mandated and non-mandated partners of the workforce system.

The result of these efforts will be an increase in employment, choice, and wages for people with disabilities through the use of customized employment, and the systemic evaluation and modification, as appropriate, of policies and practices to ensure that customized employment strategies for people with disabilities are systemically included in the services available through the One-Stop Centers.

The U.S. Department of Labor also offers Work Incentive Grants through its Employment and Training Administration. The Work Incentive Grants are designed to enhance service delivery throughout the National One-Stop delivery system for people with disabilities. The Work Incentive Grants are complementary yet distinct from the Customized Employment demonstration grants offered in this SGA. The Work Incentive Grants support systemic change through capacity building of the One-Stop infrastructure, whereas these Customized Employment Grants will serve as models of comprehensive service delivery that extend beyond WIA programs and provide services for individuals with disabilities who are the most disenfranchised under current service delivery systems.

Part IV. Funding Availability and Period of Performance

ODEP anticipates awarding approximately up to five competitive grants ranging from $500,000 to $750,000, to develop demonstration programs to support the development and coordination of customized community employment opportunities in non-stereotypical jobs for people with disabilities. This grant initiative is founded in the belief that in order to fully participate in community life, individuals with disabilities must have the opportunity for employment.

These demonstration grants will be awarded for one year, with four additional option years possible, depending upon the availability of funds and the efficacy of grant activities, established by independent reviews conducted by ODEP or its designees. It is envisioned that if funding continues for the full five years, the funding for years four and five will be at successively lower rates with funding during year four at 80 percent of the third year funds, and funding during year five at 60 percent of the third year funds. Grantees are expected to use this grant to leverage and develop other public and private resources to ensure sustainability, and the extent to which the application demonstrates such sustainability is an important rating criterion for this competition.

Funds shall not be used for modifying buildings or equipment for physical accessibility, although the strategic planning should address how resources will be leveraged for such purposes from other sources, as appropriate.

Part V. Eligible Applicants and Required Partnerships

Eligible applicants: Eligible applicants for these grants are restricted to Local Workforce Investment Boards (Local Boards) or, if appropriate, the WIA grant recipient or fiscal agent for the local area on behalf of the Local Board as established under WIA. The Local Board may coordinate numerous partnerships with other public and private entities, consistent with proposed activities of the grant and applicable administrative requirements. Local Boards are encouraged to form partnerships with other state and local entities and public and private non-profit organizations, including faith-based and community organizations.

Indian and Native American Tribal entities, or consortia of Tribes, with the written approval of their tribal council, are also eligible to receive these grants. Grants to Indian and Native American tribal grantees must recognize principles of sovereignty and self-governance established under the Indian Self-Determination and Education Assistance Act, allowing for the government-to-government relationship between the Federal and Tribal Governments. Such an application could involve coordination of services and enhancement to a One-Stop system approach for people with disabilities in a specific Indian community or covering multiple Tribal entities that may cut across multiple States and/or workforce investment areas.

Required partnerships: The purpose of this initiative is to maximize the capacity of, and outcomes from, One-Stop Centers and their partners to effectively serve people with disabilities through customized employment strategies, and to integrate those strategies into the policy and practice of the One-Stop and its partners in order to increase employment, choice and wages for people with disabilities. These efforts must include the involvement of many key partners, especially those with direct involvement in their area's One-Stop Career Centers.

For purposes of this solicitation, the target groups are people with disabilities who are either unemployed or under-employed and are:

(1) Receiving Supplementary Security Income (SSI) and/or Social Security Disability Insurance (SSDI); or

(2) Participating in day programs (such as day habilitation, day activity or day health programs) or participating in facility-based or community employment and earning less than minimum wage; or

(3) Participating in segregated employment and choosing to move to integrated, competitive employment; or

(4) Awaiting employment services and supports following a move from a residential facility, or as part of a plan to move into a community under the Supreme Court decision in Olmstead v. L.C. by Zimring, 527 U.S. 581(1999); or

(5) Transitioning from, or preparing to transition from, secondary school under a transition plan under part B of the Individuals with Disabilities Education Act, as amended (20 U.S.C. 1400 *et seq.*), and who, without access to customized employment strategies, would likely be referred to one of the environments identified in (2), (3) or (4) above, but who prefer integrated, competitive employment or self-employment.

In addition, this program is subject to the provisions of the ''Jobs for Veterans Act,'' Public Law 107–288, which provides priority of service to veterans and certain of their spouses in all Department of Labor-funded job training programs. Please note that, to obtain priority of service, a veteran must meet that program's eligibility requirements. Comprehensive policy guidance is being developed and will be issued in the near future.

As Local Boards, through their local One-Stop Center are required to coordinate and to form partnerships with other state and local entities and public and private non-profit

organizations, grant applications must include proposed methods for coordinating efforts with a wide variety of state agencies or entities.

Some of the agencies and organizations that should be considered for inclusion are:

- State programs for Vocational Rehabilitation;
- Mental Health, Medicaid, Mental Retardation/Developmental Disabilities,
- Housing and/or Transportation;
- State Councils on Developmental Disabilities;
- Protection and Advocacy Programs;
- University Centers for Excellence in Developmental Disabilities;
- Institutions of higher education;
- Centers for Independent Living (CIL);
- Disability advocacy and provider organizations;
- Organizations of parents;
- Federally-funded disability grant entities;
- Small Business Development Centers;
- Cooperatives and micro-enterprises;
- Lending and financial institutions;
- Training programs;
- Media and marketing agencies;
- Employers;
- Foundations;
- Grass roots, industry, and faith-based and community organizations;
- As well as other organizations or programs that provide or support services and/or advocacy for people with disabilities.

Letters of support and commitment from these programs may be included in the Appendix of the proposal.

Part VI. Format Requirements for Grant Application

General requirements: Applicants must submit one (1) paper copy with an original signature and two (2) additional paper copies of their signed proposal. To aid with the review of applications, DOL also encourages Applicants to submit an electronic copy of their proposal on a disc or CD using Microsoft Word. Applicants who do not provide an electronic copy will not be penalized. The Application Narrative must be double-spaced with standard one-inch margins (top, bottom, and sides) on 8½ x 11 papers, and be presented on single-sided, numbered pages with the exception of format requirements for the Executive Summary. The Executive Summary must be limited to no more than two single-spaced, single-sided pages on 8½ x 11 papers with standard one-inch margins (top, bottom, and sides) throughout. A font size of at least twelve (12) pitch is required throughout. Applications that fail to meet these requirements will be considered non-responsive.

The three required sections of the application are:

Section I—Project Financial Plan
Section II—Executive Summary—Project Synopsis
Section III—Project Narrative (including Attachments, not to exceed seventy-five (75) pages)

Mandatory requirements for each section are provided as follows in this application package. Applications that fail to meet the stated mandatory requirements of each section will be considered non-responsive.

Mandatory application requirements: Section I. Project Financial Plan (Budget) [The Project Financial Plan will not count against the application page limits.] Section I of the application must include the following three required parts:

(1) Completed ''SF 424—Application for Federal Assistance'' (See Appendix A of this SGA for required form)

(2) Completed ''SF–424A—Budget Information Form'' by line item for all costs required to implement the project design effectively. (See Appendix B of this SGA for required forms.)

(3) Budget Narrative and Justification that provides sufficient information to support the reasonableness of the costs included in the budget in relation to the service strategy and planned outcomes.

The application must include one SF–424 with the original signatures of the legal entity applying for grant funding and 2 additional copies. Applicants shall indicate on the SF–424 the organization's IRS Status, if applicable. Under the Lobbying Disclosure Act of 1995, section 18 (29 U.S.C. 1611), an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities will not be eligible for the receipt of Federal funds constituting an award, grant, or loan. [See 2 U.S.C. 1611; 26 U.S.C. 501(c)(4).] For item 10 of the SF–424, the Catalog of Federal Domestic Assistance (CFDA) number for the program is 17.720.

The Budget Narrative and Justification must describe all costs associated with implementing the project that are to be covered with grant funds. Grantees must support the travel and associated costs with sending at least one representative to the annual ODEP Policy Conference for Grantees, to be held in Washington, DC at a time and place to be determined. Grantees must comply with the ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments,'' (also known as the ''Common Rule'') codified at 29 CFR part 97, and ''Grants and Agreements with Institutes of Higher Education, Hospitals, and Other Non-Profit Organizations'' (also known as OMB Circular A–110), codified at 29 CFR part 95 and must comply with the applicable OMB cost principles circulars, as identified in 29 CFR 95.27 and 29 CFR 97.22(b).

Grantees may use funds in a flexible manner, as determined appropriate by input from stakeholders and identified needs, so long as requirements for outcome and evaluation data and other requirements of Federal statutes, regulations, administrative requirements, and OMB circulars and the requirements delineated in this SGA are met.

In addition, the budget must include on a separate page a detailed cost analysis of each line item. Justification for administrative costs must be provided. Approval of a budget by DOL is not the same as the approval of actual costs. The individual signing the SF–424 on behalf of the applicant must represent and be able to legally bind the responsible financial and administrative entity for a grant should that application result in an award. The applicant must also include the Assurances and Certifications Signature Page (Appendix C).

- Section II. Executive Summary—Project Synopsis [The Executive Summary is limited to no more than two single-spaced, single-sided pages on 8½ x 11 papers with standard margins throughout]. Each application shall include a project synopsis that identifies the following:
- The applicant;
- The amount of funds requested;
- The planned period of performance;
- The list of partners, as appropriate;
- An overview of how the applicant will identify the population to be served (including the estimated number and types of disability), the environments such individuals are currently experiencing (such as institutions, nursing homes, segregated day programs, etc.), and methods that will be used to promote community employment, including customized employment strategies listed in this SGA; and
- An overview of the plan for sustainability once Federal funding ceases.
- Section III. Project Narrative [The Project Narrative plus attachments are limited to no more than seventy-five (75), 8½ x 11 pages, double-spaced with standard one-inch margins (top, bottom, and sides), and must be presented on

single-sided, numbered pages]. (Note: The Financial Plan, the Executive Summary, and the Appendices are not included in the seventy-five (75) page limit). The requirements for the project narrative are described below under Part VII—Statement of Work.

All text in the application narrative, including titles, headings, footnotes, quotations, and captions, as well as all text in charts, tables, figures, and graphs must be double-spaced (no more than three lines per vertical inch); and, if using a proportional computer font, use no smaller than a 12-point font, and an average character density no greater than 18 characters per inch (if using a non-proportional font or a typewriter, do not use more than 12 characters per inch). Applications that fail to meet these requirements will be considered non-responsive.

Part VII. Government Requirements/ Statement of Work (Project Narrative)

The purpose of this initiative is to maximize the capacity of, and outcomes from, One-Stop Centers and their partners to effectively serve people with disabilities through customized employment strategies, and to integrate those strategies into the policy and practice of the One-Stop and its partners in order to increase employment, choice and wages for people with disabilities. These efforts must include the involvement of many key partners, including those with direct involvement in their area's One-Stop Career Centers, as described in Section V above.

For purposes of this solicitation, ODEP has specifically targeted the development and provision of customized employment to those people with disabilities identified in Part V.

ODEP expects that once capacity for using customized employment strategies is developed or enhanced, the One-Stop Centers and their partners will expand use of these strategies to other groups of people with (and without) disabilities.

For purposes of this solicitation, customized employment means individualizing the employment relationship between employees and employers in ways that meet the needs of both. It is based on an individualized determination of the strengths, needs, and interests of the person with a disability, and is also designed to meet the specific needs of the employer. It may include approaches such as supported employment; supported entrepreneurship; individualized job development; job carving and restructuring; use of personal agents (including individuals with disabilities and family members); development of micro-boards, micro-enterprises, cooperatives and small businesses; and use of personal budgets and other forms of individualized funding that provide choice and control to the person and promote self-determination. These and other job development or restructuring strategies result in job responsibilities being customized and individually negotiated to fit the needs of individuals with a disability. Customized employment assumes the provision of reasonable accommodations and supports necessary for the individual to perform the functions of a job that is individually negotiated and developed.

Each applicant for these grants shall describe its plan for expanding capacity for, and provision of, customized employment opportunities to the target groups as defined in Part V above. Upon the commencement of a grant, grantees must begin a strategic planning and implementation process that will address multiple components of needed change. Planning, implementation and ongoing evaluation for continuous improvements are expected to be implemented from year one in recognition that dynamic planning will occur and evolve over time. By the end of year five, it is expected that a more long-term strategic plan will be in place for expanding the availability of customized employment, and for systemically revising policies and practices consistent with this goal.

The Project Narrative, or Section III of the grant application, should provide complete information on how the applicant will address the following DOL priorities for fiscal year 2003:

(1) Increase the availability of skill training, employment opportunities and career advancement for persons with disabilities; and

(2) Develop comprehensive One-Stop Centers, which are welcoming and are valued providers of choice by customers with disabilities seeking workforce assistance by assuring the availability of staff trained on disability issues, personalized employment counseling, knowledgeable support that addresses employment barriers and work incentives and the availability of accommodations and technologies for diverse disability needs.

Proposals will be rated based upon the quality of the applicant's response in addressing the four criteria described below in terms of a comprehensive strategic approach that addresses ODEP's priorities noted above. The four criteria (Statement of Need/National Significance, Comprehensive Service Strategy, Sustainability, and Management Plan and Outcomes) MUST be addressed and the applicant's goals, accomplishments or status with regard to each item provided.

ODEP, however, does not expect the applicant to fully incorporate every item listed as part of their strategy and proposal design. ODEP recognizes that the needs and requirements of each state and community may be different, and therefore, some of the options identified may be more relevant than others in a particular state or community.

2. Statement of Need /Significance of the Project (15 points)

The purpose of the Statement of Need is to establish the overall status of disability issues relevant to the targeted population in the applicant's state; to identify strengths and deficiencies to be addressed by the applicant's proposal; to identify the overall scope of the proposal's objectives and design; to present the applicant's need for the grant resources; to demonstrate significance of the proposed project; and to demonstrate the development or demonstration of promising new strategies, practices, or innovations. This criteria will be rated upon the applicant's needs identified and proposed approaches to addressing the needs in the context of the Department's priorities.

The narrative in this section should include information that demonstrates:

(1) The potential contribution of the proposed project to increase knowledge or understanding of problems, issues, or effective strategies for local workforce boards and other required and potential partners to use customized employment strategies to increase employment, choice and wages, and influence systems change in the local workforce system.

(2) The extent to which the applicant has an understanding of the issues the state and proposed geographic area are currently facing in their overall Customized Employment implementation efforts;

(3) The extent to which the proposed project is likely to yield findings that may be used by other appropriate agencies and organizations;

(4) The extent to which the proposed project involves the development or demonstration of promising new strategies that build on, or are alternatives to, existing strategies;

(5) The extent to which the promising practices of the proposed project are to be disseminated in ways that will enable others to use the information or strategies;

(6) The potential replicability (national significance) of the proposed project or strategies, including, as appropriate, the potential for

implementation in a variety of settings; and

(7) The importance or magnitude of the outcomes, which are likely to be attained by the proposed project.

In evaluating the quality of the proposal narrative, ODEP will consider needs identified and the applicant's proposed approaches to addressing the needs in the context of ODEP's priorities.

2. Comprehensive Service Strategy (30 points)

The purpose of the Comprehensive Service Strategy criteria is to identify the approach proposed by the applicant to implement the Customized Employment grant. The strategy should implement the purpose and objectives of this SGA to enhance the capacity of the workforce investment system to increase employment, choice and wages for persons with disabilities through the use of customized employment strategies and to ensure that such strategies are systemically included in the policy and practice of the One-Stop Center(s).

Proposed Project Design and Its Evaluation—the application must address the proposed design for the Customized Employment grant including its response to the requirements outlined in Part V (Eligible Applicants and Required Partnerships) of this Solicitation.

The Project Design must:

(1) Develop strategic planning and implementation activities across the One-Stop required partner programs as identified in the WIA (such as Vocational Rehabilitation and others as appropriate) as well as other essential programs (such as Medicaid, Medicare, Mental Health, Transportation, Small Business Development Centers, State Councils on Developmental Disabilities, community colleges, benefits counseling and assistance programs, lending and financial institutions), whose expertise, services, and funds could contribute to employment services and supports needed by people with disabilities in order to secure customized employment. Planning activities must include a review of policy and practice as it relates to people with disabilities to provide customized employment for persons with disabilities. Such capacity includes enhancing collaboration between required WIA partners and building new collaborative initiatives with other essential programs;

(2) Develop local and statewide policy initiatives to ensure that customized employment and multiple innovative strategies and promising practices become part of the menu of services available to people with disabilities, including investigating alternative methods for performance accountability that consider the characteristics of the population;

(3) Develop employment opportunities in a variety of jobs, industries and at a variety of levels, including self-employment and entrepreneurship, based on the strengths, needs and desires of the individual with a disability as well as creating and cultivating demand for these opportunities by forging and developing relationships with employers. The design must organize services and supports in ways that provide informed choice and promote self-determination and provide services, including follow-up services to ensure job retention and career development;

(4) Develop and document the capacity of the One-Stop system to increase the wages of people with disabilities who are currently working at less than minimum wage through the use of customized employment strategies;

(5) Develop an increased understanding by One-Stop Centers' staff about health care, work incentives, benefits planning, ''tickets'' and other provisions under TTW; and document increased use of these programs by the One-Stop Center and its partner programs to secure customized employment for recipients of SSI and SSDI who are entering the workforce or returning to work. This may include registering as an Employment Network under TTW;

(6) Document the increasing use of resources from a number of system partners and other essential programs, including providing individual budgets and other forms of self-directed accounts (*e.g.*, individual training accounts or contractual services; tickets; vouchers; and other sources of individualized funding or personal funding accounts) for persons with disabilities to obtain customized employment;

(7) Develop, leverage and document linkages with other state and local initiatives that provide services and supports for people with disabilities (including, but not limited to, state systems change efforts which promote systems improvement and comprehensive coordination; initiatives involving health care; benefits planning and assistance; housing; transportation; education; supported employment; small business development; technology-related assistance; initiatives of private foundations; and faith-based and community organization programs and others, as appropriate);

(8) Establish connections to and collaborate with other entities, including employers, persons with disabilities, their parents and other family members, community rehabilitation agencies, lending and financial institutions, foundations, faith-based and community organizations, institutions of higher education, small business development centers and others, as appropriate, to further customized employment opportunities for persons with disabilities in local communities. These partners may become a subgroup or an advisory group of the Local Board. They may be specifically charged with coordinating funding, resources and expertise to increase customized employment for people with disabilities in the community and may involve grant design and implementation;

(9) Educate relevant stakeholders, including state and local policymakers and systems personnel, about needed changes in policy and practice in order to increase customized employment and wages for people with disabilities;

(10) Include education activities to enable customized employment and personalized supports to become available and used in local communities, including (as appropriate) activities necessary to secure adoption of the Medicaid buy-in by the state;

(11) Market and develop ongoing linkages with employers, and their professional, business and service organizations and trade associations, as appropriate;

(12) Expand the use of customized employment strategies over time to:

a. All groups of persons with disabilities targeted under this solicitation; and

b. Other groups of individuals with disabilities (such as individuals who are receiving TANF benefits) following completion of the grant;

(13) Track and respond to customer service and satisfaction for both persons with disabilities and employers; and

(14) Identify and purse other activities appropriate to achieving the goals of these grants.

Activities may include the following:

Necessary staffing across agencies to implement grantee activities and otherwise demonstrate effective partnerships and interactions necessary to effectively leverage resources and expertise from partnering systems and programs;

(1) Outreach to relevant stakeholders;

(2) Demonstration activities which provide methods to increase the employment, choice, and wages of people with disabilities that are designed for systemic inclusion

(including but not limited to demonstrating the use of individual training accounts or contractual services, tickets, and self-directed individual budgeting initiatives; economic stimulus activities including low-interest loans for person-centered micro-boards focused on increasing economic prosperity for specific individuals with disabilities; entrepreneurial employment initiatives that are consumer-owned or operated; demonstrations of innovation and cutting-edge strategies providing personal control, choice and customized assistance resulting in employment, including business ownership, micro-enterprise development or development of cooperatives for persons with disabilities; accessing Individual Development Accounts and financial literacy training; and other supports needed by specific individuals with disabilities to increase choice and wages in employment);

(3) Collaboration with the education system, parents, families and faith-based and community organizations to ensure transition of young people with disabilities from school to customized employment or training, and documentation of the outcomes of such efforts;

(4) Training and education activities (including training regarding Medicaid buy-in provisions and other policies with implications for increasing employment through state activities) designed to further the goal of increasing customized employment for persons with disabilities. These training activities include the education of One-Stop and partner personnel; educating state systems personnel and policymakers; developing and disseminating educational information and materials; and otherwise promoting policy and practice to increase the wide spread community-based use of customized employment strategies and personalized supports;

(5) Researching and demonstrating alternative methods of measuring WIA performance outcomes that consider the various characteristics of people with disabilities and developing demonstrations of performance measures that document new methods for measuring program effectiveness; and coordinating the availability of and access to assistive technology;

(6) Educating the media and the general public about successful strategies for and the benefits of securing employment for people with disabilities. This will assist in obtaining long-term support for continuation of grantee activities following completion of funding;

(7) Increasing the availability of personal agents and job development personnel offering customized services through customer-controlled approaches that result in customized employment (including demonstrating effectiveness of paying family members or other individuals with disabilities to serve as personal agents when selected by the individual with a disability to assist in negotiating and implementing employment plans and services);

(8) Assisting community providers of segregated employment services to develop integrated, competitive options for individuals with disabilities, including implementation of conversion and other organizational change initiatives conducted with segregated provider programs that wish to change their services to integrated employment; and

(9) Other activities necessary to address needs and achieve goals identified through strategic planning and implementation, including collection of necessary data and evaluation.

In evaluating the quality of the proposed project design, ODEP's consideration will be guided by the following factors:

(a) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable;

(b) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population and other identified needs and the quality of the applicant's plans for recruiting and retaining the target population;

(c) The extent to which the design of the proposed project provides procedures and approaches for collaboration and coordination with key agencies and organizations and identification of critical roles;

(d) The extent to which the design of the proposed project provides clear understanding of and experience with utilization of customized employment strategies for increasing employment, choice and earnings of individuals with significant disabilities;

(e) The extent to which the proposed project will be coordinated, including demonstrated support and commitment from key organizations, employers, and agencies, including faith-based and community organizations;

(f) The extent to which the applicant encourages involvement of people with disabilities and their families, experts and organizations, and other relevant stakeholders in project activities;

(g) The extent to which the design of the project will facilitate an increase in the number of faith-based and community organizations that register as eligible training providers with their local One-Stop Center.

(h) The extent to which performance feedback and continuous improvement are integral to the design of the proposed project.

(i) The extent to which the management plans for project implementation is likely to achieve the objectives of the proposed project on time and within budget; and

(j) The extent to which the proposed project design features innovative strategies to implement customized employment and choice.

3. Sustainability (25 points)

The purpose of the sustainability criteria is to identify strategies for ensuring that activities funded under the grant will continue once Federal funding ceases. Resources and partnerships are an integral element of the project. Sustainability objectives must be built into the project design and ongoing project operation.

In addition, the applicant should detail how federal, state, and local public sector commitments contribute to the sustainability of this project following completion of the grant. Examples of such commitments could include: Commitment from state vocational rehabilitation, one-stop center, state developmental disability, state Medicaid, or state general revenue funding to support expanded customized employment services for individuals securing employment through the agency; status as Employment Network under TTW providing customized employment services to eligible ticket-holders; private sector funding through foundations, financial or lending agencies, or other relevant collaborative arrangements for continuing provision and/or expansion of customized employment services in the community.

To illustrate sustainability planning, the applicant must:

(1) Identify resources and partnerships that are an integral element of the project. Projects funded under this SGA will be judged on their ability to leverage a combination of federal, state, and local public sector resources, as well as local non-profit sector resources for purposes of sustainability. Accordingly, in this section the applicant should enumerate these resources, describe any specific existing contractual commitments, and provide concrete evidence of sustainability;

(2) Identify activities and in-kind elements of sustained support. ODEP considers detailed commitments for

specific new activities as more important than promises of in-kind supports in showing sustained support for the project. Grants recently received from another agency can be discussed in the proposal, but the applicant should be precise about which activities preceded this grant and which will occur because of the grant; and

(3) Detail how federal, state, and local public sector commitments contribute to the sustainability of this project following completion of the grant. Examples of such commitments could include: Commitment from state vocational rehabilitation, one-stop center, state developmental disability, state Medicaid, or state general revenue funding to support expanded customized employment services for individuals securing employment through the agency; status as Employment Network under the Ticket to Work and Work Incentive Improvement Act providing customized employment services to eligible ticket-holders; private sector funding through foundations, financial or lending agencies, or other relevant collaborative arrangements for continuing provision or expansion of customized employment services in the community.

In evaluating the quality of the plan for sustainability, ODEP considers the following factors to be of particular importance:

(a) The extent to which the proposed project is designed to build capacity and yield results that will extend beyond the grant period, and the quality of the applicant's plans for implementing the project's activities in years four and five when Federal funding will be reduced.

(b) The likelihood of the applicant successfully securing state ownership and participation in these projects when the grant funds cease.

(c) The extent to which partnerships with outside entities (including public and private disability and faith-based and community organizations) and funding from additional federal, state, and local resources will be effectively leveraged and utilized in continuing the Customized Employment activities after the expiration of this grant.

Letters of Commitment: Applicants can include letters of support if they provide specific commitments. Such letters can increase an applicant's score by showing that the commitments in the text of the proposal are serious. Form letters will not be considered. *See also* Part V.

4. Management and Outcomes (30 points)

The purpose of the Management and Outcomes criteria is to determine whether the applicant has developed an adequate management plan to effectively carry out the objectives and scope of the proposed project on time and within budget, to describe the predicted outcomes resulting from activities funded under this SGA, and to identify the ''methods of evaluation'' that will be used by the grantee to determine success.

Applicants should provide a detailed management plan, which identifies the critical activities, time frames, milestones for accomplishing grant activities and responsibilities for effectively implementing the project, including the evaluation process for assuring successful implementation of grant objectives. Funds must be used in a flexible manner, as determined appropriate by input from stakeholders and identified needs.

In addition, applicants should outline the strategy for documenting and reporting the activities undertaken during the life of the grant for ODEP's future use in working with other grantees and constituencies.

Staff Capacity—The applicant must identify how it will ensure that trained staff are available to provide grant related services who have adequate knowledge of diverse disabilities, knowledge of diverse customized employment strategies, and employment-related experience for the target population. Resumes must be included in the Appendices.

The application must:

(1) Describe the proposed staffing of the project. Identify how it will ensure that trained staff with adequate knowledge of diverse disabilities, knowledge of diverse customized employment strategies, and employment-related experience for the target population will be available to provide grant-related services.

(2) Summarize the qualifications, including relevant education, training and experience of key project personnel, as well as the qualifications, including relevant training and experience of project consultants or subcontractors. Attach copies of resumes in the Appendices.

(3) Describe the applicant's experience in serving people with disabilities and providing customized employment services.

(4) Describe the extent to which the time commitments of the project director and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

In evaluating the management and outcomes criteria, the ODEP considers the following factors to be of particular importance:

(a) The extent to which the proposed budget and narrative justifications are adequate to support the proposed project;

(b) The extent to which performance feedback and continuous improvement are integral to the design of the proposed project;

(c) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies;

(d) The extent to which the evaluation will provide information to other programs about effective strategies suitable for replication or testing in other settings;

(e) The extent to which the methods of evaluation include the objective use of performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data;

(f) The extent to which the methods of evaluation measure in both quantitative and qualitative terms, program results and satisfaction of customers, both people with disabilities and employers;

(g) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project;

(h) The extent to which the key personnel are appropriate and adequate to meet the objectives of the proposed projects;

(i) The extent to which the budget is adequate to support and sustain the proposed project activities over the projected five-year period.

(j) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

Part VIII. Monitoring and Reporting

Monitoring: ODEP is responsible for ensuring the effective implementation of each competitive grant project in accordance with the provisions of this announcement and the terms of the grant award document. Applicants should assume that ODEP staff, or their designees, will conduct on-site project reviews periodically. Reviews will focus on timely project implementation, performance in meeting the grant's programmatic goals and objectives, expenditures of grant funds on allowable activities, integration and coordination with other resources and service providers in the local area, project management and administration of project activities. Customized Employment Grants may be subject to other additional reviews at the discretion of the ODEP.

Reporting: Grantees will be required to submit quarterly financial and

narrative progress reports. In addition, all grantees will be expected to provide information on individuals with disabilities securing employment through use of customized strategies (including information on types of jobs, wages, and benefits secured by specific individuals with disabilities) and other areas addressed through the linkages and networks facilitated by project activities.

Grantees will be required to submit periodic financial and participation reports. Specifically the following reports will be required:

A. *Quarterly reports:* The quarterly report is estimated to take ten hours to complete. The form for the Quarterly Report will be provided by ODEP. ODEP will work with the grantee to help refine the requirements of the report, which will, among other things, include measures of ongoing analysis for continuous improvement and customer satisfaction.

B. *Standard Form 269;* Financial Status Report Form (FSR) will be completed on a quarterly basis, using the on-line electronic reporting system.

C. *Final Project Report:* including an assessment of project performance and outcomes achieved. The final report is estimated to take 20 hours. This report will be submitted in hard copy and on electronic disk using a format and following instructions, which will be provided by the DOL. A draft of the final report is due to ODEP 45 days before the termination of the grant. The final report is due to the DOL 60 days following the termination of the grant.

All grantees must agree to cooperate with an independent evaluation to be conducted by ODEP. ODEP will arrange for and conduct this independent evaluation of the outcomes, impacts, and accomplishments of each funded project. Grantees must agree to make available records on all parts of project activity, including participant employment and wage data, and to provide access to personnel, as specified by the evaluator(s), under the direction of ODEP. This independent evaluation is separate from the ongoing evaluation for continuous improvement required of the grantee for project implementation. The ODEP's evaluation of the Customized Employment Grants includes a process evaluation that includes extensive information pertaining to achievements under the grant, summary information, number of people with disabilities receiving services, number of people employed through then One-Stop system and other sources.

Grantees must also agree to work with ODEP in its various national technical assistance collaboratives efforts in order to freely share with others what is learned about delivering customized employment services to the target population. Grantees must agree to collaborate with other research institutes, centers, studies, and evaluations that are supported by DOL and other relevant Federal agencies, as appropriate. In addition, ODEP has established performance goals that are consistent with the Department (GPRA) goals as noted in the introduction of Part VII—Government Requirements/ Statement of Work. Customized Employment grantees will be expected to achieve these performance goals. Finally, Grantees must agree to actively utilize the programs sponsored by the ODEP, including the Job Accommodation Network, (*http:// :www.jan.wvu.edu*), and the Employer Assistance Referral Network (*http:// www.earnworks.com*).

Part IX. Review Process and Evaluation Criteria

All applications will be reviewed for compliance with the requirements of this notice. A careful evaluation of applications will be made by a technical review panel, which will evaluate the applications against the rating criteria listed in this SGA. The panel results are advisory in nature and not binding on the Grant Officer. ODEP may elect to award grants with or without discussion with the offeror. In situations without discussions, an award will be based on the offeror's signature on the SF 424, which constitutes a binding offer. The Grant Officer may consider any information that is available and will make final award decisions based on what is most advantageous to the Government, considering such factors as:

- Panel findings;
- Geographic distribution of the competitive applications and based on location of the existing Customized Employment Grants (Anchorage, AK; Montgomery, AL; NAPA and San Diego, CA; Marietta, GA; Indianapolis, IN; Malden, MA; Bucksport, ME; Detroit, MI; Blaine, MN; Hempstead, NY; Knoxville, TN; El Paso, TX; Fairfax, VA; and Kennewick, WA;);
- Assuring a variety of program designs; and
- Availability of funds

Part X. Administration Provisions

A. Administrative Standards and Provisions

Grantees are strongly encouraged to read these regulations before submitting a proposal. The grants awarded under this SGA shall be subject to the following as applicable:

- 29 CFR part 95—Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, and With Commercial Organizations, Foreign Governments, Organizations Under the Jurisdiction of Foreign Governments, and International Organizations;
- 29 CFR part 96—Audit Requirements for Grants, Contracts, and Other Agreements.
- 29 CFR part 97—Uniform Administrative Requirement for Grants and Cooperative Agreements to State and Local Governments

B. Allowable Costs

Determinations of allowable costs shall be made in accordance with the following applicable Federal cost principles:

- State and Local Government—OMB Circular A–87
- Nonprofit Organizations—OMB Circular A–122
- Profit-Making Commercial Firms—48 CFR part 31

Profit will not be considered an allowable cost in any case.

C. Grant Assurances

As a condition of the award, the applicant must certify that it will comply fully with the nondiscrimination and equal opportunity provisions of the following laws:

- 29 CFR part 31—Nondiscrimination in Federally-assisted programs of the Department of Labor, effectuation of Title VI of the Civil Rights Act of 1964.
- 29 CFR part 32—Nondiscrimination on the Basis of Disability in Programs and Activities Receiving or Benefiting from Federal Assistance. (Implementing section 504 of the Rehabilitation Act, 29 U.S.C. 794)
- 29 CFR part 36—Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance. (Implementing title IX of the Education Amendments of 1972, 20 U.S.C. 1681 et. seq.)
- 29 CFR part 37—Nondiscrimination and Equal Opportunity Provisions of the Workforce Investment Act of 1998 (WIA), (Implementing Section 188 of the Workforce Investment Act, 29 U.S.C. 2938)

The applicant must include assurances and certifications that it will comply with these laws in its grant application. The assurances and certifications are attached as Appendix C.

Signed at Washington, DC this 3rd day of June, 2003

Lawrence J. Kuss,

Grant Officer.

Appendix A. Application for Federal Assistance, Form SF 424

Appendix B. Budget Information Sheet, Form SF 424A

Appendix C. Assurances and Certifications Signature Page

Appendix D. Survey on Ensuring Equal Opportunity

BILLING CODE 4510–CX–P

APPLICATION FOR FEDERAL ASSISTANCE

OMB Approval No. 0348-0043

		2. DATE SUBMITTED	Applicant Identifier
1. TYPE OF SUBMISSION: Application ☐ Construction ☐ Non-Construction	Preapplication ☐ Construction ☐ Non-Construction	3. DATE RECEIVED BY STATE	State Application Identifier
		4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address *(give city, county, State, and zip code):*	Name and telephone number of person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER *(EIN):*

☐☐ — ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify) _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es) ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other*(specify):*

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

☐☐ — ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(Cities, Counties, States, etc.):*

13. PROPOSED PROJECT		**14. CONGRESSIONAL DISTRICTS OF:**	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING:

a. Federal	$ .00
b. Applicant	$ .00
c. State	$ .00
d. Local	$ .00
e. Other	$ .00
f. Program Income	$ .00
g. TOTAL	$ 0.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. No. ☐ PROGRAM IS NOT COVERED BY E. O. 12372
☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.

a. Type Name of Authorized Representative	b. Title	c. Telephone Number
d. Signature of Authorized Representative		e. Date Signed

Previous Edition Usable
Authorized for Local Reproduction

Standard Form 424 (Rev. 7-97)
Prescribed by OMB Circular A-102

Appendix A

INSTRUCTIONS FOR THE SF-424

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0043), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item:	Entry:
1.	Self-explanatory.
2.	Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable).
3.	State use only (if applicable).
4.	If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5.	Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6.	Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7.	Enter the appropriate letter in the space provided.
8.	Check appropriate box and enter appropriate letter(s) in the space(s) provided: -- "New" means a new assistance award. -- "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date. -- "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9.	Name of Federal agency from which assistance is being requested with this application.
10.	Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11.	Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12.	List only the largest political entities affected (e.g., State, counties, cities).
13.	Self-explanatory.
14.	List the applicant's Congressional District and any District(s) affected by the program or project.
15.	Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16.	Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17.	This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18.	To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

BUDGET INFORMATION - Non-Construction Programs

OMB Approval No. 0348-0044

SECTION A - BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$ 0.00
2.						0.00
3.						0.00
4.						0.00
5. Totals		$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION B - BUDGET CATEGORIES

6. Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total
	(1)	(2)	(3)	(4)	(5)
a. Personnel	$	$	$	$	$ 0.00
b. Fringe Benefits					0.00
c. Travel					0.00
d. Equipment					0.00
e. Supplies					0.00
f. Contractual					0.00
g. Construction					0.00
h. Other					0.00
i. Total Direct Charges *(sum of 6a-6h)*	0.00	0.00	0.00	0.00	0.00
j. Indirect Charges					0.00
k. TOTALS *(sum of 6i and 6j)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
7. Program Income	$	$	$	$	$ 0.00

Authorized for Local Reproduction

Previous Edition Usable

Standard Form 424A (Rev. 7-97)
Prescribed by OMB Circular A-102

Appendix B

SECTION C - NON-FEDERAL RESOURCES				
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$ 0.00
9.				0.00
10.				0.00
11.				0.00
12. TOTAL *(sum of lines 8-11)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$ 0.00	$	$	$	$
14. Non-Federal	0.00				
15. TOTAL *(sum of lines 13 and 14)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT				
(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	$	$	$	$
17.				
18.				
19.				
20. TOTAL *(sum of lines 16-19)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION F - OTHER BUDGET INFORMATION	
21. Direct Charges:	22. Indirect Charges:
23. Remarks:	

Authorized for Local Reproduction

Standard Form 424A (Rev. 7-97) Page 2

INSTRUCTIONS FOR THE SF-424A

Public reporting burden for this collection of information is estimated to average 180 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0044), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

Section A. Budget Summary Lines 1-4 Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the Catalog program title and the Catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the Catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the Catalog program title on each line in *Column* (a) and the respective Catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1-4, Columns (c) through (g)

For new applications, leave Column (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 - Show the totals for all columns used.

Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Line 6a-i - Show the totals of Lines 6a to 6h in each column.

Line 6j - Show the amount of indirect cost.

Line 6k - Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7 - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount, Show under the program

INSTRUCTIONS FOR THE SF-424A (continued)

narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal Resources

Lines 8-11 Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a) - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b) - Enter the contribution to be made by the applicant.

Column (c) - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

Column (d) - Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e) - Enter totals of Columns (b), (c), and (d).

Line 12 - Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

Section D. Forecasted Cash Needs

Line 13 - Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14 - Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15 - Enter the totals of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16-19 - Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20 - Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21 - Use this space to explain amounts for individual direct object class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22 - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23 - Provide any other explanations or comments deemed necessary.

OMB Approval No. 0348-0040

ASSURANCES - NON-CONSTRUCTION PROGRAMS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0040), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

NOTE: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant, I certify that the applicant:

1. Has the legal authority to apply for Federal assistance and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project cost) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§4728-4763) relating to prescribed standards for merit systems for programs funded under one of the 19 statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. §§290 dd-3 and 290 ee 3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. §§3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and, (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally-assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply, as applicable, with provisions of the Hatch Act (5 U.S.C. §§1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

Previous Edition Usable

Authorized for Local Reproduction

Standard Form 424B (Rev. 7-97)
Prescribed by OMB Circular A-102

Appendix C

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§276a to 276a-7), the Copeland Act (40 U.S.C. §276c and 18 U.S.C. §874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§327-333), regarding labor standards for federally-assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§1451 et seq.); (f) conformity of Federal actions to State (Clean Air) Implementation Plans under Section 176(c) of the Clean Air Act of 1955, as amended (42 U.S.C. §§7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended (P.L. 93-523); and, (h) protection of endangered species under the Endangered Species Act of 1973, as amended (P.L. 93-205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. §470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. §§469a-1 et seq.).

14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. §§2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§4801 et seq.) which prohibits the use of lead-based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act Amendments of 1996 and OMB Circular No. A-133, "Audits of States, Local Governments, and Non-Profit Organizations."

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

Standard Form 424B (Rev. 7-97) Back

Survey on Ensuring Equal Opportunity

Federal Agency Use Only

OMB No. 1225-0083 Exp. 02/28/2006

NOTE: Please place survey form directly behind the Standard Application for Federal Assistance (SF 424) fact sheet.

Purpose: This form is for applicants that are private nonprofit organizations (not including private universities). Please complete it to assist the federal government in ensuring that all qualified applicants, small or large, non-religious or faith-based, have an equal opportunity to compete for federal funding. Information provided on this form will not be considered in any way in making funding decisions and will not be included in the federal grants database.

1. Does the applicant have 501(c)(3) status?

❑ Yes ❑ No

2. How many full-time equivalent employees does the applicant have? *(Check only one box).*

❑ 3 or Fewer ❑ 15-50
❑ 4-5 ❑ 51-100
❑ 6-14 ❑ over 100

3. What is the size of the applicant's annual budget? *(Check only one box.)*

❑ Less Than $150,000
❑ $150,000 - $299,999
❑ $300,000 - $499,999
❑ $500,000 - $999,999
❑ $1,000,000 - $4,999,999
❑ $5,000,000 or more

4. Is the applicant a faith-based/religious organization?

❑ Yes ❑ No

5. Is the applicant a non-religious community-based organization?

❑ Yes ❑ No

6. Is the applicant an intermediary that will manage the grant on behalf of other organizations?

❑ Yes ❑ No

7. Has the applicant ever received a government grant or contract (Federal, State, or local)?

❑ Yes ❑ No

8. Is the applicant a local affiliate of a national organization?

❑ Yes ❑ No

Survey Instructions on Ensuring Equal Opportunity for Applicants

1. 501(c) (3) statuses is a legal designation provided on application to the Internal Revenue Service by eligible organizations. Some grant programs may require nonprofit applicants to have 501(c)(3) status. Other grant programs do not.

2. For example, two part-time employees who each work half time equal one full-time equivalent employee. If the applicant is a local affiliate of a national organization, the responses to survey questions 2 and 3 should reflect the staff and budget size of the local affiliate.

3. Annual budget means the amount of money your organization spends each year on all of its activities.

4. Self-identify.

5. An organization is considered a community-based organization if its headquarters/service location shares the same zip code as the clients you serve.

6. An "intermediary" is an organization that enables a group of small organizations to receive and manage government funds by administering the grant on their behalf.

7. Self-explanatory.

8. Self-explanatory

Paperwork Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 1225-0083. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: Departmental Clearance Officer, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-1301, Washington, D.C. 20210. If you have comments or concerns regarding the status of your individual submission of this form, write directly to: Joyce I. Mays, Application Control Center, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.

[FR Doc. 03–14350 Filed 6–5–03; 8:45 am]
BILLING CODE 4510–CX–C

DEPARTMENT OF LABOR

Office of Disability Employment Policy

[SGA 03–09]

High School/High Tech State Development and Implementation Grants

AGENCY: Office of Disability Employment Policy, Department of Labor.

ACTION: Notice of availability of funds; solicitation for grant applications (SGA).

This notice contains all of the necessary information and forms needed to apply for grant funding. (SGA 03–09).

SUMMARY: The U.S. Department of Labor (DOL), Office of Disability Employment Policy (ODEP) announces the availability of $1.8 million to award up to eight competitive grants in the amount of approximately $225,000 to assist states in implementing the High School/High Tech (HS/HT) program on a statewide basis.

This grant initiative involves one competitive Solicitation for Grant Application (SGA) that will be used to award both HS/HT Implementation Grants and HS/HT Development Grants:

(1) *HS/HT State Implementation Grants:* Successful state applicants will demonstrate that all partners relevant to successful implementation of the HS/HT program in the state are in place (*e.g.*, education, Workforce Investment Act, Development Disability Councils, etc.); and that the state has the capacity to implement the HS/HT design features discussed below throughout the state. In addition, successful applicants will be able to demonstrate a strong plan for sustainability of the HS/HT program when federal funding ceases. The Implementation Grants will be awarded for a one-year period of performance and funded at a level of $225,000. These grants may be renewed up to four times for an additional year of funding with the fourth and fifth years at reduced funding levels of 80% and 60% of third year funding levels, respectively, depending upon project performance and funding availability. See also Parts IV, IX.

(2) *HS/HT State Development Grants:* These grants will be targeted to state applicants able to demonstrate their capacity to implement and sustain the HS/HT program as described above in relation to the Implementation Grants within a short time period if provided with appropriate technical assistance. The Development Grants will be awarded for a one-year period of performance and funded at $225,000, after which time grantees will be eligible to apply for Implementation Grant funding. Development Grants will not be renewable.

The purpose of these grants is to assist states, working in partnership with the State Workforce Investment Board, in implementing a statewide HS/HT program, in integrating the HS/HT program into youth services funded under the Workforce Investment Act (WIA) (Pub. L. 105–220, 29 U.S.C. 2801 et seq.), and in ensuring sustainability of the HS/HT program through state-level management and coordination. HS/HT is a career development program designed to provide high school aged youth with disabilities with an opportunity to explore careers or gain further education that may lead to technology-related careers. These programs, which have generally been locally directed and supported, serve both in-school and out-of-school youth with disabilities in a year round program of corporate site visits, mentoring, job shadowing, guest speakers, after school activities and summer internships.

The application and evaluation/selection criteria for both types of grants are the same. The first applicants selected when evaluated pursuant to the criteria set forth in Parts VII and IX of this SGA will be awarded High School/High Tech Implementation Grants. The next three applicants selected will receive HS/HT Development Grants. Revised scope of work and budget documents will be required from all Development Grantees within forty-five (45) days of the award to reflect the one-year period of performance.

Eligibility: Eligible applicants for these grants include State Workforce Investment Boards; State Departments of Education; State Departments of Labor; State Developmental Disability Councils; State Departments of Vocational Rehabilitation; or State Committees affiliated with the National Governors' Committees for People with Disabilities, and other similar state agencies. ''State'' in this context includes the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. Consortia of state agencies and not-for-profit organizations (including community and faith-based organizations, independent living centers, etc.) and local HS/HT sites are also eligible applicants. Prior recipients of state-level HS/HT grant funding are ineligible to receive additional funding under this solicitation.

DATES: Applications will be accepted commencing on June 6, 2003. The closing date for receipt of applications under this announcement is July 21, 2003. Applications must be received by 4:45 p.m. (ET) at the address below. No exceptions to the mailing and hand-delivery conditions set forth in this notice will be granted. Applications that do not meet the conditions set forth in this notice will be considered non-responsive.

ADDRESSES: Applications shall be mailed to: U.S. Department of Labor, Procurement Services Center, Attention: Cassandra Willis, Reference SGA 03–09, Room N–5416, 200 Constitution Avenue, NW., Washington, DC 20210. Telefacsimile (FAX) applications will not be accepted. Applicants are advised that mail delivery in the Washington area may be delayed due to mail decontamination procedures.

FOR FURTHER INFORMATION CONTACT: Cassandra Willis, U.S. Department of Labor, Procurement Services Center, telephone (202) 693–4570 (this is not a toll-free number), prior to the closing deadline. Persons who are deaf or hard of hearing may contact the DOL via the Federal Relay Service, (800) 877–8339. This announcement will also be published on the Internet on ODEP's online Home Page at: *http://www2.dol.gov/odep.* Award notifications will also be published on the ODEP Homepage.

Solicitation Information Conference Call: A Solicitation Information Conference Call will be held at 2 p.m., Monday, June 19, 2003. The purpose of this conference call is to provide interested parties an overview of this grant program and an opportunity to ask questions concerning this solicitation. Transcripts of the conference will be made available on request in accessible formats. Individuals who wish to participate in this conference call must register by contacting ODEP at (202) 693–7880, no later than 4:45 p.m. ET on Tuesday, June 16, 2003. Please ask to register for the HS/HT SGA Conference Call. Registrations should be made as soon as possible. At the time of registration, call-in information will be provided.

SUPPLEMENTARY INFORMATION:

Part I. Delivery of Applications

1. *Late Applications.* Any application received after the exact date and time specified for receipt at the office designated in this notice will be considered non-responsive, unless it is received before awards are made and it (a) is determined that its late receipt was caused by DOL error; (b) was sent by

U.S. Postal Service registered or certified mail not later than the fifth calendar day before the date specified for receipt of applications (*e.g.,* an application submitted in response to a solicitation requiring receipt of applications by the 20th of the month must have been post marked by the 15th of that month); or (c) was sent by the U.S. Postal Service Express Mail Next Day Service to addressee not later than 5 p.m. at the place of mailing two working days prior to the date specified for receipt of applications. The term ''working days'' excludes weekends and Federal holidays. ''Post marked'' means a printed, stamped or otherwise placed impression (exclusive of a postage meter machine impression) that is readily identifiable, without further action, as having been supplied or affixed on the date of mailing by an employee of the U.S. Postal Service.

2. *Withdrawal of Applications.* Applications may be withdrawn by written notice or telegram (including mail gram) received at any time before an award is made. Applications may be withdrawn in person by the applicant or by an authorized representative thereof, if the representative's identity is made known and the representative signs a receipt of the proposal.

3. *Hand-Delivered Proposals.* It is preferred that applications be mailed at least five days prior to the closing date. To be considered for funding, hand-delivered applications must be received by 4:45 p.m., ET, at the specified address. Failure to adhere to the above instructions will be basis for a determination of non-responsiveness. Overnight express mail from carriers other than the U.S. Postal Service will be considered hand-delivered applications and must be received by the above specified date and time.

Part II. Authority

Omnibus Appropriations Resolution, 2003, Pub. L. 108–7; Consolidated Appropriations Act, 2001, Pub. L. 106–554, 29 U.S.C. 557b.

Part III. Background

HS/HT is a career development program for high school aged youth that started almost two decades ago in Los Angeles, California, to address concerns that not enough students, especially those with disabilities, were being prepared for careers in technology-focused industries. The Atlantic Richfield Company, with support from the Los Angeles Unified School District, designed America's first technology-focused transition program for young people with disabilities.

Shortly thereafter, in 1986, the President's Committee on Employment of People with Disabilities (PCEPD), whose mission was to facilitate the communication, coordination, and promotion of public and private efforts that enhance the employment of people with disabilities, adopted the program. Building upon the strength of the public/private partnership that began in Los Angeles, program leaders developed relationships with large and small businesses, education and non-profit organizations, and government agencies. These relationships helped HS/HT grow and expand across the country.

The newly created Office of Disability Employment Policy at the United States Department of Labor assumed the role as the Federal agency responsible for continuing this program. In 2001, ODEP entered into a cooperative agreement with the National Collaborative on Workforce and Disability for Youth (NCWD/Youth) to provide technical assistance and support to HS/HT sites nationwide. During 2002, ODEP and NCWD/Youth undertook a substantial refinement of the HS/HT program standards to promote the expansion of this career development program.

HS/HT is a network of state and locally operated programs designed to provide young people with all types of disabilities the opportunity to explore jobs or gain further education leading to technology-related careers. HS/HT is a community-based partnership with 70-plus programs currently operating across the country. The programs operate year-round in a variety of settings—schools, community organizations, businesses, and other locations. Current HS/HT operators include non-profits (Goodwill, Centers for Independent Living, United Cerebral Palsy Affiliates, etc.), community colleges, universities and school districts. Its stakeholders include employers, educators, consumers, family members, workforce system agencies, and rehabilitation professionals.

The HS/HT program offers proven techniques for developing improved employment outcomes for young people with disabilities. The HS/HT program is premised on four design features, supported by experience and research, as to what youth with disabilities need to succeed in adulthood. These four design areas include preparatory experiences, connecting activities, work-based experiences, and leadership development. *See* the HS/HT Program Manual at *http://www.ncwd-youth.info/resources&Publications/hshtmanual.html* for further information. Graduates of HS/HT programs that employ these design features have demonstrated at least double the post-secondary educational achievements of similarly situated students with disabilities who do not have this opportunity. At some HS/HT sites, as many as 70 percent of HS/HT graduates move on to post-secondary education. HS/HT clearly enhances expectations, educational achievements, and eventual employment outcomes for a population who, without this intervention, may be far more likely to move onto the Supplemental Security Income (SSI) or Social Security Disability Insurance (SSDI) rolls than to find competitive employment in technology related occupations.

Funding for HS/HT sites has traditionally been managed locally. In the past several years, however, ODEP has sought to move the leadership and funding towards a state-level model through its grant activities. In 2001, ODEP funded start-up HS/HT sites that began connecting HS/HT and WIA-assisted youth programs at the community level. In 2002, ODEP expanded upon that effort by funding grants to assist states in developing statewide HS/HT infrastructure and operations and further integrating HS/HT programs into the youth services provided under the One-Stop System.

The 2003 HS/HT grants are the next step in this process and focus on both state-level implementation and long-term sustainability. HS/HT sites have traditionally worked with community systems to coordinate the delivery of educational and transitional services to youth with disabilities. The HS/HT Implementation and Development Grants to be awarded as a result of the current SGA are intended to:

(1) Assist states in implementing a statewide HS/HT network working in partnership with the State Workforce Investment Board;

(2) Integrate the HS/HT program into WIA-assisted youth services; and

(3) Ensure sustainability of the HS/HT program through state-level management and coordination.

(4) Bringing HS/HT to the state-level will to help ensure that resources within a state are maximized and coordinated for the benefit of all HS/HT sites in that state. HS/HT state directors will work with key stakeholders (workforce investment systems, colleges, developmental disability councils, governors' committees on the employment of people with disabilities, employers, educators, rehabilitation professionals, consumers, and parents) to institutionalize the program within the state. By linking HS/HT, WIA and additional resources at the state-level, students with disabilities will have an

increased opportunity to participate in meaningful school-to-career initiatives.

Part IV. Funding Availability and Period of Performance

ODEP anticipates awarding approximately eight grants under this solicitation to be funded at a level of approximately $225,000. The HS/HT Implementation awards will be for a one-year period of performance and may be renewed annually up to four additional years for a total of five years, depending upon the availability of funds and the efficacy of the grant activities as established by independent reviews conducted by the DOL or its designee. Proposals must include budgetary information for a five-year period. It is envisioned that if funding is continued for the full five years, the funding for years four and five will be at successively lower rates, with funding during year four at 80 percent of the third year funds, and funding for year five at 60 percent of the third year funds. The HS/HT Development Grants will be for a one-year period of performance and will not be renewed.

Up to five Implementation Grants and up to three Development Grants will be awarded. It is expected that the funds used for this grant program will support the costs associated with the development, implementation, and evaluation of state-level HS/HT programs. The funds may be used to conduct a variety of activities to support and sustain state-level HS/HT operations such as staff training, strategic planning, partnership building, assessment, curriculum/materials development, career development, student-focused planning, program alignment, etc. Grant funds may be used to fund the creation of new HS/HT sites as well as to support existing sites as part of the implementation of an overall statewide HS/HT system.

Part V. Eligible Applicants and Required Partnerships

Eligible Applicants: Eligible applicants include State Workforce Investment Boards; State Departments of Education; State Departments of Labor; State Developmental Disability Councils; State Departments of Vocational Rehabilitation; or State Committees affiliated with the National Governors' Committees for People with Disabilities, and other similar state agencies. ''State'' in this context includes the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. Consortia of state agencies and not-for-profit organizations (including community and faith-based organizations, independent living centers, etc.) and local HS/HT sites are also eligible applicants. Prior recipients of state-level HS/HT grant funding are ineligible to receive additional funding under this solicitation.

Indian and Native American Tribal entities, or consortia of Tribes, with the written approval of their tribal council, are also eligible to receive these grants. Grants to Indian and Native American tribal grantees must recognize principles of sovereignty and self-governance established under the Indian Self-Determination and Education Assistance Act, allowing for the government-to-government relationship between the Federal and Tribal Governments.

Required Partnerships: In addition to the State Workforce Investment Board, which is a mandatory partner in these grant activities, each grantee must, at a minimum, demonstrate the involvement of members of three of the other above-mentioned state-level groups in strategic planning and implementation activities. Tribal entities also must involve, at a minimum, members of three of the other groups mentioned above in strategic planning and implementation activities with the State Workforce Investment Board constituting a mandatory partner.

Part VI. Format Requirements for Grant Application

General Requirements: Applicants must submit one (1) paper copy with an original signature and two (2) additional paper copies of the signed proposal. To aid with the review of applications, DOL also encourages Applicants to submit an electronic copy of their proposal on a disc or CD using Microsoft Word. Applicants who do not provide an electronic copy will not be penalized. The Application Narrative must be double-spaced with standard margins on 8½ x 11 papers, and be presented on single-sided, numbered pages with the exception of format requirements for the Executive Summary. The Executive Summary must be limited to no more than two single-spaced, single-sided pages on 8½ x 11 papers with standard margins throughout. A font size of at least twelve (12) pitch is required throughout. Applications that fail to meet these requirements will be considered non-responsive.

The three required sections of the application are:

Section I—Project Financial Plan
Section II—Executive Summary—Project Synopsis
Section III—Project Narrative (including Attachments, not to exceed 40 pages)

Mandatory requirements for each section are provided as follows in this application package. Applications that fail to meet the stated mandatory requirements of each section will be considered non-responsive.

Mandatory Application Requirements

- *Section I. Project Financial Plan (Budget)* (The Project Financial Plan will not count against the application page limits.) Section I of the application must include the following three required parts:

(1) Completed ''SF 424—Application for Federal Assistance'' (See Appendix A of this SGA for required form.)

(2) Completed ''SF 424A—Budget Information Form'' by line item for all costs required to implement the project design effectively. (See Appendix B of this SGA for required forms.)

(3) Budget Narrative and Justification that provides sufficient information to support the reasonableness of the costs included in the budget in relation to the service strategy and planned outcomes.

The application must include one SF–424 with the original signatures of the legal entity applying for grant funding and 2 additional copies. Applicants shall indicate on the SF–424 the organization's IRS Status, if applicable. Under the Lobbying Disclosure Act of 1995, section 18 (29 U.S.C. 1611), an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities will not be eligible for the receipt of Federal funds constituting an award, grant, or loan. (See 2 U.S.C. 1611; 26 U.S.C. 501(c)(4).) For item 10 of the SF–424, the Catalog of Federal Domestic Assistance (CFDA) number for the program is 17.720.

The Budget Narrative and Justification must describe all costs associated with implementing the project that are to be covered with grant funds. Grantees must support the travel and associated costs with sending at least one representative to the annual ODEP Policy Conference for Grantees, to be held in Washington, DC at a time and place to be determined. Grantees must comply with the ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments,'' (also known as the ''Common Rule'') codified at 29 CFR part 97, and ''Grants and Agreements with Institutes of Higher Education, Hospitals, and Other Non-Profit Organizations (also known as OMB Circular A–110), codified at 29 CFR part 95 and must comply with the applicable OMB cost principles circulars, as identified in 29 CFR 95.27 and 29 CFR 97.22(b).

In addition, the budget must include on a separate page a detailed cost analysis of each line item. Justification for administrative costs must be provided. Approval of a budget by DOL is not the same as the approval of actual costs. The individual signing the SF 424 on behalf of the applicant must represent and be able to legally bind the responsible financial and administrative entity for a grant should that application result in an award. The applicant must also include the Assurances and Certifications Signature Page (Appendix C).

• *Section II. Executive Summary—Project Synopsis* (The Executive Summary is limited to no more than two single-spaced, single-sided pages on 8½ x 11 papers with standard margins throughout). Each application shall include a project synopsis that identifies the following:

(1) The name of the applicant;

(2) The type of organization the applicant represents, the additional consortium partners and the type of organization they represent;

(3) The amount of funds requested;

(4) The planned period of performance;

(5) The extent to which Vocational Rehabilitation and the WIA-assisted Youth Service System will be integrated or coordinated with the HS/HT system;

(6) An overview of how the applicant will capitalize on and coordinate with existing HS/HT sites, if applicable;

(7) An overview of the applicant's plan for expanding HS/HT statewide; and

(8) An overview of the applicant's plan for sustaining the HS/HT program once Federal funding ceases.

• *Section III. Project Narrative* (The Project Narrative plus attachments are limited to no more than forty (40) 8½ x 11 pages, double-spaced with standard one-inch margins (top, bottom, and sides), and be presented on single-sided, numbered pages). **Note:** The Financial Plan, the Executive Summary, and the Appendices are not included in the forty (40)—page limit]. The substantive requirements for the project narrative are described below under Part VII—Statement of Work.

All text in the application narrative, including titles, headings, footnotes, quotations, and captions, as well as all text in charts, tables, figures, and graphs must be double-spaced (no more than three lines per vertical inch); and, if using a proportional computer font, use no smaller than a 12-point font, and an average character density no greater than 18 characters per inch (if using a non-proportional font or a typewriter, do not use more than 12 characters per inch). Applications that fail to meet these requirements will be considered non-responsive.

Part VII. Government Requirements/ Statement of Work (Project Narrative)

The Project Narrative, or Section III of the grant application, should provide complete information on how the applicant will address the following DOL strategic goal priorities to ensure a Prepared Workforce:

(1) Increasing the availability of skills training, employment opportunities, and career advancement for persons with disabilities.

(2) Increasing the number of youth making a successful transition to work or who enter further training or educational programs.

Proposals will be rated based upon the quality of the applicant's response in addressing the four criteria described below in terms of a comprehensive strategic approach that incorporates the Department's priorities noted above. The four criteria (Statement of Need, Comprehensive Service Strategy, Sustainability, and Monitoring and Reporting) must be addressed and the applicant's accomplishments or status with regard to each item provided.

The DOL, however, does not expect the applicant to incorporate every item listed as part of their strategy and proposal design. The DOL recognizes that the needs and requirements of each state may be different, and therefore, some of the options identified may be more relevant than others in a particular state.

1. Statement of Need (15 points)

The purpose of the Statement of Need criteria is to: Establish the overall status of disability issues relating to youth in the applicant's state; to identify strengths and deficiencies to be addressed by the applicant's proposal; to identify the overall scope of proposal objectives and design; and, to present the applicant's need for HS/HT grant resources. This criterion will be rated based upon the applicant's identified needs and proposed approach to addressing these needs in the context of the DOL's priorities.

For proposals targeted to a specific Indian community or covering multiple Tribal entities that may cut across multiple States and/or local areas, describe the overall approach of the project, and identify the inadequacies and deficiencies of the service delivery to the applicable community, and how the project expects to address these.

The narrative in this section should:

(1) Describe the potential contribution of the proposed project to increasing the quality of transition services available in the state;

(2) Describe the overall status and actions taken to-date within the State relating to implementation of the HS/HT program and the level of commitment of any existing HS/HT program to working with the applicant;

(3) Describe the extent to which the proposed project involves the development or demonstration of promising new strategies;

(4) Describe the number of young people with disabilities expected to be served in the proposed HS/HT program within the State and the importance or magnitude of the results that are likely to be attained by the proposed project;

(5) Identify the percentage of young people with disabilities in the State including the percentage of people who are beneficiaries of Social Security Disability Insurance (SSDI) and/or Social Security Income Program (SSI);

(6) Identify the most recent state graduation rates for young people with disabilities in the State, as well as the overall graduation rate;

(7) Describe any significant deficiencies in the State or local workforce investment system that present barriers to employment for young people with disabilities and explain what will be accomplished under this grant to address them;

(8) Describe how the applicant will increase services, skill training, employment outcomes, educational and job retention, and career advancement for young people with disabilities and how the ODEP priorities identified above will be achieved; and

(9) Identify additional State and/or local funds and resources that will be leveraged to support the overall objectives of the grant.

In evaluating the quality of the proposal narrative, ODEP will consider the applicant's needs identified and proposed approaches to addressing the needs in the context of ODEP's priorities.

2. Comprehensive Service Strategy (30 points)

The purpose of the Comprehensive Service Strategy criteria is to identify the approach proposed by the grantee to implement the HS/HT program on a statewide basis. In general, this requires extensive linkages and on-site knowledge of applicable resources that address multiple disability issues and barriers to education and employment that are commonly experienced by young persons with disabilities. Specifically, applicants must address staff capacity as well as their proposed design elements.

A. *Staff Capacity*—The applicant must identify how it will ensure that trained staff with comprehensive knowledge of diverse disabilities will be available to provide grant related services. Accordingly, the application should:

(1) Describe the specific experience of the applicant(s) in serving young people with disabilities, in providing technology-related training, in addressing specific barriers to employment, in achieving expected outcomes in the delivery of such services/programs, and in implementing and administering project plans similar to that in the proposed grant project;

(2) Document that the State Director has the comprehensive knowledge and experience to expand HS/HT at a state-level. A resume or position description of the state director must be included in the Appendices to the application;

(3) List and describe key positions required to carry out the project as proposed, the key personnel proposed to fill the positions, and a detailed description of the kind of work these individuals will perform within the project; and

(4) Provide evidence of the staff's skill, knowledge and experience in carrying out these types of activities, and describe their relevant training. Resumes must be included in the Appendices to the application.

B. *Proposed Design*—The application must address the proposed design for a state-based HS/HT infrastructure. The application must also identify the plan for developing and locating HS/HT program sites and the basis for that distribution plan [*i.e.* as linked with Local Workforce Investment Boards, etc.]. Finally, the application must address incorporation of the HS/HT Manual and its four design features, and should:

(1) Describe the roles of the partners set forth in the Sustainability Section of Part VII within the state's HS/HT operations. Explain how the partners will integrate and leverage resources to advance the HS/HT model;

(2) Identify the locations of HS/HT program sites based on the number and distribution of students with disabilities in the state;

(3) Describe the strategy that will be used to integrate and maintain existing HS/HT sites in the state, and to develop and increase the number of HS/HT sites in the state;

(4) Explain how technology will be used in carrying out grant activities;

(5) Identify and explain the benefits or results expected from the grant activities proposed;

(6) Discuss how the applicant will establish leadership from, or a working relationship with, a State Workforce Investment Board, the State Department of Labor, State Department of Education, State Vocational Rehabilitation, a WIA youth-related entity, and other community partners (*e.g.*, area disability organizations, state committees on employment of people with disabilities, faith-based and community organizations, Centers for Independent Living, interested employers) in the establishment and operation of a state-level HS/HT program. The State Workforce Investment Board is a mandatory partner for this grant. At least three categories of the above listed organizations must also be represented in and be a part of the state-level leadership team;

(7) Describe the strategy for gaining the support of people with disabilities and their families;

(8) Describe the outreach and marketing strategy to the disability community and organizations that represent or work with people with disabilities;

(9) Describe specific approaches for developing relationships with disability organizations representing youth with disabilities such as Centers for Independent Living, the state's Youth Leadership Forum, and state members of the National Youth Leadership Network;

(10) Describe specific approaches for developing relationships with and the support of area employers that establish employment opportunities for individuals with disabilities, including any commitments by employers to hire these individuals;

(11) Describe linkages with Business Leadership Networks (BLNs) (that have been established in approximately 30 states) if applicable; and

(12) Describe linkages with state/local public agencies such as Special Education; Vocational Rehabilitation; State Councils for Independent Living; local Centers for Independent Living (CILs); state mental health agencies, state mental retardation and Developmental Disability Councils; Temporary Assistance for Needy Families (TANF) agencies; and private, non-profit organizations such as disability advocacy and provider organizations, as well as federally-funded disability grant recipients, including community and faith-based organizations.

In evaluating the quality of the proposed project design, ODEP will also consider the following factors:

(a) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable;

(b) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population and other identified needs and the quality of the applicant's plans for recruiting and retaining the target population;

(c) The extent to which the design of the proposed project provides procedures and approaches for collaboration and coordination with key agencies and organizations and identification of critical roles;

(d) The extent to which the applicant encourages involvement of people with disabilities and their families, experts and organizations, and other relevant stakeholders in project activities;

(e) The extent to which performance feedback and continuous improvement are integral to the design of the proposed project; and

(f) The extent to which the management plan for project implementation is likely to achieve the objectives of the proposed project on time and within budget.

3. Sustainability (30 points)

The purpose of the sustainability criteria is to identify strategies for ensuring that activities funded under the grant will continue once Federal funding ceases. Resources and partnerships are an integral element of the project, as they support and strengthen the quality of the technical skills training provided and contribute materially toward sustainability. Sustainability must be an objective built into the project design, the strategic planning and ongoing operation of the project. Projects funded under this SGA must leverage a combination of federal, state, and local public sector resources, as well as private and local non-profit sector resources for purposes of sustainability.

In evaluating the quality of the plan for sustainability, ODEP considers the following factors to be of particular importance:

(a) The extent to which the proposed project is designed to build capacity and yield results that will extend beyond the period of this grant;

(b) The likelihood of the applicant successfully securing state ownership and participation in these projects when these grant funds cease (a letter from the Governor must be included or, if this is not feasible, a letter from the head of an appropriate state agency may be substituted); and

(c) The extent to which partnerships with outside entities (including public and private disability and community

and faith-based organizations) and funding from additional Federal, State, and/or local resources will be effectively leveraged and utilized in continuing HS/HT activities after the expiration of the grant.

Accordingly, in the Sustainability section, the applicant should enumerate resources, describe any specific existing contractual commitments, and provide concrete evidence of sustainability beyond the duration of this grant.

Grantees are expected to use this grant as seed money to develop other public and private resources to ensure sustainability of grant activities following completion of the funding period. Grant monies may be used to fund the creation of new HS/HT sites as well as to support existing sites as part of the development of an overall statewide HS/HT system.

ODEP considers detailed commitments for specific new activities to be more important than promises of in-kind supports in demonstrating sustained support for the project. Grants recently received from another agency can be discussed in the proposal, but the applicant should be precise in delineating which activities precede this grant and which will occur because of this grant. In addition, the applicant should detail how public sector commitments can contribute to the sustainability of this project following completion of the grant. Examples of the types of public and private sector commitments envisioned include the following:

- The school system commits to offering credit for HS/HT training activities;
- The school system commits to incorporating HS/HT into their Individual Education Plans;
- The vocational rehabilitation office commits to funding assistive technology and transportation services for students enrolled in the program;
- A community college commits to providing technology training for HS/HT students;
- State-level elected officials commit to work towards state codification of HS/HT;
- An employer commits to providing technology-based summer internships;
- State and Local Workforce Investment Boards commit to paying internship costs;
- A university commits to providing scholarships for HS/HT students.
- A Developmental Disability Council commits to funding a new HS/HT site; and
- An independent living center commits a staff person to work full time on HS/HT.

Letters of Commitment. Applicants may include letters of support if they provide specific commitments regarding the application to this solicitation. Such letters can increase an applicant's score by showing that the commitments in the text of the proposal are grounded with actual commitments. Form letters will be considered non-responsive. Applicants are encouraged to have letters of support from all existing HS/HT programs in their states.

Letter from the Governor. A letter from the Governor or functionally equivalent entity reflecting support of state-level implementation of the HS/HT program will be viewed favorably. If a letter from the Governor is not feasible, the application must include a letter from the head of an appropriate state agency.

4. Management and Outcomes (25 points)

The purpose of the Management and Outcomes criteria is to determine whether the applicant has developed an adequate management plan to effectively carry out the objectives and scope of the proposed project on time and within budget, to describe the predicted outcomes resulting from activities funded under this SGA, and to identify the methods of evaluation that will be used by the grantee to determine success.

Applicants must provide a detailed management plan that identifies the critical activities; time frames and responsibilities for effectively implementing the project, including the evaluation process, for assuring successful implementation of grant objectives. A description of the plan to report the demographic characteristics of students, types of programming activities and program outcomes (post-secondary education and employment) of youth with disabilities served through the HS/HT program in the applicant's state; and to compare their performances with students with and without disabilities not enrolled in the program should also be provided.

In addition, applicants should outline the strategy for documenting and reporting the activities undertaken during the life of the grant for ODEP's future use in working with other grantees and constituencies.

In evaluating the management and outcomes criteria, ODEP also considers the following factors to be of particular importance:

(a) The extent to which the goals, objectives, and outcomes to be achieved are clearly specified and measurable;

(b) The extent to which the design of the proposed project features innovative methods for developing new sites and/or strengthening existing sites;

(c) The extent to which the proposal incorporates the strategic plan in Part VII, Statement of Work;

(d) The extent to which the proposed budget and narrative justification are adequate to support the proposed project;

(e) The extent to which performance feedback and continuous improvement are integral to the design of the proposed project;

(f) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, context, and outcomes of the proposed project;

(g) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies;

(h) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data;

(i) The extent to which the evaluation will provide information to other programs about effective strategies suitable for replication or testing in other settings;

(j) The extent to which the methods of evaluation measure in both quantitative and qualitative terms, program results and satisfaction of people with disabilities;

(k) The extent to which the management plan for project implementation is likely to achieve the objectives of the proposed project on time and within budget;

(l) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project; and

(m) The extent to which the time commitments of the state director and/or principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

Part VIII. Monitoring and Reporting

Monitoring: ODEP is responsible for ensuring the effective implementation of each competitive grant project in accordance with the provisions of this announcement and the terms of the grant award document. Applicants should assume that ODEP staff, or their designees will conduct on-site project reviews periodically. Reviews will focus on timely project implementation, performance in meeting the grant's programmatic goals and objectives, expenditure of grant funds on allowable activities, integration and coordination with other resources and service

providers in the local area, and project management and administration in achieving project objectives. HS/HT Implementation and Development Grants may be subject to other additional reviews at the discretion of ODEP.

Reporting: Grantees will be required to submit quarterly financial and narrative progress reports under the HS/HT Grant program as prescribed by OMB Circular A–102 and A–110, as codified by 29 CFR parts 97 and 95 respectively.

(1) A Quarterly Report will be required within thirty (30) days of the end of each quarter beginning ninety days from the award of the grant and is estimated to take five hours to prepare on average. The form for the Quarterly Report will be provided by ODEP. ODEP will work with the grantee to help refine the requirements of the report, which will, among other things, include measures of ongoing analysis for continuous improvement and customer satisfaction.

(2) Financial reporting will be required quarterly using the on-line electronic reporting system for the Standard Form 269—Financial Status Report (FSR).

(3) A Final Project Report, including an assessment of project performance and outcomes achieved will be required and is estimated to take twenty hours to complete. This report will be submitted in hard copy and on electronic disk using a format and following instructions that will be provided by ODEP. A draft of the final report is due to the ODEP thirty (30) days before the termination of the grant. The final report is due to ODEP sixty (60) days following the termination of the grant.

ODEP's evaluation of the HS/HT program encompasses a process evaluation that includes extensive information pertaining to achievements under the grant (*e.g.*, training provided to staff, coordination with disability entities, etc.), as well as summary information pertaining to HS/HT implementation and the numbers of people with disabilities registered, receiving services, and employed through the One-Stop system, among other areas.

ODEP may arrange for and conduct an independent evaluation of the outcomes, impacts, and accomplishments of each funded project. Grantees must agree to make available records on all parts of project activity, including participant post secondary and employment data, and to provide access to personnel, as specified by the evaluator(s), under the direction of ODEP. This independent evaluation is separate from the ongoing evaluation for continuous improvement required of the grantee for project implementation.

Grantees must also agree to work with ODEP in its various technical assistance efforts in order to freely share with others what is learned. Grantees must agree to collaborate with other research institutes, centers, studies, and evaluations that are supported by DOL and other relevant Federal agencies, as appropriate. Finally, Grantees must agree to actively utilize the programs sponsored by the ODEP, including the Job Accommodation Network, (*http://www.jan.wvu.edu),* and the Employer Assistance Referral Network (*http://www.earnworks.com).*

The DOL has established priorities for FY 2003 as noted in the introduction of Part VII—Government Requirements/Statement of Work. HS/HT Grantees will be expected to support these priorities.

Part IX. Review Process and Evaluation Criteria

All applications will be reviewed for compliance with the requirements of this notice. A careful evaluation of applications will be made by a technical review panel, which will evaluate the applications against the rating criteria listed in this SGA. The panel results are advisory in nature and not binding on the Grant Officer. The DOL may elect to award grants either with or without discussion with the applicant. In situations without discussions, an award will be based on the applicant's signature on the SF 424, which constitutes a binding offer. The Grant Officer may consider any information that is available and will make final award decisions based on what is most advantageous to the Government, considering factors such as:

Panel findings; Geographic distribution of the competitive applications and the currently existing state grants (Connecticut, Georgia); and Availability of funds.

X. Administration Provisions

A. Administrative Standards and Provisions

Grantees are strongly encouraged to read these regulations before submitting a proposal. The grant awarded under this SGA shall be subject to the following as applicable:

- 29 CFR Part 95—Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, and With Commercial Organizations, Foreign Governments, Organizations Under the Jurisdiction of Foreign Governments, and International Organizations;
- 29 CFR Part 96— Audit Requirements for Grants, Contracts, and Other Agreements.
- 29 CFR Part 97—Uniform Administrative Requirement for Grants and Cooperative Agreements to State and Local Governments.

B. Allowable Cost

Determinations of allowable costs shall be made in accordance with the following applicable Federal cost principles:

- State and Local Government—OMB Circular A–87.
- Nonprofit Organizations—OMB Circular A–122.
- Profit-Making Commercial Firms—48 CFR part 31.

Profit will not be considered an allowable cost in any case.

C. Grant Assurances

As a condition of the award, the applicant must certify that it will comply fully with the nondiscrimination and equal opportunity provisions of the following laws:

- 29 CFR Part 31—Nondiscrimination in Federally-assisted programs of the Department of Labor, effectuation of Title VI of the Civil Rights Act of 1964.
- 29 CFR Part 32—Nondiscrimination on the Basis of Disability in Programs and Activities Receiving or Benefiting from Federal Assistance. (Implementing section 504 of the Rehabilitation Act, 29 U.S.C. 794).
- 29 CFR Part 36—Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance. (Implementing title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.*).
- 29 CFR Part 37—Nondiscrimination and Equal Opportunity Provisions of the Workforce Investment Act of 1998 (WIA), (Implementing Section 188 of the Workforce Investment Act, 29 U.S.C. 2938).

The applicant must include assurances and certifications that it will comply with these laws in its grant application. The assurances and certifications are attached as Appendix C.

Signed at Washington, DC, this 3rd day of June, 2003.

Lawrence J. Kuss,

Grant Officer.

Appendix A. Application for Federal Assistance, Form SF 424

Appendix B. Budget Information Sheet, Form SF 424A

Appendix C. Assurances and Certifications Signature Page

Appendix D. Survey on Ensuring Equal Opportunity

BILLING CODE 4510–CX–P

APPLICATION FOR FEDERAL ASSISTANCE

OMB Approval No. 0348-0043

		2. DATE SUBMITTED	Applicant Identifier
1. TYPE OF SUBMISSION: Application ☐ Construction ☐ Non-Construction	Preapplication ☐ Construction ☐ Non-Construction	3. DATE RECEIVED BY STATE	State Application Identifier
		4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address *(give city, county, State, and zip code):*	Name and telephone number of person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER *(EIN):*

☐☐ — ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify) _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es) ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other*(specify):*

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

☐☐ — ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(Cities, Counties, States, etc.):*

13. PROPOSED PROJECT		14. CONGRESSIONAL DISTRICTS OF:	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING:

a. Federal	$ .00
b. Applicant	$ .00
c. State	$ .00
d. Local	$ .00
e. Other	$ .00
f. Program Income	$ .00
g. TOTAL	$ 0.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. No. ☐ PROGRAM IS NOT COVERED BY E. O. 12372
☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes **If "Yes," attach an explanation.** ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.

a. Type Name of Authorized Representative	b. Title	c. Telephone Number
d. Signature of Authorized Representative		e. Date Signed

Previous Edition Usable
Authorized for Local Reproduction

Standard Form 424 (Rev. 7-97)
Prescribed by OMB Circular A-102

Appendix A

INSTRUCTIONS FOR THE SF-424

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0043), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item:	Entry:
1.	Self-explanatory.
2.	Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable).
3.	State use only (if applicable).
4.	If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5.	Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6.	Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7.	Enter the appropriate letter in the space provided.
8.	Check appropriate box and enter appropriate letter(s) in the space(s) provided: -- "New" means a new assistance award. -- "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date. -- "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9.	Name of Federal agency from which assistance is being requested with this application.
10.	Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11.	Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12.	List only the largest political entities affected (e.g., State, counties, cities).
13.	Self-explanatory.
14.	List the applicant's Congressional District and any District(s) affected by the program or project.
15.	Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16.	Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17.	This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18.	To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

BUDGET INFORMATION - Non-Construction Programs

OMB Approval No. 0348-0044

SECTION A - BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$ 0.00
2.						0.00
3.						0.00
4.						0.00
5. Totals		$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION B - BUDGET CATEGORIES

6. Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total (5)
	(1)	(2)	(3)	(4)	
a. Personnel	$	$	$	$	$ 0.00
b. Fringe Benefits					0.00
c. Travel					0.00
d. Equipment					0.00
e. Supplies					0.00
f. Contractual					0.00
g. Construction					0.00
h. Other					0.00
i. Total Direct Charges *(sum of 6a-6h)*	0.00	0.00	0.00	0.00	0.00
j. Indirect Charges					0.00
k. TOTALS *(sum of 6i and 6j)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
7. Program Income	$	$	$	$	$ 0.00

Authorized for Local Reproduction

Standard Form 424A (Rev. 7-97)
Prescribed by OMB Circular A-102

Previous Edition Usable

Appendix B

SECTION C - NON-FEDERAL RESOURCES				
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$ 0.00
9.				0.00
10.				0.00
11.				0.00
12. TOTAL *(sum of lines 8-11)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$ 0.00	$	$	$	$
14. Non-Federal	0.00				
15. TOTAL *(sum of lines 13 and 14)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT				
(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	$	$	$	$
17.				
18.				
19.				
20. TOTAL *(sum of lines 16-19)*	$ 0.00	$ 0.00	$ 0.00	$ 0.00

SECTION F - OTHER BUDGET INFORMATION	
21. Direct Charges:	22. Indirect Charges:
23. Remarks:	

Authorized for Local Reproduction

Standard Form 424A (Rev. 7-97) Page 2

INSTRUCTIONS FOR THE SF-424A

Public reporting burden for this collection of information is estimated to average 180 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0044), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

Section A. Budget Summary Lines 1-4 Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the Catalog program title and the Catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the Catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the Catalog program title on each line in *Column* (a) and the respective Catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1-4, Columns (c) through (g)

For new applications, leave Column (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 - Show the totals for all columns used.

Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Line 6a-i - Show the totals of Lines 6a to 6h in each column.

Line 6j - Show the amount of indirect cost.

Line 6k - Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7 - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount, Show under the program

INSTRUCTIONS FOR THE SF-424A (continued)

narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal Resources

Lines 8-11 Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a) - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b) - Enter the contribution to be made by the applicant.

Column (c) - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

Column (d) - Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e) - Enter totals of Columns (b), (c), and (d).

Line 12 - Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

Section D. Forecasted Cash Needs

Line 13 - Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14 - Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15 - Enter the totals of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16-19 - Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20 - Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21 - Use this space to explain amounts for individual direct object class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22 - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23 - Provide any other explanations or comments deemed necessary.

OMB Approval No. 0348-0040

ASSURANCES - NON-CONSTRUCTION PROGRAMS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0040), Washington, DC 20503.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

NOTE: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant, I certify that the applicant:

1. Has the legal authority to apply for Federal assistance and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project cost) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§4728-4763) relating to prescribed standards for merit systems for programs funded under one of the 19 statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. §§290 dd-3 and 290 ee 3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. §§3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and, (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally-assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply, as applicable, with provisions of the Hatch Act (5 U.S.C. §§1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

Previous Edition Usable

Authorized for Local Reproduction

Standard Form 424B (Rev. 7-97)
Prescribed by OMB Circular A-102

Appendix C

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§276a to 276a-7), the Copeland Act (40 U.S.C. §276c and 18 U.S.C. §874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§327-333), regarding labor standards for federally-assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§1451 et seq.); (f) conformity of Federal actions to State (Clean Air) Implementation Plans under Section 176(c) of the Clean Air Act of 1955, as amended (42 U.S.C. §§7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended (P.L. 93-523); and, (h) protection of endangered species under the Endangered Species Act of 1973, as amended (P.L. 93-205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. §470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. §§469a-1 et seq.).

14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. §§2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§4801 et seq.) which prohibits the use of lead-based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act Amendments of 1996 and OMB Circular No. A-133, "Audits of States, Local Governments, and Non-Profit Organizations."

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

Standard Form 424B (Rev. 7-97) Back

Survey on Ensuring Equal Opportunity

Federal Agency Use Only

OMB No. 1225-0083 Exp. 02/28/2006

NOTE: Please place survey form directly behind the Standard Application for Federal Assistance (SF 424) fact sheet.

Purpose: This form is for applicants that are private nonprofit organizations (not including private universities). Please complete it to assist the federal government in ensuring that all qualified applicants, small or large, non-religious or faith-based, have an equal opportunity to compete for federal funding. Information provided on this form will not be considered in any way in making funding decisions and will not be included in the federal grants database.

1. Does the applicant have 501(c)(3) status?

❑ Yes ❑ No

2. How many full-time equivalent employees does the applicant have? *(Check only one box).*

❑ 3 or Fewer ❑ 15-50
❑ 4-5 ❑ 51-100
❑ 6-14 ❑ over 100

3. What is the size of the applicant's annual budget? *(Check only one box.)*

❑ Less Than $150,000
❑ $150,000 - $299,999
❑ $300,000 - $499,999
❑ $500,000 - $999,999
❑ $1,000,000 - $4,999,999
❑ $5,000,000 or more

4. Is the applicant a faith-based/religious organization?

❑ Yes ❑ No

5. Is the applicant a non-religious community-based organization?

❑ Yes ❑ No

6. Is the applicant an intermediary that will manage the grant on behalf of other organizations?

❑ Yes ❑ No

7. Has the applicant ever received a government grant or contract (Federal, State, or local)?

❑ Yes ❑ No

8. Is the applicant a local affiliate of a national organization?

❑ Yes ❑ No

Survey Instructions on Ensuring Equal Opportunity for Applicants

1. 501(c) (3) statuses is a legal designation provided on application to the Internal Revenue Service by eligible organizations. Some grant programs may require nonprofit applicants to have 501(c)(3) status. Other grant programs do not.

2. For example, two part-time employees who each work half time equal one full-time equivalent employee. If the applicant is a local affiliate of a national organization, the responses to survey questions 2 and 3 should reflect the staff and budget size of the local affiliate.

3. Annual budget means the amount of money your organization spends each year on all of its activities.

4. Self-identify.

5. An organization is considered a community-based organization if its headquarters/service location shares the same zip code as the clients you serve.

6. An "intermediary" is an organization that enables a group of small organizations to receive and manage government funds by administering the grant on their behalf.

7. Self-explanatory.

8. Self-explanatory

Paperwork Burden Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 1225-0083. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: Departmental Clearance Officer, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-1301, Washington, D.C. 20210. If you have comments or concerns regarding the status of your individual submission of this form, write directly to: Joyce I. Mays, Application Control Center, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.

[FR Doc. 03–14351 Filed 6–5–03; 8:45 am]
BILLING CODE 4510–CX–C

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–40,899A]

E.J. Footwear LLC, Franklin, Tennessee; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Notice of Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance on July 15, 2002, applicable to workers of E.J. Footwear LLC located in Franklin, Tennessee. The notice was published in the **Federal Register** on July 24, 2002 (67 FR 48485).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. Findings on review show that workers of the subject firm were previously certified eligible to apply for TAA under petition TA–W–38,042 which expired on November 2, 2002. The amended certification for TA–W–40,899A established an impact date of October 24, 2000. In order to avoid an overlap in worker group coverage, this certification is being amended to establish a new impacted date of November 3, 2002.

The amended notice applicable to TA–W–40,899A is hereby issued as follows:

All workers of E.J. Footwear LLC, Franklin, Tennessee, who became totally or partially separated from employment on or after November 3, 2002, through April 3, 2004, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed at Washington, DC this 10th day of February, 2003.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 03–14292 Filed 6–5–03; 8:45 am]
BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format; reporting burden (time and financial resources) is minimized; collection instruments are clearly understood; and the impact of collection on respondents can be properly assessed. Currently, the Employment and Training Administration (ETA) is soliciting comments concerning the proposed new collection of administrative and survey data on the Growing America Through Entrepreneurship project. A copy of the proposed information collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before August 5, 2003.

ADDRESSES: Jonathan Simonetta, U.S. Department of Labor, Employment and Training Administration/Office of Policy Development, Evaluation and Research, Rm. N–5637, 200 Constitution Avenue, NW., Washington, DC 20210, (202) 693–3911 (this is not a toll-free number); *jsimonetta@doleta.gov;* Fax: (202) 693–2766 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Many individuals have the motivation and skills to develop small businesses but lack business expertise and/or access to financing. Recognizing this untapped potential, ETA is teaming with the Small Business Administration (SBA) to create a demonstration program designed to assist individuals interested in self-employment to develop their businesses—Project GATE (Growing America Through Entrepreneurship). In helping people develop businesses, Project GATE will promote both workforce and economic development. The effectiveness of the program will be evaluated.

Entrepreneurial services provided by Project GATE will include an assessment, a structured training course, and technical assistance provided by a trained counselor. As part of the technical assistance, counselors will assist individuals in need of financing to apply for loans from SBA's Microloan program and other funding sources. DOL's One-Stop Centers will conduct Project GATE orientations where interested individuals will be informed bout the services available at the One-Stop Center, the benefits and challenges of self-employment and the services offered through Project GATE. Small Business Development Center (SBDC) counselors will conduct individuals assessments and identify the most appropriate training course for each Project GATE participant. Existing entrepreneurial training providers in the community will provide training and technical assistance.

DOL's One-Stop Centers will play a central role in recruiting for the project. Interested individuals will be able to register for an orientation to Project GATE at One-Stop Centers as well as via telephone, mail, or a Website. The orientations will also be held at the One-Stop Centers.

Eligibility for Project GATE will be broad—it is designed to serve almost anyone interested in starting a business. Special attention will be paid, however, to recruiting immigrant populations.

Project GATE will be evaluated using an experimental design. Individuals who submit an application for Project GATE in each site and who meet minimal eligibility criteria will be randomly assigned to either a program group or a control group. Members of the program group will be eligible to receive Project GATE services, while members of the control group will not be eligible to receive Project GATE services, although they will not be prohibited form receiving self-employment services from other services.

GATE will be implemented in seven sites—three urban and four rural sites. The three urban sites are in Philadelphia, Pennsylvania; Pittsburgh, Pennsylvania; and Minneapolis-St. Paul, Minnesota. The rural sites are one in Minnesota centered around Duluth, and three in Maine centered around Portland, Bangor, and Lewiston.

The evaluation will address three key questions:

1. *Is Project GATE Viable?* What are the challenges in implementing the program? Does an interagency model for the program work? Who participates in GATE? Is the outreach effective in reaching immigrants? How does the implementation of the program vary across sites?

2. *Does the Program Work?* Does the program increase self-employment, increase employment and earnings, and reduce the receipt of unemployment insurance and public assistance? Does the program promote employment and

other economic development? Is it effective in both rural and urban areas? Does the effectiveness of the program vary by population subgroup?

3. *Is the Program Cost-Effective?* Do the benefits of the program exceed its costs? Addressing these questions will involve conducting process, impact,and benefit-cost analyses. The process evaluation will be based on information collected during three rounds of visits to each site, during which detailed information will be collected on the implementation of the program from interviews with program staff, observations of services, and focus groups with program participants. Data will also be collected using a Participant Tracking System developed specifically for the study. The impact evaluation will involve comparing outcomes of members of the program group with outcomes of members of the control group. Data on these outcomes will be collected from Unemployment Insurance (UI) benefit records and quarterly wage records, and two follow-up surveys that will occur approximately 6 months and 18 months after random assignment. The benefit-cost analysis will involve placing a dollar value on all impacts of the program and comparing them with the dollar value of the costs.

II. Review Focus

DOL is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of ETA, 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 submissions of responses.

III. Current Actions

The data for the impact analysis will come from UI benefits and wage records in the three states, a computer-based Participant Tracking System developed for the demonstration and used in the seven sites, and follow-up surveys conducted twice with the expected sample of 4,000 individuals who will apply for Project GATE.

The follow-up surveys, which are the subject of this notice, will be conducted by telephone approximately 6 and 18 months following the GATE application. These voluntary surveys will collect data unavailable from administrative records. The first survey is designed to collect detailed information about sample members' participation and experiences in receiving self-employment services, their experiences starting a business, their experiences in jobs working for someone else, their receipt of public assistance, and some background data on their socio-economic and demographic characteristics. The second survey is designed to collect their experiences in self-employment and developing small businesses, their experiences in jobs working for someone else, and their income and receipt of public assistance.

Type of Review: New.

Agency: Employment and Training Administration.

Title: Partnership for Self-Sufficiency: Growing America Through Entrepreneurship.

Agency Number: 1205–ONEW.

Affected Public: Individuals.

Activity	Total respondents	Frequency	Total responses	Average time per response	Burden (hours)
GATE follow-up survey	3,200	Two times	6,400	40 minutes	2,134 (annual).
Totals	.....	.....	.....	.....	4,268 (total).

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information request; they will also become a matter of public record.

Dated: May 30, 2003.

Maria K. Flynn,

Acting Administrator.

[FR Doc. 03–14291 Filed 6–5–03; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment Standards Administration

Proposcd Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment Standards Administration is soliciting comments concerning the proposed collection: Health Insurance Claim Form (OWCP–1500). A copy of the proposed information collection request can be obtained by contacting the office listed below in the addressee section of this Notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before August 5, 2003.

ADDRESSES: Ms. Hazel M. Bell, U.S. Department of Labor, 200 Constitution Ave., NW., Room S–3201, Washington, DC 20210, telephone (202) 693–0418, fax (202) 693–1451, Email *hbell@fenix2.dol-esa.gov.* Please use only one method of transmission for comments (mail, fax, or Email).

SUPPLEMENTARY INFORMATION

I. Background

The Office of Workers' Compensation Programs (OWCP) administers the Federal Employees' Compensation Act (FECA) (5 U.S.C. 8101, *et seq.*), the Black Lung Benefits Act (BLBA) (30 U.S.C. 901 *et seq.*) and the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384 *et seq.* All three of these statutes require that OWCP pay for medical treatment of beneficiaries; BLBA also requires that OWCP pay for medical examinations and related diagnostic services to determine eligibility for benefits under that statute. The OWCP–1500 is a form

used by bill payment staff to process requests for payment for medical services provided by medical professionals other than hospitals, pharmacies, and certain other providers. This information collection is currently approved for use through November 30, 2003.

II. Review Focus

The Department of Labor 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 submissions of responses.

III. Current Actions

The Department of Labor seeks approval for the extension of this information collection in order to carry out its responsibility to provide payment for certain covered medical services to injured employees who are covered under FECA, BLBA and EEOICPA.

Type of Review: Extension.

Agency: Employment Standards Administration.

Title: Health Insurance Claim Form.

OMB Number: 1215–0055.

Agency Number: OWCP–1500.

Affected Public: Individual or households; business or other for-profit; not-for-profit institutions.

Total Respondents: 533,427.

Total Responses: 2,133,708.

Time per Response: 7 minutes.

Frequency: On occasion.

Estimated Total Burden Hours: 248,812.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: June 2, 2003.

Bruce Bohanon,

Chief, Branch of Management Review and Internal Control, Division of Financial Management, Office of Management, Administration and Planning,Employment Standards Administration.

[FR Doc. 03–14290 Filed 6–5–03; 8:45 am]

BILLING CODE 4510–CH–P

DEPAPARTMENT OF LABOR

Employment Standards Administration; Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have bee made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of the decisions listed to the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are the parentheses following the decisions being modified.

Volume I

None.

Volume II

None.

Volume III

None.

Volume IV

None.

Volume V

None.

Volume VI

None.

Volume VII

None.

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

General wage determinations issued under the Davis-Bacon and related Acts are available electronically at no cost on the Government Printing Office site at *www.access.gpo.gov/davisbacon.* They are also available electronically by subscription to the Davis-Bacon Online Service (*http://davisbacon.fedworld.gov*) of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068. This subscription offers value-added features such as electronic delivery of modified wage decisions directly to the user's desktop, the ability to access prior wage decisions issued during the year, extensive Help Desk Support, etc.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate Volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC this 28th day of May 2003.

Carl Poleskey,

Chief, Branch of Construction Wage Determinations.

[FR Doc. 03–13986 Filed 6–5–03; 8:45 am]

BILLING CODE 4510–27–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 71–0122, Approval No. 0122, EA–01–164]

J.L. Shepherd & Associates, San Fernando, California; Confirmatory Order Relaxing Order (Effective Immediately)

I

J.L. Shepherd & Associates (JLS&A) was the holder of Quality Assurance (QA) Program Approval for Radioactive Material Packages No. 0122 (Approval No. 0122), issued by the U. S. Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR part 71, Subpart H. QA activities authorized by Approval No. 0122 include: design, procurement, fabrication, assembly, testing, modification, maintenance, repair, and use of transportation packages subject to the provisions of 10 CFR part 71. Approval No. 0122 was originally issued January 17, 1980. Based on JLS&A's failure to comply with 10 CFR part 71, QA Program Approval No. 0122 was withdrawn by the immediately effective NRC Order, dated July 3, 2001, (66 FR 36603, July 12, 2001).

II

The NRC issued the July 3, 2001, Order (July 2001 Order) because the NRC lacked confidence that JLS&A would implement the QA Program approved by the NRC (71–0122, Revision No. 5) in accordance with 10 CFR part 71, Subpart H, in a manner that would assure the required preparation and use of transportation packages in full conformance with the terms and conditions of an NRC Certificate of Compliance (CoC) and with 10 CFR part 71.

Subsequent to the July 2001 Order, JLS&A requested interim relief on several occasions, from the July 2001 Order, based on JLS&A's proposed Near-Term Corrective Action Plan (NTCAP), to allow shipments in U. S. Department of Transportation (DOT) specification packaging designated as 20WC. Based on a showing of good cause, the NRC issued Confirmatory Orders, dated September 19, 2001 (66 FR 49708, September 28, 2001), December 13, 2001 (66 FR 67556, December 31, 2001), March 29, 2002 (67 FR 16457, April 5, 2002), April 26, 2002 (67 FR 22462, May 3, 2002), and June 6, 2002 (67 FR 41531, June 18, 2002), which relaxed the July 2001 Order. Each of the foregoing Confirmatory Orders allowed shipments to JLS&A customers in 20WC packages in accordance with JLS&A's NTCAP, provided JLS&A satisfactorily completed certain commitments, including the use of an Independent Auditor. The commitments ensured that JLS&A staff was properly trained and that the packaging used was in conformance with the regulations. The June 6, 2002, Confirmatory Order allowed JLS&A to make shipments through May 31, 2003.

III

By letter dated February 7, 2003, JLS&A requested rescission of the July 2001 Order for the following reasons:

- JLS&A has developed implementing procedures for its conditional QA Program Approval No. 0122, Revision No. 7.
- JLS&A completed comprehensive training of all its staff (and all but one of its contractors) on the new implementing procedures between November and December 2002. JLS&A committed that prior to permitting the remaining contractor to engage in any activity for which an NRC-approved QA program is required, all prescribed training will be conducted.
- J.L. Shepherd and the Independent Auditor provided certification under oath and affirmation that the procedures and training had been completed as stated above.
- JLS&A has successfully implemented the interim procedures contained in the Near-Term Corrective Action Program over one year of shipping operations using DOT specification packaging, as attested to in the series of monthly and quarterly reports of the Independent Auditor.
- JLS&A has reorganized and streamlined its operations and staffing, aligning its business functions with the requirements of 10 CFR part 71, Subpart H, to include designation of positions directly related to QA activities and record keeping. The reorganization included requirements for the qualifications of the QA manager and for his/her separation from operational responsibility.
- JLS&A has a compelling business need for rescission of the Order and for restoration of its ability to design, manufacture and ship devices larger than those that can be shipped in DOT specification packaging. JLS&A work involving these larger devices had accounted for about 20 percent of its annual revenues.
- The Order has imposed a continuing and increasing economic penalty on JLS&A.
- JLS&A states it is the only economical shipper for devices of its own design, and for various other manufacturers' devices, all of which

contain large quantities of Type B radioactive materials and require shipment in NRC-approved packages. JLS&A restrictions from making these shipments has meant that these devices have not been able to be relocated, decommissioned, or re-sourced.

• JLS&A committed to NRC that JLS&A will not make further international Type B shipments requiring NRC-approved packages until it is able to ensure that its Type B package designs are in compliance with all NRC requirements, including changes made in response to the International Atomic Energy Agency's International Transportation Standard TS–R–1.

• JLS&A committed to meeting obligations imposed by the part 71 rulemaking which, if approved, will require JLS&A to re-evaluate existing designs and to submit applications containing revised bases for their approval.

• JLS&A has at all times attempted to cooperate fully with the NRC staff in the enforcement action and investigation associated with the July 2001 Order. JLS&A has taken to heart the Commission's criticism of its QA program and has, in many ways, fundamentally redesigned its QA program to respond to the criticisms of the NRC staff and the Independent Auditor.

The NRC staff reviewed JLS&A's request and JLS&A's safety performance under the above-mentioned relaxation Orders during an April 22–24, 2003, inspection to determine whether to grant the request with assurances that public health and safety are maintained. As a result of the April 2003 inspection, the NRC identified one violation for a failure to follow procedures, concerns with the use of non-approved forms to document quality inspection activities, a weakness in maintaining proper configuration control of QA program documentation, and that specific training on the QA program had not been performed. While these findings were not as extensive as the events leading to the July 2001 Order, they are cause for concern. However, based on JLS&A's development of the new QA program and the progress shown, JLS&A has demonstrated good cause to relax certain provisions of the July 2001 Order.

On May 29, 2003, JLS&A consented to issuance of this Order granting interim relief from the July 2001 Order subject to the commitments as set forth in Section IV below, and agreed that this Order is to be effective upon issuance, and agreed to waive its right to a hearing on this action. Implementation of these commitments will provide assurance that sufficient resources will be applied to the QA program, and that the program will be conducted safely and in accordance with NRC requirements.

I find that JLS&A's commitments as set forth in Section IV are acceptable and necessary and conclude that with these commitments, the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health and safety require that JLS&A's commitments be confirmed by this Order. Based on the above and JLS&A's consent, this Order is effective immediately upon issuance.

IV

Accordingly, pursuant to Sections 62, 81, 161b, 161i, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR Section 2.202 and 10 CFR parts 71 and 110, it is hereby ordered, effective immediately, that the July 2001 Order is relaxed to grant JLS&A interim relief, to effect shipments in accordance with 10 CFR 71.7, 71.12, 71.13, 71.14 or 71.16 and revision 7 TO QA program approval No. 0122, through June 1, 2005, provided:

1. JLS&A fully implements and complies with Revision No. 7 of the conditionally approved QA Program Approval No. 0122;

2. JLS&A fully train JLS&A's staff, contractors, and sub-contractors, in Revision No. 7 of the conditionally approved QA program plan and implementing procedures, prior to any shipments or design, procurement, fabrication, assembly, testing, modification, maintenance, repair or use of packaging covered by Revision No. 7;

3. JLS&A uses an Independent Auditor, approved by the Commission, to ensure that Revision No. 7 of conditionally approved QA program plan is fully and completely implemented. Additionally, the Independent Auditor shall conduct monthly QA program audits and provide NRC with a report by the 20th of each month. These monthly audits shall continue for a period of seven (7) months from the date of this Order. After the seven (7) month period, audits shall be performed on a quarterly basis, with a report provided to the NRC by the 20th of the month following each quarter. The Independent Auditor shall verify the compliance of the conduct of shipping operations with Revision No. 7 of the conditionally approved QA program plan and implementing procedures;

4. JLS&A shall stop all shipping operations if the audit conducted by the Independent Auditor identifies safety concerns associated with the JLS&A conduct of shipping operations. In such an event, JLS&A shall inform the NRC of the audit findings and JLS&A proposed corrective actions within 3 business days of the identification of the audit findings to JLS&A by the Independent Auditor. JLS&A shall suspend all shipping operations until the safety concerns are corrected and the Independent Auditor has found the corrective action acceptable. The Independent Auditor shall inform NRC of the audit findings, JLS&A corrective actions, and the results of the Independent Auditor's review of the corrective actions in its audits; and

5. During the two-year interim relief period, the NRC will conduct an inspection of JLS&A operations and implementation of the JLS&A QA program, Revision No. 7. Implementation of QA Program Approval No. 0122, Revision No. 7, without restrictions, may be permitted after NRC has verified JLS&A performance through an NRC inspection program in which no violations or only minor non-conformances are identified.

The Director, Office of Enforcement, or the Director, Office of Nuclear Material Safety and Safeguards, may in writing, relax or rescind this Order upon demonstration of good cause by JLS&A.

V

In accordance with 10 CFR 2.202, any person, other than JLS&A, adversely affected by this Order may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies of the hearing request also should be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Director, Office of Nuclear Material Safety and Safeguards at the same address, to the Assistant General Counsel for Materials Litigation and Enforcement at the same address, to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, TX 76011, and to JLS&A. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that answers and requests for hearing be

transmitted to the Secretary of the Commission either by means of facsimile transmission to 301–415–1101 or by e-mail to *hearingdocket@nrc.gov* and also to the Office of the General Counsel either by means of facsimile transmission to 301–415–3725 or by e-mail to *OGCMailCenter@nrc.gov.* If such person requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received. A request for hearing shall not stay the immediate effectiveness of this order.

Dated this 30th day of May, 2003.

For the Nuclear Regulatory Commission.

James G. Luehman,

Deputy Director, Office of Enforcement.

[FR Doc. 03–14280 Filed 6–5–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Workshop on Issues Related to the Construction Inspection Program for Reactors

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of workshop.

SUMMARY: The Nuclear Regulatory Commission (NRC) is holding a workshop on issues related to the construction inspection program for reactors built under the provisions of Part 52. The public workshop is scheduled to discuss the scope and the types of inspections which are planned during the new reactor construction project.

FOR FURTHER INFORMATION, CONTACT: Mr. James A. Isom, Inspection Program Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Mr. Isom may be reached at (301) 415–109 or by e-mail at *jai@nrc.gov.*

DATES: The workshop will be held on August 27, 2003, from 8:30 a.m. to 4:30 p.m. Submit comments on the draft construction inspection program framework document by September 15, 2003. Comments received after the due date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: The workshop will be held at the U.S. Nuclear Regulatory Commission in the Two White Flint North Auditorium, 11545 Rockville Pike, Rockville, Maryland.

The draft construction inspection program framework document is available for public inspection in the NRC Public Document Room located at One White Flint North, 11555 Rockville Pike, Public File Area O1 F21, Rockville, Maryland, or from the Publicly Available Records (PARS) component of NRC's Agencywide Document Access and Management System (ADAMS), (ADAMS # ML031400849). ADAMS is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* (the Public Electronic Reading Room). For more information, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 202–634–3273 or by e-mail to *pdr@nrc.gov.*

Written comments on the draft guidance should be sent to: Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop T6–D59, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555–0001. Comments may be hand-delivered to the NRC at 11545 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. on Federal workdays. Comments may be submitted electronically by the Internet to the NRC at *nrcrep@nrc.gov.* All comments received by the Commission, including those made by Federal, State, and local agencies, Indian tribes, or other interested persons, will be made available electronically at the Commission's Public Document Room in Rockville, Maryland or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS).

SUPPLEMENTARY INFORMATION: The NRC has developed a draft construction inspection program framework document. The document describes the proposed inspections which will be conducted for reactors built under the 10 CFR part 52 process. The framework document details the proposed audits and inspections conducted by the NRC during the Early Site Permit (ESP) and Combined License (COL) phases. The document also discusses how the NRC staff will verify satisfactory completion of the inspections, tests, analyses, and acceptance criteria (ITAAC) and review operational programs.

In the ''Draft 10 CFR Construction Inspection Program Framework Document,'' the NRC staff set forth the basis for the construction inspection program for reactors built under 10 CFR part 52. The document was issued on May 30, 2003 and the public workshop is scheduled for August 27, 2003 to discuss the scope and the types of inspections which are planned during the new reactor construction project. Additionally, comments received from various stakeholders will be discussed. The following topics will be discussed:

- The scope and types of NRC inspections and when they will occur for the different phases of construction of a nuclear plant constructed under 10 CFR part 52.
- How the NRC staff plans to inspect and verify licensee's completion of inspections, tests, analyses and acceptance criteria (ITAAC).
- How the NRC staff plans to inspect the operational programs which do not have ITAAC associated with them.
- How the NRC staff plans to conduct engineering design verifications and first-of-a-kind engineering inspections.

Dated at Rockville, Maryland, this 30th day of May 2003.

For the Nuclear Regulatory Commission.

Stuart A. Richards,

Chief, Inspection Program Branch, Division of Inspection Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03–14278 Filed 6–5–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Draft Regulatory Guide; Issuance, Availability

The Nuclear Regulatory Commission (NRC) has issued for public comment a proposed revision of a guide in its Regulatory Guide Series. Regulatory Guides are developed to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits and licenses.

The draft guide is temporarily identified by its task number, DG–1121,

which should be mentioned in all correspondence concerning this draft guide. Draft Regulatory Guide DG–1121, ''Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to their Safety Significance,'' is being developed to describe a process that is acceptable to the NRC staff for the development and assessment of evaluation models that may be used to comply with the NRC's regulations with respect to the categorization of structures, systems, and components (SSCs) that are considered in risk-informing special treatment requirements. This guide conforms to a proposed amendment to 10 CFR 50.69 that was published in the **Federal Register** (68 FR 26511) on May 16, 2003.

This draft guide has not received complete staff approval and does not represent an official NRC staff position.

You may submit comments by any one of the following methods. Please include the following number (RIN3150–AG42) in the subject line of your comments. Comments on the draft guide in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking Web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: *SECY@nrc.gov.* If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415–1966. You may also submit comments via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov.* Address questions about our rulemaking web site to Carol Gallagher (301) 415–5905; e-mail *cag@nrc.gov,* for information about Draft Regulatory Guide DG–112, contact Mr. David Diec (301) 414–2834; e-mail *dtd@nrc.gov.*

Hand delivered comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone 301–415–1966).

Fax Comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415–1101.

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area 01 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments can be viewed and downloaded electronically via the NRC rulemaking Web site at *http://ruleforum.llnl.gov.*

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/NRC/ADAMS/index.html.* From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, or 301–415–4737, or by e-mail to *pdr@nrc.gov.*

Although a deadline is given for comments on this draft guide, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time. Requests for single copies of draft or final regulatory guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Reproduction and Distribution Services Section, or by fax to (301) 415–2289; e-mail *DISTRIBUTION@NRC.GOV.* Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them. (5 U.S.C. 552(a)).

Dated at Rockville, Maryland, this 22nd day of May 2003.

For the Nuclear Regulatory Commission.

Mark Flynn,

Director, Program Management, Policy Development and Analysis Staff, Office of Nuclear Regulatory Research.

[FR Doc. 03–14279 Filed 6–5–03; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Agency Report Form Under OMB Review

AGENCY: Overseas Private Investment Corporation.

ACTION: Request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), agencies are required to publish a notice in the **Federal Register** notifying the public that the Agency has prepared an information collection request for OMB review and approval and has requested public review and comment on the submission. OPIC published its first Federal Register notice on this information collection request on March 27, 2003, in 68 FR 15008, at which time a 60-calendar day comment period was announced. This comment period ended May 29, 2003. No comments were received in response to this notice.

This information collection submission had been forwarded to OMB for review through an emergency extension on April 8, 2003. Comments are again being solicited on the need for the information, its practical utility, the accuracy of the Agency's burden estimate, and on ways to minimize the reporting burden, including automated collection techniques and uses of other forms of technology. The proposed form under review is summarized below.

DATES: Comments must be received within 30 calendar days of this notice.

ADDRESSES: Copies of the subject form and the request for review submitted to OMB may be obtained from the Agency Submitting Officer. Comments on the form should be submitted to the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT: *OPIC Agency Submitting Officer:* Bruce I. Campbell, Records Management Officer, Overseas Private Investment Corporation, 1100 New York Avenue, NW., Washington, DC 20527; 202/336–8563.

OMB Reviewer: David Rostker, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503, 202/395–3897.

Summary of Form Under Review

Type of Request: Reinstatement, with change, of a previously approved collection for which approval is expiring.

Title: Self-Monitoring Questionnaire for Insurance and Finance Projects.

Form Number: OPIC–162.

Frequency of Use: Annually for duration of project.

Type of Respondents: Business or other institutions (except farms); individuals.

Standard Industrial Classification Codes: All.

Description of Affected Public: U.S. companies or citizens investing overseas.

Reporting Hours: 3 hours per project.

Number of Responses: 325 per year.

Federal Cost: $19,500 per year.

Authority for Information Collection: Sections 231 and 234(b) and (c) of the Foreign Assistance Act of 1961, as amended.

Abstract (Needs and Uses): The questionnaire is completed by OPIC-assisted investors annually. The questionnaire allows OPIC's assessment of effects of OPIC-assisted projects on the U.S. economy and employment, as well as on the environment and economic development abroad.

Dated: June 2, 2003.

Eli Landy,

Senior Counsel, Administrative Affairs, Department of Legal Affairs.

[FR Doc. 03–14288 Filed 6–5–03; 8:45 am]

BILLING CODE 3210–01–M

OFFICE OF PERSONNEL MANAGEMENT

January 2003 Pay Adjustments

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: The President adjusted the rates of basic pay and locality payments for certain categories of Federal employees effective in January 2003. This notice documents those pay adjustments for the public record.

FOR FURTHER INFORMATION CONTACT: Carey Johnston, (202) 606–2858, FAX (202) 606–0824, or email to *pay-performance-policy@opm.gov.*

SUPPLEMENTARY INFORMATION: On December 31, 2002, the President signed Executive Order 13282 (68 FR 1133, January 8, 2003), which implemented the January 2003 across-the-board increase of 3.1 percent in the rates of basic pay for the statutory pay systems. On March 21, 2003, the President signed Executive Order 13291 (68 FR 14525, March 25, 2003), which amended Executive Order 13282 to provide a locality pay increase costing approximately 1 percent of payroll retroactive to the first day of the first pay period beginning on or after January 1, 2003. The President made these adjustments consistent with Public Law 108–7, February 20, 2003, which authorized an overall average pay increase of 4.1 percent for General Schedule (GS) employees.

Schedule 1 of Executive Order 13282 provides the rates for the 2003 General Schedule and reflects a 3.1 percent across-the-board increase. Executive Order 13291 provides the percentage amounts of the 2003 locality payments. (*See* section 5 of Executive Order 13282 and Schedule 9 of Executive Order 13291.)

The publication of this notice satisfies the requirement in section 5(b) of Executive Order 13282 that the Office of Personnel Management (OPM) publish appropriate notice of the 2003 locality payments in the **Federal Register.**

GS employees receive locality payments under 5 U.S.C. 5304. Locality payments apply in the 48 contiguous States and the District of Columbia. In 2003, locality payments ranging from 9.62 percent to 21.08 percent apply to GS employees in 32 locality pay areas. These 2003 locality pay percentages, which replaced the locality pay percentages that were applicable in 2002, became effective on the first day of the first applicable pay period beginning on or after January 1, 2003. An employee's locality-adjusted annual rate of pay is computed by increasing his or her scheduled annual rate of basic pay (as defined in 5 U.S.C. 5302(8) and 5 CFR 531.602) by the applicable locality pay percentage. (*See* 5 CFR 531.604 and 531.605.)

Executive Order 13282 establishes the new Executive Schedule, which incorporates the 3.1 percent increase (rounded to the nearest $100) required under 5 U.S.C. 5318. The Executive order also reflects a decision by the President to increase the rates of basic pay for members of the Senior Executive Service (SES) by 3.1 percent (rounded to the nearest $100). The maximum rate of basic pay for SES members is limited by law to the rate for level IV of the Executive Schedule, which is now $134,000. (*See* 5 U.S.C. 5382.)

The Executive order adjusted the rates of basic pay for administrative law judges (ALJs) by 3.1 percent (rounded to the nearest $100). The maximum rate of basic pay for ALJs is also limited by law to the rate for level IV of the Executive Schedule, which is now $134,000. (*See* 5 U.S.C. 5372.)

The rates of basic pay for Board of Contract Appeals (BCA) members are calculated as a percentage of the rate for level IV of the Executive Schedule. (*See* 5 U.S.C. 5372a.) Therefore, BCA rates of basic pay were increased by approximately 3.1 percent. Also, the maximum rate of basic pay for senior-level (SL) and scientific or professional (ST) positions was increased by approximately 3.1 percent (to $134,000) because it is tied to the rate for level IV of the Executive Schedule. The minimum rate of basic pay for SL/ST positions is equal to 120 percent of the minimum rate of basic pay for GS–15 and thus was increased by 3.1 percent (to $102,168). (*See* 5 U.S.C. 5376.)

On December 5, 2002, the President's Pay Agent extended the 2003 locality-based comparability payments to the same Governmentwide and single-agency categories of non-GS employees that received the 2002 locality payments. The Governmentwide categories include members of the SES, employees in SL/ST positions, ALJs, and BCA members. The maximum locality rate of pay for these employees is the rate for level III of the Executive Schedule ($142,500 in 2003). By law, Executive Schedule officials are not authorized to receive locality pay. (*See* 5 U.S.C. 5304(h)(1)(iii).)

OPM published ''Salary Tables for 2003,'' (OPM Doc. 124–48–6) in May 2003. This publication provides complete salary tables incorporating the 2003 pay adjustments, information on general pay administration matters, locality pay area definitions, Internal Revenue Service withholding tables, and other related information. The rates of pay shown in this publication are the official rates of pay for affected employees and are hereby incorporated as part of this notice. You may purchase copies of ''Salary Tables for 2003'' from the Government Printing Office (GPO) by calling (202) 512–1800 (outside the DC area: 1–866–512–1800) or FAX (202) 512–2250. You may order copies directly from GPO on the Internet at *http://bookstore.gpo.gov.*

In addition, you can find pay tables on OPM's Internet Web site at *http://www.opm.gov/oca/payrates/index.asp.*

Office of Personnel Management.

Kay Coles James,

Director.

[FR Doc. 03–14244 Filed 6–5–03; 8:45 am]

BILLING CODE 6325–39–P

RAILROAD RETIREMENT BOARD

Privacy Act of 1974; Proposed Changes to Systems of Records

AGENCY: Railroad Retirement Board.

ACTION: Notice of proposed routine uses.

SUMMARY: The purpose of this document is to give notice of three proposed new routine uses (in different systems of records) and a revision of another routine use in two systems of records.

DATES: The proposed and amended routine uses shall become effective as proposed without further notice in 40 calendar days from the date of this publication unless comments are received before this date which would result in a contrary determination.

ADDRESSES: Send comments to Beatrice Ezerski, Secretary to the Board, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092.

FOR FURTHER INFORMATION CONTACT: LeRoy Blommaert, Privacy Act Officer, Railroad Retirement Board, 844 North

Rush Street, Chicago, Illinois 60611–2092, (312) 751–4548.

SUPPLEMENTARY INFORMATION: The RRB proposes three new routine uses, one for its System of Records, RRB–5, Master File of Railroad Employees' Creditable Compensation, one for its System of Records, RRB–20, Health Insurance and Supplementary Medical Insurance Enrollment and Premium Payment System (MEDICARE) and one for its System of Records RRB–22, Railroad Retirement Survivor and Pensioner Benefit System.

The first proposed routine use (''r'') in RRB–5 would permit the RRB to furnish to AMTRAK an employee's service history information (such as whether the employee had service before a certain date and whether the employee had at least a given number of years of service) when such information would be needed for AMTRAK to make a determination whether to award a travel pass to either the employee or the employee's widow.

The second proposed routine use (''w'') in RRB–20 would permit the RRB to furnish to a legitimate health care provider whether a qualified railroad retirement beneficiary is enrolled in Medicare part A or part B, and if so, the effective date(s) of such enrollment when such information is needed to verify Medicare enrollment.

The third proposed routine use (''qq'') in RRB–22 would permit the RRB to furnish to AMTRAK an employee's date last worked, annuity filing date, annuity beginning date, and month and year of death when such information would be needed for AMTRAK to make a determination whether to award a travel pass to either the employee or the employee's widow.

The RRB also proposes to amend an existing routine use found in two of its systems of records. The amendment would permit the disclosure of the gender of the subject individual to Members of Congress when they request the name and address in order to communicate with their constituents on matters affecting the railroad retirement or railroad unemployment and sickness programs. The current routine in the two systems of records (''q'' in RRB–5 and ''ff'' in RRB–22) permits disclosure of the subject individual's name and address. The subject's gender is needed to select the correct salutation (Mr. and Ms.) in addressing letters when only the first initial of the first name is given or when the gender cannot be ascertained from the first name (*e.g.,* Lee).

On May 28, 2003, the Railroad Retirement Board filed a new/altered system report for this system with the House Committee on Government Operations, the Senate Committee on Governmental Affairs, and the Office of Management and Budget. This was done to comply with section 3 of the Privacy Act of 1974 and OMB Circular No. A–130, Appendix I.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

RRB–5

SYSTEM NAME:

Master File of Railroad Employees' Creditable Compensation.

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

* * * * *

Paragraph ''q'' is revised to read as follows:

q. The name, address and gender of a railroad worker may be released to a Member of Congress when the Member requests it in order that he or she may communicate with the worker about legislation which affects the railroad retirement or railroad unemployment and sickness insurance program.

* * * * *

Paragraph ''r'' is added to read as follows:

r. The service history of an employee (such as whether the employee had service before a certain date and whether the employee had at least a given number of years of service) may be disclosed to AMTRAK when such information would be needed by AMTRAK to make a determination whether to award a travel pass to either the employee or the employee's widow.

* * * * *

RRB–20

SYSTEM NAME:

Health Insurance and Supplemental Medical Insurance Enrollment and Premium Payment System (Medicare)

* * * * *

Paragraph ''w'' is added to read as follows:

w. Whether a qualified railroad retirement beneficiary is enrolled in Medicare part A or part B, and if so, the effective date(s) of such enrollment may be disclosed to a legitimate health care provider, in response to its request, when such information is needed to verify Medicare enrollment.

* * * * *

RRB–22

SYSTEM NAME:

Railroad Retirement, Survivor, and pensioner Benefit System.

* * * * *

Paragraph ''ff'' is revised to read as follows:

ff. The name, address, and gender of an annuitant may be released to a Member of Congress when the Member requests it in order that he or she may communicate with the annuitant about legislation which affects the railroad retirement system.

* * * * *

Paragraph ''qq'' is added to read as follows:

qq. An employee's date last worked, annuity filing date, annuity beginning date, and the month and year of death may be furnished to AMTRAK when such information is needed by AMTRAK to make a determination whether to award a travel pass to either the employee's widow.

[FR Doc. 03–14254 Filed 6–5–03; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 12b–1; SEC File No. 270–188; OMB Control No. 3235–0212.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB''), a request for extension of the previously approved collection of information discussed below.

Rule 12b–1 permits a registered open-end investment company (''mutual fund'') to distribute its own shares and pay the expenses of distribution out of the mutual fund's assets provided, among other things, that the mutual fund adopts a written plan (''rule 12b–1 plan'') and has in writing any agreements relating to the implementation of the rule 12b–1 plan. The rule in part requires that (i) the adoption or material amendment of a rule 12b–1 plan be approved by the mutual fund's directors and shareholders; (ii) the board review

quarterly reports of amounts spent under the rule 12b–1 plan; and (iii) the board consider continuation of the rule 12b–1 plan at least annually. Rule 12b–1 also requires funds relying on the rule to preserve for six years, the first two years in an easily accessible place, copies of the rule 12b–1 plan, related agreements and reports, as well as minutes of board meetings that describe the factors considered and the basis for adopting or continuing a rule 12b–1 plan.

The board and shareholder approval requirements of rule 12b–1 are designed to ensure that fund shareholders and directors receive adequate information to evaluate and approve a rule 12b–1 plan. The requirement of quarterly reporting to the board is designed to ensure that the rule 12b–1 plan continues to benefit the fund and its shareholders. The recordkeeping requirements of the rule are necessary to enable Commission staff to oversee compliance with the rule.

Based on information filed with the Commission by funds, Commission staff estimates that there are 6,217 mutual fund portfolios with rule 12b–1 plans. As discussed above, rule 12b–1 requires the board of each fund with a rule 12b–1 plan to (i) review quarterly reports of amounts spent under the plan and (ii) annually consider the plan's continuation (which generally is combined with the fourth quarterly review). This results in a total number of annual responses per fund of four and an estimated total number of industry responses of 24,868 (6,217 fund portfolios×4 annual responses per fund=24,868 responses).

Based on conversations with fund industry representatives, Commission staff estimates that for each of the 6,217 mutual fund portfolios that currently have a rule 12b–1 plan, the average annual burden of complying with the rule is 100 hours to maintain the plan. This estimate takes into account the time needed to prepare quarterly reports to the board of directors, the board's consideration of those reports, and the board's annual consideration of the plan's continuation. Commission staff therefore estimates that the total burden of the rule's paperwork requirements for all funds is 621,700 hours (6,217 fund portfolios×100 hours per fund=621,700 hours). The estimate of 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 Commission rules.

If a currently operating fund seeks to (i) adopt a new rule 12b–1 plan or (ii) materially increase the amount it spends for distribution under its rule 12b–1 plan, rule 12b–1 requires that the fund obtain shareholder approval. As a consequence, the fund will incur the cost of a proxy. Commission staff estimates that three funds per year prepare a proxy in connection with the adoption or material amendment of a rule 12b–1 plan. Commission staff further estimates that the cost of each fund's proxy is $15,000. Thus the total annualized cost burden of rule 12b–1 to the fund industry is $45,000 (3 funds requiring a proxy x $15,000 per proxy).

The collections of information required by rule 12b–1 are necessary to obtain the benefits of the rule. Notices to the Commission will not be kept confidential. The Commission is seeking OMB approval because 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.

Please direct written comments regarding the information above to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503; and (ii) Kenneth A. Fogash, Acting Associate Executive Director/CIO, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Comments must be submitted to OMB within 30 days of this notice.

Dated: May 29, 2003.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–14293 Filed 6–5–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, 450 Fifth Street, NW., Washington, DC 20549.

Extension:

Rule 17f–2 SEC File No. 270–233 OMB Control No. 3235–0223.

Form N–17f–2 SEC File No. 270–317 OMB Control No. 3235–0360.

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'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 17f–2 is entitled: ''Custody of Investments by Registered Management Investment Company.'' Rule 17f–2 establishes safeguards for arrangements in which a registered management investment company (''fund'') is deemed to maintain custody of its own assets, such as when the fund maintains its assets in a facility that provides safekeeping but not custodial services. The rule includes several recordkeeping or reporting requirements. The fund's directors must prepare a resolution designating not more than five fund officers or responsible employees who may have access to the fund's assets. The designated access persons (two or more of whom must act jointly when handling fund assets) must prepare a written notation providing certain information about each deposit or withdrawal of fund assets, and must transmit the notation to another officer or director designated by the directors. Independent public accountants must verify the fund's assets at least three times a year, and two of the examinations must be unscheduled.

The requirement that directors designate access persons is intended to ensure that directors evaluate the trustworthiness of insiders who handle fund assets. The requirements that access persons act jointly in handling fund assets, prepare a written notation of each transaction, and transmit the notation to another designated person are intended to reduce the risk of misappropriation of fund assets by access persons, and to ensure that adequate records are prepared, reviewed by a responsible third person, and available for examination by the Commission's examination staff. The requirement that auditors verify fund assets without notice twice each year is intended to provide an additional deterrent to the misappropriation of fund assets and to detect any irregularities.

The Commission staff estimates that approximately 135 funds rely upon rule 17f–2.[1] The Commission staff estimates that each fund offers an average of 3.7 separate series or portfolios subject to rule 17f–2. Each fund makes an average of 97.4 responses each year under the rule, including 1 response (requiring .2 burden hours) per fund to draft director resolutions, 89 responses per fund to prepare notations of transactions [2]

[1] The Commission's records indicate that approximately 135 funds filed Form N–17f–2 with the Commission during calendar year 2002.

[2] This number results from 24 responses per portfolio multiplied by 3.7 portfolios in the average fund (24 × 3.7 = 88.8).

(requiring one hour each), and 7.4 responses [3] per fund for fund personnel to assist the independent public accountants when they perform unscheduled verifications (requiring 10 burden hours each). Thus, the total hour burden per fund is estimated to 163.2 hours [4] Commission staff estimates that each fund therefore spends approximately .2 burden hours of professional time at $60 per hour annually in drafting resolutions by directors (.2 × $60 = $12), 89 hours [5] of professional time at $60 per hour annually in preparing transaction notations (89 × $60 = $5,340), and 74 hours [6] of clerical time at $16 per hour annually in assisting independent public accounts perform unscheduled verifications of assets (74 × $16 = $1,184).[7] The total annual burden of rule 17f–2's paperwork requirements thus is estimated to be approximately 22,032 hours [8] at an annual cost of $882,360.[9]

Form N–17f–2 is entitled ''Certificate of Accounting of Securities and Similar Investments in the Custody of Management Investment Companies.'' Form N–17f–2 is the cover sheet for the accountant examination certificates filed under rule 17f–2 of the Investment Company Act of 1940 by registered management investment companies (''funds'') maintaining custody of securities or other investments. Form N–17f–2 facilitates the filing of the accountant's examination certificates. The use of the form allows the certificates to be filed electronically, and increases the accessibility of the examination certificates to both the Commission's examination staff and interested investors by ensuring that the certificates are filed under the proper SEC file number and the correct name of a fund.

Under rule 17f–2, each fund is required to file Form N–17f–2 at least three times a year with the Commission. Commission staff estimates that it takes approximately 1 hour per response to prepare and file a Form N–17f–2 with the Commission. Thus, the total annual burden of Form N–17f–2's paperwork requirement is estimated to be approximately 405 burden hours.[10] The entire hour burden will be borne by clerical staff at $16 per hour, for a total cost of approximately $6,480 (405 burden hours × $16 = $6,480). The increase in burden hours from 92 to 405 is attributable to updated estimates of the burden hours that reflect additional time spent by professionals and clerical staff in their compliance efforts.

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 of the costs of Commission rules and forms. Complying with the collection of information requirements of the rule is mandatory for those funds that maintain custody of their own assets. The information provided to the Commission by the fund's independent public accountants about each verification of the fund's assets 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 control number.

Please direct written comments regarding the above information to the following persons: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503; and (ii) Kenneth A. Fogash, Acting Associate Executive Director/CIO, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549. Comments must be submitted to OMB within 30 days of this notice.

[3] This number results from 2 unscheduled verifications per portfolio multiplied by 3.7 portfolios in the average fund (2 × 3.7 = 7.4 responses per fund).

[4] (1 response × .2 burden hours) + (89 responses × 1 burden hour) + (7.4 responses × 10 burden hours) = 163.2 burden hours.

[5] 89 transaction notations per fund × 1 hour = 89 hours.

[6] 7.4 verifications per fund × 10 hours = 74 hours.

[7] Each of these hour burden estimates is based upon conversations with attorneys and accountants familiar with the information collection requirements of the rule. Commission staff relied upon the Securities Industry Association, Report on Management and Professional Earnings in the Securities Industry (2002) to determine the hourly wage rates used in the calculation of this estimate. Professional time is based on the estimated average wage for associate and general counsel in the securities industry.

[8] 163.2 hours per fund × 135 funds = 22,032 total annual burden.

[9] ($12 (for drafting resolutions) + $5,340 (for transaction notations) + $1,184 (for unscheduled verifications)) × 135 funds = $882,360. The annual burden for rule 17f–2 does not include time spent preparing Form N–17f–2. The burden for Form N–17f–2 is included in a separate collection of information.

[10] The Commission staff estimates that there are 135 funds that file Form N–17f–2 each year. Each fund is required to make three responses per year, and each response requires 1 hour to prepare. The hour burden is calculated as follows: 135 (respondents) × 3 (responses per fund per year) × 1 (hours per response) = 405 hours.

Dated: May 30, 2003.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–14294 Filed 6–5–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 68 FR 32781, June 2, 2003.

STATUS: Closed Meeting.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: Tuesday, June 3, 2003 at 2 p.m.

CHANGE IN THE MEETING: Time change.

The closed meeting scheduled for Tuesday, June 3, 2003 at 2 p.m. has been changed to Tuesday, June 3, 2003 at 1 p.m.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 942–7070.

Dated: June 3, 2003.

Jonathan G. Katz,

Secretary.

[FR Doc. 03–14366 Filed 6–3–03; 4:50 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47954; File No. SR–NASD–2003–87]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc. Regarding the Issuance of Market Participant Identifiers

May 30, 2003.

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 May 22, 2003, the National Association of Securities Dealers, Inc. (''NASD''), through its subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq''), 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 Nasdaq. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 would enable members that are registered as market makers or electronic communications networks (''ECNs'') to request and receive a second market participant identifier (''MMID'') with which to enter a second Attributable Quote/Order in the Nasdaq Quotation Montage or to enter non-attributable orders into SIZE in SuperMontage. The rule change would be established as a two-month pilot program currently scheduled to begin on July 1, 2003. Nasdaq will issue a Head Trader Alert publicly announcing the precise start and end dates of the pilot. The text of the proposed rule change is set forth below. Proposed new language is in *italics;* proposed deletions are in [brackets].

* * * * *

4613.Character of Quotations

(a) [Two-Sided] Quotation[s] *Requirements and Obligations*

(1) *Two-Sided Quote Obligation.* For each security in which a member is registered as a market maker, the member shall be willing to buy and sell such security for its own account on a continuous basis and shall enter and maintain a two-sided quotation (''Principal Quote''), which is attributed to the market maker by a special maker participant identifier (''MMID'') and is displayed in the Nasdaq Quotation Montage at all times, subject to the procedures for excused withdrawal set forth in Rule 4619.

(A) No Change.

(B) No Change.

(2) For a two-month pilot period, market makers and ECNs may request the use of a second MMID. A market maker may request the use of a second MMID for displaying Attributable Quotes/Orders in the Nasdaq Quotation Montage for any security in which it is registered and meets the obligations set forth in subparagraph (1) of this rule. An ECN may request the use of a second MMID for displaying Attributable Quotes/Orders in the Nasdaq Quotation Montage for any security in which it meets the obligations set forth in Rule 4623. A market maker or ECN that ceases to meet the obligations appurtenant to its first MMID in any security shall not be permitted to use the second MMID for any purpose in that security.

(3) Members that are permitted the use of second MMIDs for displaying Attributable Quotes/Orders pursuant to subparagraph (2) of this rule are subject to the same rules applicable to the members' first quotation, with two exceptions: (a) The continuous two-sided quote requirement and excused withdrawal procedures described in subparagraph (1) above, as well as the procedures described in Rule 4710(b)(2)(B) and (b)(5), do not apply to market makers' second MMIDs; and (b) the second MMID may not be used by market makers to engage in passive market making or to enter stabilizing bids pursuant to NASD Rules 4614 and 4619.

(b)–(e) No Change.

* * * * *

IM–4613–1—Procedures For Allocation of Second Displayable MMIDs

Nasdaq has a technological limitation on the number of displayed, attributable quotations in an individual security, although it has not reached that maximum to date in any security. Therefore, Nasdaq must consider the issuance and display of a second MMID to be a privilege and not a right. Nasdaq has developed the following method for allocating the privilege of receiving and displaying a second MMID in an orderly, predictable, and fair manner on a stock-by-stock basis.

Nasdaq will automatically designate a market maker's first MMID as a ''Primary MMID'' and its second MMID as a ''Secondary MMID.'' Market makers are required to use their Primary MMID in accordance with the requirements of NASD Rule 4613(a)(1) above, as well as all existing requirements for the use of MMIDs in Nasdaq systems. Market makers' use of Secondary MMIDs are subject to the requirements set forth in NASD Rule 4613(a)(2) and (a)(3) above, including the prohibition on passive market making. However, the two-sided quote requirement, and the excused withdrawal procedures under NASD Rule 4619, and 4710(b)(2)(B) and (b)(5) will not apply to the secondary MMID. Nasdaq will automatically designate each ECN's MMIDs as Primary and Secondary. Each ECN MMID will be subject to the requirements of NASD Rule 4623 and the existing ECN requirements of the NASD Rule 4700 Series. Members may also use a Secondary MMID to enter non-attributable orders into SIZE.

Nasdaq, in conjunction with the NASD, has developed procedures to maintain a high level of surveillance and member compliance with its rules with respect to members' use of both Primary and Secondary MMIDs to display quotations in Nasdaq systems. If it is determined that a Secondary MMID is being used improperly, Nasdaq will withdraw its grant of the Secondary MMID for all purposes for all securities. In addition, if a market maker or ECN no longer fulfills the conditions appurtenant to its Primary MMID (e.g., by being placed into an unexcused withdrawal), it may not use the Secondary MMID for any purpose in that security.

The first priority of Nasdaq's method for allocating the privilege of displaying a second MMID is that each market maker or ECN should be permitted to register to display a single quotation in a security under its Primary MMID before any is permitted to register to display a second quotation under a Secondary MMID. Each market maker or ECN may register its Primary MMID to display a quotation in a security, on a first-come-first-served basis. After each market maker or ECN has been permitted to register its Primary MMID to display quotations in a stock, Nasdaq will then register Secondary MMIDs to display Attributed Quotes/Orders in that security on a first-come-first-served basis, consistent with the procedures listed below. If Nasdaq comes within five MMIDs of its maximum in a particular security, Nasdaq will temporarily cease registering additional Secondary MMIDs in that security and reserve those five remaining MMIDs for members that may register their Primary MMID in that stock in the future. If Nasdaq allocates those reserved MMIDs to members requesting Primary MMIDs and then receives additional requests for Primary MMIDs, it will use the procedure described below to reallocate Secondary MMIDs to members requesting Primary MMIDs.

For any stock in which Nasdaq has reached the maximum number of members registered to display quotations, once each month, Nasdaq will rank each of the market participants that has two MMIDs in the stock according to their monthly volume of trading, based on the lower volume of that participant's two MMIDs. Nasdaq will withdraw the second MMID display privilege of the lowest volume participant in that ranking and assign that privilege to the first member that requested the ability to display a second quotation. Nasdaq will repeat this process as many times as needed to accommodate all pending requests for Primary and Secondary MMIDs. The low-ranking member(s) will lose the ability to display a second quotation in that security for that month, but will still be permitted to use the second MMID to enter non-attributable orders into SIZE

for that security or any other, and to display a second quote in any stocks in which it is properly registered to do so, subject to the conditions described in the rule and this interpretive material.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq 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. Nasdaq 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

An NASD member that registers as a market maker or ECN is permitted to enter one two-sided quotation per security in the Nasdaq Quotation Montage, and is assigned a unique market participant identifier (''MMID'') with which to enter such quotations. The NASD 4600 Rule Series governs the character of such quotations and the rights and obligations of members that display quotations in the Nasdaq Quotation Montage via their MMIDs. The NASD Rule 4700 Series sets forth the rights and obligations of members that participate in the Nasdaq National Market Execution System (''SuperMontage''), including the entry of quotes and orders and the display of quotations. Numerous other NASD and Commission rules govern the conduct of members in their use of MMIDs to enter and execute orders and display quotes, including, for example, NASD IM–2110–2 (the ''Manning Interpretation''), NASD Rule 6950 (the ''Order Audit Trail System''), and NASD Rule 2320 (the ''Best Execution'' rule).

Nasdaq proposes to amend NASD Rule 4613(a) to permit market makers and ECNs to request the use of a second MMID for displaying Attributable Quotes/Orders in the Nasdaq Quotation Montage. A market maker would be entitled to request the use of a second MMID for displaying Attributable Quotes/Orders in any security in which it is registered and meets the obligations set forth in NASD Rule 4613(a)(1), including the maintenance of a continuous two-sided quotation. An ECN would be entitled to request the use of a second MMID for displaying Attributable Quotes/Orders in the Nasdaq Quotation Montage for any security in which it meets the obligations set forth in Rule 4623.

Members that are permitted the use of second MMIDs for displaying Attributable Quotes/Orders would be subject to the same rules applicable to the members' first quotation. In other words, market makers that display a second Attributable Quote/Order would be required to comply with all rules applicable to market makers that display a single Attributable Quote/Order, and ECNs would be required to comply with all rules applicable to ECNs in their display of Attributable Quotes/Orders. There would be only two exceptions to that general principle. First, the continuous two-sided quote requirement and excused withdrawal procedures, as well as the procedures described in NASD Rule 4710(b)(2)(B) and (b)(5) would not apply to market makers' use of second MMIDs. Second, a market maker would be permitted to use only one MMID, its Primary MMID, to engage in passive market making or to enter stabilizing bids pursuant to NASD Rules 4614 and 4619. In all other respects, members would have the same rights and obligations in using a second MMID to enter quotes and orders and to display quotations as they do today.

Nasdaq believes that the ability to enter quotes and orders and to display quotations under a second MMID would benefit the Nasdaq market by enabling members to contribute more liquidity to the market, add to the transparency of trading interest, and better serve the needs of investors.[3] Members would use the second MMID to route orders and quotes to SuperMontage from different units within their firms, including market making, arbitrage, retail, and institutional trading desks, among others. Within the same firm, these desks serve a variety of functions and investors, often with different needs and goals that are accomplished by differing trading strategies or practices. Members that, in the past, have specialized in a particular investor type or trading practice have expanded and integrated their operations. Nasdaq believes that these members require the ability to participate in Nasdaq trading in new ways.

At the same time, Nasdaq believes that it is essential for it to maintain its regulation of trading on Nasdaq and the same high level of compliance with NASD and Commission rules that it believes it has achieved to date. Except as noted in the proposed rule, members that use a second MMID would be required to comply with all NASD and Commission rules applicable to their current use of a single MMID. Members would be prohibited from using a second MMID to accomplish indirectly what they are prohibited from doing directly through a single MMID. For example, members would not be permitted to use a second MMID to avoid their Manning obligations under IM–2110–2, best execution obligations under NASD Rule 2320, or their obligations under the Commission Order Handling Rules. Members would be required to continue to comply with the firm quote rule, the OATS rules, and the Commission order routing and execution quality disclosure rules. In addition, Rule 4613(a) specifically prohibits firms from displaying a second Attributable Quote/Order to engage in passive market making or to enter stabilizing bids because this could violate NASD Rules 4614 and 4619 and Commission Regulation M. To the extent that the allocation of second MMIDs were to create regulatory confusion or ambiguity, every inference would be drawn against the use of a second MMID in a manner that would diminish the quality or rigor of the regulation of the Nasdaq market.

Nasdaq represents that it has a technological limitation on the number of displayed, attributable quotations in an individual security, although it has not reached that maximum to date in any security. Therefore, Nasdaq must consider the issuance and display of a second MMID to be a privilege and not a right. Nasdaq has developed the following method for allocating the privilege of receiving and displaying a second MMID in an orderly, predictable, and fair manner on a stock-by-stock basis.

Nasdaq would automatically designate a market maker's first MMID as a Primary MMID and its second MMID as a Secondary MMID. Market makers would be required to use their Primary MMID in accordance with the requirements of NASD Rule 4613(a)(1), as well as all existing requirements for the use of MMIDs in Nasdaq systems. Market makers' use of Secondary MMID's would be subject to the requirements set forth in NASD Rule 4613(a)(2) and (a)(3), including the prohibition on passive market making. However, the two-sided quote requirement, and the excused withdrawal procedures under NASD Rule 4619, and 4710(b)(2)(B) and (b)(5)

[3] Nasdaq will assess no fees for the issuance or use of a second MMID, other than the SEC-approved transaction fees set forth in NASD Rule 7010.

would not apply to the Secondary MMID. Nasdaq would automatically designate each ECN's MMIDs as Primary and Secondary. Each ECN MMID would be subject to the requirements of NASD Rule 4623 and the existing ECN requirements of the NASD Rule 4700 Series. Members would also be permitted to use a Secondary MMID to enter non-attributable orders into SIZE.

Nasdaq represents that it, in conjunction with the NASD, has developed procedures to maintain a high level of surveillance and member compliance with its rules with respect to members' use of both Primary and Secondary MMIDs to display quotations in Nasdaq systems. If it were to be determined that a Secondary MMID was being used improperly, Nasdaq would withdraw its grant of the Secondary MMID for all purposes for all securities. In addition, if a market maker or ECN were no longer to fulfill the conditions appurtenant to its Primary MMID (*e.g.*, by being placed into an unexcused withdrawal), it would not be permitted to use the Secondary MMID for any purpose in that security.

The first priority of Nasdaq's method for allocating the privilege of displaying a second MMID is that each market maker or ECN should be permitted to register to display a single quotation in a security under its Primary MMID before any is permitted to register to display a second quotation under a Secondary MMID. Each market maker or ECN would register its Primary MMID to display a quotation in a security on a first-come-first-served basis. After each market maker or ECN has been permitted to register its Primary MMID to display quotations in a stock, Nasdaq would then register Secondary MMIDs to display Attributed Quotes/Orders in that security on a first-come-first-served basis, consistent with the procedures listed below. If Nasdaq were to come within five MMIDs of its maximum in a particular security, Nasdaq would temporarily cease registering additional Secondary MMIDs in that security and reserve those five remaining MMIDs for members that may register their Primary MMID in that stock in the future. If Nasdaq were to allocate those reserved MMIDs to members requesting Primary MMIDs and were then to receive additional requests for Primary MMIDs, it would use the procedure described below to reallocate Secondary MMIDs to members requesting Primary MMIDs.

For any stock in which Nasdaq has reached the maximum number of members registered to display quotations, once each month, Nasdaq would rank each of the market participants that has two MMIDs in the stock according to their monthly volume of trading, based on the lower volume of that participant's two MMIDs. Nasdaq would withdraw the second MMID display privilege of the lowest volume participant in that ranking and assign that privilege to the first member that requested the ability to display a second quotation. Nasdaq would repeat this process as many times as needed to accommodate all pending requests for Primary and Secondary MMIDs. The low-ranking member(s) would lose the ability to display a second quotation in that security for that month, but would still be permitted to use the second MMID to enter non-attributable orders into SIZE for that security or any other, and to display a second quote in any stocks in which it is properly registered to do so, subject to the conditions described in the rule and this interpretive material.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[4] which requires, among other things, that a registered national securities association's rules must be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system, and to protect investors and the public interest. Nasdaq believes that the proposed rule change is consistent with these requirements because it will facilitate transactions in securities, remove impediments to a free and open market, and protect investors by improving the transparency and efficiency of transactions.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

[4] 15 U.S.C. 78*o*–3(b)(6).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has been filed by Nasdaq as a ''non-controversial'' rule change pursuant to section 19(b)(3)(A)(i) of the Act[5] and subparagraph (f)(6) of Rule 19b–4 thereunder.[6] Consequently, because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not 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,[7] and Nasdaq provided the Commission with written notice of its intent to file the proposed rule change at least five days prior to the filing date, it has become effective pursuant to section 19(b)(3)(A) of the Act and Rule 19b–4 thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate the 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.

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. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. 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

[5] 15 U.S.C. 78s(b)(3)(A)(i).

[6] 17 CFR 240.19b–4(f)(6).

[7] Nasdaq withdrew its request that the Commission waive the 30-day operative delay in view of the fact that the 30-day operative delay will have expired prior to the scheduled start date of the pilot program, July 1, 2003. Telephone conversation between Jeffrey S. Davis, Associate General Counsel Nasdaq, and Ann E. Leddy, Attorney, Division of Market Regulation, Commission (May 30, 2003).

the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR–NASD–2003–87 and should be submitted by June 27, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–14257 Filed 6–5–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47946; File No. SR–NASD–2002–148]

Self-Regulatory Organizations; Order Granting Approval of Proposed Rule Change and Amendment Nos. 1 and 2, and Notice of Filing and Order Granting Accelerated Approval to Amendment Nos. 3 and 4 to the Proposed Rule Change by the National Association of Securities Dealers, Inc., to Eliminate the Regulatory Fee and Institute a Transaction-Based Trading Activity Fee

May 30, 2003.

I. Introduction

On October 18, 2002, the National Association of Securities Dealers, Inc. (''NASD'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to eliminate the NASD's Regulatory Fee and institute a new, transaction-based Trading Activity Fee (''TAF''). The NASD amended the proposed rule change on November 5, 2002,[3] and November 8, 2002.[4] The proposed rule change, as modified by Amendment Nos. 1 and 2, was published for notice and comment in the **Federal Register** on November 19, 2002.[5] The Commission received 23 comments[6] on the proposal.[7] On March 18, 2003, the NASD responded to the comments, and amended the proposed rule change again.[8] On April 14, 2003, the NASD extended the pilot program through June 1, 2003.[9] On May 19, 2003, the NASD amended the proposed rule change a fourth time.[10] This order

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* November 4, 2002 letter from Barbara Z. Sweeney, Senior Vice President (''SVP'') and Corporate Secretary, NASD, to Katherine A. England, Assistant Director, Division of Market Regulation (''Division''), SEC, and attachments (''Amendment No. 1''). Amendment No. 1 completely replaced and superseded the original proposed rule change.

[4] *See* November 7, 2002 letter from Barbara Z. Sweeney, SVP and Corporate Secretary, NASD, to Katherine A. England, Assistant Director, Division, SEC, and attachments (''Amendment No. 2''). Amendment No. 2 completely replaced and superseded Amendment No. 1 and the original proposed rule change.

[5] *See* Securities Exchange Act Release No. 46817 (November 12, 2002), 67 FR 69784.

[6] There are 15 comment letters submitted for the instant proposed rule change. However, the Commission also is considering comment letters submitted for SR–NASD–2002–98, SR–NASD–2002–147, SR–NASD–2003–26 and SR–NASD–2003–73. *See* footnotes 7 and 9, *infra.*

[7] The NASD eliminated the Regulatory Fee and instituted the TAF when it filed SR–NASD–2002–98. *See* Securities Exchange Act Release No. 46416 (August 23, 2002), 67 FR 55901 (August 30, 2002). The proposal was effective upon filing with the Commission, pursuant to section 19(b)(3)(A)(ii) of the Act, and Rule 19b–4(f)(2) thereunder. 15 U.S.C. 78s(b)(3)(A)(ii), 17 CFR 240.19b–4(f)(2). The Commission received 10 comments on SR–NASD–2002–98. *See* September 17, 2002 letter from Lanny A. Schwartz, Philadelphia Stock Exchange, Inc. (''Phlx''), to Jonathan G. Katz, Secretary, SEC (''Phlx Letter''); September 18, 2002 letter from Edward J. Joyce, President and Chief Operating Officer, The Chicago Board Options Exchange, Inc. (''CBOE''), to Jonathan G. Katz, Secretary, SEC (''CBOE Letter #1''); September 20, 2002 letter submitted jointly by The American Stock Exchange LLC (''Amex''), CBOE, the International Securities Exchange, Inc. (''ISE''), The Options Clearing Corporation (''OCC''), The Pacific Exchange, Inc. (''PCX''), and the Phlx, to Jonathan G. Katz, Secretary, SEC (''OCC Joint Letter #1'') (OCC Joint Letter #1 was later withdrawn.); September 23, 2002 letter from Susan Milligan, First Vice President and Special Counsel, OCC, to Jonathan G. Katz, Secretary, SEC (''OCC Joint Letter #2'') (withdraws OCC Joint Letter #1 and substitutes a new letter that is identical to OCC Joint Letter #1 except for the removal of the Amex as a signatory to the letter); September 27, 2002 letter from Jeffrey T. Brown, Senior Vice President (''SVP''), Secretary and General Counsel (''GC''), The Cincinnati Stock Exchange, Inc. (''CSE''), to Jonathan G. Katz, Secretary, SEC (''CSE Letter #1''); September 26, 2002 letter from Stuart J. Kaswell, Senior Vice President (''SVP'') and GC, The Securities Industry Association (''SIA''), to Jonathan G. Katz, Secretary, SEC (''SIA Letter #1''); October 21, 2002 letter from Margaret Wiermanski, Chief Compliance Officer, TD Securities, to Jonathan G. Katz, Secretary, SEC (''TD Securities Letter''); March 13, 2003 letter from John Boese, VP, Legal and compliance, The Boston Stock Exchange (''BSE''), to Jonathan G. Katz, Secretary, SEC (''BSE Letter''); March 27, 2003 letter from Edward J. Joyce, President and Chief Operating Officer, CBOE, to Jonathan G. Katz, Secretary, SEC (''CBOE Letter #3); May 15, 2003 letter from Margaret Wiermanski, VP-Compliance, TD Options, LLC, to Jonathan G. Katz, Secretary, SEC (''TD Options Letter'').

The NASD also filed SR–NASD–2002–147, which transformed the TAF into a pilot program, scheduled to terminate on December 31, 2002. *See* Securities Exchange Act Release No. 46818 (November 12, 2002), 67 FR 69782 (November 19, 2002). The Commission received eight comments on SR–NASD–2002–147, which were submitted as joint letters for SR–NASD–2002–147 and SR–NASD–2002–148. Letters for SR–NASD–2002–147 are not listed separately in this order, because they are fully documented in the list of comment letters for SR–NASD–2002–148.

Subsequently, the NASD filed the instant proposed rule change (SR–NASD–2002–148), which contained substantially the same proposed rule language as was contained in SR–NASD–2002–98, but was submitted pursuant to Section 19(b)(2) of the Act to allow for an additional notice and comment period per the commenters' requests. *See* Securities Exchange Act Release No. 46817 (November 12, 2002), 67 FR 69785 (November 19, 2002). The Commission received 15 comments on SR–NASD–2002–148. *See* December 6, 2002 letter from Edward J. Joyce, President and Chief Operating Officer, CBOE, to Jonathan G. Katz, Secretary, SEC (''CBOE Letter #2''); December 6, 2002 letter from William C. McGowan, Managing Director, TD Professional Execution, Inc., to Jonathan G. Katz, Secretary, SEC (''TD ProEx Letter''); December 10, 2002 letter from Eric Noll, Susquehanna International Group, LLP, to Jonathan G. Katz, Secretary, SEC (''Susquehanna Letter''); December 10, 2002 letter from Jeffrey T. Brown, SVP, Secretary and GC, CSE, to Jonathan G. Katz, Secretary, SEC (''CSE Letter #2''); December 9, 2002 letter from Barry S. Augenbraun, SVP and Corporate Secretary, Raymond James Financial, Inc., to Jonathan G. Katz, Secretary, SEC (''Raymond James Letter''); December 9, 2002 letter from Stuart J. Kaswell, SVP and GC, SIA, to Jonathan G. Katz, Secretary, SEC (''SIA Letter #2''); January 23, 2003 letter from Mary McDermott-Holland, Vice Chairman, Chair, Trading Issues Committee, to Jonathan G. Katz, Secretary, SEC (''STA Letter''); December 11, 2002 letter from Darla C. Stuckey, Corporate Secretary, The New York Stock Exchange, Inc. (''NYSE''), to Jonathan G. Katz, Secretary, SEC (''NYSE Letter #1''); December 5, 2002 letter, submitted jointly by CBOE, OCC, ISE, PCX, and Phlx, to Jonathan G. Katz, Secretary, SEC (''OCC Joint Letter #3''); BSE Letter; CBOE Letter #3; March 24, 2003 letter submitted jointly by CBOE, OCC, ISE, PCX, and Phlx, to Jonathan G. Katz, Secretary, SEC (''OCC Joint Letter #4''); TD Options Letter; April 10, 2003 letter from Darla C. Stuckey, Corporate Secretary, NYSE, to Jonathan G. Katz, Secretary, SEC (''NYSE Letter #2''); May 27, 2003 letter from Gabriel A. Duran, Chief Compliance Officer, GVR Company, LLC, to Jonathan G. Katz, Secretary, SEC (''GVRC Letter'').

The NASD extended the pilot in SR–NASD–2002–182, through March 1, 2003. The Commission received no comments on SR–NASD–2002–182. The NASD extended the pilot through April 1, 2003 in SR–NASD–2003–26. *See* Securities Exchange Act Release No. 47436 (March 4, 2003), 68 FR 11422 (March 10, 2003). The Commission received two comments on SR–NASD–2003–26. NYSE Letter #2; GVRC Letter.

[8] *See* March 18, 2003 letter from Barbara Z. Sweeney, SVP and Corporate Secretary, NASD, to Katherine A. England, Assistant Director, Division, SEC, (''NASD Response Letter'' or ''Amendment No. 3''). In Amendment No. 3, the NASD (1) responded to the comments; (2) incorporated the interpretations contained in *Notices to Members 02–36* and *02–75* in the proposed rule language. *See also,* March 28, 2003 letter from Kathleen A. O'Mara, Associate General Counsel, Regulatory Policy and Oversight, NASD, to Katherine A. England, Assistant Director, and Joseph Morra, Special Counsel, Division of Market Regulation, SEC (via email) (''NASD Response Letter #2'').

[9] See Securities Exchange Act Release No. 47685 (April 16, 2003), 68 FR 20198 (April 24, 2003) (SR–NASD–2003–73). The Commission received two comments on the proposed rule change. *See* May 13, 2003 letter from Robert Bellick, Christopher Gust, Wolverine Trading, LLC, to Jonathan G. Katz, Secretary, SEC (''Wolverine Letter''); GVRC Letter.

[10] *See* May 19, 2003 letter from Barbara Z. Sweeney, SVP and Corporate Secretary, NASD, to Katherine A. England, Assistant Director, Division, SEC (''Amendment No. 4''). In Amendment No. 4, the NASD proposes to exempt from the TAF listed

Continued

approves the proposed rule change as modified by Amendment Nos. 1 and 2. Simultaneously, the Commission provides notice of filing of Amendment Nos. 3 and 4, and grants accelerated approval of Amendment Nos. 3 and 4.

II. Summary of Comments

The Commission received a total of 23 comment letters on the NASD's proposal to eliminate the Regulatory Fee and institute the TAF,[11] all of which objected to the proposal, either for substantive or procedural reasons.[12] The following summary of comments provides an overview of the commenters' concerns.

• *The NASD Should Not Charge Its Members for Services Related to Transactions on Other Markets, Where the NASD Does Not Provide the Relevant Service*

A number of commenters stated it is improper for the NASD to collect a fee from its members relating to transactions on other markets, because in that case, other markets, not the NASD, provide the relevant services.[13] For example, one commenter objected to the NASD's proposal to apply the TAF to transactions for options market makers who are non-NASD members who effect a transaction on an away exchange, emphasizing that the NASD and the options exchanges share options sales practice responsibilities, and that the NASD's responsibilities ''are likely to decrease, not increase in the near future.''[14] Expanding on that theme, another commenter suggested that the NASD provide more specific information about the costs to be borne by the NASD, and the relationship of those costs to the fees the NASD intends to charge, as well as the precise regulatory services the NASD performs and the NASD's authority to impose fees ''for services not unique to it.''[15]

• *The TAF Proposal Is Anti-Competitive Because It Indirectly Subsidizes Nasdaq by Effectively Reducing the Cost of Regulatory Services the NASD Provides to Nasdaq*

Some commenters objected to the proposed rule change on the basis that, by charging NASD members for securities transactions regardless of where a trade is executed, the NASD is providing an indirect subsidization to Nasdaq by reducing the cost to Nasdaq of regulatory services that the NASD provides to Nasdaq.[16] They claimed that the TAF proposal is the NASD's and Nasdaq's attempt to ensure that the revenue stream generated by trading in Nasdaq securities remains available, asserting that the NASD is subjecting transactions on competing markets to the TAF in an effort to subsidize Nasdaq's regulatory burden.[17]

• *Applying the TAF to Listed Options Transactions That Are Cleared by NASD Members Is Inappropriate*

Several commenters said that applying the TAF to listed options transactions that are cleared by NASD members is inappropriate because the NASD's regulatory responsibility for the listed options market is minimal.[18] Making a similar point, but from the opposite perspective, a number of commenters said the TAF is inequitable because the NASD will not apply the TAF to many over-the-counter instruments, such as debt and variable annuities, where the NASD has primary regulatory responsibility.[19]

• *The TAF Proposal Sets a Dangerous Precedent; a Single Transaction Could Incur Multiple Charges, Regardless of Regulatory Responsibilities or Nexus of Business Interest*

Some commenters expressed concern about the precedent the TAF proposal would set, where other self-regulatory organizations (''SROs'') might impose fees on transactions executed on markets for which the SRO performs no regulatory tasks, or for which the SRO has no business interest.[20] However, one commenter acknowledged, ''assessing a fee on trading activity occurring in other markets may be justified given the NASD's responsibility for *member* regulation * * *'' (Emphasis in original).[21] The commenter suggested that this concept is unprecedented, and that the impact should be examined carefully, given the concern that other self-regulatory organizations may impose similar fees, resulting in firms possibly paying considerably more than what is fair for regulation.[22]

• *The Interpretations in Notices to Members 02–75 and 02–63 Should Be Included in the Proposed Rule Language*

Notice to Members 02–75 states the TAF is not imposed on transactions for non-member broker-dealers who clear through an NASD member, unless the NASD clearing member firm also acts as executing broker in the transaction. Also, *Notice to Members 02–63* states that transactions effected on a national securities exchange by a dually registered specialist or floor based market maker will not be subject to the TAF. Several commenters suggested that this language be included in the proposed rule language, to ensure that the language is not removed from the rule without the filing of a proposed rule change.[23]

---

options transactions for members for which the NASD is not the designated options examining authority. The NASD proposes to make this amendment effective on January 1, 2004.

[11] *See* footnotes 6, 7 and 9, *supra.*

[12] Some commenters expressed their disapproval that the NASD filed the initial TAF proposal for immediate effectiveness. *See, e.g.*, Raymond James Letter. The Commission notes, however, that the point is moot, since the NASD subsequently filed SR–NASD–2002–147 and SR–NASD–2002–148, thereby allowing for full notice and comment on the proposal. Additionally, some commenters objected to the TAF being effective upon filing with the Commission because they believe the lack of notice and comment was unreasonable, and that it imposed hardship on member firms that were required to make extensive programming changes with insufficient notice. SIA Letter #1; Raymond James Letter at 1–2; SIA Letter #2 at 2, 5, 7.

[13] Phlx Letter at 1; CSE Letter #1 at 4–5 (''To go outside its own jurisdiction to recoup regulatory expenses without justification inappropriately places the burden for the operation and regulation of the [NASD] on other exchanges.''); TD Securities Letter (TD Securities Letter concurs completely with CSE Letter #1); SIA Letter #1 at 3; CBOE Letter #2 at 2; Susquehanna Letter at 1–3; CSE Letter #2 at 1–2; STA Letter at 2; NYSE Letter #1 at 2 (''* * * NASD is not empowered to act as the primary regulator across markets and over activities unique to other SROs. Consequently, no basis exists for it to impose such fees.'')

[14] CBOE Letter #2 at 2.

[15] NYSE Letter #1 at 2.

[16] Phlx Letter at 2; CSE Letter #1 at 8–9; CSE Letter #2 at 3.

[17] *See, e.g.*, CSE Letter #1 at 3–4; NYSE Letter #1 at 1 (''* * * NASD plans to capture new revenue sources so as to supplant and supplement fees lost when Nasdaq securities began to trade on markets other than the Nasdaq. Thus, the NASD proposes to impose regulation-related costs to fill a shortfall caused by competitively induced market share loss. This approach clearly is anti-competitive.''); BSE Letter at 2 (''* * * they are attempting to regain market share through anti-competitive rules * * *'').

[18] CBOE Letter #1 at 1–2; CBOE Letter #2 at 2; TD ProEx Letter at 1; Susquehanna Letter at 2; STA Letter at 2; BSE Letter at 4.

[19] CBOE Letter #1 at 2; OCC Joint Letter #2 at 1–2; CBOE Letter #2 at 2; TD ProEx Letter at 1; STA Letter at 3; OCC Joint Letter #3 at 3–4.

[20] *See, e.g.*, CBOE Letter #1 at 2; OCC Joint Letter #2 at 2 (''NASD should not be permitted to generate revenue and raise the costs of trading on the options exchanges without a showing that the amount of the TAF is limited to the recovery of its costs in connection with regulating listed options.''); CBOE Letter #2 at 3; TD ProEx Letter at 2–3; STA Letter at 2; OCC Joint Letter #3 at 4; BSE Letter at 2, 4.

[21] SIA Letter #2 at 6.

[22] *Id.* (''Given this significant expansion of the scope of the fee, and the possible precedential effect it may have in the industry, we believe that the NASD should be required to provide in more detail a fair and reasonable basis for expanding the scope of the TAF to cover transactions executed in any market.'')

[23] CBOE Letter #2 at 2 and Susquehanna Letter at 2 (regarding Notice to Members 02–75); TD ProEx Letter at 3 (regarding *Notice to Members 02–63*); OCC Joint Letter #3 at 6 (regarding both *Notices to Members*).

• *The NASD Could Raise the Fee at Any Time*

Some commenters expressed concern that the NASD could raise the fee at any time, within its own discretion without notice and comment and Commission approval.[24]

• *The Proposed Rule Language is Vague and Discretionary*

One commenter stated that the proposed rule language was ambiguous, and that such vagueness would allow the NASD to ''arbitrarily apply the fees to certain members while exempting others.'' [25] The same commenter said that the proposed rule language that allows the NASD to exempt other securities and transactions as it deems appropriate would provide the NASD with discretion to create exemptions without having to present the exemptions to the Commission for approval.[26]

III. The NASD's Response to Comments

The NASD responded to the comments,[27] discussing its rationale for the structure of its TAF proposal, and modifying the proposal to accommodate some of the commenters' concerns. The NASD's responses to the more significant issues are addressed below.

The NASD clarified that the TAF is to be used only to fund its member regulatory activities in a variety of areas such as ''sales practices, routine examinations, financial and operational reviews, new member applications, enforcement * * *'' wherever such member activity occurs.[28] Although the NASD will regulate activities of its members in all securities, including Nasdaq securities, the NASD states that revenues from the TAF will not fund regulatory activities of the Nasdaq stock market, and also states that Nasdaq will not receive any subsidy based on the TAF.[29]

Regarding suggestions that the TAF proposal is unfair or inequitable, the NASD stated that it chose to model the TAF after the SEC's Section 31 fee to simplify its framework for recouping its regulatory costs, and, in part, to minimize the programming impact on firms.[30] Debt, mutual funds, and variable annuities were excluded from the TAF, in keeping with this model, and the NASD set its Personnel Assessment and Gross Income Assessment rates at a level designed to ensure that regulatory expense levels for such products were funded fairly and adequately.[31] The NASD asserted that listed options are properly assessed under the TAF, since the NASD maintains regulatory responsibility for its members for options, and the ''NASD continues to assume the largest share of options self-regulatory allocation through the Options Self-Regulatory Council.'' [32] Furthermore, the NASD stated that its current costs for options regulation exceed the revenue the NASD anticipates receiving from this portion of the TAF.[33]

In response to the commenters' concern that the TAF proposal does not contain the exemptions to the TAF provided in *Notices to Members 02–63* and *02–75,* the NASD amended the proposed rule change to accommodate the commenters' request.[34]

With regard to comments that suggest that the NASD has not established a clear nexus between the TAF and the corresponding NASD regulatory responsibilities, the NASD maintained that its mandate is broad, and that its regulatory obligations ''exist separate and apart from any market-specific rules and obligations.'' [35] Additionally, the NASD filed Amendment No. 4, which creates an exemption from the TAF for listed options transactions for members for which the NASD is not the designated options examining authority.

IV. Discussion and Commission Findings

The Commission has reviewed carefully the proposed rule change, the comment letters, and the NASD's response to the comments, and finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association [36] and, in particular, the requirements of section 15A(b)(5) of the Act.[37] Section 15A(b)(5) requires, among other things, that the rules of a national securities association provide for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system which the association operates or controls. The Commission finds that the elimination of the Regulatory Fee, and the implementation of the TAF, as described in the instant proposed rule change, is consistent with section 15A(b)(5) of the Act, in that the proposal is reasonably designed to recover NASD costs related to regulation and oversight of its members.

The Commission recognizes the difficulties inherent in restructuring the NASD's regulatory fees, and believes that the NASD has done so in a manner that is fair and reasonable. The Commission believes that the NASD's proposed TAF, in conjunction with the Gross Income Assessment, is reasonably tailored to apportion fees based on the regulatory services the NASD provides.

With respect to the commenters' assertion that the NASD should not charge its members with respect to transactions on other markets, a conclusive factor in the Commission's approval of the rule is the NASD's broad responsibilities with respect to its members' activities, irrespective of where securities transactions take place. As a national securities association, the NASD has the responsibility to oversee its members' finances and conduct toward their customers, except in limited circumstances where this responsibility is allocated to another SRO. The NASD's responsibility exists even if the conduct involves a transaction executed on a market not directly regulated by the NASD. With respect to its members doing business with the public, the NASD incurs costs to regulate its members through financial responsibility reviews, examinations, and other compliance monitoring.

The NASD's proposal uses volume of transactions as a means of allocating regulatory costs to its members, in addition to gross income and personnel fees. Assessing fees in relation to transactions correlates to heightened NASD responsibilities regarding firms that engage in the trading. In most cases,

[24] CBOE Letter #2 at 3 (''Even though the current level of the TAF options fee is relatively small, the NASD could raise the fee at any time. Once the NASD establishes the precedent that it can tax options trades, there will be little check on its ability to raise the fee substantially.''); Susquehanna Letter at 3.

[25] CSE Letter #2 at 3.

[26] *Id.*

[27] *See* footnote 8, *supra.*

[28] NASD Response Letter #1 at 3–4.

[29] *Id.* at 4.

[30] *Id.*

[31] *Id.*

[32] *Id.* at 5.

[33] *Id.*

[34] In response to some commenters' assertion that the NASD should codify the exemption discussed in *Notice to Members 02–75* for non-member broker-dealers that clear through an NASD member broker-dealer, unless the NASD member executes the transaction, the NASD stated that the NASD does not assess a fee on a non-NASD member for its role in effecting a transaction, regardless of where the transaction is cleared; however, if an NASD member clearing firm acts as executing broker for a non-NASD member broker-dealer correspondent, the NASD will assess a fee to the NASD clearing member. The NASD does not believe this qualifies as an exemption to the TAF, and therefore, does not think it should be included in the rule.

[35] *Id.* at 5–6.

[36] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[37] 15 U.S.C.78o–3(b)(5).

the NASD has direct responsibility to oversee the firm's dealing with the public in effecting the transactions; the NASD may also have responsibility to oversee the impact of the trading on the firm's financial condition. In most cases, where responsibility for certain member activities has been allocated to other SROs, the NASD retains responsibility for other member functions. Thus, while trading activity is not wholly correlated to the full range of NASD responsibility for members in all instances, the Commission believes that they are closely enough connected to satisfy the statutory standard. To more narrowly tailor the transaction fees to regulatory duties, the NASD filed Amendment No. 4 to create an exemption from the TAF for listed options transactions of members for which the NASD is not the designated options examining authority. The Commission is granting accelerated approval of Amendment Nos. 3 and 4 to ensure that these changes are made simultaneously with the approval of the TAF proposal.[38] The Commission is satisfied that the NASD has made a good faith effort to exclude those types of transactions where there does not exist a substantial nexus to the NASD's regulatory responsibilities.

The Commission does not believe that approval of the NASD's TAF proposal opens the door to the imposition of fees on transactions executed on markets for which an SRO either has little or no nexus to regulatory tasks performed by the SRO or for which the SRO has no business interest. In setting their fees, the SROs must meet the statutory standard established in sections 6(b)(5)[39] and 15A(b)(5) of the Act.[40] Most SROs do not have the broad aegis of the NASD regarding members' customer business, and so will not have a regulatory nexus to support a transaction fee applicable to other markets.

The NASD currently excludes debt, mutual funds, and variable annuities from the scope of the TAF, because of difficulties of measurement. The Commission urges the NASD to consider ways to take into account activity in all the areas the NASD must oversee, to better allocate regulatory costs to these activities.[41]

Similarly, the Commission does not share the commenters' concern that the NASD could raise the TAF at any time. The NASD must file any proposed changes to the TAF with the Commission, and the NASD has agreed to file all future changes to the TAF for full notice and comment pursuant to section 19(b)(2) of the Act.[42] Therefore, if the NASD wishes to modify the TAF in the future, the NASD must file a proposed rule change pursuant to section 19(b)(2) of the Act,[43] for notice, public comment, and approval by the Commission.

In response to the commenters' concerns that the interpretations contained in *Notice to Members 02–63* and *Notice to Members 02–75* could be revoked or modified at any time, the NASD filed Amendment No. 3 to include the relevant language in the proposed rule language.

The Commission finds good cause for approving proposed Amendment Nos. 3 and 4 before the 30th day after the date of publication of notice of filing thereof in the **Federal Register**. The NASD filed Amendment Nos. 3 and 4 in response to comments it received after publication of the notice of filing of the proposed rule change, to address certain commenters' concerns. Because Amendment Nos. 3 and 4 are responsive to commenters' concerns, the Commission finds good cause for accelerating approval of the proposed rule change, as modified by Amendment Nos. 3 and 4.

The Commission expects that the NASD will continue to monitor the manner in which the TAF is implemented, and will take whatever steps are necessary to ensure that the fees remain consistent with the mandate established in section 15A(b)(5) of the Act,[44] so that the TAF remains equitable, as well as consistent with the NASD's expressed goal.

V. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning Amendment Nos. 3 and 4, including whether Amendment Nos. 3 and 4 are consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to Amendment Nos. 3 and 4 that are filed with the Commission, and all written communications relating to Amendment Nos. 3 and 4 between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD.

All submissions should refer to file number SR–NASD–2002–148 and should be submitted by June 27, 2003.

VI. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[45] that the proposed rule change (SR–NASD–2002–148), as modified by Amendment Nos. 1 and 2, be, and it hereby is, approved, and that Amendment Nos. 3 and 4 to the proposed rule change be, and hereby are, approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[46]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–14258 Filed 6–5–03; 8:45 am]

BILLING CODE 8010–01–P

[38] The Commission notes that an SRO may not grant exemptions to its rules unless the SRO has Commission-approved rules that gives it the authority to do so. Furthermore, where such authority exists, an SRO must file a proposed rule change to grant an exemption, unless the circumstances for the exemption are truly unique. The NASD stated the exemption created by Amendment No. 4 will be implemented on January 1, 2004.

[39] 15 U.S.C. 78f(b)(5).

[40] 15 U.S.C. 78o–3(b)(5). In reviewing other similar fee proposals, the Commission will, as it has done here, examine the proposals to ensure that the costs borne by firms are commensurate with the functions performed.

[41] Although the NASD did not delineate its responsibility for regulating trading in the over-the-counter market in unlisted securities, the Commission believes that the NASD indeed shoulders such a responsibility, and that it should devote an appropriate portion of the TAF to expanding and enhancing its examination and surveillance programs in that particular area. In this connection, the Commission notes that it approved recently an NASD proposal that will give the NASD access to real-time quotation activity in such securities. *See* Securities Exchange Act Release No. 47587 (March 27, 2003), 68 FR 16328 (April 3, 2003) (SR–NASD–2000–42)(approval order). The Commission expects the NASD to devote appropriate resources to take advantage of this expanded information.

[42] 15 U.S.C. 78s(b)(2). *See* NASD Response Letter #2.

[43] 15 U.S.C. 78s(b)(2).

[44] 15 U.S.C. 78o–3(b)(5).

[45] 15 U.S.C. 78s(b)(2).

[46] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47949; File No. SR–NASD–2001–75]

Self-Regulatory Organizations; Order Granting Approval of Proposed Rule Change and Amendment No. 1 by the National Association of Securities Dealers, Inc., and Notice of Filing and Order Granting Accelerated Approval of Amendment No. 2 To Make Permanent a Pilot Amendment to NASD Rule 4120 Relating to Nasdaq's Authority To Initiate and Continue Trading Halts

May 30, 2003.

I. Introduction

On October 18, 2001, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association''), through its subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission'' or ''SEC''), 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 make permanent a pilot amendment to NASD Rule 4120 relating to Nasdaq's authority to initiate and continue trading halts in circumstances where Nasdaq believes that extraordinary market activity in a security listed on Nasdaq is caused by the misuse or malfunction of an electronic quotation, communication, reporting, or execution system. On January 28, 2002, Nasdaq amended the proposal.[3] The proposed rule change, as modified by Amendment No. 1, was published for notice and comment in the **Federal Register** on February 5, 2002.[4]

The Commission received one comment letter on the proposed rule change.[5] On April 14, 2003, Nasdaq again amended the proposed rule change.[6] This order approves the proposed rule change as modified by Amendment No. 1, and, simultaneously, the Commission provides notice of filing of Amendment No. 2 and grants accelerated approval of Amendment No 2.

II. Discussion and Commission Findings

The Commission has reviewed carefully the proposed rule change and the comment letters, and finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association[7] and, in particular, the requirements of Section 15A of the Act,[8] which requires, among other things, that a registered national securities association's rules be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, and, in general, protect investors and the public interest.

The Commission believes that, in circumstances where the misuse or malfunction of electronic systems that trade Nasdaq-listed securities may impact the price and volume of transactions in such securities, Nasdaq should have the authority to halt trading in an affected security until the problem can be addressed. Such a decision to halt trading requires Nasdaq to make a determination that the action is necessary for the protection of investors and the public interest pursuant to NASD Rule 4120. Nasdaq has stated ''the rule would not be invoked merely because a system malfunction rendered a particular venue for transactions in a security temporarily unavailable, nor would it be applied in other circumstances where the system problems of an individual firm or market center did not give rise to extraordinary market activity.''[9] Instead, Nasdaq states the rule is intended to address circumstances where there is ''a market-wide regulatory concern that system misuse or malfunction is likely to harm investors by leading them to enter into transactions whose terms are materially influenced by the misuse or malfunction.''[10] Nasdaq also states that it will terminate trading halts initiated under the rule ''as soon as Nasdaq can conclude that the system misuse or malfunction will no longer have a material effect on the market for the security that is the subject of the halt or that system misuse or malfunction is not the cause of an instance of extraordinary market activity.''[11] The Commission believes that the proposed rule change is consistent with the Act, and believes that the proposed rule may assist Nasdaq in exercising its responsibility to maintain fair and orderly markets.

The Commission notes that Nasdaq, in Amendment No. 2, indicates that it believes that trading halts instituted by Nasdaq under the proposed rule would constitute ''regulatory'' trading halts under the Reporting Plan for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privilege Basis (''Reporting Plan''). Under the Reporting

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* January 25, 2002 letter from Mary M. Dunbar, Vice President, Nasdaq, to Katherine A. England, Assistant Director, Division of Market Regulation (''Division''), SEC, and attachments (''Amendment No. 1''). Amendment No. 1 completely replaced and superseded the original proposal.

[4] *See* Securities Exchange Act Release No. 45355 (January 29, 2002), 67 FR 5351.

[5] *See* October 2, 2002 letter from Richard T. Chase, Executive Vice President, Member Firm Regulation, The American Stock Exchange LLC (''Amex''), to Jonathan G. Katz, Secretary, SEC (''Amex Letter''). In its comment letter, the Amex expressed its support of Nasdaq's efforts to protect investors and the public interest through the use of trading halts. The Amex further stated that Nasdaq should clarify that Nasdaq's ''authority to determine what is and what is not extraordinary market activity is limited to transactions within its jurisdiction and does not extend to transactions within the jurisdiction of other self-regulatory organizations.'' Amex Letter at 2. The Amex expressed no objection to Nasdaq's proposal if it is applied to situations that involve a Nasdaq system or the system of a broker-dealer or electronic communications network that is a Nasdaq member firm and over which Nasdaq has regulatory authority. *Id.* Nasdaq opposed the proposed rule change to the extent that Nasdaq wants to regulate the systems of UTP exchanges over which Nasdaq has no regulatory authority. *Id.* The Amex further stated that any authority for additional regulation of activity in Nasdaq securities having an inter-market impact should be exercised pursuant to the Reporting Plan for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privilege Basis. *Id.*

The Commission notes that Instinet Corporation (''Instinet'') filed a comment letter in response to SR–NASD–2001–37, the proposed rule change that established the pilot amendment to NASD Rule 4120. *See* July 27, 2001 letter from Jon Kroeper, First Vice President—Regulatory Policy/Strategy, Instinet, to Jonathan G. Katz, Secretary, Commission. Instinet stated that the proposed rule change (1) failed to properly define ''extraordinary market activity;'' (2) lacked objective standards for Nasdaq to make a determination to initiate and terminate trading halts; and (3) should be amended to allow NASD Regulation, Inc. to initiate and terminate trading halts based on extraordinary market activity instead of Nasdaq. Because Instinet's comment letter essentially addresses the same issues in the instant filing, the Commission has considered Instinet's letter in approving the instant proposed rule change.

[6] *See* April 11, 2003 letter from John M. Yetter, Assistant General Counsel, Nasdaq, to Katherine A. England, Assistant Director, Division, SEC, and attachments (''Amendment No. 2''). In Amendment No. 2, Nasdaq proposes changes to clarify the effect of a trading halt under the rule on exchanges trading Nasdaq securities on an unlisted trading privileges basis, as well as the NASD's Alternative Display Facility. Nasdaq filed Amendment No. 2 in response to concerns the Amex raised, and discussed the proposed rule change with members of the UTP Operating Committee on October 23, 2002. *See* Amendment No. 2 at 4. At that time, Nasdaq asked that members of the UTP Operating Committee inform Nasdaq of objections either to the permanent adoption of the proposed rule as amended, or to the conclusion that a trading halt initiated pursuant to the proposed rule would constitute a regulatory halt under the UTP Plan. At the time Nasdaq filed Amendment No. 2, Nasdaq had received no objections.

[7] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78o–3.

[9] Amendment No. 2 at 2–3.

[10] *Id.* at 3.

[11] *Id.*

Plan, regulatory trading halts instituted by Nasdaq would be honored by exchanges trading Nasdaq securities on an unlisted trading privileges basis (''UTP Exchanges'') and the NASD's Alternative Display Facility (''ADF'') participating in the Reporting Plan (collectively, ''Plan Participants''). The Commission understands that Nasdaq and the other Plan Participants are still discussing this issue. The Commission believes that an agreement would need to be reached among the Plan Participants on this subject before trading halts instituted by Nasdaq under the proposed rule would be considered ''regulatory'' trading halts under the Reporting Plan. Thus, approval of the proposed rule change, as amended, does not resolve the issue of whether a trading halt instituted by Nasdaq under the proposed rule constitutes a ''regulatory'' trading halt under the Reporting Plan.

The Commission finds good cause for approving proposed Amendment No. 2 before the 30th day after the date of publication of notice of filing thereof in the **Federal Register.** Nasdaq filed Amendment No. 2 to further clarify the manner in which Nasdaq envisions implementing the proposed rule change. The Commission believes the substance of Amendment No. 2 does not warrant republication of the proposed rule change as amended. Therefore, the Commission finds good cause for accelerating approval of the proposed rule change, as amended by Amendment No. 2.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning Amendment No. 2, including whether Amendment No. 2 is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to Amendment No. 2 that are filed with the Commission, and all written communications relating to Amendment No. 2 between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR–NASD–2001–75 and should be submitted by June 27, 2003.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act[12], that the proposed rule change (SR–NASD–2001–75), as amended by Amendment No. 1, be, and it hereby is, approved, and that Amendment No. 2 to the proposed rule change be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–14295 Filed 6–5–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47958; File No. SR–Phlx–2002–87]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. and Amendment No. 1 Thereto Relating to the Imposition of a 500 Contract Cap on Payment for Order Flow Fees

May 30, 2003.

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 December 26, 2002, the Philadelphia Stock Exchange, Inc. (''Phlx'') filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III, below, which the Phlx has prepared. The Phlx submitted Amendment No. 1 to the proposed rule change on May 29, 2003. 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 Phlx proposes to amend its options payment for order flow program by imposing a 500 contract cap per individual cleared side of a transaction. Specifically, the applicable payment for order flow fee would not apply to any contracts over 500, per individual cleared side of a transaction. For example, if a transaction consists of 750 contracts by one Registered Options Trader (''ROT''), the applicable payment for order flow fee would be applied to, and capped at, 500 contracts for that transaction. Also, if a transaction consists of 600 contracts, but is divided equally among three ROTs, the 500 contract cap would not apply to any such ROT and each ROT would be assessed the applicable payment for order flow fee on 200 contracts, as the payment for order flow fee is assessed on a per ROT, per transaction basis.[3] The Phlx is proposing to implement the 500 contract cap for trades settling on or after June 2, 2003.[4]

The text of the proposed rule change is available at the Phlx 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, the Phlx included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it had received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Phlx has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The Phlx recently filed a rule change with the Commission to reinstate its payment for order flow program.[5] Under

---

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Currently, specialists may request reimbursement for payment for order flow funds in connection with any transactions to which they were not a party, based on the percentage of ROT monthly volume to total specialist and ROT monthly volume. The 500 contract cap would be imposed in connection with calculating the amount of the payment for order flow fee, and not for determining the percentage of ROT monthly volume to total specialist and ROT monthly volume.

[4] The proposed rule change specifies that the Phlx's fee schedule, entitled ''Exchange's ROT Equity Option Payment for Order Flow Charges,'' are subject to a 500 contract cap, by individual cleared side of a transaction. The Phlx's original rule change proposal included a fee schedule that was current as of December 2002 but has been superseded by more recent schedules. The Phlx submitted Amendment No. 1 to the proposed rule change to indicate the current fee schedule and to propose that the cap be implemented for trades settling on or after June 2, 2003. *See* letter from Cindy Hoekstra, Counsel, Philadelphia Stock Exchange, to Patrick Joyce, Senior Counsel, Commission, dated May 29, 2003.

[5] *See* Securities Exchange Act Release No. 47090 (December 23, 2002), 68 FR 141 (January 2, 2003) (SR–Phlx–2002–75). The rule change proposal, which originally included the 500-contract cap that is the subject of the current proposal, became effective immediately upon filing with the Commission in November 2002. In December 2002, the Phlx amended the filing to remove the 500-

the program, Phlx ROTs are assessed a payment for order flow fee, per contract, per options issue, as set forth in the Phlx's ROT Equity Option Payment for Order Flow Charges Schedule, subject to certain exceptions.[6]

1. Purpose

The purpose of the proposed rule change is to establish a 500 contract cap, which the Phlx believes is reasonable and equitable because capping each trade with a 500 contract cap should provide sufficient payment for order flow funds for the specialists while lessening the economic burden on ROTs.[7] In the Phlx's view, the imposition of a cap should provide increased liquidity and encourage competition in markets where ROTs may otherwise not be able to compete. Moreover, the Phlx believes that the absence of a cap would cause ROTs to incur expenses that may impair their ability to participate in a larger share of the market.

2. Statutory Basis

The Phlx believes that its proposal to amend its schedule of dues, fees and charges is consistent with section 6(b) of the Act[8] and furthers the objectives of sections 6(b)(4) and 6(b)(5) of the Act.[9] The Phlx believes that the proposed rule change would serve as an equitable allocation of reasonable fees among Phlx members because the 500 contract cap per individual cleared side of a transaction imposed in connection with the payment for order flow fee should lessen the economic burden on ROTs. Moreover, the Phlx believes that the 500 contract cap should attract more order flow to the Phlx, which should result in increased liquidity, tighter markets, and more competition among exchange members, thereby promoting just and equitable principles of trade, removing impediments to and perfect the mechanism of a free and open market, and protecting investors and the public interest consistent with section 6(b)(5) of the Act.[10]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Phlx 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 Phlx did not solicit or receive written comments concerning the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Phlx. All submissions should refer to File No. SR–Phlx–2002–87 and should be submitted by June 27, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–14255 Filed 6–5–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47953; File No. SR–Phlx–2003–16]

Self-Regulatory Organizations; Order Approving Proposed Rule Change and Notice of Filing and Order Accelerating Approval of Amendment No. 3 Thereto, by the Philadelphia Stock Exchange, Inc., Relating to a Pilot Program for Options Intermarket Linkage Fees

May 30, 2003.

On March 18, 2003, the Philadelphia Stock Exchange, Inc. (''Phlx'' 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 its fee structure to clarify which fees apply to trades pertaining to the options intermarket linkage (''Linkage'') and to specify that such fees are for a one-year pilot.[3] On March 21, 2003, Phlx submitted Amendment No. 1 to the proposed rule change.[4] The proposed rule change, as amended by Amendment No. 1, was originally published for comment in the **Federal Register** on April 2, 2003.[5] On April 23, 2003, Phlx filed Amendment No. 2 to the proposed rule change.[6] On April 23, 2003, Phlx filed a supplementary letter to Amendment No. 2.[7] Amendment No. 2 was published for comment in the

contract cap. Accordingly, the 500 contract cap was in effect for only those trades executed on or after November 18 that settled through December 31, 2002.

[6] The payment for order flow fee does not apply to transactions between: (1) A ROT and a specialist; (2) a ROT and a ROT; (3) a ROT and a firm; and (4) a ROT and a broker-dealer. Also, the payment for order flow fee does not apply to index or foreign currency options.

[7] According to the Phlx, the imposition of a monetary cap has been implemented by other exchanges in connection with payment for order flow programs. *See, e.g.*, Securities Exchange Act Release Nos. 45240 (January 7, 2002), 67 FR 1531 (January 11, 2002) (SR–PCX–2001–53) (implementing a ceiling on marketing charges of $200 per trade); 46976 (December 9, 2002), 67 FR 77116 (December 16, 2002) (SR–ISE–2002–26) (lowering the cap on each payment for order flow fund from $650,000 to $550,000).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4) and 78f(b)(5).

[10] 15 U.S.C. 78f(b)(5).

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Richard S. Rudolph, Director and Counsel, Phlx to Nancy Sanow, Assistant Director, Division of Market Regulation (''Division''), Commission, dated March 17, 2003 (''Original Filing'').

[4] *See* letter from Richard S. Rudolph, Director and Counsel, Phlx to Jennifer Lewis, Attorney, Division, Commission, dated March 20, 2003 (''Amendment No. 1'').

[5] *See* Securities Exchange Act Release No. 47561 (March 21, 2003), 68 FR 15250.

[6] *See* letter from Richard S. Rudolph, Director and Counsel, Phlx to Jennifer Lewis, Attorney, Division, Commission, dated April 22, 2003 (''Amendment No. 2'').

[7] *See* letter from Richard S. Rudolph, Director and Counsel, Phlx to Jennifer Lewis, Attorney, Division, Commission, dated April 22, 2003.

Federal Register on May 5, 2003.[8] The Commission received one comment on the proposal.[9]

On May 30, 2003, Phlx submitted Amendment No. 3 to the proposed rule change.[10] Amendment No. 3 replaces Amendments No. 1 and 2 in their entirety.[11] This order approves the proposed rule change, and grants accelerated approval to Amendment No. 3. The Commission also solicits comment from interested persons on Amendment No. 3.

Pursuant to the Original Filing, Phlx proposed to charge Exchange members for orders for the principal account of market makers sent to the Exchange through the Linkage from the floor of another exchange (''P Orders'') $.35 per contract executed. In the Original Filing, Phlx stated that its proposed linkage fees were consistent with other fees charged by the Exchange for non-Linkage orders. In Amendment No. 2, Phlx explained that it had amended its fee schedule on April 11, 2003 to modify the fees applicable to broker/dealers for non-AUTO-X trades.[12] Previously, such fee was $.35 per contract. Now, the fee ranges from $.35 per contract to $.20 per contract, depending on the number of contracts.[13] In Amendment No. 2, Phlx clarified that due to this recent change, the proposed Linkage fee for P Orders would no longer be consistent with other fees charged by the Exchange for non-Linkage orders.

In the ISE Comment Letter, ISE argued that by charging more for Linkage access than for access through regular order-routing systems, the Phlx would be imposing inappropriate barriers to members of other exchanges.[14] ISE also explained that the general consensus and understanding of the parties to the plan implementing the Linkage was that Linkage fees would be no greater than fees charged to professional traders outside of Linkage and that the other four exchanges have proposed, and the Commission has approved, such limited fees for the other options exchanges.[15] ISE further argued, ''Phlx is the only exchange proposing to discourage use of the Linkage through its fee schedule. This will require members on the other exchanges to pay a premium for access to the efficiencies of Linkage,'' and would ''result in ''unfair discrimination'' on broker-dealer access.''

In Amendment No. 3, Phlx proposes to amend its fee schedule to provide that P Orders would be subject to the same fees as non-Linkage non-AUTO–X broker-dealer orders. Therefore, the proposed fee for P Orders ranges from $.35 per contract to $.20 per contract, depending on the number of contracts.[16] Phlx proposes that the fees applicable to P Orders would be implemented as a pilot, expiring on January 31, 2004.

The Commission finds that the proposed rule change, as amended by Amendment No. 3, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange[17] and, in particular, the requirements of Section 6 of the Act.[18] The Commission finds that the proposed rule change, as amended by Amendment No. 3, is consistent with Section 6(b)(4) of the Act,[19] which requires that the rules of an exchange provide equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities. The Commission believes the pilot will give the Exchange and the Commission the opportunity to evaluate whether these fees are appropriate.

The Commission finds good cause, consistent with Section 19(b)(2) of the Act,[20] to approve Amendment No. 3 to the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. The Commission notes that the issues addressed in the comment letter received in response to Amendment No. 2 related to Phlx's proposal to charge higher fees for Linkage orders than for non-Linkage orders. In Amendment No. 3, Phlx revises its proposal to provide for fees for Linkage orders that would be consistent with fees for non-Linkage orders. Accordingly, the Commission believes good cause exists, pursuant to Sections 6(b)(5) and 19(b) of the Act[21] to accelerate approval of Amendment No. 3 to the proposed rule change.

Interested persons are invited to submit written data, views and arguments concerning Amendment No. 3, including whether it is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Phlx. All submissions should refer to File No. SR–Phlx–2003–16 and should be submitted by June 27, 2003.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[22] that the proposed rule change (SR–Phlx–2003–16), as amended, is approved on a pilot basis until January 31, 2004, and Amendment No. 3 is also approved on an accelerated basis until January 31, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[23]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–14256 Filed 6–5–03; 8:45 am]

BILLING CODE 8010–01–P

[8] *See* Securities Exchange Act Release No. 47750 (April 28, 2003), 68 FR 23789.

[9] *See* letter from Michael J. Simon, Senior Vice President and Secretary, International Securities Exchange, to Jonathan G. Katz, Secretary, Commission, dated May 27, 2003 (''ISE Comment Letter'').

[10] *See* letter from Richard S. Rudolph, Director and Counsel, Phlx to Jennifer Lewis, Attorney, Division, Commission, dated May 29, 2003.

[11] Telephone call between Richard S. Rudolph, Director and Counsel, Phlx, and Jennifer Lewis, Special Counsel, Division, Commission, on May 30, 2003.

[12] *See* Securities Exchange Act Release No. 47715 (April 23, 2003), 68 FR 22446 (April 28, 2003).

[13] The fee is $.35 per contract for up to 2,000 contracts, $.25 per contract for between 2,001 and 3,000 contracts; and $.20 per contract above 3,001 contracts (with the first 3,000 contracts charged $.25 per contract).

[14] *See* ISE Comment Letter, *supra* note 9.

[15] *See* Securities Exchange Act Release Nos. 47719 (April 23, 2003), 68 FR 22764 (April 29, 2003) (File No. SR–ISE–2003–11); 47822 (May 9, 2003), 68 FR 27115 (May 19, 2003) (File No. SR–Amex–2003–14); 47761 (April 29, 2003), 68 FR 24042 (May 6, 2003) (File No. SR–CBOE–2003–11); and 47786 (May 2, 2003), 68 FR 24779 (May 8, 2003) (File No. SR–PCX–2003–08).

[16] *See supra*, note 13.

[17] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[18] 15 U.S.C. 78f.

[19] 15 U.S.C. 78f(b)(4).

[20] 15 U.S.C. 78s(b)(2).

[21] 15 U.S.C. 78f(b)(5) and 15 U.S.C. 78s(b).

[22] 15 U.S.C. 78s(b)(2).

[23] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new and/or currently approved information collection.

DATES: Submit comments on or before August 5, 2003.

ADDRESSES: Send all comments regarding whether this information collection is necessary for the proper performance of the function of the agency, whether the burden estimates are accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collection, to Stephen Kucharski, Financial Assistance Specialist, Office of Financial Assistance, Small Business Administration, 409 3rd Street, SW., Suite 8300, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Stephen Kucharski, Financial Assistance Specialist, 202–205–7551 or Curtis B. Rich, Management Analyst, 202–205–7030.

SUPPLEMENTARY INFORMATION:

Title: ''SBAExpress Data Collection; Eligibility Information Required for SBAExpress Submission, SBAExpress Loan Number Request (Parts A & B), PLP/SBAExpress Servicing Checklist, SBA Express & Community Express Borrower Information Form, SBA Express Authorization and Supplementary Loan Guarantee Agreement.''

Form Nos.: 1918, 1919, 1920, 2091, 2092, 2232.

Description of Respondents: Participating Lending Institutions with an active lending agreement.

Annual Responses: 20,000.

Annual Burden: 20,000.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 03–14298 Filed 6–5–03; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new and/or currently approved information collection.

DATES: Submit comments on or before August 5, 2003.

ADDRESSES: Send all comments regarding whether this information collection is necessary for the proper performance of the function of the agency, whether the burden estimates are accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collection, to Jill Baker, Director of Research, National Women's Business Council, Small Business Administration, 409 3rd Street, SW., 2nd Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Jill Baker, Director of Research, 202–205–6826 or Curtis B. Rich, Management Analyst, 202–205–7030.

SUPPLEMENTARY INFORMATION:

Title: ''Alternate Sources of Capital for Women Business Owners.''

Form No.: N/A.

Description of Respondents: Women who have completed loan applications with Count Me In, an on-line micro-lender.

Annual Responses: 500.

Annual Burden: 79.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 03–14299 Filed 6–5–03; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice No. 4350]

Secretary of State's Advisory Committee on Private International Law: Study Group on International Jurisdiction and Judgments; Notice of Meeting

There will be a public meeting of the Study Group on International Jurisdiction and Judgments of the Secretary of State's Advisory Committee on Private International Law, on Monday June 16, from 9 a.m. to 12:30 p.m. at 1300 I Street, NW., Suite 400 West, Washington DC. Registration will be from 9 to 9:30 a.m., with the business meeting beginning promptly at 9:30 a.m.

The Hague Conference on Private International Law has prepared a new draft of a convention on jurisdiction and the enforcement of judgments that would apply only to cases in which business and commercial parties have chosen a forum in their contract. The draft convention would provide for the enforceability of such choice of court agreements and the enforceability of judgments resulting from courts designated in such agreements.

The Department of State has been asked to inform the Hague Conference by early July whether the United States would support convening international negotiations on the basis of the new draft business-business choice of court convention. It would mean putting aside the more wide-ranging draft convention on jurisdiction and the enforcement of judgments that has been the subject of negotiations at the Hague Conference for more than a decade.

The purpose of the meeting is to hear the views of the private sector on the draft choice of court convention and the possibility of initiating a new round of negotiations on the basis of this text. A copy of the new draft and other documents relevant to the project may be found on the Web site of the Hague Conference (*www.hcch.net*), or may be requested from Cherise Reid, Office of the Legal Adviser, telephone 202–776–8420, e-mail *reidcherised@ms.state.gov.*

The Advisory Committee meeting is open to the public up to the capacity of the meeting room. Interested persons are invited to attend and to express their views. Persons who wish to have their views considered may also submit written comments. Written comments should be submitted by e-mail to Jeffrey Kovar at *kovarj@ms.state.gov.* All comments received will be made available to the public by request to Mr. Kovar via e-mail or by telephone (202–776–8342).

Persons interested in attending the meeting should inform Aaliya K. Bokhari. Interested persons should provide name, affiliation, postal and e-mail addresses, and telephone/telefax numbers to Ms. Bokhari by phone (202–515–2431), fax (202–289–7983) or e-mail (*aaliya.k.bokhari@verizon.com*), no later than 3 p.m. on Friday June 13. Persons desiring to participate by teleconference should so inform Ms. Bokhari, who will provide call-in information.

Jeffrey D. Kovar,

Assistant Legal Adviser for Private International Law, U.S. Department of State.

[FR Doc. 03–14308 Filed 6–5–03; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket OST–02–11658]

Application of Línea Aérea Puertorriqueña, Inc. for Certificate Authority

AGENCY: Department of Transportation.

ACTION: Notice of Order to Show Cause (Order 2003–5–37) Docket OST–02–11658.

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should

not issue an order finding Línea Aérea Puertorriqueña, Inc., fit, willing, and able, and awarding it a certificate of public convenience and necessity to engage in interstate charter air transportation of persons, property and mail.

DATES: Persons wishing to file objections should do so no later than June 13, 2003.

ADDRESSES: Objections and answers to objections should be filed in Docket OST–02–11658 and addressed to the Department of Transportation Dockets (M–30, Room PL–401), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, and should be served upon the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Mrs. Janet Davis, Air Carrier Fitness Division (X–56, Room 6401), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–2341.

Dated: May 30, 2003.

Read C. Van de Water,

Assistant Secretary for Aviation and International Affairs.

[FR Doc. 03–14165 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Requirements (ICRs) abstracted below have been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICRs describes the nature of the information collections and their expected burdens. The **Federal Register** notice with a 60-day comment period soliciting comments on the following collections of information was published on April 1, 2003 (68 FR 15790).

DATES: Comments must be submitted on or before July 7, 2003.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Office of Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1120 Vermont Ave., NW., Mail Stop 17, Washington, DC 20590 (telephone: (202) 493–6292), or Debra Steward, Office of Information Technology and Productivity Improvement, RAD–20, Federal Railroad Administration, 1120 Vermont Ave., NW., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493–6139). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, section 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), 1320.12. On April 1, 2003, FRA published a 60-day notice in the **Federal Register** soliciting comment on ICRs that the agency was seeking OMB approval. 68 FR 15790. FRA received no comments after issuing this notice. Accordingly, DOT announces that these information collection activities have been re-evaluated and certified under 5 CFR 1320.5(a) and forwarded to OMB for review and approval pursuant to 5 CFR 1320.12(c).

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30 day notice is published. 44 U.S.C. 3507 (b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes that the 30 day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect. 5 CFR 1320.12(c); *see also* 60 FR 44983, Aug. 29, 1995.

The summaries below describe the nature of the information collection requirements (ICRs) and the expected burden. The revised requirements are being submitted for clearance by OMB as required by the PRA.

Title: Railroad Signal System Requirements.

OMB Control Number: 2130–0006.

Type of Request: Extension of a currently approved collection.

Affected Public: Railroads.

Form(s): FRA F 6180.14; FRA F 6180.47.

Abstract: The regulations pertaining to railroad signal systems are contained in 49 CFR parts 233 (Signal System Reporting Requirements), 235 (Instructions Governing Applications For Approval of a Discontinuance or Material Modification of a Signal System), and 236 (Rules,Standards, and Instructions Governing the Installation, Inspection, Maintenance, and Repair of Systems, Devices, and Appliances). Section 233.5 provides that each railroad must report to FRA within 24 hours after learning of an accident or incident arising from the failure of a signal appliance, device, method, or system to function or indicate as required by part 236 of this title that results in a more favorable aspect than intended or other condition hazardous to the movement of a train. Section 233.7 sets forth the specific requirements for reporting signal failures within 15 days in accordance with the instructions printed on Form FRA F 6180.14. Finally, section 233.9 sets forth the specific requirements for the ''Signal System Five Year Report.'' It requires that every five years each railroad must file a signal system status report. The report is to be prepared on a form issued by FRA in accordance with the instructions and definitions provided. Title 49, part 235 of the Code of Federal Regulations, sets forth the specific conditions under which FRA approval of modification or discontinuance of railroad signal systems is required and prescribes the methods available to seek such approval. The application process prescribed under part 235 provides a vehicle enabling FRA to obtain the necessary information to make logical and informed decisions concerning carrier requests to modify or discontinue signaling systems. Section 235.5 requires railroads to apply for FRA approval to discontinue or materially modify railroad signaling systems. Section 235.7 defines ''material modifications'' and identifies those changes that do not require agency approval. Section 235.8 provides that any railroad may petition FRA to seek relief from the requirements under 49 CFR part 236. Sections 235.10, 235.12, and 235.13 describe where the petition must be submitted, what information must be included, the organizational format, and the official authorized to sign the application. Section 235.20 sets forth the process for protesting the granting of a carrier application for signal changes or relief from the rules, standards, and instructions. This section provides the information that must be included in the protest, the address for

filing the protest, the item limit for filing the protest, and the requirement that a person requesting a public hearing explain the need for such a forum. Section 236.110 requires that the test results of certain signaling apparatus be recorded and specifically identify the tests required under sections 236.102–109; sections 236.377 to 236.387; sections 236.576, 236.577; and sections 236.586–236.589. Section 236.110 further provides that the test results must be recorded on preprinted or computerized forms provided by the carrier and that the forms show the name of the railroad; place and date of the test conducted; equipment tested; tests results; repairs; and the condition of the apparatus. This section also requires that the employee conducting the test must sign the form and that the record be retained at the office of the supervisory official having the proper authority. Results of tests made in compliance with section 236.587 must be retained for 92 days, and results of all other tests must be retained until the next record is filed, but in no case less than one year. Additionally, section 236.587 requires each railroad to make a departure test of cab signal, train stop, or train control devices on locomotives before that locomotive enters the equipped territory. This section further requires that whoever performs the test must certify in writing that the test was properly performed. The certification and test results must be posted in the locomotive cab with a copy of the certification and test results retained at the office of the supervisory official having the proper authority. However, if it is impractical to leave a copy of the certification and test results at the location of the test, the test results must be transmitted to either the dispatcher or one other designated official, who must keep a written record of the test results and the name of the person performing the test. All records prepared under this section are required to be retained for 92 days. Finally, section 236.590 requires the carrier to clean and inspect the pneumatic apparatus of automatic train stop, train control, or cab signal devices on locomotives every 736 days, and to stencil, tag, or otherwise mark the pneumatic apparatus indicating the last cleaning date.

Annual Estimated Burden Hours: 480,301 hours.

Title: Filing of Dedicated Cars.

OMB Control Number: 2130–0502.

Type of Request: Extension of a currently approved collection.

Affected Public: Railroads.

Form(s): None.

Abstract: Title 49, part 215 of the Code of Federal Regulations, prescribes certain conditions to be followed for the movement of freight cars that are not in compliance with this part. These cars must be identified in a written report to FRA before they are assigned to dedicated service, and the words ''Dedicated Service'' must be stenciled on each side of the freight car body. FRA uses the information to determine whether the equipment is safe to operate and that the operation qualifies for dedicated service. *See* 49 CFR 215.5(c)(2), 215.5(d).

Annual Estimated Burden Hours: 4 hours.

Title: Remotely Controlled Switch Operations.

OMB Control Number: 2130–0516.

Type of Request: Extension of a currently approved collection.

Affected Public: Railroads.

Form(s): None.

Abstract: Title 49, section 218.30 of the Code of Federal Regulations (CFR), ensures that remotely controlled switches are lined to protect workers who are vulnerable to being struck by moving cars as they inspect or service equipment on a particular track or, alternatively, occupy camp cars. FRA believes that production of notification requests promotes safety by minimizing mental lapses of workers who are simultaneously handling several tasks. Sections 218.30 and 218.67 require the operator of remotely controlled switches to maintain a record of each notification requesting blue signal protection for 15 days. Operators of remotely controlled switches use the information as a record documenting blue signal protection of workers or camp cars. This record also serves as a valuable resource for railroad supervisors and FRA inspectors monitoring regulatory compliance.

Annual Estimated Burden Hours: 120,267 hours.

Title: Bad Order and Home Shop Card.

OMB Control Number: 2130–0519.

Type of Request: Extension of a currently approved collection.

Affected Public: Railroads.

Form(s): None.

Abstract: Under 49 CFR part 215, each railroad is required to inspect freight cars placed in service and take the necessary remedial action when defects are identified. Part 215 defects are specific in nature and relate to items that have or could have caused accidents or incidents. Section 215.9 sets forth specific procedures that railroads must follow when it is necessary to move defective cars for repair purposes. For example, railroads must affix a ''bad order'' tag describing each defect to each side of the freight car. It is imperative that a defective freight car be tagged ''bad order'' so that it may be readily identified and moved to another location for repair purposes only. At the repair point, the ''bad order'' tag serves as a repair record. Railroads must retain each tag for 90 days to verify that proper repairs were made at the designated location. FRA and State inspectors review all pertinent records to determine whether defective cars presenting an immediate hazard are being moved in transportation.

Annual Estimated Burden Hours: 6,750 hours.

Title: Stenciling Reporting Mark on Freight Cars.

OMB Control Number: 2130–0520.

Type of Request: Extension of a currently approved collection.

Affected Public: Railroads.

Form(s): None.

Abstract: Title 49, section 215.301 of the Code of Federal Regulations, sets forth certain requirements that must be followed by railroad carriers and private car owners relative to identification marks on railroad equipment. FRA, railroads, and the public refer to the stenciling to identify freight cars.

Annual Estimated Burden Hours: 15,000 hours.

Title: Locomotive Certification (Noise Compliance Regulations).

OMB Control Number: 2130–0527.

Type of Request: Extension of a currently approved collection.

Affected Public: Railroads.

Form(s): None.

Abstract: Part 210 of title 49 of the United States Code of Federal Regulations (CFR) pertains to FRA's noise enforcement procedures which encompass rail yard noise source standards published by the Environmental Protection Agency (EPA). EPA has the authority to set these standards under the Noise Control Act of 1972. The information collected by FRA under part 210 is necessary to ensure compliance with EPA noise standards for new locomotives.

Annual Estimated Burden Hours: 3,520 hours.

Title: Disqualification Proceedings.

OMB Control Number: 2130–0529.

Type of Request: Extension of a currently approved collection.

Affected Public: Railroads.

Form(s): None.

Abstract: Under 49 U.S.C. 20111(c), FRA is authorized to issue orders disqualifying railroad employees, including supervisors, managers, and other agents, from performing safety-sensitive service in the rail industry for violations of safety rules, regulations, standards, orders, or laws evidencing

unfitness. FRA's regulations, 49 CFR part 209, subpart D, implement the statutory provision by requiring (i) a railroad employing or formerly employing a disqualified individual to disclose the terms and conditions of a disqualification order to the individual's new or prospective employing railroad; (ii) a railroad considering employing an individual in a safety-sensitive position to ask the individual's previous employing railroad whether the individual is currently serving under a disqualification order; and (iii) a disqualified individual to inform his new or prospective employer of the disqualification order and provide a copy of the same. Additionally, the regulations prohibit a railroad from employing a person serving under a disqualification order to work in a safety-sensitive position. This information serves to inform a railroad whether an employee or prospective employee is currently disqualified from performing safety-sensitive service based on the issuance of a disqualification order by FRA. Furthermore, it prevents an individual currently serving under a disqualification order from retaining and obtaining employment in a safety-sensitive position in the rail industry.

Annual Estimated Burden Hours: 5 hours.

Title: Grade Crossing Signal System Safety.

OMB Control Number: 2130–0534.

Type of Request: Extension of a currently approved collection.

Affected Public: Railroads.

Form(s): None.

Abstract: FRA believes that highway-rail grade crossing (grade crossing) accidents resulting from warning system failures can be reduced. Motorists lose faith in warning systems that constantly warn of an oncoming train when none is present. Therefore, the fail-safe feature of a warning system loses its effectiveness if the system is not repaired within a reasonable period of time. A greater risk of an accident is present when a warning system fails to activate as a train approaches a grade crossing. FRA's regulations require railroads to take specific responses in the event of an activation failure. FRA uses the information to develop better solutions to the problems of grade crossing device malfunctions. With this information, FRA is able to correlate accident data and equipment malfunctions with the types of circuits and age of equipment. FRA can then identify the causes of grade crossing system failures and investigate them to determine whether periodic maintenance, inspection, and testing standards are effective. FRA also uses the information collected to alert railroad employees and appropriate highway traffic authorities of warning system malfunctions so that they can take the necessary measures to protect motorists and railroad workers at the grade crossing until repairs have been made.

Annual Estimated Burden Hours: 4,151 hours.

Addressee: Send comments regarding these information collections to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 Seventeenth Street, NW., Washington, DC 20503, Attention: FRA Desk Officer.

Comments are invited on the following: Whether the proposed collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collections; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collections of information on respondents, including the use of automated collection techniques or other forms of information technology.

A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

Authority: 44 U.S.C. 3501–3520.

Issued in Washington, DC on June 3, 2003.

Kathy A. Weiner,

Director, Office of Information Technology and Support Systems, Federal Railroad Administration.

[FR Doc. 03–14319 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Community Development Financial Institutions Fund (the ''Fund'') within the Department of the Treasury is soliciting comments concerning the Fund's reporting requirement for an annual report from awardees of the Fund's Community Development Financial Institutions (CDFI) Program.

DATES: Written comments should be received on or before August 5, 2003, to be assured of consideration.

ADDRESSES: Direct all comments to Owen Jones, Deputy Director for Management/CFO, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005, facsimile number (202) 622–7754.

FOR FURTHER INFORMATION CONTACT: A draft of the information collection for the annual report may be obtained from the Fund's Web site at *http://www.cdfifund.go.* Requests for additional information should be directed to Owen Jones, Deputy Director for Management/CFO, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005, or call (202) 622–8662.

SUPPLEMENTARY INFORMATION:

Title: The Community Development Financial Institutions Fund—Annual Report.

OMB Number: 1559–0006.

Abstract: The purpose of the Fund's CDFI Program is to promote economic revitalization and community development through investment in and assistance to certified CDFIs. Through the CDFI Program, the Fund provides financial and technical assistance in the form of grants, loans, equity investments, and deposits to competitively selected CDFIs and entities proposing to become CDFIs. The Fund provides such assistance to CDFIs to enhance their capacity to address the community development and capital access needs of their particular target markets, including Native American, Alaska Native, and Native Hawaiian communities.

All CDFI Program awardees are required to submit an annual report to the Fund. The annual report consists of narrative and quantitative information both at the institution and transaction levels. The annual report is used to assess the awardee's: (1) Activities in support of its Comprehensive Business Plan; (2) use of the Fund's financial and technical assistance; (3) financial condition; and (4) overall compliance with the terms and conditions of the

Assistance Agreement executed by the Fund and the awardee.

Current Action: N/A.

Type of review: Renewal.

Affected Public: Not-for-profit institutions, businesses or other for-profit institutions and tribal entities.

Estimated Number of Respondents: 600.

Estimated Annual Time Per Respondent: 8 hours.

Estimated Total Annual Burden Hours: 4,800 hours.

Requests for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Fund, including whether the information shall have practical utility; (b) the accuracy of the Fund's estimate of the burden of the collection of information; (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 respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Authority: 12 U.S.C. 4703, 4703 note, 4707, 4710, 4714, 4717; 31 U.S.C. 321; and 12 CFR part 1805.

Dated: June 2, 2003.

Tony T. Brown,

Director, Community Development Financial Institutions Fund.

[FR Doc. 03–14296 Filed 6–5–03; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0209]

Agency Information Collection Activities Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C., 3501 *et seq.*), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before July 7, 2003.

FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT: Denise McLamb, Records Management Service (005E3), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030, FAX (202) 273–5981 or e-mail: *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–0209.''

Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503, (202) 395–7316. Please refer to ''OMB Control No. 2900–0209'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Titles:

a. Application for Work-Study Allowance (38 Up.So.CA. Chapters 30, 31, 32 and 35; 10 Up.So.CA Chapter 1606), VA Form 22–8961.

b. Student Work-Study Agreement (Student Services), VA Form 22–8692.

c. Extended Student Work-Study Agreement, VA Form 22–8692a.

d. Work-Study Agreement (Student Services), VA Form 22–8692b.

OMB Control Number: 2900–0209.

Type of Review: Revision of a currently approved collection.

Abstract:

a. Eligible veterans, Selected Reservists, and survivors or dependents complete VA Form 22–8691 to apply for work-study benefits.

b. VA Form 22–8692 is used by claimants to request an advance payment of work-study allowance.

c. VA Form 22–8692a is used by the claimant to extend his or her contract.

d. VA Form 22–8692b is used by claimants who do not want a work-study advanced allowance payment.

The information collected is use to determine the applicant's eligibility to work-study allowance and the amount payable.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on March 19, 2003, at pages 13365–13366.

Affected Public: Individuals or households.

Estimated Annual Burden: 9,566.

a. Application for Work-Study Allowance (38 Up.So.CA. Chapters 30, 31, 32 and 35; 10 Up.So.CA Chapter 1606), VA Form 22–8691—6,625 hours.

b. Student Work-Study Agreement (Student Services), VA Form 22–8692—1,333 hours.

c. Extended Student Work-Study Agreement, VA Form 22–8692a—275 hours.

d. Work-Study Agreement (Student Services), VA Form 22–8692b—1,333 hours

Estimated Average Burden Per Respondent:

a. Application for Work-Study Allowance (38 Up.So.CA. Chapters 30, 31, 32 and 35; 10 Up.So.CA Chapter 1606), VA Form 22–8691—15 minutes.

b. Student Work-Study Agreement (Student Services), VA Form 22–8692—5 minutes.

c. Extended Student Work-Study Agreement, VA Form 22–8692a—3 minutes.

d. Work-Study Agreement (Student Services), VA Form 22–8692b—5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 64,000.

a. Application for Work-Study Allowance (38 Up.So.CA. Chapters 30, 31, 32 and 35; 10 Up.So.CA Chapter 1606), VA Form 22–8961—26,500.

b. Student Work-Study Agreement (Student Services), VA Form 22–8692—16,000.

c. Extended Student Work-Study Agreement, VA Form 22–8692a—5,500.

d. Work-Study Agreement (Student Services), VA Form 22–8692b—16,000.

Dated: May 27, 2003.

By direction of the Secretary.

Martin L. Hill,

Acting Director, Records Management Service.

[FR Doc. 03–14284 Filed 6–5–03; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; Computer Matching Program

AGENCY: Department of Veterans Affairs.

ACTION: Notice of Computer Match Program.

SUMMARY: Pursuant to 5 U.S.C. section 552a, the Privacy Act of 1974, as amended, and the Office of Management and Budget (OMB) Guidelines on the Conduct of Matching Programs, notice is hereby given that the Department of Veterans Affairs (VA) intends to conduct a computer matching program

with the Internal Review Service (IRS). Data from the proposed match will be utilized to verify the unearned income (*i.e.* interest, dividends, etc.) of nonservice-connected veterans, and zero percent noncompensable service-connected veterans, whose eligibility for VA medical care is based on their inability to defray the cost of medical care. These veterans supply household income information that includes their spouses and dependents at the time of application for VA health care benefits.

EFFECTIVE DATE: This match will start no sooner than 30 days after publication in the **Federal Register**, unless comments dictate otherwise.

ADDRESSES: Mail or hand-deliver written comments to: Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Room 1154, Washington, DC 20420. All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1158, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Kathleen E. Watkins, Assistant Director, Income Verification Division, Health Eligibility Center, (404) 235–1340.

SUPPLEMENTARY INFORMATION:

A. General

The Computer Matching and Privacy Protection Act of 1988 Public Law (Pub. L. 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the manner in which computer matching involving Federal agencies could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, further amended the Privacy Act regarding protections for such individuals.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the approval of the matching agreement by the Data Integrity Boards (DIB) of the participating Federal agencies;

(3) Furnish detailed reports about matching programs to Congress and OMB;

(4) Notify applicants and beneficiaries that their records are subject to matching; and

(5) Verify matching findings before reducing, suspending, terminating or denying an individual's benefits or payments.

B. VHA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of VHA's computer matching programs comply with the requirements of the Privacy Act, as amended.

Approved: May 29, 2003.

Anthony J. Principi,

Secretary of Veterans Affairs.

[FR Doc. 03–14283 Filed 6–5–03; 8:45 am]

BILLING CODE 8320–01–M

Federal Register

Friday,
June 6, 2003

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926
Assigned Protection Factors; Proposed Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. H049C]

RIN 1218–AA05

Assigned Protection Factors

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

ACTION: Proposed rule; request for comments and scheduling of informal public hearings.

SUMMARY: OSHA is proposing to revise its existing Respiratory Protection Standard to add definitions and specific requirements for assigned protection factors (APFs) and maximum use concentrations (MUCs). The proposed revisions also would supersede the respirator selection provisions of existing substance-specific standards with these new APFs (except the APFs for the 1,3-Butadiene Standard).

The Agency developed the proposed APFs after thoroughly reviewing the available literature, including chamber simulation studies and workplace protection factor studies. The proposed APFs would provide employers with critical information to use when selecting respirators for employees exposed to atmospheric contaminants found in general industry, construction, shipyard, longshoring, and marine terminal workplaces. Proper respirator selection using APFs is an important component of an effective respirator protection program. Accordingly, OSHA has made a preliminary conclusion that the proposed APFs are necessary to protect employees who use respirators against atmospheric contaminants.

DATES: *Written comments.* The Agency invites interested parties to submit written comments regarding the proposed rule, including comments to the information-collection determination under the Supplementary Information section of this **Federal Register** notice, by mail, facsimile, or electronically. You must send all comments, whether submitted by mail, facsimile, or electronically through OSHA's Web site, by September 4, 2003.

Informal public hearings. The Agency plans to hold an informal public hearing in Washington, DC in late summer or early fall of 2003. OSHA expects the DC hearing to last from 9:30 a.m. to 5:30 p.m. on the first day, and from 8:30 a.m. to 5:30 p.m. on subsequent days; however, the exact daily schedule is at the discretion of the presiding administrative law judge. If an additional hearing is held, the Agency will announce the date, time, and location of this hearing later in the subsequent **Federal Register** notice.

Notice of intention to appear to provide testimony at the informal public hearing. Interested parties who intend to present testimony at the informal public hearing in Washington, DC, must notify OSHA of their intention to do so no later than September 4, 2003.

Hearing testimony and documentary evidence. Interested parties who will be requesting more than 10 minutes to present their testimony, or who will be submitting documentary evidence at the hearing, must provide the Agency with copies of their full testimony and all documentary evidence they plan to present by September 4, 2003.

ADDRESSES: *Written comments.* You may submit three copies of written comments to the Docket Office, Docket No. H049C, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210; telephone (202) 693–2350. If your written comments are 10 pages or fewer, you may fax them to the OSHA Docket Office, telephone number (202) 693–1648. You do not have to send OSHA a hard copy of your faxed comments. You may submit comments electronically through OSHA's Home page at *http://ecomments.osha.gov/.* If you would like to submit additional studies or journal articles, you must submit three copies of them to the OSHA Docket Office at the address above. These materials must clearly identify your electronic comments by name, date, subject, and docket number so we can attach them to your comments.

Informal public hearings. The informal public hearing to be held in Washington, DC will be located in the Auditorium on the plaza level of the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC.

Notice of intention to appear to provide testimony at the informal public hearing. Notices of intention to appear at the informal public hearing should be submitted in triplicate to the Docket Office, Docket No. H049C, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Notices may also be faxed to the Docket Office at (202) 693–1648 or submitted electronically at *http://ecomments.osha.gov.* OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m.

Hearing testimony and documentary evidence. Interested parties who will be requesting more than 10 minutes to present their testimony, or who will be submitting documentary evidence at the informal public hearing must mail three copies of the testimony and the documentary evidence to the Docket Office, Docket No. H049C, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington DC 20210. Additional information for submitting testimony and evidence is found under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: For technical inquiries, contact Mr. John E. Steelnack, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210; telephone (202) 693–2289 or fax (202) 693–1678. For hearing information contact Ms. Veneta Chatmon, OSHA Office of Information, Docket No. H–49C, Room N–3649, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210 (telephone (202) 693–1999). For additional copies of this **Federal Register** notice, contact the Office of Publications, Room N–3103, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210 (telephone (202) 693–1888). Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are available at OSHA's Home page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

OMB Review Under the Paperwork Reduction Act

After a thorough analysis of the proposed provisions, OSHA believes that these provisions would not add to the existing collection-of-information (*i.e.*, paperwork) requirements regarding respirator selection. OSHA determined that its existing Respiratory Protection Standard at 29 CFR 1910.134 has two provisions that involve APFs and also impose paperwork requirements on employers. These provisions require employers to: Include respirator selection in their written respiratory protection program (29 CFR 1910.134(c)(1)(i)); and inform employees regarding proper respirator selection (29 CFR 1910.(k)(ii)). The information on respirator selection addressed by these two provisions must include a brief discussion of the purpose of APFs, and how to use them in selecting a respirator that affords an employee protection from airborne contaminants. The burden imposed by this requirement remains the same

whether employers currently use the APFs published in the 1987 NIOSH RDL or the ANSI Z88.2–1992 Respiratory Protection Standard, or implement the APFs proposed in this rulemaking. Therefore, the proposed use of APFs in the context of these two existing respirator-selection provisions does not require an additional paperwork-burden determination because OSHA already accounted for this burden under its existing Respiratory Protection Standard (*see* 63 FR 1152–1154; OMB Control Number 1218–0099).

Both OSHA's existing Respiratory Protection Standard and the proposed APF provisions require employers to use APFs as part of the respirator-selection process. This process includes obtaining information about the workplace exposure level to an airborne contaminant, identifying the exposure limit (*e.g.*, permissible exposure limit) for the contaminant, using this information to calculate the required level of protection (*i.e.*, the APF), and referring to an APF table to determine which respirator to select. Admittedly, this process involves the collection and use of information, but it does not require employers to inform others, either orally or in writing, about the process they use to select respirators for individual employees, or the outcomes of this process; by not requiring employers to communicate this information to others, OSHA removed this process from the ambit of the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)). In the alternative, even if PRA–95 applies, the proposal involves the same information-collection and -use requirements with regard to APFs as the existing standard (*see* paragraphs (d)(1) and (d)(3)(i) of 29 CFR 1910.134, and the rationale for the existing APF requirements in the preamble to the final Respiratory Protection Standard, 63 FR 1163 and 1203–1204); accordingly, the paperwork burden imposed by the proposal would be equivalent to the burden already imposed under the existing standard.

Interested parties who want to comment on OSHA's determination that the proposed provisions contain no additional paperwork burden compared to the existing paperwork requirements must send their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503. The Agency also encourages commenters to submit their comments on this paperwork determination to OSHA along with their other comments.

Federalism

The Agency reviewed the proposed APF provisions according to the most recent Executive Order on Federalism (Executive Order 13132, 64 FR 43225, August 10, 1999). This Executive Order requires that federal agencies, to the extent possible, refrain from limiting state policy options, consult with states before taking actions that restrict their policy options, and take such actions only when clear constitutional authority exists and the problem is of national scope. The Executive Order allows federal agencies to preempt state law only with the expressed consent of Congress; in such cases, federal agencies must limit preemption of state law to the extent possible.

Under section 18 of the Occupational Safety and Health Act (the ''Act'' or ''OSH Act''), Congress expressly provides OSHA with authority to preempt state occupational safety and health standards to the extent that the Agency promulgates a federal standard under section 6 of the Act. Accordingly, section 18 of the Act authorizes the Agency to preempt state promulgation and enforcement of requirements dealing with occupational safety and health issues covered by OSHA standards unless the state has an OSHA-approved occupational safety and health plan (*i.e.*, is a state-plan state) [*see Gade* v. *National Solid Wastes Management Association,* 112 S. Ct. 2374 (1992)]. Therefore, with respect to states that do not have OSHA-approved plans, the Agency concludes that this proposal conforms to the preemption provisions of the Act. Additionally, section 18 of the Act prohibits states without approved plans from issuing citations for violations of OSHA standards; the Agency finds that the proposed rulemaking does not expand this limitation.

OSHA asserts that it has authority under Executive Order 13132 to propose APF requirements because the problems addressed by these requirements are national in scope. As noted in section VI (''Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis'') of this preamble, hundreds of thousands of employers must select appropriate respirators for millions of employees. These employees are exposed to many different types and levels of airborne contaminants found in general industry, construction, shipyard, longshoring, and marine terminal workplaces. Accordingly, the proposed requirements would provide employers in every state with critical information to use when selecting respirators to protect their employees from the risks of exposure to airborne contaminants. However, while OSHA drafted the proposed APF and MUC requirements to protect employees in every state, section 18(c)(2) of the Act permits state-plan states to develop their own requirements to deal with any special workplace problems or conditions, provided these requirements are at least as effective as the final requirements that result from this proposal.

State Plans

The 26 states and territories with their own OSHA-approved occupational safety and health plans must adopt comparable provisions within six months after the Agency publishes the final APF and MUC requirements. These states and territories are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Connecticut, New Jersey and New York have OSHA approved State Plans that apply to state and local government employees only. Until a state-plan state promulgates its own comparable provisions, Federal OSHA will provide the state with interim enforcement assistance, as appropriate.

Unfunded Mandates

The Agency reviewed the proposed APF and MUC provisions according to the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*) and Executive Order 12875. As discussed in section VI (''Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis'') of this preamble, OSHA estimates that compliance with this proposal would require private-sector employers to expend about $4.5 million each year. However, while this proposal establishes a federal mandate in the private sector, it is not a significant regulatory action within the meaning of section 202 of the UMRA (2 U.S.C. 1532).

OSHA standards do not apply to state and local governments, except in states that have voluntarily elected to adopt an OSHA-approved state occupational safety and health plan. Consequently, the proposed provisions do not meet the definition of a ''Federal intergovernmental mandate'' [*see* section 421(5) of the UMRA (2 U.S.C. 658(5)]. Therefore, based on a review of the rulemaking record to date, the Agency believes that few, if any, of the affected employers are state, local, and tribal governments. Therefore, the

proposed APF requirements do not impose unfunded mandates on state, local, and tribal governments.

Protecting Children From Environmental Health and Safety Risks

Executive Order 13045 requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866 must provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. Executive Order 13045 defines ''covered regulatory actions'' as rules that may (1) be economically significant under Executive Order 12866 (*i.e.*, a rulemaking that has an annual affect on the economy of $100 million or more, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities), and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. In this context, the term ''environmental health risks and safety risks'' means risks to health or safety that are attributable to products or substances that children are likely to come in contact with or ingest (*e.g.*, through air, food, water, soil, product use).

The proposed provisions are not economically significant under Executive Order 12866 (*see* section VI (''Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis'') of this preamble). In addition, after reviewing the proposed APF provisions, OSHA has determined that these provisions do not impose environmental health or safety risks to children as set forth in Executive Order 13045. The proposed provisions would require employers to use APFs in selecting proper respirators for employee use, with the objective of limiting employee exposures to airborne contaminants. To the best of OSHA's knowledge, no employees under 18 years of age work under conditions that require respirator use. However, if such conditions exist, children who use respirators selected according to these proposed provisions would receive adequate protection from the airborne contaminants. In this regard, the Agency is requesting public comment on whether employees under the age of 18 years use respirators, and, if they do, the extent to which the respirators provide them with adequate protection. Based on this discussion, OSHA believes that the APF and MUC requirements proposed in this rulemaking do not constitute a covered regulatory action as defined by Executive Order 13045.

Applicability of Existing Consensus Standards

Section 6(b)(8) of the OSH Act requires OSHA to explain ''why a rule promulgated by the Secretary differs substantially from an existing national consensus standard,'' by publishing ''a statement of the reasons why the rule as adopted will better effectuate the purposes of the Act than the national consensus standard.'' [*see* 29 U.S.C. 655(b)(8)]. Accordingly, the Agency compared the proposed APF requirements with the APF provisions of ANSI Z88.2–1992 (''Respiratory Protection''). This consensus standard, published by the American National Standards Institute in 1992, is the only publicly available consensus standard that includes APFs. In most instances, the APFs being proposed by the Agency are identical to ANSI's APFs, however, some differences exist. Where OSHA has proposed an APF that differs from ANSI's, the Summary and Explanation provides the basis for that decision.

Environmental Impact Assessment

The Agency reviewed the proposed provisions according to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the regulations of the Council of Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11). OSHA estimates that this proposed rule would have a direct impact on a relatively small number of respirator users and, in so doing , merely alter the type of respirator they are using. The Agency does not anticipate that this will significantly alter solid waste patterns, water quality, or ambient air quality. As a result of this review, OSHA concludes that the proposed provisions would have no significant environmental impact.

I. General

Table of Contents

The following Table of Contents identifies the major preamble sections of this proposal and the order in which they are presented:

Glossary

This glossary specifies the terms represented by acronyms, and provides definitions of other terms, used frequently in this proposal. This glossary does not change the legal requirements as proposed in this notice of proposed rulemaking, nor is it intended to propose new regulatory requirements or definitions. It is presented simply to assist the reader.

A. Acronyms

ACGIH: American Conference of Governmental Industrial Hygienists.
AIHA: American Industrial Hygiene Association.
ANSI: American National Standards Institute.
APF: Assigned Protection Factor (*see* definition in proposed regulatory text).
DOP: Dioctylphthalate (an aerosolized agent used for quantitative fit testing).
DFM: Dust/Fume/Mist filter.
EPF: Effective Protection Factor (*see* definition below under ''Protection factor study'').
HEPA: High efficiency particulate air [filter] (*see* definition below).
IDLH: Immediately dangerous to life or health (*see* definition below).

LANL: Los Alamos National Laboratory.
LLNL: Lawrence Livermore National Laboratory.
MSHA: Mine Safety and Health Administration.
MUC: Maximum Use Concentration (*see* definition in proposed regulatory text).
NIOSH: National Institute for Occupational Safety and Health.
NRC: Nuclear Regulatory Commission.
OSHA: Occupational Health and Safety Administration.
PAPR: Powered air-purifying respirator (*see* definition below).
PEL: Permissible Exposure Limit (an occupational exposure level specified by OSHA).
PPF: Program Protection Factor (*see* definition below under ''Protection factor study'').
QLFT: Qualitative fit test (*see* definition below).
QNFT: Quantitative fit test (*see* definition below).
RDL: Respirator Decision Logic (respirator selection guidance developed by NIOSH that contains a set of respirator protection factors).
REL: Recommended Exposure Limit (an occupational exposure level recommended by NIOSH).
SAR: Supplied-air respirator (*see* definition below).
SCBA: Self-contained breathing apparatus (*see* definition below).
WPF: Workplace Protection Factor (*see* definition below under ''Protection factor study'').
TLV: Threshold Limit Value (an occupational exposure level recommended by ACGIH).
SWPF: Simulated Workplace Protection Factor (*see* definition below under ''Protection factor study'').

B. Definitions

Terms followed by an asterisk (*) refer to definitions that can be found in paragraph (b) (''Definitions'') of OSHA's Respiratory Protection Standard (29 CFR 1910.134).

Air-purifying respirator:* A respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

Atmosphere-supplying respirator:* A respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes SARs and SCBA units.

Canister or cartridge:* A container with a filter, sorbent, or catalyst, or combination of these items, which removes specific contaminants from the air passed through the container.

Continuous flow respirator: An atmosphere-supplying respirator that provides a continuous flow of breathable air to the respirator facepiece.

Demand respirator:* An atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Filter or air-purifying element:* A component used in respirators to remove solid or liquid aerosols from the inspired air.

Filtering facepiece (or dust mask):* A negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium.

Fit factor:* A quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test:* The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

Helmet:* A rigid respiratory inlet covering that also provides head protection against impact and penetration.

High-efficiency particulate air filter:* A filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter. The equivalent NIOSH 42 CFR 84 particulate filters are the N100, R100, and P100 filters.

Hood:* A respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Immediately dangerous to life or health:* An atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual's ability to escape from a dangerous atmosphere.

Loose-fitting facepiece:* A respiratory inlet covering that is designed to form a partial seal with the face.

Negative pressure respirator (tight-fitting):* A respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Positive pressure respirator:* A respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator:* An air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator:* A positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Protection factor study: A study that determines the protection provided by a respirator during use. This determination is generally accomplished by measuring the ratio of the concentration of an agent (*e.g.*, hazardous substance) outside the respirator (Co) to the agent's concentration inside the respirator (Ci) (*i.e.*, Co/Ci). Therefore, as the ratio between Co and Ci increases, the protection factor increases, indicating an increase in the level of protection provided to employees by the respirator. Four types of protection factor studies are:

Effective Protection Factor (EPF) study—a study, conducted in the workplace, that measures the protection provided by a properly selected, fit-tested, and functioning respirator when used intermittently for only some fraction of the total workplace exposure time (*i.e.*, sampling is conducted during periods when respirators are worn and not worn). EPFs are not directly comparable to WPF values because the determinations include both the time spent in contaminated atmospheres with and without respiratory protection; therefore, EPFs tend to understate the protection that would be obtained if the respirator were being worn at all times.

Program Protection Factor (PPF) study—a study that estimates the protection provided by a respirator within a specific respirator program. Like the EPF, it is focused not only on the respirator's performance, but also the effectiveness of the complete respirator program. PPFs are affected by all factors of the program, including respirator selection and maintenance, user training and motivation, work activities, and program administration.

Workplace Protection Factor (WPF) study—a study, conducted under actual conditions of use in the workplace, that measures the protection provided by a properly selected, fit-tested, and functioning respirator, when the respirator is correctly worn and used as part of a comprehensive respirator program. Measurements of Co and Ci are obtained only while the respirator is being worn during performance of normal work tasks (*i.e.*, samples are not collected when the respirator is not being worn). As the degree of protection afforded by the respirator increases, the WPF increases.

Simulated Workplace Protection Factor (SWPF) study—a study, conducted in a controlled laboratory setting and in which Co and Ci

sampling is performed while the subject performs a series of set exercises. The laboratory setting is used to control many of the variables found in workplace studies, while the exercises simulate the work activities of respirator users. This type of study is designed to determine the optimum performance of respirators by reducing the impact of sources of variability through maintenance of tightly controlled study conditions.

Qualitative fit test:* A pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quantitative fit test:* An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Self-contained breathing apparatus:* An atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Supplied-air respirator (or airline) respirator:* An atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Tight-fitting facepiece:* A respiratory inlet covering that forms a complete seal with the face.

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.* (the ''OSHA Act'' or ''Act'') is to ''assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources.'' [29 U.S.C. 651(b)]. To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards [*see* 29 U.S.C. 654(b) (requiring employers to comply with OSHA standards), 29 U.S.C. 655(a) (authorizing summary adoption of existing consensus and federal standards within two years of the Act's enactment), and 29 U.S.C. 655(b) (authorizing promulgation of standards pursuant to notice and comment)].

A safety or health standard is a standard ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment.'' [29 U.S.C. 652(8)]. A standard is reasonably necessary or appropriate within the meaning of section 652(8) of the Act when it substantially reduces or eliminates significant risk, and is technologically and economically feasible, cost effective, consistent with prior Agency action or supported by a reasoned justification for departing from prior Agency action, and supported by substantial evidence; it must also effectuate the Act's purposes better than any national consensus standard it supersedes [*see International Union, UAW* v. *OSHA* (*LOTO II*), 37 F.3d 665 (DC Cir. 1994; and 58 FR 16612–16616 (March 30, 1993)].

OSHA has discussed the nature of adverse health effects caused by exposure to airborne chemical hazards many times in previous rulemaking activities [*see,* for example, the preambles to any of OSHA's substance-specific standards codified in 29 CFR 1910.1001 to 1910.1052]. As discussed in the Significance of Risk section of the Respiratory Protection Standard, the health risk presented to workers can be represented by the risk that a respirator will not be properly selected or used, which increases the possibility that the user will be overexposed to a harmful air contaminant. The risks that are addressed by the Respiratory Protection Standard are not characterized as illness-specific risks but, instead, relate to a more general probability that when a respirator provides insufficient protection, the wearer may be exposed to a level of air contaminant that is associated with material impairment of the worker's health.

The Agency believes that a standard is technologically feasible when the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed [*see American Textile Mfrs. Institute* v. *OSHA* (*Cotton Dust*), 452 U.S. 490, 513 (1981); *American Iron and Steel Institute* v. *OSHA* (*Lead II*), 939 F.2d 975, 980 (DC Cir. 1991)]. A standard is economically feasible when industry can absorb or pass on the costs of compliance without threatening the industry's long-term profitability or competitive structure [*see Cotton Dust,* 452 U.S. at 530 n. 55; *Lead II,* 939 F.2d at 980], and a standard is cost effective when the protective measures it requires are the least costly of the available alternatives that achieve the same level of protection [*see Cotton Dust,* 453 U.S. at 514 n. 32; *International Union, UAW* v. *OSHA* (*LOTO III*), 37 F.3d 665, 668 (DC Cir. 1994)].

All standards must be highly protective [see 58 FR 16612, 16614–15 (March 30, 1993); *LOTO III,* 37 F.3d at 669]. Accordingly, section 8(g)(2) of the Act authorizes OSHA ''to prescribe such rules and regulations as [it] may deem necessary to carry out its responsibilities under the Act'' [*see* 29 U.S.C. 657(g)(2)]. However, health standards must also meet the ''feasibility mandate'' of section 6(b)(5) of the OSH Act, 29 U.S.C. 655(b)(5). Section 6(b)(5) of the Act requires OSHA to select ''the most protective standard consistent with feasibility'' needed to reduce significant risk when regulating health hazards [*see Cotton Dust,* 452 U.S. at 509]. Section 6(b)(5) also directs OSHA to base health standards on ''the best available evidence,'' including research, demonstrations, and experiments [*see* 29 U.S.C. 655(b)(5)]. In this regard, OSHA must consider ''in addition to the attainment of the highest degree of health and safety protection * * * the latest scientific data * * * feasibility and experience gained under this and other health and safety laws.'' (Id.). Furthermore, section 6(b)(5) of the Act specifies that standards must ''be expressed in terms of objective criteria and of the performance desired'' [*see* 29 U.S.C. 655(b)(7)].

The proposed APF and MUC provisions are integral components of an effective respiratory protection program. Respiratory protection is a supplemental method used by employers to protect employees against airborne contaminants in workplaces where feasible engineering controls and work practices are not available, have not yet been implemented, or are not in themselves sufficient to protect employee health. Employers also use respiratory protection under emergency conditions involving the accidental release of airborne contaminants. The proposed amendments to OSHA's Respiratory Protection Standard, and the Agency's substance-specific standards, would provide employers with critical information to use when selecting respirators for employees exposed to airborne contaminants found in general industry, construction, shipyard, longshoring, and marine terminal workplaces. Since it is generally recognized that different types of respiratory protective equipment provide different degrees of protection against hazardous exposures, proper respirator selection is of critical importance. The proposed APF and MUC provisions provide additional guidance on the point at which an increase in the level of respiratory protection is necessary. The APF and MUC provisions will greatly enhance an employer's ability to select a respirator that will adequately protect employees. OSHA believes that in the absence of these proposed provisions, employers will be less certain about which respirators to select for adequate employee protection.

The Agency also developed the proposed provisions to be feasible and cost effective, and is specifying them in terms of objective criteria and the level of performance desired. In this regard, section VI (''Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis'') of this preamble provides the benefits and costs of this proposal, and describes several other alternatives as required by section 205 of the UMRA (2 U.S.C. 1535). Based on this information, OSHA preliminarily concludes that the proposed APF and MUC provisions constitute the most cost-effective alternative for meeting its statutory objective of reducing risk of adverse health effects to the extent feasible.

III. Events Leading to the Proposed Standard

A. Regulatory History

Congress created the Occupational Safety and Health Administration (OSHA) in 1970, and gave it the responsibility for promulgating standards to protect the health and safety of American workers. As directed by the OSH Act, the Agency adopted existing Federal standards and national consensus standards developed by various organizations such as the American Conference of Governmental Industrial Hygienists (ACGIH), the National Fire Protection Association (NFPA), and the American National Standards Institute (ANSI). The ANSI standard Z88.2–1969, ''Practices for Respiratory Protection,'' was the basis of the first six sections (permissible practice, minimal respirator program, selection of respirators, air quality, use, maintenance and care) of OSHA's Respiratory Protection Standard (29 CFR 1910.134) adopted in 1971. The seventh section was a direct, complete incorporation of ANSI Standard K13.1–1969, ''Identification of Gas Mask Canisters.''

The Agency promulgated an initial Respiratory Protection Standard for the construction industry (29 CFR 1926.103) in April 1971. On February 9, 1979, OSHA formally applied 29 CFR 1910.134 to the construction industry (44 FR 8577). Agencies that preceded OSHA developed the original maritime respiratory protection standards in the 1960s (*e.g.*, section 41 of the Longshore and Harbor Worker Compensation Act). The section designations adopted by OSHA for these standards, and their original promulgation dates, are: Shipyards—29 CFR 1915.82, February 20, 1960 (25 FR 1543); Marine Terminals—29 CFR 1917.82, March 27, 1964 (29 FR 4052); and Longshoring—29 CFR 1918.102, February 20, 1960 (25 FR 1565). OSHA incorporated 29 CFR 1910.134 by reference into its Marine Terminal standards (Part 1917) on July 5, 1983 (48 FR 30909). The Agency updated and strengthened its Longshoring and Marine Terminal standards in 1996 and 2000, and these standards now incorporate 29 CFR 1910.134 by reference.

Under the Respiratory Protection Standard that OSHA initially adopted, employers needed to follow the guidance of the Z88.2–1969 ANSI standard to ensure proper selection of respirators. Subsequently, OSHA published an Advance Notice of Proposed Rulemaking (''ANPR'') to revise the Respiratory Protection Standard on May 14, 1982 (47 FR 20803). Part of the impetus for this notice was the Agency's inclusion of new respirator requirements in the comprehensive substance-specific standards promulgated under Section (6)(b) of the OSH Act, *e.g.*, fit testing protocols, respirator selection tables, use of PAPRs, changing filter elements whenever an employee detected an increase in breathing resistance, and requirements referring employees with breathing difficulties to a physician trained in pulmonary medicine, either at fit testing or during routine respirator use [*see, e.g,* 29 CFR 1910.1025 (OSHA's Lead Standard)]. The respirator provisions in these substance-specific standards took into account advances in respirator technology and changes in related guidance documents that were state-of-the-art when OSHA published these substance specific standards and, in particular, recognized that effective respirator use depends on a comprehensive respiratory protection program that includes use of APFs.

OSHA's 1982 ANPR sought information on the effectiveness of its current Respiratory Protection Standard, the need to revise this standard, and suggestions on the nature of the revisions. The 1982 ANPR referenced the ANSI Z88.2–1980 standard on respiratory protection with its table of protection factors, the 1976 report by Dr. Ed Hyatt from the LASL titled ''Respiratory Protection Factors'' (Ex. 2), and the RDL developed jointly by OSHA and NIOSH, as revised in 1978 (Ex. 9, Docket No. H049). Questions #2, #3, and #4 in the 1982 ANPR asked for comments on how OSHA should use protection factors. The Agency received responses from 81 interested parties. The commenters generally supported revising OSHA's Respiratory Protection Standard, and provided recommendations regarding approaches for including a table of protection factors (Ex. 15).

On September 17, 1985, OSHA announced the availability of a preliminary draft of the proposed Respiratory Protection Standard. This preproposal draft standard included the public comments received in response to 1982 ANPR, and OSHA's own analysis of revisions needed in the Respiratory Protection Standard to account for state-of-the-art respiratory protection. The Agency received 56 responses from interested parties (Ex. 36) which OSHA carefully reviewed in developing the proposal.

On November 15, 1994, OSHA published the proposed rule to revise 29 CFR 1910.134, and provided public notice of an informal public hearing on the proposal (59 FR 58884). The Agency convened the informal public hearing on June 6, 1995. On June 15, 1995, as part of the public hearing, OSHA held a one-day panel discussion by respirator experts of APFs. Areas discussed included difficulties in measuring performance of respiratory protection in WPF and SWPF studies, statistical uncertainties regarding the distribution of data from these studies, and the problems associated with setting APFs for all respirators that protect all potential respirator users across a wide variety of workplaces and exposure conditions.

OSHA reopened the rulemaking record for the revised Respiratory Protection Standard on November 7, 1995 (60 FR 56127), requesting comments on a study performed for OSHA by Dr. Mark Nicas titled ''The Analysis of Workplace Protection Factor Data and Derivation of Assigned Protection Factors' (Ex. 1–156). That study, which the Agency placed in the rulemaking docket on September 20, 1995, addressed the use of statistical modeling for determining respirator APFs. OSHA received 12 comments on the Nicas report. This report, and the comments received in response to it, convinced OSHA that more information would be necessary before it could resolve the complex issues regarding how to establish APFs, including what methodology to use in analyzing existing protection factor studies (*see* Section IV below for a more detailed explanation of the Nicas report and the comments made on it).

OSHA published the final, revised Respiratory Protection Standard, 29 CFR 1910.134, on January 8, 1998 (63 FR 1152). The standard contains worksite-specific requirements for program administration, procedures for respirator selection, employee training, fit testing, medical evaluation, respirator

use, and other provisions. However, OSHA reserved the sections of the final standard related to APFs and maximum use concentration (MUC) pending further rulemaking (see 63 FR 1182 and 1203). The Agency stated that, until a future rulemaking on APFs is completed:

> [Employers must] take the best available information into account in selecting respirators. As it did under the previous [Respiratory Protection] standard, OSHA itself will continue to refer to the [APFs in the 1987 NIOSH RDL] in cases where it has not made a different determination in a substance specific standard. (*see* 63 FR 1163)

The Agency subsequently established a separate docket (*i.e.*, H049C) for the APF rulemaking. This docket includes copies of material related to APFs that it previously placed in the docket (H049) for the revised Respiratory Protection Standard. The APF rulemaking docket also contains other APF-related materials, studies, and data that OSHA obtained after it promulgated the final Respiratory Protection Standard in 1998.

History of Assigned Protection Factors

In 1965, the Bureau of Mines published ''Respirator Approval Schedule 21B,'' which contained the term ''protection factor'' as part of its approval process for half-mask respirators (for protection up to 10 times the TLV) and full facepiece respirators (for protection up to 100 times the TLV). The Bureau of Mines based these protection factors on quantitative fit tests, using dioctyl pthalate (DOP), that were conducted on six male test subjects performing simulated work exercises.

The Atomic Energy Commission (AEC) published proposed protection factors for respirators in 1967, but later withdrew them because quantitative fit testing studies were available for some, but not all, types of respirators. To address this shortcoming, the AEC subsequently sponsored respirator studies at LASL, starting in 1969.

ANSI standard Z88.2–1969, which OSHA adopted by reference in 1971, did not contain APFs for respirator selection. Nevertheless, this ANSI standard recommended that ''due consideration be given to potential inward leakage in selecting devices,'' and contained a list of the various respirators grouped according to the quantity of leakage into the facepiece expected during routine use.

In 1972, NIOSH and the Bureau of Mines published new approval schedules for respiratory protection under 30 CFR Part 11. However, these new approval schedules did not include fit testing provisions as part of the respirator certification process.

NIOSH sponsored additional respirator studies at LASL, beginning in 1971, that used quantitative test systems to measure the overall performance of respirators. Dr. Edwin C. Hyatt of LASL included a table of protection factors for, single-use dust respirators; quarter-mask, half-mask, and full facepiece air-purifying respirators; and SCBAs in a 1976 report titled ''Respirator Protection Factors'' (Ex. 2). The protection factors were based on data from DOP and sodium chloride quantitative fit test studies performed on these respirators at LASL between 1970 and 1973. The table also contained recommended protection factors for respirators that had no performance test data. Dr. Hyatt based these recommended protection factors on the judgment and experience of LASL researchers, as well as extrapolations from available facepiece leakage data for similar respirators. For example, he assumed that performance data for SCBAs operated in the pressure demand mode could be used to represent other (non-tested) respirators that maintain positive pressure in the facepiece, hood, helmet, or suit during inhalation. In addition, he recommended in his report that NIOSH continue testing the performance of respirators that lacked adequate fit test data. Relative to this, staff members at LASL (from 1974 to 1978) used a representative 35-person test panel to conduct quantitative fit tests on all air-purifying particulate respirators approved by the Bureau of Mines and NIOSH.

In August 1975, the Joint NIOSH-OSHA Standards Completion Program published the RDL (Ex. 25–4, Appendix F, Docket No. H049). The RDL contained a table of protection factors that were based on quantitative fit testing performed at LASL and elsewhere, as well as the expert judgment of the RDL authors. The 1978 NIOSH update of the RDL contained the following protection factors:

5 for single-use respirators;

10 for half-mask respirators with DFM or HEPA filters;

50 for full facepiece air-purifying respirators with HEPA filters or chemical cartridges;

1,000 for PAPRs with HEPA filters;

1,000 for half-mask SARs operated in the pressure demand mode;

2,000 for full facepiece SARs operated in the pressure demand mode; and

10,000 for full facepiece SCBAs operated in the pressure demand mode.

ANSI's respiratory protection Subcommittee decided to revise Z88.2–1969 in the late 1970s. During its deliberations, the Subcommittee conducted an extensive discussion regarding the role of respirator protection factors in an effective respiratory protection program. As a result, the Subcommittee decided to add an APF table to the revised standard. In May 1980, ANSI published the revision as Z88.2–1980 (Ex. 10, Docket No. H049) and it contained the first ANSI Z88.2 respiratory protection factor table. The ANSI Subcommittee based the table on Hyatt's protection factors, which it updated using results from fit testing studies performed at LANL and elsewhere since 1973. For example, the protection factor for full facepiece air-purifying particulate respirators was 100 when qualitatively fit tested, or 1,000 when equipped with high efficiency filters and quantitatively fit tested. The table consistently gave higher protection factors to tight-fitting facepiece respirators when employers performed quantitative fit testing rather than qualitative fit testing. The ANSI Subcommittee concluded that PAPRs (with any respiratory inlet covering), atmosphere-supplied respirators (in continuous flow or pressure demand mode), and pressure demand SCBAs required no fit testing because they operated in a positive pressure mode. Accordingly, it gave these respirators high protection factors, limited only by IDLH values. The Subcommittee assigned protection factors of 10,000 and over to respirators used in IDLH atmospheres.

In response to a complaint to NIOSH that the PAPRs used in a plant did not appear to provide the expected protection factor of 1,000, Myers and Peach of NIOSH conducted a WPF study during silica bagging operations. Myers and Peach tested half-mask and full facepiece PAPRs and found protection factors that ranged from 16 to 215. They published the results of the study in 1983 (Ex. 1–64–46). The results of this study led NIOSH and other researchers, as well as respirator manufacturers, to perform additional WPF studies on PAPRs and other respirators.

NIOSH revised its RDL in 1987 (Ex. 1–54–437Q). While the revision retained many of the provisions of the 1978 RDL, it recognized the problems involved in developing APFs. The 1987 RDL also revised the APFs for some respirators, based on NIOSH's WPF studies. For example, the APFs were lowered for the following respirator classes: PAPRs with a loose-fitting hood or helmet to 25; PAPRs with a tight-fitting facepiece and a HEPA filter to 50; supplied-air continuous flow hoods or helmets to 25; and supplied-air continuous flow tight-fitting facepiece respirators to 50.

NIOSH stated that it may revise the 1987 RDL if warranted by subsequent WPF studies.

In August 1992, ANSI again revised its Z88.2 Respiratory Protection Standard (Ex. 1–50). The ANSI Z88.2–1992 standard contained a revised APF table, based on the Z88.2 Subcommittee's review of the available protection factor studies. In a report describing the revised standard (Ex. 1–64–423), Nelson, Wilmes, and daRoza described the rationale used by the ANSI Subcommittee in setting APFs:

> If WPF studies were available, they formed the basis for the [APF] number assigned. If no such studies were available, then laboratory studies, design analogies, and other information was used to decide what value to place in the table. In all cases where the assigned protection factor changed when compared to the 1980 standard, the assigned number is lower in the 1992 standard.

In addition, the 1992 ANSI Z88.2 standard abandoned the 1980 standard's practice of giving increased protection factors to some respirators if quantitative fit testing was performed.

Tom Nelson, the co-chair of the ANSI Z88.2–1992 Subcommittee, published a second report, entitled ''The Assigned Protection Factor According to ANSI'' (Ex. 135), four years after the Z88.2 Subcommittee completed the revised 1992 standard. In the report, he reviewed the reasoning used by the ANSI Subcommittee in setting the 1992 ANSI APFs. He noted that the Z88.2 Subcommittee gave an APF of 10 to all half-mask air-purifying respirators, including quarter-mask, elastomeric, and disposable respirators. The Subcommittee also recommended that full facepiece air-purifying respirators retain an APF of 100 (from the 1980 ANSI standard) because no new data were available to justify another value. The Z88.2 Subcommittee also reviewed the 1987 NIOSH RDL values, particularly the RDL's reduction of loose-fitting facepiece and PAPRs with helmets or hoods to an APF of 25 based on their performance in WPF studies. For half-mask PAPRs, the ANSI Subcommittee set an APF of 50 based on a WPF study by Lenhart (Ex. 1–64–42). The ANSI Subcommittee had no WPF data available for full facepiece PAPRs, so it decided to select an APF of 1,000 to be consistent with the APF for PAPRs with helmets or hoods. The Subcommittee, in turn, based its APF of 1,000 for PAPRs with helmets or hoods on design analogies (*i.e.*, same facepiece designs, operation at the same airflow rates) between these respirators and airline respirators. Nelson noted that a subsequent WPF report by Keys (Ex. 1–64–40) on PAPRs with helmets or hoods was consistent with an APF of 1,000. According to Nelson, the Subcommittee used WPF studies by Myers (Ex. 1–64–48), Gosselink (Ex. 1–64–23), Myers (Ex. 1–64–47), and Que Hee and Lawrence (Ex. 1–64–60) to set an APF of 25 for PAPRs with loose-fitting facepieces. Nelson stated that two WPF studies, conducted by Gaboury and Burd (Ex. 1–64–24) and Stokes (Ex. 1–64–66) subsequent to publication of ANSI Z88.2–1992, supported the APF of 25 selected by the Subcommittee for PAPRs with loose-fitting facepieces.

Tom Nelson stated in his report that the ANSI Subcommittee had no new information on atmosphere-supplying respirators. Therefore, the APFs for these respirators were based on analogies with other similarly designed respirators (Ex. 135). The ANSI Subcommittee based the APF of 50 for half-mask continuous flow atmosphere-supplying respirators, and the APF of 25 for loose-fitting facepiece continuous flow atmosphere-supplying respirators, on the similarities between these respirators and PAPRs with the same airflow rates. Nelson noted that the ANSI Subcommittee set the APF of 1,000 for full facepiece continuous flow atmosphere-supplying respirators to be consistent with the APF for SARs with helmets or hoods found in two earlier studies—a WPF study by Johnson (Ex. 1–64–36) and a SWPF study by Skaggs (Ex. 1–3803). The Subcommittee used the analogy between PAPRs and continuous flow supplied-air respirators to select the APF of 50 for half-mask pressure demand SARs and 1,000 for full facepiece pressure demand SARs. Nelson stated: ''The committee believed that setting a higher APF because of the pressure demand feature was not warranted, but rather that the total airflow was critical.''

Nelson noted in the report that the Subcommittee selected no APF for SCBAs. In explaining the committee's decision, he stated that ''the performance of this type of respirator may not be as good as previously measured in quantitative fit test chambers.'' Nelson also observed that the ANSI 88.2–1992 standard justified this approach in a footnote to the APF table. The footnote states:

> A limited number of recent simulated workplace studies concluded that all users may not achieve protection factors of 10,000. Based on [these] limited data, a definitive assigned protection factor could not be listed for positive pressure SCBAs. For emergency planning purposes where hazardous concentrations can be estimated, an assigned protection factor of no higher than 10,000 should be used.

A new ANSI Z88.2 Subcommittee currently is reviewing the ANSI Z88.2–1992 standard, in accordance with ANSI policy specifying that each standard receive a periodic review. This review likely will result in revisions to the Z88.2 APF table based on WPF and SWPF respirator performance studies conducted since publication of the current standard in 1992.

B. Need for APFs

The proposed APF definition and regulatory text are important additions to, and an integral part of, OSHA's Respiratory Protection Standard because employers need this information to select appropriate respirators for employee use when engineering and work-practice controls are insufficient to maintain hazardous substances at safe levels in the workplace. Employers need the consistent and valid information contained in the proposed APF provisions to select respirators for employee protection, based on the type of hazardous substance and the level of employee exposure to that substance.

As noted in Table I of the proposed regulatory text, the proposed APFs differ for each class of respirator. In this regard, the proposed APF for a class of respirators specifies the workplace level of protection that class of respirator should provide under an effective respiratory protection program. Therefore, when the concentration of a hazardous substance in the workplace is less than 10 times the PEL, the employer must select a respirator from a respirator class with an APF of at least 10 for use by employees exposed to that substance. However, when the concentration of the hazardous substance is greater than 10 times the PEL, the employer must select a respirator that has an APF greater than 10 for this purpose. In addition, employers would derive MUCs from the APFs proposed for the different respirator classes. These MUCs determine the maximum atmospheric concentration of toxic gasses and vapors at which respirators equipped with cartridges and canisters can be used to protect employees.

In summary, when used in conjunction with the existing provisions of the Respiratory Protection Standard, especially the respirator selection requirements specified in paragraph (d), the proposed APF definition and regulatory text would provide employers with the information they need to select the appropriate respirators for reducing employee exposures to hazardous substances to safe levels. Accordingly, integrating the proposed APF provisions into the Respiratory Protection Standard will

ensure that employees receive the optimum level of protection afforded by that standard.

C. Review of the Proposed Standard by the Advisory Committee for Construction Safety and Health (ACCSH)

The proposed provisions would replace the existing respirator-selection requirements specified by the Respiratory Protection Standard for the construction industry (29 CFR 1926.103). Accordingly, OSHA's regulation governing the Advisory Committee on Construction Safety and Health (ACCSH) at 29 CFR 1912.3 requires OSHA to consult with the ACCSH whenever the Agency proposes a rulemaking that involves the occupational safety and health of construction employees. On December 5, 2002, OSHA briefed the ACCSH membership on the proposed provisions and responded to their questions. On March 27, 2003, the APF proposal was distributed to the ACCSH membership for their review prior to their next regular meeting on May 22, 2003. OSHA staff discussed the APF proposal and answered questions from the ACCSH members during their meeting on May 22, 2003. The ACCSH then recommended that OSHA proceed with publishing the proposal.

IV. Methodology for Developing Assigned Protection Factors

This section contains an overview of the analyses performed for OSHA and summaries of the studies used in these analyses. OSHA entered the complete analyses and studies into Docket H049C as Exhibits 3, 4, and 5 and Exhibit 1–156 (Dr. Nicas' report). Studies and information supporting the APF for each class of respirator are discussed in Section VII of this document. The analyses discussed below assisted OSHA in determining its proposed approach to deriving APFs. Commenters expressed appreciation for the approach suggested by Dr. Nicas, but nearly all did not support implementation of his methods. However, his recommendations provided guidance to the Agency regarding the types of studies and data needed for determining APFs. Dr. Brown's complex statistical analyses demonstrated the widespread variability inherent in current workplace protection factor studies. However, he found in his final analysis that the performance of filtering facepiece and elastomeric half-mask respirators could not be differentiated, thereby supporting grouping of these two types of respirator under one APF.

A. Dr. Nicas' Proposal and Response From Commenters

During the June 1995 APF hearings, OSHA devoted a full day to a panel discussion on the uncertainties associated with sample statistics and their use for deriving APFs. Based on this discussion, OSHA contracted with Dr. Mark Nicas to develop a statistical method for deriving APFs. Nicas used two approaches to account for within-wearer and between-wearer variabilities. For penetration data collected from a specific cohort of respirator wearers, he used a one-factor lognormal analysis of variance. He used a two-factor lognormal analysis of variance to perform a meta-analysis of the data from studies of different cohorts of respirator wearers. Using these approaches, Nicas proposed assigning two different protection factors; he recommended one for chronic toxicants (*i.e.*, substances regulated by an 8-hour PEL), and the other for acute toxicants (*i.e.*, substances regulated by a STEL). Nicas also made recommendations regarding sampling data management and inclusion of studies in statistical analyses of respirator performance.

OSHA reopened the rulemaking record on November 7, 1995 (60 FR 56127) to request comment on Dr. Nicas' report titled ''The Analysis of Workplace Protection Factor Data and Derivation of Assigned Protection Factors'' (Ex. 1–156). OSHA received 12 comments on the report. While some commenters expressed general support for Nicas' approach (*e.g.*, Ex. 1–182–4, American College of Occupational and Environmental Medicine), others had serious reservations about establishing APFs using this approach. The issues raised by these commenters are described below.

1. Lack of Valid and Reliable WPF Data

Two commenters stated that the available WPF data were of insufficient quality to permit a sophisticated statistical analysis. The 3M Company (3M) commended OSHA for ''attempting to use science to evaluate workplace studies for determining Assigned Protection Factors,'' but stated that insufficient valid data were available for such an evaluation, and that the data that were available were too variable (Ex. 1–182–5). In addition, Organization Resource Counselors, Inc. (ORC) stated: ''The use of existing, often flawed, workplace protection factor studies, is not a solution to the problem. * * * A reliance on sophisticated statistics in an attempt to compensate for a lack of reliable scientific data on respirator performance is both bad science and bad policy'' (Ex. 1–182–10).

2. Inappropriate Use of ANOVA Model

Three commenters believed that using Nicas' lognormal ANOVA model to analyze existing data was inappropriate (Exs. 1–174, 1–182–5, 1–182–1). Two of these commenters advocated using a simple analysis of the aggregate data instead (Exs. 1–174, 1–182–5). Thomas Nelson (Ex. 1–174) and 3M (1–182–5) expressed concern that the ANOVA model focuses primarily on within-wearer and between-wearer variability, while ignoring the potential variability contributed by other sources such as work site, respirator model, filter, and contaminant. Nelson stated: ''A simple analysis of the entire data (*i.e.*, geometric mean, estimates of percentiles and confidence intervals) includes these and other possible sources of variation and the within-person variability in the model.'' Two other commenters, Drs. Rappaport and Kupper [contractors for the Industrial Safety Equipment Association (ISEA)] believed that using an ANOVA model provided some benefits; however, they had concerns regarding the assumption of log-normality of penetration values, the lack of validation of the model, and errors that appeared in some of the equations. Therefore, they regarded ''implementation of Dr. Nicas' ideas as being problematic at this time,'' and encouraged the industry to develop improved methods and data for deriving APFs (Ex. 1–182–1).

3. ANOVA Model Fails To Account for Differences Between WPF Studies

Five commenters stated that the proposed analysis fails to account for important differences between studies that could affect WPF values. Thomas Nelson and 3M believed that the ANOVA model does not account for other sources of variability (Exs 1–174, 1–182–5). NIOSH stated that Nicas' report did not address the effect of the test subjects' work rates and other activities on a respirator's performance (Ex. 1–182–3), and did not account for employee training and program surveillance (Ex. 1–182–9). The Chemical Manufacturers Association (CMA) also commented on factors not considered in the Nicas report, ''including differences in training, experience, work site, work rate and sample collection'' (Ex. 1–182–7). ORC noted: '' The results of a WPF study are based on at least the following components: quality of the respirator chosen; quality of the training program; quality of the fit testing and selection program; nature of the work and ability

to challenge the fit of a respirator (sedentary versus high exercise work)'' (Ex. 1–182–10).

4. Using a Conservative Criterion for Setting APFs

Five commenters stated that Nicas' criterion for setting APF values was overly conservative. The Dow Chemical Company (Dow) stated that the Nicas approach ''would result in protection factors which are very conservative'' (Ex. 1–182–2), while 3M believed that OSHA's use of Nicas's recommendation would result in a major change in the pattern of respirator use (Ex. 1–182–5). NIOSH commented that the approach may result in very low APF estimates because of high WPF variability, and that while the approach would derive more conservative (*i.e.*, more protective) APFs, its use for ''WPF studies with small sample sizes * * * could result in APF estimates less than or equal to 1.0 (APF values less than 1.0 are meaningless)'' (Ex. 1–182–3). Drs. Rappaport and Kupper stated that only weak precedence existed for Nicas' use of 95th percentiles to define APFs, and suggested that other percentiles (*e.g.*, the 90th percentile) would be more practical to implement (ISEA, Ex. 1–182–1). Finally, CMA believed that the proposed criterion rated ''all respirators on the lowest protection achieved by the lowest performing person'' (Ex. 1–182–7).

5. APFs Based on a Contaminant's Toxicity (Acute Versus Chronic Toxicants)

Dr. Nicas proposed that two APFs be assigned to a respirator, depending on its use against either a chronic toxicant or an acute toxicant. Four commenters remarked on the feasibility and effects of this approach. NIOSH commented that ''defining acceptable protection against short-term exposures is very complex * * *.'' (Ex. 1–182–3). 3M commented that dual APFs would be confusing to the user community and workers, and would make program management difficult (Ex. 1–182–5). CMA provided similar comments, and noted that many materials have both chronic and acute effects (Ex. 1–182–7). ORC believed that:

> * * * different APFs for different contaminants or types of exposure is not appropriate. Occupational exposure standards should have adequate safety factors which are based on the health outcome (*e.g.*, irritation, systemic toxicity, carcinogenicity) of exposure. (Ex. 1–182–10)

While Drs. Rappaport and Kupper stated that Nicas' argument about respiratory protection for substances with chronic effects was logical, they regarded the question of how to deal with acutely toxic substances as unresolved (Ex. 1–182–1).

6. Distribution of Contaminant Concentrations

Two participants believed that it was necessary to incorporate information on the variability of ambient exposure concentrations, as well as the maximum anticipated concentration, when discussing respirator selection. CMA stated that since an employee's exposures will vary from day to day, employers should select respirators with maximum use limits well above the mean exposure levels to ensure ''that there is less than 5% probability of exposures above the maximum use limit of the respirator'' (Ex. 1–182–7). In a related comment, ORC stated that many industrial applications typically have exposures only 2–3 times the acceptable exposure limit; therefore, ''selecting a respirator with an APF of 10 may mean there is only a remote chance of overexposure to a contaminant due to fit/wear variability'' (Ex. 1–182–10).

7. Other Concerns With Nicas' Method

The commenters raised several other issues with Dr. Nicas' methodology. For example, 3M (Ex. 1–182–5) and CMA (Ex. 1–182–7) believed that the relationship between outside concentration and WPF (*i.e.*, WPF increases with increasing Co) was poorly understood; therefore, a sophisticated analysis of the data is questionable. Other commenters noted errors in the equations of the proposed model (*e.g.*, Ex. 1–182–1) and with the distribution of the respirator penetration values (Ex. 1–182–1).

8. Miscellaneous Comments (*e.g.*, ANSI APFs)

In addition to responding to the Nicas report, a number of commenters supported using the APFs recommended in the ANSI Z88.2–1992 respiratory protection standard (Exs. 1–182–1, 1–182–2, 1–182–5, 1–182–7, 1–182–10). These commenters stated that the members of the ANSI Z88.2 committee were ''respected industrial hygiene and respirator experts'' (Ex. 1–182–5), that the ANSI Z88.2–1992 APFs were ''the appropriate values'' (Ex. 1–182–7), and that the ANSI APFs ''have been through the ANSI peer review process'' (Ex. 1–182–5). In advocating use of the ANSI APFs, none of the commenters described the process by which the ANSI Z88.2 committee derived its APFs, or identified the studies and other information on which that committee relied. Furthermore, several commenters (Exs. 1–182–7, 1–182–5, 1–182–10, 1–182–6, 1–182–8) noted that the ANSI Z88.2–1992 standard does not explicitly account for several factors in assigning APF values to different respirator classes, or the use of a respirator in different situations, which they indicated were necessary considerations. Moreover, some commenters (Exs. 1–182–11,1–182–12) recommended APFs that differ from those published by the ANSI Z88.2 Committee. Other commenters believed that it was OSHA's responsibility to show that the commonly used ANSI Z88.2 1992 APFs were erroneous (Ex. 1–182–2), and that the Agency should not use SWPF studies to derive APFs (Ex. 1–182–5). Several participants at the hearing for the final Respiratory Protection Standard stated that OSHA should issue a second NPRM to address the development of APFs (Exs. 1–182–1, 1–182–5, 1–182–10).

After carefully considering Dr. Nicas' model and the comments received in response to his report of the model, the Agency concluded that other possible approaches to deriving APFs should be investigated. Accordingly, the Agency identified and collected available data for this purpose. Of particular interest were data that OSHA could use to discriminate between the performance of different respirator classes. The Agency gathered information from both published and non-published papers and reports, and included WPF, SWPF, PPF, and EPF studies; Health Hazard Evaluations conducted by NIOSH; respirator performance data from manufacturers, such as SWPF data submitted to OSHA by Bullard (Ex. 3–8); and other material related to assessing respirator performance. This information is in Docket H049 as Exhibits 2, 3, and 4.

To assist in evaluating the data, OSHA employed Dr. Kenneth Brown (a statistician) and several respirator authorities: Mr. Harry Ettinger, Dr. Gerry Wood of LANL, and Drs. James Johnson, Kenneth Foote, and Arthur Bierman of LLNL. After the Agency reviewed all of the studies and information, it decided to attempt to analyze only WPF and SWPF studies since they address respirator performance exclusively. OSHA discusses the work and findings of these individuals below.

B. Analyses of WPF Studies

OSHA contracted with Dr. Brown to investigate possible approaches, other than those approaches proposed by Nicas, to evaluate respirator performance data from WPF studies. The following discussion is a general description of the analyses performed by Brown, as well as his overall

conclusions. For a detailed explanation of the methodology and rationale used in the analyses, refer to Brown's reports in the docket (Exs. 5–1, 5–2).

OSHA reviewed the available WPF studies for possible inclusion in Brown's analyses. Early in this review process, the Agency decided to exclude WPF studies with a gas or vapor workplace challenge agent because: The preponderance of studies were conducted in workplaces with particulate challenges; gas/vapor studies did not provide any further insight or clarification regarding sources of variability in WPF studies (most likely, gas/vapor studies add variability to the data such as the effects of humidity on sampling media collection and desorption efficiencies); and pulmonary elimination differs between gases/vapors and particulates. Therefore, OSHA decided to analyze only WPF studies using particulate challenge agents. The Agency evaluated those studies initially selected for further analysis for compliance with the requirements of OSHA's Respiratory Protection Standard (29 CFR 1910.134), as well as completeness of the data. The Agency compiled a list of review items to use in evaluating each study (Ex. 5–5).

OSHA then divided the remaining studies into two categories: Half-mask negative-pressure air-purifying respirators (APRs) and atmosphere-supplying respirators (PAPRs and SARs). This procedure resulted in 22 APR studies and 16 PAPR/SAR studies for analysis. OSHA placed a list of these studies, and their respective respirators, in the docket (Ex. 7–4). Brown subsequently identified 14 APR studies and 13 PAPR/SAR studies for further analysis (see Exs. 5–1 and 5–2 for more information on the evaluation criteria).

Brown's analyses divided the respirators used in these studies into separate respirator classes. The analyses divided APRs into 5 classes, listed below in Table 1. As this table shows, Brown's analyses separated filtering facepieces into four classes based on the characteristics listed under the Description column heading, with the fifth class comprised of elastomeric facepiece APRs.

TABLE 1.—HALF-MASK APR CLASSES

Class	Type	Description			
		Adjustable head straps	Exhalation valve	Double shell construction	Foam ring liner
1	Filtering facepiece				
2	Filtering facepiece	X		X	
3	Filtering facepiece	X	X	X	
4	Filtering facepiece	X	X	X	X
5	Elastomeric facepiece.				

In addition, Brown's analyses divided PAPRs into five classes and SARs into two classes, as shown in Table 2.

TABLE 2.—PAPR AND SAR CLASSES

Class	Type	Description
1	PAPR	Loose-fitting facepiece.
2	PAPR	Loose-fitting facepiece with hood and/or helmet.
3	PAPR	Hood and/or helmets—not loose-fitting.
4	PAPR	Tight-fitting half-mask facepiece.
5	PAPR	Tight-fitting full facepiece.
6	SAR	Loose-fitting.
7	SAR	Hood or helmet.

Later in the analyses, Brown further divided these classes according to class of respirator, study, and challenge agent (CLSA). This division resulted in 26 CLSAs for the APRs and 14 CLSAs for the PAPRs/SARs.

The data from the WPF studies consisted of simultaneous measurements of the challenge agent concentration inside the respirator facepiece (*i.e.*, concentration inside or Ci) and outside the respirator facepiece (*i.e.*, concentration outside or Co) in the ambient workplace atmosphere. Corresponding Co and Ci measurements can be used to calculate the workplace protection factor (WPF = Co/Ci) or penetration of the contaminant into the respirator (PEN = Ci/Co = 1/WPF). The APR studies had a total of 917 data pairs, while the PAPR/SAR studies provided 443 data pairs.

1. Half-Mask APRs

In the first phase of his analysis, Brown statistically analyzed the data for half-mask negative pressure APRs, both filtering facepiece and elastomeric APRs, using the following three approaches: (1) Pooled the data within classes, corrected the data for the positive relationship found between WPF values and increasing Co, and compared the differences in WPF statistics between classes; (2) conducted an intra-study analysis of the performance of two different classes of respirator used against the same contaminant under similar workplace conditions; and (3) divided the data into class-study-agent combinations, and evaluated WPF as a function of Co. The following sections discuss these approaches in detail.

Approach 1. Brown's initial approach was to determine if he could pool the data within each respirator class and estimate the fifth percentile WPF for that respirator class; he then tested for differences in WPFs between the respirator classes. He divided and analyzed the data by study, treating the data from each study as a homogeneous sample arising from the same parent distribution. Then he examined the data in each study for a Co effect, and constructed a scatterplot of ln(WPF) versus ln(Co) for each respirator class. In doing so, he treated extreme or poorly fitting data as outliers and removed them from the analysis. He subsequently derived a linear regression of ln(WPF) on ln(Co) for each study, and extrapolated from the observed range to the entire range of Co values in all of the data. The positive slopes, which he found for most classes, showed that ln(WPF) increased as ln(Co) increased. In addition, the regression lines were well mixed, indicating that studies within the same respirator class varied more than anticipated. This result indicated that variability occurring within respirator classes could obscure differences between respirator classes.

These studies collected data over different ranges of Co. Therefore, to compare the WPFs observed in the studies, Brown corrected the WPF values for all studies, using a common Co adjustment factor. He pooled the adjusted WPFs by class, and then plotted the cumulative distributions to determine if he could identify differences between respirator classes, despite intra- and inter-study differences. Finding no differences

between respirator classes using the Co adjustment factor, he concluded that:

> Observed 5th percentiles for WPFs, and their lower confidence intervals when adjusted for the Co effect, showed no clear evidence that any class was preferable to another. In particular, there was no indication that Class 5 (elastomerics) performed better than four disposable classes. (Ex. 5–1, p. 8)

The results of these analyses prompted a more detailed examination of the data. To control for study-related and agent-related factors that may contribute to variability, Brown performed an intra-study analysis on two different respirator classes used against the same workplace challenge agent under similar workplace conditions (Approach 2).

Approach 2. The second approach attempted to determine respirator performance after controlling for study-to-study and agent-to-agent sources of variability. Among the half-mask APRs, the chance of detecting performance differences appeared to be greatest for comparisons between elastomeric and filtering facepiece respirators. In implementing this approach, Brown assumed that controlling for study and agent sources of variability would result in WPF differences attributable, in large part, to variability in respirator performance.

Four of the studies compared the performance of elastomeric and filtering facepiece respirators against the same challenge agent in the same workplace. After reviewing these studies, a study by Meyers and Zhuang (Ex. 1–64–51) was selected for further analysis because it was recent, followed a protocol patterned after other published WPF study protocols, and was well documented. Brown's statistical analyses of this study (see Ex. 5–1, Appendix C) indicated large sources of variability within the study, making comparison of the two respirator classes difficult and tenuous. Based on plots of the data and the occurrence of several outliers, it appeared that even data on the same agent, obtained under similar workplace conditions, may not have come from the same parent distribution. In addition, the variability of WPFs within the study (regardless of adjustment for the Co effect) was large. Therefore, the results of this second approach led Brown to state that, at least in this analysis, ''workplace studies may have too much intra-study variability for reasonably valid/accurate/reliable assessments and comparisons of respirator effectiveness.'' (Ex. 5–1, p. C–17)

Approach 3. Brown began the third statistical approach by dividing the data into units smaller than respirator class, *i.e.*, units based on class of respirator, study, and workplace challenge agent (class-study-agent or CLSA). This procedure resulted in 42 CLSA combinations. After removing deficient data (*e.g.*, no data on Co), he narrowed the data set to 26 combinations. Again, he tested the data for each CLSA to determine if WPF increases with Co and, if so, whether the effect held for all respirator classes. Data analyses of the 26 CLSAs indicated that WPF increased with Co; Brown then derived a common estimate (across all CLSAs) of the Co effect. He subsequently estimated the means for the CLSAs within each class of respirator, both with and without adjustment for Co effect. Brown compared the means of these CLSAs within and between respirator classes. For each respirator class, he grouped the CLSAs that had no significant difference between their means into common subclasses, and plotted both the adjusted and non-adjusted means [*i.e.*, mean of ln(PEN)] of the subclasses, as well as their associated confidence intervals. The results of the comparisons showed that: the estimated means of CLSAs vary so much within a class that the mean of one CLSA is likely to be a poor predictor of the mean of another CLSA within the same class; and it was not visually apparent from the plots that one class of respirator performed better than another class. In general, the comparison indicated that study outcomes, even within the same class of respirator, are highly heterogeneous.

Final analysis. Since the three approaches discussed above could not distinguish between respirator effectiveness within or across classes, the data were viewed, as a whole, from the relationship of Ci and Co. Brown pooled the data for all 26 CLSAs and derived several functional relationships from the pooled data. This approach showed that the majority of the observed data pairs achieved a WPF of 10. (See Ex. 5–1 for more details.)

After performing the above analyses, Brown made a number of observations and conclusions. He noted that the range of WPF values within a CLSA was typically wide, and that the observations were highly variable. In addition, he believed that variability in WPF studies can affect the accuracy, validity, and reliability of study results, as well as the ability to compare study results. Brown noted several possible sources of variability in WPF studies, including: (1) Study characteristics related to study design, execution, sample analysis, and data management and reporting; (2) measurements of Ci at different outside concentrations (Co effect), taken in conjunction with other poorly described factors (*e.g.*, particle size, temperature, humidity) that may affect the relationship of Ci and Co; (3) characteristics of the ambient agent itself (*e.g.*, possible effects of the agent occurring in a mixture with other agents); and (4) variations in data among studies related to using different study procedures (*e.g.*, repeated measurements on the same worker in some studies versus single measurements on each worker in other studies, random versus non-random selection of study participants). He also commented that the analyses assumed that the data were representative of workplace conditions; however, the data may not represent either current or future workplaces in which employees use respirators. Finally, Brown observed that studies with high Ci values, relative to Co, may have influenced his findings. He believed that these studies should be closely reviewed because some study weakness, unrelated to respirator performance, could be the reason for the high Ci values.

Brown also made some general observations about WPF studies. First, he believed that the role of WPF studies in assessing and comparing respirator effectiveness, and influencing APFs, should be reevaluated. He believed that a more refined instrument that is amenable to experimental design and control, such as chamber studies, is better suited for providing information during determination of assigned protection factors. Brown noted that the use of high concentrations of a challenge agent in chamber studies may minimize the uncertainty of extrapolating test results obtained at low outside concentrations to levels well above the observed range. Therefore, WPF studies would serve as a counterpart to chamber studies, *i.e.*, WPF studies would provide data on the respirator during actual use in the workplace, and identify workplace conditions in which a respirator may perform poorly. To improve comparability of results, he advocated using uniform procedures to: select the challenge agent; collect samples; record the data; and measure and interpret Ci and Co (Ex. 5–1, pp. 42–44).

Overall, the analyses led Brown to several conclusions. First, workplace studies have limitations for comparing respirator performance because of uncontrolled sources of variability. Support for this conclusion comes from the wide confidence intervals for the means of the CLSAs, and the wide range of those confidence intervals within the same respirator class. Second, Brown believed that the WPF has limits as a

measure of respirator effectiveness because, in general, it tends to increase as Co increases. This relationship complicates comparisons of WPF values measured at different Co levels. Third, he found no clear evidence that one class of respirator is better than any other class, particularly between elastomeric half-mask and filtering facepiece respirators. In addition, the differing results between CLSAs within the same class of respirators indicated that the outcome of one CLSA may be a poor predictor for another CLSA in the same class.

2. PAPRs and SARs

Dr. Brown analyzed 13 studies to evaluate and compare the effectiveness of PAPRs and SARs. Ten of the studies were conducted with PAPRs, and three with SARs. Brown's analyses divided these ''high-performance'' respirators into seven classes (*i.e.*, five types of PAPR and two types of SAR) based on their design features (*see* Table 2), with subsequent separation of these respirator classes into 14 CLSAs.

Brown used the CLSAs to determine whether any differences in respirator effectiveness existed among the respirator classes. He analyzed the data for trends of WPFs, either upward or downward, as Co increases, and for homogeneity. Brown plotted all of the data, fitted lines to these plots, made comparisons of study results within each respirator class, and developed functions from the fitted lines. (For additional details on these statistical analyses and the data plots, *see* Ex. 5–2.)

On reviewing the data plots, Brown concluded that the data were consistent with a linear relationship between ln(Ci) and ln(Co). Also, the presence of outliers and/or an imbalanced distribution of the observations influenced the results. He recommended further investigation of the outliers, particularly those with unusually high Ci values, to determine if they resulted from characteristics of the respirator or other variables. He also recommended studying the imbalanced distributions to determine if they represented individual study biases caused, for example, by collecting data at different work sites or on different work shifts. Finally, Brown noted that the robust least trimmed squares line may be useful for estimating the relationship between ln(Ci) and ln(Co).

Fifth percentiles are commonly used as a benchmark for respirator performance. Brown's analyses showed that fifth percentile estimates differed considerably within respirator classes that contained more than one CLSA. The range of the fifth percentile estimates was 28–389 for the five CLSAs in Class 2, 17–107 for the two CLSAs in Class 4, 29–1779 for two CLSAs in Class 5, and 74–188 for the two CLSAs in Class 7. The fifth percentile estimates in Classes 3 and 6 were large, while the fifth percentile estimates were small in Classes 1, 4, and 7. Brown believed that, while some of these differences may be attributed to a real difference in respirator performance between classes, the sample sizes were too small and/or the sampling variability too large to obtain reliable estimates at low percentile levels. He noted that the fifth percentile estimates were variable, and were not predictable from one CLSA to another CLSA within the same respirator class. Thus, he concluded that the fifth percentile estimates of WPFs have limited utility for setting assigned protection factors. Table 3 lists the descriptive statistics for WPFs, for each class-study-agent combination.

TABLE 3.—DESCRIPTIVE STATISTICS FOR WPF, BY CLASS, STUDY AGENT

	CL1.26.Cd	CL2.22.Pb	CL2.23.Pb	CL2.24.Si	CL2.3.BAP	CL2.5.Asb	CL3.27.EBZ
Curve Label	1	2a	2b	2c	2d	No curves	3
Median	2,972.97	127.88	155.29	3,553.72	1,788.32	156.00	11,935.87
Range	25,186.05	1,040.75	6,131.76	95,518.07	8,203.89	537.00	4,746,673.83
Minimum	53.70	22.58	28.24	36.31	371.49	66.00	1,152.26
Maximum	25,239.75	1,063.33	6,160.00	95,554.38	8,575.38	603.00	4,747,826.09
No. Observations (N)	33	46	43	59	20	7	58
5th Percentile	280.25	27.82	35.03	92.07	388.70	70.50	1,797.79
10th Percentile	581.87	53.04	43.08	267.60	407.51	75.00	2,365.29
Reject Lognormality?	No	No	No	No	No	No	Yes
Geometric Mean	2,523.49	126.85	184.69	2,765.75	1,408.10	151.95	15,623.81
Geometric Stan. Dev	3.56	2.28	3.21	6.33	2.50	2.54	5.56
	CL4.21.Si	CL4.6.Pb	CL5.18.Pb	CL5.21.Si	CL6.19.Si	CL7.25.Sr	CL7.28.Si
Curve Label	4a	4b	5	No curves	6	7a	7b
Median	48.67	438.60	7,948.14	85.44	9,178.81	3,827.16	2,480.55
Range	176.27	2,310.33	73,081.90	189.92	34,735.48	87,137.82	33,384.67
Minimum	16.40	23.00	579.04	24.75	668.34	41.67	43.33
Maximum	192.67	2,333.33	73,660.94	214.67	35,403.82	87,179.49	33,428.00
No. Observations (N)	7	25	53	4	15	21	52
5th Percentile	17.20	107.06	1,779.12	29.10	1,407.60	74.07	188.14
10th Percentile	18.00	160.95	2,300.18	33.50	2,229.66	79.37	383.47
Reject Lognormality?	No	No	No	N too small	No	No	No
Geometric Mean	49.20	400.34	8,319.09	76.10	7,389.62	2,315.04	2,066.00
Geometric Stan. Dev	23.60	2.81	3.03	25.60	2.92	9.99	4.02

The objective of the review of these 13 WPF studies was to see what can be learned about the performance of each respirator class, and its relative effectiveness, based on the data for Co and Ci. He also attempted to determine how Ci changes as Co changes, and what factors affected this relationship.

Brown found too much unexplained variability between study outcomes, even within the same respirator class and within similar ranges of Co, to make valid and reliable comparisons. He noted that study outcomes for the same class of respirator may differ significantly, which raised concerns about interpreting the outcome for a class from a single study. More specifically, he questioned whether the results from one study would be similar

to another study. He concluded that it is not possible to know to what extent the outcome of a study is attributable to characteristics of the respirator used.

Brown believed that the variability identified in this analysis was probably due to uncontrolled parameters in the workplace test situations, such as aerosol particle size distributions and densities, and work activities. Based on the data from these studies, he found that WPF tends to increase as Co increases (equivalently, penetration, or PEN., tends to decrease). He believed that the probability of a Co dependence for WPFs seemed to be established by his analyses.

C. Analyses of SWPF Studies

1. Bullard Models 77 and 88, Clemco Apollo Models 20 and 60, and 3M Whitecap II

In the mid-1980s, SWPF studies provided OSHA with information on the effects of temperature, relative humidity, airflow, and facial hair on respirator performance (LANL, 1988; Ex. 1–64–101, LLNL, 1986; Ex. 1–64–94). More recent SWPF studies provided additional information on the performance of the following abrasive blasting respirators: the Bullard Models 77 and 88 (Ex. 3–8–3), the Clemco Apollo Models 20 and 60 (Ex. 3–7–3), and the 3M Whitecap II (Ex. 3–9–2).

OSHA contracted with Mr. Harry Ettinger to review and comment on the study principles and protocols described in the five reports (Bullard, Clemco, 3M Whitecap, the LLNL study, and the LANL study). His report (Ex. 3–3) contained the following observations and conclusions.

Mr. Ettinger noted that while the reports do not satisfy the typical criteria for defining peer-reviewed publications, this was not a serious problem because the studies were conducted in national laboratories by knowledgeable and experienced investigators. Furthermore, the review procedures generally used by these national laboratories most likely provide a sufficient peer-review process. He noted that none of the reports provided sufficient detail to permit a statistical re-analysis of the data by OSHA. In addition, he observed that the studies of the Bullard, Clemco, and 3M respirators reported considerably higher fit factors than the 1986 and 1988 national laboratory studies. However, he believed that it was not appropriate to compare the results of recent studies with the older studies, but he noted that older respirators may not perform as well as newer designs.

Mr. Ettinger also noted that the tests of the Bullard, Clemco, and 3M respirators satisfied the established criteria of fit factors that exhibited only brief negative pressure spikes. He believed these results indicated that if these devices are used and maintained properly, they appear to have fit factors of at least 20,000. He believed that, using a safety factor of 20, a protection factor of 1,000 is attainable, assuming that the testing protocol is adequate.

Ettinger stated that he could not define clearly a relationship between the older and more recent study results. For example, he suggested that the additional exercises in the more recent study (ORC, 2001; Ex. 3–4–2) did not adequately represent normal or extreme work situations. Ettinger cautioned against assuming that all blasting helmets would achieve the high fit factors measured in the recent studies because performance is device specific, and indicated that older respirator designs may need to be reevaluated. Furthermore, he believed that quality control, human factors, minimum flow rate, and the sturdiness of respirator construction are important variables that should be evaluated in the testing protocol.

2. NIOSH N95 Study

In 1999, NIOSH conducted a chamber study of 21 N95 respirators (20 filtering facepiece, and 1 elastomeric, respirators) and statistically analyzed the respirators' performance (Ex. 4–14). At the request of OSHA, Drs. Johnson, Foote, and Bierman of LLNL undertook a review of this study to assist the Agency in evaluating APFs of half-mask respirators (Ex. 3–2). OSHA provided the raw data files from the study to LLNL for independent evaluation.

The NIOSH investigators used ambient (*i.e.*, room) aerosol as the challenge agent, and a PortaCount to measure respirator penetration. Use of ambient aerosol does not require aerosol generation equipment, thereby circumventing use of a possibly hazardous chemical. However, if this technique generates a low ambient particle concentration it is difficult to detect the reduced number of particles that penetrate the respirator; this effect results in an artificially low protection factor. In addition, an ambient aerosol that is varying in concentration during testing can cause error in the penetration measurements. Study participants can also produce aerosols ranging from 0.1 to 3 particles/cc through their breathing (*i.e.*, ''breathing'' background). Whenever the amount of challenge agent that penetrates the respirator is low (*i.e.*, on the order of particles/cc or less), the PortaCount cannot distinguish between particles in the breathing background and the challenge aerosol penetrating the respirator. The LLNL researchers believed that the breathing background can limit fit factor measurements to 1,000 and less when the challenge concentration is below 2,000 particles/cc (Ex. 4–15). They concluded that challenge aerosol concentrations can be better controlled in chamber studies than under this protocol.

When calculating faceseal leakage, the NIOSH authors assumed that all study participants have the same constant volumetric flow rate through the respirator. Using a filtration model developed by Rubow (Ex. 3–7–3), the LLNL reviewers determined media penetration that was approximately 5% less than the media penetration calculated by the NIOSH authors using the constant flow rate assumption. Since the method used by the NIOSH authors results in only a 5% error, and gives a conservative estimate of the filter penetration, the LLNL reviewers believed that the constant flow rate assumption is reasonable. The LLNL reviewers also discussed other considerations, including fluctuations in peak flows under various exercise conditions, and the correction factor for filter media penetration used by the NIOSH authors.

Investigating the possible effect of breathing background on the PortaCount fit factor measurement, the LLNL reviewers applied an estimated worst-case scenario to the data. The scenario consisted of the following two assumptions: (1) A challenge aerosol concentration of 3,000 particles/cc, and (2) a breathing background of 5 particles/cc. Applying these assumptions to the NIOSH data, the LLNL reviewers recalculated total penetrations, and adjusted the results for breathing background. They found that, when compared to the NIOSH results, 14 of the 21 respirators had more tests passing the 0.01 penetration criteria than before. The LLNL reviewers also calculated the 50th and 95th percentiles for the penetration data, both with and without applying the breathing background assumption. In view of their results, they believed that the original NIOSH analysis and findings result in a conservative estimate of the respirators' performance.

The LLNL reviewers also used the NIOSH raw data to reproduce values, geometric standard deviations, and the 95th percentile for total penetration, filter penetration, and face seal leakage. They then compared these results to total penetration and face seal leakage penetrations summarized in the NIOSH study (Exs. 4–1, Table 2; 4–14, Table I).

The few discrepancies were small, and could be attributed, for example, to rounding off values. The 95th percentiles in the NIOSH study were based on a formula using the geometric mean and geometric standard deviation, and assumed that the distribution was log normal. For comparison, the reviewers calculated the 50th and 95th percentiles based on the raw data alone (*i.e.*, assuming no distribution). Using this approach, the LLNL reviewers noted that, for many respirator models, the 50th percentile differed markedly from the geometric mean. They also saw differences between the 95th percentile calculated using a log normal distribution and the corresponding percentile determined directly from the data. LLNL reviewers stated that the NIOSH study demonstrated the advantages of SWPF studies for half-mask respirators. Their results confirm the quality of this important SWPF study of filtering facepiece and elastomeric half-mask respirators.

3. ORC Study of PAPRs and SARs

In 1997, ORC and a group of its member companies sponsored a study of 11 powered air-purifying and supplied-air respirators (PAPRs and SARs) to evaluate the protection that these respirators afforded to workers in the pharmaceutical industry. The study, ''Simulated Workplace Protection Factor Study of Powered Air Purifying and Supplied Air Respirators' (Ex. 3–4–1) was completed in 1998 by researchers at LLNL. OSHA requested Dr. Gerry Wood of LANL to evaluate ORC's LLNL study. He evaluated the study using the data received from ORC, as well as information on the study published in the American Industrial Hygiene Association Journal (Exs. 3–1, 3–4–2).

The raw data files from the study consisted of instantaneous (0.1 second) photometer aerosol measurements obtained before, during, and after 12 exercise periods (including four periods of normal breathing) performed by each study participant. The instantaneous penetration results for the 144 tests were plotted against time. Wood examined patterns of aerosol penetration into the respirator that occurred throughout testing, noting that certain exercises often exhibited penetration spikes. He found that running in place produced the most penetration spikes. However, he also noted other respirator/subject combinations result in spikes. Wood indicated that such non-random distributions of readings was not surprising, as different movements during an exercise should affect instantaneous penetrations differently.

Wood calculated 95% confidence limits for the average and maximum penetration values during each exercise. In doing so, he assumed that pre-test and post-test background, and chamber aerosol measurements were distributed normally, since no movement variables were present. He then calculated aerosol penetration. Wood found that the photometer reading averages and standard deviations that he analyzed for all 144 data sets were in agreement with the LLNL figures, and that rounding off figures accounted for any minor differences in average penetrations that he calculated.

In summary, Dr. Wood believed that the quality of the data, experimental protocol, measurements and data, and calculations applied to the data in the ORC–LLNL study were excellent. He agreed with the authors' conclusions that SWPF studies are useful for comparing respirators, and that the study protocol was reproducible.

D. OSHA's Overall Summary Conclusions

Prior to this current rulemaking, OSHA explored several procedures to evaluate and compare respirator performance across models, studies, agents, and testing protocols. The Agency thoroughly reviewed the available data on respirator performance to determine the current concepts, and possible methodologies, for deriving APFs. To evaluate the data, OSHA had to make several decisions.

For example, while OSHA was aware that particle size can affect concentration values, the Agency was unable to quantify this factor based on available information. Consequently, OSHA did not attempt to adjust for differences in particle size in the analyses. Furthermore, the Agency had to decide how to address sampling results that were below the limit of detection (LOD). Accordingly, whenever sampling results were below the limit of detection, OSHA set the Ci at a percentage of the LOD reported in the study. When the study reported extremely low Ci results as a percentage of the LOD, the Agency used the values provided by the authors.

OSHA was concerned that the analyses be those best able to account for parameter uncertainty, and be a measure of respirator effectiveness that is valid over a plausible range of concentrations for each of the agents against which the respirator is to be used. As discussed above, the Agency contracted with Drs. Nicas and Brown to independently evaluate the raw WPF data. As a result of these analyses, OSHA preliminarily agrees with Drs. Rappaport and Kupper, who indicated that, while some modeling may be useful, concerns remain regarding the lack of model validation (Ex. 1–182–1). Furthermore, OSHA finds merit in Thomas Nelson's comment that a simple analysis of the entire data may sufficiently cover the relevant sources of variation in these data (Ex. 1–174). Databases of the information used by the Agency in its analyses have been placed in the docket for review by interested parties (Exs. 5–3, 5–4, 5–5).

The Agency also recognizes that WPF and SWPF studies have their strengths and weaknesses. SWPF studies can control for a number of variables, thus providing less variable results across respirators classes than WPF studies. Also, SWPF studies can test respirators safely at the limits of their effectiveness. However, WPF studies evaluate respirators during use in the workplace. Therefore, the Agency believes that WPF or SWPF studies provide complementary information.

OSHA developed the proposed APFs using a multi-faceted approach. The Agency reviewed the various analyses of respirator authorities, available WPF and SWPF studies, and other APF literature. For example, OSHA reviewed Brown's analyses and noted no difference in performance between filtering facepiece and elastomeric half-mask APRs, and that few data pairs from the combined data sets analysis failed to achieve a WPF of 10. In addition, the data from WPF and SWPF studies, as well as a qualitative review of the available APF literature, supported an APF of 10 for all half-mask APRs. Therefore, OSHA is proposing an APF of 10 for half-mask APRs. The Agency used a similar approach in developing the remaining proposed APFs.

In conclusion, the APFs proposed by OSHA in this rulemaking represent the Agency's evaluation of all the available data and research literature; *i.e.*, a composite evaluation of all the relevant quantitative and qualitative information. The Agency seeks comment on this approach, as well as the proposed APFs developed using this approach.

E. Summaries of Studies

Researchers often determine the protection afforded by a respirator by conducting Workplace Protection Factor (WPF) studies and Simulated Workplace Protection Factor (SWPF) studies. A WPF study measures the effectiveness of respirators under workplace conditions. Workers participating in a WPF study wear respirators while performing their usual job tasks. The WPF is a measure of the reduction in exposure achieved while using respiratory protection and

is the ratio of the concentration of the contaminant found in the workplace air to the concentration found inside the respirator facepiece. Similarly, a SWPF study measures the ratio of a contaminant's concentration both outside and inside the facepiece. However, researchers obtain these measurements in test chambers, which allows them to control some important variables (*e.g.*, outside concentration of the challenge agent). Rather than performing the actual job tasks found in a particular work setting, the study participants perform a series of exercises in the test chamber that simulate the actions of workers in general.

In developing the proposed APFs listed in Table 1 of the proposed amendments to the standards (Section XII). OSHA reviewed data from properly conducted WPF studies and SWPF studies. In addition, the Agency reviewed published APF tables. These data formed the basis for OSHA's proposed APFs. OSHA also reviewed other types of studies, such as Effective Protection Factors (EPF) and Program Protection Factor (PPF) studies, along with respirator performance studies that lacked raw data. A review of those studies can be found in the Docket (Exs. 3–10, 3–11). However, EPF and PPF studies account for aspects of respirator use other than effectiveness of the respirator while it is being worn, while studies that lack raw data give little information for in-depth statistical analysis. Therefore, OSHA relied on WPF and SWPF studies, since they attempt to account for actual use conditions and focus on the performance characteristics of the respirator only.

1. WPF Studies—Filtering Facepiece and Elastomeric Half-Mask Respirators

Study 1B. C.E. Coulton, H.E. Mullins, and J.O. Bidwell gave a presentation at the May 1994 American Industrial Hygiene Conference and Exposition (AIHCE) on worker protection afforded by the same respirator in two different environments and against two different contaminants (Ex. 1–64–13). At the first site, the authors determined exposure to cadmium dust for 18 workers in a plastic colorant manufacturing facility. They determined exposure to lead fume for 18 workers during ship breaking and recycling at the second site. At the colorant facility, cadmium-containing pigments were weighed, mixed with plastic resin, and fed into extruders for production of concentrated colorant. Samples were obtained from workers in the weighing, mixing, and extruding areas. Workers at the ship breaking facility used torches to cut an aircraft carrier into large sections that were then cut into smaller pieces on shore. Burners and firemen, on the ship and on shore, were sampled for lead. Work rate at the colorant facility was judged to be low, while the work rate of the ship breaking workers was assessed as being moderate. The respirator used in the study was a 3M 6000 series elastomeric half-mask equipped with either 3M 2040 or 3M 2047 HEPA filters (the 2047 HEPA filter has some activated charcoal for removal of nuisance levels of organic vapors). Employees normally wore the study respirator and were provided with training in its proper donning, fitting, and operation. In addition, the employees had to pass a saccharin qualitative fit test prior to study participation; they also had to be clean-shaven. The study was explained to the participants and they were observed on a one-on-one basis throughout the sampling periods.

The inside-the-facepiece sampling train consisted of a 25 mm three-piece cassette with a 0.8 micron pore size mixed cellulose ester filter. Respirators were probed with a Liu probe inserted opposite the mouth and projecting one cm into the facepiece. The sampling cassette was attached directly to the probe, and a cassette heater was utilized to prevent condensation of moisture from exhaled breath. Outside-the-facepiece samples used a 25 mm three-piece cassette with a 0.8 micron pore size mixed cellulose ester filter. The outside sample cassette was also connected to a Liu probe, and this combination was attached in the worker's breathing zone. Inside samples and outside samples were collected at a flow rate of 2 Lpm. Respirators were donned and doffed, and sampling trains started and stopped, in a clean area. Field blanks were used for contamination evaluation. Particle size distribution was ascertained with a six-stage single-jet cascade impactor that sampled all day at 1 Lpm.

Samples were analyzed by inductively coupled plasma (ICP) spectroscopy. For both cadmium and lead, the authors presented the range of outside concentrations, inside concentrations, and the associated geometric means and standard deviations. Three sets of WPFs were determined for cadmium and lead, based on three different methods for reporting inside samples that were below the limit of detection (LOD) (*i.e.*, calculating WPF using 70% of the LOD; calculating WPF using the LOD; or eliminating these samples from the WPF calculation database). No field blank adjustments were made (*i.e.*, no cadmium or lead detected), and no mention is made of adjusting the data for pulmonary retention of particles. In addition, samples were invalidated as a result of equipment and procedural problems, and if the outside filter weights were less than 100 times the limit of detection (or 101 times the field blank value). The authors reported a mean WPF of 353, with a fifth percentile of 34, for the cadmium samples, and a mean WPF of 135, with a fifth percentile of 15, for the lead fume samples. The authors noted a sizable difference in WPFs for cadmium and lead (using the same respirator), and discussed a number of possible reasons for the difference (*e.g.*, differences in particle size, work environment, work rate). The authors concluded that the ANSI Z88.2–1992 recommended APF of 10 for half-facepieces was appropriate.

Study 1C. In a poster presentation at the 1992 AIHCE, C.E. Coulton and H.E. Mullins provided results of a study of several contaminants (Ex. 1–146). Exposure to iron (Fe), manganese (Mn), titanium(Ti), and zinc (Zn) were determined for shipyard workers involved with welding and grinding. The respirators studied were 3M 9920 and 3M 9925 dust/fume/mist disposable respirators.

At the Agency's request, 3M provided the raw data from the study, but the information provided had no discussion of sampling or analytical methodologies. However, in a brief abstract, the authors mention using blank samples and observing participants during sampling (in the context of discarding particular sample sets). Outside- and inside-the-facepiece concentrations, and associated WPFs, were provided for the four analytes: Fe (31 data sets), Mn (32 data sets), Ti (28 data sets), and Zn (32 data sets). Calculated WPFs ranged as follows: 24 to 1010 for Fe, 10.21 to 715 for Mn, 50.38 to 2545 for Ti, and 27.41 to 854.89 for Zn. Tom Nelson (Ex. 135) calculated a geometric mean (GM) of 147, a geometric standard deviation (GSD) of 2.5, and a best estimate fifth percentile of 33 for the 32 sample sets he used in evaluating this study. The information he provided contained no additional discussion of the results or study conclusions.

Study 1D. Workplace performance of an elastomeric half-mask against exposure to lead was reported in 1984 by S.W. Dixon and T.J. Nelson for 11 workers in an unidentified work environment (Ex. 1–64–19). The participants' work rate was judged to be moderate to heavy. Workers viewed a training program and selected from three mask sizes of a Survivair 2000 elastomeric half-mask respirator,

equipped with organic vapor/high-efficiency particulate filters. Participants were qualitatively fit tested with isoamyl acetate. Prior to participation, employees were quantitatively fit tested with a Dynatec/Frontier FE250A portable unit while wearing the Survivair with high-efficiency filters and performing six ANSI-recommended exercises. In addition, paired (before and after) quantitative fit tests were performed for about half of the WPF determinations to ascertain if quantitative fit tests can predict WPFs. Participants were instructed not to break the faceseal during sampling, and were observed throughout the sampling period.

Samples were collected on 25 mm 0.8 micron pore size polycarbonate filters, for 30 to 120 minutes (a complete job cycle) at a flow rate of 2 Lpm. Sampling trains were calibrated before and after each day's sampling, and respirators were disassembled, cleaned, and reassembled at the end of each day. The authors do not provide a more detailed discussion of the inside or outside sampling trains (*e.g.*, type of respirator probe, placement of outside sampling apparatus). Particle size analysis was performed using light microscopy and scanning electron microscopy.

Proton induced x-ray emission analysis (PIXEA) was used to analyze the samples. This method's limit of detection was 2 nanograms per sample. The authors provide an approximate particle aerodynamic diameter based on the particle size analyses. Inside-the-facepiece results were corrected for losses caused by the sample probe but were not corrected for lung deposition (which the authors believed caused only a small bias). Thirty-seven WPFs were determined; however, the individual data sets (*i.e.*, inside concentration, outside concentration, and associated WPF) were not provided. During the study, some participants were observed to break the faceseal to talk. The authors provide an overall range of WPFs achieved, GM, and GSD, for undisturbed facepiece samples and pooled disturbed and undisturbed facepiece samples. The authors reported a GM WPF of 3,400, and a best estimate of the fifth percentile of 390 when the facepiece was not disturbed, and a GM WPF of 2,400, and a best estimate of the fifth percentile of 160 when the facepiece was disturbed. The authors also found no correlation (at the 5% level) between WPF and outside concentration, or the relationship between WPF and quantitative fit factors for predicting workplace protection. The authors also estimated the program protection factor based on historical measures of air lead concentrations versus blood lead levels (a table and graph of this data was provided). They concluded that the half-mask respirator they tested provided WPFs that exceeded an APF of 10, and provided program protection factors (PPFs) that exceeded 10.

Study 2. Workplace protection against exposure to asbestos fibers (chrysotile and amosite) was reported at the 1985 AIHCE by T.J. Nelson and S.W. Dixon for 17 workers who removed asbestos-containing materials at two sites (Ex. 1–64–54). Six of these workers were removing asbestos fireproofing from a ceiling at the first site, while eleven workers at the second site were removing asbestos-containing pipe insulation. The participants' work rate was judged to be moderate, site temperatures ranged from 65–85 degrees Fahrenheit, and humidity was very high.

The following six brands of half-mask respirators were studied: 3M 8710 disposable dust/mist respirator; 3M 9910 disposable dust/mist respirator; American Optical R1050 disposable dust/mist respirator; Survivair 2000 elastomeric respirator with high-efficiency filters or DFM filters; MSA Comfo II elastomeric respirator with high-efficiency filters or DFM filters; and a North 7000 elastomeric respirator with high-efficiency filters. Participants were trained in respirator use by the investigators and were qualitatively fit tested using the saccharin fit test. Supplemental data indicate that participants wore one or more respirator brands. No mention is made of respirator donning and doffing procedures, or starting sampling trains in a clean area; however, the sampling procedures state pumps were stopped and cassettes removed in a dust-free area. Participants were observed by the researchers throughout the sampling period.

The inside-the-facepiece sampling train was a 25 mm closed-face three-piece cassette with a ½-inch extender, containing a 0.8 micron pore size mixed cellulose ester filter. The cassette was attached directly to a tapered probe inserted into the respirator midway between the nose and mouth. In-mask samples were collected at a flow rate of 2.0 Lpm. The outside-the-facepiece sampling cassettes and probes were identical to the inside-the-facepiece sampling train and were fastened to the lapel of the subject. Outside samples were gathered at 0.5 to 1.0 Lpm. Sampling times ranged from 30 to 120 minutes, and the pumps were calibrated before and after each sampling period. The authors investigated uniform deposition of asbestos fibers across the filters; they noticed a slight trend for heavier deposition at the filter center using both methods. They also computed the precision of sample gathering using open- versus closed-face cassettes and found no difference between the methods.

Asbestos analysis was based on NIOSH method P&CAM 239 and NIOSH method 7400 (*i.e.*, the filter mounting and ''A'' counting rules). To increase analytical sensitivity, the methodology was modified by counting fibers in a minimum of 500 fields per inside-the-facepiece filter when less than 100 fibers were counted. The actual number of fibers counted in each sample was used to compute the airborne concentration. In addition, one microscopist performed all fiber counting. The distributions of fiber length and diameter were determined by transmission electron microscopy using lapel sample filters. The GM and GSD values for the fiber length, fiber diameter, and equivalent aerodynamic diameter at each worksite and the combined data from both sites were reported, but the values for fiber density and the length-diameter correlation coefficient were not provided. A total of 84 pairs of inside and outside fiber concentrations, and corresponding WPFs, were provided by participant, respirator brand, and sampling period in supplemental data tables. However, the authors considered seven WPF values measured for the American Optical respirator as suspect because the inside-the-facepiece filter samples contained glass fibers, originating from the respirator's filter matrix. These glass fibers have the same appearance as asbestos fibers under light microscopy. The authors did not adjust measured values for field blank values (*i.e.*, blanks were below the limit of quantification) or fiber retention in the respiratory tract (*i.e.*, the authors believed that pulmonary fiber retention resulted in only a slight change in concentration inside the facepiece).

The 3M 8710 results showed a GM WPF of 310, a GSD of 5.3, and a best estimate of the fifth percentile of 20. The 3M 9910 had a GM WPF of 580, a GSD of 4.2, and a best estimate of the fifth percentile of 55. The AO R1050 had a GM WPF of 52, a GSD of 4.2, and a best estimate of the fifth percentile of 5. The Survivair 2000 or MSA Comfo II equipped with DFM filters had a GM WPF of 240, a GSD of 6.3, and a best estimate of the fifth percentile of 12. With high-efficiency filters, the GM WPF was 94, the GSD was 3, and the best estimate of the fifth percentile was 16. For the North 7700 equipped with high-efficiency filters, the GM WPF was

250, the GSD was 6.9, and the best estimate of the fifth percentile was 11.

Since the WPFs for respirators equipped with DFM and high-efficiency filters were similar, and were well below the protection expected if filter efficiency alone was the determining performance factor, the authors concluded that ''* * * filter efficiency was not as significant a factor in determining the relative workplace performance against asbestos as the face fit''. The authors also noted comparable performance between disposable and elastomeric respirators. With regard to this, the authors noted that perspiration and wetting solutions led to the elastomeric facepieces slipping on the participants' faces, something that was not noted with the fibrous disposable respirators. The authors postulate that the effect of this slippage could be a reason why the two types of respirators had similar performance.

Study 3. In 1993, A. Gaboury and D.H. Burd performed a WPF study by measuring exposure to benzo(a)pyrene [B(a)P] on particles among 22 workers in a primary aluminum smelter (Ex. 1–64–24). The participants were rack raisers, stud pullers, and rod raisers on anode crews. The following three brands of elastomeric half-mask respirator devices were studied: Willson, Survivair, and American Optical. (**Note:** Respirator model numbers were not provided) The respirators were equipped with combination organic vapor/acid gas cartridges and DFM pre-filters, with the exception that dust/mist pre-filters were used on the American Optical respirator. The study also examined the performance of a powered air-purifying respirator (PAPR), but only the negative-pressure, air-purifying half-mask respirator data are presented here (the PAPR results are discussed below). The participants had used respirators for several years, had been previously trained in the use of the particular respirator under study, and had used it for more than six months. All participants in half-mask respirators were clean-shaven and were quantitatively fit tested using the TSI Portacount. The minimum acceptable fit factor was 100. Industrial hygiene technologists assisted participants with donning and doffing respirators, cleaned and maintained the respirators at the end of each work cycle, and observed participants on a one-to-one basis throughout the sampling period. Participants were directed not to tamper with the respirator or sampling equipment. Due to the high heat in the work area, the employer required that employees rest in a cool environment for one-half hour during each hour.

The inside-the-facepiece sampling train consisted of a closed-face three-piece cassette with a 25 mm organic binder free glass fiber filter, backed with a cellulose ester pad. The sampling cassettes were connected to a tapered Liu probe inserted into the respirator between the nose and mouth. The outside-the-facepiece sampling train was identical to the inside-the-facepiece sampling train; however, no mention is made of connecting the cassette to a Liu probe. All filters were pre-calcined at 400 degrees Centigrade for 24 hours. Both inside and outside samples were collected at a flow rate of 2 Lpm for approximately 300 minutes, or one-half of the 10-hour work shift. Respirators and sampling trains were worn and operated until the employee entered the rest area; they were donned and started prior to leaving the rest area for the next work cycle. Sampling cassettes were plugged when not in use and the respirators were cleaned after each work cycle. Field blanks were used to identify possible contamination due to handling. Sampling train airflow rates were checked at the beginning, middle (*i.e.*, after lunch), and end of the work day; on changing the cassettes; and when a problem was suspected. Sampling occurred over a five-day period. Only stud pullers and rod raisers used the elastomeric half-mask respirators.

B(a)P analysis followed the Alcan Method #1223–84. The ambient B(a)P particle size distribution was determined by collecting four samples, as close as possible to the workers, using an 8-stage Anderson cascade impactor (Model 296). Impactor samples were collected for two to five hours at a flow rate of 2 Lpm. The average percent of B(a)P mass (across four samples) per impactor stage (defined by an aerodynamic diameter cut point, in micrometers) was reported. About 93% of the B(a)P mass was associated with particles having diameters of less than 9.8 micrometers. A total of 18 pairs of inside and outside sample concentrations, with associated WPFs, were provided by brand of respirator and job category, but were not linked to specific participants. Overall GM, GSD, and 95% confidence interval on the mean were also provided for the inside and outside concentrations and WPF, along with an overall fifth percentile WPF. The authors stated that some employees participated more than once during the study. No mention is made of adjusting inside-the-facepiece concentrations for particle retention in the respiratory tract. The half-masks had WPF ranging from 13 to 410, with a GM of 47. The two-sided 95% confidence intervals were 30 and 74 for the dual cartridge respirators. The fifth percentile was 9. The authors found no significant relationship between B(a)P concentrations inside and outside the facepiece. Also, while the data were limited, the authors believed no correlation existed between WPF and quantitative fit factor. The authors concluded that the fifth percentile for the half-masks they tested were in agreement with the APF of 10 recommended by the NIOSH RDL.

Study 6. S.W. Lenhart and D.L. Campbell reported in 1984 on a WPF study in which they measured protection against exposure to particulate lead (Pb) for 25 primary lead smelter workers; seven of whom worked in the sinter plant and eighteen of whom were in the blast furnace area (Ex. 1–64–42). The predominant aerosol forms of lead were dust in the sinter plant and fume in the blast furnace. In both areas, lead comprised about 50% of the total aerosol particulate with composition of the remaining 50% being unknown. All participants wore an MSA elastomeric half-mask with high-efficiency filters. (**Note:** No respirator model number was provided) The study also examined the performance of an MSA PAPR, but only data for the negative-pressure, air-purifying half-mask respirator are presented here (the PAPR results are discussed below). The employees routinely used respirators; however, no mention is made of them with respirator training. Participants were quantitatively fit tested using an unspecified method, and had to achieve the employer's required fit factor of 250. Workers were instructed not to remove or manipulate the respirator during sampling, and were observed by the researchers throughout the sampling period.

The inside-the-facepiece sampler consisted of a closed-face 37 mm cassette containing an AA filter and AP10 support pad. This cassette was connected to a tapered Liu probe that was inserted into the respirator between the nose and upper lip. In-mask samples were collected at 2 Lpm. The outside-the-facepiece sampling train was a closed-face 37 mm cassette containing an AA filter and AP 10 support pad; no tapered Liu probe was used. The outside sample cassette was attached to the worker's lapel. Outside samples were gathered at 2 Lpm. The authors collected samples for as much of each 8-hr work shift as possible. Respirators and sampling trains were donned and doffed, and samplers were started and stopped, in a lead-free area. Respirator facepieces were wiped clean inside

prior to donning after each break and cleaned and sanitized after each shift. One WPF was measured for each employee. The ambient particle size distribution was determined using 19 Marple cascade impactor samples (11 in the sinter plant; 8 in the blast furnace area).

Lead analysis was by flame atomic absorption spectroscopy according to NIOSH Method S–341. Inside-the-facepiece samples that contained less than l0ug of lead were reanalyzed by graphite furnace atomic absorption (limit of detection = 0.2 μg). The ranges for the mass median aerodynamic diameters (in micrometers) and for the GSD values were reported. A total of 25 pairs of inside and outside half-mask values, and the corresponding WPFs, were provided by employee, job title, and job location. An overall GM and GSD of the WPFs, and various percentile WPFs, were provided. When samples contained lead below the level of detection, the authors reported concentration values ''* * * determined from the least amount of lead detectable by the analytical method and the sampled volume of air.''

In-mask values were not adjusted for particle retention in the respiratory tract (the authors imply retention probably had a non-significant effect on results, but could result in overestimated WPFs). No mention is made of the investigators using field blanks. They reported that approximately 98% of the WPFs would be expected to be at or above 10, 90% above 30, and 75% would be expected to be above 100. They concluded that an APF of 10 was appropriate for the half-mask negative pressure air-purifying respirator evaluated in this study. The authors also discussed two proportional methods of defining an APF.

Study 7. W.R. Meyers and Z. Zhuang conducted a 3-part workplace protection factor study in three different work environments. In addition to presenting the study findings, the authors also discuss their rationale for selecting exposure agents, study facilities, and workers; study procedures followed at the sites; and analytical methods. W.R. Meyers and Z. Zhuang in January, 1993 (Ex. 1–64–51) and W.R. Meyers, Z. Zhuang, and T.J. Nelson in 1996 (Ex. 3–12) reported on the first part of the study in which the authors determined protection against exposure to particulate lead (Pb), zinc (Zn), and total airborne mass (TAM) for 25 workers, on day and evening shifts, in three brass foundries (3, 9, and 13 participants, respectively). (**Note:** The reports mention 26 participants, but data were presented for only 25 participants.) Four brands of half-mask devices were studied: 3M 9920 disposable DFM respirator; American Optical 5-Star elastomeric respirator with DFM filters (R56A); MSA Comfo II elastomeric respirator with DFM filters (Type S); and Scott Model 65 elastomeric respirator with DFM filters (642–F).

Participants were selected from volunteers who normally wore respirators, were clean-shaven, and passed a fit test. Their work rate was subjectively determined by observing their work activities. Respirators were worn for the usual period. For the elastomeric half-mask respirators, the participants were quantitatively fit tested using a TSI Portacount; a fit factor of 100 or more constituted a pass. Disposable respirators were fit tested using the saccharin qualitative fit test. The investigators trained the participants in the proper donning and adjustment of the respirators, and instructed them not to remove or lift the respirator from their face in the work area. Readjustment of the respirator had to be accomplished by sliding the facepiece on their face. Workers were observed throughout the sampling period. Each participant wore two or more respirator brands, and one WPF was measured per employee for each brand worn.

The inside-the-facepiece sampling train was a 25 mm closed-face cassette attached directly to a flared mouth probe, inserted into the respirator opposite the mouth. The cassette contained a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A 4.5 mm ring under the filter restricted airflow to an 18 mm circle in the center of the filter to keep deposition in an area that could be entirely covered by the proton beam used for sample analysis. A heating bonnet was slid over the outside of the cassette to minimize condensation of moisture from exhaled breath. Sampled air was then drawn through a moisture trap using a personal sampling pump operating at 2 Lpm. The outside-the-facepiece sampling train was a 10 mm nylon cyclone attached to 25 mm closed-face cassette (the cassette was not connected to a flared mouth probe). The cassette contained a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A 4.5 mm ring under the filter restricted airflow to an 18 mm circle in the center of the filter. This sampling train was attached in the lapel area and samples were collected at a flow rate of 1.7 Lpm.

Two separate samples were gathered during the shift, one during the first half and another during the second half. Individual WPFs were based on monitoring times of approximately one to four hours. Respirators were donned and doffed, and sampling trains were started and stopped, in a clean area. Elastomeric facepieces were cleaned and inspected at the end of each shift, but were not wiped out during the shift unless such wiping was a standard practice before the study (the authors noted that most of the time workers did not wipe out facepieces). Air-purifying filters (cartridges) and disposable respirators were changed at the end of each shift unless the employer's policy dictated more frequent changing. In addition, the mouth of the in-mask probe was plugged whenever the respirator was not being worn. Working (field) blanks and manufacturer's (media) blanks were used to determine possible contamination of filters due to handling or manufacturing. The investigators also washed the interior of the sampling cassettes to ascertain retention of sample particles on the cassette wall. The ambient particle size distribution was determined by PIXE 8-stage cascade impactor samples at several work locations in each foundry. These area samples were collected at roughly mid-chest to shoulder level of workers for approximately 1 hour, to prevent impactor overloading.

All samples were analyzed by proton induced X-ray emission analysis (PIXEA). The mass distribution of Pb, Zn, and TAM by particle aerodynamic diameter was graphically presented for all cascade impactor samples. Across the three foundries, 66 pairs of inside-the-facepiece and outside-the-facepiece concentrations, and the corresponding WPFs, were provided by job task, employee, brand of respirator, and analyte (Pb, Zn, and TAM). The authors did not adjust measured values for particle retention on sampling cassette walls since these losses appeared to be random, independent of collected mass, and of a negligible amount. No mention is made of correcting measured in-mask values for pulmonary particle retention. A foundry-specific average of the field blank loadings was used as a correction factor for estimating background and handling contamination for each foundry. Outside-the-facepiece samples were collected as respirable particulate, thereby providing respirable mass levels, while in-mask samples were collected as total particulate mass. The authors initially assumed that particles larger than 10 microns did not penetrate respirator faceseals; however, this was found to be incorrect after analyzing in-mask particle size. Therefore, to avoid comparison of dissimilar measurements, the investigators used particle size data

obtained by ambient sampling to convert the respirable mass levels to total mass levels (using Chimera/TSI Disfit software). The reported levels represent these total mass values, and form the basis of the reported WPF values. The authors also provide data and discussion on a number of sampling analyses, including GM concentration of analyte by job task, GM concentration of analyte for in-mask and ambient concentrations, particle size distribution by job category, GM WPF estimates by job category, GM WPF by respirator type, within shift sampling variation, and variation between foundries. For the pooled data from the three foundries, the 3M 9920 filtering facepiece had a 50% WPF of 108, a GSD of 5.2, and a fifth percentile estimate of 7. The AO half-mask had a 50% WPF estimate of 98, a geometric standard deviation (GSD) of 5.8, and a fifth percentile WPF of 5. The MSA Comfo II half-mask had a 50% WPF of 163, a GSD of 3.1, and a fifth percentile WPF of 26. The Scott half-mask had a 50% WPF of 94, a GSD of 4.8, and a fifth percentile WPF of 7. For all respirators a 50% WPF of 114, a GSD of 4.6, and a fifth percentile estimate of 9 was reported. The authors concluded that ''* * * dust-fume-mist (DFM) half-facepiece respirators, when conscientiously used, worn, and maintained, provided effective worker protection.''

Study 8. W.R. Meyers and Z. Zhuang in January, 1993 (Ex. 1–64–51) and W.R. Myers, Z. Zhuang, and T.J. Nelson in 1996 (Ex. 3–12) reported on the second part of the three-part study, which evaluated protection against exposure to particulate iron (Fe) for 16 workers in the sinter plant and basic oxygen process (BOP) facility of a steel manufacturing plant. In addition, exposure to particulate calcium (Ca) in the BOP facility was determined for one worker. The five brands of half-mask respirators studied were: 3M 8710 disposable dust/mist respirator; Gerson 1710 disposable dust/mist respirator; American Optical 5-Star elastomeric respirator with dust/mist filters (R30); MSA Comfo II elastomeric respirator with dust/mist filters (Type F); and Scott, Model 65 elastomeric respirator with dust/mist filters (642–D).

In general, each participant wore two or more brands, and one WPF was measured per employee per brand worn. One employee had one WPF determined for only one respirator brand. For the elastomeric half-mask respirators, the participants were quantitatively fit tested. A fit factor of 100 or more constituted a pass. Disposable respirators were fit tested using the saccharin qualitative fit test. The overall study and sampling protocols were discussed by the authors in the foundry portion of the investigation (*see* Study 7 discussion above). While not specifically discussed, it is assumed that the same sampling parameters used in the foundry study were in place during this particular study, unless the authors stated otherwise. These assumptions include: composition of the sampling trains was unchanged; individual WPFs were based on monitoring times of one to four hours; elastomeric facepieces were cleaned and inspected at the end of each shift but the insides were not wiped during the shift such wiping was the employer's standard practice before the study; air-purifying filter cartridges and disposable respirators were changed at the end of each shift unless the employer's policy dictated more frequent changing; and the in-mask probe mouth was plugged whenever the respirator was not being worn. In addition, it is assumed that the participants were clean shaven, normally used respirators, were trained in the proper donning and adjustment of the respirators, were instructed not to remove or lift the respirator from their face in the work area, and were observed throughout the sampling period.

The inside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A reducing ring under the filter restricted airflow to an 18 mm circle in the center of the filter to aid in PIXE analysis. A heating bonnet was slid over the outside of the cassette to minimize condensation of moisture from exhaled breath. This cassette was attached directly to a flared mouth probe, inserted into the respirator opposite the mouth. Sampled air was drawn through a moisture trap using a personal sampling pump operating at 1.5 Lpm. The outside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A reducing ring under the filter restricted airflow to an 18 mm circle in the center of the filter. The cassette was not connected to a flared mouth probe. This sampling train was attached in the lapel area and samples were collected at a flow rate of 1.5 Lpm. (Note: Unlike the foundry portion of the study, outside samples were collected as total mass rather than respirable mass samples.) Sampling pump flows were calibrated before and after each sampling period and pumps were monitored at approximately 15–20 minute intervals. Respirators were donned and doffed, and sampling trains were started and stopped, in a clean area. New cassettes were used for each sampling period. Working (*i.e.*, field) blanks and manufacturer's (media) blanks were used to determine possible contamination of filters due to handling or manufacturing. The investigators also washed the interior of the sampling cassettes to determine retention of sample particles on the cassette wall. The ambient particle size distribution was determined by PIXE cascade impactor samples. Personal impactor samples, rather than area samples, were collected at the steel mill sites (*see* foundry sampling procedures discussed above in Study 7).

Analysis for Fe and Ca on inside-the-facepiece filters was by proton induced X-ray emission analysis (PIXEA). Due to filter overloading, analysis for Fe and Ca on outside-the-facepiece filters was by atomic absorption spectroscopy. The mass distribution of Fe by particle aerodynamic diameter was tabulated for all cascade impactor samples. A total of 54 individual pairs of inside- and outside-the-facepiece concentrations, and the corresponding WPFs, were provided by shift and date, job category, employee, and brand of respirator. For 16 workers, the WPFs reported were based on the Fe data, while Ca data were used to calculate the WPF for one worker (flux unloader) in the BOP facility. Based on analytical information, the authors did not adjust measured values for particle retention on the walls of the sampling cassette. No mention is made of adjusting inside-the-facepiece values for particle retention in the respiratory tract. The average field blank mass loading was used as a correction factor for estimating background contamination. The 3M 8710 had a reported GM WPF of 377, a GSD of 3.7, and a fifth percentile WPF of 44. The Gerson 1710 had a reported GM WPF of 123, a GSD of 2.7, and a fifth percentile WPF of 24. The American Optical elastomeric half-mask had a reported GM WPF of 280, a GSD of 2.7, and a fifth percentile WPF of 56. The MSA Comfo II had a reported GM WPF of 427, a GSD of 4.3, and a fifth percentile WPF of 39. The Scott elastomeric half-mask had a reported GM WPF of 252, a GSD of 2.9, and a fifth percentile WPF of 45. The authors concluded that ''The 5th percentiles for the WPF distributions for each respirator or pooled data were greater than 20.''

The authors also provided data and discussion on a number of sampling analyses, including GM concentration of analyte and GM WPF by job task, GM concentration of Fe inside the facepiece

and ambient and GM WPF by respirator brand, and particle size distribution by job category. The authors stated that ''* * * half-facepiece respirators (maximum use concentration 10 times the PEL) were a suitable selection for the tasks included in this study.''

Study 9. In January 1993, W.R. Meyers and Z. Zhuang reported on the third part of their investigation, in which they determined protection against exposure to particulate titanium (Ti), chromium (Cr), strontium (Sr) and total ambient mass (TAM) for 22 workers who spray painted aircraft on day, evening, and night shifts (Ex. 1–64–52). The three brands of half-mask elastomeric respirators studied were the: American Optical 5-Star, MSA Comfo II, and Scott Model 65. All respirators were equipped with combination high-efficiency filter/organic vapor cartridges.

Twelve participants each wore two brands of respirator with a WPF determined for each brand worn; nine participants wore one brand of respirator and had one WPF determined; and one employee had one WPF determined for one respirator brand and two WPFs determined for another brand. The participants were quantitatively fit tested and a fit factor of 100 or more constituted a pass. The overall study and sampling protocol was discussed by the authors in the foundry portion of the studies, summarized in Study 7 above (Ex. 1–64–51). While not specifically discussed, it is assumed that the same sampling parameters were in place during this particular study as in the foundry study, unless the authors stated otherwise. These assumptions include: composition of the sampling trains was unchanged; individual WPFs were based on monitoring times of one to four hours; elastomeric facepieces were cleaned and inspected at the end of each shift but were not the inside was not wiped during the shift, unless such wiping was the employer's standard practice before the study; filters and disposable respirators were changed at the end of each shift unless the employer's policy dictated more frequent changing; and the mouth of the in-mask probe was plugged whenever the respirator was not being worn. In addition, it is assumed that the participants were clean-shaven, normally used respirators, were trained in the proper donning and adjustment of the respirators, were instructed not to remove or lift the respirator from their face in the work area, and were observed by the researchers throughout the sampling period.

The inside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A reducing ring under the filter restricted airflow to an 18 mm circle in the center of the filter to aid in sample analysis. A heating bonnet was slid over the outside of the cassette to minimize condensation of moisture from exhaled breath. This cassette was attached directly to a flared mouth probe, inserted into the respirator opposite the mouth. Sampled air was then drawn through a moisture trap using a personal sampling pump operating at approximately 2 Lpm. The outside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.5 micron pore size polyethylene filter and polypropylene backup pad. A reducing ring under the filter restricted airflow to an 18 mm circle in the center of the filter. The cassette was not connected to a flared mouth probe. This sampling train was attached in the lapel area, and samples were collected at a flow rate of 1 Lpm. (**Note:** Unlike the foundry portion of the study, outside samples were collected as total mass rather than respirable mass samples.) Sampling pump flows were calibrated before and after each sampling period and pumps were monitored at approximately 15–20 minute intervals. Respirators were donned and doffed, and sampling trains were started and stopped, in a clean area. New cassettes were used for each sampling period. Working (*i.e.*, field) blanks and manufacturer's (media) blanks were used to determine possible contamination of filters due to handling or manufacturing. The investigators did not wash the interior of the sampling cassettes to determine retention of particles on the cassette wall, since a simple alcohol wash would not have removed dried paint spray. Ambient particle size distributions were not characterized.

Analysis of all filters was by proton induced X-ray emission analysis (PIXEA). The average field blank mass loading was used as a correction factor for estimating background contamination. The authors did not mention adjusting inside-the-facepiece measured values for particle retention in the respiratory tract. A total of 36 individual pairs of inside-the-facepiece and outside-the-facepiece concentrations of each analyte (total airborne mass, titanium, chromium, strontium) were provided by shift and date, painting location on the plane (*i.e.*, top, side, or underside of the aircraft), employee, brand of respirator, and paint type (*i.e.*, top coat, primer). A total of 36 WPFs were reported by shift, task location on the plane, employee, and respirator brand; of the original 38 data sets, two sets were eliminated as outliers. For primer spraying, the reported WPFs were based on Cr data, while WPFs for spraying topcoat were based on Ti data. WPFs were not calculated for total airborne mass. The authors also provided data and discussion on a number of sampling analyses, including GM concentration of analyte (TAM, Ti, Cr) for both in-mask and ambient measurements by task location on the plane; GM WPF as a function of painting location on plane and paint type, and respirator brand; and GM WPF by respirator brand. The fifth percentile estimates for all WPF data were reported to be much greater than 10. The authors concluded that these half-facepiece elastomeric respirators, when properly worn and used in conjunction with existing controls provided effective worker protection.

Study 13. G. Wallis, R. Menke, and C. Chelton reported in 1993 on a WPF study in which they evaluated exposure to manganese dioxide dust for an unknown number of participants in several alkaline battery manufacturing plants (number of plants not provided) (Ex. 1–64–70). All participants wore the disposable 3M 8710 dust/mist respirator and performed their normal work activities. The participants were not trained by the investigators, but had been previously trained and routinely used respirators. It was not stated whether the participants had ever been fit tested for the 3M 8710 respirators. Prior to sampling, the participants washed their faces and were taken to a clean area, where the study was explained. The participants were observed throughout the sampling period.

The inside-the-facepiece sampling train was a closed-face 37 mm cassette containing a 0.8 micron pore size mixed cellulose ester filter. The cassette was connected to a tapered Liu probe (made of nylon) which was inserted into the respirator midway between the nose and mouth. The outside-the-facepiece sampling train was a closed-face 37 mm cassette containing a 0.8 micron pore size mixed cellulose ester filter. The outside sampling cassette was attached to the employee's lapel. No mention is made of connection of the outside cassette to a tapered Liu probe. Inside- and outside-the-facepiece samples were collected at an airflow rate of 1.5 Lpm for 30 to 40 minutes. The authors chose a short sampling interval to prevent resistance across the inside-the-facepiece sampling filter due to a buildup of moisture from exhaled breath. Sampling pump flows were

calibrated before, and rechecked after, each sampling period. Respirators were donned and doffed, and the sampling trains started (and assumed stopped), in the clean area. Field blanks were used to identify possible contamination of filters due to handling. The number of sample pairs collected per subject was not specified. The ambient manganese particle size distribution was determined by 6-stage Marple Cascade impactor equipped with an inlet cowl to prevent debris from entering the impactor. Samples were collected for several hours at a flow rate of 2 Lpm, and flows were calibrated before and after each sampling interval. Four samples were gathered: One in the powder drop area (Plant A) and three at the bag slitting operations (one in Plant A, two in Plant B).

Samples were analyzed for Mn by atomic absorption (AA) spectroscopy according to NIOSH Method 7300. The mass distribution of Mn by particle aerodynamic diameter was tabulated for all cascade impactor samples. Less than 30% of the mass was associated with respirable particles. A total of 70 individual pairs of inside-the-facepiece and outside-the-facepiece concentrations, and the corresponding WPFs, were provided by job activity (but not by employee or plant). No mention is made of adjusting measured values for particle retention in the respiratory tract or results of field blank analysis. A GM of 50 and a GSD of 3.5 was reported for all the WPF values measured. A calculated fifth percentile protection factor of 7.5 was also reported. The authors reported that their data indicated a systematic dependence of WPF on the concentration outside the respirator. In their discussion of this observation, the investigators refer to three possible causes presented by authors of other studies: Program protection factors tend to be low in low exposure settings since the workers, aware of the low exposure, exercise less care; low outside concentrations result in inside-the-facepiece concentrations so small that reliable quantification is difficult; and filter efficiency increases with loading, and low concentrations do not adequately load the filter. The authors discuss these causes relative to their study results, and postulate that another cause may be particle size selectivity (*i.e.*, smaller particles have a higher probability of entering the respirator). They conclude that it is important to characterize respirator performance in the environment where the respirator will be used.

Study 14. At the 1990 AIHCE, C.E. Colton, A.R. Johnston, H.E. Mullins, C.R. Rhoe, and W.R. Meyers presented a WPF study in which they measured protection against exposure to aluminum dust for five participants working as carbon changers in an aluminum smelter (Ex. 1–64–15). All participants wore the disposable 3M 9906 dust/mist respirator. The investigators trained the participants in donning the respirator and the participants were qualitatively fit tested, although the fit test method was not described. The total number of samples collected per employee was not specified, although it is stated that the five employees were sampled daily for five days. Participants were observed throughout the sampling period.

The inside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.8 micron pore size polycarbonate filter. The cassette was connected to a tapered Liu probe, inserted into the facepiece in an unspecified location. In-mask samples were collected at an airflow rate of 2.0 Lpm. The outside-the-facepiece sampling train was a closed-face 25 mm cassette containing a 0.8 micron pore size polycarbonate filter. Outside samples were gathered as respirable dust samples with the cassette being connected downstream from a cyclone apparatus. Sampling airflow rate was 1.7 Lpm. Sampler airflow rates were calibrated before and after each sample period. No mention is made of donning and doffing procedures. Field blanks were used to identify possible filter contamination caused by handling. The ambient aluminum particle size distribution was determined through 12 area samples (unspecified locations) collected by Marple personal cascade impactors. In addition, particulates that passed a cyclone selector were sized by optical microscopy.

Aluminum was determined by proton induced x-ray emission analysis (PIXEA). The mass distribution of aluminum by particle diameter and percent penetration to the collector was graphically presented. Final calculations used only those outside filter weights that were greater that 11 times the detection limit. A total of 24 time-weighted-average (TWA) inside-the-facepiece and outside-the-facepiece concentrations, with corresponding TWA WPFs, are provided in supplemental data (Ex. 1–146). The sample pairs are not linked to specific participants. No mention is made of adjusting sample results for particle retention in the respiratory tract. The mean blank value was zero, so no adjustment to measured values was made. The authors reported a GM of 27, a GSD of 1.5, and a fifth percentile of 13 for the 23 sample sets used. The report concluded that the respirator provided reliable WPFs of 10. Cumulative probability of achieving a particular WPF, and the effect of filter weight on WPF, were also graphically presented. The authors stated that the WPFs represented conservative estimates of protection since outside concentrations were measured as respirable dust. In the summary of this study (Ex. 1–146), submitted to OSHA along with the raw sampling data, the authors recommended that the study not be used to assess the ultimate APF for this class of respirator since they felt that the real WPF of the respirator was significantly underestimated.

Study 15. C.E. Colton, H.E. Mullins, and C.R. Rhoe presented a WPF study at the 1990 AIHCE in which they determined exposure to particulate Pb and Zn for 17 participants working in core making, mold making, pouring, and cleaning areas of a brass foundry (Ex. 1–64–16). All participants wore the disposable 3M 9970 high-efficiency respirator. The investigators trained the participants in the proper donning and fitting of the respirator, and participants were fit tested using the saccharin qualitative fit test method described in Appendix D of OSHA's Lead Standard (29 CFR 1910.1025). Sampling took place over five days.

The inside-the-facepiece sampling train was a 25 mm three-piece cassette containing a 0.8 micron pore size polycarbonate filter (open- versus closed-face was not specified). The cassette was directly connected to a tapered nylon Liu probe, inserted into the facepiece midway between the nose and mouth. The inside-the-facepiece samples were collected at a flow rate of 2.0 Lpm. The outside-the-facepiece sampling train was a 25 mm three-piece cassette containing a 0.8 micron pore size polycarbonate filter. Outside samples were gathered as respirable dust samples, with the cassette being connected downstream from a 10 mm nylon cyclone. Samples were collected at a flow rate of 1.7 Lpm, and sampling pumps were calibrated before and after each sample. The authors do not mention using of field or manufacturer's blanks, respirator donning and doffing procedures, or methods of starting and stopping sampling trains in a clean area. The ambient Pb and Zn particle size distributions were determined by an unspecified number of Marple personal cascade impactor (Model 2401) samples.

Pb and Zn were determined by proton-induced x-ray emission analysis (PIXEA). The particle size data were not presented; however, the report stated that the Pb and Zn aerosols were present as both dust and fume. The range of

outside-the-facepiece and inside-the-facepiece concentrations for Pb and Zn were provided. For the purpose of WPF calculation, inside-the-facepiece samples with non-detected concentrations were treated as containing analyte at the detection limit (This situation only arose with lead, not zinc). For the 62 sample sets taken for lead, the GM WPF was 415, the GSD was 4.4, and the fifth percentile WPF was 36. For zinc, the GM WPF was 681, the GSD was 5.6, and the fifth percentile WPF was 40. The authors believe they handled their results conservatively since outside concentrations were collected as respirable particulate, rather than total mass, and inside-the-facepiece samples with non-detected concentrations were given values of the analytical detection limit when calculating WPF. In the study summary, the authors concluded that when the respirator is properly selected, fit tested, and used, their results supported its use for concentrations up to 10 times the PEL.

Study 16. A.R. Johnston and H.E. Mullins reported at the 1987 AIHCE on a WPF study in which they measured exposure to particulate aluminum (Al), titanium (Ti) and silicon (Si) for three participants working in the polishing and grinding area of an aircraft components manufacturing facility (Exs. 1–64–34, 1–146, 1–133). Although WPFs were also measured for two other participants, one in the blasting area and one in the coating area, no data were presented for these employees. All participants wore the disposable 3M 8715 dust/mist respirator. Prior to testing, the investigators trained the participants in the proper fitting of the respirator, fit tested the employees using the OSHA Lead Standard's saccharin qualitative fit test method, and explained the study to them. Participants had previously worn respirators, but on an ''as needed'' or elective basis only. Employees were observed one-on-one throughout the sampling period. The number of WPFs measured per subject was not specified, although it appears that about six WPFs were measured per subject.

The inside-the-facepiece sampling train was a closed 25 mm three-piece cassette containing a polycarbonate filter. The cassette was connected to a tapered nylon Liu probe that was inserted into the facepiece at an unspecified location. Inside-the-facepiece samples were collected at a flow rate between 1.5 and 2 Lpm. The outside-the-facepiece sampling train was a closed 25 mm three-piece cassette containing a polycarbonate filter. The cassette was connected downstream from a tapered Liu probe. Outside samples were collected at a flow rate between 1.5 and 2 Lpm. Sampling times ranged from 35 to 235 minutes. Sampling pumps were calibrated three times a day—at the beginning of the shift, lunch, and the end of the shift. Sampling equipment was removed for breaks, which occurred multiple times in some instances. While no mention is made of using a clean area to don and doff respirators, and start and stop sampling trains, the authors noted that cassettes had to be removed in the work area. Field blanks were used to identify possible filter contamination due to handling. The ambient particle size distribution was not characterized.

Samples were analyzed by proton induced x-ray emission analysis (PIXEA). Sample results were adjusted for field blank values, but no mention was made of adjustments for particle retention in the respiratory tract. The authors rejected sample sets in which: the outside filter weight was less than 11 times the mean blank value; the inside filter weight was non-detectable, or less than the mean field blank value; or the measured WPF was determined to be an outlier (*i.e.*, too far above or below the geometric mean WPF using 5% confidence intervals). A total of 38 sample sets were accepted for Al (10), Ti (14), and Si (14). Pairs of inside-the-facepiece and outside-the-facepiece concentrations, and the corresponding WPFs, are provided in supplemental data (Exs. 1–146, 1–133), but were not linked to specific participants. Also, a table of GM WPF, GSD, and fifth percentile WPF, by analyte, was presented. The authors calculated WPF values for the 10 sample sets of Al, reporting a GM of 145, a GSD of 2.3, and a fifth percentile of 32. For the 14 sample sets measured for Ti, the GM was 59, the GSD was 1.7, and the fifth percentile was 24. For Si, using 14 sample sets, the GM was 172, the GSD was 3.1, and the fifth percentile was 24. The authors concluded that their study supports using this respirator for concentrations up to 10 times the PEL. In addition, the authors noted a positive correlation between filter weight and WPF. Two explanations put forth for this effect were that respirators work better with higher dust loadings, and that WPF measurements are more accurate at higher dust loadings. The authors favored the latter explanation, and believed that to assess true respirator performance capabilities, testing should be conducted at or near the respirator's APF, or a filter weight versus protection factor curve should be defined for predicting performance at higher concentrations. In a summary of this study submitted to OSHA (Ex. 1–146) the authors stated that:

> * * * the mass outside the respirator was very low. For this reason, the ability of the respirator to provide protection was not challenged. Therefore, this study should not be used for direct comparison to others in assigning protection factors as they are artificially low.

The authors also discussed sampling and analytical considerations for WPF studies, such as calibration reliability, sample cassette integrity, analytical sensitivity, and sample handling procedures.

2. WPF Study—Full Facepiece APR

Study 2A. C.E. Colton, A.R. Johnston, H.E. Mullins and C.R. Rhoe of the 3M Occupational Health and Environmental Safety Division in May,1989 gave a presentation at the AIHCE on their WPF study (Ex.1–64–14) performed with full facepiece air-purifying respirators worn in a secondary lead smelter. Air sampling for lead was conducted over 5 days in four areas of the plant; the blast furnace, reverberatory furnace, casting, and warehouse areas.

The respirator evaluated was the 3M 7800 Easi-Air full facepiece respirator used with 3M 7255 high efficiency filters. The respirator was equipped with a nosecup inside the facepiece. The sampling probe was inserted into the respirator in place of the speaking diaphragm to assure a gas tight seal and consistent probe location close to the breathing zone of the wearer. The respirators were equipped with sampling probes using a design by Dr. Ben Liu to minimize particle entry losses. Both the inside and outside sampling trains used the Liu designed probe for consistency.

Thirteen workers who normally wore full facepiece respirators in the plant qualified to participate in the study. They were trained in proper respirator use, the procedures to be followed for the study, and how to don and fit the 3M respirator. Quantitative fit testing was performed using the Portacount QNFT instrument and fit test operators followed the OSHA Lead standard exercise protocol for fit testing. The workers were fit tested wearing their normally required personal protective equipment (PPE), and care was taken to assure that this additional PPE did not interfere with facepiece fit. The criterion the authors used for passing the QNFT was a minimum fit factor of 500; 10 times the assigned protection factor of 50 given in the lead standard for a full facepiece negative pressure respirator. The 13 qualified workers were measured for face length and width, and

all the workers except 1 were in Grids 1–4 of the Los Alamos Test Panel. The one remaining worker's his face was wider than those accommodated by the Los Alamos Test Panel.

Samples were analyzed by proton induced x-ray emission analysis (PIXEA) for lead. The authors reported that for PIXEA the sensitivity is good, typically 10 nanograms per sample. Area samples for particle size analysis were also collected, using Marple cascade impactors, in the reverberatory furnace, casting, and warehouse areas. Three particle size ranges were found; less than 1 μm (15% of the total aerosol), between 1 to 10 μm (20% of the total aerosol), and greater that 10 μm (65% of the total aerosol). The particle size distribution showed that both lead dust and lead fume were present.

The authors had pre-established that if the outside filter weights were less than 51 times the field blank value, the sample set would be rejected. The authors stated, ''You need at least this much differential between inside and outside samples if you want to prove or disprove that a respirator provides a PF of 50.'' None of the workplace samples were rejected for being less than 51x the field blank value. However, several sample sets were rejected for other reasons such as the inside sample coming loose from the probe, sample pump failure, *etc.* Field blanks were used, and were handled the same as other samples. Detectable amounts of lead were found on the field blanks. The mean value of the field blanks was used to correct the sample values by subtracting the mean field blank value from the inside and outside sample weights. WPFs were calculated by dividing the outside concentration (C_o) by its corresponding inside concentration (C_i), and checked for outliers. The authors reported that for the 20 samples collected the geometric mean WPF was 3929 and the GSD was 9.6, and the 5th percentile WPF estimate was 95. The outside concentrations ranged from 150 to 8380 μg/m^3, and the inside concentrations ranged from 0.03 μg/m^3 to 3.0 μg/m^3. Sampling periods ranged from 30 minutes to 3 hours. The workers were under constant observation to ensure proper respirator use and wear and to ensure sample validity.

The authors looked at subsets of the data using multiples of the field blank mean values ranging from 1,000 times the field blank to 25,000 times the field blank value. The authors found a strong correlation between filter weight and workplace protection factor when they looked at the log of the mean filter weight and the log of the mean WPF. The authors stated that the data appeared to be close to the plateau region. The authors also stated that the quantitative fit factors measured during worker fit testing did not correlate with the WPFs measured in this study.

The authors concluded that '' * * * the results of this study indicate that this full facepiece respirator with high efficiency filters reliably provides workplace protection factors in excess of 50 against lead dust and fume aerosol.'' The authors stated that they would expect 95% of the workplace protection factors to be above 95. They also stated that ''The ANSI Z88.2 proposed Standard for Practices for Respiratory Protection has assigned a protection factor of 100 to this type respirator. These data support that recommendation.''

3. WPF Studies—Powered Air-Purifying and Supplied-Air Respirators Half-Mask PAPRs

Study 21. In 1983, W.R. Meyers and M.J. Peach of NIOSH reported half and full facepiece PAPR performance measurements for four workers during bagging of micro-crystalline silica (Si) in a silica processing plant (Ex. 1–64–46). The study examined several aspects of the respirator's performance. Prior to the workplace evaluation, dioctyl phthalate (DOP) was used to determine filter efficiency. A 4-hour Si dust chamber study was performed by mounting the PAPR on an anthropomorphic head, simulating worker breathing, and gathering inside- and outside-the-facepiece silica samples. Workers were provided with an unspecified brand of PAPR, with either a tight-fitting half-mask or full facepiece, and equipped with high-efficiency filters. Both styles of facepiece were made of natural rubber and had two exhalation valves. The sealing edge of the facepiece was either an internal roll (half-mask) or a flat edge with an inner flap (full facepiece). The filters were located downstream of the respirator's blower unit.

The PAPRs used in the study were identical to those already being used by the employees; the authors did not mention training the participants in proper use of the respirator. Respirators were placed on and removed from the participants by the investigators, as needed (*e.g.,* start of shift, lunch break, personal breaks, end of shift). Donning and doffing the respirator, and sampling train starting and stopping, occurred in a clean area. Samplers were started after the PAPR was donned and turned on, and were stopped before the PAPR was turned off for doffing. Facepiece interiors were examined for dust contamination after each removal (gross contamination was not observed), and the facepieces were cleaned by the investigators after each shift. In addition, each PAPR's volumetric air output (with the facepiece removed) was measured with a dry gas meter. Filters and batteries were changed according to the manufacturer's instructions. While no mention is made of fit testing the participants, the investigators instructed them not to manipulate, lift, or remove the facepiece during sampling. Participants were observed 100% of the time during donning and doffing, and about 80% of the time at their workstations. The authors used field blanks to assess contamination caused by handling.

The sampling train for the inside-the-facepiece samples consisted of a 37 mm two-piece cassette containing a 5 micron pore size FWS–B polyvinyl chloride filter. The cassette was attached directly to a modified Luer adaptor sampling probe, inserted into the facepiece between the nose and upper lip of the employee. The flow rate of the pump was 1.5 Lpm. The outside-the-facepiece samples were collected with a 37 mm two-piece cassette and a 5 micron pore size FWS–B polyvinyl chloride filter. The sampling airflow rate was 1.5 Lpm, and the cassette was attached to the subject's lapel. Outside samples were collected as total dust since previous sampling revealed 70% or more of the dust particles to be 10 microns or less in size (*i.e.,* respirable). Sample times ranged from 84 to 320 minutes, with cassettes being changed during the employees' lunch break. Overall PAPR performance (leakage) was determined by replacing the facepiece of two respirators with an air-filtering head containing a pre-weighed 76 mm glass fiber filter. The respirators were mounted in a free-standing stationary position, and run for 6–7 hours (with a battery change at 4 hours). The air output was measured, the filter weighed, and the ambient Si concentration estimated. Area samples were collected to determine particle size. An Anderson impactor was placed 4–8 feet from the participants and collected samples for about 3 hours at a flow rate of 1 cfm.

Samples were analyzed for free Si according to NIOSH P&CAM 259 (*i.e.,* gravimetric weight and x-ray powder diffraction for Si). Results were corrected for the average blank filter weight gain, but not for pulmonary retention (which the authors believed was negligible). Ten individual inside- and outside-the-facepiece concentrations, with associated WPFs, are tabulated by sample period, worker,

type of facepiece, and sample time. The study reported that the half-mask PAPR did not provide the protection factor of 1,000 previously expected; instead, the protection factors ranging from 16 to 193. The authors also provided results for DOP filter penetration, aerodynamic mass median particle size and GSD, x-ray powder diffraction tests, and free-standing PAPR leakage measurements. The researchers discussed several parameters that could have affected results, including poor respirator use practices of the participants (which the authors believed they controlled and maintained at a minimal level); inside-the-facepiece sampling flow rate (which the authors believed was not a major source of error); and inherent PAPR leakage (however, the free standing PAPR results indicated minimal leakage). Also discussed as reasons for the low protection factors were possible leakage of Si past the blower housing grommet when employees bumped the PAPR during work (the effect of this was unknown) and leakage from inadequate facepiece fit (which the authors considered could be significant at moderate to heavy work rates).

Study 6. S.W. Lenhart and D.L. Campbell of NIOSH reported in 1984 on a WPF study in which they measured protection against exposure to particulate lead (Pb) for 25 primary lead smelter workers; 7 of the employees worked in the sinter plant, and 18 worked in the blast furnace area (Ex. 1–64–42). The predominant aerosol forms of Pb were dust in the sinter plant and fume in the blast furnace. In both areas, Pb comprised about 50% of the total aerosol particulate, with composition of the remaining 50% of particulates being unknown. All participants wore an MSA half-mask PAPR with high-efficiency filters (the authors provided no respirator model number in the report). The study also examined the performance of an MSA negative-pressure air-purifying respirator, which is discussed above in the half-mask air-purifying respirator study summaries. The participants routinely used respirators, but the investigators do not mention respirator training for the employees. The participants were not normally fit tested with the half-mask PAPR facepiece; however, for this study, they had to achieve a fit factor of at least 250 while wearing a negative pressure air-purifying respirator with the same half facepiece as the PAPR. Employees were instructed not to remove or manipulate the respirator during sampling, and were observed throughout the sampling period.

The inside-the-facepiece sampler consisted of a closed-face 37 mm cassette containing an AA filter and AP10 support pad. This cassette was connected to a tapered Liu probe that was inserted into the respirator between the nose and upper lip. In-mask samples were collected at 2 Lpm. The outside-the-facepiece sampling train was a closed-face 37 mm cassette containing an AA filter and AP 10 support pad (with no tapered Liu probe used). The outside sample cassette was attached to the worker's lapel. Outside samples were gathered at 2 Lpm. Samples were collected for ''as much of the 8-hr work shift as possible.'' Respirators and sampling trains were donned and doffed, and started and stopped, in a lead-free area. The inside of the respirator facepieces were wiped clean prior to donning after each break, and were cleaned and sanitized after each shift. The PAPR batteries were replaced after four hours of use (*i.e.,* according to manufacturer's instructions). Battery voltage was checked, and airflow rates were verified to exceed 15 Lpm before use. One WPF was measured for each participant. The ambient particle size distribution was determined by 19 Marple cascade impactor samples (11 in the sinter plant; 8 in the blast furnace area).

Analysis of Pb was by flame atomic absorption spectroscopy according to NIOSH Method S–341. Inside-the-facepiece samples that contained less than 10 μg of lead were reanalyzed by graphite furnace atomic absorption (limit of detection = 0.2 μg). The report provided ranges of the mass median aerodynamic diameters (in micrometers), as well as the GSD values. The authors provided a total of 25 pairs of inside- and outside-the-facepiece concentrations, and the corresponding WPFs, by employee, job title, and job location, as well as the overall GM and GSD of the PAPR WPFs and several percentile values. For samples containing Pb below the level of detection, the authors determined concentration values ''* * * from the least amount of lead detectable by the analytical method and the sampled volume of air.'' In-mask measured values were not adjusted for particle retention in the respiratory tract (the authors imply that retention had a non-significant effect on the results, but could cause WPF to be overestimated). No mention is made of using field blanks. Two approaches to defining an assigned protection factor (APF) were also discussed. These approaches are: Defining the APF in terms of a specific proportion of WPFs expected to exceed the APF, and defining the APF ''in terms of a one-sided lower tolerance limit above which we may predict with a specific confidence level that 95% of the workplace protection factors lie.''

The WPF for the PAPR had a GM of 380 and a GSD of 2.6, and the individual WPFs ranged from 23 to 1,600. Approximately 98% of the WPFs for the half-mask PAPR were above 50, 90% above 110, 75% above 200, 40% above 500, and only 25% above 1,000. The authors concluded that an APF of 50 was appropriate for the PAPR they tested, and that an APF of 500 was inappropriately high for the half-mask PAPR. A protection factor not in excess of 50 was recommended for half-mask PAPRs. The authors noted that the WPFs may be too high because the workers did not routinely undergo a quantitative fit test screen with negative pressure respirators before receiving their PAPR.

4. WPF Studies—Full Facepiece PAPRs

Study 21. W.R. Myers and M.J. Peach of NIOSH reported in 1983 on the performance of an unspecified brand of PAPR equipped with a tight-fitting elastomeric full facepiece and HEPA filters; four employees used the respirator in a silica bagging operation (A detailed description of the work setting, sampling methodology, and study protocol for this study is presented in the discussion of Study 21 in the section on half-mask PAPRs above) (Ex. 1–64–46). The full facepiece PAPR had a sealing edge consisting of a flat edge with an inner flap. The participants routinely used this PAPR and, therefore, the investigators did not train them in its use. Fit testing was not performed.

The investigators calculated WPFs for only three of the four employees because the sample for the fourth employee had an inside-the-facepiece concentration less than the limit of detection, making it unsuitable for WPF determination. The samples were evaluated for crystalline Si by x-ray diffraction. The full facepiece WPFs ranged from 25 to 215, which are low for a PAPR. In this regard, the authors reported that the employees routinely bumped and rubbed the belt-mounted motor blower housing and filter assembly during the bagging operation. They believed such action may have caused movement between the neck of the filter and the blower housing grommet; thereby resulting in the seal failing and allowing unfiltered air to bypass the filter. They reported some evidence to support this conclusion, but could not determine the contribution of this problem to the overall leakage into the facepiece. Although the blowers were checked to ensure each PAPR

delivered a minimum 115 Lpm (4 cfm) airflow to the facepiece, the authors concluded that ''* * * migration of contaminant into the facepiece of the PAPR system could be a significant source of leakage when the respirator is exposed to the wide ranging conditions that exist in the work environment.'' While the WPFs measured in this study were well below the level expected of a PAPR, the authors stated that these results ''* * * represent a more accurate measure of the level of worker protection that can be expected from this type of PAPR system.''

Study 18. At the 1990 AIHCE, C.E. Colton and H.E. Mullins presented a WPF study in which they assessed protection against exposure to lead fume and dust for 20 employees working in the blast furnace, reverberatory furnace, casting, and baghouse areas of a secondary lead smelter (Ex. 1–64–12). The employees were provided with a 3M Whitecap PAPR with a high-efficiency filter (TC–21C–456). The investigators trained the employees in the proper donning, fitting, and operation of the respirators. Using a TSI Portacount, the investigators conducted fit testing while the participants performed the exercise sequence contained in Appendix D of OSHA's Lead Standard; the required fit factor was 500. Participants were observed continuously throughout the sampling.

The inside-the-facepiece sampling train consisted of a 25 mm three-piece cassette containing a 0.8 micron pore size polycarbonate filter. The authors mounted the sampling cassette directly to an ABS Liu probe and inserted the probe into the facepiece in place of the speaking diaphragm. The outside-the-facepiece sampling train was a 25 mm three-piece cassette containing a 0.8 micron pore size polycarbonate filter. The authors did not mention attaching the outside cassette to a probe or the location of the sampling cassette on the employee. Airflow rates of the sampling pumps were calibrated in-line before and after each sampling interval, but no sampling airflow rate was provided. Sampling was conducted for as much of the 8-hour shift as possible, with sampling intervals ranging from 1 to 4 hours. Field blanks were used, and area samples for particle size analysis were gathered with a Marple personal cascade impactor (Model 2401).

Sample and field blank analyses were performed using proton induced x-ray emission (PIXE) analysis. Particle size analysis by inductively-coupled plasma—mass spectrometry indicated particles in the dust and fume range. While the range of inside- and outside-the-facepiece concentrations were presented, individual inside and outside concentrations or results by employee or job classification were not provided. Similarly, the report presented an overall GM WPF, GSD, and fifth percentile WPF, but not individual WPFs. Of the 55 sample measurements, 34 of the inside-the-facepiece results were below the analytical limit of detection. In these instances, the authors used a conservative WPF calculation by setting the values at the limit of detection. No lead was detectable on the field blanks so no adjustments were made to sample weights. The authors do not mention adjusting inside-the-facepiece values for pulmonary particle retention. Final calculations used only those sample pairs with outside sample weights greater than 1,000 times the detection limit. The authors believed this procedure was necessary to determine that the respirator was capable of providing a protection factor of 1,000. The authors also analyzed the data for outliers (at the 99% confidence level). The overall data analysis resulted in a GM WPF of 8,843, a GSD 3.2, and a fifth percentile WPF of 1,335. The authors concluded that the data supported ANSI's proposed APF of 1,000 for full facepiece PAPRs. They also recommended that fit testing be performed on all tight-fitting respirators.

5. WPF Study—Helmet/Hood PAPRs

Study 27. At the 1990 AIHCE, D.R. Keys, H.P. Guy, and M. Axon reported on a 3-month WPF study in which they evaluated exposure to estradiol benzoate (a steroid) for an unspecified number of workers in a pharmaceutical facility (Ex. 64–40). They included three loose-fitting hood/helmet type PAPRs in the study: Racal Breathe Easy 10, Bullard Quantum, and 3M Whitecap II. All three PAPRs had double-bibbed capes, were equipped with HEPA filters, and did not have lift-up visors. A Tyvek hood was part of the Racal and Bullard PAPRs while the 3M had a hard helmet. PAPRs were previously used at the facility, so workers were already properly trained in their use and were familiar with wearing them. The investigators observed the participants continuously, one-on-one, during sampling. While the authors used field blanks, they did not mention determining particle size or using a clean area for donning and doffing or for starting and stopping the sampling train.

The inside- and outside-the-facepiece sampling trains consisted of a 37 mm two-piece cassette with a glass fiber filter, attached to a nylon Liu probe. Location of the inside-the-facepiece probe was not specified. Samples were gathered for ½–3 hours at a flow rate of 2.5–3.5 Lpm. Pumps were calibrated in-line before and after each sampling period.

The authors used radioimmunoassay (RIA), a very sensitive analytical technique, to analyze inside-the-facepiece samples, and HPLC to analyze outside samples; they rejected inside samples with weights below the limit of quantification. Also, the investigators rinsed the outside sample probes with methanol and analyzed the rinsate by HPLC to determine sample loss due to probe use. The authors did not provide any further analytical information.

Sixty valid sample sets were obtained from the study. Results were not adjusted for blank value (*i.e.,* all blank values were below 1 nanogram per filter) or probe loss (*i.e.,* the GM of 1% was not statistically significant). Individual inside and outside concentrations or WPFs were not reported. Instead, the authors presented the range of inside- and outside-the-facepiece concentrations. They determined an overall fifth percentile WPF for each respirator, along with the number of samples, the minimum and maximum WPF achieved, a GM WPF, and the GSD. In addition, the authors determined the percentage of WPFs that fell in selected ranges (*e.g.,* <1,000, 1,000–10,000) for each PAPR, and they briefly discussed the correlation between WPF and outside concentration (*i.e.,* they found WPF to be independent of outside filter loading in this study). The Racal Breathe Easy 10, with 29 sample pairs, had a GM WPF of 11,137, a GSD of 3.9, and a fifth percentile WPF of 1,197. The Bullard Quantum, with 9 sample pairs, had a GM WPF of 9,574, a GSD of 3.1, and a fifth percentile WPF of 1,470. The 3M Whitecap II helmet, with 22 sample pairs, had a GM WPF of 42,260, a GSD of 9.8, and a fifth percentile WPF of 997. The authors stated that they obtained WPFs above 10,000 for the three PAPRs at least 44% of the time, and that the three respirators provided WPFs above 1,000 throughout the study. The authors concluded that the results of their study agreed with the then-proposed ANSI Z88.2–1992 APF of 1,000 for PAPRs with hoods or helmets.

6. WPF Studies—Loose-Fitting Helmet/Hood PAPRs & Loose-Fitting Facepiece PAPRs

Study 23. W.R. Meyers, M.J. Peach, K. Cutright, and W. Iskander reported in 1984 on a study in which they examined lead (Pb) exposure of 12 workers in a secondary lead smelter (Ex. 1–64–47). The job classifications studied were furnace operator, helper,

and pig caster. They selected two employees from each classification on two shifts. The PAPRs used in the study were the 3M W–344 and the Racal AH3; each employee wore both respirators twice. Pre-shift quantitative fit testing was performed each day. The investigators trained the participants, but did not describe the training; they monitored the employees continuously during sampling.

The authors referred to a companion paper for a description of the sampling protocol used in this study; therefore, they provided no information is provided on sampling or analytical methodologies in this report. Eight impactor samples were collected at each work activity to determine particle size distribution. Samples were collected for the full shift, but the investigators did not provide specific sampling times. The authors also provided the range of inside-the-facepiece concentrations, with associated GM and GSD, for both brands of respirator; they measured these concentrations with the PAPRs placed on manikins which were located at the worksites where employees in the three job classifications worked.

For each respirator, the study provided 24 individual inside- and outside-the-facepiece (front and rear) concentrations, along with associated WPFs and each employee's fit factor. It also provided the overall GM, GSD, and 95% confidence level on the mean for the inside-the-facepiece concentrations, WPFs, and fit factors. The authors tabulated the data by day, shift and work activity. For both respirators, two samples were discarded due to sampling pump failure, giving 22 usable measurements for each respirator. The WPFs measured on the Racal AH3 ranged from 42 to 2,323, with a GM of 205 and a GSD of 2.83. The 3M W–344 had WPFs that ranged from 28 to 5,500, with a GM of 165 and a GSD of 3.57. The two-sided 95% confidence limits around the mean of the WPFs were 128 and 325 for the Racal AH3, and 94 and 292 for the 3M W–344. The authors provided a detailed discussion of their statistical analyses of the data; they also discussed several potential sources of variation in the workplace performance of PAPRs, including: a possible relationship between fit factor and WPF; a possible relationship between fit factor and inside-the-facepiece concentration; day of the week; shift; leakage into the facepiece due to ambient air currents; and worker activity. The only sources found to be potentially significant were leakage into the facepiece due to ambient air currents and worker activity. The authors stated that ''* * * using the pooled 3M and Racal WPF data and a probability of 0.95 the assigned protection factor calculated by this method for these PAPRs would be 26.'' They recommended a reduction in the RDL's APF of 1,000 for loose-fitting PAPRs with helmets and HEPA filters.

Study 5. W.H. Albrecht, G.R. Carter, D.W. Gosselink, H.E. Mullins, and D.P. Wilmes reported at the 1986 AIHCE on a study they conducted that evaluated protection against exposure to asbestos fibers for 12 workers who manufactured asbestos-containing brake shoes for trucks (Ex. 1–64–23). The employees performed six operations at the facility: mixing brake shoe components, weighing mixed formulation, pre-forming molding press charges, molding the shoe, grinding the brake shoe surface, and drilling shoe mounting holes. The investigators sampled at each operation. The PAPR studied was the 3M Airhat with high-efficiency (HEPA) filters. The participants and supervisory staff were shown an audio slide presentation explaining how to fit respirators and the procedures for saccharin fit testing; they then received the saccharin qualitative fit test (since the authors do not specifically mention fit testing the PAPR, it is assumed that only the half-mask respirators studied were fit tested). Fit testing was not conducted prior to each study test. The PAPR was fitted and worn according to the manufacturer's instructions. Each employee was observed on a one-on-one basis during testing to assure that they properly donned and used the respirator and that sampling train integrity was maintained.

The inside-the-facepiece sampling train was a closed-face filter cassette connected to a tapered Liu probe, inserted into the respirator between the nose and mouth. The outside-the-facepiece sampling train was a closed-face filter cassette connected to a Liu probe attached in the employee's lapel area; the authors do not mention cassette size. Samples were collected for 30 minutes, but other sampling times were occasionally used; sampling pump flow rates were 2 Lpm (inside-the-facepiece) and 0.5 Lpm (outside-the-facepiece). The report does not mention modifying the inside-the-facepiece probe location (midway between the nose and mouth) or the sampling flow rate for the PAPR versus that used for the half-mask respirators studied.

Sampling trains were calibrated before the shift, at lunch, and at the end of the shift; average airflow rate was used to calculate sampled air volume. The investigators did not mention determining the PAPR's airflow rate.

Asbestos analysis was based on NIOSH method 7400, with 500 fields counted per inside sample filter and 100 fields counted per outside sample filter. The distributions of fiber length and fiber diameter were not characterized. The authors stated that blanks were submitted for fiber counting; however, no further mention is made of the blank results or how they were addressed. None of the PAPR samples were comparison counted by Phase Contrast Microscopy (PCM) and Scanning Electron Microscopy (SCM). A total of seven PAPR WPFs were reported (5 employees). Individual pairs of inside and outside concentration values were not provided. Individual WPFs were reported for each of the seven sampling intervals, but were not linked to specific participants or jobs. The authors provided an overall GM, GSD, and fifth percentile for the Airhat PAPR; a range of asbestos concentrations and the associated GM and GSD were also reported by job. An inside-the-facepiece fiber count of 1,000 was used in calculating the WPF when the sampling result was at or below the limit of detection (*i.e.*, 1,000 fibers per filter). The investigators did not mention adjusting inside-the-facepiece values for fiber retention in the respiratory tract. In addition, the authors determined that sampling results were not affected, at the 95% confidence level, by sampling flow rate or open-versus closed-face sampling cassette. The mean breathing zone concentration of asbestos for the Airhat PAPR was 4.14 fibers/cc, with a mean breathing zone concentration range of 1.23 to 8.05 fibers/cc. The authors reported a GM WPF for the PAPR of 199, with a GSD of 2.36 and a fifth percentile of 42. Five employees tested the PAPR, resulting in a total of nine sample sets, including two unusable sets of data. The authors noted that respirators that had the highest GM and fifth percentile WPFs (*i.e.*, the 3M Airhat and 3M 9920 DFM respirators) were also tested at higher breathing zone fiber concentrations. They believed that this factor probably led to these respirators' increased performance measurements.

Study 22. In 1986, W.R. Meyers, M.J. Peach, K. Cutright, and W. Iskander reported on a study in which they evaluated exposure to lead (Pb) dust and mist for 12 workers on two lead acid plate production lines of a battery manufacturer (Ex. 1–64–48). They sampled the pasting operator and two slitter operators on each line for two different shifts. The respirators studied were the Racal Airstream AH5 and the 3M W–3316, equipped with a helmet, visor enclosure, and dust/mist filters. Participants were clean-shaven, and

each employee wore both types of respirator twice. The AH5 provided a seal between the employee's face and the face shield by using two flexible face seals; air was exhausted at the chin. The size of the faceseal (*i.e.*, large or small) was selected based on the appearance of best fit and wearer comfort. The 3M's soft flexible face seal gave a loose-fitting seal between the face and face shield, with air exhausted at the temples. Prior to field testing, randomly-selected filters underwent silica dust penetration testing. The investigators put on and removed the respirators from the employees in a clean area, except when the employees took personal breaks (in which case, the employees donned and doffed the respirator in the work area). Employees were not fit tested, but were instructed in the proper use of the PAPR and directed not to remove the helmet, lift the face shield, or tamper with the sampling equipment without notifying the investigators. The investigators continuously monitored donning and doffing and work activities. Respirator helmets and visors were cleaned between each use, and volumetric air output was periodically checked (usually at the beginning of the shift, lunch, and shift's end). The authors replaced the batteries according to manufacturer's instructions, and when low airflow occurred. They also installed new filters at the beginning of each shift. The investigators started the sampling pumps after the employees donned the respirators and the PAPR blower was functioning; they stopped the pumps before turning off the PAPR blower.

Sampling trains were identical and consisted of a closed-face 37 mm two-piece cassette, containing a 0.45 micron pore size cellulose ester filter and back-up pad. Inside-the-facepiece sample cassettes were attached directly to a modified Luer adapter sampling probe, inserted through the face shield about one to two inches in front of the employee's mouth. Outside-the-facepiece sample cassettes were located at the front lower right side of the facepiece, away from the PAPR's exhaust airflow; they located a second cassette located the employee near the PAPR's filter, to determine the filter's contaminant challenge. All samples were collected as total dust at a flow rate of approximately 2 Lpm over the full shift (The report did not provide actual sample times). Sampling pumps were calibrated in the laboratory, and the flow rates confirmed at the worksite. Performance of the PAPR filtration system was checked by placing operating respirators on manikins (without simulated breathing), located about 4 feet from the subjects. Two filter blanks were used for each shift. Particle size distribution was determined through using a Marple cascade impactor operating at a flow rate of 3 Lpm.

Inside-the-facepiece samples were analyzed by graphite furnace using a modified NIOSH P&CAM 214 method, with perchloric acid in the wet ashing step. Outside-the-facepiece samples were analyzed by atomic absorption spectroscopy (NIOSH Method S–341 with the perchloric acid wet ashing step modification). Forty-seven individual inside- and outside-the-facepiece (*i.e.*, front and rear) time-weighted-average (TWA) measurements, with associated TWA WPFs, were provided (AH5 = 24; W–316 = 23). These results were tabulated by day, shift, and work activity. Overall GM and GSD were also given for the concentration measurements and WPFs. All blanks were below the analytical limit of detection; the authors did not mention adjustments for pulmonary retention. Particle size (large) and stationary manikin filter efficiency (98%–99.9%) were briefly discussed. The WPFs for the Racal AH 5 ranged from 23 to 1,063, with a GM of 120 and a GSD of 2.64. The WPFs for the 3M W–316 ranged from 31 to 392, with a GM of 135 and a GSD of 1.89. Since the authors found no statistical difference between the performance of the respirators, they pooled the data for both respirators; they then graphically plotted the percent of WPFs less than specific values. The pooled data for the two PAPRs resulted in a distribution with a GM of 127 and a GSD of 2.28. The authors stated that, at a 0.95 probability level, this class of PAPRs would receive an assigned protection factor of 25. The authors also stated that the results ''* * * strongly suggest that the respirator user community not view current generation powered air-purifying respirators equipped with helmets as positive pressure respiratory devices.''

Study 3. A. Gaboury and D.H. Burd (Ex. 1–64–24) and A. Gaboury, D.H. Burd, and R.S. Friar (Ex. 1–64–348) reported in 1993 on the WPF study they performed in a primary aluminum smelter. Exposure to benzo(a)pyrene [B(a)P] on particles was measured for 22 employees who worked as rack raisers, stud pullers, and rod raisers on anode crews. The employees used a Racal Breathe-Easy 1 (BE1/AP3), a loose-fitting helmeted PAPR. The PAPR came equipped with one-piece non-woven flame-retardant face seals, visor locking clips, and combination organic vapor and HEPA filters. (The authors also tested the performance of several negative-pressure, air-purifying half-mask respirators; see Study 7 above). The employees previously received training on this PAPR, and used it for more than six months prior to the study. Forty percent of the employees had beards (*i.e.*, more than two weeks growth), but the investigators did not find a significant difference between bearded and non-bearded participants. No fit testing was performed on the employees, but previous quantitative fit testing showed fit factors ''greater than 1000 in all cases.'' Industrial hygiene technologists assisted participants with donning and doffing respirators, cleaned and maintained the respirators at the end of each work cycle, and observed participants on a one-to-one basis throughout the sampling period. The investigators directed the employees not to tamper with the respirator or sampling equipment. Due to high heat levels in the work area, the employer required employees to rest in a cool environment for one-half hour during each work hour.

The inside-the-facepiece sampling train consisted of a closed-face three-piece cassette with a 25 mm organic-binder-free glass fiber filter, backed with a cellulose ester pad. Inside sampling cassettes were connected to a tapered Liu probe, which was inserted through the PAPR's visor and into the employee's breathing zone. The outside-the-facepiece sampling train was identical to the above; however, the investigators did not mention connecting the cassette to a Liu probe. The outside cassette was mounted on a bracket at the top of the visor. All filters were pre-calcined at 400 degrees Centigrade for 24 hours. Both inside and outside samples were collected at a flow rate of 2 Lpm for approximately 300 minutes, or one-half of the 10-hour work shift. Respirators and sampling trains were worn and operated until the employee entered the rest area; they donned and turned on the respirators prior to leaving the rest area for the next work cycle. The authors plugged the sampling cassettes when not in use, and cleaned the respirators after each work cycle. Field blanks were used to identify contamination due to handling. Sampling train airflow rates were checked at the beginning, middle (*i.e.*, after lunch), and end of the work day; upon changing cassettes; and when a problem was suspected. PAPR turbo-unit flow rate was checked every two hours to assure flow was greater than six cubic feet per minute (cfm). Sampling occurred over a five-day period.

B(a)P analysis followed Alcan Method #1223–84. The ambient B(a)P particle size distribution was determined by collecting four samples, as close as possible to the workers, using an 8-stage Anderson cascade impactor (Model 296). Impactor samples were collected for two to five hours at a flow rate of 2 Lpm. The average percent of B(a)P mass (across four samples) per impactor stage (defined by an aerodynamic diameter cut point, in micrometers) was reported. About 93% of the B(a)P mass was associated with particles having diameters of ≤9.8 micrometers. A total of 20 pairs of inside and outside sample concentrations, with associated WPFs, were provided by job category (but not for individual employees), and whether the employee had a beard. An overall GM, GSD, and 95% confidence interval on the mean were also provided for the inside and outside concentrations and WPFs, along with an overall fifth percentile WPF. The authors stated that some employees participated more than once during the study. They did not mention adjusting inside-the-facepiece values for particle retention in the respiratory tract. The authors found no significant relationship between B(a)P concentrations inside and outside of the facepiece, but they did find a correlation between WPF and outside B(a)P concentrations. The authors stated that, while the data were limited, they recommended testing PAPRs at relatively high concentrations to obtain an accurate measure of their performance. The inside B(a)P concentration ranged from 0.006 to 0.072 $\mu g/m^3$, with a GM of 0.012 $\mu g/m^3$. The outside B(a)P concentration ranged from 246 to 111.48 $\mu g/m^3$ with a GM of 16.73 $\mu g/m^3$. WPFs ranged from 371 to 8658, with a GM of 1,414. The two-sided 95% confidence interval limits around the overall GM WPF were 918 and 2,173; the fifth percentile was 275. The authors cautioned that these results WPFs achieved under conditions of good worker compliance and tight administrative control; however, without these conditions, WPFs may be less because: close surveillance of workers is not usually performed; cleaning during rest periods is not done prior to returning to the workplace; visor locking clips are not routinely used; and no respirator is used 100% of the time while in the workplace.

Study 26. At the 2001 AIHCE, D.V. Collia, *et al.* presented a study on the workplace performance of a PAPR against exposure to cadmium (Cd) for seven workers, over three days, in a nickel-cadmium battery manufacturing facility (Ex. 3–5). The respirator studied was the 3M Breathe-Easy 12 (BE–12), a loose-fitting facepiece PAPR equipped with high-efficiency filters; the employees were using this PAPR prior to the study. During a preliminary visit, the investigators discussed the study with the union, management and workers. The authors also evaluated the worksite and took area samples to identify areas with the highest exposures. Prior to sampling, they informed the employees about their role in the study, as well as the study's purpose and procedures. The investigators continuously observed the employees during sampling, and used field blanks to identify contamination from handling. The study contained no additional information on sampling protocols (*e.g.*, donning and doffing procedures).

Inside-the-facepiece samples were gathered using 25 mm three-piece cassettes containing an unspecified membrane filter and a porous plastic back-up pad. A nylon Liu probe was used, and the samplers were positioned directly across from the midline between the employee's nose and mouth. Outside-the-facepiece samples used 25 mm three-piece cassettes containing an unspecified membrane filter, backed with a cellulose pad. Outside samples were positioned close to the employee's breathing zone (the investigators provided no further details). All samples were collected at 2 Lpm for approximately one and one-half hours (range: 67–156 minutes).

Inside-the-facepiece samples and blanks were analyzed by flame atomic absorption spectroscopy and heated graphite furnace atomizer (AAS–HGA). Analysis of outside-the-facepiece samples was by AAS. The analytical methodology used OSHA's method for Cd in workplace atmospheres (OSHA ID–189). The authors provided the mean mass for inside and outside blanks, but made no mention of data adjustments for blanks or pulmonary retention. They also reported minimum and maximum concentrations of inside- and outside-the-facepiece samples for each employee. Supplemental data contained 41 individual measurements of inside and outside concentrations, tabulated by employee, job area, sample period and set, sample time, pump flow rate, and sampled air volume.

WPFs were calculated for 33 of the sample sets (8 of the 41 inside-the-facepiece samples had no detectable Cd). The calculated GM WPFs ranged from 1,460 to 9,440. The fifth percentile WPF was calculated in three different ways: the traditional approach yielded a fifth percentile WPF of 315; an analysis of variance (ANOVA) model, yielded a fifth percentile of 280; and the Monte Carlo simulation model approach resulted in a fifth percentile of 220 when the non-detected inside values had a value of 0.002, a fifth percentile of 303 with the non-detected values excluded, and a fifth percentile of 103 with Employee C excluded. The authors concluded that the BE–12 PAPR provided a level of protection consistent with an APF of 25.

Study 24. D.W. Stokes, A.R. Johnston, and H.E. Mullins determined exposure to silica (Si) dust for five workers in a roofing granule production plant (Ex. 1–64–66). The participants were involved in cleanup of silica dust byproduct by sweeping, brushing walls, and shoveling. The respirator studied was the 3M Airhat, a loose-fitting PAPR with helmet, equipped with dust/mist or high-efficiency filters, and worn with and without a Tyvek shroud. The investigators assisted the participants were assisted with donning the sampling equipment; however, they did not mention training the employees. They observed the employees during sampling, and used field blanks to determine the effects of handling on sample contamination. They did not mention determining the particle size of the contaminant.

Inside-the-facepiece samples were collected through a Liu probe inserted into the faceshield (they did not provide the probe's specific location). A 25 mm cassette containing a 0.8 micron pore size polycarbonate filter was used, and sampling airflow rate was 1.5 Lpm. Outside-the-facepiece samples were gathered as both total and respirable dust. Respirable dust samples were collected at 1.8 Lpm using a 37 mm 0.8 micron pore size polycarbonate filter placed in a cyclone that attached to the employee's lapel. Total dust samples also used a 37 mm 0.8 micron pore size polycarbonate filter. Sampling airflow rate was 2 Lpm, with the sampling cassette attached to the employee's lapel. The investigators calibrated the sampling pumps each day, and checked proper airflow rate three times throughout the day. They collected samples over a four-day period, with sampling times ranging from 30 minutes to 1 hour. At the beginning and end of each sample, the authors confirmed that each PAPR's airflow rate was in excess of 6 cfm.

The authors used proton induced x-ray emission (PIXE) to analyze the samples. They adjusted the inside- and outside-the-facepiece concentrations by subtracting the mean blank value, but did not mention adjustments for pulmonary retention of particles. They also did not provide individual inside-

and outside-the-facepiece concentrations and WPFs. They presented results in two tables showing respirable dust samples with values 25 times the mean blank level, and total dust samples with values 100 times the mean blank level. The investigators provided tables reporting sample size and overall GM, GSD, and fifth percentile WPF by type of filter (*i.e.*, dust/mist, HEPA) and the presence or absence of a shroud (*i.e.*, dust/mist with shroud, dust/mist without shroud). Using the respirable dust samples that were 25 times the mean blank value, the authors combined the sampling results of the PAPR with dust/mist filters (*i.e.*, with and without a shroud) and found an overall GM WPF of 2,480 and a fifth percentile of 95. The combined respirable dust results of the HEPA-filtered PAPR gave an overall GM WPF of 5,730 and a fifth percentile of 762.

Atmosphere-Supplying (Supplied-Air) Respirators

Atmosphere-supplying respirators, also referred to as supplied-air respirators (SARs) or airline respirators, operate in one of three modes: Demand, continuous flow, and pressure demand. Demand and pressure demand respirators can be equipped with half or full facepieces. Continuous flow respirators can also be equipped with a helmet, hood, or loose-fitting facepiece.

7. WPF Studies—Loose-Fitting Atmosphere-Supplying Respirators With Hood or Helmet

Study 28. A.R. Johnston, *et al.* in 1987 conducted a WPF study evaluating exposure to silica (Si) among four shipyard workers who wore a 3M Whitecap II loose-fitting, continuous flow SAR with hood/helmet while sandblasting paint from the flat top of a barge (Ex. 1–64–36). The respirator was comprised of a W–8100 abrasive blasting helmet, a W–5114 breathing tube, a W–2862 air / temperature control valve, 50 feet of W–9435 air hose, and a W–8054 extended length shroud. To permit evaluation of the respirator at its low and high range of airflow rates, air pressure was maintained at 60 or 80 psi, resulting in an in-helmet airflow rate of either 6.4 or 14.4 cfm. The investigators informed the employees of the purpose and protocols of the study, and instructed them in the proper donning and use of the respirator. They also directed the employees not to adjust or remove the respirator after sampling began. Sampling trains were connected and disconnected in a clean area when possible. Sampling pumps were started after confirming proper operation and donning of the respirator, as well as airflow rate into the helmet. Pumps were stopped before the helmet was disconnected from the air supply and removed. The authors maintained continuous one-on-one observation of the employees during sampling, and used several field blanks during each day of sampling.

The authors collected inside-the facepiece samples on 25 mm cassettes containing 0.8 micron pore size polycarbonate membrane filters. They attached the cassettes directly to a Liu probe inserted through the center of the faceshield, about midway between the nose and mouth; the probe extended about 3 mm into the helmet. The flowrate for the inside samples was approximately 2 Lpm. The authors collected outside-the-facepiece samples as both total and respirable dust, using a 37 mm cassette with a 0.8 micron pore size polycarbonate membrane filter. They used a Bendix or SKC cyclone, operating at 1.7 Lpm airflow rate, to gather the respirable dust samples and obtained total dust samples at flow rates ranging between 0.5 and 2 Lpm. Both outside-the-facepiece sample cassettes were located on the employee's lapel. The investigators calibrated the sampling pumps at least three times a day, and sampling periods ranged from 10 to 60 minutes to prevent filter overloading.

The authors analyzed all samples using PIXE. They found Si on all 18 blanks. Of 68 initial sample sets, they discarded 16 (11 due to test malfunctions and 5 due to outside loadings less than 10 times the mean blank level and inside loadings at or below the blank level). They corrected the remaining 52 sample sets for blank value, and then tabulated by inside and outside filter weights, inside and outside sample volume, and associated WPFs. Since nearly all of the dust was of respirable size, the authors did not report results for the total dust samples. Comparing the sampling results with the mean blank levels, the investigators stated that the analytical confidence limits of the data were poor, with only 11 samples being better than plus or minus 25%. The authors considered samples with inside concentrations greater than 1,000 times the mean field blank to be an accurate indicator of the respirator's performance capability; seventeen sample sets met this criteria, but they removed two samples WPF calculation database as outliers. For the remaining 15 samples, the GM WPF was 4,076, the GSD was 2.3, and the fifth percentile WPF was 1,038.

The authors concluded that WPFs generated from sample sets with light outside dust loadings significantly underestimated respirator performance; higher outside sample loadings appeared to be less influenced by non-respirator variables. The investigators judged WPF estimates derived from data subsets with higher outside filter loadings as providing a better indication of respirator performance capability. The authors also discussed an apparent correlation between WPFs and outside filter loadings (*i.e.*, a higher loading equaled higher a WPF until reaching a plateau about 600 times the mean blank value); however, the correlation between WPFs and outside concentrations was not statistically significant. In addition, the effect of higher versus lower helmet airflow rate on sample results and WPFs was not significant. They also discussed the daily and overall WPFs achieved when using time-weighted-averages for the calculations. They concluded that their data supported the ANSI Z88.2 proposed APF of 1,000 for loose-fitting SARs with hoods or helmets.

Study 20. At the 1989 AIHCE, A.R. Johnston, C.E. Colton, D.W. Stokes, H.E. Mullins, and C.R. Rhoe presented a WPF study on a 3M W–8000 Whitecap II SAR with a helmet, and equipped with a breathing tube (W–5114), a compressed air hose (W–9435), and either a vortex cooling assembly (W–2862) or air regulating valve (W–2907) (Ex. 1–64–37). They evaluated exposure to iron (Fe) dust and silicon (Si) dust for six workers involved in grinding iron parts at a foundry. Air supply pressure was 60 psi with the vortex cooler or 25 psi with the regulating valve, thereby maintaining a helmet airflow rate of 6.7 cfm throughout the test. They did not mention employee selection procedures, previous use of respiratory protection, provision of training, or respirator donning and doffing procedures. They verified air supply pressure; valve settings; and integrity of the respirator, connections, and sampling train before starting the sampling pumps. They stopped the samplers before disconnecting the respirator from the air supply; they then took the participants to a clean area to remove the sampling cassette. The investigators observed the employees on a one-on-one basis during sampling, and used field blanks to evaluate possible contamination due to sample handling.

The inside-the-facepiece sampling train consisted of a 25 mm cassette containing a 0.8 micron pore size polycarbonate filter. The authors attached the cassette to a Liu probe installed into the faceshield approximately midway between the nose and mouth; it extended a few millimeters into the helmet. They

collected inside-the-facepiece samples at an airflow rate of 2 Lpm. The outside-the-facepiece sampling train also used 25 mm cassettes containing 0.8 micron pore size polycarbonate filters. The investigators collected outside samples as respirable dust using a MSA or Bendix cyclone operating at an airflow rate of 1.7 Lpm; however, they did not mention the location of the outside sample cassette. They collected area samples for particle size analysis using cellulose acetate filters and a personal sampling pump operating at 2 Lpm. They calibrated the sampling pumps at least three times a day, but did not mention specific calibration times.

The authors analyzed the samples for Fe and Si using proton induced x-ray emission (PIXE) analysis. Having detected Fe and Si on the field blanks, they used the mean blank value to correct inside- and outside-the-facepiece sample weights. They used optical microscopy to determine mean particle size range from 6 area samples. The investigators presented no data for individual inside- and outside-the-facepiece concentrations, and associated WPFs; however, they did provide the range of outside sampling measurements, and the overall average outside concentration, for both analytes. While they presented the range of inside-the-facepiece concentrations, they did not report the average inside concentrations. Outside samples averaged 1,500 μg/m^3 for iron dust, and ranged from less than 100 to 2,800 μg/m^3. Outside samples for silicon averaged about 1,000 μg/m^3, with a range from less than 100 to 1,500 μg/m^3. Inside concentrations were at or near the detection limits for both elements. For the 39 samples with values greater than 25 times the field blank, the authors reported a GM WPF of 273, a GSD of 5.7, and a fifth percentile of 39. For samples with outside filter weights greater than 750 times the field blank, they reported a GM WPF of 1,012, a GSD of 2.6, and a fifth percentile of 199. The investigators found a significant correlation between mean filter weights and WPFs; this correlation did not plateau at higher filter loadings. The authors stated that their measurements never reached a level at which the protection factors were independent of the outside filter weight. They concluded that the relatively low sample loadings resulted in WPFs that significantly underestimated the respirator's performance. They stated that, in the case of SARs, the researchers:

* * * should attempt to target outside loadings of at least 1000 times the anticipated analytical detection limit. If we do not, the data we get is likely to reflect limitations of our sampling and analysis procedures, rather than the respirators we are testing.

Study 19. At the 1993 AIHCE, C.E. Colton, H.E. Mullins, and J.O. Bidwell of 3M presented a WPF study on the 3M Snapcap W–3256 airline respirator (TC 19C–70) with a loose-fitting hood, fitted with a W–3258 hard hat, W–5114 breathing tube, W–2862 vortex tube air regulating valve, and 50–100 feet of W–9435 compressed-air hose (Ex. 1–64–17). They measured exposure to silica (Si) for four workers involved in furnace teardown at a foundry. The respirators were operated at an air pressure of 75 psi, with the participants were permitted to regulate the airflow rate to a comfortable level. The authors later determined that this level was 8–9 cfm. The job task consisted of using pneumatic chippers to remove the furnace wall and bottom. Pieces of wall and bottom either fell into or were shoveled into a barrel for removal. The employees then vacuumed of the furnace bottom. The job consumed most of the eight-hour shift. Since the furnace was warm and the work was physical, the employees worked in pairs for about one hour before switching with other employees; therefore, sampling times varied over the two separate days of the study. Participants normally wore air-line respirators. The investigators informed them of the study's purpose, procedures, and their role, and provided them with instruction on the proper donning, fitting, and operation of the respirator; however, the authors did not mention fit testing the participants. The investigators observed the employees on a one-on-one basis during sampling. The employees donned and doffed the respirators and sampling trains in a clean area, and the investigators checked the integrity of the respirator and sampling train before the respirator was connected to the air supply. The authors started the sampling pump after connecting the respirator to the air line, and stopped the pump before disconnecting the respirator from the air supply. They used field blanks to evaluate the possibility of contamination from handling the samples.

Inside- and outside-the-facepiece samples were collected in 25 mm three-piece cassettes containing 0.8 micron pore size polycarbonate filters and porous plastic back-up pads. Inside-the-facepiece cassettes were attached to the inside of the hood, directly across from the employee's mouth, with the cassette pointed toward the employee. A nylon Liu probe was attached to the inside cassette, and a sample line ran through the elasticized inner shroud and out to the sampling pump; the inside sampling flow rate was 2 Lpm. Outside-the-facepiece samples were collected as respirable dust through use of a 10 mm nylon cyclone; the outside sampling flow rate was 1.7 Lpm. The authors do not mention the location of the outside sampling cassettes, or what method they used to conduct particle size sampling.

The investigators used PIXE to analyze collected samples for Si; however, overloading of many of the outside-the-facepiece samples prevented PIXE analysis, requiring analysis of these samples by Inductively Coupled Plasma (ICP) spectroscopy. The authors made no field blank adjustments to the measured sample weights (*i.e.*, Si was not detected on the field blanks). The investigators intended to invalidate sample pairs with an outside filter weight less than 1,001 times the field blank value, or limit of detection if the field blank value was zero; all outside sample weights were more that 10,000 times the detection limit. In addition, they rejected sample pairs with inside sample weights that were less than the mean blank value. They did not mention correcting inside-the-facepiece values for pulmonary retention of particles, or how they managed sample results that were below the analytical detection limit. Particle size analysis showed the contaminant to be ''a dust with over 50 percent of the mass greater than 10 μm.'' The authors established a correlation between the PIXE and ICP analytical methods by analyzing 37 samples using both methods. They developed a linear regression equation that permitted PIXE equivalents to be predicted from the ICP results. They reviewed the WPF results using: The ICP results for the outside concentrations, and PIXE results for the inside concentrations; and the regression to predict PIXE equivalents for the outside concentrations, and PIXE results for the inside concentrations.

The authors calculated WPFs and checked the resulting values for outliers at the 99% confidence level. They did not provide individual inside- and outside-the-facepiece concentrations, but instead reported an overall range of inside and outside concentrations, along with the ranges' associated GM and GSD. In addition, the authors did not provide individual WPF values, but presented calculated WPFs as an overall fifth percentile WPF, GM, and GSD for each of the 2 days, based on both methods discussed above (*i.e.*, ICP and PIXE equivalent). They found that the two methods gave similar results. Using the equivalent PIXE values (*i.e.*, calculated from ICP values), and the

PIXE in-facepiece values, the GM WPF was 10,344, the GSD was 2.5, and the fifth percentile WPF was 2290. The authors stated that the loose-fitting hood performed differently than a loose-fitting PAPR, and this difference should be reflected in the APF assigned. In addition, they briefly discussed a comparison of the study results with the results of several other PAPR and air-line respirator studies.

Study 25. In 2001, T.J. Nelson, T.H. Wheeler, and T.S. Mustard published a WPF study of a supplied-air hood (Ex. 3–6). They measured exposure to strontium (Sr) for 19 painters and helpers involved in sanding and painting operations on several types of aircraft. They judged the work rate to be light to moderate. Prior to sampling, they informed the employees about the study, and instructed them to remain connected to the air supply during calibration and sampling. The participants used a 3M H–422 series supplied-air hood, equipped with an outer bib with an inner shroud and hard hat, H–420 hood, W–3258 hard hat, W–2878 suspension, 50 feet of W–9435 hose, and either the W–2862 vortex cooling assembly or the W–2863 vortex heating assembly. The investigators regulated the supply air pressure to between 60 and 80 psi. Employees donned the hoods in the work area, but investigators did not attach the sampling cassettes until after the employees connected the hood to the air supply and airflow began. They used field blanks to identify possible contamination due to handling, storage or shipment. In addition, they used manufacturer's blanks to detect contamination from manufacture of the filter, and a system blank to determine if contamination was present in the air supply.

The investigators collected inside- and outside-the-facepiece samples using 37 mm or 25 mm three-piece cassettes containing mixed cellulose ester filters. The first 19 samples (*i.e.*, collected during sanding) utilized 37 mm cassettes/filters, but half of the outside samples had no detectable Sr. To increase analytical sensitivity, they collected the remaining 18 samples with 25 mm cassettes and filters. Once the employee was connected to the air supply, they attached a sampling cassette inside the hood at a point midway between the nose and mouth, and to the side of the face. They then uncapped the cassette and connected a Liu probe to the cassette inlet. The authors placed the outside cassette in the lapel area and pointed it forward and down. They started the sampling pumps simultaneously, and performed in-line calibration. They collected samples at an airflow rate of 2 Lpm, for a period consisting of 2 hours for sanding and 90 minutes for painting. At the end of sampling period, they in-line calibrated the pumps, stopped the pumps, capped and removed the cassettes, and the employees disconnected and doffed the hood. They collected the system blank by mounting a cassette in an operating hood that was located away from the work area, and sampled air from inside the hood at 2 Lpm for 2 hours The authors did not mention making a particle size determination.

The investigators analyzed the outside-the-facepiece samples and one of the manufacturer's blanks using NIOSH Method 7300. They used PIXE analysis for the inside-the-facepiece samples, field blanks, system blank, and the other manufacturer's blank. They tabulated the sampling results by date, activity, employee, sample time, inside and outside sampled volumes, inside and outside concentrations, and WPF. The authors reported thirty-one individual inside- and outside-the-facepiece concentrations. However, the results of the outside samples obtained during sanding operations were only 30 times greater than the inside sample values. Therefore, the authors did not consider the data from the sanding operations to be a very useful indicator of respirator performance, and they did not calculate WPFs for the initial 19 sanding samples. Of the remaining 18 painting samples, they calculated WPFs for only 15 samples, after discarding 3 samples due to sampling errors. The Sr levels measured outside of the respirator ranged from 340 to 24,529 $\mu g/m^3$, but the investigators found no detectable amounts of Sr on any inside-the-facepiece sample. Therefore, the authors could not directly determine WPFs for the respirator. However, they estimated WPFs by substituting the limit of detection for the inside concentration values. This procedure resulted in estimated WPFs that ranged from more than 920 to 52,000. The authors concluded that their study was ''* * * consistent with other simulated and WPF studies in that the ANSI Z88.2 WPF of 1000 is supported.''

8. SWPF Studies—Type CE Abrasive Blasting Respirators

Bullard: 1995 LLNL Evaluation. During the development of the Interim Final Standard for Lead (Pb) in Construction (1926.25; 1996) and the Final Respiratory Protection Standard (63 FR 1152; 1998), the E.D. Bullard Company (Bullard) expressed concern about the APF of 25 for Type CE respirators. The concern was that the interim final lead rule, as issued, went far beyond the HUD guidelines by assigning a different and lower protection factor to Type CE respirators than the HUD guidelines, which incorporated the general industry standard at 29 CFR § 1910.1025. Bullard maintained that its Model 77 and 88 respirators provide much greater protection, and sought to have the APF for these models elevated to 1,000 in the Lead in Construction Standard. OSHA agreed to provide Bullard with the relief sought only if it contracted with an acceptable third party to design, monitor, and interpret the results of a simulated workplace study of these models under an appropriate and acceptable test protocol. As a condition for granting that relief, the study had to demonstrate that the abrasive blasting respirators achieved, at a minimum, a protection factor rating of at least 20,000 and maintained positive pressure throughout the testing.

Bullard contracted with Lawrence Livermore National Laboratory (LLNL) which designed, conducted, and interpreted the results of the SWPF study, based on a protocol that was acceptable to OSHA. The LLNL informal report resulting from the testing indicated (based on computerized data backed up by strip chart recordings) that the two Bullard abrasive blast respirators achieved a minimum protection factor of 40,000 and maintained positive pressure throughout the testing.

Therefore, the SWPF study conducted by LLNL demonstrated that, if used properly, the Bullard respirators were acceptable for lead exposures that are less than or equal to 1,000 times the PEL (50,000 $\mu g/m^3$). In an August 30, 1995 memo to its Regional Administrators, OSHA recognized that the SWPF study results indicated that an APF greater than 25 was appropriate for the Bullard Model 77 and Model 88 respirators, and the Agency granted these models an interim APF of 1,000 when used for lead in construction (Ex. 3–8–4; memo to RAs dated 8/30/95). However, the memo also noted that the Agency was aware of other data and at least one field study showing that in the workplace these respirators may provide considerably less protection when used in ways that do not conform to the manufacturer's specifications (*e.g.*, the air supply hose is too long; the hose diameter is incorrect; the manufacturer's specified air pressure is not maintained) or that do not comply with the requirements of paragraphs (b), (d), (e) and (f) of 1910.134 (*e.g.*, the respirator is not inspected frequently enough for

possible deterioration). The memo further stated that respirators will provide less protection than they are capable of, when used improperly (*e.g.*, donning and doffing the respirators while still in containment; disconnecting the air hose prior to leaving the exposure area). In addition, these respirators are used in extreme conditions during construction activities (*e.g.*, substantial and, sometimes rapid, deterioration caused by high-speed ''bounceback'' of the abrasive blasting material; very high levels of exposure). The impact of ''bounceback'' on the integrity of the respirator was not evaluated in the LLNL SWPF study since the study challenge agent was a liquid, not a particulate (which is typically the type of contaminant found in workplaces). Also, because these respirators may, at times, be used near the limits of their protective capability, workers wearing these respirators in abrasive blasting operations could receive acute exposures if the respirators do not perform properly. Therefore, performance consonant with the elevated APF can only be assured when the respirators are properly used.

As a result of the above, OSHA adopted a modified enforcement policy for these two respirators. This policy was limited to the Lead in Construction Standard (29 CFR 1926.62) and applied only to the Bullard Models 77 and 88. Also, the interim APF of 1,000 was pending until a final APF for this class of respirators could be determined through this rulemaking. Since OSHA believes that proper use of these respirators is imperative, the policy made it clear that the Agency would be very strict in assuring that these respirators are used in accordance with the manufacturer's specifications and the requirements of 1926.62.

Clemco Apollo Models 20 and 60 and 3M Whitecap II. With the assistance of the Industrial Safety Equipment Association (ISEA), other respirator manufacturers of Type-CE, continuous-flow, abrasive blasting respirators covered by the Lead in Construction Standard were contacted. By participating in a similar study, these manufacturers were provided with an equal opportunity to obtain the same relief afforded to Bullard. The Clemco Apollo Models 20 and 60 and the 3M Whitecap II were tested under conditions similar to the Bullard Model 77and 88 study. Based on the results of the studies, OSHA granted the respirators the interim APF of 1,000, and developed the same enforcement policy for Clemco (Ex. 3–7–4; memo to Regional Administrators dated 03/31/97) and 3M (Ex. 3–9–3; memo to Regional Administrators dated 12/08/98). Again, the interim APF was contingent on the final APF for these respirators being determined through this rulemaking.

9. SWPF Studies—N95 Air-Purifying Respirators

NIOSH N95 Chamber Studies. In 1999, NIOSH conducted a chamber study of N95 respirators and statistically analyzed the respirators' performance (Ex. 4–14). The study involved twenty-five subjects meeting the criteria of the LANL respirator panel. Twenty-one respirators were tested and included twenty filtering-facepiece and one elastomeric half-mask. Each test involved a sequence of six sedentary-type exercises: Normal breathing, deep breathing, moving the head side to side, moving the head up and down, reading the rainbow passage out loud, and normal breathing. Each exercise took about 80 seconds. For all tests, the subjects donned the respirator and conducted a user seal check in accordance with the manufacturer's instructions. After each test, the test operator returned the respirator to its original pre-test configuration (*e.g.,* strap was loosened). The investigators used a PortaCount Plus, a condensation nucleus type of particle detector, to determine the protection factor by measuring both the challenge aerosol (*i.e.*, ambient aerosol) and the aerosol penetrating the respirator.

The total penetration of an aerosol into a respirator includes the penetration through the filter media in addition to that resulting from face seal leakage. To determine face seal leakage, the study authors subtracted estimated filter media penetration from the total observed penetration. Filter media penetration was ascertained by separate testing performed on the filter media after human subject testing. Testing was conducted at an airflow rate of 31.4 Lpm, as determined from a volume-weighted average cycle having a peak flow rate of 40 Lpm. The same penetration for a given media was subtracted from the total penetration for all subjects using a respirator with that media. Calculating face seal leakage in this manner assumes all subjects have the same constant, volumetric flow rate through the respirator. The authors also summarized total penetration and face seal leakage penetrations. The 95th percentiles presented by NIOSH were based on a formula using the geometric mean and geometric standard deviation, and assumes the distribution to be log normal.

LLNL Study of Four N95 Filtering Facepiece Respirators. At OSHA's request, researchers at LLNL conducted chamber testing on four of the same commercial N95 filtering facepiece half-mask respirators used in the NIOSH study (Ex. 4–14). The four N95 filtering facepieces selected by OSHA for study were: 3M Model 8210, 3M Model 8511, Wilson Model 9501, and MSA Affinity Ultra (formerly Uvex/Pro Tech Model 4010). Six subjects (three male, three female) with six different face dimensions (according to lip length) used each filtering facepiece. These subjects represented six different boxes on the Los Alamos National Laboratory half-mask test panel (Boxes 4, 5, 7, 8, 9, and 10). Subjects used the manufacturer's instructions prior to donning the respirator. Each subject tested each respirator 4 times, for a total of 16 tests per subject and 96 tests overall. The investigators probed the respirators in the area of the nose, using the TSI fit-test probe kit, and measured penetration values with a TSI PortaCount Model 8020. They used ambient room aerosol as the challenge atmosphere and monitored it continuously during testing with a second PortaCount. They used room aerosol at concentrations greater that 2,000 particles/cc. Subjects removed the filtering facepiece at the conclusion of each test and, after approximately 2 minutes, redonned the same unit. The test operator restored the respirator to pre-test configuration (*e.g.*, straps were loosened) after each donning. Each test consisted of nine exercises: normal breathing, deep breathing, side-to-side head movement, up and down head movement, reading the rainbow passage, normal breathing, scooping rocks between buckets, stacking 30-pound concrete blocks and normal breathing. Subjects performed each exercise for 80 seconds, with a 20-second instrument purge cycle and 60 seconds of data collection per exercise.

For each model of respirator, the investigators used the size that showed the least penetration when the subject performed a 60-second reading of the rainbow passage. This was a change from using the penetration measured during normal breathing (as done in the original NIOSH tests), and was chosen because reading is frequently found to be an exercise that permits high penetration. A 60-second normal breathing fit test was performed in addition to the reading fit test. Multiple fit tests (both reading and normal breathing) were performed, if necessary, to select a model size. Once fitted, each

subject completed four full nine-exercise tests.

The NIOSH penetration results without fit-testing were compared to the LLNL test results. In general, the investigators found good agreement between the two studies, with the range of penetrations being similar in both studies. However, two differences were noted. For one model, (referred to by the researchers as Model D), the OSHA/LLNL study result indicated slightly more penetration than was observed in the NIOSH study. While the minimum penetration for Model D was 2 in both studies, the maximum penetration was 460 in the OSHA/LLNL study compared to 370 in the NIOSH study. However, both studies showed this respirator to be in the low performance range of penetrations. The researchers believed that this could be attributed to a poor-fitting individual that participated in the larger NIOSH study, but whose fit factor attributes were not represented by any participants in the smaller OSHA/LLNL study. They also noted that the design features of Model D, such as its folded shape and the plastic nose clip, may explain this respirator's poor performance. Furthermore, while this respirator was available in three sizes, it was very difficult to determine which size provided the best fit for several of the subjects.

The LLNL penetration result for another respirator, referred to by the researchers as Model A, was slightly better than the NIOSH result for the same respirator. The LLNL researchers believed that the lower penetration they measured for Model A was possibly due to the difference in model size/fit selection criteria between the NIOSH tests and the LLNL tests (discussed above). Again, they felt that another possible reason could have been a poor-fitting individual in the larger NIOSH study that was not represented by the smaller OSHA/LLNL study.

The LLNL researchers further investigated the apparent difference between the LLNL and NIOSH results for Model A. They found that eliminating subjects with poorly-fitting respirators significantly affects results. For example, a subject was started in the LLNL/OSHA test but was not tested because the investigators were unable to maintain a proper fit on the individual when using Model A (*i.e.*, it fell completely off the nose of the subject upon donning). If tested, this subject or another less obvious subject who experienced poor fit, could have skewed the results of the LLNL/OSHA N95 evaluation significantly. The LLNL researchers believed that this latter analysis illustrates the potential influence of a single outlier on the overall results of a study. The advantages of controlled SWPF testing are apparent in this example.

10. SWPF Studies—PAPRs and SARs

ORC Study on Respirators Used in the Pharmaceutical Industry. Before the publication of the final respiratory protection standard, Organization Resources Counselors, Inc. (ORC) raised an issue that had been the subject of discussions between ORC and OSHA for several years. In 1997, ORC and a group of its member companies sponsored a study of certain models of powered air-purifying and supplied-air respirators to evaluate the ability of these respirators to protect workers from exposures in the pharmaceutical industries. The study, ''Simulated Workplace Protection Factor Study of Powered Air Purifying and Supplied Air Respirators,'' (Ex. 3–4–1) was completed in 1998, and the initial results, along with detailed experimental data, were presented to OSHA.

The experimental protocol used in the study was developed by the Organization Resources Counselors' respirator task force, LLNL investigators, participating respirator manufacturers, and representatives from NIOSH and OSHA. The study included a simulated workplace exercise protocol consisting of 12 exercises: normal breathing, twisting the head from side-to-side, moving the head up and down, touching toes, raising arms above the head, twisting at the waist, running in place, normal breathing, hand scooping of pebbles, normal breathing, building a concrete block wall, and normal breathing. Two exercises, hand scooping of pebbles and building a concrete block wall, were included to simulate tasks in the pharmaceutical industry. Seventeen subjects participated in the evaluation of five powered air-purifying respirators (PAPRs) and six supplied-air respirators (SARs). Twelve tests were conducted for each respirator, with the study being performed in the LLNL respirator test facility.

Input from OSHA resulted in two modifications to the protocol. It was decided that at least one of the three units for each respirator model tested would be purchased from the open market with the others being supplied directly from the manufacturer. A second change resulted from the Agency's interest in evaluating intra-personal variability in the performance of respirators. This was accomplished by testing one PAPR model and one SAR model during six wearings by a single individual. No significant difference in respirator performance was noted as a result of these modifications, and the overall results are presented below.

The results of the ORC study indicated that although simulated workplace protection factors (SWPFs) greater than one million were recorded during some of these tests, a reporting limit of 250,000 was established as the highest value in which reliable facepiece leakage could be detected (limit of quantification). The median SWPFs for all respirators, except one SAR, were at or above the reporting limit of 250,000. Lower fifth percentiles were above 100,000, with the exception of the one SAR. APFs were established for each of the 11 respirators by dividing the lower 5th percentile by a safety factor of 25. APFs ranged from 6,000–10,000 for PAPRs (including one loose-fitting PAPR), and 3,000–10,000 for SARs, with the exception of one device. This SAR had lower 5th percentile of less than 20 and an APF of 1. Results are presented in the table below.

TABLE 4.—SUMMARY OF SIMULATED WORKPLACE PROTECTION FACTOR RESULTS

Device	Range of SWPFs	Median SWPF	5th percentile SWPF
PAPR 1	140,000–>250,000	>250,000	>250,000
PAPR 2	11,000–>250,000	>250,000	170,000–210,000
PAPR 3	11,000–>250,000	>250,000	>250,000
PAPR 4	94,000–>250,000	>250,000	246,000–>250,000
PAPR 5	240–>250,000	>250,000	150,000–230,000
SAR 1	68,000–>250,000	>250,000	>250,000
SAR 2	13,000–>250,000	>250,000	170,000–220,000
SAR 3	9,700–>250,000	>250,000	86,000–114,000
SAR 4	5,500–>250,000	>250,000	150,000–240,000
SAR 5	5–>250,000	GM=1217	13–18

TABLE 4.—SUMMARY OF SIMULATED WORKPLACE PROTECTION FACTOR RESULTS—Continued

Device	Range of SWPFs	Median SWPF	5th percentile SWPF
SAR 6	160,000–>250,000	>250,000	>250,000

List of Respirators

Powered Air-Purifying Respirators With Hoods/Helmets

(PAPR1) 3M Whitecap helmet with chinstrap with GVP blower (hard plastic helmet with bib).
(PAPR 2) 3M Snapcap hood with chinstrap with GVP–100 blower (Tyvek hood with bib).
(PAPR 3) Racal BE–5 (clear PVC hood with bib).
(PAPR 4) Racal BE–10 (Polycoated Tyvek hood with bib and head suspension).

Loose-Fitting Powered Air-Purifying Respirator

(PAPR 5) Racal BE–12 (Polycoated Tyvek loose-fitting facepiece).

Supplied-Air Respirators

(SAR 1) 3M Whitecap helmet with chinstrap (hard plastic helmet with bib).
(SAR 2) 3M Snapcap hood with chinstrap (Tyvek hood with bib).
(SAR 3) MSA VERSA-Hood with #5–613–1 direct hose connection for 3/8'' hose system (Tyvek hood).
(SAR 4) North Model 85302 TB (Tyvek hood with ratchet head suspension and bib).
(SAR 5) North Model 85302 T (Tyvek hood with ratchet head suspension).
(SAR 6) Bullard CC2OTIC with 2ORT suspension and 2ONC chinstrap (Tyvek hood with bib).

Note: All PAPRs tested with high-efficiency filters.

The study report was finalized in 1999, and ORC requested that OSHA consider assigning an interim final APF of 1,000 to the study's high-performing respirator models, with provisions for an APF as high as 5,000 based on programmatic and environmental factors (Ex. 3–4–3, 1999 communication with OSHA). ORC also recommended that, because the current NIOSH respirator certification procedures are not capable of distinguishing between high-performing PAPRs and SARs (and that some respirators may not provide adequate protection), the study methodology should be the basis for determining APFs for all respiratory protective equipment regulated by OSHA.

In 2000, ORC renewed its requests. They pointed out that the study demonstrated that the PAPRs tested, including the loose-fitting facepiece PAPRs, were capable of achieving protection factors of 6,000 to 10,000 (rather than the APF of 25 assigned by NIOSH and adopted by OSHA), and that the tested SARs achieved protection factors of 3,000 to 10,000. However, one tested SAR model did not provide a protection factor of 25, demonstrating to the Agency the importance of testing specific equipment being considered for an increased APF to assure the expected protection.

ORC asserted that new APFs for the models tested in the study were warranted. They believed that the study results justified a re-evaluation of the methods for assessing the ability of PAPRs and SARs to provide protection against airborne particulates, and asked OSHA to issue a directive or similar document assigning an interim APF of 1,000 for the SARs and PAPRs that tested successfully in the study. ORC believed that SWPF testing of PAPRs and SARs was beneficial, and strongly supported use of a collaborative approach as was pursued in developing the study.

OSHA permitted use of an interim APF of 1,000 for 9 of the 11 respirators tested and developed an enforcement policy similar to that followed for the Bullard, Clemco, and 3M respirators (Ex. 3–4–4; 2002 memo to RAs). Again, the interim APFs are subject to a final APF determination resulting from this rulemaking. OSHA requests comments on all aspects of this study.

LLNL/OSHA PAPR Study. OSHA requested that LLNL conduct two additional PAPR studies using the protocol of the 1995–96 ORC study. The raw data from the two evaluations were then compared with the ORC SWPF study data.

A modified SWPF protocol was used to test two additional PAPRs, an MSA OptimAir and a Neoterik, selected by OSHA. The testing employed the same exercise protocol as the ORC study; however, only three test subjects participated in the evaluation. The three test subjects each performed four separate donnings of each respirator model. The 50th and 95th percentiles of the penetration and protection factors for the two respirators are shown in Table 5.

TABLE 5

Respirator model	Penetration		Protection factor	
	50th percentile	95th percentile	50th percentile	95th percentile
MSA OptimAir	1.67×10^{-6}(a)	4.08×10^{-5}	250,000(a)	24,510
Neoterik	2.74×10^{-5}	1.43×10^{-3}	36,563	698

For the Neoterik, SWPFs of 100 and somewhat less were observed for the running in place and the moving bricks (building a concrete block wall) exercises. The Neoterik demonstrated SWPFs near 1,000 and somewhat less for the twisting head side to side, moving the head up and down, and touching toes exercises. For the MSA OptimAir, SWPFs approaching 100 for the running in place exercise were observed, while all of the other exercises resulted in SWPFs of 10,000 or greater. Penetration levels by type of exercise were compared between the OSHA PAPR analyses and the ORC results. In general, the comparison indicated that the same exercises triggered increased penetration values. That is, sources of penetration were ''running-in-place'' (for both respirators) and ''moving bricks'' (for the Neoterik PAPR).

V. Health Effects

In a number of previous rulemakings, OSHA discussed the serious health effects caused by exposure to airborne chemical hazards (*see, e.g.*, Appendix A of the Hazard Communication Standard

at 29 CFR 1910.1200, and the preambles to any of the Agency's substance-specific standards codified at 29 CFR 1910.1001 to 1910.1052). When OSHA promulgates a new or revised PEL for a chemical air contaminant, (*e.g.*, Arsenic, 29 CFR 1910.1018; Asbestos, 29 CFR 1910.1001; Benzene, 29 CFR 1910.1028; Lead, 29 CFR 1910.1025; Ethylene Oxide, 29 CFR 1910.1047), it determines at what level of exposure to the contaminant employees develop serious health effects (*e.g.*, exposure to the contaminant is life-threatening, causes permanent damage, or significantly impairs employees' ability to perform their jobs safely).

As discussed in Section VI, ''Summary of the Final Economic Analysis,'' of the final Respiratory Protection Standard (63 FR 1171), OSHA estimated that improvements and clarifications made to the previous Respiratory Protection Standard would prevent, each year, between 843 and 9,282 (best estimate, 4,046) work-related injuries and illnesses, and between 351 and 1,626 (best estimate, 932) work-related deaths from cancer and chronic diseases such as cardiovascular disease. To support this estimate, OSHA used its Integrated Management Information System database to identify several substances that had a wide range of adverse effects, as well as documented workplace exposures that exceeded the PELs for these substances. The health effects associated with exposure to these substances include:

- Sudden death or asphyxiation (*e.g.*, from exposure to carbon monoxide, carbon dioxide);
- Loss of lung function (*e.g.*, from exposure to wood dust, welding fumes, manganese fumes, copper fumes, cobalt metal fumes, silica);
- Central nervous system disturbances (*e.g.*, from exposure to carbon monoxide, trichloroethylene);
- Cancer (*e.g.*, from exposure to chromic acid, wood dust, silica); and
- Cardiovascular problems (*e.g.*, from exposure to carbon monoxide).

Furthermore, most of the airborne contaminants measured as part of the workplace protection factor studies considered during development of this proposal cause serious health effects. For example, acute lung, skin, and eye irritation occur as a result of occupational exposures to styrene, lead, strontium, benzo(a)pyrene, and silica. Longer-term exposures to other substances sampled in these studies cause bone and blood effects (lead particulates), neurological effects (mercury fumes), chronic lung damage (cotton dust), and cancer (asbestos fibers and chromium particulates).

The risk that an employee will experience an adverse health outcome while exposed to a hazardous airborne substance is a function of the toxicity or hazardous characteristics of the substance, the concentrations of the substance in the air, the duration of exposure, the physiology of the employee, and workplace conditions. These factors combined assist in determination of the type of respirator selected to reduce an employee's exposure below the PEL for the hazardous substance. Under many workplace-exposure conditions, prevention of serious health effects depends substantially on the protection afforded to employees by a respirator.

Employers need the APFs provided in this proposal to select appropriate respirators for employee use when engineering and work-practice controls are insufficient to maintain hazardous substances at safe levels in the workplace. In this regard, the proposed APFs will permit employers to select respirators for employee protection based on the type of hazardous substance and the level of employee exposure to that substance, among other factors. OSHA strongly believes that proper respirator selection using the proposed APFs will protect employees from overexposure to hazardous substances, thus preventing the serious health effects that result from such overexposure.

While APFs are an important factor in respirator selection, employers must consider other factors as well. In this regard, simply applying an APF to the level of an airborne contaminant in a workplace will not ensure that employees receive adequate protection. Throughout the preamble of the final Respiratory Protection Standard, OSHA demonstrated that adequate fit testing, proper respirator use, employee training, and thorough inspection and maintenance of respirators are some of the other factors essential to an effective respiratory protection program. The Agency believes that failure to comply with any of these program requirements substantially increases the chance that the respirator selected by the employer will not protect employees against hazardous air contaminants because of respirator malfunction, excessive leakage, improper use, or some combination of these problems. Therefore, employers should expect respirators to provide effective employee protection against the serious health effects of hazardous airborne substances only when they use the respirators in the context of a comprehensive respiratory protection program. If respirators are to provide employees with at least the minimum level of exposure protection listed in the proposed APF table, employers must comply with the other respiratory protection requirements specified under OSHA's Respiratory Protection Standard at 29 CFR 1910.134.

In this rulemaking, OSHA also is proposing to supersede the existing APF requirements in its substance-specific standards. By superceding these requirements, the Agency expects that the benefits estimated for the proposed APFs under the Respiratory Protection Standard would be available to employers who must select respirators for employee use under the substance-specific standards. In addition, OSHA would be harmonizing the APF requirements in the substance-specific standards with the APF requirements proposed for its Respiratory Protection Standard. The Agency believes that harmonization would reduce confusion among the regulated community and aid in uniform application of APFs, while maintaining employee protection at levels at least as protective as the existing APF requirements.

VI. Summary of the Preliminary Economic and Regulatory Flexibility Screening Analysis

A. Introduction

OSHA's Preliminary Economic and Regulatory Flexibility Screening Analysis (PERFSA) addresses issues related to the costs, benefits, technological and economic feasibility, and economic impacts (including small business impacts) of the Agency's proposed Assigned Protection Factors (APF) rule. The Agency preliminarily determined that this rule is not an economically significant rule under Executive Order 12866. The economic analysis meets the requirements of both Executive Order 12866 and the Regulatory Flexibility Act (RFA; as amended in 1996). The PERFSA presents OSHA's full economic analysis and methodology. The Agency entered the complete PERFSA into the docket as Exhibit 6–1. The remainder of this section summarizes the results of that analysis.

The purpose of this PERFSA is to:

- Identify the establishments and industries potentially affected by the rule;
- Evaluate the costs employers would incur to meet the requirements of proposed APF rule;
- Estimate the benefits of the rule;
- Assess the economic feasibility of the rule for affected industries; and
- Determine the impacts of the rule on small entities and the need for a Regulatory Flexibility Analysis.

B. The Rule and Affected Respirator Users

OSHA's proposed APF rule would amend 29 CFR 1910.134(d)(3)(i)(A) of the Respiratory Protection Standard by specifying a set of APFs for each class of respirators. These APFs specify the highest multiple of a contaminant's permissible exposure limit (PEL) at which an employee can use a respirator safely. The proposed APFs would apply to respirator use for protection against overexposure to any substance regulated under 29 CFR 1910.1000. In addition, OSHA rules for specific substances under subpart Z (regulated under the authority of section 6(b)(5) of the OSH Act of 1970, 29 U.S.C. 655) specify APFs for respirators used for protection against these chemicals (hereafter referred to as section 6(b)(5) substances). The proposed rule would supercede most of these protection factors, and harmonize APFs for these substances with those for general respirator use.

OSHA based estimates of the number of employees using respirators and the corresponding number of respirator-using establishments on the recent NIOSH–BLS survey of respirator use and practices [1] (Ex. 6–3). The NIOSH–BLS survey provides up-to-date use estimates by two-digit industry sector and respirator type for establishments in which employees used respirators during the previous 12 months.[2] As shown in Table VI–1, an estimated 291,085 establishments reported respirator use in industries covered by OSHA's proposed regulation. Most of these establishments (208,528 or 71.6 percent) reported use of filtering facepieces. Substantial percentages of establishments also reported the use of half-mask and full facepiece nonpowered air-purifying respirators (49.0 and 21.4 percent, respectively). A smaller number of establishments reported use of powered air-purifying respirators (PAPRs) and supplied-air respirators (SARs). Fifteen percent of establishments with respirators (43,154) reported using PAPRs and 19 percent (56,022) reported using SARs. Table VI–2 presents estimates of the number of respirator users by two-digit industry sector. An estimated 2.3 million employees used filtering facepiece respirators in the last 12 months, while 1.5 million used half masks, and 0.7 million used full facepiece nonpowered air-purifying respirators. Fewer employees reported using PAPRs (0.3 million) and SARs (0.4 million). The industry-specific estimates show substantial respirator use in several industries, including the construction sector, several manufacturing industries (SICs 28, 33, 34, and 37), and Health services (SIC 80).

[1] Preliminary results from the 2001 NIOSH–BLS ''Survey of Respirator Use and Practices'', in press. NIOSH commissioned the survey to be conducted by BLS, who also tabulated the data after completing the survey.

[2] The survey was conducted between August 2001 and January 2002. It asked: ''During the past 12 months, how many of your current employees used respirators at your establishment?'' It excluded voluntary use of respirators from detailed followup respirator use questions (Ex. 6–3).

BILLING CODE 4510–26–P

Table VI-1

Estimated Number of Establishments With Respirator Users, by Type

SIC	Title	All Respirator Types	Nonpowered Air-Purifying				Supplied-Air	
			Filtering Facepiece	Half-mask	Full-face	PAPR	Total	SCBA
07	Agricultural services	7,566	6,466	1,142	33 *	105 *	240 *	164 *
08	Forestry	261	261	208	1 *	4 *	8 *	6 *
09	Fishing, hunting, and trapping	0	0	0	0	0	0	0
13	Oil and gas extraction	1,097	490	1,097	499	220	412	250
15	General building contractors	19,071	15,069	6,729	1,859	1,520	1,213	674
16	Heavy construction, except building	4,718	3,816	2,432	915	757	1,213	355
17	Special trade contractors	40,823	31,380	17,025	10,161	7,136	8,198	2,693
20	Food and kindred products	3,608	1,926	1,433	1,901	428	1,010	720
21	Tobacco products	30	17	13 *	0	20	20	20
22	Textile mill products	720	627	272	201	139	9	0
23	Apparel and other textile products	1,111	943 *	925	14 *	0	0	0
24	Lumber and wood products	1,995	1,326	1,273	353	197	168	106
25	Furniture and fixtures	2,053	1,745	1,469	317	80	83	28
26	Paper and allied products	649	448	329	293	122	193	153
27	Printing and publishing	124	105 *	45	2 *	0	3	0
28	Chemicals and allied products	5,052	3,047	2,896	2,698	910	2,077	1,632
29	Petroleum and coal products	432	64	189	200	99	249	151
30	Rubber and misc. plastics products	3,140	2,094	1,707	1,117	695	938	121
31	Leather and leather products	14 *	12 *	6 *	0	0	340	0
32	Stone, clay, and glass products	3,109	2,089	1,765	495	589	530	119
33	Primary metal industries	1,974	1,533	861	385	491	550	183
34	Fabricated metal products	7,374	4,601	4,988	1,103	1,510	2,456	361
35	Industrial machinery and equipment	7,458	4,425	4,151	1,700	1,093	2,131	441
36	Electronic and other electric equipment	2,731	1,676	1,412	656	341	525	252
37	Transportation equipment	3,788	1,957	2,158	1,656	738	1,225	337
38	Instruments and related products	1,282	711	1,033	736	468	568	155
39	Miscellaneous manufacturing industries	3,140	2,389	2,295	1,442	1,276	439	133
40	Railroad transportation	846	417	803	380	375	503	134
41	Local and interurban passenger transit	809	405	522	87 *	73	86	86
42	Trucking and warehousing	4,090	3,240	793	850	463	751	617
43	United States Postal Service	1,012 **	801 **	196 **	210 **	115 **	186 **	153 **
44	Water transportation	50 *	7 *	50 *	5 *	14 *	55	0
45	Transportation by air	48 *	7 *	48 *	5 *	13	10 *	0
46	Pipelines, except natural gas	252	35 *	180	74	69 *	96 *	91
47	Transportation services	8 *	1 *	7 *	0	2	7	0
48	Communications	100 *	14 *	99 *	11 *	27	18 *	0
49	Electric, gas, and sanitary services	5,085	1,856	2,975	1,486	821	2,737 *	1,956
50	Wholesale trade--durable goods	18,854	10,795	9,641	3,259	2,776	2,926	1,278
51	Wholesale trade--nondurable goods	8,573	4,660	3,619	4,303	2,192	3,045	2,533
52	Building materials and garden supplies	2,386	2,386	1,433	688 *	496	89	66
53	General merchandise stores	687 *	211 *	471 *	190 *	143 *	19 *	19 *
54	Food stores	2,394 *	736 *	1,642 *	662 *	498	67 *	67 *
55	Automotive dealers and service stations	10,243	7,139	6,127	2,271	2,403	3,211 *	1,048 *
56	Apparel and accessory stores	308 *	95 *	211 *	85 *	64	1,442	9
57	Furniture and homefurnishings stores	2,769	2,586	1,710	799 *	576 *	77 *	77 *
58	Eating and drinking places	0	0	0	0	0	0	0
59	Miscellaneous retail	978	679	700 *	282 *	203	27	27
60	Depository institutions	1,372 *	1,349 *	36 *	59 *	6 *	0	0
61	Nondepository institutions	299 *	294 *	8 *	13 *	1	0	0
62	Security and commodity brokers	278 *	274 *	7 *	12 *	1	0	0
63	Insurance carriers	442 *	435 *	62	19 *	2	0	0
64	Insurance agents, brokers, and services	744 *	732 *	19 *	32 *	3	0	0
65	Real estate	1,541	1,031	1,115	67 *	7	0	0
67	Holding and other investment offices	157 *	155 *	4 *	7 *	0	0	0
70	Hotels and other lodging places	1,326	1,326	621	531	7 *	0	0
72	Personal services	9,743	4,779	9,115	1,192	52 *	0	0
73	Business services	13,517	11,574	4,952	4,578	72 *	925	925
75	Auto repair, services, and parking	32,113	26,523	19,568	5,793	5,655	8,778 *	3,263 *
76	Miscellaneous repair services	3,375	3,375	1,199 *	313 *	18 *	4,259	0

Table VI-1

Estimated Number of Establishments With Respirator Users, by Type

SIC	Title	All Respirator Types	Nonpowered Air-Purifying			PAPR	Supplied-Air	
			Filtering Facepiece	Half-mask	Full-face		Total	SCBA
78	Motion pictures	17 *	8 *	6 *	2 *	0	2	0
79	Amusement and recreation services	1,612	1,348	1,184	150 *	9 *	0	0
80	Health services	16,486	14,625	1,991	1,307	879	303	260
81	Legal services	61 *	29 *	22 *	6 *	0	3	0
82	Educational services	564	267 *	431	52 *	3 *	0	0
83	Social services	6,668	5,812	2,217 *	579 *	36 *	0	0
84	Museums, botanical, zoological gardens	235	112 *	235	22 *	1 *	16	16
86	Membership organizations	533	252 *	383	49 *	3 *	0	0
87	Engineering and management services	10,292	4,004	7,297	1,800	5,117	254	254
89	Services, n.e.c.	6 *	3 *	2 *	0	0	3	0
	State and local governments	6,893 ***	4,936 ***	3,392 ***	1,479 **	1,023 **	1,327 **	530 **
	Totals	291,085	208,528	142,947	62,448	43,154	56,022	22,461

Source: Preliminary results from the 2001 NIOSH/BLS Survey of Respirator Use and Practices, in press. Benchmarked to 1997 establishment counts from U.S. Bureau of the Census, Statistics of U.S. Businesses, 1997.

* Suppressed industry-level estimates extrapolated from sector totals.

** Estimated based on respirator use patterns in SIC 42.

*** Estimated based on private-sector respirator use patterns.

Table VI-2

Estimated Number of Respirator Users, by Type

SIC	Title	Nonpowered Air-Purifying				Supplied-Air	
		Filtering Facepiece	Half-mask	Full-face	PAPR	Total	SCBA
07	Agricultural services	52,919	6,030 *	1,713 *	139 *	942 *	567 *
08	Forestry	765 *	208 *	23 *	3 *	32 *	20 *
09	Fishing, hunting, and trapping	0	0	0	0	0	0
13	Oil and gas extraction	12,086 *	14,108	1,587 *	6,242	3,071	2,405
15	General building contractors	77,827	36,770	7,752	2,750	6,047	4,744
16	Heavy construction, except building	31,518	30,503	8,747	4,929	8,652	1,933
17	Special trade contractors	259,240	247,483	156,559	49,285	81,803	17,005
20	Food and kindred products	31,317	15,454	13,559	2,465	9,693	7,093
21	Tobacco products	4,232 *	390 *	0	173	412	412
22	Textile mill products	31,996 *	3,198	3,510	3,243	41	0
23	Apparel and other textile products	3,326 *	2,444	213 *	0	0	0
24	Lumber and wood products	17,615 *	8,855	2,869	3,083	1,761	1,096
25	Furniture and fixtures	15,196	7,544	1,916 *	843	530	180
26	Paper and allied products	13,435	16,139	6,313	1,808	6,724	6,222
27	Printing and publishing	1,060 *	341 *	57 *	0	0	0
28	Chemicals and allied products	62,742	88,807	71,534	14,156	46,708	28,306
29	Petroleum and coal products	3,021 *	20,737	20,737	3,448	19,007	12,675
30	Rubber and misc. plastics products	20,523	15,285	5,902	1,729	5,803	1,383
31	Leather and leather products	101 *	8 *	0	0	0	0
32	Stone, clay, and glass products	34,520 *	17,862	5,433	2,595	2,025	705
33	Primary metal industries	42,014	50,150	8,770	6,316	12,168	5,827
34	Fabricated metal products	41,546	38,192	6,824	6,135	11,960	2,335
35	Industrial machinery and equipment	29,381	23,080	9,998	4,313	9,605	2,448
36	Electronic and other electric equipment	20,550	28,259	10,688	2,339	11,422	7,882
37	Transportation equipment	42,965	86,796	18,958	6,520	16,930	3,493
38	Instruments and related products	11,414	13,602	9,192	1,342	4,470	1,296
39	Miscellaneous manufacturing industries	18,431	15,452	2,401	6,554	2,337	555
40	Railroad transportation	9,190	128,159	4,124	1,267	1,215	0
41	Local and interurban passenger transit	5,589 *	2,536	203 *	467	587 *	419 *
42	Trucking and warehousing	26,422 *	9,486 *	7,702	4,299	4,879	2,446
43	United States Postal Service	6,536 **	2,347 **	1,905 **	1,064 **	1,207 **	605 **
44	Water transportation	973 *	20,591 *	143 *	20,591	64 *	0
45	Transportation by air	3,443 *	3,443 *	3,443 *	13	11,282	0
46	Pipelines, except natural gas	40 *	471 *	237 *	160	295	215
47	Transportation services	25 *	214 *	0	2	8 *	0
48	Communications	336 *	2,844 *	49 *	27	18 *	0
49	Electric, gas, and sanitary services	22,784	62,648	35,279	7,147	27,403	13,905
50	Wholesale trade--durable goods	35,783	22,876	16,548 *	4,734	6,936	5,072
51	Wholesale trade--nondurable goods	75,813 *	50,120	13,576	16,524	19,157	4,244
52	Building materials and garden supplies	34,024 *	8,296 *	4,061 *	496	89 *	66 *
53	General merchandise stores	1,008 *	1,008 *	190 *	1,008	19 *	19 *
54	Food stores	2,786 *	2,110 *	802 *	498	921	921
55	Automotive dealers and service stations	66,440	52,361	22,888	16,426	19,415	7,139
56	Apparel and accessory stores	867 *	345 *	85 *	64	1,442 *	9 *
57	Furniture and homefurnishings stores	4,556 *	2,723 *	799 *	1,494	77 *	77 *
58	Eating and drinking places	0	0	0	0	0	0
59	Miscellaneous retail	7,034 *	1,577 *	767 *	203	27 *	27 *
60	Depository institutions	1,933 *	1,790 *	59 *	57	0	0
61	Nondepository institutions	294 *	238 *	13 *	1	0	0
62	Security and commodity brokers	274 *	222 *	12 *	1	0	0
63	Insurance carriers	1,055 *	761 *	19 *	2	0	0
64	Insurance agents, brokers, and services	732 *	593 *	32 *	3	0	0

Table VI-2

Estimated Number of Respirator Users, by Type

SIC	Title	Nonpowered Air-Purifying				Supplied-Air	
		Filtering Facepiece	Half-mask	Full-face	PAPR	Total	SCBA
65	Real estate	5,760 *	10,161	218 *	7	0	0
67	Holding and other investment offices	595 *	165 *	7 *	0	0	0
70	Hotels and other lodging places	72,978 *	4,959	16,012 *	21 *	0	0
72	Personal services	10,771 *	19,239 *	12,074 *	188 *	0	0
73	Business services	78,724	45,461 *	24,576 *	261 *	30,116	29,997
75	Auto repair, services, and parking	115,969	56,952	15,320	12,868	23,583	6,787
76	Miscellaneous repair services	26,018	15,868 *	6,066 *	72 *	4,730	0
78	Motion pictures	859 *	650 *	243 *	0	0	0
79	Amusement and recreation services	14,915	7,217	3,650 *	26 *	0	0
80	Health services	637,932	123,157	64,125	69,893	4,230	3,829
81	Legal services	3,145 *	2,379 *	890 *	0 *	0	0
82	Educational services	29,197 *	2,891	8,259 *	226	0	0
83	Social services	7,868 *	5,128 *	1,813 *	129 *	0	0
84	Museums, botanical, zoological gardens	2,212 *	2,652 *	586 *	4 *	625	624
86	Membership organizations	1,035 *	1,276 *	326 *	9 *	0	0
87	Engineering and management services	69,687 *	42,515 *	19,530 *	6,350	3,354	3,354
89	Services, n.e.c.	715 *	928 *	0	0	0	0
	State and local governments	53,692 ***	35,756 ***	15,683 **	7,173 **	10,742 **	4,491 **
	Totals	2,319,745	1,542,809	677,569	304,186	434,565	192,824

Source: Preliminary results from the 2001 NIOSH/BLS Survey of Respirator Use and Practices, in press. Benchmarked to 1997 establishment counts from U.S. Bureau of the Census, Statistics of U.S. Businesses, 1997.
* Suppressed industry-level estimates extrapolated from sector totals.
** Estimated based on respirator use patterns in SIC 42.
*** Estimated based on private-sector respirator use patterns.

The proposed standard would have different impacts on employers using respirators to comply with OSHA substance-specific standards than for employers using respirators for other purposes. Therefore, OSHA used findings from the NIOSH–BLS survey of establishments that reported respirator use, by general respirator class, for protection against specific substances (*see* Table VI–3). OSHA applied these numbers to all respirator users and establishments within the industries that make up each sector to derive substance-specific estimates of respirator use. For those section 6(b)(5) substances not reported by NIOSH, OSHA used expert judgments of a consultant with experience in the respirator industry to estimate the percentage of establishments and employees that use respirators for protection against these chemicals (Ex. 6–2) (*see* Table VI–3).

Table VI-3A

Establishments Using Respirators to Protect Against Selected Substances

Sector/Respirator Class	Establishments with Respirators [a,b]	Arsenic		Asbestos		Cadmium		Lead		Cotton Dust [a]		Coke Oven Emissions	
Air-Purifying Respirators													
Agriculture	13,200	1,200	9.1%	1,200	9.1%	1,200	9.1%	1,100	8.3%	2,500	18.9%	1,000	7.6%
Mining	3,500	200	5.7%	400	11.4%	200	5.7%	300	8.6%	100	2.9%	100	2.9%
Construction	60,000	2,900	4.8%	6,000	10.0%	2,600	4.3%	7,900	13.2%	800	1.3%	900	1.5%
Manufacturing	46,200	2,500	5.4%	4,000	8.7%	2,700	5.8%	5,500	11.9%	1,400	3.0%	2,000	4.3%
Transportation and utilities	9,700	900	9.3%	2,200	22.7%	600	6.2%	1,400	14.4%	200	2.1%	200	2.1%
Wholesale trade	28,000	800	2.9%	2,600	9.3%	1,800	6.4%	3,700	13.2%	1,100	3.9%	700	2.5%
Retail trade	16,100	100	0.6%	300	1.9%	200	1.2%	600	3.7%	100	0.6%	0	0.0%
Finance, insurance, and real estate	4,200	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Services	86,600	1,600	1.8%	8,700	10.0%	1,500	1.7%	10,800	12.5%	1,000	1.2%	800	0.9%
Total	267,500	10,200	3.8%	25,400	9.5%	10,800	4.0%	31,300	11.7%	7,200	2.7%	5,700	2.1%
Supplied-Air Respirators													
Agriculture	500	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.05%	0	0.0%
Mining	600	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.00%	0	0.0%
Construction	10,500	1,700	16.2%	1,000	9.5%	1,600	15.2%	2,400	22.9%	0	0.00%	0	0.0%
Manufacturing	12,700	400	3.1%	600	4.7%	600	4.7%	1,100	8.7%	3	0.02%	200	1.6%
Transportation and utilities	3,800	100	2.6%	1,000	26.3%	100	2.6%	300	7.9%	1	0.02%	0	0.0%
Wholesale trade	6,800	0	0.0%	0	0.0%	0	0.0%	700	10.3%	1	0.01%	0	0.0%
Retail trade	2,900	0	0.0%	0	0.0%	0	0.0%	200	6.9%	0	0.00%	0	0.0%
Finance, insurance, and real estate	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Services	9,500	0	0.0%	0	0.0%	0	0.0%	400	4.2%	0	0.00%	0	0.0%
Total	47,300	2,200	4.7%	2,600	5.5%	2,300	4.9%	5,100	10.8%	6	NA	200	0.4%

Source: The 2001 NIOSH/BLS Survey of Respirator Use and Practices. "Respirator Use and Practice." Bureau of Labor Statistics Press Release, March 20, 2002.
[a] Estimates for supplied-air respirators provided by ERG consultant Jeffrey Stull of International Personal Protection, Inc.
[b] Establishment estimates as reported by NIOSH. These may differ from establishment estimates shown in Table VI-1 that have been benchmarked to the to 1997 establishment counts from U.S. Bureau of the Census, Statistics of U.S. Businesses, 1997.

Table VI-3B

Establishments Using Respirators to Protect Against Selected Substances

Sector/Respirator Class	Establishments with Respirators [a,b]	Acrylonitrile		Formaldehyde		DBCP		Ethylene oxide		Vinyl chloride		Butadiene	
Air-Purifying Respirators													
Agriculture	13,200	0	0.00%	66	0.50%	1	0.01%	0	0.00%	0	0.00%	0	0.00%
Mining	3,500	0	0.00%	4	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Construction	60,000	0	0.00%	480	0.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Manufacturing	46,200	92	0.20%	554	1.20%	5	0.01%	231	0.50%	462	1.00%	370	0.80%
Transportation and utilities	9,700	5	0.05%	1	0.01%	0	0.00%	1	0.01%	1	0.01%	0	0.00%
Wholesale trade	28,000	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Retail trade	16,100	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Finance, insurance, and real estate	4,200	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Services	86,600	0	0.00%	0	0.00%	0	0.00%	43	0.05%	0	0.00%	0	0.00%
Total	267,500	97	0.04%	1,105	0.4%	6	0.00%	275	0.1%	463	0.17%	370	0.14%
Supplied-Air Respirators													
Agriculture	500	0	0.00%	0	0.00%	0	0.01%	0	0.01%	0	0.00%	0	0.00%
Mining	600	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Construction	10,500	0	0.00%	5	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Manufacturing	12,700	64	0.50%	102	0.80%	1	0.01%	114	0.90%	152	1.20%	76	0.60%
Transportation and utilities	3,800	1	0.02%	1	0.02%	0	0.00%	1	0.02%	1	0.03%	0	0.01%
Wholesale trade	6,800	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Retail trade	2,900	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Finance, insurance, and real estate	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Services	9,500	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%
Total	47,300	64	0.14%	108	0.2%	1	0.0%	116	0.2%	NA	NA	77	0.16%

Source: Estimates provided by ERG consultant Jeffery Stull of International Personal Protection, Inc.
[a] The 2001 NIOSH/BLS Survey of Respirator Use and Practices. "Respirator Use and Practice." Bureau of Labor Statistics Press Release, March 20, 2002.
[b] Establishment estimates as reported by NIOSH. These may differ from establishment estimates shown in Table VI-1 that have been benchmarked to the to 1997 establishment counts from U.S. Bureau of the Census, Statistics of U.S. Businesses, 1997.

BILLING CODE 4510–26–C

C. Compliance Costs

The proposal does not raise issues of technological feasibility because it requires only that employers use respirators already on the market. However, costs of the proposed APFs result from requiring some users to switch to more protective respirators than they currently use. When the proposed APF is lower than the baseline (current) APF, respirator users must upgrade to a more protective model. Both the 1992 ANSI Z88.2 Respiratory Protection Standard and the 1987 NIOSH RDL specify APFs for certain classes of respirators. The Agency assumed that employers currently use the ANSI or NIOSH APFs, or the APFs in the OSHA substance-specific standards, as applicable, to select respirators. While the Agency currently refers to the NIOSH RDL as its primary reference for APFs, in the absence of an applicable OSHA standard, this analysis assumes that, in most cases, adhering to the existing ANSI APFs fulfills employers' legal obligation for proper respirator selection under the existing Respiratory Protection Standard. However, in the case of full facepiece negative pressure respirators, the Agency has established that an APF of 50, as opposed to ANSI's APF of 100, is currently acceptable. In this regard, all but one of the substance-specific standards with APFs for full facepiece negative pressure respirators set an APF of 50. In addition, the existing respirator rule and its supporting preamble require that quantitative fit testing of full facepiece negative pressure respirators must achieve a fit factor of 500 when employees use them in atmospheres in excess of 10 times the PEL; this requirement assumes a safety factor of 10. Therefore, based on a fit factor of 500, such respirators would be safe to wear in atmospheres up to 50 times the PEL, consistent with similar requirements regarding respirator use found in existing standards for section 6(b)(5) chemicals.

For each respirator type, OSHA compared the proposed and current APF requirements, including existing APFs for section 6(b)(5) substances, and identified an incrementally more protective respirator model. To be adequate, the more protective respirator must have a proposed APF greater than the current APF.

1. Number of Users Required To Upgrade Respirator Models

For a given respirator type, the number of users required to shift to a more protective respirator depends on two factors: The total number of users of that type, and the percentage of those users for whom the ambient exposure level is greater than the proposed APF. While survey data are available to estimate the number of users, virtually no information is available in the literature that provides a basis for estimating the percentage of users required to upgrade respirators. The percentage of workers switching respirators would depend on the profile or frequency distribution of users' exposure to contaminants relative to the PEL. For example, the Agency proposed to lower the APF for full facepiece respirators used to protect against cotton dust from 100 to 50; accordingly, when workers have ambient exposures that are greater than 50 times the PEL, employers must upgrade the respirator from a full facepiece negative pressure respirator to a more protective respirator (*e.g.*, a PAPR).

Because of the absence of data on this issue, OSHA made several assumptions regarding the requirement to upgrade respirators. First, OSHA assumed that employers use respirators only when their employees have exposures above the PEL. Second, OSHA assumed employers use the most inexpensive respirator permitted. These assumptions most likely overestimate the cost of compliance because many employers require their employees to use respirators when OSHA does not require such use, or they require respirators with higher APFs than OSHA currently requires. As a result, this analysis assumes shifts in respirators that employers may have implemented already.

The Agency estimated distributions of exposures above the PELs based on reports from its Integrated Management Information System describing workplace monitoring of section 6(b)(5) toxic substances performed during OSHA health inspections. Of the 9,095 samples reported above the PELs, 68.0 percent reported exposures between 1 and 5 times the PEL, 13.1 percent found exposures between 5 and 10 times the PEL, and 9.5 percent documented exposures between 10 and 25 times the PEL. Exposures for the remaining 9.4 percent of the samples were greater than 25 times the PEL. Based on these data, OSHA modeled the current exposure distribution for each respirator type.

2. Incremental Costs of Upgrading Respirator Models

OSHA also analyzed the costs of upgrading from the current respirator to a more protective alternative. In doing so, OSHA estimated the annualized unit costs for each respirator type, including equipment and accessory costs, and the costs for training and fit testing. OSHA then calculated the incremental cost for each combination of upgrades from an existing model to a more protective one, taking into account the effect of replacement before the end of the respirator's useful life. These annualized costs range from $49.98 (for upgrading from a supplied-air, demand mode, full facepiece respirator to a supplied-air, continuous flow, half-mask respirator) to $963.73 (for upgrading from a nonpowered, air-purifying full facepiece respirator to a full facepiece PAPR).

In certain instances, workers who use respirators under the substance-specific standards may have to upgrade to a SAR with an auxiliary escape SCBA. Several substance-specific standards currently specify SARs for exposures that exceed 1,000, times the PEL.[3] OSHA believes that workers are unlikely to regularly use respirators at such extreme exposure levels, *i.e.*, they are most likely to use them only in exceptional, possibly emergency-related situations. Furthermore, exposures at levels more than 1,000 times the PEL would generally be at or above levels deemed immediately dangerous to life or health (IDLH), so employers already are required by the Respiratory Protection Standard to provide each worker with a respirator that has SCBA capability. For these reasons, this PERFSA estimated no impacts for these situations.[4]

3. Aggregate Compliance Costs

For each respirator type affected by the proposed regulation, OSHA combined the incremental costs of upgrading to a more protective respirator, the estimated share of users forecast to upgrade, and the number of users involved to estimate the compliance costs associated with each respirator type. Table VI–4 shows estimated compliance costs for OSHA's proposed APF rule of $4.6 million. The proposed rule would require 1,918 users of nonpowered air-purifying respirators to upgrade to some respirator more expensive than they are now using at a cost of $1.8 million. The Agency estimates that 22,848 PAPR users would upgrade their respirators at a cost of $2.3 million. A relatively small number of SAR users (5,110) would upgrade to more expensive respirators at a cost of

[3] These standards regulate cotton dust, coke oven emissions, acrylonitrile, arsenic, DBCP, ethylene oxide, and lead.

[4] Paragraph (d)(2) of the Respiratory Protection Standard requires employers to provide either a pressure demand SCBA or a pressure demand SAR with auxiliary SCBA to any employee who works in IDLH atmospheres.

$0.4 million. Industry-specific compliance costs vary according to the number of respirator users and the proportion of these users affected by the proposed rule. Industries with relatively large compliance costs include SIC 17, Special trade contractors ($0.8 million), and SIC 80, Health services ($0.8 million). Potentially offsetting these costs are a limited number of cases where employers would be allowed to shift to a less expensive respirator.

As discussed previously, however, the Agency believes the actual costs of the proposal almost certainly are overestimated. The cost analysis assumes all respirator wearers have levels of exposures that require the particular respirator they are using. Under this assumption, OSHA estimates over 15,000 employees would be allowed to safely shift to a less expensive respirator, which could lead to cost savings for the employer. Such potential cost savings are not accounted for in this cost analysis.

In many cases, however, employers use respirators when respirators are not required by OSHA, or use respirators more protective than required by OSHA. As a result, OSHA's cost analysis overestimates the number of employees who are affected by the standard, and therefore overestimates costs associated with the standard.

BILLING CODE 4510–26–P

Table VI-4

Summary of Costs by Respirator Class

		Nonpowered Air-Purifying Respirators			Powered Air-Purifying Respirators			Supplied-Air Respirators			
SIC	Industry	Users [a]	No. Upgrading	Cost	Users [a]	No. Upgrading	Cost	Users [a,b]	No. Upgrading	Cost	Total Cost
07	Agricultural services	60,662	46	$43,030	139	7	$657	467	2	$81	$43,768
08	Forestry	996	0	$0	3	0	$0	16	0	$0	$0
09	Fishing, hunting, and trapping	0	0	$0	0	0	$0	0	0	$0	$0
13	Oil and gas extraction	27,781	6	$6,016	6,848	415	$50,887	666	12	$1,399	$58,302
15	General building contractors	122,350	15	$13,713	4,355	288	$30,519	5,846	80	$9,067	$53,300
16	Heavy construction, except building	70,768	17	$15,472	7,342	380	$38,426	6,719	90	$9,445	$63,344
17	Special trade contractors	663,282	296	$276,942	102,625	3,933	$428,165	86,591	1,007	$87,432	$792,539
20	Food and kindred products	60,330	58	$54,509	4,105	107	$12,643	2,600	60	$6,620	$73,772
21	Tobacco products	4,621	0	$0	271	0	$0	121	3	$125	$125
22	Textile mill products	38,704	15	$14,112	5,071	36	$4,153	164	4	$190	$18,455
23	Apparel and other textile products	5,984	0	$0	0	0	$0	0	0	$0	$0
24	Lumber and wood products	29,339	12	$11,535	3,178	102	$12,283	792	11	$535	$24,353
25	Furniture and fixtures	24,657	8	$7,703	844	15	$1,847	521	5	$387	$9,937
26	Paper and allied products	35,888	27	$25,382	2,086	73	$7,507	2,662	57	$2,853	$35,742
27	Printing and publishing	1,458	0	$0	0	0	$0	3	0	$0	$0
28	Chemicals and allied products	223,083	307	$287,588	18,791	238	$25,243	27,066	443	$22,139	$334,970
29	Petroleum and coal products	44,494	89	$83,367	5,207	35	$4,099	6,333	147	$8,052	$95,518
30	Rubber and misc. plastics products	41,711	25	$23,728	4,437	43	$5,152	6,253	84	$8,583	$37,463
31	Leather and leather products	108	0	$0	0	0	$0	340	11	$1,651	$1,651
32	Stone, clay, and glass products	57,815	23	$21,844	4,123	131	$13,691	1,648	5	$248	$35,783
33	Primary metal industries	100,933	38	$35,257	7,163	270	$27,951	7,061	80	$6,326	$69,534
34	Fabricated metal products	86,562	29	$27,435	8,885	152	$15,766	12,536	93	$8,955	$52,156
35	Industrial machinery and equipment	62,459	43	$40,196	5,501	38	$4,362	8,549	51	$4,156	$48,714
36	Electronic and other electric equipment	59,497	46	$42,968	2,967	99	$11,927	5,419	109	$6,441	$61,337
37	Transportation equipment	148,719	81	$76,217	9,511	125	$14,084	18,614	241	$24,308	$114,609
38	Instruments and related products	34,208	39	$36,953	2,412	17	$2,073	4,737	50	$3,320	$42,345
39	Miscellaneous manufacturing industries	36,285	10	$9,653	10,640	539	$64,860	2,161	22	$1,915	$76,427
40	Railroad transportation	141,472	12	$11,280	1,267	52	$5,395	1,215	27	$2,722	$19,397
41	Local and interurban passenger transit	8,327	0	$0	1,086	86	$8,330	168	2	$124	$8,453
42	Trucking and warehousing	43,611	22	$21,069	6,492	326	$39,424	5,832	104	$9,349	$69,843
43	United States Postal Service	10,789	6	$5,212	1,606	80	$9,677	1,443	25	$2,204	$17,093
44	Water transportation	21,707	0	$0	21,490	2,368	$290,046	64	1	$197	$290,243
45	Transportation by air	10,328	10	$9,417	17	0	$0	12,008	225	$11,267	$20,684
46	Pipelines, except natural gas	747	0	$0	237	3	$312	80	1	$58	$369
47	Transportation services	240	0	$0	2	0	$0	8	0	$0	$0
48	Communications	3,229	0	$0	37	0	$0	18	0	$0	$0
49	Electric, gas, and sanitary services	120,711	103	$96,504	7,545	65	$7,532	14,630	249	$15,425	$119,461
50	Wholesale trade--durable goods	75,206	92	$86,246	5,430	52	$6,040	5,217	107	$8,545	$100,831
51	Wholesale trade--nondurable goods	139,508	76	$70,757	16,524	1,788	$164,785	15,428	38	$4,140	$239,682
52	Building materials and garden supplies	46,382	4	$3,347	852	19	$1,842	89	3	$494	$5,683
53	General merchandise stores	2,206	0	$0	1,111	32	$2,935	0	0	$0	$2,935
54	Food stores	5,698	0	$0	854	19	$1,848	0	0	$0	$1,848
55	Automotive dealers and service stations	141,690	20	$18,860	21,635	177	$19,874	17,645	435	$21,720	$60,454

Table VI-4

Summary of Costs by Respirator Class

SIC	Industry	Nonpowered Air-Purifying Respirators			Powered Air-Purifying Respirators			Supplied-Air Respirators			Total Cost
		Users [a]	No. Upgrading	Cost	Users [a]	No. Upgrading	Cost	Users [a,b]	No. Upgrading	Cost	
56	Apparel and accessory stores	1,297	0	$0	110	1	$105	1,442	56	$8,561	$8,667
57	Furniture and homefurnishings stores	8,078	0	$0	2,989	71	$7,253	0	0	$0	$7,253
58	Eating and drinking places	0	0	$0	0	0	$0	0	0	$0	$0
59	Miscellaneous retail	9,378	0	$0	349	7	$699	0	0	$0	$699
60	Depository institutions	3,782	0	$0	57	0	$0	0	0	$0	$0
61	Nondepository institutions	545	0	$0	1	0	$0	0	0	$0	$0
62	Security and commodity brokers	508	0	$0	1	0	$0	0	0	$0	$0
63	Insurance carriers	1,835	0	$0	2	0	$0	0	0	$0	$0
64	Insurance agents, brokers, and service	1,357	0	$0	3	0	$0	0	0	$0	$0
65	Real estate	16,139	0	$0	7	0	$0	0	0	$0	$0
67	Holding and other investment offices	766	0	$0	0	0	$0	0	0	$0	$0
70	Hotels and other lodging places	93,949	26	$24,531	21	0	$0	0	0	$0	$24,531
72	Personal services	42,084	20	$18,497	188	0	$0	0	0	$0	$18,497
73	Business services	148,761	40	$37,651	261	0	$0	119	3	$132	$37,783
75	Auto repair, services, and parking	188,241	25	$23,471	28,435	1,308	$141,436	27,832	815	$91,407	$256,314
76	Miscellaneous repair services	47,952	10	$9,293	464	0	$0	4,730	179	$25,988	$35,281
78	Motion pictures	1,752	0	$0	0	0	$0	2	0	$0	$0
79	Amusement and recreation services	25,782	6	$5,592	26	0	$0	0	0	$0	$5,592
80	Health services	825,213	105	$98,238	78,349	8,094	$740,937	1,355	14	$691	$839,865
81	Legal services	6,414	1	$1,363	0	0	$0	3	0	$0	$1,363
82	Educational services	40,347	14	$12,652	226	0	$0	0	0	$0	$12,652
83	Social services	14,809	3	$2,778	129	0	$0	0	0	$0	$2,778
84	Museums, botanical, zoological gardens	5,450	0	$0	4	0	$0	2	0	$0	$0
86	Membership organizations	2,638	0	$0	9	0	$0	0	0	$0	$0
87	Engineering and management services	131,731	32	$29,919	12,085	734	$67,171	1,114	28	$1,399	$98,488
89	Services, n.e.c.	1,643	0	$0	0	0	$0	3	0	$0	$0
	State and local governments	105,131	60	$56,002	10,094	525	$53,472	7,568	133	10,662	$120,137
	Totals	4,540,123	1,918	$1,796,299	436,498	22,848	$2,345,407	325,898	5,110	$429,315	$4,571,022

Source: OSHA estimates based on preliminary results from the 2001 NIOSH/BLS Survey of Respirator Use and Practices, in press.
[a] Includes users who use more than one type of respirator. For this reason, some respirator users may be double counted, and the totals may exceed the number of users for the respirator class.
[b] Excludes employees exclusively using SCBAs.

BILLING CODE 4510–26–C

D. Benefits

The benefits that would accrue to respirator users and their employers take several forms. The proposed standard would benefit workers by reducing their exposures to respiratory hazards. Improved respirator selection would augment previous improvements to the Respiratory Protection Standard, such as better fit-test procedures and improved training, contributing substantially to greater worker protection. Estimates of benefits are difficult to calculate because of uncertainties regarding the existing state of employer respirator-selection practices and the number of covered work-related illnesses. At the time of the 1998 revisions to the Respiratory Protection Standard, the Agency estimated that the standard would avert between 843 and 9,282 work-related injuries and illnesses annually, with a best estimate (expected value) of 4,046 averted illnesses and injuries annually (63 FR 1173). In addition, OSHA estimated that the standard would prevent between 351 and 1,626 deaths annually from cancer and many other chronic diseases, including cardiovascular disease, with a best estimate (expected value) of 932 averted deaths from these causes. The APFs proposed in this rulemaking help ensure these benefits are achieved, as well as provide an additional degree of protection. The proposed APFs would reduce employee exposures to several section 6(b)(5) chemicals covered by standards with outdated APF criteria, thereby reducing exposures to chemicals such as asbestos, lead, cotton dust, and arsenic.[5] While the Agency did not quantify these benefits, it estimates that 29,655 employees would have a higher degree of respiratory protection under the proposed APF standard. Of these employees, an estimated 8,384 have exposure to lead, 7,287 to asbestos, and 3,747 to cotton dust, all substances with substantial health risks.

In addition to health benefits, OSHA believes other benefits would result from the harmonization of APF specifications, thereby making compliance with the respirator rule easier for employers. Employers also would benefit from greater administrative ease in proper respirator selection. Employers would no longer have to consult several sources and several OSHA standards to determine the best choice of respirator, but could make their choices based on a single, easily found regulation. Some employers who now hire consultants to aid in choosing the proper respirator should be able to make this choice on their own with the aid of the proposed rule. In addition to having only one set of numbers (*i.e.*, APFs) to assist them with respirator selection for nearly all substances, some employers may be able to streamline their respirator stock by using one respirator class to meet their respirator needs instead of several respirator classes. The increased ease of compliance would also yield additional health benefits to employees using respirators.

The proposed APFs would clarify when employers can safely place employees in respirators that impose less stress on the cardiovascular system (*e.g.*, filtering facepiece respirators). Many of these alternative respirators may have the additional benefit of being less expensive to purchase and operate. As previously discussed, OSHA estimates that over 15,000 employees currently use respirators that would fall in this group (*i.e.*, shift to a less expensive respirator).

E. Economic Feasibility

OSHA is required to set standards that are feasible. To demonstrate that a standard is feasible, the courts have held that OSHA must ''construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry'' (*United Steelworkers of America, AFL–CIO–CLC* v. *Marshall* (the ''Lead'' decision), 647 F2d 1189 (DC Cir. 1980)).

OSHA conducted its analysis of economic feasibility on an establishment basis. Accordingly, for each affected industry, the Agency compared estimates of per-establishment annualized compliance costs with per-establishment estimates of revenues and per-establishment estimates of profits. It used two worst-case assumptions regarding the ability of employers to pass the costs of compliance through to their customers: The no-cost-pass-through assumption, and the full-cost-pass-through assumption. Based on the results of these comparisons, which define the universe of potential impacts of the proposed APFs, OSHA then assessed the proposal's economic feasibility for all affected establishments, *i.e.*, those covered by the proposal.

The Agency assumed that establishments falling within the scope of the proposal would have the same average sales and profits as other establishments in their industries. OSHA believes this assumption is reasonable because no evidence is available showing that the financial characteristics of those firms with employees who use respirators are different from firms that do not use respirators. Absent such evidence, OSHA relied on the best available financial data (those from the Bureau of the Census (Ex. 6–4) and Robert Morris Associates (Ex. 6–5)), used a commonly accepted methodology to calculate industry averages, and based its analysis of the significance of the projected economic impacts and the feasibility of compliance on these data.

The analysis of the potential impacts of the proposed APF standard on before-tax profits and sales shown in Table VI–5 is a ''screening analysis,'' so called because it simply measures costs as a percentage of pre-tax profits and sales under the worst-case assumptions discussed above, but does not predict impacts on these before-tax profits or sales. OSHA used the screening analysis to determine whether the compliance costs potentially associated with the proposed standard could lead to significant impacts on all affected establishments. The actual impact of the proposal on the profit and sales of establishments in a specific industry would depend on the price elasticity of demand for the products or services of these establishments.

[5] In the 1998 rulemaking revising the Respiratory Protection Standard, the Final Economic Analysis noted that the standard would not directly affect the benefits for the estimated 5% of employees who use respirators under OSHA's substance-specific health standards (except to the extent that uniformity of provisions improve compliance). Therefore, the Agency likely over-estimated the benefits of that rulemaking since the standard did not affect directly the type of respirator used by those employees (63 FR 1173). Conversely, this proposed rulemaking directly addresses the APF provisions of the substance-specific standards; therefore, this proposal would affect directly the respirators used by employees covered by these standards.

Table VI–5 shows the economic impacts of these costs. For each industry, OSHA constructed the average compliance cost per affected establishment and compared it to average revenues and average profits.[6] These costs are quite small, *i.e.*, less than 0.005 percent of revenues; the one major exception is SIC 44 (Water transportation), for which OSHA estimated the costs impacts to be 0.16 percent of revenues. When the Agency compared average compliance costs with profits, the costs also are small, *i.e.*, less than 0.17 percent; again, the major exception was SIC 44, which had an estimated impact of 2.12 percent of profits.[7] Based on the data for establishments in all industries shown in Table VI–5, OSHA concludes that the APF proposal is economically feasible for the affected establishments.

BILLING CODE 4510–26–P

[6] OSHA defines ''affected establishment'' as any facility that uses respirators, as represented in the NIOSH–BLS survey data.

[7] For some industries, such as SIC 44, data from the NIOSH–BLS survey were suppressed due to low response rates. In these cases, the Agency, for the purposes of assessing economic feasibility, imputed broader sector-level data from the survey to form an estimate of respirator use. This procedure may result in overestimating the impact of the proposal in some industries. See the full PEA (Ex. 6–1) for further details.

Table VI-5

Costs as a Percentage of Affected Establishment Revenues and Profits
(Based on Average Compliance Costs)

SIC	Industry	Revenues ($1,000)	Establish-ments	Average Revenues ($1,000)	Profit Rate	Average Profits	Affected Establishments		Average Compliance Costs to Affected Establishments	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
07	Agricultural services	$46,797,618	111,841	$418.4	6.02%	$25,183	7,566	6.8%	$5.78	0.00%	0.02%
08	Forestry	$2,533,391	2,689	$942.1	10.30%	$97,040	261	9.7%	$0.00	0.00%	0.00%
09	Fishing, hunting, and trapping	$2,066,630	2,443	$845.9	5.80%	$49,099	0	0.0%	NA	NA	NA
13	Oil and gas extraction	$118,956,993	17,957	$6,624.5	8.65%	$573,023	1,097	6.1%	$53.14	0.00%	0.01%
15	General building contractors	$354,383,931	197,940	$1,790.4	4.00%	$71,614	19,071	9.6%	$2.79	0.00%	0.00%
16	Heavy construction, except building	$129,200,925	37,918	$3,407.4	4.00%	$136,295	4,718	12.4%	$13.43	0.00%	0.01%
17	Special trade contractors	$351,559,520	433,522	$810.9	4.00%	$32,438	40,823	9.4%	$19.41	0.00%	0.06%
20	Food and kindred products	$488,381,169	22,317	$21,883.8	3.46%	$757,938	3,608	16.2%	$20.45	0.00%	0.00%
21	Tobacco products	$36,626,849	185	$197,983.0	4.02%	$7,953,335	30	16.2%	$4.18	0.00%	0.00%
22	Textile mill products	$81,180,135	6,464	$12,558.8	2.77%	$347,644	720	11.1%	$25.63	0.00%	0.01%
23	Apparel and other textile products	$81,000,847	24,460	$3,311.6	2.56%	$84,716	1,111	4.5%	$0.00	0.00%	0.00%
24	Lumber and wood products	$111,381,076	37,716	$2,953.2	3.90%	$115,143	1,995	5.3%	$12.21	0.00%	0.01%
25	Furniture and fixtures	$61,269,677	12,388	$4,945.9	3.51%	$173,603	2,053	16.6%	$4.84	0.00%	0.00%
26	Paper and allied products	$163,517,039	6,863	$23,825.9	4.50%	$1,072,385	649	9.5%	$55.10	0.00%	0.01%
27	Printing and publishing	$209,740,895	63,986	$3,277.9	3.80%	$124,545	124	0.2%	$0.00	0.00%	0.00%
28	Chemicals and allied products	$406,616,253	13,691	$29,699.5	4.49%	$1,332,353	5,052	36.9%	$66.30	0.00%	0.00%
29	Petroleum and coal products	$178,393,963	2,459	$72,547.4	2.99%	$2,168,714	432	17.6%	$221.09	0.00%	0.01%
30	Rubber and misc. plastics products	$160,224,448	17,343	$9,238.6	4.02%	$371,834	3,140	18.1%	$11.93	0.00%	0.00%
31	Leather and leather products	$10,125,106	1,922	$5,268.0	2.20%	$115,725	14	0.7%	$119.63	0.00%	0.10%
32	Stone, clay, and glass products	$87,857,611	17,167	$5,117.8	4.93%	$252,139	3,109	18.1%	$11.51	0.00%	0.00%
33	Primary metal industries	$189,655,505	6,992	$27,124.6	4.52%	$1,225,408	1,974	28.2%	$35.23	0.00%	0.00%
34	Fabricated metal products	$231,787,815	39,399	$5,883.1	4.55%	$267,453	7,374	18.7%	$7.07	0.00%	0.00%
35	Industrial machinery and equipment	$410,878,326	57,563	$7,137.9	4.05%	$288,782	7,458	13.0%	$6.53	0.00%	0.00%
36	Electronic and other electric equipment	$349,240,947	18,619	$18,757.2	5.59%	$1,048,780	2,731	14.7%	$22.46	0.00%	0.00%
37	Transportation equipment	$522,250,748	13,210	$39,534.5	3.74%	$1,479,823	3,788	28.7%	$30.26	0.00%	0.00%
38	Instruments and related products	$158,693,978	12,385	$12,813.4	5.06%	$648,479	1,282	10.4%	$33.03	0.00%	0.01%
39	Miscellaneous manufacturing industries	$52,171,899	18,711	$2,788.3	3.80%	$106,073	3,140	16.8%	$24.34	0.00%	0.02%
40	Railroad transportation	$36,900,000	4,802	$7,684.3	11.08%	$851,036	846	17.6%	$24.34	0.00%	0.00%
41	Local and interurban passenger transit	$18,741,822	20,067	$934.0	4.51%	$42,101	809	4.0%	$10.45	0.00%	0.02%
42	Trucking and warehousing	$197,132,918	135,874	$1,450.9	3.91%	$56,783	4,090	3.0%	$17.08	0.00%	0.03%
43	United States Postal Service	$56,600,000	33,613	$1,683.9	NA	NA	1,012	3.0%	$0.00	0.00%	NA
44	Water transportation	$34,059,390	9,392	$3,626.4	7.48%	$271,426	50	0.5%	$5,755.39	0.16%	2.12%
45	Transportation by air	$175,932,797	13,694	$12,847.4	3.62%	$465,132	48	0.4%	$427.74	0.00%	0.09%
46	Pipelines, except natural gas	$7,830,792	971	$8,064.7	6.55%	$528,055	252	25.9%	$1.47	0.00%	0.00%
47	Transportation services	$39,490,484	52,884	$746.7	3.39%	$25,322	8	0.0%	$0.00	0.00%	0.00%
48	Communications	$343,904,510	46,030	$7,471.3	5.58%	$416,833	100	0.2%	$0.00	0.00%	0.00%
49	Electric, gas, and sanitary services	$446,859,099	22,716	$19,671.6	10.37%	$2,040,874	5,085	22.4%	$23.49	0.00%	0.00%
50	Wholesale trade--durable goods	$2,290,609,326	341,942	$6,698.8	2.54%	$170,449	18,854	5.5%	$5.35	0.00%	0.00%
51	Wholesale trade--nondurable goods	$1,931,943,829	189,025	$10,220.6	4.46%	$456,162	8,573	4.5%	$27.96	0.00%	0.01%
52	Building materials and garden supplies	$152,492,069	70,064	$2,176.5	2.37%	$51,621	2,386	3.4%	$2.38	0.00%	0.00%
53	General merchandise stores	$334,801,710	36,481	$9,177.4	2.70%	$248,028	687	1.9%	$4.27	0.00%	0.00%
54	Food stores	$424,619,077	179,120	$2,370.6	1.41%	$33,443	2,394	1.3%	$0.77	0.00%	0.00%
55	Automotive dealers and service stations	$787,955,460	202,525	$3,890.7	1.45%	$56,246	10,243	5.1%	$5.90	0.00%	0.01%
56	Apparel and accessory stores	$117,838,184	126,658	$930.4	1.85%	$17,181	308	0.2%	$28.16	0.00%	0.16%

Table VI-5

Costs as a Percentage of Affected Establishment Revenues and Profits (Based on Average Compliance Costs)

SIC	Industry	Revenues ($1,000)	Establish-ments	Average Revenues ($1,000)	Profit Rate	Average Profits	Affected Establishments		Average Compliance Costs to Affected Establishments	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
57	Furniture and homefurnishings stores	$138,532,297	117,939	$1,174.6	2.28%	$26,812	2,769	2.3%	$2.62	0.00%	0.01%
58	Eating and drinking places	$249,718,654	484,719	$515.2	3.00%	$15,447	0	0.0%	NA	NA	NA
59	Miscellaneous retail	$372,192,817	374,786	$993.1	2.49%	$24,711	978	0.3%	$0.71	0.00%	0.00%
60	Depository institutions	$626,235,388	115,268	$5,432.9	10.80%	$586,749	1,372	1.2%	$0.00	0.00%	0.00%
61	Nondepository institutions	$208,902,233	53,365	$3,914.6	15.05%	$589,102	299	0.6%	$0.00	0.00%	0.00%
62	Security and commodity brokers	$267,894,402	50,032	$5,354.5	13.32%	$712,970	278	0.6%	$0.00	0.00%	0.00%
63	Insurance carriers	$977,328,464	41,776	$23,394.5	6.82%	$1,596,288	442	1.1%	$0.00	0.00%	0.00%
64	Insurance agents, brokers, and service	$76,085,799	132,265	$575.3	6.83%	$39,261	744	0.6%	$0.00	0.00%	0.00%
65	Real estate	$191,986,451	257,248	$746.3	13.31%	$99,329	1,541	0.6%	$0.00	0.00%	0.00%
67	Holding and other investment offices	$119,637,007	28,175	$4,246.2	24.01%	$1,019,487	157	0.6%	$0.00	0.00%	0.00%
70	Hotels and other lodging places	$103,075,607	59,897	$1,720.9	6.96%	$119,782	1,326	2.2%	$18.50	0.00%	0.02%
72	Personal services	$53,965,771	208,546	$258.8	5.86%	$15,151	9,743	4.7%	$1.90	0.00%	0.01%
73	Business services	$538,701,000	410,246	$1,313.1	4.79%	$62,857	13,517	3.3%	$2.80	0.00%	0.00%
75	Auto repair, services, and parking	$102,979,805	194,877	$528.4	4.39%	$23,214	32,113	16.5%	$7.98	0.00%	0.03%
76	Miscellaneous repair services	$39,030,526	68,439	$570.3	5.44%	$31,000	3,375	4.9%	$10.45	0.00%	0.03%
78	Motion pictures	$72,351,766	46,844	$1,544.5	5.14%	$79,355	17	0.0%	$0.00	0.00%	0.00%
79	Amusement and recreation services	$94,816,288	99,642	$951.6	4.28%	$40,728	1,612	1.6%	$3.47	0.00%	0.01%
80	Health services	$824,840,187	505,878	$1,630.5	6.17%	$100,610	16,486	3.3%	$50.94	0.00%	0.05%
81	Legal services	$124,335,948	170,271	$730.2	17.50%	$127,789	61	0.0%	$22.44	0.00%	0.02%
82	Educational services	$136,669,596	50,146	$2,725.4	8.14%	$221,895	564	1.1%	$22.44	0.00%	0.01%
83	Social services	$95,229,314	165,519	$575.3	4.44%	$25,535	6,668	4.0%	$0.42	0.00%	0.00%
84	Museums, botanical, zoological gardens	$6,636,189	5,466	$1,214.1	21.45%	$260,421	235	4.3%	$0.00	0.00%	0.00%
86	Membership organizations	$111,881,925	249,022	$449.3	7.21%	$32,400	533	0.2%	$0.00	0.00%	0.00%
87	Engineering and management services	$332,197,903	301,160	$1,103.1	6.39%	$70,494	10,292	3.4%	$9.57	0.00%	0.01%
89	Services, n.e.c.	$20,335,429	17,650	$1,152.1	6.80%	$78,346	6	0.0%	$0.00	0.00%	0.00%
	State and local governments	$763,300,000	167,788	$4,549.2	NA	NA	6,893	4.1%	$17.43	0.00%	NA
	Totals	$19,043,065,527	7,060,972	$2,696.9	4.87%	$131,423	291,085	4.1%	$15.70	0.00%	0.01%

Source: OSHA Office of Regulatory Analysis. See full PEA (Ex. 6-1).

F. Economic Impacts to Small Entities

OSHA also estimated the economic impacts of the proposed rule on affected entities with fewer than 20 employees, and for affected small entities as defined by the Small Business Administration (SBA). Table VI–6 shows the estimated economic impacts for small entities with fewer than 20 employees: Average compliance costs by industry are less than 0.005 percent of average revenues, and less than 0.19 percent of profits, in all industries. Table VI–7 presents the economic impacts for small entities as a whole, as defined by SBA. For these firms, average compliance costs are less than 0.005 percent of average revenues and less than 0.03 percent of average profits. Thus, the Agency projects no significant impacts from the proposed rule on small entities.

When costs exceed one percent of revenues or five percent of profits, OSHA considers the impact on small entities significant for the purposes of complying with the RFA. For all classes of affected small entities, the Agency found that the costs were less than one percent of revenues and five percent of profits. Therefore, OSHA certifies that this proposed regulation would not have a significant impact on a substantial number of small entities.

Table VI-6

Costs as a Percentage of Revenues and Profits for Affected Small Entities with Fewer than 20 Employees (Based on Average Compliance Costs)

SIC	Industry	Revenues ($1,000)	Entities	Average Revenues ($1,000)	Profit Rate	Average Profits	Affected Entities		Average Compliance Costs to Affected Entities	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
07	Agricultural services	$28,456,904	104,822	$271.5	6.02%	$16,339	6,514	6.2%	$0.09	0.00%	0.00%
08	Forestry	$1,005,916	2,225	$452.1	10.30%	$46,566	212	9.5%	$0.00	0.00%	0.00%
09	Fishing, hunting, and trapping	$934,691	2,327	$401.7	5.80%	$23,313	0	0.0%	NA	NA	NA
13	Oil and gas extraction	$9,568,821	13,330	$717.8	8.65%	$62,093	622	4.7%	$0.94	0.00%	0.00%
15	General building contractors	$140,742,413	185,770	$757.6	4.00%	$30,305	17,656	9.5%	$1.06	0.00%	0.00%
16	Heavy construction, except building	$25,680,517	29,075	$883.3	4.00%	$35,330	2,526	8.7%	$0.20	0.00%	0.00%
17	Special trade contractors	$156,222,049	395,090	$395.4	4.00%	$15,816	35,004	8.9%	$4.09	0.00%	0.03%
20	Food and kindred products	$13,034,058	10,852	$1,201.1	3.46%	$41,599	504	4.6%	$8.59	0.00%	0.02%
21	Tobacco products	$36,982	58	$637.6	4.02%	$25,614	6	10.6%	$0.00	0.00%	0.00%
22	Textile mill products	$2,804,537	3,026	$926.8	2.77%	$25,655	96	3.2%	$0.00	0.00%	0.00%
23	Apparel and other textile products	$7,444,651	16,162	$460.6	2.56%	$11,784	258	1.6%	$0.00	0.00%	0.00%
24	Lumber and wood products	$15,544,934	29,353	$529.6	3.90%	$20,648	430	1.5%	$2.22	0.00%	0.01%
25	Furniture and fixtures	$4,131,575	8,093	$510.5	3.51%	$17,919	401	5.0%	$2.45	0.00%	0.01%
26	Paper and allied products	$2,406,977	1,922	$1,252.3	4.50%	$56,366	43	2.2%	$0.00	0.00%	0.00%
27	Printing and publishing	$22,196,893	47,557	$466.7	3.80%	$17,734	26	0.1%	$0.00	0.00%	0.00%
28	Chemicals and allied products	$8,762,403	5,616	$1,560.3	4.49%	$69,995	1,610	28.7%	$6.89	0.00%	0.01%
29	Petroleum and coal products	$2,213,850	650	$3,405.9	2.99%	$101,816	92	14.2%	$10.74	0.00%	0.01%
30	Rubber and misc. plastics products	$7,183,667	7,483	$960.0	4.02%	$38,638	382	5.1%	$6.79	0.00%	0.02%
31	Leather and leather products	$570,806	1,223	$466.7	2.20%	$10,253	2	0.2%	$0.00	0.00%	0.00%
32	Stone, clay, and glass products	$6,351,359	8,423	$754.0	4.93%	$37,150	538	6.4%	$0.00	0.00%	0.00%
33	Primary metal industries	$2,848,236	2,530	$1,125.8	4.52%	$50,860	273	10.8%	$0.00	0.00%	0.00%
34	Fabricated metal products	$17,077,020	22,251	$767.5	4.55%	$34,890	3,378	15.2%	$0.95	0.00%	0.00%
35	Industrial machinery and equipment	$24,064,335	39,977	$602.0	4.05%	$24,354	4,188	10.5%	$1.41	0.00%	0.01%
36	Electronic and other electric equipment	$8,356,375	9,070	$921.3	5.59%	$51,514	1,134	12.5%	$1.52	0.00%	0.00%
37	Transportation equipment	$5,835,684	7,727	$755.2	3.74%	$28,269	2,022	26.2%	$3.55	0.00%	0.01%
38	Instruments and related products	$5,684,460	7,207	$788.7	5.06%	$39,918	616	8.6%	$3.63	0.00%	0.01%
39	Miscellaneous manufacturing industries	$6,908,160	14,575	$474.0	3.80%	$18,031	1,973	13.5%	$2.80	0.00%	0.02%
40	Railroad transportation	NA	NA	NA	NA	NA	NA	NA	ERR	NA	NA
41	Local and interurban passenger transit	$3,052,031	13,557	$225.1	4.51%	$10,148	576	4.2%	$0.49	0.00%	0.00%
42	Trucking and warehousing	$42,301,497	104,401	$405.2	3.91%	$15,858	3,298	3.2%	$1.72	0.00%	0.01%
44	Water transportation	$4,501,041	7,061	$637.5	7.48%	$47,711	40	0.6%	$4.00	0.00%	0.01%
45	Transportation by air	$3,397,447	5,352	$634.8	3.62%	$22,982	21	0.4%	$0.00	0.00%	0.00%
46	Pipelines, except natural gas	$64,316	21	$3,062.7	6.55%	$200,536	4	17.2%	$16.05	0.00%	0.01%
47	Transportation services	$12,815,924	38,195	$335.5	3.39%	$11,378	6	0.0%	$0.00	0.00%	0.00%
48	Communications	$9,283,329	14,256	$651.2	5.58%	$36,330	26	0.2%	$0.00	0.00%	0.00%
49	Electric, gas, and sanitary services	$10,824,146	8,938	$1,211.0	10.37%	$125,641	1,335	14.9%	$3.53	0.00%	0.00%
50	Wholesale trade--durable goods	$467,174,837	228,351	$2,045.9	2.54%	$52,056	8,636	3.8%	$0.94	0.00%	0.00%
51	Wholesale trade--nondurable goods	$321,562,895	126,151	$2,549.0	4.46%	$113,768	3,944	3.1%	$2.56	0.00%	0.00%
52	Building materials and garden supplies	$37,776,200	46,450	$813.3	2.37%	$19,289	1,511	3.3%	$0.00	0.00%	0.00%
53	General merchandise stores	$3,346,901	8,796	$380.5	2.70%	$10,283	50	0.6%	$0.00	0.00%	0.00%
54	Food stores	$57,468,235	111,162	$517.0	1.41%	$7,293	439	0.4%	$0.00	0.00%	0.00%
55	Automotive dealers and service stations	$149,337,410	116,015	$1,287.2	1.45%	$18,609	5,083	4.4%	$0.84	0.00%	0.00%
56	Apparel and accessory stores	$18,706,435	50,308	$371.8	1.85%	$6,867	36	0.1%	$0.00	0.00%	0.00%
57	Furniture and homefurnishings stores	$45,392,798	78,842	$575.7	2.28%	$13,142	1,660	2.1%	$0.00	0.00%	0.00%

Table VI-6

Costs as a Percentage of Revenues and Profits for Affected Small Entities with Fewer than 20 Employees (Based on Average Compliance Costs)

SIC	Industry	Revenues ($1,000)	Entities	Average Revenues ($1,000)	Profit Rate	Average Profits	Affected Entities		Average Compliance Costs to Affected Entities	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
58	Eating and drinking places	$61,841,796	293,318	$210.8	3.00%	$6,322	0	0.0%	NA	NA	NA
59	Miscellaneous retail	$119,265,615	258,538	$461.3	2.49%	$11,479	448	0.2%	$0.00	0.00%	0.00%
60	Depository institutions	$15,538,559	14,378	$1,080.7	10.80%	$116,718	163	1.1%	$0.00	0.00%	0.00%
61	Nondepository institutions	$13,454,697	21,262	$632.8	15.05%	$95,230	103	0.5%	$0.00	0.00%	0.00%
62	Security and commodity brokers	$19,644,662	27,262	$720.6	13.32%	$95,949	140	0.5%	$0.00	0.00%	0.00%
63	Insurance carriers	$9,416,333	5,668	$1,661.3	6.82%	$113,357	63	1.1%	$0.00	0.00%	0.00%
64	Insurance agents, brokers, and service	$33,660,359	116,075	$290.0	6.83%	$19,792	543	0.5%	$0.00	0.00%	0.00%
65	Real estate	$108,609,341	221,549	$490.2	13.31%	$65,246	1,047	0.5%	$0.00	0.00%	0.00%
67	Holding and other investment offices	$35,174,755	21,022	$1,673.2	24.01%	$401,733	102	0.5%	$0.00	0.00%	0.00%
70	Hotels and other lodging places	$12,241,793	40,186	$304.6	6.96%	$21,204	783	1.9%	$0.76	0.00%	0.00%
72	Personal services	$27,470,741	168,826	$162.7	5.86%	$9,527	7,156	4.2%	$0.23	0.00%	0.00%
73	Business services	$108,448,938	307,737	$352.4	4.79%	$16,869	7,651	2.5%	$0.74	0.00%	0.00%
75	Auto repair, services, and parking	$52,027,411	160,544	$324.1	4.39%	$14,236	22,900	14.3%	$1.01	0.00%	0.01%
76	Miscellaneous repair services	$18,035,716	60,601	$297.6	5.44%	$16,178	2,626	4.3%	$7.32	0.00%	0.05%
78	Motion pictures	$13,026,870	29,959	$434.8	5.14%	$22,341	8	0.0%	$0.00	0.00%	0.00%
79	Amusement and recreation services	$26,704,545	79,317	$336.7	4.28%	$14,410	1,159	1.5%	$0.00	0.00%	0.00%
80	Health services	$167,087,490	385,533	$433.4	6.17%	$26,742	11,346	2.9%	$0.22	0.00%	0.00%
81	Legal services	$54,265,197	156,877	$345.9	17.50%	$60,534	41	0.0%	$0.00	0.00%	0.00%
82	Educational services	$8,902,333	30,770	$289.3	8.14%	$23,555	367	1.2%	$0.00	0.00%	0.00%
83	Social services	$22,228,579	99,911	$222.5	4.44%	$9,874	3,696	3.7%	$0.13	0.00%	0.00%
84	Museums, botanical, zoological gardens	$1,283,445	4,300	$298.5	21.45%	$64,023	164	3.8%	$0.00	0.00%	0.00%
86	Membership organizations	$43,669,772	222,292	$196.5	7.21%	$14,167	396	0.2%	$0.00	0.00%	0.00%
87	Engineering and management services	$90,405,763	254,295	$355.5	6.39%	$22,720	6,189	2.4%	$0.18	0.00%	0.00%
89	Services, n.e.c.	$5,728,501	15,743	$363.9	6.80%	$24,744	3	0.0%	$0.00	0.00%	0.00%
	Totals	$2,781,206,926	4,930,213	$564.1	5.00%	$28,183	174,264	3.5%	$1.71	0.00%	0.01%

Source: OSHA Office of Regulatory Analysis. See full PEA (Ex. 6-1).

Table VI-7

**Costs as a Percentage of Revenues and Profits for all Affected Small Entities*
(Based on Average Compliance Costs)**

SIC	Industry	Revenues ($1,000)	SBA Entities	Average Revenues ($1,000)	Profit Rate	Average Profits	Affected Entities		Average Compliance Costs to Affected Entities	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
07	Agricultural services	$38,501,047	109,663	$351.1	6.02%	$21,130	6,718	6.1%	$0.14	0.00%	0.00%
08	Forestry	$1,496,747	2,400	$623.6	10.30%	$64,235	233	9.7%	$0.00	0.00%	0.00%
09	Fishing, hunting, and trapping	NA	NA	NA	5.80%	NA	NA	NA	NA	NA	NA
13	Oil and gas extraction	$29,931,841	14,787	$2,024.2	8.65%	$175,093	890	6.0%	$22.40	0.00%	0.01%
15	General building contractors	$234,203,450	195,315	$1,199.1	4.00%	$47,964	17,540	9.0%	$1.12	0.00%	0.00%
16	Heavy construction, except building	$68,664,092	35,618	$1,927.8	4.00%	$77,112	3,314	9.3%	$3.53	0.00%	0.00%
17	Special trade contractors	$270,401,924	426,477	$634.0	4.00%	$25,361	34,756	8.1%	$15.67	0.00%	0.06%
20	Food and kindred products	$104,629,113	15,992	$6,542.6	3.46%	$226,600	1,781	11.1%	$10.88	0.00%	0.00%
21	Tobacco products	$1,255,255	91	$13,794.0	4.02%	$554,130	10	11.1%	$0.00	0.00%	0.00%
22	Textile mill products	$20,377,246	4,845	$4,205.8	2.77%	$116,423	458	9.4%	$3.49	0.00%	0.00%
23	Apparel and other textile products	$38,507,048	22,383	$1,720.4	2.56%	$44,010	841	3.8%	$0.00	0.00%	0.00%
24	Lumber and wood products	$58,343,756	35,076	$1,663.4	3.90%	$64,854	1,278	3.6%	$2.23	0.00%	0.00%
25	Furniture and fixtures	$26,295,821	11,217	$2,344.3	3.51%	$82,285	1,540	13.7%	$2.05	0.00%	0.00%
26	Paper and allied products	$31,334,277	4,057	$7,723.5	4.50%	$347,629	249	6.1%	$12.01	0.00%	0.00%
27	Printing and publishing	$85,620,541	57,018	$1,501.6	3.80%	$57,055	91	0.2%	$0.00	0.00%	0.00%
28	Chemicals and allied products	$59,010,014	8,227	$7,172.7	4.49%	$321,776	1,955	23.8%	$84.99	0.00%	0.03%
29	Petroleum and coal products	$13,950,653	1,047	$13,324.4	2.99%	$398,317	118	11.3%	$120.02	0.00%	0.03%
30	Rubber and misc. plastics products	$58,709,872	13,043	$4,501.3	4.02%	$181,167	1,627	12.5%	$6.74	0.00%	0.00%
31	Leather and leather products	$4,003,751	1,675	$2,390.3	2.20%	$52,509	184	11.0%	$4.92	0.00%	0.01%
32	Stone, clay, and glass products	$34,254,470	11,791	$2,905.1	4.93%	$143,127	1,393	11.8%	$20.47	0.00%	0.01%
33	Primary metal industries	$36,511,582	4,806	$7,597.1	4.52%	$343,213	1,023	21.3%	$26.50	0.00%	0.01%
34	Fabricated metal products	$113,752,781	34,250	$3,321.2	4.55%	$150,988	4,015	11.7%	$3.72	0.00%	0.00%
35	Industrial machinery and equipment	$127,178,710	52,548	$2,420.2	4.05%	$97,917	4,176	7.9%	$3.78	0.00%	0.00%
36	Electronic and other electric equipment	$69,499,940	14,355	$4,841.5	5.59%	$270,705	1,292	9.0%	$7.11	0.00%	0.00%
37	Transportation equipment	$41,544,504	10,653	$3,899.8	3.74%	$145,974	1,984	18.6%	$12.89	0.00%	0.01%
38	Instruments and related products	$33,908,725	10,190	$3,327.6	5.06%	$168,410	787	7.7%	$10.59	0.00%	0.01%
39	Miscellaneous manufacturing industries	$30,627,905	17,837	$1,717.1	3.80%	$65,322	2,267	12.7%	$13.48	0.00%	0.02%
40	Railroad transportation	$2,897,433	541	$5,355.7	12.89%	$690,234	95	17.6%	$71.75	0.00%	0.01%
41	Local and interurban passenger transit	$7,690,615	16,537	$465.1	4.51%	$20,964	540	3.3%	$1.62	0.00%	0.01%
42	Trucking and warehousing	$79,888,400	114,623	$697.0	3.91%	$27,278	3,166	2.8%	$3.08	0.00%	0.01%
44	Water transportation	$14,075,608	8,051	$1,748.3	7.48%	$130,855	46	0.6%	$4.33	0.00%	0.00%
45	Transportation by air	$15,156,218	6,386	$2,373.4	3.62%	$85,925	22	0.3%	$0.00	0.00%	0.00%
46	Pipelines, except natural gas	$986,979	39	$25,307.2	6.55%	$1,657,050	5	13.9%	$10.64	0.00%	0.00%
47	Transportation services	$19,513,397	40,529	$481.5	3.39%	$16,327	6	0.0%	$0.00	0.00%	0.00%
48	Communications	$41,125,079	17,482	$2,352.4	5.58%	$131,244	28	0.2%	$0.00	0.00%	0.00%
49	Electric, gas, and sanitary services	$10,824,146	8,938	$1,211.0	10.37%	$125,641	1,323	14.8%	$3.03	0.00%	0.00%
50	Wholesale trade--durable goods	$837,107,306	258,492	$3,238.4	2.54%	$82,401	9,740	3.8%	$9.88	0.00%	0.01%
51	Wholesale trade--nondurable goods	$637,454,650	143,751	$4,434.4	4.46%	$197,917	4,455	3.1%	$53.66	0.00%	0.03%
52	Building materials and garden supplies	$37,776,200	46,450	$813.3	2.37%	$19,289	1,368	2.9%	$0.00	0.00%	0.00%
53	General merchandise stores	$3,346,901	8,796	$380.5	2.70%	$10,283	85	1.0%	$0.00	0.00%	0.00%
54	Food stores	$101,566,550	123,572	$821.9	1.41%	$11,595	852	0.7%	$0.00	0.00%	0.00%
55	Automotive dealers and service stations	$149,337,410	116,015	$1,287.2	1.45%	$18,609	5,043	4.3%	$0.93	0.00%	0.00%
56	Apparel and accessory stores	$18,706,435	50,308	$371.8	1.85%	$6,867	63	0.1%	$0.00	0.00%	0.00%
57	Furniture and homefurnishings stores	$45,392,798	78,842	$575.7	2.28%	$13,142	1,494	1.9%	$0.00	0.00%	0.00%

Table VI-7

**Costs as a Percentage of Revenues and Profits for all Affected Small Entities*
(Based on Average Compliance Costs)**

SIC	Industry	Revenues ($1,000)	SBA Entities	Average Revenues ($1,000)	Profit Rate	Average Profits	Affected Entities		Average Compliance Costs to Affected Entities	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
58	Eating and drinking places	$128,561,814	355,297	$361.8	3.00%	$10,850	0	0.0%	NA	NA	NA
59	Miscellaneous retail	$119,265,615	258,538	$461.3	2.49%	$11,479	488	0.2%	$0.00	0.00%	0.00%
60	Depository institutions	$15,538,559	14,378	$1,080.7	10.80%	$116,718	186	1.3%	$0.00	0.00%	0.00%
61	Nondepository institutions	$13,454,697	21,262	$632.8	15.05%	$95,230	117	0.6%	$0.00	0.00%	0.00%
62	Security and commodity brokers	$19,644,662	27,262	$720.6	13.32%	$95,949	157	0.6%	$0.00	0.00%	0.00%
63	Insurance carriers	$5,850,805	4,967	$1,177.9	6.82%	$80,375	73	1.5%	$0.00	0.00%	0.00%
64	Insurance agents, brokers, and service	$47,083,678	119,907	$392.7	6.83%	$26,800	616	0.5%	$0.00	0.00%	0.00%
65	Real estate	$142,479,284	230,304	$618.7	13.31%	$82,340	1,139	0.5%	$0.00	0.00%	0.00%
67	Holding and other investment offices	$35,174,755	21,022	$1,673.2	24.01%	$401,733	116	0.6%	$0.00	0.00%	0.00%
70	Hotels and other lodging places	$24,876,889	47,698	$521.5	6.96%	$36,302	1,070	2.2%	$1.00	0.00%	0.00%
72	Personal services	$36,957,629	176,477	$209.4	5.86%	$12,262	7,222	4.1%	$0.35	0.00%	0.00%
73	Business services	$188,061,601	337,126	$557.8	4.79%	$26,703	9,637	2.9%	$0.98	0.00%	0.00%
75	Auto repair, services, and parking	$66,003,052	167,057	$395.1	4.39%	$17,356	22,771	13.6%	$1.16	0.00%	0.01%
76	Miscellaneous repair services	$25,861,556	63,328	$408.4	5.44%	$22,198	2,756	4.4%	$7.17	0.00%	0.03%
78	Motion pictures	$13,026,870	29,959	$434.8	5.14%	$22,341	9	0.0%	$0.00	0.00%	0.00%
79	Amusement and recreation services	$47,922,810	90,742	$528.1	4.28%	$22,604	1,231	1.4%	$0.00	0.00%	0.00%
80	Health services	$243,370,668	413,561	$588.5	6.17%	$36,312	11,837	2.9%	$0.21	0.00%	0.00%
81	Legal services	$54,265,197	156,877	$345.9	17.50%	$60,534	47	0.0%	$0.00	0.00%	0.00%
82	Educational services	$25,677,552	40,592	$632.6	8.14%	$51,502	398	1.0%	$0.00	0.00%	0.00%
83	Social services	$50,553,841	117,544	$430.1	4.44%	$19,088	3,960	3.4%	$0.22	0.00%	0.00%
84	Museums, botanical, zoological gardens	$2,928,264	4,912	$596.1	21.45%	$127,873	186	3.8%	$0.00	0.00%	0.00%
86	Membership organizations	$78,452,141	242,081	$324.1	7.21%	$23,371	429	0.2%	$0.00	0.00%	0.00%
87	Engineering and management services	$151,671,072	271,169	$559.3	6.39%	$35,745	8,091	3.0%	$3.20	0.00%	0.01%
89	Services, n.e.c.	$8,169,059	16,395	$498.3	6.80%	$33,882	4	0.0%	$0.00	0.00%	0.00%
	State and local governments	$101,000,000	17,289	$5,841.9	NA	NA	509	2.9%	$24.07	0.00%	NA
	Totals	$5,200,213,260	5,383,168	$966.0	4.68%	$45,203	191,389	3.6%	$7.53	0.00%	0.02%

* "Small entity" as defined by the Small Business Administration (Ex. 6-6).
Source: OSHA Office of Regulatory Analysis. See full PEA (Ex. 6-1).

BILLING CODE 4510–26–C

VII. Summary and Explanation of the Proposed Standard

This section of the preamble provides a summary and explanation of each proposed revision to OSHA's Respiratory Protection Standard involving assigned protection factors.

A. Revisions to the Respiratory Protection Standard

This section addresses the revisions proposed for paragraphs (b), (d)(3)(i)(A), (d)(3)(i)(B), and (n) of OSHA's exiting Respiratory Protection Standard at 29 CFR 1910.134).

Paragraph (b)—Definitions

Revisions to this paragraph would add two important definitions''—assigned protection factor'' and ''maximum use concentration''—to OSHA's Respiratory Protection Standard. The following sections explain these proposed definitions in detail.

1. Assigned Protection Factor

As part of its 1994 proposed rulemaking for the Respiratory Protection Standard, OSHA proposed a definition for assigned protection factors (APFs) that read as follows: ''[T]he number assigned by NIOSH [the National Institute for Occupational Safety and Health] to indicate the capability of a respirator to afford a certain degree of protection in terms of fit and filter/cartridge penetration'' (59 FR 58938). OSHA proposed this definition on the assumption that NIOSH would develop APFs for the various respirator classes, building on the APFs in the 1987 NIOSH Respirator Decision Logic (RDL) (59 FR 58901–58903). However, NIOSH subsequently decided not to publish a list of APFs as part of its 42 CFR part 84 Respirator Certification Standards (60 FR 30338), and reserved APFs for a future NIOSH rulemaking.

During his opening statement on June 15, 1995 at an OSHA-sponsored expert-panel discussion on APFs, Dr. Adam Finkel, then Director of the Agency's Directorate of Health Standards Programs, noted that OSHA would explore developing its own list of APFs (H–049, Ex. 707–X). The Agency then announced in the preamble to the final Respiratory Protection Standard (63 FR 1182) that it would propose an APF table ''based on a thorough review and analysis of all relevant evidence'' in a subsequent rulemaking. In the final Respiratory Protection Standard, OSHA reserved a table for APFs, a paragraph [(d)(3)(i)(A)] for APF requirements, and a definition of APF under paragraph (b).

In its 1987 RDL, NIOSH defined APF as ''[t]he minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users'' (Ex. 1–54–437Q). The American National Standards Institute (ANSI) developed a definition for APF in its Z88.2–1992 Respiratory Protection Standard that reads, ''The expected workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators to properly fitted and trained users' (Ex. 1–50). The ANSI Z88.2 Subcommittee that developed the 1992 standard used the NIOSH definition of APF as a template for its APF definition; however, the Z88.2 Subcommittee revised the phrase ''minimum anticipated protection'' in the NIOSH definition to ''expected workplace level of respiratory protection.'' It also dropped the NIOSH phrase ''to a given percentage'' from its definition.

The phrase ''a given percentage'' implies that some respirator users will not achieve the full APF under workplace conditions. The ''given percentage'' usually is about five percent, which is a percentage derived from statistical analyses of workplace protection factor (WPF) studies. In this regard, five percent represents the fifth percentile of the geometric distribution of protection factors for individual participants in a WPF study. Each participant's protection factor is the concentration of challenge agent outside the respirator (C_o) divided by the concentration of that agent inside the participant's respirator (C_i), or C_o/C_i); therefore, the fifth percentile is the threshold for specifying the APF for the respirator tested under those workplace conditions. Using the fifth percentile means that about five percent of the employees who use the respirator under these workplace conditions may not achieve the level of protection assigned to the respirator (or class of respirators). Most WPF studies adopt the fifth-percentile threshold as the conventional standard, recognizing that about five percent of respirator users will not attain the APF determined for the respirator or class of respirators even when they receive proper fit testing and use the respirator correctly as part of a comprehensive respiratory protection program. However, ANSI dropped the phrase ''to a given percentage'' to reduce confusion (*i.e.*, the phrase did not specify a percentage), and to emphasize the level of protection needed by the vast majority of employees who use respirators in the workplace.

The Agency's review of the available data on respirator performance, as well as findings from the personal protective equipment surveys (Exs. 6–1, 6–2), indicate that the existing definitions of APF are confusing to the respirator-using public. Accordingly, OSHA believes that the proposed definition would reduce confusion among employers and employees regarding APFs, thereby assisting employers in providing their employees with effective respirator protection consistent with its Respiratory Protection Standard.

The Agency revised the terms in the ANSI APF definition to improve clarity. OSHA's proposed definition for APF reads as follows:

> *Assigned protection factor* (*APF*) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by 29 CFR 1910.134.

The revisions made to the ANSI APF definition in developing this proposed APF definition include adding the phrase ''when the employer implements a continuing, effective respiratory protection program as specified by 29 CFR 1910.134.'' The Agency added this phrase to emphasize the requirement that employers must select a respirator in the context of a comprehensive respiratory protection program. Accordingly, the APFs in Table I of this proposal do not apply when any of the program elements required by OSHA's Respiratory Protection Standard are absent from an employer's respirator program, including fit testing, maintenance, selection, use, training, and other specified elements. This wording is necessary because the level of employee protection afforded by the proposed APFs depends on the other elements of a comprehensive respiratory protection program being in place continuously, and operating effectively. Employers and employees cannot expect to achieve an APF reliably unless employers ensure that their employees use respirators in accordance with a continuing, effective respiratory protection program.

The proposed APF definition is an important addition to the Respiratory Protection Standard because it informs employers how the APF constrains respirator use. The APF can only be achieved by a respirator or class of respirators that are functioning properly in accordance with paragraphs (b) and (j) of the Respiratory Protection Standard. This means that the respirator must be capable of performing its

function of reducing employee exposures to airborne contaminants by being in correct working order. Accordingly, employers must maintain the respirator properly, with no defects such as cracked or distorted facepiece seals, missing exhalation valves, broken straps, or any other defect that would cause leakage into the respirator or prevent proper operation. For air-purifying respirators, the filters must be appropriate for the airborne contaminant, and provide an adequate service life.

Employers must properly fit and train employees for respirator use, which addresses the requirements in paragraphs (f) and (k) of the Respiratory Protection Standard. Therefore, employers must fit employees with the size and model of respirator they will be using in the workplace. They must then wear that same size and model of respirator in the workplace, and follow the training they receive for performing respirator seal checks, inspections for correct respirator operation, and proper donning and wearing the respirator.

2. Maximum Use Concentration

Employers use MUCs to select appropriate respirators, especially for use against organic vapors and gases since the MUC specifies the maximum atmospheric concentration of a hazardous substance against which a specific respirator or class of respirators with a known APF can protect employees who use these respirators. MUCs are a function of the assigned protection factor (APF) determined for a respirator (or class of respirators) and the exposure limit of the hazardous substance.

Ed Hyatt in the 1976 LASL report on Respiratory Protection Factors (Ex. 2) recounted the early history of maximum use concentration (MUC), starting with the MUC recommendations of the joint American Industrial Hygiene Association and American Conference of Governmental Industrial Hygienists committee in 1961. This committee recommended that, for highly toxic compounds, full facepiece respirators with high-efficiency filters should use a maximum limit of 100 x the threshold limit value (TLV). In 1961, in the United Kingdom, Hyatt noted that Letts recommended that half-mask dust respirators provided effective protection against airborne contaminants no greater than 10 x the TLV.

In 1974, NIOSH and OSHA started the Standards Completion Program to develop standards for substances with existing permissible exposure limits (PELs). This process resulted in the development of NIOSH Criteria Documents, each of which provided technical information and recommendations for specific airborne contaminants. These documents also recommended MUCs for different types of respirators; NIOSH obtained the information for these MUCs from various sources, including NIOSH Current Intelligence Bulletins and recognized industrial hygiene references. NIOSH later published this information in its Pocket Guide to Chemical Hazards. Other source documents for MUC definitions and regulations include the 1987 NIOSH RDL, and the ANSI Z88.2–1980 and ANSI Z88.2–1992 respiratory protection standards.

OSHA's 1994 proposed Respiratory Protection Standard contained the following definition for MUC:

Maximum use concentration (*MUC*) means the maximum concentration of an air contaminant in which a particular respirator can be used, based on the respirator's assigned protection factor. The MUC cannot exceed the use limitations specified on the NIOSH approval label for the cartridge, canister, or filter. The MUC can be determined by multiplying the assigned protection factor for the respirator by the permissible exposure limit for the air contaminant for which the respirator will be used.

Several commenters to the 1994 proposal recommended alternatives to this definition. Reynolds Metal Company recommended defining MUC as ''the maximum concentration of an air contaminant in which a particular respirator can be used, based on the respirator's assigned protection factor'' (Ex. 1–54–222). The American Petroleum Institute (API) noted NIOSH developed the term ''MUC,'' and that, to avoid confusion, OSHA should not use the term (Ex. 1–54–330). API proposed using the term ''assigned use concentration'' to replace ''MUC''; API defined ''assigned use concentration'' as ''the maximum concentration of an air contaminant in which a particular respirator can be used, based on the respirator's assigned protection factor'' (Ex. 1–54–330). However, when the Agency published the final Respiratory Protection Standard in 1998, it reserved the definition of MUC in paragraph (b) and MUC requirements in paragraph (d)(3)(i)(B) for future rulemaking.

Employers use MUCs to select appropriate respirators, especially for use against organic vapors and gases. In this regard, the MUC specifies the maximum concentration of a toxic vapor or gas at which a respirator will provide protection to an employee who uses the respirator. Accordingly, in this proposed rulemaking, OSHA defines MUC as follows:

Maximum use concentration (*MUC*) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The MUC usually can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the permissible exposure limit, short-term exposure limit, ceiling limit, peak limit, or any other exposure limit used for the hazardous substance.

Under this proposed definition, MUC represents the maximum atmospheric concentration of a hazardous substance against which a specific respirator or class of respirators with a known APF can protect employees who use these respirators. Accordingly, MUCs are a function of the assigned protection factor (APF) determined for a respirator (or class of respirators) and the exposure limit of the hazardous substance.

The last sentence in the proposed definition describes this function in terms of a mathematical calculation, *i.e.*, that employers can ''usually'' determine the MUC by multiplying the APF for the respirator by the exposure limit used for the hazardous substance.[8] The term ''usually'' in this sentence is consistent with paragraph (d)(3)(i)(B)(*2*), which is part of the proposed MUC requirements (see section below titled ''Regulatory Text for Maximum Use Concentrations.'') This proposed paragraph reads, ''Employers must comply with the respirator manufacturer's MUC for a hazardous substance when the manufacturer's MUC is lower than the calculated MUC specified by this standard.'' Therefore, while employers would use the proposed calculation to determine most MUCs, they would have to use MUCs determined by respirator manufacturers when these MUCs are lower than the MUCs determined using the proposed calculation. As noted below in the explanation of proposed paragraph (d)(3)(i)(B)(*2*), OSHA believes that this requirement would provide employees with a necessary added measure of protection from hazardous substances in the workplace.

Importantly, the last part of the proposed definition specifies exposure limits as ''permissible exposure limit (PEL), short-term exposure limit (STEL),

[8] For example, when the hazardous substance is nitrobenzene (with a PEL of 1 ppm), and the respirator used by employees has an APF of 10, then the calculated MUC is 10 ppm (*i.e.,* 1ppm x 10).

ceiling limit (CL), peak limit, or any other exposure limit used for the hazardous substance.'' The exposure limits are consistent with the terms used in the Z tables in 29 CFR 1910.1000 and the substance-specific standards in 29 CFR parts 1910, 1915, and 1926.

The phrase ''any other exposure limit used for the hazardous substance'' refers to exposure limits other than the exposure limits specified in the OSHA Z tables or in its substance-specific standards; employers use the other exposure limits to provide additional protection to employees or to comply with OSHA's general-duty clause (Section 5(a)(1) of the OSH Act; 29 U.S.C. 654 where OSHA has no standard). Employers may adopt such exposure limits from existing consensus standards (*e.g.*, the ACGIH TLVs), or develop them specifically for the unique hazardous substances found in their workplaces.

Paragraph (d)(3)(i)(A)—APF Provisions

1. Introduction

As early as 1976, respirator scientists were classifying respirators into distinct groups based on the level of protection they provided. These early respirator classes are similar to the classes now in use, as well as the classes developed by OSHA for this proposal. In the following parts of this section, the Agency describes the historical development of APFs for specific classes of respirators, and then explains OSHA's proposed APF for each of these respirator classes.

In addition to basing the APFs proposed in this rulemaking on the studies and previous APF standards described in this section, the Agency contracted with Dr. Kenneth Brown to conduct statistical analyses of the original data reported in most of the WPF studies reported below. Dr. Brown's quantitative analyses justify combining data for filtering facepiece and elastomeric half-mask respirators in determining an APF for these two respirator classes, and using a qualitative analysis of the data for identifying APFs separately for powered air-purifying respirators, supplied-air respirators, and self-contained breathing apparatuses. (Note that insufficient WPF data were available for Brown to include full facepiece air-purifying respirators in his analyses.) OSHA discusses the procedures and results of these statistical analyses in section IV of this preamble. The Agency believes that the APFs developed through the procedures discussed below are consistent with the results of the analyses performed by Dr. Brown.

2. Half-Mask Air-Purifying Respirators

Historical development of APFs for half-mask air-purifying respirators. In 1976, Ed Hyatt of LANL tested eight commercially available Bureau of Mines (the Federal agency then designated to approve respirators) half-mask respirators (Ex. 2). Based on quantitative fit testing results obtained from a respirator test panel,[9] Hyatt assigned six of these respirators an APF of 10; the remaining two respirators performed less effectively than the other six, thereby achieving an APF of less than 10. Hyatt did not use data from the two poor performing respirators to set the APF of 10 for the class because, as he stated in his report, ''For practical purposes, the remaining two models are not available.''

In 1980, the ANSI Z88.2 Respiratory Protection Standard (*i.e.*, ''the 1980 ANSI standard;'' Ex. 10, Docket H049) required fit testing to identify grossly misfitting half-mask respirators. That standard assigned an APF of 10 to half-mask air-purifying respirators when employers performed qualitative fit testing, and an APF as high as 100 when they performed quantitative fit testing (Ex. 10, Table 5, p. 21, Docket H049). ANSI based the latter APF on the results of studies that quantitatively fit tested a panel of respirator users, much as Hyatt did in 1976 (Ex. 2).

NIOSH developed its RDL in 1987 (Ex. 1–54–437Q), which assigned an APF of 5 to single-use and quarter mask air-purifying respirators, and an APF of 10 to half-mask respirators, including disposable half-mask respirators. In developing these APFs, NIOSH used results from quantitative fit-test studies performed on its own respirator test panel, several LANL quantitative fit-test studies (including Hyatt's 1976 study), and several WPF studies that it conducted in the early 1980s (Exs. 1–64–42, 1–64–47).

The 1992 Z88.2 ANSI Respiratory Protection Standard (*i.e.*, ''the 1992 ANSI standard''; Ex. 1–50) retained an APF of 10 for half-mask air-purifying respirators, including quarter masks, disposable half-masks, and half-masks with elastomeric facepieces. In determining these APFs, a committee of respirator experts convened by ANSI reviewed and discussed available APF studies, and then arrived at a final decision using a consensus process.

The following table summarizes the previous APFs assigned to half-mask air-purifying respirators, beginning with Hyatt's studies at LLNL in 1976 through the 1992 ANSI standard.

Half-mask air-purifying respirators	APFs			
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	1992 ANSI standard
Single use (no longer available)[1] ..	5	.....	5	.....
Filtering facepiece	.....	.....	10 (disposable)	10
Half-mask (elastomeric)	10	10 (with QLFT) 100 max. (with QNFT).	10	10

[1] Filtering facepieces replaced single-use respirators.

OSHA's proposed APFs for half-mask air-purifying respirators. Respirator manufacturers construct elastomeric half-masks using malleable compounds (*e.g.*, silicon, natural or synthetic rubber) that readily conform to the respirator user's face, thereby effectively sealing the inside of the mask against penetration by airborne hazardous substances. Filtering facepieces also are available in a variety of designs and materials that affect their fit to a user's face. For example, the design of the ''fold flat'' filtering facepiece allows employees to fold them for easy carrying and storage; when employees need this respirator for protection, they unfold the mask and place the fabric filter over their mouth and nose and then position the attached elastic headbands or straps around their head.

Half-mask respirators, including the subclasses of elastomeric and filtering facepiece respirators, vary widely in

[9] LANL developed a respirator test panel consisting of 25 men and women selected to have face sizes representing about 95% of the U.S. working population (Ex. 7, docket H049).

design and construction; these characteristics could result in different fitting characteristics which, in turn, can affect the level of employee protection afforded by the respirators. In this regard, an important question is whether available WPF and SWPF studies demonstrate sufficient variability in protection between and among filtering facepiece and elastomeric respirators to warrant different APF levels.

OSHA reviewed available WPF and SWPF studies that determined APFs for separate models of half-mask respirators based on each respirator's performance. These studies usually determine a protection factor for each respirator user (*e.g.*, an employee in a WPF study, or a member of a panel of respirator users in a SWPF study) who participates in the study, with each of these values expressed as the concentration of challenge agent outside the respirator (C_o) divided by the concentration of that agent inside the respirator (C_i), *i.e.*, C_o/C_i. After collecting these values, a statistical analysis determines the geometric distribution of the values; the overall APF for the respirator is the estimated value that lies at the fifth percentile of the geometric distribution. Listed in the table below are the WPF studies on filtering facepiece and elastomeric respirators reviewed by the Agency.

WPF studies for filtering facepieces (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Cohen (Ex. 1–64–11):				
Prototype Mercury (disposable respirator)	26	28		5
Albrecht *et al.* (Ex. 1–64–23):				
3M 8710	13	81	1.99	25
3M 9910	13	107	2.50	20
3M 9920	10	223	2.38	45
Nelson and Dixon (Ex 1–64–54):				
3M 8710	18	310	5.3	20
3M 9910	14	580	4.2	55
AO R1050	7	52	4.2	5
Reed *et al.* (Ex. 1–64–61):				
3M 9910	19	18	3.1	3
Johnston and Mullins (Ex. 1–64–34):				
3M 8715 (with aluminum particulate)	10	145	2.3	32
3M 8715 (with titanium particulate)	14	59	1.7	24
3M 8715 (with silicon particulate)	14	172	3.1	24
Colton *et al.* (Ex. 1–64–15):				
3M 9906	23	27	1.5	13
Colton *et al.* (Ex. 1–64–16):				
3M 9970 (with lead particulate)	62	415	4.4	36
3M 9970 (with zinc particulate)	62	681	5.6	40
Myers and Zhuang (Ex. 1–64–51) (conducted in a brass foundry):				
3M 9920 (with zinc particulate)	20	108	5.2	7
Myers and Zhuang (Ex. 3–14) (conducted in a steel mill):				
3M 8710 (with iron particulate)	10	377	3.7	44
Gerson 1710 (with iron particulate)	11	123	2.7	24
Colton and Mullins (Ex. 1–146):				
3M 9920 and 3M 9925	32	147	2.5	33
Wallis *et al.* (Ex. 1–64–70):				
3M 8710	70	50	3.5	7.5
Lenhart and Decker (Ex. 1–64–56):				
3M 9920	5			12
3M 9970 (two separate studies)	2			86 and 98
Gaboury and Burd (Ex. 1–64–24):				
AO, Willson, Survivair	18	47	2.5	9
Gavin *et al.* (Ex. 1–64–22):				
North 7709 (with OV cartridge)	63	75	3.1	11.7
Weber and Mullins (Ex. 3–15):				
3M 5000 (with OV cartridge)	46	39.7	2.14	11
Myers and Zhuang (Ex. 1–64–51) (conducted in a brass foundry):				
AO 5-Star (with DFM filter)	6	98	5.8	5
MSA Combo II (with DFM filter)	9	163	3.1	26
Scott 65 (with DFM filter)	6	94	4.8	7
Myers and Zhuang (Ex. 3–14) (conducted in a steel mill):				
AO 5-Star (with DM filter)	11	280	2.7	56
MSA Combo II (with DM filter)	8	427	4.3	39
Scott 65 (with DM filter)	11	252	2.9	45
Myers and Zhuang (Ex. 1–64–52) (conducted in a paint-spraying facility):				
AO 5-Star (with HEPA or OV filter)	38	2,211		171
MSA Combo II (with HEPA or OV filter)	38	4,580		437
Scott 65 (with HEPA or OV filter)	38	6,630		1,121
Lenhart and Campbell (Ex. 1–64–42):				
MSA Combo (with HEPA filter)	25	180	4.1	18
Albrecht *et al.* (Ex. 1–64–23):				
3M Easi-Air 7000 (with HEPA filter)	8	56	1.35	31
3M Easi-Air 7000 (with DM filter)	6	68	1.66	28
Dixon and Nelson (Ex. 1–64–54):				
Survivair 2000 and MSA Combo II (with DFM filter)	17	240	6.3	12

WPF studies for filtering facepieces (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Survivair 2000 and MSA Combo II (with HEPA filter)	14	94	3.0	16
North 7700 (with HEPA filter)	14	250	6.9	11
Dixon and Nelson (Ex. 1–64–19):				
Survivair 2000 (with HEPA or OV filter)	37	3,400	3.8	390
Colton *et al.* (Ex. 1–64–13):				
3M 6000 (with HEPA filter and cadmium particulate)	25	333	4.18	32
3M 6000 (with HEPA filter and lead fume)	31	129	3.15	19
Colton and Bidwell (Ex. 4–10–4):				
3M 7000 (with 7255 HEPA mechanical filter)	21	1,006	4.65	80
3M 7000 (with 2040 HEPA electrostatic filter)	22	562	3.5	71

OSHA found only one SWPF study on half-mask air-purifying respirators. In 1987, Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) of LANL performed a SWPF study that included laboratory testing of the MSA Comfo II half-mask air-purifying elastomeric respirator. The geometric mean fit factors they measured during simulated work exercises ranged from 800 to 5,700 for this half-mask. These results appear to complement the WPF results discussed in the following paragraph.

The summary statistics for WPF studies of filtering facepieces and elastomeric half-masks presented in the previous tables show little difference between these two major subclasses of half-mask respirators. Most importantly, the estimated protection factors for these two subclasses evidence considerable overlap. In addition, both tables show that many respirators in each class received estimated protection factors above 10, while a few respirators performed below that level. Accordingly, the WPF studies overall support assigning an APF of 10 for this respirator class (*i.e.*, half-masks), which consists of quarter masks, filtering facepieces, and elastomeric half-mask respirators. OSHA could find no studies on the performance of quarter masks, but just as in the 1992 ANSI standard (Ex. 1–50) has included quarter masks with half-masks.

The statistical analyses of these studies performed by Dr. Kenneth Brown (see section IV above) corroborate these conclusions. These analyses could not differentiate between filtering facepieces and elastomeric half-masks, which justifies combining the study data for these two subclasses into a single class for a subsequent APF determination. This determination showed that nearly 96% of the WPF data in these combined studies were at or above an APF of 10.

3. Full Facepiece Air-Purifying Respirators

Historical development of APFs for full facepiece air-purifying respirators. In 1976, Ed Hyatt of LANL developed an APF table that included this respirator class (Ex. 2). In this report, Hyatt used the results from quantitative fit testing to assess six models of full facepiece negative pressure air-purifying respirators equipped with HEPA filters. Five of these respirators achieved a protection factor of at least 100 for 95% of the respirator users; the sixth respirator attained this level of protection for 70% of the users. Based on the results for the sixth respirator, Hyatt recommended an APF of 50 for the respirator class as a whole.

The 1980 ANSI standard listed an APF of 100 for full facepiece air-purifying respirators with DFM filters. ANSI increased the APF for this respirator class from 50 to 100 because the poorly performing respirator in Hyatt's study was no longer in production. Using the 1976 LANL quantitative fit-testing results, the 1980 ANSI standard increased this APF to a maximum of 1,000 when the respirator used HEPA filters and the respirator users received quantitative fit testing.

Based on Hyatt's 1976 data, the 1987 NIOSH RDL recommended that this respirator class receive an APF of 50 when equipped with a HEPA filter, and an APF of 10 when using DFM filters. NIOSH developed the lower APF of 10 for respirators equipped with DFM filters after it tested the efficiency of these filters. In the absence of workplace protection factor studies of full facepiece respirators, NIOSH based these APFs on results from earlier quantitative fit testing performed by LANL on panels of respirator users.

The 1992 ANSI standard retained the 1980 ANSI standard's APF of 100 for full facepiece air-purifying respirators, but required that respirator users perform fit testing and achieve a minimum fit factor of 1,000 prior to using the respirators; in this regard, quantitative fit testing was necessary because no qualitative fit test could achieve a fit factor of 1,000. The ANSI standard kept this APF because the ANSI committee found that no new WPF or SWPF studies had been performed for this respirator class since it last issued APFs in 1980.

The following table summarizes the previous APFs assigned to full facepiece air-purifying respirators, beginning with Hyatt's studies at LLNL in 1976 through the 1992 ANSI standard.

Full facepiece air-purifying respirators	APFs			
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	1992 ANSI standard
All respirators in the class	50 (with HEPA filter)	10 (with QLFT) 100 max. (with QNFT)	10 (with DFM filter) 50 (with HEPA filter).	100

OSHA's proposed APFs for full facepiece air-purifying respirators. Although the 1992 ANSI standard assigned an APF of 100 to full facepiece air-purifying respirators, OSHA believes that studies completed after 1992 indicate that an APF of 100 is too high. Colton, Johnston, Mullins, and Rhoe (Ex. 1–64–14) assessed the protection afforded to 13 employees over a four day period by the 3M 7800 full facepiece air-purifying respirator equipped with a HEPA filter. In this WPF study, the employees performed their regular tasks in the blast furnace,

reverberatory furnace, and casting and warehouse areas of a lead smelter while the authors sampled lead dust and fumes inside and outside the respirator. The authors found a fifth percentile protection factor of 95 for the combined samples, but concluded that the respirator provided reliable protection at protection factors in excess of 50.

Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) completed the only SWPF study on a full facepiece air-purifying respirator at LANL; this study measured the protection afforded by the MSA Ultra Twin with a HEPA filter. Ten members of the respirator test panel used the respirator under varying temperature and humidity conditions in a test chamber while performing simulated work tasks. The authors reported fit factors with geometric means ranging from 1,000 to 5,300 for this respirator. However, 23 of the 60 measurements reported were less than 1,000, 7 were less than 100, and 3 of these measurements were less than 50.

After carefully reviewing these studies, OSHA is proposing an APF of 50 for full facepiece air-purifying respirators. The proposed APF agrees with the conclusion of Colton, Johnston, Mullins, and Rhoe (Ex. 1–64–14) that this class of respirators provides reliable protection at an APF of 50. Additionally, the geometric mean simulated work fit factors reported by Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) were low for a SWPF study, and a few of the individual measurements were below an APF of 50; in the workplace, the fifth percentile APF for this respirator may fall well below 100. Therefore, in view of the paucity of data reported for this class of respirators, and the constraints imposed by the available studies, the Agency is proposing a conservative APF that it believes would afford employees an adequate and consistent level of respirator protection in the workplace.

Importantly, an APF of 50 corresponds with the APF assigned to full facepiece air-purifying respirators by OSHA in its substance specific standards, and by NIOSH in its 1987 RDL. In determining that an APF of 50 was appropriate for protecting employees against the contaminants identified in its substance specific standards, the Agency reviewed the existing scientific and technical information, and carefully considered comments in the records. OSHA believes that the information now available does not justify revising the previous APF determined for its substance specific standards. To ensure that the final APF for this class of respirators provides employees with appropriate protection, the Agency requests that commenters submit to the record any additional WPF and SWPF studies that may be available on full facepiece air-purifying respirators.

4. Powered Air-Purifying Respirators (PAPRs)

Historical development of APFs for PAPRs. In 1976, Ed Hyatt of LANL gave PAPRs equipped with high efficiency filters, regardless of facepiece type, a protection factor of 1,000. In doing so, Hyatt assumed, based on quantitative fit tests, that both tight-fitting and loose-fitting facepiece PAPRs would always maintain a positive pressure inside the facepiece.

The committee responsible for drafting the 1980 ANSI standard assigned an APF of 3,000 to PAPRs equipped with high efficiency filters. When the respirators used DFM filters, they received an APF of 100. The ANSI committee did not require fit testing for PAPRs because it assumed, as did Hyatt, that these respirators would maintain positive pressure during use.

The 1987 NIOSH RDL assigned an APF of 25 to half-mask PAPRs after NIOSH reviewed the results of two WPF studies that it conducted on these respirators (Ex. 1–64–42 and 1–64–46). The RDL also gave loose-fitting PAPRs with hoods or helmet an APF of 25 based on data from two studies performed by Myers, Peach, Cutright, and Iskander (Exs. 1–64–47 and 1–64–48). However, the RDL recommended an APF of 50 for other PAPRs equipped with a tight-fitting facepiece or a hood or helmet, as well as high efficiency filters or gas-vapor cartridges used in combination with high efficiency filters.

The committee developing the 1992 ANSI standard updated the APFs specified in the 1980 ANSI standard. Accordingly, the committee recommended an APF of 50 for tight-fitting half-mask PAPRs based on the same WPF studies used by NIOSH in developing the 1987 RDL. Tight-fitting full facepiece PAPRs received an APF of 100 when equipped with dust filters (based on performance limitations of the filters), and an APF of 1,000 when used with HEPA filters. While the ANSI committee retained an APF of 25 for loose-fitting facepiece PAPRs, including loose-fitting hoods and helmets, it treated tight-fitting PAPRs with hoods or helmets much as it did tight-fitting full facepiece PAPRs (*i.e.,* by assigning them an APF of 100 when used with a dust filter, and an APF of 1,000 when equipped with a HEPA filter).

The following table summarizes the previous APFs assigned to PAPRs, beginning with Hyatt's studies at LANL in 1976 through the 1992 ANSI standard.

Powered air-purifying respirators (PAPRs)	APFs			
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	1992 ANSI standard
Half-mask	1,000	100 (with DFM filter), 3,000 max. (with HEPA filters).	50 (with HEPA filter)	50.
Full facepiece	1,000	100 (with DFM filter), 3,000 max. (with HEPA filters).	50 (with HEPA filter)	100 (with dust filter), 1,000 (with HEPA filter).
Hoods or helmets	1,000	100 (with DFM filter), 3,000 max. (with HEPA filters).	50 (with HEPA filter)	100 (with dust filter), 1,000 (with HEPA filter).
Loose-fitting facepiece	1,000	100 (with DFM filter), 3,000 max. (with HEPA filters).	25 (with any filter)	25.

OSHA's proposed APFs for half-mask PAPRs. In 1983, Meyers and Peach performed a WPF study on tight-fitting half-mask and full facepiece PAPRs in a silica-bagging operation (Ex. 1–64–46). The geometric mean protection factors for each of the seven employees who used the half-mask PAPRs ranged from 19 to 193, with a geometric mean protection factor of 54 for the entire sample. The authors attributed the poor performance of the half-mask PAPRs to leakage around the filter assembly connection where it attached to the PAPR blower housing, as well as to inadequate facepiece fit.

Lenhart and Campbell of NIOSH in 1984 conducted another WPF study of tight-fitting half-mask PAPRs used by employees in the sinter plant and furnace areas of a primary lead smelter

(Ex. 1–64–42). For the entire sample, the authors reported a geometric mean protection factor of 380 and a fifth-percentile protection factor of 58.

Two SWPF studies also evaluated tight-fitting half-mask PAPRs. Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) used fit testing to assess the performance of the respirators in a test chamber under variable temperature and humidity conditions. They found that the geometric mean protection factor for the entire sample ranged from 14,200 to 20,000. In the second SWPF study, da Roza, Cadena-Fix, and Kramer tested a panel of respirator users who exercised on a treadmill at different work rates (Ex. 1–64–94). The geometric mean protection factor for the entire sample (*i.e.,* combining respirator performance at all work rates) was 5,000.

The following table provides a summary of the WPF and SWPF studies for tight-fitting half-mask PAPRs.

WPF studies for half-mask PAPRs (by name of authors and type/model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Lenhart and Campbell (Ex. 1–64–42), MSA	25	380	2.6	58
Myers and Peach (Ex. 1–64–46), PAPR (manufacturer and model not specified)	10	54	2.44	.....

SWPF studies for half-mask PAPRs (by name of authors and type/model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile SWPF
Skaggs *et al.* (Ex. 1–38–3), MSA with Comfo II facepiece	60	14,200–20,000	.....	.....
da Roza *et al.* (Ex. 1–64–94), MSA with Comfo facepiece	[1] 6	[2] 5,000	.....	.....

[1] The six respirator users of the test panel exercised on a treadmill.
[2] The geometric mean is for all exercise rates combined.

In arriving at a proposed APF of 50 for tight-fitting half-mask PAPRs, OSHA relied to a large extent on the WPF study conducted by Lenhart and Campbell. This study was well controlled and collected data under actual workplace conditions; these conditions ensure that the results are reliable and represent the protection employees likely would receive under conditions of normal respirator use. The Agency did not consider the Meyers and Peach WPF study for this purpose because of problems involving filter assembly leakage and poor facepiece fit reported by the authors; consequently, the abnormally high levels of silica measured inside the mask would most likely underestimate the true protection afforded by the respirator. The two SWPF studies reported much higher geometric mean protection factors than did the WPF study performed by Lenhart and Campbell. However, OSHA believes that the higher protection factors reported for these SWPF studies are consistent with the proposed APF of 50 based on data obtained for this respirator class in the Lenhart and Campbell WPF study because SWPF studies typically report significantly higher protection factors than WPF studies of the same respirator. In addition, the proposed APF duplicates the APFs assigned to tight-fitting half-mask respirators by the 1987 NIOSH RDL and the 1992 ANSI standard, both of which based their APF determinations on data reported in the existing scientific literature, as well as the opinions of well known experts on respiratory protection.

OSHA's proposed APFs for full facepiece PAPRs and PAPRs with hoods or helmets. Two WPF studies determined protection factors for tight-fitting full facepiece PAPRs. Myers and Peach conducted the first of these studies in 1983 (Ex. 1–64–46); OSHA described this study in its earlier discussion of tight-fitting half-mask PAPRs. As noted in this discussion, the Agency did not use the results of this study because of problems involving filter assembly leakage and poor facepiece fit reported by the authors. The second WPF study, by Colton and Mullins, reported a geometric mean protection factor of 4,226, and a fifth percentile protection factor of 728 for employees in a secondary lead smelter (Ex. 1–64–12). Thirty-four samples in this study had no detectable lead inside the respirators; therefore, the authors used the limit of detection for lead as a proxy for the concentration of lead inside the facepiece. When the authors corrected their data analysis by including these samples, the geometric mean protection factor increased to 8,843, and the fifth percentile protection factor rose to 1,335. No SWPF studies on full facepiece PAPRs were available.

One WPF study and one SWPF study are available for tight-fitting PAPRs with hoods or helmets. In the WPF study, Keys, Guy, and Axon, determined the protection afforded to employees in a pharmaceutical manufacturing plant by three different respirators in this class (Ex. 1–64–40). The fifth percentile protection factors for these respirators were 997, 1,197, and 1,470. Johnson, Biermann, and Foote of LLNL and Cohen, Hecker, and Mattheis of the Organization Resources Counselors (ORC) performed the single SWPF study (referred to here as ''the ORC-LLNL SWPF Study'') in which they collected 576 test samples from four different PAPRs with hoods or helmets, and equipped with bibs (Ex. 3–4–2). The lowest protection factor among the 576 test samples was 11,000; overall, the 576 test samples had a fifth percentile protection factor greater than 250,000.

The following tables summarize the WPF studies for tight-fitting full facepiece PAPRs, and the WPF and SWPF studies involving PAPRs with hoods or helmets.

WPF studies for full facepiece PAPRs (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Colton and Mullins (Ex. 1–64–12) 3M W–3205 Whitecap (with 3M 7800 full facepiece and HEPA filter):				
Study 1[1]	20	4,226	2.9	728

WPF studies for full facepiece PAPRs (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Study 2	55	8,843	3.2	1,335
Myers and Peach (Ex. 1–64–46) Full facepiece PAPR (manufacturer and model not specified)	10	54	2.44	.....

[1] Study 1 consisted of 20 samples with C_i values over the detection limit, while Study 2 consisted of 34 samples that had C_i values below the detection limit; for analytic purposes, the investigators assigned these 34 samples a C_i value equal to the detection limit.

WPF studies for PAPRs with hoods or helmets (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Keys *et al.* (Ex. 1–64–40):				
Racal Breathe Easy 10 (hood, double bib, HEPA filter)	29	11,137	3.9	1,197
Bullard Quantum (hood, double bib, HEPA filter)	9	9,574	3.1	1,470
3M Whitecap II (helmet, double bib, HEPA filter)	22	42,260	9.8	997

SWPF studies for PAPRs with hoods or helmets (by name of authors and model of respirator tested)	Range of SWPFs	Geometric median SWPF	5th percentile SWPF
ORC–LLNL SWPF Study (Ex. 3–4):			
3M Whitecap (helmet with bib and HEPA filter)	140,000–>250,000	>250,000	>250,000
3M Snapcap (Tyvek hood with bib and HEPA filter)	11,000–>250,000	>250,000	>170,000–210,000
Racal BE–5 Clear PVC (hood with bib and HEPA filter)	11,000–>250,000	>250,000	>250,000
Racal BE–10 (Tyvek hood with bib and HEPA filter)	94,000–>250,000	>250,000	246,000–>250,000

OSHA is proposing an APF of 1,000 for full facepiece PAPRs and PAPRs with hoods or helmets. With regard to full facepiece PAPRs, the corrected fifth percentile protection factor of 1,335 reported by Colton and Mullins in their WPF study fully supports the proposed APF. The WPF study of PAPRs with hoods or helmets by Keys, Guy, and Axon justifies the proposed APF of 1,000 for this respirator class. These authors reported that the average fifth percentile protection factor for the three respirators tested in their study was well over 1,000. Moreover, the ORC–LLNL SWPF Study (Ex. 3–4), in which this class of respirators received extremely high fifth percentile protection factors, lends substantial validation to OSHA's proposed APF. In addition, the proposed APFs for full facepiece PAPRs and PAPRs with hoods or helmets corresponds with the APFs assigned to these respirator classes in the 1992 ANSI standard; ANSI made these APF determinations only after a careful review and discussion of the available research by a panel of respirator experts. While the proposed APF for these respirators is much higher than the APF recommended in the 1987 NIOSH RDL, the Agency believes that the WPF and SWPF studies conducted on these respirators since publication of the RDL justify the proposed increase.

Footnote 4 of the proposed APF table states that ''* * * only helmet/hood respirators that ensure the maintenance of a positive pressure inside the facepiece during use, consistent with performance at a level of protection of 1000 or greater, receive an APF of 1,000.'' The footnote continues, ''All other helmet/hood respirators are treated as loose-fitting facepiece respirators and receive an APF of 25.'' OSHA is proposing that respirators from this class be able to demonstrate that they maintain a positive pressure inside the facepiece during use and achieve a level of protection of 1000 or greater. Available WPF and SWPF studies have found that some of these respirators were shown to only achieve protection factors well below 1,000 (Exs. 3–4, 3–5). In all likelihood, the burden of conducting any testing would fall on respirator manufacturers, but the employer would be responsible for selecting a properly tested respirator, thereby assuring employees that they will receive adequate protection against toxic hazards.

OSHA's proposed APFs for loose-fitting PAPRs. A number of WPF and SWPF studies are available for loose-fitting facepiece PAPRs. An important purpose of these studies was to determine if APFs differed between loose-fitting facepiece PAPRs and PAPRs with tight-fitting hoods or helmets. The NIOSH WPF study by Myers, Peach, Cutright, and Iskander (Ex. 1–64–47) was the first to report that loose-fitting facepiece PAPRs did not perform at an APF of 1,000, the value determined by Ed Hyatt in 1976 after quantitatively fit testing a panel of respirator users. A follow-up study by Myers, Peach, Cutright, and Iskander (Ex. 1–64–48) reported a fifth percentile protection factor of 25 for this respirator class.

A WPF study conducted later by Albrecht, Gosselink, Wilmes, and Mullins (Ex. 1–64–23) reported a fifth percentile protection factor of 42 for the 3M Airhat, a loose-fitting facepiece PAPR with a helmet. Stokes, Johnston, and Mullins (Ex. 1–64–66) performed a WPF study in a roofing granule production plant using the 3M Airhat; they found a fifth percentile protection factor of 95. However, when employees used the respirator with a Tyvek shroud, the fifth percentile protection factor increased to 1,615. Gaboury and Burd (Ex. 1–64–24) reported a fifth percentile protection factor of 275 in a WPF study in which employees in an aluminum smelter wore a Racal Breathe Easy loose-fitting facepiece PAPR with a helmet. Collia, Colton, and Bidwell (Ex. 3–5) found a fifth percentile protection factor of 315 in a WPF study performed on the 3M Breathe Easy 12 PAPR with a loose-fitting head cover.

OSHA evaluated three SWPF studies addressing the performance of loose-fitting facepiece PAPRs with hoods or helmets. Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) reported geometric mean protection factors ranging from 1,900 to 5,600 for the 3M Airhat, and from 1,200 to 3,500 for the Racal AH3 PAPR with a loose-fitting helmet. A study by da Roza, Cadena-Fix, and Kramer (Ex. 1–64–94) found geometric mean protection factors ranging from 10 to 10,000, and from 100 to 20,000, for the two loose-fitting facepiece PAPRs with helmets they tested.

Johnson, Biermann, and Foote of LLNL and Cohen, Hecker, and Mattheis of ORC (Ex. 3–4) assessed the performance of one loose-fitting facepiece PAPR with a Tyvek head cover as part of the ORC–LLNL SWPF Study; the results of this study reported three APFs below 10,000, with the lowest value being 240. The fifth percentile protection factor for this respirator ranged from 150,000 to 230,000.

The following tables summarize the WPF and SWPF studies for loose-fitting facepiece PAPRs with hoods or helmets.

WPF studies for loose-fitting facepiece PAPRs with hoods or helmets (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Myers *et al.*(Ex. 1–64–47):				
3M W–344 (helmet with HEPA filter)	23	165	3.57	26
Racal AH 3 (helmet with HEPA filter)	23	205	2.83	26
Albrecht *et al.* (Ex. 1-64–23) 3M Airhat (helmet with HEPA filter)	7	199	2.36	42
Myers *et al.* (Ex. 1–64-48):				
3M W–316 (helmet with DM filter)	22	135	1.89	25
Racal AH 5 (helmet with DM filter)	24	120	2.64	25
Gaboury and Burd (Ex. 1–64–24) Racal Breathe Easy I (helmet with HEPA or OV filter)	20	1,414	2.51	275
Collia *et al.* (Ex. 3–5) 3M Breathe Easy 12 (Tyvek head cover with HEPA filter)	41	2,523	.....	315
Stokes *et al.* (Ex. 1-64–66):				
3M Airhat (helmet) with:				
HEPA filter (total)[1]	12	5,370	3.0	762
DM filter (without shroud)	27	877	5.2	53
DM filter (with shroud)	18	11,792	3.1	1,615
DM filter (total)	45	2,480	7.0	95

[1] The total consists of the shroud and no-shroud samples combined.

SWPF studies for loose-fitting facepiece PAPRs with hoods or helmets (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric median	5th percentile SWPF
Skaggs *et al.* (Ex. 1–38–3):				
3M Airhat W–344 (helmet)	60	1,900–5,600	.....	.....
Racal AH3 Airstream (helmet)	60	1,200–3,500	.....	.....
da Roza *et al.* (Ex. 1–64–94):				
3M Airhat W–344 (helmet)	[1] 6	10–10,000	.....	.....
Racal Breathe-Easy 1 (helmet)	6	100–20,000	.....	.....
ORC–LLNL SWPF Study (Ex. 3–4):				
Racal BE–12 (Tyvek head cover)	144	240–250,000	250,000	150,000–230,000

[1] Used same panel of six respirator users for both respirators; panel exercised on treadmill at 80% cardiac capacity.

OSHA is proposing an APF of 25 for loose-fitting PAPRs with hoods or helmets, which is consistent with both WPF studies conducted by Myers, Peach, Outright, and Iskander (Ex. 1–64–47 and 1–64–48), as well as the APFs for this respirator class established by the 1987 NIOSH RDL and by the 1992 ANSI standard. The extreme variability of the fifth percentile protection factors in the WPF studies warrants a conservative approach in proposing an APF for this respirator class. In this regard, seven of the 11 WPF studies found fifth percentile protection factors of less than 100, and five of these APFs were below 50. The Agency believes that a proposed APF of 25 would provide employees who use these respirators with an adequate safety margin in view of the unreliability of the protection factors found for this respirator class.

The geometric means reported by Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3) were low for a SWPF study, as were a number of the geometric means determined by de Rosa, Cadena-Fix, and Kramer (Ex. 1–64–94) in their SWPF assessments. In the workplace, these low geometric mean SWPFs likely would translate into fifth percentile WPFs of less than 50. Therefore, the limited and highly variable data in the SWPF studies support OSHA's conclusion that a conservative APF of 25 would afford employees an adequate and consistent level of respirator protection in the workplace.

5. Supplied-Air Respirators (SARs)

Historical development of APFs for SARs. SARs operate in one of three modes—demand, continuous flow, or pressure demand. Demand or pressure demand respirators have either a tight-fitting half-mask or a tight-fitting full facepiece, while continuous flow respirators have either a tight-fitting, or a loose-fitting, hood or helmet, or a tight-fitting half-mask or full facepiece.

In 1976, Ed Hyatt of LANL published the initial protection factors for SARs (Ex. 2). In making these determinations, Hyatt gave an APF of 10 to half-mask SARs operated in the demand mode, while full facepiece SARs received an APF of 50 in the demand mode. These APFs are the same APFs that Hyatt assigned to negative pressure half-masks, and full facepiece, air-purifying respirators. Hyatt based the APF of 10 for half-mask SARs operating in the demand mode on LANL studies performed in 1971 and 1972 on a respirator test panel wearing eight half-mask air-purifying respirators equipped with HEPA filter. In determining an APF of 50 for full facepieces, Hyatt relied on LANL studies in which a respirator test panel consisting of 31 firemen wore full facepiece SCBAs operating in the demand mode.

Hyatt regarded SARs that operate in a positive pressure mode to be more protective than SARs used in a negative pressure mode; therefore, he assigned half-mask and full facepiece SARs that function in the continuous flow, pressure demand, or other positive pressure modes APFs of 1,000 and 2,000, respectively; the half-mask respirators received a lower APF than the full facepiece respirators because

Hyatt considered a half-mask to be less stable on the face than a full facepiece. SARs with hoods or helmets operated in continuous flow mode received an APF of 2,000, consistent with the APF Hyatt gave to full facepiece SARs operating in the continuous flow or pressure demand mode.

The 1980 ANSI standard differentiated APFs for some SARs depending on the type of fit testing performed. Accordingly, half-mask and full facepiece SARs used in the demand mode received APFs of 10 and 100, respectively, when qualitatively fit tested. When tested quantitatively, the APFs for these respirators were the protection factors achieved during fit testing, with the APF limited to the sub-IDLH value [10] of the hazardous substance in the workplace.

Half-mask or full facepiece SARs that functioned in continuous flow or pressure demand modes required no fit testing because of their positive pressure operation; consequently, these respirators received an APF limited only to the sub-IDLH value of the hazardous substance in the workplace when used without an auxiliary air supply or escape bottle (*i.e.*, the ''escape configuration''). When equipped in an escape configuration, these respirators had a maximum APF of 10,000. Continuous flow or pressure demand SARs with hoods or helmets also received a maximum APF of 10,000 when not used in an escape configuration; however, when operated in a escape configuration, the maximum APF for these respirators was of 10,000+ (*i.e.*, employees could use them to escape from IDLH atmospheres).

The 1987 NIOSH RDL recommended APFs of 10, 50, and 1,000, respectively, for half-mask SARs when operated in demand, continuous flow, and positive pressure (including pressure demand) modes. All SARs with hoods or helmets received an APF of 25 when used in the continuous-flow mode. The RDL assigned full facepiece SARs an APF of 50 when they functioned in the demand or continuous flow mode, an APF of 2,000 when operated in the pressure demand or other positive pressure mode, and a maximum APF of 10,000 when used in the pressure demand mode with an auxiliary SCBA.

The 1992 ANSI standard did not set different APFs for the same class of respirator based on the type of fit testing conducted because WPF studies performed after publication of the 1980 ANSI standard did not support this practice. After comparing the operational characteristics of half-mask and full facepiece SARs to half-mask and full facepiece air-purifying respirators, the 1992 ANSI standard gave APFs of 10 and 100, respectively, to half-mask and full facepiece SARs when operated in the demand mode. Pressure demand and continuous flow half-mask SARs received an APF of 50, consistent with their operational similarities with half-mask PAPRs. Full facepiece continuous flow SARs received an APF of 1,000, determined from their operational analogy to SARs having tight-fitting hoods or helmets. Based on their operational similarities to loose-fitting continuous flow PAPRs, the committee drafting the 1992 ANSI standard gave loose-fitting facepiece SARs operated in the continuous flow mode an APF of 25.

The following table summarizes the APFs given to the various classes of SARs (*i.e.*, half-mask, full facepiece, tight-fitting with hoods or helmets, and loose-fitting facepiece), beginning with Hyatt's studies at LLNL in 1976 through the 1992 ANSI standard.

SARs	APFs			
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	1992 ANSI standard
Half-mask	10 (demand)	10 (demand; with QLFT).	10 (demand)	10 (demand).
	1,000 (continuous flow)	Same as QNFT factor (demand; sub-IDLH value max.).	50 (continuous flow)	50 (continuous flow).
	1,000 (pressure demand)	Sub-IDLH (continuous flow or pressure demand; no escape configuration). 10,000 max. (with escape configuration).	1,000 (pressure demand)	50 (pressure demand).
Full facepiece	50 (demand)	100 (demand; with QLFT).	50 (demand)	100 (demand).
	2,000 (continuous flow)	Same as QNFT factor (demand; sub-IDLH value max.).	50 (continuous flow)	1,000 (continuous flow).
	2,000 (pressure demand)	Sub-IDLH (continuous flow or pressure demand; no escape configuration). 10,000 max. (with escape configuration).	2,000 (pressure demand)	1,000 (pressure demand).
Hood or helmet	2,000 (continuous flow)	Sub-IDLH (continuous flow or pressure demand; no escape configuration). 10,000 max. (with escape configuration).	25 (continuous flow)	1,000 (continuous flow).
Loose-fitting facepiece			25 (continuous flow)	25 (continuous flow).

[10] The concentration of the hazardous substance just below its IDLH value.

OSHA's proposed APFs for half-mask SARs. No WPF studies were available for half-mask SARs. Therefore, OSHA is proposing an APF of 10 for this respirator class when used in the demand mode based on their analogous operational performance with negative pressure half-mask air-purifying respirators tested during WPF and SWPF studies. In addition, the Agency proposes to give half-mask SARs that function in the continuous flow or pressure demand modes an APF of 50, consistent with the performance of half-mask PAPRs in WPF and SWPF studies (and operated at the same airflow rates). Additional support for the proposed APFs comes from the 1992 ANSI standard, which assigned an APF of 10 to half-mask airline SARs operated in the demand mode, and an APF of 50 when operated in the continuous flow or pressure demand mode. The 1987 NIOSH RDL also gave half-mask demand SARs an APF of 10, but recommended an APF of 1,000 for these respirators when functioning in the pressure demand or other positive pressure modes.

Regarding the recommended APF of 1,000, OSHA preliminarily finds that these respirators warrant the more conservative APF of 50 because of the possibility that negative pressure could develop inside the mask during tasks that stress the facepiece seal; moreover, in the absence of WPF and SWPF data for these respirators, the Agency believes that a conservative approach to setting this APF is appropriate.

OSHA's proposed APFs for full facepiece SARs. No WPF or SWPF studies were available involving tight-fitting full facepiece SARs operated in the demand mode. Therefore, in the absence any such data, the Agency is assigning this respirator class an APF of 50 based on the analogous operational characteristics between these respirators and negative pressure air-purifying respirators when operated in the demand mode under WPF conditions. The proposed APF is the same as the APF recommended for this respirator class by the 1987 NIOSH RDL, and similar to the APF (*i.e.*, 100) given to these respirators by the 1992 ANSI standard. In choosing an APF of 50 instead of 100 for this class of respirators, the Agency believes that the paucity of WPF and SWPF studies warrants taking a conservative approach in this determination.

While no WPF studies for full facepiece SARs operated in the pressure demand or other positive pressure modes were available, there was one SWPF study of this respirator class by Skaggs, Loibl, Carter, and Hyatt (Ex. 1–38–3). The study, performed at LANL, evaluated the respirators under different temperature and humidity conditions; the results of the study showed that these respirators had geometric mean protection factors ranging from 8,500 to 20,000. Therefore, the Agency is proposing an APF of 1,000 for full facepiece SARs used in the pressure demand or other positive pressure modes based on their performance in this study (*i.e.*, that the likelihood is high that the geometric mean SWPFs would translate to fifth percentile WPF of 1,000. Further justification for the proposed APF comes from the similarity in operational characteristics (including the same minimum airflow rates) between these respirators and tight-fitting full facepiece continuous flow PAPRs, which are receiving a proposed APF of 1,000 in this rulemaking. (See the discussion of these PAPRs above).

The proposed APF of 1,000 for full facepiece SARs operated in the pressure demand or other positive pressure modes also is consistent with the APFs of 1,000 assigned by the 1992 ANSI standard to these respirators when used in the continuous flow or pressure demand modes, and the APF of 2,000 recommended by the 1987 NIOSH RDL for pressure demand respirators in this class. Although the RDL gave an APF of 50 to these respirators in a continuous flow mode, the Agency believes that the SWPF study, as well as the WPF studies performed on analogous tight-fitting full facepiece continuous flow PAPRs, justify the proposed APF.

OSHA's proposed APF for SARs with hoods or helmets. The Agency found a number of WPF studies on these respirators, including one by Johnston, Stokes, Mullins, and Rhoe (Ex. 1–64–36).

These authors performed a WPF study on the 3M Whitecap continuous flow abrasive blasting helmet (equipped with an extended length shroud) used by four shipyard employees while sandblasting a barge. After performing several data analyses, the authors concluded that outside-the-respirator samples with filter loadings at least 1,000 times greater than the mean blank value were most representative of the respirator's performance. Therefore, OSHA is using only statistics based on these samples for its APF determinations; these statistics indicate that the estimated fifth percentile protection factor is 1,038 for these samples.

Johnston, Stokes, Mullins, and Rhoe (Ex. 1–64–37) conducted a second WPF study on the 3M Whitecap II general purpose SAR with a helmet. In this study, the authors sampled six employees while they performed grinding operations in a foundry. The authors stated that ''because of the relatively low sample loadings, the WPF numbers obtained significantly underestimate the performance capability of the respirator.'' Therefore, OSHA did not use the WPFs from this study in developing the proposed APF for this respirator class.

Colton, Mullins, and Bidwell (Ex. 1–64–17) published a WPF study on foundry employees who used the 3M Snapcap continuous flow SAR with an abrasive blasting hood while exposed to silica during tear-down operations. The authors reported a fifth percentile protection factor over 1,000, which they noted was consistent with the APF of 1,000 assigned to these respirators by the 1992 ANSI standard.

In another WPF study, Nelson, Wheeler, and Mustard (Ex. 3–6) sampled aircraft assembly employees involved in sanding and primer spraying operations while using the 3M H–422 continuous flow SAR hood with both an outer and inner shroud. The authors reported that 14 of the 31 samples taken during primer spraying operations showed measurable concentrations of strontium (Sr) outside the facepiece (C_o), but none of the samples showed any measurable concentration of Sr inside the facepiece (C_i). Based on these C_o data, and using the lowest detectable limit for C_i, the authors concluded that ''the WPFs were greater than 1,200 for all samples with a mass of Sr on the C_o samples 1,000 times the detection limit for the C_i samples.'' They stated further that their study supports the APF of 1,000 given to these respirators by the 1992 ANSI standard.

In a WPF study conducted at Avondale shipyard, Kiefer, Trout, and Wallace (Ex. 2–1) sampled the total particulate exposures (*i.e.*, small and large particle fractions combined) of employees involved in abrasive blasting operations while using the Bullard Type 88 CE (continuous flow) SAR abrasive blasting hood. The authors reported WPFs ranging from 2,817 to 10,000.

OSHA identified four SWPF studies of this respirator class, all performed by LLNL or LANL for manufacturers of continuous flow SARs with abrasive blasting hoods or helmets. The geometric mean protection factors found for these respirators were 40,000 for the Bullard Model 77 and 88 Type CE (continuous flow) SARs with an abrasive blasting hood (Ex. 1–157), and 100,000 for the Clemco Apollo 20 and 60 Type CE (continuous flow) SARs with an abrasive blasting hood (Ex. 3–7–3) and the 3M Whitecap Model W–8100 Type CE (continuous flow) SAR

with abrasive blasting helmet (Ex. 3–9–2). Based on the results of these studies, OSHA granted these respirators an interim APF of 1,000 (Exs. 3–7–4, 3–8–4, 3–9–3).

In the latest SWPF study, Johnson, Biermann, and Foote of LLNL and Cohen, Hecker, and Mattheis of ORC (Ex. 3–4) tested six models of continuous flow SARs with hoods or helmets as part of the ORC–LLNL SWPF Study. Five of these respirators had fifth percentile SWPFs ranging from 86,000 to over 250,000. However, the fifth percentile SWPFs for the sixth respirator (the North Model 85302 T) ranged from 13 to 18. The authors attributed the poor performance of this respirator to the absence of a ''tuck-in'' bib. When the manufacturer corrected this design problem by adding a tuck-in bib, the resulting model (designated the North Model 85302 TB) performed as well as most of the other respirators tested in the study.

The following tables summarize the WPF and SWPF studies for tight-fitting SARs with hoods or helmets.

WPF studies for SARS with hoods or helmets (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Johnston *et al.* (Ex. 1–64–36) 3M W–8100 Whitecap II (abrasive blasting helmet with extended-length shroud)	15	4,076	2.3	1,038
Johnston *et al.* (Ex. 1–64–37):				
3M W–8000 Whitecap II (helmet)				
Study 1 (using >750 x field blank with iron dust samples)	8	1,012	2.6	199
Study 2 (using >30 x field blank with silicon dust samples)	8	1,417	3.0	224
Colton *et al.* (Ex. 1–64–17), 3M Snapcap W–3256 (abrasive blasting hood)	14	10,344	2.5	2,290
Nelson *et al.* (Ex. 3–6), 3M H–422 (hood)	31	.....	.....	>1,000
Kiefer *et al.* (Ex. 2–1), Bullard 88 Type Type CE (abrasive blasting hood)	11	.....	.....	>1,000

SWPF studies for SARs with hoods or helmets (by name of authors and model of respirator tested)	Range of SWPFs	Geometric mean/ median SWPF	5th percentile SWPF
Bullard-LLNL (Ex. 1–157) [1], Bullard 77 and 88 Type CE (abrasive blasting helmet)	.....	>40,000 (mean)	.....
Clemco-LANL (Ex. 3–7–3) [2], Apollo 20 and 60 Type CE (abrasive blasting hood)	.....	>100,000 (mean)	.....
3M–LANL (Ex. 3–9–2) [3], 3M Whitecap Model W–8100 Type CE (abrasive blasting helmet)	.....	>100,000 (mean)	.....
ORC–LLNL SWPF Study (Ex. 3–4–2):			
3M Whitecap SAR (helmet with bib and chinstrap)	68,000–>250,000	>250,000 (median)	>250,000
3M Snapcap (Tyvek hood with bib and chinstrap)	13,000–>250,000	>250,000 (median)	170,000–250,000
MSA Versa-hood (Tyvek hood)	9,700–>250,000	>250,000 (median)	86,000–114,000
North Model 85302 TB (Tyvek hood with bib)	55,000–>250,000	>250,000 (median)	150,000–240,000
North Model 85302 T (Tyvek hood, no bib)	5–>250,000	1,217 (mean)	13–18
Bullard CC20TIC (Tyvek hood and bib and chinstrap)	160,000–>250,000	>250,000 (median)	>250,000

[1] Collected 288 samples (a panel of 4 respirator users × 12 exercises × 6 helmets).
[2] Collected 264 samples (a panel of 4 respirator users × 11 exercises × 6 helmets).
[3] Collected 132 samples (a panel of 4 respirator users × 11 exercises × 3 helmets).

The Agency is proposing an APF of 1,000 for continuous flow SARs with hoods or helmets based on their performance in the WPF and SWPF studies. In each of the WPF studies [except the second WPF study by Johnston, Colton, Stokes, Mullins and Rhoe (Ex. 1–64–37)], these respirators attained a fifth percentile protection factor over 1,000. In addition, the large geometric mean protection factors found for these respirators provide substantial evidence for this proposed APF.

The Agency qualified the proposed APF in footnote 4 of its proposed APF table. This footnote states that * * * only helmet/hood respirators that ensure the maintenance of a positive pressure inside the facepiece during use, consistent with performance at a level of protection of 1000 or greater, receive an APF of 1000.'' and that ''[a]ll other helmet/hood respirators are treated as loose-fitting facepiece respirators and receive an APF of 25.'' Under this proposed requirement, an employer must select for employee use only continuous flow SARs with hoods or helmets that attained a protection factor of at least 1,000. While better performance has been associated with certain designs (*e.g.*, double bibs, neck seals or dams, blouses, higher airflows), the presence of such design considerations are no guarantee of superior performance. In order to receive an APF of 1,000, it is contingent upon the respirator manufacturer to be able to demonstrate that their particular respirator meets the criteria specified in Table I of the proposed standard. This level of performance can best be demonstrated by performing a WPF or SWPF study. OSHA is proposing this requirement because previous WPF and SWPF testing conducted on these respirators shows that they do not always result in the requisite protection factor (Exs. 3–4, 3–5).

Accordingly, researchers have recommended that such testing be performed to ensure that employees use only respirators from this class that provide them with the specified level of protection during exposure to hazardous substances. In this regard, while the respirator manufacturer most likely would perform the required testing, it would be incumbent on the employer to ensure that the respirators they selected for employee use received this testing.

While the 1987 NIOSH RDL recommended an APF of 25 for continuous flow SARs with hoods or helmets, this recommendation is the result of combining these respirators into a single class with loose-fitting facepiece SARs, and giving the entire class the low APF (*i.e.*, 25) assigned originally to loose-fitting facepiece respirators. However, the 1992 ANSI standard established a separate class for continuous flow SARs with hoods or helmets based on analogous operating

characteristics between these respirators and airline respirators at the same flow rates, with the new class having an APF of 1,000 (loose-fitting facepiece SARs continued to receive an APF of 25). Accordingly, OSHA is proposing in this rulemaking to follow the procedure adopted by the 1992 ANSI standard and divide the two respirator types into separate classes, based principally on the WPF and SWPF performance of the continuous flow SARs with hoods or helmets.

OSHA's proposed APF for loose-fitting facepiece SARs. No WPF or SWPF studies involving this respirator class were available. Therefore, using analogous operational characteristics between these respirators and loose-fitting facepiece PAPRs, OSHA is proposing to assign loose-fitting facepiece SARs an APF of 25. In this regard, loose-fitting facepiece SARs, when evaluated under the NIOSH respirator-certification standards (42 CFR part 84), had the same minimum airflow rates found for loose-fitting facepiece PAPRs. Additional support for the proposed APF comes from the 1987 NIOSH RDL and the 1992 ANSI standard, both of which gave this respirator class an APF of 25.

6. Self-Contained Breathing Apparatuses (SCBAs)

Historical development of APFs for SCBAs. As he did with full facepiece SARs used in the demand mode, Hyatt in 1976 assigned a protection factor of 50 to a full facepiece SCBA operated in this mode. Based on results from a panel of 31 respirator users tested at LANL, he gave full facepiece SCBAs used in the pressure demand mode an APF of 10,000+ (Ex. 2). The 1980 ANSI standard listed half-mask and full facepiece SCBAs operated in the demand mode as having APFs of 10 and 100, respectively, when qualitatively fit tested; when quantitatively fit tested, the APFs for half-mask or full facepiece SCBAs functioning in the demand mode were the protection factors obtained during fit testing, with this APF limited to the sub-IDLH value. Full facepiece SCBAs used in the pressure demand mode received an APF of 10,000+. The 1987 NIOSH RDL recommended that half-mask and full facepiece SCBAs operated in the demand mode receive APFs of 10 and 50, respectively, and that the APF for full facepiece SCBAs operated in the pressure demand or other positive pressure mode be 10,000.

The committee responsible for the 1992 ANSI standard could not reach a consensus on an APF for full facepiece pressure demand SCBAs. As noted in footnote 4 of the APF table in this ANSI standard, available WPF and SWPF studies reported that, in some individual cases, the respirators did not achieve an APF of 10,000 (Ex. 1–50). Nevertheless, the committee found that a maximum APF of 10,000 was appropriate when employers used the respirators for emergency planning purposes and could estimate levels of hazardous substances in the workplace.

Two newly developed respirators equipped with hoods, Draeger's Air Boss Guardian and Survivair's Puma, have operational characteristics similar to SCBAs. The facepiece of the Draeger respirator consists of a hood with an inner nose cup and a seal at the neck; an air cylinder supplies air to the facepiece. NIOSH reviewed this respirator in accordance with its certification requirements specified at 42 CFR part 84, and in January 2001 certified the respirator as a tight-fitting full facepiece demand SCBA, with the cylinder having a 30-minute service life; NIOSH also approved the respirator for use in entering and escaping from hazardous atmospheres. In a May 16, 2001 letter to OSHA's Directorate of Compliance Programs (Ex. 7–1), Mr. Richard Metzler of NIOSH justified the classification of the Draeger respirator as an SCBA on the basis that the neck seal, which is integral to the facepiece, forms a gas-tight or dust-tight fit with the face, consistent with the definition of a tight-fitting facepiece specified by 42 CFR 84.2(k). This letter also noted that the fit testing procedures used for full facepiece demand SCBAs apply to the Draeger SCBA, and that, as a full facepiece demand SCBA, NIOSH recommended that the respirator receive an APF of 50 in accordance with its 1987 RDL.

NIOSH subsequently reviewed the Survivair Puma respirator, which has a tight-fitting hood supplied by an air cylinder; and certified the respirator as a pressure demand SCBA with a tight-fitting facepiece. As part of the certification process, NIOSH specified that fit testing required of SCBAs would apply to this respirator. However, Steve Weinstein of Survivair (Ex. 7–2) stated that the hood totally encapsulates the respirator user's hair, making quantitative fit testing (*e.g,* with a Portacount) impossible; in such cases, the fit testing instrumentation treats dander and other material shed by the hair as particulates from outside the respirator, causing the fit factor to be artificially low. However, qualitative fit testing with the hood is possible because Survivair provides an adapter and P100 filters for this purpose; such fit testing meets the fit-testing requirements for tight-fitting SCBAs specified in paragraph (f)(8) of OSHA's Respiratory Protection Standard.

The table below provides a summary of APFs given to the half-mask and full facepiece SCBAs from Hyatt's 1976 studies at LLNL to the 1992 ANSI standard.

SCBAs	APFs			
	LANL (1976)	1980 ANSI standard	NIOSH RDL (1987)	1992 ANSI standard
Tight-fitting half-mask	10 (demand)	10 (demand; with QLFT) Same as QNFT factor (demand; sub-IDLH value max.).	10 (demand).	
Tight-fitting full facepiece.	50 (demand)	100 (demand; with QLFT) Same as QNFT factor (demand; sub-IDLH value max.).	50 (demand).	
Tight-fitting full facepiece.	10,000 (pressure demand)	10,000+ (pressure demand).	10,000 (pressure demand)	10,000 max. (emergency planning purposes only).

OSHA's proposed APFs for SCBAs. No WPF or SWPF studies for tight-fitting half-mask SCBAs and tight-fitting full facepiece SCBAs operated in the demand mode were available. In the only WPF study conducted on full

facepiece positive pressure SCBAs, Campbell, Noonan, Merinar, and Stobbe of NIOSH assessed the performance of two different models of full facepiece pressure demand SCBAs that met the NFPA 1981 airflow requirements for respirators used by firefighters (Ex. 1–64–7). While the authors could not determine WPFs for these respirators because contaminant levels measured inside the facepiece were too low, pressure measurements taken inside the facepiece proved more useful. These measurements showed that four of the 57 firefighters experienced one or more negative-pressure incursions inside the facepiece while performing firefighting tasks. After analyzing the data for these firefighters using two different methods, the authors estimated that the overall protection factor exceeded 10,000.

In the first of two SWPF studies performed on full facepiece SCBAs used in the pressure demand mode, McGee and Oestenstad (Ex. 1–64–86) determined the protection afforded to members of a respirator test panel consisting of 23 men wearing the Biopack 60 closed circuit SCBA (Ex. 1–64–86). Three members of the panel had protection factors of 4,889, 7,038, and 18,900, with the remaining members having protection factors over 20,000. In the second study, Johnson, da Roza, and McCormack of LLNL (Ex. 1–64–98) tested the Survivair Mark 2 SCBA that met NFPA 1981 airflow requirements; during testing, a panel of 27 respirator users exercised on a treadmill at 80% of their cardiac reserve capacity. Although the authors found negative-pressure incursions inside the facepiece at high work rates, they concluded that the respirator ''provided [a minimum] average fit factor of 10,000 [for any single subject], with no single subject having a fit factor less than 5,000 at a high work rate.''

The tables below summarize the results of the WPF and SWPF studies performed on full facepiece pressure demand SCBAs.

WPF studies for tight-fitting full facepiece pressure demand SCBAs (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
Campbell et al. (Ex. 1–64–7), Unspecified model (with NFPA-compliant airflow)	57	.....	.....	10,000 (estimated)

SWPF studies for tight-fitting full facepiece pressure demand SCBAs (by name of authors and model of respirator tested)	Sample size	Geometric mean	Geometric standard deviation	5th percentile WPF
McGee and Oestenstad (Ex. 1–64–86), Biopack 60 (closed circuit)	23	20,000	.....	.....
Johnson et al. (Ex. 1–64–98), Survivair Mark 2 (with NFPA-compliant airflow)	27	29,000	1.63	.....

OSHA is proposing APFs of 10 and 50, respectively, for tight-fitting half-mask SCBAs and tight-fitting full facepiece SCBAs operated in the demand mode. In the absence of any WPF and SWPF studies on these respirators, the Agency derived the proposed APFs based on analogous operational characteristics between these respirators and half-mask facepiece and full facepiece air-purifying respirators for which WPF and SWPF studies (described previously) are available. In addition, the proposed APFs are consistent with the APFs recommended by the 1987 NIOSH RDL for these respirators. (Note that the 192 ANSI standard did not assign APFs for these respirator classes.)

For tight-fitting full facepiece SCBAs used in the pressure demand or other positive pressure modes, OSHA is proposing an APF of 10,000, which is consistent with the 1987 NIOSH RDL and the 1992 ANSI standard. Empirical support for the proposed APF comes from the WPF study conducted by Campbell, Noonan, Merinar, and Stobbe (Ex. 1–64–7). This study showed that individual protection factors for these respirators, when operating at NFPA-compliant airflows, far exceed 10,000; however, four respirator users experienced momentary negative-pressure spikes inside the facepiece, indicating possible leakage of ambient contamination into the facepiece, and the breathing zone of the user, under some workplace conditions.

The two SWPF studies also provide support for the proposed APF, although several individual protection factors fell below 10,000 in the two studies, and the Johnson, da Roza, and McCormack study (Ex. 1–64–98) found negative-pressure incursions inside the facepiece during high exercise rates. Since the WPF and SWPF studies indicate that these respirators fail to provide the designated level of protection under some conditions, OSHA states in footnote 5 of its proposed APF table that ''[w]hen employers can estimate hazardous concentrations for emergency planning purposes, they must use a maximum assigned protection factor no higher than 10,000.'' Therefore, this proposed provision limits use of tight-fitting full facepiece positive pressure SCBAs to conditions for which an emergency-response plan exists and the employer can estimate the concentration of the hazardous substance in those conditions; in addition, the employer must restrict respirator use to conditions in which the required level of employee protection is at or below an APF of 10,000.

In proposing to limit use of tight-fitting full facepiece positive pressure SCBAs to planned emergency conditions only, OSHA acknowledges that while these respirators are among the most protective respirators available, the existing WPF and SWPF data demonstrate that they do not consistently provide employees with a protection level of 10,000 under some exposure conditions. Therefore, the Agency is proposing that employers not use these respirators routinely for protecting employees against workplace exposures requiring an APF above 1,000, but instead limit their use to non-routine (*i.e.*, emergency) conditions that require high levels of respirator protection. In this regard, the Agency believes that few, if any, routine exposure conditions in the workplace require protection above an APF of 1,000; consequently, the proposed restriction would have minimal effect on routine respirator use.[11]

[11] In preparing the risk analysis for the final Respiratory Protection Standard, OSHA reviewed data in its Integrated Management Information System for the years 1992 to 1996 to determine overexposure rates to the hazardous substances listed in Table Z (''Limits for air contaminants'') of

Continued

To use full facepiece positive pressure SCBAs under emergency exposure conditions, the proposal specifies that employers must develop an emergency plan (which several substance specific standards already require), and provide an estimate of the concentration levels likely to result under the emergency conditions. Emergency plans would limit employee exposure to the hazardous conditions by informing them in advance of the specific tasks they are to perform, while estimating concentration levels of the hazardous substance would increase the likelihood that their exposures to the substance will remain within the APF assigned to the respirator. In addition, OSHA's proposal to limit use of these respirators to emergency conditions is similar to the restriction placed on them in footnote 4 of the APF table published in the 1992 ANSI standard; this restriction reads, in part:

> [A] definitive assigned protection factor could not be listed for positive-pressure SCBAs. For emergency planning purposes where hazardous concentrations can be estimated, an assigned protection factor of no higher than 10,000 should be used. (Ex. 1–50)

For the class of respirators designated as pressure demand SCBAs with tight-fitting hoods or helmets, including the Survivair Puma, OSHA is proposing an APF of 10,000 maximum. The basis for this proposed APF are the analogous operational characteristics between these respirators and tight-fitting full facepiece pressure demand SCBAs. Accordingly, the Agency proposes to limit use of demand SCBAs with tight-fitting hoods or helmets to emergency planning purposes, similar to the restriction it is placing on tight-fitting full facepiece pressure demand SCBAs.

Paragraph (d)(3)(i)(B)—MUC Provisions

These proposed requirements consist of four separate paragraphs [(d)(3)(i)(B)(*1*) through (d)(3)(i)(B)(*4*)]. Paragraph (d)(3)(i)(B)(*1*), which proposes requirements on the use and application of MUCs, reads, ''The employer must select a respirator for employee use that maintains the employee's exposure to the hazardous substance, when measured outside the respirator, at or below the MUC.'' This proposed paragraph requires employers to select respirators for employee protection that are appropriate to the ambient levels of the hazardous substance found in the workplace, *i.e.*, that the ambient level of the hazardous substance must never exceed the conditions specified by the MUC, which is the exposure limit specified for the hazardous substance multiplied by the respirator's APF. Accordingly, the proposed requirement ensures that employers maintain employees' direct exposure to hazardous substances (*i.e.*, inside the respirator) within levels specified by OSHA's Z tables and substance-specific standards, and where OSHA has no standards, within consensus standards levels. Therefore, this provision would not only provide employee protection consistent with prevailing industrial-hygiene practice, but with existing regulatory and statutory requirements as well.

The single note in the proposed MUC provisions follows paragraph (d)(3)(i)(B)(*1*). This note reads that ''MUCs are effective only when the employer has a continuing, effective respiratory protection program as specified by 29 CFR 1910.134, including training, fit testing, maintenance and use requirements.'' This provision implies that MUCs are dependent on the APFs of the respirators selected by employers to protect employees against airborne contaminants. In this regard, the Agency determined the APF for a respirator or class of respirators based on studies that assessed the respirator under conditions that met or exceeded the program requirements of its Respiratory Protection Standard at 29 CFR 1910.134. These studies ensured that the study participants who used the respirators received thorough respirator training and fit testing, and used the respirators correctly; also, employers (or research staff in the case of SWPF studies) maintained the respirators in proper operating condition. Consequently, the APF used in calculating a MUC is valid for this purpose only if employers implement a continuing, effective, and comprehensive respiratory-protection program as required by OSHA's Respiratory Protection Standard. When employers do not meet the conditions specified in this note, they may not use the respirator's APF in determining the MUC.

The next MUC provision, proposed paragraph (d)(3)(i)(B)(*2*), states that ''[e]mployers must comply with the respirator manufacturer's MUC for a hazardous substance when the manufacturer's MUC is lower than the calculated MUC specified by this standard.'' While OSHA believes that a MUC calculated according to the proposed MUC definition normally would provide adequate employee protection, it defers to respirator manufacturers when they recommend a lower MUC for their respirators under specific hazardous-substance conditions. Respirator manufacturers warrant such deference because they are most familiar with the functional limitations of their respirators when exposed to airborne concentrations of hazardous substances. Also, manufacturer's may base their recommended MUCs on unpublished WPF or SWPF studies; such studies, when conducted properly, would increase the validity of their recommendations. As with a MUC determined using OSHA's proposed calculation method, the Agency believes that the protection afforded to employees by a respirator manufacturer's MUC depends on the employer's full compliance with the comprehensive respiratory-protection program specified by OSHA's Respiratory Protection Standard.

The Agency would not defer to respirator manufacturers who recommend higher MUCs than an employer would obtain using the proposed calculation method because such results would not be consistent with the maximum ambient level of a hazardous substance in which employees can use the respirators, *i.e.*, the maximum ambient level of a hazardous substance would exceed the level determined from the known exposure limit for the hazardous substance and the protection of the APFs determined by this proposed rulemaking. Under these conditions, the respirator manufacturer would be basing the recommendation on an invalid application of the known exposure limit or the APF (or both); therefore, such an invalid application would cause employers to select respirators that are incapable of protecting employees from the ambient level of a hazardous substance, resulting in serious health impairments to their employees.

Paragraph (d)(3)(i)(B)(*3*) of the proposed MUC provisions states, ''Employers must not apply MUCs to conditions that are immediately dangerous to life or health (IDLH); instead, they must use respirators listed for IDLH conditions in paragraph (d)(2) of this standard.'' Accordingly, employers could not use the proposed MUC calculation method (or a respirator manufacturer's MUC) to select a respirator for employees who are entering an IDLH atmosphere. OSHA found support for these proposed requirements in comments cited in the preamble to the final Respiratory Protection Standard. These comments noted that employers should not use MUCs to select respirators for employees exposed to IDLH

29 CFR 1910.1000. The Agency found that less than 0.01% of the exposures to these substances exceeded an APF of 1,000.

atmospheres (Ex. 1–54–381), or stated that employees should not use air-purifying respirators, including powered air-purifying respirators, while exposed to IDLH or oxygen-deficient atmospheres (Ex. 1–54–38); these commenters believed that the MUCs (and the APFs on which they are based) would not protect employees under these extremely hazardous exposure conditions.

For employees exposed to IDLH conditions, employers must select a respirator according to the requirements specified by paragraph (d)(2) of OSHA's Respiratory Protection Standard. Paragraph (d)(2) requires employers to select a full facepiece, pressure demand SCBA certified by NIOSH to have a service life of at least 30 minutes, or a combination full facepiece, pressure demand, supplied-air respirator with an auxiliary self-contained air supply, for IDLH exposures. In the preamble to the final Respiratory Protection Standard, the Agency justified selecting these respirators as follows:

> In [IDLH] atmospheres there is no tolerance for respirator failure. This record supported OSHA's preamble statement that IDLH atmospheres ''require the most protective types of respirators for workers.

(59 FR 58896.) Commenters and respirator authorities, including NIOSH, ANSI, and both labor and management, agree that, for IDLH atmospheres, the most highly protective respirators, with escape capability, should be required (63 FR 1201).

The last proposed MUC provision, paragraph (d)(3)(i)(B)(*4*), requires that ''[w]hen the calculated MUC exceeds another limiting factor such as the IDLH level for a hazardous substance, the lower explosive limit (LEL), or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.'' As with manufacturers' MUCs, these limiting factors would take precedence over the calculated MUC when they result in lower employee exposures to the hazardous substances than the calculated MUC; consequently, employees would receive increased protection against these hazardous substances.

This proposed paragraph cites several performance limits (*i.e.*, the IDLH or LEL for a hazardous substance, or the service life of a cartridge or canister) as examples of limiting factors. In this regard, OSHA is including these limiting factors as examples only; other limiting factors specified in a variety of OSHA standards, or used by employers to meet their obligation to provide a safe and healthful workplace, also would be applicable to this proposed requirement. In addition, commenters cited in the preamble to the final Respiratory Protection Standard believed that employers should not rely on MUCs determined using the proposed calculation method to estimate the service life of cartridges and canisters (Exs. 1–54–153, 1–54–165A, 1–54–222, 1–54–381).

B. Superseding the Respirator-Selection Provisions of Substance-Specific Standards in Parts 1910, 1915, and 1926

1. Introduction

The substance-specific standards in 29 CFR parts 1910, 1915, and 1926 specify numerous requirements for regulating employee exposure to toxic substances, including APFs for respirator selection. Under this proposed rulemaking, OSHA would revise the provisions in its substance-specific standards that regulate APFs (except the APF requirements for the 1,3-Butadiene Standard at 29 CFR 1910.1051). These proposed revisions would remove the APF tables from these standards, as well as any references to these tables, and would replace them with a reference to the APF and MUC provisions specified in proposed paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) of the Respiratory Protection Standard at 29 CFR 1910.134. The Agency believes that the proposed revisions would simplify compliance for employers by removing many inconsistencies in APF requirements across its substance-specific standards; therefore, the proposed revisions would enhance consolidation and uniformity of these requirements. Accordingly, the purpose of revising the APF provisions of OSHA's substance-specific standards is to conform these standards, to the extent possible, to each other and to general APF and MUC requirements specified by 29 CFR 1910.134.

The proposed revisions would improve the substance-specific standards because the Agency developed these proposed APF requirements after careful review and analysis of the available scientific data and the most recent consensus standards (*i.e.*, the APF provisions in the NIOSH RDL and the ANSI Z88.2–1992 respiratory protection standard). In this regard, the Agency preliminarily finds that the proposed APFs are a significant improvement over the existing NIOSH and ANSI APFs because it developed them based on the latest WPF and SWPF studies, and used advanced statistical methods to identify common and unique variance among respirator classes. Therefore, the proposed APFs represent the best data and analytic techniques available, thereby lending a high degree of reliability and validity to the results. Accordingly, the proposed APFs will provide employers with confidence that their employees will receive the level of protection from airborne contaminants signified by these APFs. In addition, applying the proposed APFs to the substance-specific standards is consistent with OSHA's goal of bringing uniformity to its respiratory-protection requirements. Moreover, protection for workers is increased since the proposed APFs will provide equivalent or increased protection compared to the ANSI Z88.2–1992 standard, and incorporates the use of APFs into the employer's respiratory protection program. The Agency believes that superseding the APF requirements of its existing substance-specific standards would result in regulatory consistency, which would improve employer compliance with these provisions, reduce the compliance burden on the regulated community, and, consequently, further enhance the protection afforded to employees who use respirators.

In the final rulemaking for its Respiratory Protection Standard, OSHA noted that the revised standard was to ''serve as a 'building block' standard with respect to future standards that may contain respiratory protection requirements.'' (*See* 63 FR 1265, 1998.) In this regard, the Agency believes that, to the extent possible, future substance-specific standards should refer to provisions of the final Respiratory Protection Standard instead of containing their own respirator requirements, including the generic APF and MUC provisions specified in this proposed rulemaking. However, on occasion a substance-specific standard may have respirator-selection requirements that supplement or supplant the generic APF and MUC provisions (*e.g.*, organic-vapor cartridge and canister procedures, prohibiting use of filtering facepieces or half-mask respirators) that are necessary for ensuring adequate employee protection against the toxic substance regulated by the standard. Accordingly, the Agency is retaining a number of existing respirator-selection provisions that are unique to the substance-specific standards; the following paragraphs describe these provisions, and provide OSHA's rationale for retaining them.

2. Retaining the Respirator-Selection Provisions of the 1,3-Butadiene Standard

As noted earlier in this section, OSHA is not proposing to revise the respirator-selection provisions of the 1,3-Butadiene Standard (''BD Standard''). Therefore, the APFs located in Table 1 (''Minimum Requirements for Respiratory Protection for Airborne BD'') of the BD Standard would remain as currently published in paragraph (h)(3) (''Respirator selection'') of 29 CFR 1910.1051.

The BD Standard requires that employers use respirators during work operations when engineering and work-practice controls ''are not yet sufficient to reduce employee [BD] exposures to or below the [permissible exposure limits]'' [*see* 29 CFR 1910.1051(h)(1)(iii)]. Employers must select these respirators based on the APFs listed in Table 1 of the BD Standard; in addition, they must equip air-purifying respirators with organic-vapor cartridges or canisters.

OSHA adopted the APFs in Table 1 from the Respirator Decision Logic developed by the National Institute for Occupational Safety and Health (NIOSH), even though a negotiated agreement between manufacturers who use BD and the unions representing their employees recommended the more permissive ANSI Z88–1992 APFs.

In the preamble to the final BD Standard, the Agency noted that its ''decision to rely on the more protective NIOSH APFs is based on evidence showing that organic-vapor cartridges and canisters have limited capacity for adsorbing BD and may have too short a service life when used in environments containing greater than 50 ppm BD.'' (*See* 61 FR 56816.) While developing the final BD Standard, OSHA reviewed the breakthrough test data that were available for organic-vapor cartridges and canisters challenged against BD (and summarized in Table X–1 of the preamble to the final BD Standard; see 61 FR 56817). Based on this review, the Agency concluded:

> Allowing for a reasonable margin of protection, and given that test data were available only for a few makes of cartridges and canisters, OSHA believes that air-purifying devices should not be used for protection against BD present in concentrations greater than 50 ppm, or 50 times the 1 ppm PEL. Thus, OSHA finds that the ANSI APFs of 100 for full facepiece, air-purifying respirators and 1,000 for PAPRs equipped with tight-fitting facepieces are inappropriate for selecting respirators for BD.

In summary, test data cited by the Agency in the final BD Standard demonstrate short breakthrough times for BD concentrations above 50 ppm. Accordingly, these short breakthrough times justified limiting to 50 ppm the upper limit at which employees can use air-purifying respirators for protection against BD exposures. From the Agency's analysis of these data, OSHA also developed change schedules for cartridges and canisters that are unique for BD exposures (*see* Table 1 of the BD Standard). Additionally, these conclusions still are likely to be valid because OSHA reviewed the test data only six years ago (*i.e.*, 1996). Therefore, the Agency is proposing to retain the conservative NIOSH APFs as necessary to protect employees from BD exposures. Nevertheless, OSHA is asking employers and employees who are subject to the provisions of the existing BD Standard to provide additional information that supports retaining the existing APFs or adopting the generic APFs specified under this proposed rulemaking (See Section VII , Issues, of this preamble).

3. Retaining the Respirator-Selection Provisions in Other Substance-Specific Standards

While OSHA is proposing to retain the existing BD Standard in its entirety, it also is proposing to retain a number of respirator-selection provisions in other substance-specific standards as well. The respirator-selection requirements proposed for retention often provide protection against a hazardous characteristic or condition that is unique to the regulated substance. Additionally, OSHA believes that retaining these requirements in their present form (except for plain-language revisions, as appropriate) would not increase existing employer burden because they already must comply with these requirements; consequently, retaining these provisions will maintain the level of respirator protection currently afforded to employees. The following sections describe the most important provisions that the Agency is proposing to retain.[12]

[12] Most of the provisions described in these sections are in, or are footnotes to, the respirator-selection tables proposed for removal from the substance-specific standards. These sections also describe several other respirator-selection provisions that are not part of these tables, but which OSHA is retaining and which may be of interest to the regulated community. If this proposal does not specifically identify or describe a respirator-selection provision for removal or revision, then OSHA is retaining that provision in its existing form. The Agency believes that retaining these provisions does not increase the regulatory burden of employers because they must currently comply with them.

- Lines 13–17 [13] and 21–21 under ''Required apparatus'' in the undesignated table of 29 CFR 1910.1017 (Vinyl Chloride (VC) Standard); and footnote 1 to Table 1 of 29 CFR 1910.1028 (Benzene Standard). These provisions specify a minimum service life for cartridges and canisters used to protect employees during exposure to these substances. In the VC Standard, employers must provide organic-vapor cartridges or canisters with a service life of at least one hour at VC concentrations up to 10 ppm when using chemical-cartridge respirators. These cartridges and canisters must have a service life of at least four hours at VC concentrations up to 25 ppm when using a canister with a powered air-purifying respirator that has a hood, helmet, half-mask, or full facepiece; the four-hour service-life requirement also applies when an employee uses a gas mask, but in this case, the employee must use a front-or back-mounted canister. According to the Benzene Standard, employers must ensure that canisters used with non-powered air-purifying respirators have a minimum service life of four hours when tested at 150 ppm benzene at a flow rate of 64 liters per minute (Lpm), a temperature of 25° C, and a relative humidity of 85%; testing for canisters used with tight-fitting and loose-fitting powered air-purifying respirators must be at flow rates of 115 Lpm and 170 Lpm, respectively.

  The Agency believes that these minimum service-life specifications ensure that employers use the designated respirators at appropriate concentration levels of the regulated substances. Accordingly, OSHA is proposing to retain these specifications to provide employees with a minimum level of cartridge and canister endurance when they use the designated respirators at these concentrations. While retaining these specifications may limit employers' flexibility in adopting change schedules, the Agency considers this limitation warranted in view of the properties of the substance that require greater protection or a higher level of protection for employees. Moreover, retaining these specifications adds no regulatory burden on employers because they must use the specifications under the existing standards.

- Paragraphs (h)(3)(ii), and lines 6, 7, 10, and 11 under ''Required respirator'' in Table II of 29 CFR 1910.1018 (Inorganic Arsenic Standard); lines 1–4

[13] Only lines with written text were counted in determining the number of lines; blank lines that occurred before a written line were ignored for counting purposes.

under ''Respirator type'' in Table 1 of 29 CFR 1910.1028 (Benzene Standard); line 1 under ''Minimum required respirator'' in Table 1 of 29 CFR 1910.1047 (Ethylene Oxide Standard); lines 1–4 under ''Minimum respirator required'' in Table 1 of 29 CFR 1910.1048 (Formaldehyde Standard); and lines 1–3 and 8, and footnote 2, under ''Respirator type'' in Table 1 of 29 CFR 1910.1050 and 1926.60 (Methylenedianiline (MDA) Standards).

These paragraphs identify the types of cartridges and canisters employers must select under specific respirator-use conditions. The Inorganic Arsenic Standard requires employers to provide employees with: Air-purifying respirators that have a combination high-efficiency particulate air (HEPA) filter with an appropriate gas-sorbent cartridge or canister when their exposure exceeds the permissible exposure level for inorganic arsenic, and their exposure also exceeds the relevant limit for other gases; front- or back-mounted gas masks equipped with HEPA filters and acid-gas canisters or any full facepiece supplied-air respirators when the inorganic arsenic concentration is at or below 500 $\mu g/m^3$; and half-mask air-purifying respirators equipped with HEPA filters and acid-gas cartridges when the inorganic arsenic concentration is at or below 100 $\mu g/m^3$. The Benzene Standard specifies that employers must use an organic-vapor cartridge or canister with air-purifying respirators, and a chin-style canister with full facepiece gas masks. The Ethylene Oxide Standard states that employers are to equip air-purifying, full facepiece respirators with front- or back-mounted canisters approved for protection against ethylene oxide, while the same respirators under the Formaldehyde Standard must use a cartridge or canister approved for protection against formaldehyde. The MDA Standard requires that employers provide air-purifying respirators with a combination HEPA filter and organic-vapor cartridge or canister when MDA is in liquid form or is part of a heated process.

• Line 1 under ''Required respirator'' in Table 1 of 29 CFR 1910.1001, 1915.1001, and 1926.1101(Asbestos Standards); line 6 under ''Required respirator'' in Table I of 29 CFR 1910.1029 (Coke Oven Emissions Standard); and line 2 under ''Required respirator'' in Table I of 29 CFR 1910.1043 (Cotton Dust Standard).

These provisions prohibit the use of disposable respirators (single-use respirators in the Coke Oven Emissions Standard) to protect employees against these toxic substances; the Cotton Dust Standard prohibits their use at exposures greater than five times the permissible exposure level (PEL). However, the Agency does not define the terms ''disposable respirator'' or ''single-use respirator'' in any of its standards, including its Respiratory Protection Standard at 29 CFR 1910.134; therefore, to update these requirements, the Agency is proposing to replace these terms with ''filtering facepiece,'' which it defines in paragraph (b) of 29 CFR 1910.134. OSHA believes this revision will not only make these provisions consistent with its new Respiratory Protection Standard, but will prevent employers from using respirators not designed with the high-efficiency particulate filters necessary to capture respirable asbestos fibers (*see* 51 FR 22718) and coke oven emissions (*see* 41 FR 46773–46774), and, in the case of cotton dust, to provide protection at exposure levels higher than five times the PEL (*see* 50 FR 51153–51154).

• Paragraphs (h)(2)(iv) of 29 CFR 1915.1001 and (h)(3)(iii) of 29 CFR 1926.1101 (Asbestos Standards) also prohibit employers from selecting disposable respirators for employees who conduct specific types of Class II and III asbestos work. Consistent with the explanation and rationale provided in the previous section, OSHA is proposing to revise the term ''disposable respirator'' to ''filtering facepiece'' in these standards. The Agency also is proposing to revise these paragraphs, as well as paragraph (h)(2)(v) of 29 CFR 1915.1001 and (h)(3)(iv) of 29 CFR 1926.1101 (which address respirator selection for conducting Class I asbestos work in regulated areas), into plain language to clarify the multifaceted requirements specified by these paragraphs. By improving employer understanding of the respirator-selection requirements, OSHA believes that the revisions proposed for these paragraphs would enhance employee protection without increasing employers' regulatory burden.

• Lines 2, 3, and 4 under ''Required respirator'' in Table 1 of 29 CFR 1910.1001, 1915.1001, and 1926.1101(Asbestos Standards); lines 5–6, 8, and 11 under ''Required respirator'' in Table I , and lines 6 and 10 under ''Required respirator'' in Table II, of 29 CFR 1910.1018 (Inorganic Arsenic Standard); lines 1, 2, and 3 under ''Required respirator'' in Table II of 29 CFR 1910.1025 (Lead Standard); lines 1, 3, 5, 6, and 10 under ''Required respirator type'' in Table 2 of 29 CFR 1910.1027 (Cadmium Standard); lines 1, 3, 4, and 5 under ''Required respirator'' in Table I of 29 CFR 1910.1043 (Cotton Dust Standard); lines 1, 2, 3, and 8 under ''Respirator type'' in Table 1 of 29 CFR 1910.1050 and 1926.60 (Methylenedianiline Standard); lines 1, 3–4, 7, and 8 under ''Required respirator'' in Table 1 of 29 CFR 1926.62 (Lead Standard); and lines 1, 3, 6, 8, and 11 under ''Required respirator type'' in Table 1 of 29 CFR 1926.1127 (Cadmium Standard).

Under these provisions, employers must equip air-purifying (including powered air-purifying) respirators with high-efficiency particulate air (HEPA) filters, high-efficiency and high-efficiency particulate filters (defined as a filter that is at least 99.97% efficient against mono-dispersed particles of 0.3 micrometers in diameter or larger), and particulate filters (for the Cotton Dust Standard only). While OSHA is proposing to retain these provisions, it is also proposing to replace the terms ''high-efficiency filters'' and ''high-efficiency particulate filters'' with the term ''HEPA filters.'' These three terms have the same meaning, so use of the term ''HEPA'' would impose no additional burden on employers, nor would it diminish employee protection. The Agency believes that the usual and customary practice among employers in the cotton-dust industry is to use HEPA filters with air-purifying respirators; therefore, employers should experience no additional burden, and employee protection should remain at current levels, as a result of this revision. In addition, the proposed revision would make the filter requirements of the Cotton Dust Standard consistent with other OSHA substance-specific standards and with its Respiratory Protection Standard, thereby reducing any confusion that may exist among the regulated community regarding the appropriate filter to use with air-purifying respirators.

• Footnote 2 to Table II of 29 CFR 1910.1018 (Inorganic Arsenic Standard). This provision prohibits the use of half-mask respirators for protection against arsenic trichloride because it is rapidly absorbed through the skin. OSHA is retaining this provision to protect employees from the cumulative toxic effects that result from skin absorption.

• Footnote 2 to Table II of 29 CFR 1910.1025, and footnote 2 to Table 1 of 29 CFR 1926.62 (Lead Standard). These footnotes specify that employers must provide employees with full facepiece respirators when employees experience eye or skin irritation that results from exposure to lead aerosols at use concentrations. These provisions prevent serious eye and skin injuries among employees.

• Footnote b to Table 2 of 29 CFR 1910.1027 and footnote b to Table 1 of

29 CFR 1926.1127 (Cadmium Standard). These provisions require a full facepiece respirator when an employee experiences eye irritation, thereby reducing the risk of eye injury among employees.

• Table 1 of 29 CFR 1910.1047 (Ethylene Oxide (EtO) Standard). This table lists only full facepiece respirators, or respirators with hoods or helmets, implying that employers must not select half-mask respirators for protection against EtO. The preamble to the final EtO Standard states:

> The record reflects that high exposures to EtO have been shown to cause eye irritation and that such effects may occur at exposures that may be reached for short periods. Therefore, OSHA has chosen to retain the requirement for full-facepiece respirators in the final rule. (49 FR 25781)

Accordingly, in this proposal the Agency is making explicit the prohibition against the use of half-mask respirators to ensure that employers select only those respirators (*i.e.*, full facepiece respirators, and respirators with hoods or helmets) that OSHA found, in the earlier rulemaking, will provide the requisite level of protection to their employees.

• Footnote 2 to Table 1 of 29 CFR 1910.1048 (Formaldehyde Standard). This provision requires that employers who select half-mask respirators instead of full facepiece respirators for formaldehyde exposures up to 7.5 ppm provide effective gas-proof goggles for employees to use in combination with the half-mask respirators.

• Table 2 of 29 CFR 1910.1052 (Methylene Chloride (MC) Standard). This table lists only full facepiece respirators, or respirators with hoods or helmets, thereby indicating that employers are not to select half-mask respirators for protection against MC. In the preamble to the final MC Standard, the Agency states:

> OSHA has determined that this standard is necessary because exposure to MC places employees at significant risk of developing exposure-related adverse health effects. These effects include * * * skin and eye irritation. (62 FR 1572)

Later in the preamble, the Agency states that ''employers are required to provide employees who are at risk of skin and/or eye contact with MC with appropriate protective clothing and eye protection.'' (*See* 62 FR 1589.)

The risk of MC-related skin and eye irritation and the need for proper skin and eye protection convinced OSHA to limit respirator selection to full facepiece respirators and respirators with hoods and helmets in the final MC Standard to ensure that employees' facial skin and eyes are protected during MC exposure. Here the Agency is directly prohibiting the selection of half-masks, and explicitly limiting respirator selection to respirators (*i.e.*, full facepiece respirators, and respirators with hoods or helmets) that would provide the appropriate level of protection to employees.

• Lines 10 and 11 under ''Respirator type'' in Table 1 of 29 CFR 1910.1028 (Benzene Standard); lines 6–11 under ''Respirator type'' in Table 1 of 29 CFR 1910.1044 (1,2-dibromo-3-chloropropane Standard); lines 16 and 17 under ''Respirator type'' in Table I of 29 CFR 1910.1045 (Acrylonitrile Standard); line12 under ''Minimum required respirator'' in Table 1 of 29 CFR 1910.1047 (Ethylene Oxide Standard); lines 11–13 under ''Minimum respirator required'' in Table 1 of 29 CFR 1910.1048 (Formaldehyde Standard); lines 8–10 under ''Respirator type'' in Table 1 of 29 CFR 1910.1050 and 1926.60 (Methylenedianiline Standards); lines 13 and 14 under ''Minimum respirator required'' in Table 2 of 29 CFR 1910.1052 (Methylene Chloride Standard).

These provisions specify which respirators employers are to use under emergency-escape conditions. With regard to respirators used for escape, OSHA adopts the same position it did in the final rulemaking for the Respiratory Protection Standard. In the final rulemaking for this standard, the Agency noted the variety of escape respirators permitted under its substance-specific standards, and found that these standards addressed hazards associated with many different substances and escape situations. In support of this conclusion, the Agency cited the following examples:

> [U]nder current 29 CFR 1910.1050, the standard covering exposure to methylenedianiline (MDA), escape respirators may be any full facepiece air-purifying respirator equipped with HEPA cartridges, or any positive pressure or continuous flow self-contained breathing apparatus with full facepiece or hood; for formaldehyde exposure, escape respirators may be a full facepiece with chin style, front, or back-mounted industrial canister approved against formaldehyde (29 CFR 1910.1048).

(63 FR 1202.) As noted earlier in this section, the adverse physical effects of specific substances (*e.g.*, skin and eye irritation) often limit respirator selection; these limitations would apply as well to the selection of escape respirators. Accordingly, OSHA is retaining the requirements for escape respirators identified in the existing substance-specific standards because previous rulemakings identified these respirators based on the unique characteristics of the regulated substances, as well as the conditions under which employees must use escape respirators.

As is required currently, respirators covered by these emergency-escape provisions must meet the requirements of paragraph (d)(2)(ii) of OSHA's Respiratory Protection Standard, which specifies that these respirators must be NIOSH-certified for escape from the atmosphere in which employees will use them. In addition, employees are to use these respirators only for escaping from, not entering, IDLH atmospheres. For entering such atmospheres, paragraph (d)(2)(i) of the Respiratory Protection Standard requires that employees use only full facepiece, pressure demand SCBAs certified by NIOSH for a minimum service life of 30 minutes, or full facepiece, pressure demand SARs with an auxiliary self-contained air supply.

• Paragraphs (g)(2)(ii) of 29 CFR 1910.1001, (h)(2)(iii)(A) of 29 CFR 1915.1001, and (h)(3)(ii) of 29 CFR 1926.1101 (Asbestos Standards); (f)(3)(ii) of 29 CFR 1910.1025 (Lead Standard); (f)(3)(ii) of 29 CFR 1910.1043 (Cotton Dust Standard); and (g)(3)(iii) of 29 CFR 1910.1048 (Formaldehyde Standard).

These paragraphs require employers to upgrade a negative pressure respirator, or a non-powered air-purifying respirator in the case of the Cotton Dust Standard, to a tight-fitting powered air-purifying respirator (PAPR) when the employee chooses to use a tight-fitting PAPR; for the Formaldehyde Standard, this requirement applies when the employee has difficulty using a negative pressure respirator and the tight-fitting PAPR provides the employee with adequate protection against the airborne contaminant. OSHA is proposing to retain these requirements because tight-fitting PAPRs increase the protection provided to employees when the respirator-selection provisions identify a low-end respirator (*i.e.*, a negative pressure respirator or a non-powered air-purifying respirator) for use.

• Paragraph (h)(2)(iii)(B) of 29 CFR 1915.1001 (Asbestos Standard). The Agency also is proposing to retain this paragraph in the Asbestos Standard for Shipyards, which specifies that employers must inform employees that they (the employees) may require employers to provide them with a tight-fitting PAPR instead of a negative pressure respirator. This requirement provides an extra margin of protection to employees by ensuring that

employers take positive action to inform them of their option to upgrade to a more protective respirator than the one that they would normally receive for use when exposed to asbestos.

• While the paragraphs described in the previous section require employers to upgrade employee respirators, every substance-specific standard has a provision, usually as a footnote to its APF table, that gives employers discretion to select respirators that provide employees with more protection from atmospheric contaminants than the required respirator. Under this proposal, the Agency would consolidate this discretionary alternative into a generic provision in proposed paragraph (d)(3)(i)(A) of the Respiratory Protection Standard (*i.e.*, ''[employees must * * * select a respirator that meets or *exceeds* the required level of employee protection'' [emphasis added]). The Agency concludes that relocating this provision in proposed paragraph (d)(3)(i)(A) of the Respiratory Protection Standard will highlight this alternative to employers, and will encourage more of them to select more protective respirators for their employees than is now the case.

4. Substantive Revisions to the Respirator-Selection Requirements in Substance-Specific Standards

OSHA is proposing to revise respirator-selection requirements in several substance-specific standards that regulate employee exposure to organic-vapor substances. The following sections describe these proposed revisions.

• Paragraphs (g)(2) of 29 CFR 1910.1017 (Vinyl Chloride Standard), (g)(2)(i) of 29 CFR 1910.1028 (Benzene Standard), (h)(2)(i) of 29 CFR 1910.1045 (Acrylonitrile Standard), and (g)(2)(i) of 29 CFR 1910.1048 (Formaldehyde Standard). These paragraphs exempt employers from paragraphs (d)(3)(iii)(B)(1) and (B)(2) of OSHA's Respiratory Protection Standard; the exempted paragraphs consist of respirator-selection provisions that protect employees against gases and vapors. Because OSHA would be removing the existing change schedules from these substance-specific standards under this proposed rulemaking, it becomes necessary to identify requirements that it believes would provide employees with at least the same level of protection as the existing provisions. These requirements are paragraphs (d)(3)(iii)(B)(1) and (B)(2) of its Respiratory Protection Standard; by removing the current exemptions, employers would apply paragraphs (d)(3)(iii)(B)(1) and (B)(2) of the Respiratory Protection Standard to select respirators that protect employees against the gases and vapors regulated by these substance-specific standards. In addition, this revision would provide employers with increased flexibility in selecting respirators without adding to their compliance burden (*i.e.*, their existing respirator-selection procedures would be acceptable under this revision). (Note that the exemption would still remain for the 1,3-Butadiene Standard because, as noted above, the Agency is retaining the existing respirator-selection provisions of that standard.)

• Paragraph (g)(2)(ii) of 29 CFR 1910.1048 (Formaldehyde Standard). This paragraph specifies a change schedule for chemical cartridges and canisters used for formaldehyde exposures that do not have an end-of-service life indicator (ESLI) approved by NIOSH. OSHA is proposing that employers select respirators according to paragraphs (d)(3)(iii)(B)(1) and (B)(2) of its Respiratory Protection Standard instead of these requirements.

The paragraphs proposed for removal require employers who use a change schedule to select a cartridge or canister that has a NIOSH-approved ESLI, or to use a change schedule for which they must provide ''objective information or data that will ensure that canisters and cartridges are changed before the end of their service life'' (*see* paragraph (d)(3) of OSHA's Respiratory Protection Standard). When they choose the latter option, this revision would limit the change schedule to one work shift because of possible vapor migration in the cartridges and canisters during storage. The Agency believes that this revision would: Provide employers with flexibility to use other change schedules when a NIOSH-approved ESLI is not available; not increase the regulatory burden of employers because the existing change schedule would remain valid; and ensure that employees receive at least the same level of protection as they receive with the existing change schedule, because employers must use a change schedule that they can demonstrate is safe for this purpose.

5. Use of Plain Language for Proposed Revisions

Whenever possible, OSHA is using plain language in revising the regulatory text of the substance-specific standards identified in this proposal. The Agency believes that this approach improves the comprehensibility and uniformity of the proposed revisions. OSHA believes that these improvements would enhance employer compliance with the provisions, thereby increasing the level of protection afforded to employees.

6. Summary of Superseding Actions

The following table summarizes OSHA's proposed revisions to existing substance-specific standards. This table lists only those provisions for which the Agency is proposing substantive revisions (*e.g.*, proposing to replace existing requirements with new requirements); it does not list provisions that OSHA is proposing to retain in their present form (although the Agency is rewriting them in plain language).

SUMMARY OF SUPERSEDING ACTIONS FOR SPECIFIC STANDARDS

Existing section (29 CFR 1910)	Proposed action (29 CFR 1910)
1001(g)(2)(ii)	Revise.
1001(g)(3)	Remove Table 1 and revise.
1001(l)(3)(ii)	Redesignate Table 2 as Table 1.
1017(g)(3)(i)	Remove table and revise.
1017(g)(3)(iii)	Remove.
1018 Tables I and II	Remove.
1018(h)(3)(i)	Revise.
1018(h)(3)(ii)	Remove.
1018(h)(3)(iii)	1018(h)(3)(ii).
1025(f)(2)(ii)	Remove Table II.
1025(f)(3)(i)	Revise.
1027(g)(3)(i)	Remove Table 2 and revise.
1028(g)(3)(ii)	Remove Table 1.
1028(g)(2)(i)	Revise.
1028(g)(3)(i)	Revise.
1029(g)(3)	Remove Table I and revise.
1043(f)(3)(i)	Remove Table I and revise.
1043(f)(3)(ii)	Revise.
1044(h)(3)	Remove Table I and revise.
1045(h)(2)(i)	Revise.
1045(h)(3)	Remove Table I and revise.
1047(g)(3)	Remove Table I and revise.
1048(g)(2)	Revise.
1048(g)(3)	Remove Table 1 and revise.
1050(h)(3)(i)	Remove Table 1 and revise.
1052(g)(3)	Remove Table 2 and revise.

Existing section (29 CFR 1915)	Proposed action (29 CFR 1915)
1001(h)(2)(i) through (h)(2)(v).	Remove Table 1 and revise.

Existing section (29 CFR 1926)	Proposed action (29 CFR 1926)
60(i)(3)(i)	Remove Table 1 and revise.
62(f)(3)(i)	Remove Table 1 and revise.
1101(h)(3)(i) through (h)(3)(iv).	Remove Table 1 and revise.
1127(g)(3)(i)	Remove Table 1 and revise.

Section XII (''Proposed Amendments to Standards'') of this notice provides the full regulatory text of the proposed revisions to OSHA's existing substance-specific standards dealing with respirator selection. This section describes both substantive revisions proposed for the existing respirator-selection requirements, as well as respirator-selection requirements retained in their current form but rewritten in plain language.

VIII. Issues

OSHA requests the public to comment on, and to provide additional information regarding, any of the issues listed below. Please provide a detailed explanation of each response you make.

Developing and Updating APFs

1. Is the method used by OSHA in developing the proposed APFs appropriate? OSHA used a multi-faceted approach incorporating both analyses of data collected in WPF and SWPF studies, as well as OSHA's review of all relevant materials. OSHA requests comment on the usefulness of this approach to data collection.

2. Are there any additional studies that may be useful in determining APFs, that have not already been identified by OSHA in Section IV of this proposal? Please provide these to the Agency.

3. Are statistical analyses, treatments, or approaches, other than those described in Section IV of the proposal, available for differentiating between or comparing the highly variable respirator-performance data?

4. OSHA is aware of discussions within the respirator community indicating some sentiment for setting APFs for filtering facepiece respirators at 5, and for setting an APF of 10 for other half-mask air-purifying respirators. Based upon OSHA's reviews, OSHA cannot differentiate between the performance of the two types of respirator, and OSHA finds compelling evidence from the large number of observed data points (N = 917 Co/Ci pairs) to support proposing an APF of 10 for both of these classes of respirators. Is there evidence that a different APF should be provided for these respirator classes?

5. While there are no WPF or SWPF studies for quarter-mask respirators, the 1976 LANL Respiratory Protection Factor by Hyatt found protection factors ranging from 5 to 10. Should OSHA continue to include quarter-masks in the half-mask class, or separate them into a class of their own with and APF of 5?

6. OSHA is proposing a method by which to separate loose-fitting facepiece supplied-air and PAPR hood/helmet respirators from the better-performing hood/helmet respirators. Respirator performance studies have shown that some PAPR and continuous-flow supplied-air respirators provide greater protection than others of the same class. The 1987 NIOSH Respirator Decision Logic gives an APF of 25 for all of these respirators while ANSI's 1992 respirator standard gives an APF of 25 to loose-fitting facepiece models and an APF of 1000 to hood/helmet models. OSHA is proposing an APF of 25 except for those models that ensure the maintenance of a positive pressure inside the facepiece during use, consistent with a protection factor of 1000 or greater, in which case those models would receive an APF of 1000. Is this the appropriate method by which to distinguish high-performing hood/helmet respirators from others?

7. The assigned protection factor for a full facepiece respirator in Table 1 of the proposed standard does not currently take into account the type of particulate filter that is used. An N95 particulate filter could potentially, under a worst case scenario, have up to 5% leakage through the filter. This would decrease the APF for a full facepiece respirator to a maximum of 20 when N95 filters are used. Should OSHA take into account the limitations of the filter and assign an APF of 20 for full facepiece respirators when N95 filters are used?

8. Other Federal Agencies, such as the Nuclear Regulatory Commission (NRC), have set no APF for filtering facepiece air-purifying respirators (APRs) for use in their particular work environments. In some cases, such APRs are not allowed to be used at all. In other settings, *e.g.*, the healthcare industry, some employers rely very heavily upon such APRs to protect their employees who work with patients who have infectious airborne illnesses. How should OSHA incorporate such information, if at all, into an APF requirement for all industries under OSHA's jurisdiction?

9. Proper facepiece fit is important in achieving the proposed APF for tight-fitting respirators. Accordingly, the Agency would appreciate receiving information on current testing and procedures used by respirator manufacturers to ensure that the facepieces they make will fit respirator users properly.

10. When a limiting factor such as IDLH, LEL, or the performance limit specified for a cartridge and canister by the manufacturers are less than the calculated MUC, proposed paragraph (d)(3)(i)(B)(*4*) requires employers to set the MUC at the lower limit. Accordingly, OSHA is seeking comment on the following questions:

a. What other limiting factors should OSHA include as examples in this proposed paragraph?

b. Should the Agency specify the LEL or 10% of the LEL as the limiting factor?

11. Some hazardous substances found in the workplace do not have an OSHA PEL. However, a number these substances may have an exposure limit designated by sources other than OSHA (*e.g.*, recommended by the chemical manufacturer, ACGIH, NIOSH, EPA). Accordingly, the Agency is asking for comment on the following issues involving MUCs:

a. Should OSHA expand the definition and application of MUC to hazardous substances that it does not regulate?

b. Should the Agency require employers to determine MUCs for substances that have no OSHA PEL (*i.e.*, substances not regulated specifically by OSHA), and to base respirator selection on such a determination?

c. For hazardous substances that OSHA does regulate, should it require employers to comply with the MUC values developed by NIOSH when these values are lower than the calculated MUC values (*i.e.*, MUC = APF × PEL)?

12. A prevailing view is that exposure to multiple contaminants in the workplace affect the performance of respirator filters and cartridges differently than exposure to single contaminants. To assist it in developing MUCs for single and multiple contaminants, OSHA is asking the public to address the following issues:

a. What information and data are available that either support or do not support this view?

b. Should MUCs for contaminant mixtures differ from MUCs for single mixtures?

13. Section VII proposes to revise most of the respirator-selection requirements in OSHA's substance-specific standards. Accordingly, the Agency is asking for comment on the following questions:

a. This proposal excludes the respirator-selection provisions of the 1,3-Butadiene Standard from any revision. Is this exclusion warranted?

b. Special or unique respirator-selection requirements in the substance-specific standards (*e.g.*, requirements for emergency-escape, HEPA filters, upgrading respirators at the employee's request, eye protection) remain largely intact. Should the Agency standardize these provisions across all of its substance-specific standards, and, if so, what requirements should it standardize.

14. The Agency has developed its Preliminary Economic Analysis (PEA) based on survey data indicating what types of respirators employees are using currently. The Agency does not, however, have data on the exposure levels as a multiple of the PEL that respirator users are currently exposed to. For the purposes of this analysis, the Agency has used its internal Integrated Management and Information System (IMIS) data to estimate the distribution of exposures as a multiple of the PEL. The Agency also assumes that employers are currently using the respirator with the lowest possible costs that can still satisfy existing guidance on APFs, allowing employees to be exposed up to the full limit of a currently assigned APF for that class of respirator. OSHA seeks comment on whether other data sources or methodologies for making this projection exist.

a. Is it common for employers to put employees in respirators at the highest exposure levels permitted by the APF range?

b. Are there particular types of respirators that frequently do not fit this pattern (*i.e.*, are selected for reasons other than having a high APF or due to a medical reason for a particular employee)?

c. How do employers approach the issue of uncertainty in possible exposure levels when integrating APFs into their respirator selection?

d. To what extent will having a single OSHA APF table result in less confusion than the existing multiplicity of APF tables?

e. Do OSHA's cost estimates of using different types of respirators adequately represent all of the costs associated with each type of respirator use?

f. Are their any alternative approaches consistent with the OSH Act that could reduce the burden of this standard on small entities?

IX. Public Participation—Comments and Hearings

OSHA encourages members of the public to participate in this rulemaking by submitting comments on the proposal, and by providing oral testimony and documentary evidence at the informal public hearing that the Agency will convene after the comment period ends. In this regard, the Agency invites interested parties having knowledge of, or experience with, APFs and MUCs to participate in this process, and welcomes any pertinent data and cost information that will provide it with the best available evidence on which to develop the final regulatory requirements.

This section describes the procedures the public must use to submit their comments to the docket in a timely manner, and to schedule an opportunity to deliver oral testimony and provide documentary evidence at the informal public hearings. Comments, notices of intention to appear, hearing testimony, and documentary evidence will be available for inspection and copying at the OSHA Docket Office. You also should read the sections above titled **DATES** and **ADDRESSES** for additional information on submitting comments, documents, and requests to the Agency for consideration in this rulemaking.

Written Comments. OSHA invites interested parties to submit written data, views, and arguments concerning this proposal. In particular, OSHA would encourage interested parties to comment on the issues raised in section VIII (''Issues'') of the preamble. When submitting comments, parties must follow the procedures specified above in the sections titled **DATES** and **ADDRESSES.** The comments must clearly identify the provision of the proposal you are addressing, the position taken with respect to each issue, and the basis for that position. Comments, along with supporting data and references, received by the end of the specified comment period will become part of the proceedings record, and will be available for public inspection and copying at the OSHA Docket Office.

Informal Public Hearings. Pursuant to section 6(b)(3) of the Act, members of the public will have an opportunity at an informal public hearing to provide oral testimony concerning the issues raised in this proposal. The hearings will commence at 9:30 a.m. on the first day. At that time, the presiding administrative law judge (ALJ) will resolve any procedural matters relating to the proceeding. The hearings will reconvene on subsequent days at 8:30 a.m.

The legislative history of section 6 of the OSH Act, as well as OSHA's regulation governing public hearings (29 CFR 1911.15), establish the purpose and procedures of informal public hearings. Although the presiding officer of such hearings is an ALJ, and questioning by interested parties is allowed on crucial issues, the proceeding is informal and legislative in purpose. Therefore, the hearing provides interested parties with an opportunity to make effective and expeditious oral presentations in the absence of procedural restraints or rigid procedures that could impede or protract the rulemaking process. In addition, the hearing is an informal administrative proceeding, rather than adjudicative one in which the technical rules of evidence would apply, because its primary purpose is to gather and clarify information. The regulations that govern public hearings, and the pre-hearing guidelines issued for this hearing, will ensure participants fairness and due process, and also will facilitate the development of a clear, accurate, and complete record. Accordingly, application of these rules and guidelines will be such that questions of relevance, procedure, and participation generally will favor development of the record.

Conduct of the hearing will conform to the provisions of 29 CFR part 1911, ''Rules of Procedure for Promulgating, Modifying, or Revoking Occupational Safety and Health Standards.'' The regulation at 29 CFR 1911.4 ''Additional or Alternative Procedural Requirements,'' specifies that the Assistant Secretary may, on reasonable notice, issue alternative procedures to expedite proceedings or for other good cause. Although the ALJs who preside over these hearings make no decision or recommendation on the merits of OSHA's proposal, they do have the responsibility and authority to ensure that the hearing progresses at a reasonable pace and in an orderly manner.

To ensure that interested parties receive a full and fair informal hearing as specified by 29 CFR part 1911, the ALJ has the authority and power to: Regulate the course of the proceedings; dispose of procedural requests, objections, and comparable matters; confine the presentations to matters pertinent to the issues raised; use appropriate means to regulate the conduct of the parties who are present at the hearing; question witnesses, and permit others to question witnesses; and limit the time for such questioning. At the close of the hearing, the ALJ will establish a post-hearing comment period for parties who participated in the hearing. During the first part of this period, the participants may submit additional data and information to OSHA, while during the second part of this period, they may submit briefs, arguments, and summations.

Notice of Intention To Appear To Provide Testimony at the Informal

Public Hearings. Interested parties who intend to provide oral testimony at the informal public hearings must file a notice of intention to appear by using the procedures specified above in the sections titled **DATES** and **ADDRESSES.** This notice must provide the: Name, address, and telephone number of each individual who will provide testimony, and their preferred hearing location; capacity (*e.g.*, name of the establishment/organization the individual is representing; the individual's occupational title and position) in which each individual will testify; approximate amount of time required for each individual's testimony; specific issues each individual will address, including a brief statement of the position that the individual will take with respect to each of these issues; and any documentary evidence the individual will present, including a brief summary of the evidence.

OSHA emphasizes that the hearings are open to the public, and that interested parties are welcome to attend. However, only a party who files a proper notice of intention to appear may ask questions and participate fully in the proceedings. While a party who did not file a notice of intention to appear may be allowed to testify at the hearing if time permits, this determination is at the discretion of the presiding ALJ.

Hearing Testimony and Documentary Evidence. Any party requesting more than 10 minutes to testify at the informal public hearing, or who intends to submit documentary evidence at the hearing, must provide the complete text of the testimony and the documentary evidence as specified above in the sections titled **DATES** and **ADDRESSES**. The Agency will review each submission and determine if the information it contains warrants the amount of time requested. If OSHA believes the requested time is excessive, it will allocate an appropriate amount of time to the presentation, and will notify the participant of this action, and the reasons for the action, prior to the hearing. The Agency may limit to 10 minutes the presentation of any participant who fails to comply substantially with these procedural requirements; in such instances, OSHA may request the participant to return for questioning at a later time.

Certification of the Record and Final Determination After the Informal Public Hearing. Following the close of the hearing and post-hearing comment period, the presiding ALJ will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health; the record will consist of all of the written comments, oral testimony, and documentary evidence received during the proceeding. However, the ALJ does not make or recommend any decisions as to the content of the final standard. Following certification of the record, OSHA will review the proposed APF provisions in light of all the evidence received as part of the record, and then will issue the final APF provisions based on the entire record.

List of Subjects in 29 CFR Parts 1910, 1915, and 1926

Assigned protection factors, Hazardous substances, Health, Occupational safety and health, Respirators, Respirator selection.

Authority and Signature

John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210, directed the preparation of this notice. The Agency issues the proposed sections under the following authorities: Sections 4, 6(b), 8(c), and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); section 107 of the Contract Work Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 333); section 41, the Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); Secretary of Labor's Order No. 5–2002 (67 FR 65008); and 29 CFR Part 1911.

Signed at Washington, DC, on May 28, 2003.

John L. Henshaw,

Assistant Secretary of Labor.

X. Proposed Amendments to Standards

OSHA proposes to amend 29 CFR parts 1910, 1915, and 1926 as follows:

PART 1910—[AMENDED]

Subpart I—[Amended]

1. The authority citation for subpart I of part 1910 is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 3–2000 (62 FR 50017).

Sections 1910.132, 1910.134, and 1910.138 or 29 CFR also issued under 29 CFR part 1911.

Sections 1910.133, 1910.135, and 1910.136 of 29 CFR also issued under 29 CFR part 1911 and 5 U.S.C. 553.

2. Section 1910.134 is amended as follows:

a. The text of the definitions for ''Assigned protection factor (APF)'' and ''Maximum use concentration (MUC)'' is added to paragraph (b);

b. The text of paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) is added; and

c. Paragraph (n) is revised.

The added and revised text read as follows:

§ 1910.134 Respiratory protection.

* * * * *

(b) * * *

Assigned protection factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by 29 CFR 1910.134.

* * * * *

Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The MUC usually can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the permissible exposure limit, short term exposure limit, ceiling limit, peak limit, or any other exposure limit used for the hazardous substance.

* * * * *

(d) * * *

(3) * * *

(i) * * *

(A) *Assigned Protection Factors (APFs).* Employers must use the assigned protection factors listed in Table I to select a respirator that meets or exceeds the required level of employee protection. When using a combination respirator (*e.g.*, airline respirators with an air-purifying filter), employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.

Note to paragraph (d)(3)(i)(A): The assigned protection factors listed in Table I are effective only when the employer has a continuing, effective respiratory protection program as specified by 29 CFR 1910.134, including training, fit testing, maintenance and use requirements. These assigned protection factors do not apply to respirators used solely for escape.

TABLE I.—ASSIGNED PROTECTION FACTORS

Type of respirator [1] [2]	Half mask	Full facepiece	Helmet/hood	Loose-fitting facepiece
1. Air-Purifying Respirator	[3] 10	50	.....	.....
2. Powered Air-Purifying Respirator (PAPR)	50	1000	[4] 1000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator:				
• Demand mode	10	50	.....	.....
• Continuous-flow mode	50	1,000	[4] 1,000	25
• Pressure-demand or other positive-pressure mode	50	1,000	.....	.....
4. Self-Contained Breathing Apparatus (SCBA):				
• Demand mode	10	50	50	.....
• Pressure-demand or other positive-pressure mode (*e.g.*, open/closed circuit)	.....	10,000 [5] (maximum)	10,000 [5] (maximum)	.....

Notes:

[1] Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for use at lower concentrations of that substance or when required respirator use is independent of concentration.

[2] The assigned protection factors in Table I only apply when the employer implements a continuing, effective respirator program as specified by OSHA's Respiratory Protection Standard at 29 CFR 1910.134, including training, fit testing, maintenance and use requirements.

[3] This APF category includes quarter masks, filtering facepieces, and half-masks.

[4] Previous studies involving Workplace Protection Factor (WPF) and Simulated Workplace Protection Factor (SWPF) testing on helmet/hood respirators show that some of these respirators do not provide a level of protection consistent with an APF of 1000. Therefore, only helmet/hood respirators that ensure the maintenance of a positive pressure inside the facepiece during use, consistent with performance at a level of protection of 1000 or greater, receive an APF of 1000. All other helmet/hood respirators are treated as loose-fitting facepiece respirators and receive an APF of 25.

[5] Although positive pressure SCBAs appear to provide the highest level of respiratory protection, a SWPF study of SCBA users concluded that all users may not achieve protection factors of 10,000 at high work rates. When employers can estimate hazardous concentrations for planning purposes, they must use a maximum assigned protection factor no higher than 10,000.

(B) *Maximum Use Concentration (MUC).* (*1*) The employer must select a respirator for employee use that maintains the employee's exposure to the hazardous substance, when measured outside the respirator, at or below the MUC.

Note to paragraph (d)(3)(i)(B)(1): MUCs are effective only when the employer has a continuing, effective respiratory protection program as specified by 29 CFR 1910.134, including training, fit testing, maintenance and use requirements.

(*2*) Employers must comply with the respirator manufacturer's MUC for a hazardous substance when the manufacturer's MUC is lower than the calculated MUC specified by this standard.

(*3*) Employers must not apply MUCs to conditions that are immediately dangerous to life or health (IDLH); instead, they must use respirators listed for IDLH conditions in paragraph (d)(2) of this standard.

(*4*) When the calculated MUC exceeds another limiting factor such as the IDLH level for a hazardous substance, the lower explosive limit (LEL), or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.

* * * * *

(n) *Effective date.* Paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) of this section become effective September 4, 2003.

* * * * *

Subpart Z—[Amended]

3. The general authority citation for subpart Z of part 1910 is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 3–2000 (62 FR 50017); and 29 CFR Part 1911.

* * * * *

4. Section 1910.1001 is amended by:

a. Removing Table 1 in paragraph (g)(3);

b. Redesignating Table 2 in paragraph (l)(3)(ii) as Table 1;

c. Removing the reference to ''Table 2'' in paragraph (l)(3)(ii) and adding ''Table 1'' in its place; and

d. Revising paragraphs (g)(2)(ii) and (g)(3).

The revisions read as follows:

§ 1910.1001 Asbestos.

* * * * *

(g) * * *

(2) * * *

(ii) Employers must provide an employee with tight-fitting, powered air-purifying respirator (PAPR) instead of a negative-pressure respirator selected according to paragraph (g)(3) of this standard when the employee chooses to use a PAPR and it provides adequate protection to the employee.

* * * * *

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use filtering-facepiece respirators for protection against asbestos fibers.

(ii) Provide HEPA filters for air-purifying respirators.

* * * * *

5. In § 1910.1017, remove the table in paragraph (g)(3)(i), remove paragraph (g)(3)(iii), and revise paragraph (g)(3)(i) to read as follows:

§ 1910.1017 Vinyl chloride.

* * * * *

(g) * * *

(3) * * * (i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide an organic-vapor cartridge that has a service life of at least one hour when using a chemical-cartridge respirator at vinyl chloride concentrations up to 10 ppm.

(C) Select a canister that has a service life of at least four hours when using a powered air-purifying respirator having a hood, helmet, or full or half facepiece, or a gas mask with a front- or back-mounted canister, at vinyl chloride concentrations up to 25 ppm.

* * * * *

6. In § 1910.1018, remove Tables I and II and paragraph (h)(3)(ii), redesignate paragraph (h)(3)(iii) as paragraph

(h)(3)(ii), and revise paragraph (h)(3)(i) to read as follows:

§ 1910.1018 Inorganic arsenic.

* * * * *

(h) * * *

(3) * * *(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Ensure that employees do not use half-mask respirators for protection against arsenic trichloride because it is absorbed rapidly through the skin.

(C) Provide HEPA filters for air-purifying respirators.

(D) Select for employee use:

(*1*) Air-purifying respirators that have a combination HEPA filter with an appropriate gas-sorbent cartridge or canister when the employee's exposure exceeds the permissible exposure level for inorganic arsenic and the relevant limit for other gases.

(*2*) Front- or back-mounted gas masks equipped with HEPA filters and acid-gas canisters or any full-facepiece supplied-air respirators when the inorganic arsenic concentration is at or below 500 μg/m^3; and half-mask air-purifying respirators equipped with HEPA filters and acid-gas cartridges when the inorganic arsenic concentration is at or below 100 μg/m^3.

* * * * *

7. In § 1910.1025, remove Table II in paragraph (f)(2)(ii) and revise paragraphs (f)(3)(i) and (f)(3)(ii) to read as follows:

§ 1910.1025 Lead.

* * * * *

(f) * * *

(3) * * *(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with full-facepiece respirators instead of half-mask respirators for protection against lead aerosols that cause eye or skin irritation at the use concentrations.

(C) Provide HEPA filters for air-purifying respirators.

(ii) Employers must provide employees with a powered air-purifying respirator (PAPR) instead of a negative-pressure respirator selected according to paragraph (f)(3)(i) of this standard when an employee chooses to use a PAPR and it provides adequate protection to the employee as specified by paragraph (f)(3)(i) of this standard.

* * * * * .

8. In § 1910.1027, remove Table 2 in paragraph (g)(3)(i) and revise paragraph (g)(3)(i) to read as follows:

§ 1910.1027 Cadmium.

* * * * *

(g) * * *

(3) * * *(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with full-facepiece respirators when they experience eye irritation.

(C) Provide HEPA filters for air-purifying respirators.

* * * * *

9. In § 1910.1028, remove Table 1 in paragraph (g)(3)(ii) and revise paragraphs (g)(2)(i) and (g)(3)(i) to read as follows:

§ 1910.1028 Benzene.

* * * * *

(g) * * *

(2) * * *

(i) Employers must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m).

* * * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with any organic-vapor gas mask or any self-contained breathing apparatus with a full facepiece to use for escape.

(C) Use an organic-vapor cartridge or canister air-purifying respirators, and a chin-style canister with full-facepiece gas masks.

(D) Ensure that canisters used with nonpowered air-purifying respirators have a minimum service life of four hours when tested at 150 ppm benzene at a flow rate of 64 liters per minute (LPM), a temperature of 25° C, and a relative humidity of 85%; for canisters used with tight-fitting or loose-fitting, powered air-purifying respirators, the flow rates for testing must be 115 LPM and 170 LPM, respectively.

* * * * *

10. In § 1910.1029, remove Table I in paragraph (g)(3) and revise paragraph (g)(3) to read as follows:

§ 1910.1029 Coke oven emissions.

* * * * *

(g) * * *

(3) *Respirator selection.* Employers must select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use filtering facepieces for protection against coke oven emissions.

* * * * *

11. In § 1910.1043, remove Table I in paragraph (f)(3)(i) and revise paragraphs (f)(3)(i) and (f)(3)(ii) to read as follows:

§ 1910.1043 Cotton dust.

* * * * *

(f) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use filtering facepieces for protection against cotton dust concentrations greater than five times (5 X) the PEL.

(B) Provide HEPA filters for air-purifying respirators used at cotton dust concentrations greater than ten times (10 X) the PEL.

(ii) Employers must provide an employee with a powered air-purifying respirator (PAPR) instead of a nonpowered air-purifying respirator selected according to paragraph (f)(3)(i) of this standard when the employee chooses to use a PAPR and it provides adequate protection to the employee as specified by paragraph (f)(3)(i) of this standard.

* * * * *

12. In § 1910.1044, remove Table 1 in paragraph (h)(3) and revise paragraph (h)(3) to read as follows:

§ 1910.1044 1,2-Dibromo-3-chloropropane.

* * * * *

(h) * * *

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate atmosphere-supplying respirator specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(ii) Provide employees with one of the following respirator options to use for entry into, or escape from, unknown DBCP concentrations:

(A) A combination respirator that includes a supplied-air respirator with a full facepiece operated in a pressure-demand or other positive-pressure or continuous-flow mode, as well as an auxiliary self-contained breathing apparatus (SCBA) operated in a pressure-demand or positive-pressure mode.

(B) An SCBA with a full facepiece operated in a pressure-demand or other positive-pressure mode.

* * * * *

13. In § 1910.1045, remove Table I in paragraph (h)(3) and revise paragraphs (h)(2)(i) and (h)(3) to read as follows:

§ 1910.1045 Acrylonitrile.

* * * * *

(h) * * *

(2) * * *

(i) Employers must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m).

* * * * *

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(ii) For escape, provide employees with any organic-vapor respirator or any self-contained breathing apparatus permitted for use under paragraph (h)(3)(i) of this standard.

* * * * *

14. In § 1910.1047, remove Table 1 in paragraph (g)(3) and revise paragraph (g)(3) to read as follows:

§ 1910.1047 Ethylene oxide.

* * * * *

(g) * * *

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use half-masks of any type because EtO may cause eye irritation or injury.

(ii) Equip each air-purifying, full facepiece respirator with a front- or back-mounted canister approved for protection against ethylene oxide.

(iii) For escape, provide employees with any respirator permitted for use under paragraph (g)(3)(i) of this standard.

* * * * *

15. In § 1910.1048, remove Table 1 in paragraph (g)(3)(i) and revise paragraphs (g)(2) and (g)(3) to read as follows:

§ 1910.1048 Formaldehyde.

* * * * *

(g) * * *

(2) *Respirator programs.* (i) Employers must implement a respiratory protection program in accordance with 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m).

(ii) If employees use air-purifying respirators with chemical cartridges or canisters that do not contain end-of-service-life indicators approved by the National Institute for Occupational Safety and Health, employers must replace these cartridges or canisters as specified by paragraphs (d)(3)(iii)(B)(1) and (B)(2) of 29 CFR 1910.134, or at the end of the workshift, whichever condition occurs first.

(3) *Respirator selection.* (i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Equip each air-purifying, full facepiece respirator with a canister or cartridge approved for protection against formaldehyde.

(C) For escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the demand or pressure-demand mode; or a full facepiece respirator having a chin-style, or a front- or back-mounted industrial-size, canister or cartridge approved for protection against formaldehyde.

(ii) Employers may substitute an air-purifying, half-mask respirator for an air-purifying, full facepiece respirator if they equip the half-mask respirator with a cartridge approved for protection against formaldehyde and provide the affected employee with effective gas-proof goggles.

(iii) Employers must provide employees who have difficulty using negative-pressure respirators with powered air-purifying respirators permitted for use under paragraph (g)(3)(i)(A) of this standard and that provide adequate protection against their formaldehyde exposures.

* * * * *

16. In § 1910.1050, remove Table 1 in paragraph (h)(3)(i) and revise paragraph (h)(3)(i) to read as follows:

§ 1910.1050 Methylenedianiline.

* * * * *

(h) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide HEPA filters for air-purifying respirators.

(C) For escape, provide employees with one of the following respirator options: Any self-contained breathing apparatus with a full facepiece or hood operated in the positive-pressure or continuous-flow mode; or a full-facepiece, air-purifying respirator.

(D) Provide a combination HEPA filter and organic-vapor canister or cartridge with air-purifying respirators when MDA is in liquid form or part of a process requiring heat.

* * * * *

17. In § 1910.1052, remove Table 2 in paragraph (g)(3) and revise paragraph (g)(3) to read as follows:

§ 1910.1052 Methylene chloride.

* * * * *

(g) * * *

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate atmosphere-supplying respirator specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use half-masks of any type because MC may cause eye irritation or damage.

(ii) For emergency escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the continuous-flow or pressure-demand; or a gas mask with an organic-vapor canister.

* * * * *

PART 1915—[AMENDED]

18. The authority citation for part 1915 is revised to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (20 U.S.C. 653, 655, and 687); and Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 3–2000 (62 FR 50017).

Sections 1915.120 and 1915.152 also issued under 29 CFR 1911.

Subpart Z—[Amended]

19. In § 1915.1001, remove Table 1 in paragraph (h)(2)(iii) and revise paragraph (h)(2) to read as follows:

§ 1915.1001 Asbestos.

* * * * *

(h) * * *

(2) *Respirator selection.* (i) Employers must select, and provide to employees at no cost, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use filtering-facepiece respirators for use against asbestos fibers.

(ii) Employers are to provide HEPA filters for air-purifying respirators.

(iii) Employers must:

(A) Inform employees that they may require the employer to provide a tight-fitting, powered air-purifying respirator (PAPR) permitted for use under paragraph (h)(2)(i) of this standard instead of a negative-pressure respirator.

(B) Provide employees with a tight-fitting PAPR instead of a negative-pressure respirator when the employees choose to use a tight-fitting PAPR and it provides them with the required protection against asbestos.

(iv) Employers must provide employees with an air-purifying, half-

mask respirator, other than a filtering-facepiece respirator, whenever the employees perform:

(A) Class II or Class III asbestos work for which no negative-exposure assessment is available.

(B) Class III asbestos work involving disturbance of TSI or surfacing ACM or PACM.

(v) Employers must provide employees with:

(A) A tight-fitting, powered air-purifying respirator or a full-facepiece, supplied-air respirator operated in the pressure-demand mode and equipped with either HEPA egress cartridges or an auxiliary positive-pressure, self-contained breathing apparatus (SCBA) whenever the employees are in a regulated area performing Class I asbestos work for which a negative-exposure assessment is not available and the exposure assessment indicates that the exposure level will be at or below 1 f/cc as an 8-hour time-weighted average (TWA).

(B) A full-facepiece, supplied-air respirator operated in the pressure-demand mode and equipped with an auxiliary positive-pressure SCBA whenever the employees are in a regulated area performing Class I asbestos work for which a negative-exposure assessment is not available and the exposure assessment indicates that the exposure level will be above 1 f/cc as an 8-hour TWA.

* * * * *

PART 1926—[AMENDED]

Subpart D—[Amended]

20. The authority citation for subpart D of part 1926 is revised to read as follows:

Authority: Section 107, Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333); sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 3–2000 (62 FR 50017); and 29 CFR part 11.

Sections 1926.58, 1926.59, 1926.60, and 1926.65 also issued under 5 U.S.C. 553 and 29 CFR part 1911.

Section 1926.62 also issued under section 1031 of the Housing and Community Development Act of 1992 (42 U.S.C. 4853).

Section 1926.65 of 29 CFR also issued under section 126 of the Superfund Amendments and Reauthorization Act of 1986, as amended (29 U.S.C. 655 note), and 5 U.S.C. 553.

21. In § 1926.60, remove Table 1 and revise paragraph (i)(3)(i) to read as follows:

§ 1926.60 Methylenedianiline.

* * * * *

(i) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide HEPA filters for air-purifying respirators.

(C) For escape, provide employees with one of the following respirator options: Any self-contained breathing apparatus with a full facepiece or hood operated in the positive-pressure or continuous-flow mode; or a full-facepiece, air-purifying respirator.

(D) Provide a combination HEPA filter and organic-vapor canister or cartridge with air-purifying respirators when MDA is in liquid form or part of a process requiring heat.

* * * * *

22. In § 1926.62, remove Table 1 in paragraph (f)(3) and revise paragraph (f)(3)(i) to read as follows:

§ 1926.62 Lead.

* * * * *

(f) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with a full-facepiece respirator instead of a half-mask respirator for protection against lead aerosols that cause eye or skin irritation at the use concentrations.

(C) Provide HEPA filters for air-purifying respirators.

* * * * *

Subpart Z—[Amended]

23. The authority citation for subpart Z of part 1926 is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Orders 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 3–2000 (62 FR 50017); and 29 CFR part 11.

Section 1926.1102 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

24. In § 1926.1101, remove Table 1 in paragraph (h)(3)(i) and revise paragraph (h)(3) to read as follows:

§ 1926.1101 Asbestos.

* * * * *

(h) * * *

(3) *Respirator selection.* (i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use filtering-facepiece respirators for use against asbestos fibers.

(B) Provide HEPA filters for air-purifying respirators.

(ii) Employers must provide an employee with tight-fitting, powered air-purifying respirator (PAPR) instead of a negative-pressure respirator selected according to paragraph (h)(3)(i)(A) of this standard when the employee chooses to use a PAPR and it provides adequate protection to the employee.

(iii) Employers must provide employees with an air-purifying, half-mask respirator, other than a filtering-facepiece respirator, whenever the employees perform:

(A) Class II or Class III asbestos work for which no negative-exposure assessment is available.

(B) Class III asbestos work involving disturbance of TSI or surfacing ACM or PACM.

(iv) Employers must provide employees with:

(A) A tight-fitting, powered air-purifying respirator or a full-facepiece, supplied-air respirator operated in the pressure-demand mode and equipped with either HEPA egress cartridges or an auxiliary positive-pressure, self-contained breathing apparatus (SCBA) whenever the employees are in a regulated area performing Class I asbestos work for which a negative-exposure assessment is not available and the exposure assessment indicates that the exposure level will be at or below 1 f/cc as an 8-hour time-weighted average (TWA).

(B) A full-facepiece, supplied-air respirator operated in the pressure-demand mode and equipped with an auxiliary positive-pressure SCBA whenever the employees are in a regulated area performing Class I asbestos work for which a negative-exposure assessment is not available and the exposure assessment indicates that the exposure level will be above 1 f/cc as an 8-hour TWA.

* * * * *

25. In § 1926.1127, remove Table 1 in paragraph (g)(3)(i) and revise paragraph (g)(3)(i) to read as follows:

§ 1926.1127 Cadmium.

* * * * *

(g) * * *

(3) * * *

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in

paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Provide employees with full-facepiece respirators when they experience eye irritation.

(C) Provide HEPA filters for air-purifying respirators.

* * * * *

[FR Doc. 03–13749 Filed 6–5–03; 8:45 am]

BILLING CODE 4510–26–P

Federal Register

Friday,
June 6, 2003

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates and Policy Changes; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1472–F]

RIN 0938–AL92

Medicare Program; Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates and Policy Changes

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes the annual update of the payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs). It also changes the annual period for which the rates are effective. The rates will be effective from July 1 to June 30 instead of from October 1 through September 30, establishing a ''long-term care hospital rate year'' (LTCH PPS rate year). We also change the publication schedule for these updates to allow for an effective date of July 1. The payment amounts and factors used to determine the updated Federal rates that are described in this final rule have been determined based on this revised LTCH PPS rate year. The annual update of the long-term care diagnosis-related groups (LTC–DRG) classifications and relative weights remains linked to the annual adjustments of the acute care hospital inpatient diagnosis-related group system, and will continue to be effective each October 1.

The outlier threshold for July 1, 2003, through June 30, 2004, is also derived from the LTCH PPS rate year calculations.

In addition, we are making an adjustment to the short-stay outlier policy for certain LTCHs and a policy change eliminating bed-number restrictions for pre-1997 LTCHs that have established satellite facilities and elect to be paid 100 percent of the Federal rate or when the LTCH is fully phased-in to 100 percent of the Federal prospective rate after the transition period.

EFFECTIVE DATE: The provisions of this final rule are effective June 30, 2003.

FOR FURTHER INFORMATION CONTACT:

Tzvi Hefter, (410) 786–4487 (General information);

Judy Richter, (410) 786–2590 (General information, transition payments, payment adjustments, and onsite discharges and readmissions, interrupted stays and short-stay outliers);

Michele Hudson, (410) 786–5490 (Calculation of the payment rates, relative weights and case-mix index, market basket update, and payment adjustments);

Ann Fagan, (410) 786–5662 (Patient classification system);

Miechal Lefkowitz, (410) 786–5316 (High-cost outliers and budget neutrality);

Linda McKenna, (410) 786–4537 (Payment adjustments, interrupted stay, and transition period);

Kathryn McCann, (410) 786–7623 (Medigap);

Robert Nakielny, (410) 786–4466 (Medicaid).

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/nara/index.html.*

To assist readers in referencing sections contained in this preamble, we are providing the following table of contents.

Table of Contents

Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding terms in alphabetical order below:

BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106–554
CMS Centers for Medicare & Medicaid Services
DRGs Diagnosis-related groups
FY Federal fiscal year
HCRIS Hospital Cost Report Information System
HHA Home health agency
HIPAA Health Insurance Portability and Accountability Act, Public Law 104–191
IPPS Acute Care Hospital Inpatient Prospective Payment System
IRF Inpatient rehabilitation facility
LTC—DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare provider analysis and review file
OSCAR Online Survey Certification and Reporting (System)
PPS Prospective Payment System
QIO Quality Improvement Organization (formerly Peer Review organization (PRO))
SNF Skilled nursing facility
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248

I. Background

A. Legislative and Regulatory Authority

The Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L.106–554) provide for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare part A based on prospectively set rates. The Medicare prospective payment system for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Social Security Act (the Act), effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines a LTCH as ''a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.'' Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: Specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (as determined by the Secretary) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

Section 123 of Public Law 106–113 requires the prospective payment system for LTCHs to be a per discharge system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs while maintaining budget neutrality.

Section 307(b)(1) of Public Law 106–554, among other things, mandates that the Secretary shall examine and may provide for adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In a **Federal Register** document issued on August 30, 2002 (67 FR 55954), we implemented the LTCH PPS authorized under Public Law 106–113 and Public Law 106–554. This system uses information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Payments are calculated for each LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Public Law 97–248, for payments for inpatient services provided by a LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA (reasonable cost-based) payment provisions are located at 42 CFR part 413.) With the implementation of the prospective payment system for inpatient acute care hospitals authorized by the Social Security Amendments of 1983 (Public Law 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. The August 30, 2002, final rule further details payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002, final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of Public Law 106–113. The same final rule, that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements.

We refer readers to the August 30, 2002, final rule (67 FR 55954)for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS.

B. Criteria for Classification as a LTCH

LTCHs must have a provider agreement with Medicare and (1) must have an average Medicare inpatient length of stay of greater than 25 days, or (2), for a hospital that was first excluded from the PPS in 1986, must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days and demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principle diagnosis that reflects a finding of neoplastic disease. Subject to the provisions of § 412.23(e)(3), for the first type of LTCHs as noted above, the average Medicare inpatient length of stay is determined based on all covered and noncovered days of stay of Medicare patients as calculated by dividing the total number of covered and noncovered days of stay of Medicare inpatients (less leave or pass days) by the number of total Medicare discharges for the hospital's most recent complete cost reporting period. Fiscal intermediaries verify that LTCHs meet the average length of stay requirements. We note that the inpatient days of a patient who is admitted to a LTCH without any remaining Medicare days of coverage, regardless of the fact that the patient is a Medicare beneficiary, will not be included in the above calculation. Because Medicare would not be paying for any of the patient's treatment, data on the patient's stay would not be included in our systems. In order for noncovered days of a LTCH

hospitalization to be included, a patient must have at least one remaining benefit day as described in § 409.61.

The fiscal intermediary's determination of whether or not a hospital qualifies as an LTCH is based on the hospital's discharge data from its most recent cost reporting period and is effective at the start of the hospital's next cost reporting period, as set forth under § 412.22(d). If a hospital does not meet the length of stay requirement, the hospital may provide the intermediary with data indicating a change in the hospital's average length of stay by the same method for the immediately preceding 6-month period (§ 412.23(e)(3)(ii)). (For procedural efficiency and in order to comply with the timing requirement of § 412.22(d), we have a longstanding policy of allowing hospitals to submit data for a period greater than 5-months for this purpose.) Requirements for hospitals seeking classification as LTCHs that have undergone a change in ownership, as described in § 489.18, are set forth in § 412.23(e)(3)(iii).

LTCHs that exist as hospitals-within-hospitals or satellite facilities must also meet the criteria set forth in § 412.22(e) or § 412.22(h), respectively, to be excluded from the IPPS and paid under the LTCH PPS.

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR Part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 (42 U.S.C. 1395b–1) or section 222(a) of Public Law 92–603 (42 U.S.C. 1395b–1 (note)) (statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

C. Transition Period for Implementation of the LTCH PPS

In the August 30, 2002, final rule, we provided for a 5-year transition period from cost-based reimbursement to fully Federal prospective payment for LTCHs (67 FR 56038). During the 5-year period, two payment percentages are to be used to determine a LTCH's total payment under the PPS. The blend percentages are as follows:

Cost reporting periods beginning on or after	Prospective payment Federal rate percentage	Cost-based reimbursement rate percentage
October 1, 2002	20	80
October 1, 2003	40	60
October 1, 2004	60	40
October 1, 2005	80	20
October 1, 2006	100	0

D. Limitation on Charges to Beneficiaries

In the August 30, 2002, final rule, we presented an in-depth discussion of beneficiary liability under the LTCH prospective payment system (67 FR 55974–55975). Under § 412.507, as consistent with other established hospital prospective payment systems, a LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87 and for items and services as specified under § 489.30(a), if the Medicare payment to the LTCH is the full LTC–DRG payment amount. However, if the Medicare payment was for a short-stay outlier case (§ 412.529) that was less than the full LTC–DRG payment amount, the LTCH could also charge the beneficiary for services for which the costs of those services or the days those services were provided were not a basis for calculating the Medicare short-stay outlier payment (§ 412.507).

Since the origin of the Medicare system, the intent of our regulations has been to set limits on beneficiary liability and to clearly establish the circumstances under which the beneficiary would be required to assume responsibility for payment; that is, upon exhausting benefits described in 42 CFR part 409, subpart F. The discussion in the August 30, 2002, final rule was not meant to establish rates or payments for, or define, Medicare-eligible expenses. While we regulate beneficiary liability for coinsurance and deductibles for hospital stays that are covered by Medicare, payments from Medigap insurers to providers for inpatient hospital coverage after Medicare benefits are exhausted are not regulated by us. Furthermore, regulations beginning at § 403.200 and the 1991 National Association of Insurance Commissioners (NAIC) Model Regulation for Medicare Supplemental Insurance, which was incorporated by reference into section 1882 of the Act, govern the relationship between Medigap insurers and beneficiaries.

E. System Implementation for the LTCH PPS

When we established the regulations to implement the LTCH PPS on August 30, 2002 (67 FR 55954), effective for cost reporting periods that began on or after October 1, 2002, we did not have computer system changes in place that were necessary to accommodate claims processing and payment under the system. However, after January 1, 2003, we made the necessary system changes. Accordingly, after January 1, 2003, the fiscal intermediary has been required to reconcile the payment amounts that had been made to LTCHs for all covered inpatient hospital services furnished to Medicare beneficiaries from cost reporting periods that began on or after October 1, 2002, through January 1, 2003, with the amounts that were payable under the LTCH PPS methodology. Because the LTCH PPS was effective at the start of the LTCH's first cost reporting period that began on or after October 1, 2002, only those LTCHs with cost reporting periods that started October 1, 2002, through January 1, 2003, will experience the payment reconciliation necessitated by this 3-month period prior to systems implementation. The claims submission procedure of using ICD–9–CM codes has not changed following the systems implementation of the LTCH PPS.

We also want to note that as of October 16, 2002, a LTCH that was required to comply with the Administrative Simplification Standards under the Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104–191) and that had not obtained an extension in compliance with the Administrative Compliance Act (Pub. L. 107–105) is obligated to comply with the standards for submitting claim forms to the

LTCH's Medicare fiscal intermediary (45 CFR 162.1002 and 45 CFR 162.1102). Beginning October 16, 2003, LTCHs that obtained an extension and that are required to comply with the HIPPA Administrative Simplification Standards must start submitting electronic claims in compliance with the HIPPA regulations cited above, among others.

II. Publication of Proposed Rulemaking

On March 7, 2003, we published a proposed rule in the **Federal Register** (67 FR 11234) that set forth the proposed annual update of the payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs). In that rule, we proposed to change the annual period during which the updated payment rates for the LTCH PPS would be effective from October 1 through September 30 to a LTCH PPS rate year from July 1 through June 30. We also proposed to change the publication schedule for these updates to allow for an effective date of July 1. The proposed payment amounts and factors used to determine the proposed updated Federal rates that were described in the March 7, 2003, proposed rule were determined based on the proposed revised update LTCH PPS rate year. However, the annual update of the long-term care diagnosis-related groups (LTC–DRG) classifications and relative weights remain linked to the annual adjustments of the acute care hospital inpatient diagnosis-related group system, effective each October 1. In the March 7, 2003, proposed rule, we also proposed the outlier threshold for July 1, 2003, through June 30, 2004, that was derived from the proposed LTCH PPS rate year calculations. We also proposed a change for outlier payments under the LTCH PPS. In addition, we proposed a policy change eliminating bed-number restrictions for pre-1997 LTCHs that have established satellite facilities and that elect to be paid 100 percent of the Federal rate or when the LTCH is fully phased-in to 100 percent of the Federal prospective rate after the transition period.

We received a total of 32 timely items of correspondence containing multiple comments on the proposed rule. The major issues addressed by the commenters included: The establishment of the LTCH PPS rate year and its relation to the update of the Federal rates; the LTC–DRGs and the wage index; satellite policy and budget neutrality calculations; high-cost and short-stay outliers; market basket and labor share; disproportionate share (DSH) and Graduate Medical Education (GME) policies.

Summaries of the public comments received and our responses to those comments are described below under the appropriate subject heading.

III. Summary of the Major Contents of This Final Rule

In this final rule, we set forth the annual update to the payment rates for the Medicare LTCH PPS and make other policy changes. The following is a summary of the major areas that we are addressing in this final rule:

A. Change in the Annual Update

We are changing the annual update to the Federal payment rate under the LTCH PPS from the Federal fiscal year (October 1 through September 30) to a ''LTCH PPS rate year'' of July l through June 30, beginning July l, 2003, as discussed in section IV. of this preamble. (In this final rule, we define the LTCH PPS rate year as the period from July 1 to June 30 for updates to the LTCH PPS.) As noted below, we will now publish information on the annual update in the **Federal Register** on or before May 1 prior to the start of each long-term care hospital prospective payment system rate year that begins July 1, unless for good cause it is published after May 1, but before June 1. We have already noted that the annual update of the LTC–DRGs will be published in the proposed and final rules for the IPPS. We also recognize that it may be necessary to address issues affecting LTCHs at a time that does not conform to the schedule above. In such a situation, we would use another **Federal Register** document (that is, the acute care hospital inpatient prospective payment system (IPPS) proposed rule or final rule) as the vehicle to present that issue.

B. Update Changes

- In section IV. of this preamble, the annual update of the LTC–DRG classifications and relative weights remain linked to the annual adjustments of the acute care hospital inpatient DRG system, which are based on the annual revisions to the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) codes, effective each October 1.
- In section VI. of this preamble, we discuss a policy change on how Medicare payment under the LTCH PPS will be made to certain LTCHs that have satellite facilities.
- In sections VII. through XI. of this preamble, we discuss our determination of the LTCH PPS rates that are applicable to the LTCH PPS rate year of July 1, 2003, through June 30, 2004, including revisions to the wage index, the excluded hospital with capital market basket that will be applied to the current standard Federal rate to determine the prospective payment rates, the applicable adjustments to payments, the outlier threshold, the short-stay outlier policy for certain LTCHs, the transition period, and the budget neutrality factor.
- In section XII. of this preamble, we discuss our continuing monitoring efforts to evaluate the LTCH PPS.
- In section XIV. of this preamble, we set forth an analysis of the impact of the changes in this final rule on Medicare expenditures and on Medicare-participating LTCHs and Medicare beneficiaries.

IV. Changes in the Annual Update of the LTCH PPS

In existing regulations at § 412.535 that were issued in the August 30, 2002, final rule, we specify a schedule for publishing information on the LTCH PPS on or before August 1, which coincided with the statutorily mandated publication schedule for the IPPS. In the March 7, 2003, proposed rule, we proposed to revise § 412.535 to provide generally for a change in the annual rate update for the LTCH PPS, starting on July 1.

Section 1886(e)(5)(A) of the Act requires that, for the IPPS, the proposed rule be published in the **Federal Register** ''not later than the April 1 before each fiscal year; and the final rule, not later than the August 1 before such fiscal year.'' The statute imposes no such publication schedule for the LTCH PPS. In the August 30, 2002, final rule, we stated that we were considering changing the publication schedule of the LTCH PPS annual rulemaking cycle in order to avoid concurrent publication of annual rules for these two systems for purposes of administrative feasibility and efficiency (67 FR 55977). In considering a change in the publication schedule of the LTCH PPS final rule, we contemplated a change in the effective date for updating the Federal rates for the LTCH PPS. Therefore, in the March 7, 2003, proposed rule, we proposed changing the effective date of the annual update for the LTCH PPS from October 1 to July 1 of each year in order to facilitate a timely publication of these two significant payment updates (IPPS and LTCH PPS). Thus, the annual update of the LTCH PPS Federal rates would no longer be linked to the start of the Federal fiscal year, as is the update of the IPPS. We had proposed that this change would necessitate publication of the final rule for the

LTCH PPS by no later than June 1 of each year (proposed revised § 412.535).

In the March 7, 2003, proposed rule, we also proposed to amend § 412.503 to include a definition of ''LTCH PPS rate year''. A ''LTCH PPS rate year'' would mean the 12-month period of July 1 through June 30. In the proposed rule, we stated that we would use this period for those calculations related to updating the Federal rate for payments under the LTCH PPS. We also stated that the determination of the proposed fixed-loss threshold for outlier payment calculations, under § 412.525(a), would also be calculated based on the LTCH PPS rate year. (Section VII.C. of this final rule includes a more detailed discussion of our outlier policy.)

Proposing a change for the annual Federal rate update period for the LTCH PPS also necessitated a proposed recalculation of the excluded hospital market basket with capital estimate for the proposed forthcoming payment year, July 1, 2003, through June 30, 2004. In the August 30, 2002, final rule, we established a Federal rate of $34,956 that was computed based on the excluded hospital with capital market basket calculated for the 12-month Federal fiscal year of October 1, 2002, through September 30, 2003. As already noted, we proposed to change the Federal rate update for the LTCH PPS from the Federal fiscal year to a 12-month LTCH PPS rate year of July 1 through June 30, and the proposed rates in the March 7, 2003, proposed rule were based on this period. Because the Federal rate of $34,956 was originally computed based on a 12-month year, but in actuality will only be used for 9 months, if the proposed change in the LTCH PPS rate update year was finalized, we proposed, in the March 7, 2003, proposed rule, to make a budget neutral adjustment to the market basket update taking this 3-month differential into account in setting the Federal rate for July 1, 2003, through June 30, 2004. In addition, we proposed that the change in the 2004 LTCH PPS rate year would be budget neutral. In section VII.B.1 of this final rule, we describe this adjustment in greater detail.

In the March 7, 2003, proposed rule, we proposed to update the LTCH PPS wage index that adjusts for differences in area wages under § 412.525(c) using the FY 1999 IPPS wage data because these are the best available wage data (as discussed in section VII.C. of this preamble).

We also stated that we were proposing to recalculate the budget neutrality offset to account for the effect of the transition period and the policy allowing LTCHs to elect 100 percent Federal rate payments rather than the transition blend.

We also proposed an updated fixed-loss amount for determining outlier payments based on the updated proposed Federal rate (as discussed in section VII. of this preamble).

In section IV.C. of the March 7, 2003, proposed rule, we stated that we did not propose an update to the LTC–DRG classifications or relative weights at this time. Currently, the LTC–DRG patient classifications used by the LTCH PPS for FY 2003 are based directly on the same version of DRGs used by the IPPS, that is, GROUPER 20.0. Therefore, we did not propose any change to the timing of the annual update of the LTC–DRG classifications and relative weights. They will remain linked to the annual adjustments of the acute care hospital inpatient DRG system, which are based on the annual revisions to the ICD–9–CM codes, effective each October 1. Table 3 of the Addendum to the August 30, 2002, final rule (67 FR 56076–56084), which were reprinted as Table 3 of the Addendum to the March 7, 2003, proposed rule, contains the LTC–DRG classifications and relative weights that we proposed to continue to apply to discharges occurring during the period of July 1, 2003, through September 30, 2003. As an aid in calculating payment under the short-stay outlier policy, under § 412.529, we also are including, in column 3 of Table 3, the proposed five-sixths average length of stay that will be applied to each LTC–DRG in determining whether the LTCH stay is a short-stay outlier. The average length of stay for each DRG based on the FY 2001 MedPAR data, which were used for the FY 2003 LTCH PPS final rule, are still the best available complete LTCH discharge data available at this time.

The revised LTC–DRG classifications and relative weights for discharges occurring from October 1, 2003, through September 30, 2004, for payments under the LTCH PPS during that period would continue to be updated on a Federal fiscal year cycle as is the case for the acute care hospital inpatient DRG system. The FY 2004 DRGs and relative weights for the IPPS had not yet been proposed by the time the March 7, 2003, proposed rule was published and we were unable to propose updated LTC–DRGs and relative weights (which would be based on the proposed updated acute care hospital inpatient DRGs). Thus, we proposed that the LTC-DRG classifications and relative weights would be presented for public comment in the proposed rule for the IPPS and finalized in the IPPS final rule, with an effective date of October 1, 2003.

The proposed change in the LTCH PPS rate year for the LTCH PPS from October 1 through September 30 to July 1 through June 30 means that, although the Federal rate calculations in the August 30, 2002, final rule were based on a 12-month year, only 9 months will elapse before the July 1, 2003, update. In the March 7, 2003, proposed rule, we proposed to make a prospective adjustment to the market basket update to take into account this 3-month differential in setting the rates for July 1, 2003, through June 30, 2004.

Specifically, we explained that the proposed updates for the proposed 2004 LTCH PPS rate year would be affected as follows:

- The proposed update to the standard Federal rate calculated in accordance with § 412.523(c)(3) would be adjusted to account for updating the standard Federal rate on July 1, 2003, instead of October 1, 2003.
- The fixed-loss amount for determining high-cost outlier payments under § 412.525(a) would also be updated based on the Federal rate effective for July 1, 2003, through June 30, 2004.

In section VI.B.1 of the March 7, 2003, proposed rule, we discussed the proposed computational adjustments resulting from our proposed establishment of a LTCH PPS rate year beginning July 1, 2003, through June 30, 2004.

In the March 7, 2003, proposed rule, we stated that several provisions of the LTCH PPS would not be affected by the change in the annual rate update year for the LTCH PPS from October 1 to July 1 because these policies are not based on any of the Federal rate calculations for the LTCH PPS. Specifically, the following provisions would not be affected:

- The transition blends provided for under § 412.533(a) will not be affected because they are linked to the start of each LTCH's cost reporting period, rather than to the start of the Federal fiscal year. (LTCHs being paid under the transition blend methodology will receive those blends for the entire 5-year transition period, unless they elect payments based on 100 percent of the Federal rate.) For instance, for cost reporting periods that began on or after October 1, 2002, and before October 1, 2003, the total payment for a LTCH is 80 percent of the amount that will be calculated under the reasonable cost-based payment system for that specific LTCH and 20 percent of the Federal prospective payment amount. For cost reporting periods beginning on or after October 1, 2003, and before October 1, 2004, the total payment for a LTCH is

60 percent of the amount that will be calculated under the reasonable cost-based payment system for that specific LTCH and 40 percent of the Federal prospective payment amount.

• The 5-year phase-in of the adjustment for differences in area wage levels under § 412.525(c) will not be affected because they are linked to the start of each LTCH's cost reporting period, rather than to the start of the Federal fiscal year. For cost reporting periods that began on or after October 1, 2002, and before September 30, 2003, the applicable LTCH PPS wage index is one-fifth of the full LTCH wage index value, and for cost reporting periods beginning on or after October 1, 2003, and before September 30, 2004, the applicable LTCH PPS wage index is two-fifths of the full LTCH wage index value.

• The LTC–DRGs and their relative weights and the GROUPER will not be affected since they will continue to be updated effective October 1 through September 30 each year based on the changes to the DRGs published in the IPPS final rule.

We received eight comments regarding our proposal to change the effective date of the annual update for the LTCH PPS from October 1 to July 1 of each year.

Comment: Two commenters supported the establishment of the LTCH PPS rate year, but suggested that publishing the final rule each year by May 1, rather than by June 1 would allow LTCHs additional time for adjustments to their payment systems.

Response: We thank the commenters for endorsing the establishment of the revised LTCH PPS rate year. In changing the effective date of the LTCH PPS rate year update and the resulting publication dates of the proposed and final regulations for the system, we stated that this shift in the schedule would promote ''administrative feasibility and efficiency,'' by avoiding concurrent rulemaking and publishing with the IPPS final rule. As we have already noted, section 1886(e)(5)(A) of the Act requires that, for the IPPS, the proposed rule be published in the **Federal Register** ''not later than the April 1 before each fiscal year; and the final rule, not later than the August 1 before such fiscal year,'' but no similar requirement is imposed on the LTCH PPS.

Publishing a final rule annually by May 1 in order to allow 60-days between publication and effective date of the LTCH PPS rate update does not invalidate our stated objectives. Therefore, we will revise the regulations to require publication of the final LTCH rule by May 1 of each year unless for ''good cause'' we are unable to publish by that date, but before June 1. (We note that ''good cause'' used in this context is not coextensive and is broader than the ''good cause'' standard used in the Administrative Procedures Act (A.P.A.) at 5 U.S.C. section 553(d)(3).)

Comment: Several commenters took issue with the proposed change in the effective date of the annual update for the LTCH PPS from October 1 to July 1 of each year while still retaining the October 1 effective date for updating LTC–DRG classifications and weights. They believe that this policy change will be burdensome to LTCHs, requiring two separate updates during one cost reporting period as well as increased systems costs. These commenters urged us to remain with the existing update and publication schedule and some suggested deferring the change until full implementation of the LTCH PPS in FY 2006. One commenter raised the issue that this ''fragmentary'' implementation of individual updates will increase potential payment calculation errors for LTCHs. Another commenter urged us to pay LTCHs as a ''pass through'' for any expenses that they incur in complying with the new regulations, should they be made final.

One commenter stated that administrative feasibility and efficiency at CMS did not justify burdening LTCHs in this manner. One of the commenters asserted that the costs for updating LTCH billing systems to accommodate this change in the LTCH PPS rate year will have a considerable impact on LTCHs as Small Businesses and, therefore, should have been reviewed under the A.P.A and the Regulatory Flexibility Act (RFA).

Response: In response to these commenters, we first want to establish the fact that we have no requirement that LTCHs maintain payment systems or coding software in order to be paid under the LTCH PPS. We understand that it is common for many hospitals, consultants, and industry associations to do so, but we believe that some of the commenters who oppose the proposed change in the LTCH PPS rate year for the LTCH PPS to July 1 through June 30 while retaining October 1 through September 30 for the LTC–DRG update are oversimplifying what presently exists from a systems standpoint. Currently, all providers with cost reporting periods beginning in any month other than October already are subject to two separate updates. In addition, rate changes may occur during the fiscal year because of Congressional action for services rendered ''on or after'' the date that the rate change was effective. Additionally, ongoing audit and review procedures, provider-generated appeals procedures, and either administrative or judicial decisions also can produce hospital-level rate changes not associated with the start of a Federal fiscal year.

As noted above, we do not require providers to process claims or to determine LTC–DRG assignments, but should a LTCH or any other group choose to duplicate the PRICER software that is required for fiscal intermediaries, or the GROUPER software that we use, it is an individual business determination.

We primarily want to remind the commenters that the determination of Medicare payments based on submitted claims is solely a responsibility of each fiscal intermediary. Since payments to LTCHs will be based on claims processing done by fiscal intermediaries, we do not understand one commenter's assertion that we should not implement this policy because one of the payment consequences in establishing the LTCH PPS rate year will be to cause potential calculation errors by LTCHs.

Nowhere in our regulations are LTCHs required to maintain the systems capability to calculate payments. Therefore, although individual LTCHs and other groups may elect, for their own purposes, to purchase software packages in order to duplicate work done by our contractors, we do not agree that those costs should be paid as a pass-through by us. Moreover, we continue to believe that since the start of cost reporting periods for many LTCHs, as well as acute care hospitals, have not generally coincided with the October starting date of the Federal fiscal year, those hospitals that choose to have their own payment software are very familiar with the virtually seamless routine of inputting new numbers to their existing systems when a final rule is published. We do not believe that this policy will be unduly burdensome to such LTCHs. We also point out to the commenters that with publication of the proposed rule on March 7, 2003, we have complied with the A.P.A. As to the RFA, as stated in the proposed rule (68 FR 11259), this rule would not have a significant impact on small entities (this includes small businesses).

In response to the two comments suggesting that we delay implementation of this policy until full phase-in of the LTCH PPS in FY 2006, based on our evaluation of the above comments, we do not believe that such a decision is warranted.

Comment: One commenter suggested that if we found it necessary to

reschedule the effective date and publication cycle of one of the post-acute care prospective payment systems, we should do so for Home Health Agency (HHA) or Skilled Nursing Facilities (SNF) which are not DRG-based, and, therefore, not linked to the October 1 update.

Response: As we have noted elsewhere in this final rule, there is no statutory authority requiring the update of the LTCH PPS to coincide with the October 1 start of the Federal fiscal year. On the contrary, annual updates linked to the October 1 start of the Federal fiscal year are required for both the SNF PPS, under section 1888(e)(4)(H) of the Act (implemented in § 413.345), and the HHA PPS, under section 1895(b)(3)(B) (implemented in § 484.225). Therefore, although we do not have the authority to shift the annual update for the SNF PPS or the HHA PPS, we believe that such a policy is appropriate under section 123 of Public Law 106–113 and section 307(b) of Public Law 106–554, which conferred broad authority on the Secretary in designing and implementing a PPS for LTCHs.

Comment: One commenter noted that ''the use of two GROUPERs will not in and of itself create any hardship on LTCHs [which] will be able to adapt to this process. Most hospitals today do not have fiscal years that coincide with the federal (sic) fiscal year and must adapt to the use of two GROUPERs during their cost reporting year.'' This commenter did express concern, however, about the additional rate changes caused by the cost report reconciliation if the proposed outlier policy was finalized. The commenter suggested that we require fiscal intermediaries to update cost to charge ratios either at July 1 or October 1 in order to limit the number of changes during a 12-month period of time.

Response: We agree with the commenter's assessment of most LTCHs' (and acute care hospital's) ability to adapt to the use of two GROUPERs during one cost reporting period. Regarding rate changes brought about by changes in our outlier policy, as noted elsewhere in this final rule, all discussions of the outlier policy are presented in the IPPS high-cost outlier final rule.

In this final rule, we amend § 412.535 to indicate that information on the unadjusted Federal payment rates and a description of the methodology and data used to calculate the payment rates under the LTCH PPS will be published in the **Federal Register** on or before May 1 prior to the beginning of each LTCH PPS rate year beginning July 1, unless for good cause we are unable to make the May 1 publication date, but before June 1. We proposed that information on the DRG classification system and associated weighting factors, with the DRGs from which the LTC–DRGs are derived, would be published in the proposed IPPS rule and, ultimately, the final rule for the IPPS (the final IPPS rule is published on or before August 1 of each Federal fiscal year). Section XIV. of this final rule contains an impact analysis that reflects the impact of these changes.

V. Changes in Long-Term Care Diagnosis-Related Group (LTC–DRG) Classifications and Relative Weights

A. Background

Section 123 of Public Law 106–113 specifically requires that the PPS for LTCHs be a per discharge system with a DRG-based patient classification system reflecting the differences in patient resources and costs in LTCHs while maintaining budget neutrality. Section 307(b)(1) of Public Law 106–554 modified the requirements of section 123 of Public Law 106–113 by specifically requiring that the Secretary examine ''the feasibility and the impact of basing payment under such a system [the LTCH PPS] on the use of existing (or refined) hospital diagnosis-related groups (DRGs) that have been modified to account for different resource use of long-term care hospital patients as well as the use of the most recently available hospital discharge data.''

In accordance with section 307(b)(1) of Public Law 106–554 and § 412.515 of our existing regulations, the LTCH PPS uses information from LTCH patient records to classify patient cases into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. The LTC–DRGs used as the patient classification component of the LTCH PPS correspond to the DRGs in the IPPS. We apply weights to the existing hospital inpatient DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In a departure from the IPPS, we use low volume LTC–DRGs (less than 25 LTCH cases) in determining the LTC–DRG weights, since LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. In order to deal with the large number of low volume DRGs (all DRGs with fewer than 25 cases), we group low volume DRGs into 5 quintiles based on average charge per discharge. (A listing of the composition of low volume quintiles appears in the August 30, 2002, final rule at 67 FR 55986.) We also take into account adjustments to payments for cases in which the stay at the LTCH is five-sixths of the geometric average length of stay and classify these cases as short-stay outlier cases. (A detailed discussion of the application of the Lewin Group model that was used to develop the LTC–DRGs appears in the August 30, 2002, final rule at 67 FR 55978.)

B. Patient Classifications Into DRGs

Generally, under the LTCH PPS, Medicare payment is made at a predetermined specific rate for each discharge; that payment varies by the LTC–DRG to which a beneficiary's stay is assigned. Cases are classified into LTC–DRGs for payment based on the following six data elements:

(1) Principal diagnosis.
(2) Up to eight additional diagnoses.
(3) Up to six procedures performed.
(4) Age.
(5) Sex.
(6) Discharge status of the patient.

Upon the discharge of the patient from a LTCH, the LTCH must assign appropriate diagnosis and procedure codes from the ICD–9–CM. As of October 16, 2002, a LTCH that was required to comply with the HIPAA Administrative Simplification Standards and that had not obtained an extension in compliance with the Administrative Compliance Act (Pub. L. 107–105) is obligated to comply with the standards at 45 CFR 162.1002 and 45 CFR 162.1102. Completed claim forms are to be submitted to the LTCH's Medicare fiscal intermediary.

Medicare fiscal intermediaries enter the clinical and demographic information into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a DRG can be made. During this process, the following type of cases are selected for further development:

- Cases that are improperly coded. (For example, diagnoses are shown that are inappropriate, given the sex of the patient. Code 68.6, Radical abdominal hysterectomy, would be an inappropriate code for a male.)
- Cases including surgical procedures not covered under Medicare. (For example, organ transplant in a nonapproved transplant center.)
- Cases requiring more information. (For example, ICD–9–CM codes are required to be entered at their highest level of specificity. There are valid 3-digit, 4-digit, and 5-digit codes. That is,

code 136.3, Pneumocystosis, contains all appropriate digits, but if it is reported with either fewer or more than 4 digits, the claim will be rejected by the MCE as invalid.)

• Cases with principal diagnoses that do not usually justify admission to the hospital. (For example, code 437.9, Unspecified cerebrovascular disease. While this code is valid according to the ICD–9–CM coding scheme, a more precise code should be used for the principal diagnosis.)

After screening through the MCE, each claim will be classified into the appropriate LTC–DRG by the Medicare LTCH GROUPER. The LTCH GROUPER is specialized computer software based on the same GROUPER used by the IPPS. The GROUPER software was developed as a means of classifying each case into a DRG on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). Following the LTC–DRG assignment, the Medicare fiscal intermediary will determine the prospective payment by using the Medicare PRICER program, which accounts for hospital-specific adjustments. As provided for under the IPPS, we provide an opportunity for the LTCH to review the LTC–DRG assignments made by the fiscal intermediary and to submit additional information within a specified timeframe (§ 412.513(c)).

The GROUPER is used both to classify past cases in order to measure relative hospital resource consumption to establish the DRG weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weights during our annual update. DRG weights are based on data for the population of LTCH discharges, reflecting the fact that LTCH patients represent a different patient mix than patients in short-term acute care hospitals.

C. Organization of DRGs

The DRGs are organized into 25 Major Diagnostic Categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Accordingly, the principal diagnosis determines MDC assignment. Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER does not recognize all ICD–9–CM procedure codes as procedures that affect DRG assignment, that is, procedures which are not surgical (for example, EKG), or minor surgical procedures (for example, 86.11, Biopsy of skin and subcutaneous tissue).

The medical DRGs are generally differentiated on the basis of diagnosis. Both medical and surgical DRGs may be further differentiated based on age, sex, discharge status, and presence or absence of complications or comorbidities (CC). We note that CCs are defined by certain secondary diagnoses not related to, or not inherently a part of, the disease process identified by the principal diagnosis. (For example, the GROUPER would not recognize a code from the 800.0x series, Skull fracture, as a CC when combined with principal diagnosis 850.4, Concussion with prolonged loss of consciousness, without return to preexisting conscious level.) In addition, we note that the presence of additional diagnoses does not automatically generate a CC, as not all DRGs recognize a comorbid or complicating condition in their definition. (For example, DRG 466, Aftercare without History of Malignancy as Secondary Diagnosis, is based solely on the principal diagnosis, without consideration of additional diagnoses for DRG determination.)

In its June 2000 Report to Congress, MedPAC recommended that the Secretary ''* * * improve the hospital inpatient prospective payment system by adopting, as soon as practicable, diagnosis-related group refinements that more fully capture differences in severity of illness among patients.'' (Recommendation 3A, p. 63) We have determined it is not practical at this time to develop a refinement to inpatient hospital DRGs based on severity due to time and resource requirements. However, this does not preclude us from development of a severity-adjusted DRG refinement in the future. That is, a refinement to the list of comorbidities and complications could be incorporated into the existing DRG structure. It is also possible a more comprehensive severity adjusted structure may be created if a new code set is adopted. That is, if ICD–9–CM is replaced by ICD–10–CM (for diagnostic coding) and ICD–10-PCS (for procedure coding) or by other code sets, a severity concept may be built into the resulting DRG assignments. Of course any change to the code set would be adopted through the process established in the HIPAA Administrative Simplification provisions.

D. Update of LTC–DRGs

For FY 2003, the LTC–DRG patient classification system was based on LTCH data from the FY 2001 MedPAR file, which contained hospital bills received through March 31, 2001, for hospital discharges occurring in FY 2001. The patient classification system consisted of 510 DRGs that formed the basis of the FY 2003 LTCH PPS GROUPER. The 510 LTC–DRGs included two ''error DRGs''. As in the IPPS, we included two error DRGs in which cases that cannot be assigned to valid DRGs will be grouped. These two error DRGs are DRG 469 (Principal Diagnosis Invalid as a Discharge Diagnosis) and DRG 470 (Ungroupable). (*See* the August 1, 2001, Medicare Program final rule, Changes to the Hospital Inpatient Prospective Payment Systems and Rates and Costs of Graduate Medical Education; Fiscal Year 2002 Rates (66 FR 40062).) The other 508 LTC–DRGs are the same DRGs used in the IPPS GROUPER for FY 2003 (Version 20.0).

In the health care industry, annual changes to the ICD–9–CM codes are effective for discharges occurring on or after October 1 each year. Thus, the manual and electronic versions of the GROUPER software, which are based on the ICD–9–CM codes, are also revised annually and effective for discharges occurring on or after October 1 each year. As discussed earlier, the patient classification system for the LTCH PPS (LTC–DRGs) is based on the IPPS patient classification system (CMS–DRGs), which is updated annually and effective for discharges occurring on or after October 1 through September 30 each year. The updated DRGs and GROUPER software are based on the latest revision to the ICD–9–CM codes, which are published annually in the IPPS proposed rule and final rule. The new or revised ICD–9–CM codes are not used by the industry for either the IPPS or the LTCH PPS until the beginning of the next Federal fiscal year (effective for discharges occurring on or after October 1 through September 30). (The use of the ICD–9–CM codes in this manner is consistent with current usage and the HIPAA regulations.) October 1 is also when the changes to the CMS–DRGs and the next version of the GROUPER software becomes effective.

As indicated previously in the March 7, 2003, proposed rule, we proposed to make the annual update to the LTCH PPS effective from July 1 through June 30 each year. As a result of this change, we proposed that the LTCH PPS would

use two GROUPERS during the course of a 12-month period: One GROUPER for 3 months (from July 1 through September 30); and an updated GROUPER for 9 months (from October 1 through June 30). The need to use two GROUPERs is based upon the October 1 effective date of the updated ICD–9–CM coding system. As previously discussed, new ICD–9–CM codes may result in changes to the structure of the DRGs. In order for the industry to be on the same schedule (for both the IPPS and the LTCH PPS) for the use of the most current ICD–9–CM codes, it was necessary for us to propose to apply two GROUPER programs to the LTCH PPS. Although we did not believe that this would have any adverse effect on LTCHs, we were interested in receiving comments on this issue. LTCHs would continue to code diagnosis and procedures using the most current version of the ICD–9–CM coding system.

Currently, for Federal FY 2003, we are using Version 20.0 of the GROUPER software for both the IPPS and the LTCH PPS. For discharges beginning on October 1, 2003 (Federal FY 2004), in the March 7, 2003, LTCH PPS proposed rule, we proposed to use Version 21.0 of the GROUPER software for both the IPPS and the LTCH PPS. Thus, changes to the CMS–DRGs (the DRGs on which the LTC–DRGs are based), and their relative weights, as well as the LTC–DRGs and their relative weights that will be effective for October 1, 2003, through September 30, 2004, are presented in the IPPS FY 2004 proposed rule that was published on May 19, 2003, in the **Federal Register** (68 FR 27154). Accordingly, we will notify LTCHs of any revised LTC–DRG relative weights based on the final DRGs and Version 21.0 GROUPER for the IPPS that would be effective October 1, 2003.

Comment: Two commenters suggested that we synchronize the LTCH rate year (that is, July 1 through June 30) with the update of the LTC DRGs which occurs on October 1 by delaying the October 1 update until the following July 1. As an alternative, one commenter suggested that the LTCHs could continue to use the LTC–DRG weights determined the previous October 1 until the start of the next LTCH rate year (July 1, 2004), and conduct a readjustment for the LTCH PPS on July 1 of the following year.

Response: With regard to the commenters' suggestion to continue to use the current ICD–9–CM and DRG Grouper Version 20 until June 30, 2004, delaying the update until the following year, we believe that this suggestion is not feasible. This would require coders to use two different ICD–9–CM versions, one for IPPS use (Version 21 will be implemented October 1, 2003) and another for LTCH PPS. Moreover, the HIPPA (45 CFR part 162) requires that the ICD–9–CM be the standard medical code set and each code set is valid within the dates specified by the organization (Department of Health and Human Services) responsible for maintaining that code set. The use of other than the current code set (most recent update to the ICD–9–CM will be effective October 1, 2003) would be in direct violation of the current HIPPA requirements.

In this final rule, while we are adopting the proposed use of two GROUPER software programs over the course of the LTCH rate year, one GROUPER for 3 months (from July 1 through September 30); and an updated GROUPER for 9 months (from October 1 through June 30), the existing GROUPER and the updated GROUPER will be in effect for 12 months. These two GROUPER programs will be the same programs in use for the IPPS.

E. ICD–9–CM Coding System

1. Uniform Hospital Discharge Data Set (UHDDS) Definitions

Because the assignment of a case to a particular LTC–DRG will help determine the amount that will be paid for the case, it is important that the coding is accurate. Classifications and terminology used in the LTCH PPS are consistent with the ICD–9–CM and the UHDDS, as recommended to the Secretary by the National Committee on Vital and Health Statistics (''Uniform Hospital Discharge Data: Minimum Data Set, National Center for Health Statistics, April 1980'') and as revised in 1984 by the Health Information Policy Council (HIPC) of the U.S. Department of Health and Human Services.

We wish to point out that the ICD–9–CM coding terminology and the definitions of principal and other diagnoses of the UHDDS are consistent with the requirements of the HIPPA Administrative Simplification Act of 1996 (45 CFR part 162). Furthermore, the UHDDS has been used as a standard for the development of policies and programs related to hospital discharge statistics by both governmental and nongovernmental sectors for over 30 years. In addition, the following definitions (as described in the 1984 Revision of the UHDDS, approved by the Secretary of Health and Human Services for use starting January 1986) are requirements of the ICD–9–CM coding system, and have been used as a standard for the development of the CMS–DRGs:

- Diagnoses include all diagnoses that affect the current hospital stay.
- Principal diagnosis is defined as the condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care.
- Other diagnoses (also called secondary diagnoses or additional diagnoses) are defined as all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received or the length of stay or both. Diagnoses that relate to an earlier episode of care that have no bearing on the current hospital stay are excluded.
- All procedures performed will be reported. This includes those that are surgical in nature, carry a procedural risk, carry an anesthetic risk, or require specialized training.

We provide LTCHs with a 60-day window after the date of the notice of the initial LTC–DRG assignment to request review of that assignment. Additional information may be provided by the LTCH to the fiscal intermediary as part of that review.

2. Maintenance of the ICD–9–CM Coding System

The ICD–9–CM Coordination and Maintenance (C&M) Committee is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS) and CMS, that is charged with maintaining and updating the ICD–9–CM system. The C&M Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD–9–CM to reflect newly developed procedures and technologies and newly identified diseases. The C&M Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The NCHS has lead responsibility for the ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The C&M Committee encourages participation by health-related organizations in the above process and holds public meetings for discussion of educational issues and proposed coding changes twice a year at the CMS Central Office located in Baltimore, Maryland. The agenda and dates of the meetings

can be accessed on the CMS Web site at: *http://www.cms.gov/paymentsystems/icd9.*

All changes to the ICD–9–CM coding system affecting DRG assignment are addressed annually in the IPPS proposed and final rules. Because the DRG-based patient classification system for the LTCH PPS is based on the IPPS DRGs, these changes will also affect the LTCH PPS LTC–DRG patient classification system.

As discussed above, the ICD–9–CM coding changes that have been adopted by the C&M Committee become effective at the beginning of each Federal fiscal year, October 1. Regardless of the change to the annual update of the LTCH PPS year to July 1, coders will use the most current updated ICD–9–CM coding book from October 1 through September 30 of each year. This means that coders and LTCHs that use the updated ICD–9–CM coding system will be on the same schedule (effective October 1) as the rest of the health care industry. The newest version of ICD–9–CM is not available for use until October 1, which would be 4 months after the date that we will publish the LTCH annual payment rate update final rule. The new codes on which the LTC–DRGs are based will go into effect and be available for use for discharges occurring on or after October 1 through September 30 of each year. This annual schedule of the revision to the ICD–9–CM coding system and the change of the ICD–9–CM coding books or electronic coding programs has been in effect since the adoption of Revision 9 of the ICD in 1979.

Of particular note to LTCHs will be the invalid diagnosis codes (Table 6C) and the invalid procedure codes (Table 6D) located in the annual proposed and final rules for the IPPS. Claims with invalid codes will not be processed by the Medicare claims processing system.

3. Coding Rules and Use of ICD–9–CM Codes in LTCHs

We emphasize the need for proper coding by LTCHs. Inappropriate coding of cases can adversely affect the uniformity of cases in each LTC–DRG and produce inappropriate weighting factors at recalibration. We continue to urge LTCHs to focus on improved coding practices. Because of concerns raised by LTCHs concerning correct coding, we have asked the American Hospital Association (AHA) to provide additional clarification or instruction on proper coding in the LTCH setting. The AHA will provide this instruction via their established process of addressing questions through their publication ''Coding Clinic for ICD–9–CM''. Written questions or requests for clarification may be addressed to the Central Office on ICD–9–CM, American Hospital Association, One North Franklin, Chicago, IL 60606. A form for the question(s) is available to be downloaded and mailed on AHA's Web site at: *www.ahacentraloffice.org.* In addition, current coding guidelines are available at the National Center for Health Statistics (NCHS) Web site: *www.cdc.gov/nchs.icd9.htm.*

In conjunction with the cooperating parties (AHA, AHIMA, and NCHS), we have reviewed actual medical records and are concerned about the quality of the documentation under the LTCH PPS, as was the case at the beginning of the IPPS. We fully believe that, with experience, the quality of the documentation and coding will improve, just as it did for the IPPS. As noted above, the cooperating parties have plans to assist their members with improvement in documentation and coding issues for the LTCHs through specific questions and coding guidelines. The importance of good documentation is emphasized in the revised ICD–9–CM Official Guidelines for Coding and Reporting (October 1, 2002): ''A joint effort between the attending physician and coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation, the application of all coding guidelines is a difficult, if not impossible, task. (Coding Clinic for ICD–9–CM, Fourth Quarter 2002, page 115).

To improve medical record documentation, LTCHs should be aware that if the patient is being admitted for continuation of treatment of an acute or chronic condition, guidelines at section I.B.10 of the Coding Clinic for ICD–9–CM, Fourth Quarter 2002 (page 129) are applicable concerning selection of principal diagnosis. To clarify coding advice issued in the August 30, 2002 final rule (67 FR 55979–55981), we would like to point out that, at Guideline I.B.12, Late Effects, a late effect is considered to be the residual effect (condition produced) after the acute phase of an illness or injury has terminated (Coding Clinic for ICD–9–CM, Fourth Quarter 2002, page 129). We have received a question regarding whether a LTCH should report the ICD–9–CM code(s) for an unresolved acute condition instead of the code(s) for late effect of rehabilitation. Depending on the documentation in the medical record, either code could be appropriate in a LTCH. Since implementation of the LTCH PPS, our Medicare fiscal intermediaries have been conducting training and providing assistance to LTCHs in correct coding. We have also issued manuals containing procedures as well as coding instructions to LTCHs and fiscal intermediaries. We will continue to conduct such training and provide guidance on an as-needed basis. We also refer readers to the detailed discussion on correct coding practices in the August 30, 2002, final rule (67 FR 55979–55981).

Comment: Two commenters expressed their support for our adherence to the official ICD–9–CM coding guidelines.

Response: We appreciate the commenters support and anticipate working closely with both the AHA and the AHIMA to increase awareness of proper documentation and correct coding in the LTCH setting.

F. Changes to the Method for Updating the LTC–DRG Relative Weights

As discussed in the March 7, 2003, proposed rule, under the LTCH PPS, each LTCH will receive a payment that represents an appropriate amount for the efficient delivery of care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly. Therefore, in accordance with § 412.523(c), we adjust the standard Federal PPS rate by the LTC–DRG relative weights in determining payment to LTCHs for each case.

Under this payment system, relative weights for each LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients who are classified to each LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each LTC–DRG that represents the resources needed by an average inpatient LTCH case in that LTC–DRG. For example, cases in a LTC–DRG with a relative weight of 2 will, on average, cost twice as much as cases in a LTC–DRG with a weight of 1.

As we discussed in the August 30, 2002, final rule (67 FR 55984–55995), the LTC–DRG relative weights effective under the LTCH PPS for Federal FY 2003 were calculated using the March 2002 update of FY 2001 MedPAR data and Version 20.0 of the CMS GROUPER software. We use total days and total

charges in the calculation of the LTC–DRG relative weights.

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients and rehabilitation and wound care. Some case types (DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. Such distribution of cases with relatively high (or low) charges in specific LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, we use a hospital-specific relative value method to calculate relative weights. We believe this method removes this hospital-specific source of bias in measuring average charges. Specifically, we reduce the impact of the variation in charges across providers on any particular LTC–DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge. (*See* the August 30, 2002, final rule (67 FR 55985) for further information of the hospital-specific relative value methodology.)

In order to account for LTC–DRGs with low volume (that is, with fewer than 25 LTCH cases), we grouped those low volume LTC–DRGs into one of five categories (quintiles) based on average charges, for the purposes of determining relative weights. For FY 2003 based on the FY 2001 MedPAR data, we identified 161 LTC–DRGs that contained between 1 and 24 cases. This list of low volume LTC–DRGs was then divided into one of the five low volume quintiles, each containing a minimum of 32 LTC–DRGs (161/5 = 32 with 1 LTC–DRG as a remainder). Each of the low volume LTC–DRGs grouped to a specific quintile received the same relative weight and average length of stay using the formula applied to the regular LTC–DRGs (25 or more cases), as described below. (*See* the August 30, 2002, final rule (67 FR 55985–55988) for further explanation of the development and composition of each of the five low volume quintiles for FY 2003.)

After grouping the cases in the appropriate LTC–DRG, we calculate the relative weights by first removing statistical outliers and cases with a length of stay of 7 days or less. Next, we adjust the number of cases in each LTC–DRG for the effect of short-stay outlier cases under § 412.529. The short-stay adjusted discharges and corresponding charges were used to calculate ''relative adjusted weights'' in each LTC–DRG using the hospital-specific relative value method described above. (*See* the August 30, 2002, final rule (67 FR 55989–55995) for further details on the steps for calculating the LTC–DRG relative weights.)

We also adjust the LTC–DRG relative weights to account for nonmonotonically increasing relative weights. That is, we make an adjustment if cases classified to the LTC–DRG ''with comorbidities (CCs)'' of a ''with CC''/''without CC'' pair had a lower average charge than the corresponding LTC–DRG ''without CCs'' by assigning the same weight to both LTC–DRGs in the ''with CC''/''without CC'' pair. (*See* August 30, 2002, 67 FR 55990–55991). In addition, of the 510 LTC–DRGs in the LTCH PPS for FY 2003, based on the FY 2001 MedPAR data, we identified 159 LTC–DRGs for which there were no LTCH cases in the database. That is, no patients who would have been classified to those DRGs were treated in LTCHs during FY 2001 and, therefore, no charge data were reported for those DRGs. Thus, in the process of determining the relative weights of LTC–DRGs, we were unable to determine weights for these 159 LTC–DRGs using the method described above. However, since patients with a number of the diagnoses under these LTC–DRGs may be treated at LTCHs beginning in FY 2003, we assigned relative weights to each of the 159 ''no volume'' LTC–DRGs based on clinical similarity and relative costliness to one of the remaining 351 (510 − 159 = 351) LTC–DRGs for which we were able to determine relative weights, based on the FY 2001 claims data. (A list of the no volume LTC–DRGs and further explanation of their relative weight assignment can be found in the August 30, 2002, final rule (67 FR 55991–55994).)

Furthermore, we establish LTC–DRG relative weights of 0.0000 for heart, kidney, liver, lung, pancreas, and simultaneous pancreas/kidney transplants (LTC–DRGs 103, 302, 480, 495, 512 and 513, respectively) because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. If in the future, however, a LTCH applies for certification as a Medicare-approved transplant center, we believe that the application and approval procedure would allow sufficient time for us to propose appropriate weights for the LTC–DRGs effected. At the present time, though, we only include these six transplant LTC–DRGs in the GROUPER program for administrative purposes because since the LTCH PPS uses the same GROUPER program for LTCHs as is used under the IPPS, removing these DRGs would be administratively burdensome.

As we stated in the March 7, 2003, proposed rule, we proposed that we would continue to use the same LTC–DRGs and relative weights until October 1, 2003. Accordingly, Table 3 in the Addendum to the March 7, 2003, proposed rule lists the LTC–DRGs and their respective relative weights and arithmetic mean length of stay that we proposed would continue to be used for the period of July 1, 2003, through September 30, 2003. (This table is the same as Table 3 of the Addendum to the August 30, 2002, final rule (67 FR 56076–56084), except that it includes the proposed five-sixth of the average length of stay for short-stay outliers under § 412.529.) As we noted in section IV.D. of the March 7, 2003, proposed rule, we proposed that the final DRGs and GROUPER for FY 2004 that will be used for the IPPS and the LTCH PPS, effective October 1, 2003, would be presented in the IPPS FY 2004 final rule published no later than August 1, 2003, in the **Federal Register**.

Accordingly, we will notify LTCHs of the revised LTC–DRG relative weights for use in determining payments for discharges occurring between October 1, 2003, and September 30, 2004, based on the final DRGs and Version 21.0 GROUPER published in the IPPS rule on or before August 1, 2003.

VI. Policy Change Related to Payments to LTCHs That Are Satellite Facilities

Provisions of the Proposed Rule

In proposing the LTCH PPS (March 7, 2002, 67 FR 13416), we stated that we were considering proposing the elimination of the bed limit in § 412.22(h)(2)(i) for pre-1997 excluded hospitals once the prospective payment system was fully phased-in and all payments were based on 100 percent of the Federal prospective payment rates. This statement generated a number of comments and in the August 30, 2002, final rule (67 FR 56012), we stated our agreement with commenters who urged us to adopt a policy eliminating the bed-number restrictions for pre-1997 LTCHs with satellite facilities, as soon as a LTCH is paid based on 100 percent of the Federal prospective rate. However, we also noted that we would address a change in the policy concerning bed limits in the next update of the LTCH PPS. Therefore, in the March 7, 2003, proposed rule (68 FR 11243–11244), we proposed to eliminate the application of the bed-number restrictions set forth in § 412.22(h)(2)(i) for LTCHs established prior to 1997 with satellite facilities, effective at the start of the first cost

reporting year that a LTCH is paid under the 100 percent fully Federal prospective payment system. This will be either when a LTCH elects to be paid based on 100 percent of the Federal prospective rate or when the LTCH is fully transitioned to 100 percent of the Federal prospective rate, whichever comes first.

Section 1886(b)(3) of the Act, as amended by section 4414 of Public Law 105–33, required existing LTCHs to be subject to caps on their target amounts for cost reporting periods beginning on or after October 1, 1997, through September 30, 2002. For purposes of calculating these caps, the statute required the Secretary to ''estimate the 75th percentile of the target amounts for such hospitals within [each] class for cost reporting periods ending during fiscal year 1996.'' Section 1886(b)(3)(H) of the Act, as amended by section 121 of Public Law 106–113, directed the Secretary to provide for an appropriate wage adjustment to the caps on the target amounts for psychiatric and rehabilitation hospitals and units and LTCHs effective for cost reporting periods beginning on or after October 1, 1999 through September 30, 2002. In addition, payment limits were established for new excluded hospitals or units (excluding children's hospitals) effective October 1, 1997. For new excluded hospitals (that is, post-1997 LTCHs), section 1886(b)(7) of the Act, as added by section 4416 of Public Law 105–33, specified that the payment amount for the facility's first two 12-month cost reporting periods, for which the hospital has a settled cost report, must not exceed 110 percent of the national median of target amounts of similarly classified hospitals for cost reporting periods ending during FY 1996, updated by the hospital market basket increase percentage to the first cost reporting period in which the hospital receives payment, as adjusted by section 1886(b)(7)(C) of the Act. The result of sections 4414 and 4416 of Public Law 105–33 was a distinction between the LTCHs established prior to, and those established after 1997, with lower payment caps for the post-1997 LTCHs.

In the July 30, 1999, IPPS final rule (64 FR 41532–41533), we promulgated regulations at § 412.22(h)(2)(i) to discourage pre-1997 excluded hospitals, which had the higher caps on target amounts as discussed above (under § 413.40(c)(4)(iii)), from creating satellites rather than establishing new hospitals, in order to avoid the payment impact of the lower caps that apply to new hospitals (under § 413.40(f)(2)(ii)). In the July 30, 1999, IPPS final rule (64 FR 41490), we required that where a pre-1997 excluded hospital, such as a LTCH, established a satellite facility and, in doing so, its total beds, in both the parent hospital (or unit) and the satellite facility, exceeded the number of State-licensed and Medicare-certified beds in the parent hospital on the last day of its last cost reporting period beginning before October 1, 1997, the excluded hospital would be paid under the inpatient DRG system, instead of receiving payment as an excluded hospital under the reasonable cost-based payment system. Although the excluded hospital could ''transfer'' beds from the parent facility to the satellite, it could not increase its total bed capacity (at the parent and satellite(s)) beyond the level the hospital had in the most recent cost reporting period beginning before October 1, 1997, and still be paid as a hospital excluded from the IPPS. However, no such limitation was imposed on a LTCH established after October 1, 1997. Since this type of hospital would have already been subject to the lower payment limit of 110 percent of the national median of target amounts for similarly classified hospitals under § 413.40(f)(2)(ii), it would not benefit by establishing a satellite facility instead of a separate free-standing hospital, as would a pre-1997 LTCH.

The rationale for applying the bed-limit provision only on pre-1997 hospitals was the potential for gaming by those hospitals, by creating a satellite facility with a higher TEFRA target cap where, in reality, the satellite facility should have been a separately certified excluded facility, which would have been subject to the lower cap on payments to new (post-1997) facilities paid under the TEFRA system. Once the LTCH is paid based on 100 percent of the Federal prospective rate, however, the LTCH will no longer be subject to TEFRA caps and LTCH prospective payments will be the same regardless of when the LTCH was established. Therefore, consistent with the March 7, 2003, proposed rule, we are eliminating the bed-limit provision once a LTCH is paid based on 100 percent of the LTCH Federal PPS rate. Finally, under this policy, the bed limitation on ''existing'' LTCHs will, however, continue to apply to those LTCHs while they are paid based on the transition blend, and, therefore, continue to receive a percentage of their payments based on the reasonable cost-based payment rules, until these hospitals are paid based on 100 percent of the Federal prospective payment rate.

Comment: Several commenters expressed their strong support for our proposal to eliminate the bed number limitation for pre-1997 LTCHs with satellite facilities for those LTCHs receiving 100 percent of the Federal rate. One commenter recommended that the bed number limitation should also be eliminated for the IRFs since they are now receiving payment at 100 percent of the Federal rate.

Response: We appreciate the strong endorsement in response to this proposed change. Regarding the commenter who recommended eliminating the bed size limitation for IRFs, we would suggest that the commenter look to the IRF proposed rule that was published on May 16, 2003 (68 FR 26785).

Accordingly, in this final rule, we are adopting the proposal to eliminate the bed size limitation for pre-1997 LTCHs with satellite facilities once the LTCH is paid at 100 percent of the Federal rate. We note that in the preamble to the March 7, 2003, proposed rule, we stated the two circumstances under which a LTCH would be paid based on 100 percent of the Federal rate, which are for the start of the first cost reporting period that a LTCH elects fully Federal payment, as set forth in § 412.533(c) or when the LTCH PPS is fully phased-in after the transition period. We inadvertently omitted the second circumstance in the proposed regulation text at § 412.22(h)(6), therefore, we are revising that section to reflect this policy.

VII. Changes to the LTCH PPS Rates for the 2004 LTCH PPS Rate Year

A. Overview of the Development of the Payment Rates

The LTCH PPS was effective for a LTCH's first cost reporting period beginning on or after October 1, 2002. Effective with that cost reporting period, LTCHs are paid, during a 5-year transition period, on the basis of an increasing proportion of the LTCH PPS Federal rate and a decreasing proportion of a hospital's payment under reasonable cost-based payment system, unless the hospital makes a one-time election to receive payment based on 100 percent of the Federal rate (*see* § 412.533). New LTCHs (as defined at § 412.23(e)(4)) are paid based on 100 percent of the Federal rate, with no phase-in transition payments.

The basic methodology for determining LTCH PPS Federal prospective payment rates is set forth in the regulations at §§ 412.515 through 412.532. Below we discuss the proposed factors used to update the LTCH PPS standard Federal rate for the proposed 2004 LTCH PPS rate year published in

the March 7, 2003, proposed rule. We also discuss the factors used to establish the final update to the LTCH PPS standard Federal rate for the 2004 LTCH PPS rate year in this final rule, which will be effective for LTCHs paid under the LTCH PPS for discharges occurring on or after July 1, 2003, through June 30, 2004. In the final rule published on August 30, 2002 (67 FR 56029–56031), for cost reporting periods beginning on or after October 1, 2002 (FY 2003), we computed the LTCH PPS standard Federal payment rate by updating the best available (FY 1998 or FY 1999) Medicare inpatient operating and capital costs per case data, using the excluded hospital market basket.

Section 123(a)(1) of Public Law 106–113 requires that the PPS developed for LTCHs be budget neutral. Therefore, in calculating the standard Federal rate for FY 2003 under § 412.523(d)(2), we set total estimated PPS payments equal to estimated payments that would have been made under the reasonable cost-based payment methodology had the PPS for LTCHs not been implemented. Section 307(a) of Public Law 106–554 specified that the increases to the hospital-specific target amounts and cap on the target amounts for LTCHs for FY 2002 provided for by section 307(a)(1) of Public Law 106–554 shall not be taken into account in the development and implementation of the LTCH PPS. In addition, the statute as amended by section 122 of Public Law 106–113 provides for enhanced bonus payments for LTCHs for two years, FY 2001 and FY 2002. Furthermore, as specified at § 412.523(d)(1), the standard Federal rate is reduced by an adjustment factor to account for the estimated proportion of outlier payments under the LTCH PPS to total LTCH PPS payments (8 percent). For further details on the development of the FY 2003 standard Federal rate, *see* the August 30, 2002, final rule (67 FR 56027–56037). Under the existing regulations at § 412.523(c)(3)(ii) for fiscal years after FY 2003, we update the standard Federal rate annually to adjust for the most recent estimate of the projected increases in prices for LTCH inpatient hospital services.

B. Update to the Standard Federal Rate for the 2004 LTCH PPS Rate Year

In the August 30, 2002, final rule (67 FR 56033), we established a LTCH PPS standard Federal rate of $34,956.15 for FY 2003. As discussed in the March 7, 2003, proposed rule (68 FR 11248), based on the most recent estimate of the excluded hospital with capital market basket, adjusted to account for the change in the rate year update cycle for the LTCH PPS rates, we proposed that the LTCH PPS standard Federal rate, effective from July 1, 2003, through June 30, 2004, would be $35,726.64. Based on updated data, including the most recent estimate of the excluded hospital with capital market basket adjusted to account for the change in the rate year update cycle for the LTCH PPS rates, and the policies described in this final rule, the LTCH PPS standard Federal rate, effective from July 1, 2003, through June 30, 2004, is $35,726.18 (as discussed below).

In the discussion that follows, we explain how we developed the update to the final standard Federal rate for the 2004 LTCH PPS rate year in this final rule. The final standard Federal rate for the 2004 LTCH PPS rate year is calculated based on the final update factor of 1.0220. Thus, we estimate that the final standard Federal rate for the 2004 LTCH PPS rate year will increase 2.2 percent compared to the FY 2003 standard Federal rate.

1. Standard Federal Rate Update

In the August 30, 2002, final rule, we established at § 412.523 that, for years after FY 2003, the annual update to the LTCH PPS standard Federal rate will be equal to the percentage change in the excluded hospital with capital market basket (described in further detail below). As we discussed in the August 30, 2002, final rule (67 FR 56087), in the future we may propose to develop a framework to update payments to LTCHs that would account for other appropriate factors that affect the efficient delivery of services and care provided to Medicare patients. As we stated in the March 7, 2003, proposed rule (68 FR 11244), because the LTCH PPS has only recently been implemented (for cost reporting periods beginning on or after October 1, 2002), we have not yet collected sufficient data to allow for the analysis and development of an update framework under the LTCH PPS. Therefore, in that same proposed rule, we did not propose an update framework for the 2004 LTCH PPS rate year. However, we noted that a conceptual basis for the proposal of developing an update framework in the future can be found in Appendix B of the August 30, 2002, final rule (67 FR 56086–56090).

a. Description of the Market Basket for LTCHs for the 2004 LTCH PPS Rate Year

A market basket has historically been used in the Medicare program to account for price increases of the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. The development of the LTCH PPS standard Federal rate is discussed in further detail in the August 30, 2002 final rule (67 FR 56027–56037).

Under the reasonable cost-based payment system, the excluded hospital market basket was used to update the hospital-specific limits on payment for operating costs of LTCHs. The excluded hospital market basket is based on operating costs from FY 1992 cost report data and includes data from Medicare-participating long-term care, rehabilitation, psychiatric, cancer, and children's hospitals. Since LTCHs' costs are included in the excluded hospital market basket, this market basket index, in part, also reflects the costs of LTCHs. However, in order to capture the total costs (operating and capital-related) of LTCHs, we added a capital component to the excluded hospital market basket for use under the LTCH PPS. We refer to this index as the excluded hospital with capital market basket.

As we discussed in both the August 30, 2002, final rule (67 FR 56016 and 56086–56086) and the March 7, 2003, proposed rule (68 FR 11245–11247), beginning with the implementation of the LTCH PPS in FY 2003, the excluded hospital with capital market basket based on FY 1992 Medicare cost report data has been used for updating payments to LTCHs. The FY 1992-based market basket reflected the distribution of costs in FY 1992 for Medicare-participating freestanding rehabilitation, long-term care, psychiatric, cancer, and children's hospitals. This information was derived from the FY 1992 Medicare cost reports. A full discussion of the methodology and data sources used to construct the FY 1992-based excluded hospital with capital market basket is included in Appendix A of the August 30, 2001, final rule (67 FR 56085–56086). In the March 7, 2003, proposed rule, we proposed to revise and rebase the excluded hospital with capital market basket, using more recent data, that is, using FY 1997 base year data beginning with the proposed 2004 LTCH PPS rate year.

As we stated in the March 7, 2003, proposed rule (68 FR 11245–11247), we believe it was appropriate to propose to revise and rebase the LTCH PPS market basket based on the most recent complete data available (FY 1997) because these data would more accurately reflect LTCHs' current costs. Furthermore, we noted that this proposed revising and rebasing of the LTCH PPS market basket from an FY

1992 base year to a FY 1997 base year would be consistent with the rebasing of both the hospital inpatient market basket used under the IPPS and the excluded hospital market basket used to update the target amounts under the reasonable cost-based payment system for FY 2003, as discussed in the August 1, 2002, IPPS final rule (67 FR 50032–50047). We received no comments on the proposed revising and rebasing of the LTCH PPS market basket. Therefore, in this final rule, we are adopting the FY 1997-based excluded hospital with capital market basket as the LTCH PPS market basket beginning with the 2004 LTCH PPS rate year. Below we are providing a discussion of the development of the FY 1997-based excluded hospital with capital market basket, as we presented in the March 7, 2003, proposed rule (68 FR 11245–11247).

The operating portion of the FY 1997-based excluded hospital with capital market basket that we are using under the LTCH PPS beginning with the 2004 LTCH PPS rate year is derived from the FY 1997-based excluded hospital market basket used under the reasonable cost-based payment system. The methodology we used to develop the operating portion of the market basket under the LTCH PPS is the same methodology used to revise and rebase the excluded hospital market basket used under the reasonable cost-based payment system, which is described in greater detail in the August 1, 2002, IPPS final rule (67 FR 50042–50044). In brief, the operating cost category weights in the FY 1997-based excluded market basket add up to 100.0. These weights were determined based on FY 1997 Medicare cost report data, the 1997 Business Expenditure Survey, and the 1997 Annual Input-Output data from the Bureau of the Census. In determining the FY 1997-based market basket, as we discussed in the March 7, 2003, proposed rule (68 FR 11245–11247), we also revised the market basket by making the same two methodological revisions that we established when we revised and rebased the hospital inpatient market basket and the excluded hospital market basket in the August 1, 2002, IPPS final rule—(1) Changing the wage and benefit price proxies to use the Employment Cost Index (ECI) wage and benefit data for hospital workers; and (2) adding a cost category for blood and blood products.

When we add the weight for capital costs to the excluded hospital market basket, the sum of the operating and capital weights must still equal 100.0. Based on data from FY 1997 Medicare cost reports for excluded hospitals, the capital cost weight is 8.968 percent. Because capital costs account for 8.968 percent of total costs for excluded hospitals in FY 1997, operating costs must, therefore, account for 91.032 percent (100 percent minus 8.968 percent). Each operating cost category weight in the FY 1997-based excluded hospital market basket from the August 1, 2002, IPPS final rule (67 FR 50442–50444) was multiplied by 0.91032 to determine its weight in the FY 1997-based excluded hospital with capital market basket.

As we discussed in the March 7, 2003, proposed rule (68 FR 11245–11247), the aggregate capital component of the FY 1997-based excluded hospital market basket (8.968 percent) was determined from the same set of Medicare cost reports used to derive the operating component. The detailed capital cost categories of depreciation, interest, and other capital expenses were also determined using those Medicare cost reports. We needed to determine two sets of weights for the capital portion of the proposed revised and rebased market basket. The first set of weights identifies the proportion of capital expenditures attributable to each capital cost category; the second set represents relative vintage weights for depreciation and interest. The vintage weights identify the proportion of capital expenditures that is attributable to each year over the useful life of capital assets within a cost category (*see* 67 FR 50046–50047, August 1, 2002, for a discussion of how vintage weights are determined).

The cost categories, price proxies, and base-year FY 1992 and FY 1997 weights for the excluded hospital with capital market basket used under the LTCH PPS beginning with the 2004 LTCH PPS rate year are presented below in Table I. The vintage weights for the FY 1997-based excluded hospital with capital market basket are presented below in Table II.

TABLE I.— EXCLUDED HOSPITAL WITH CAPITAL INPUT PRICE INDEX (FY 1992-BASED AND FY 1997-BASED) STRUCTURE AND WEIGHTS

Cost category	Price/wage variable	Weights (%) Base-Year FY 1992[1,2]	Weights (%) Base-Year FY 1997[1,2]
Total		100.000	100.000
Compensation		57.935	57.579
Wages and Salaries	ECI—Wages and Salaries, Civilian Hospital Workers	47.417	47.335
Employee Benefits	ECI—Benefits, Civilian Hospital Workers to Capture Total Costs.	10.519	10.244
Professional fees	ECI—Compensation: Professional & Technical	1.908	4.423
Utilities		1.524	1.180
Electricity	PPI—Commercial Electric Power	0.916	0.726
Fuel Oil, Coal, etc	PPI—Commercial Natural Gas	0.365	0.248
Water and Sewerage	CPI–U—Water & Sewerage Maintenance	0.243	0.206
Professional Liability	CMS—Professional Liability Insurance Premiums Index	0.983	0.733
All Other Products and		28.571	27.117
All Other Products		22.027	17.914
Pharmaceuticals	PPI—Ethical (Prescription) Drugs	2.791	6.318
Food: Direct Purchase	PPI—Processed Foods and Feeds	2.155	1.122
Food: Contract	CPI–U—Food Away from Home	0.998	1.043
Chemicals	PPI—Industrial Chemicals	3.413	2.133
Blood and Blood	PPI—Blood and Blood Derivatives, Human Use		0.748
Medical Instruments	PPI—Medical Instruments & Equipment	2.868	1.795
Photographic Supplies	PPI—Photographic Supplies	0.364	0.167
Rubber and Plastics	PPI—Rubber & Plastic Products	4.423	1.366
Paper Products	PPI—Converted Paper and Paperboard Products	1.984	1.110
Apparel	PPI—Apparel	0.809	0.478
Machinery and	PPI—Machinery & Equipment	0.193	0.852

TABLE I.— EXCLUDED HOSPITAL WITH CAPITAL INPUT PRICE INDEX (FY 1992-BASED AND FY 1997-BASED) STRUCTURE AND WEIGHTS—Continued

Cost category	Price/wage variable	Weights (%) Base-Year FY 1992[1,2]	Weights (%) Base-Year FY 1997[1,2]
Miscellaneous	PPI—Finished Goods Less Food and Energy	2.029	0.783
All Other Services		6.544	9.203
Telephone	CPI–U—Telephone Services	0.574	0.348
Postage	CPI–U—Postage	0.268	0.702
All Other: Labor	ECI—Compensation for Private Service Occupations	4.945	4.453
All Other: Non-Labor	CPI–U—All Items	0.757	3.700
Capital-Related Costs		9.080	8.968
Depreciation		5.611	5.586
Building & Fixed	Boeckh-Institutional Construct. Index—Vintage Weighted (23)	3.570	3.503
Movable Equipment	PPI—Machinery & Equipment—Vintage Weighted (11 Years)	2.041	2.083
Interest Costs		3.212	2.682
Government/Nonprofit	Yield on Domestic Municipal Bonds (Bond Buyer 20 Bonds)—Vintage Weighted (23 years).	2.730	2.280
For-profit	Yield on Moody's Aaa Bonds—Vintage Weighted (23 Years)	0.482	0.402
Other Capital-Related Costs	CPI–U—Residential Rent	0.257	0.699

[1] The operating cost category weights in the excluded hospital market basket described in the August 1, 2002 IPPS final rule (67 FR 50042–50044) add to 100.0. When we add an additional set of cost category weights (total capital weight = 8.968 percent) to this original group, the sum of the weights in the new index must still add to 100.0. Capital costs account for 8.968 percent of the market basket; operating costs account for 91.032 percent. Each weight in the FY 1997-based excluded hospital market basket from the August 1, 2002 IPPS final rule (67 FR 50042–50044) was multiplied by 0.91032 to determine its weight in the FY 1997-based excluded hospital with capital market basket.

[2] Weights may not sum to 100.0 due to rounding.

TABLE II.—EXCLUDED HOSPITAL WITH CAPITAL INPUT PRICE INDEX (FY 1997) VINTAGE WEIGHTS

Year (from farthest to most recent)*	Building and fixed equipment (23-year weights)*	Movable equipment (11-year weights)*	Interest: capital-related (23-year weights)*
1	0.018	0.063	0.007
2	0.021	0.068	0.009
3	0.023	0.074	0.011
4	0.025	0.080	0.012
5	0.026	0.085	0.014
6	0.028	0.091	0.016
7	0.030	0.096	0.019
8	0.032	0.101	0.022
9	0.035	0.108	0.026
10	0.039	0.114	0.030
11	0.042	0.119	0.035
12	0.044		0.039
13	0.047		0.045
14	0.049		0.049
15	0.051		0.053
16	0.053		0.059
17	0.057		0.065
18	0.060		0.072
19	0.062		0.077
20	0.063		0.081
21	0.065		0.085
22	0.064		0.087
23	0.065		0.090
Total	1.0000	1.0000	1.0000

* Weights may not sum to 1.000 due to rounding.

Table III. compares the FY 1992-based excluded hospital with capital market basket to the FY 1997-based excluded hospital with capital market basket. As shown in the table and as we discussed in the March 7, 2003, proposed rule (68 FR 11247), the revised and rebased market basket grows slightly faster over the FY 1999–2001 period than the FY 1992-based market basket. The major reason for this was the switching of the wage and benefit proxy to the ECI for hospital workers from the previous occupational blend. This revision had a similar impact on the IPPS and excluded market baskets, as described in the August 1, 2002, IPPS final rule (67 FR 50043–50047).

TABLE III.—PERCENT CHANGES IN THE FY 1992-BASED AND FY 1997-BASED EXCLUDED HOSPITAL WITH CAPITAL MARKET BASKETS, FYS 1999–2004

Fiscal year (FY)	Percentage change	
	FY 1992-based excluded hospital market basket	Rebased FY 1997-based excluded market basket
1999	2.3	2.7
2000	3.4	3.1
2001	3.9	4.0
2002	2.7	3.6
Average historical	3.1	3.4
2003	3.1	3.7
2004	2.9	3.3
Average forecast	3.0	3.5

In the August 30, 2002, LTCH PPS final rule (67 FR 56016 and 56085–56086), we discussed why we believe the excluded hospital with capital market basket provides a reasonable measure of the price changes facing LTCHs. However, as we discussed in the March 7, 2003, proposed rule (68 FR 11247), we have been researching the feasibility of developing a market basket specific to LTCH services. This research has included analyzing data sources for cost category weights, specifically the Medicare cost reports, and investigating other data sources on cost, expenditure, and price information specific to LTCHs. Based on this research, we did not propose to develop a market basket specific to LTCH services.

As we stated in the March 7, 2003, proposed rule (68 FR 11247), our analysis of the Medicare cost reports indicates that the distribution of costs among major cost report categories (wages, pharmaceuticals, capital) for LTCHs is not substantially different from the 1997-based excluded hospital with capital market basket. Data on other major cost categories (benefits, blood, contract labor) that we would like to analyze were excluded by many LTCHs in their Medicare cost reports. An analysis based on only the data available to us for these cost categories presented a potential problem since no other major cost category weight would be based on LTCH data.

Furthermore, as we discussed in the March 7, 2003, proposed rule (68 FR 11247), we conducted a sensitivity analysis of annual percent changes in the market basket when the weights for wages, pharmaceuticals, and capital in LTCHs were substituted into the excluded hospital with capital market basket. Other cost categories were recalibrated using ratios available from the IPPS market basket. On average between FY 1995 and FY 2002, the excluded hospital with capital market basket shows increases at nearly the same average annual rate (2.9 percent) as the market basket with LTCH weights for wages, pharmaceuticals, and capital (2.8 percent). This difference is less than the 0.25 percentage point criterion that determines whether a forecast error adjustment is warranted under the IPPS update framework.

We believe that an excluded hospital with capital market basket adequately reflects the price changes facing LTCHs. In the March 7, 2003, proposed rule, we stated that we would continue to solicit comments about issues particular to LTCHs that should be considered in relation to the FY 1997-based excluded hospital with capital market basket and to encourage suggestions for additional data sources that may be available.

As we noted above, we received no comments on the proposed revising and rebasing of the LTCH PPS market basket. Accordingly, in this final rule, we are adopting the FY 1997-based excluded hospital with capital market basket as the LTCH PPS market basket for application beginning with the 2004 LTCH PPS rate year.

b. LTCH Market Basket Increase for the 2004 LTCH Rate Year

As we discussed in the March 7, 2003, proposed rule (68 FR 11247), for LTCHs paid under the LTCH PPS, we proposed that the 2004 rate year update would apply to discharges occurring from July 1, 2003, through June 30, 2004. Because we are changing the timeframe of the LTCH PPS standard Federal rate annual update, as we discuss in section IV. of this preamble, we needed to calculate an update factor that will reflect this change in the update cycle. Presently, the current rate cycle is October 1, 2002, through September 30, 2003. This means that the FY 2003 standard Federal rate ($34,956.15; *see* the August 30, 2002, final rule (67 FR 56033)) was determined based on the market basket increase through September 30, 2003. As we explained in the March 7, 2003, proposed rule (68 FR 11247), since we proposed to change the rate update cycle and, therefore, update the standard Federal rate 3 months early (that is, July 1, 2003, instead of October 1, 2003), we needed to propose an adjustment to the projected full (12-month) market basket increase to eliminate the projected increase for the 3-month overlapping period (July 1, 2003, through September 30, 2003).

Thus, we need to account for the fact that the FY 2003 standard Federal rate of $34,956.15 already includes an update for the 3-month period from July 1, 2003, through September 30, 2003. In the absence of this proposed change, as we discussed in the March 7, 2003, proposed rule (68 FR 11247–11248), the update for FY 2004 would have been calculated using the estimated increase between FY 2003 and FY 2004. For the proposed update for the proposed 2004 LTCH PPS rate year, we calculated the estimated increase between FY 2003 and the proposed 2004 LTCH PPS rate year. As we discussed in that same proposed rule, based on the fourth quarter 2002 forecast of the proposed revised and rebased FY 1997-based excluded hospital with capital market basket, we determined that the projected market basket increase for the 3-month period of July 1, 2003, through September 30, 2003, would be 0.8 percentage points. The projected market basket increase for this 3-month period (0.8 percent) was already included in the FY 2003 standard Federal rate and, therefore, needed to be deducted from the projected market basket increase for the 12-month period of July 1, 2003, through June 30, 2004 (3.3 percent), in order to account for the proposed change in the update cycle. Therefore,

in the March 7, 2003, proposed rule (68 FR 11248), based on Global Insights' (formerly DRI–WEFA) fourth quarter 2002 forecast of the proposed revised and rebased FY 1997-based excluded hospital with capital market basket we proposed an update of 2.5 percent for the 2004 LTCH PPS rate year.

We received no comments on our proposed methodology for calculating the market basket increase for the 2004 LTCH PPS rate year. Therefore, consistent with our historical practice of estimating market basket increases, based on Global Insights' (formerly DRI–WEFA) first quarter 2003 forecast of the revised and rebased FY 1997-based excluded hospital with capital market basket, in this final rule using the methodology described above, we determined an update of 2.5 percent (as shown in Table IV. below) for the 2004 LTCH PPS rate year.

TABLE IV.—CALCULATION OF MARKET BASKET INCREASE FOR THE 2004 LTCH PROSPECTIVE PAYMENT SYSTEM RATE YEAR

	Percent
Full 12-month market basket with capital increase	3.3
Adjustment for the change in the update cycle *	−0.8
2004 rate year market basket increase **	2.5

* Projected market basket increase for the 3-month period of July 1, 2003, through September 30, 2003, already included in the FY 2003 standard Federal rate.

** Projected market basket increase for the 12-month period of July 1, 2003, through June 30, 2004, from FY 2003.

In addition, as we discussed in the March 7, 2003, proposed rule (68 FR 11248), based on the best available data for 194 LTCHs, we estimated that LTCH prospective payment system payments would be approximately $1.960 billion for the proposed 2004 LTCH PPS rate year. Furthermore, as we discussed in the August 30, 2002, final rule (67 FR 56027), we proposed that the proposed change to the annual update of the FY 2003 factors and rates from a rate year beginning October 1, 2003, to a rate year beginning July 1, 2003, would maintain budget neutrality. In that same final rule, we explained that, as required by statute, total estimated LTCH PPS payments in FY 2003 will equal estimated payments that would have been made under the reasonable cost-based principles if the LTCH PPS were not implemented. Therefore, in order to maintain budget neutrality for the proposed change in the rate update cycle, in the March 7, 2003, proposed rule (68 FR 11248), under proposed § 412.523(c)(3)(ii), we proposed to adjust the standard Federal rate by a factor of 0.997 (($1.960 billion − $5.66 million)/$1.960 billion) or − 0.003 to account for the resulting additional cost of $5.66 million to the FY 2003 Federal budget that we estimated based on the most recent data for the 3-month period from July 1, 2003, through September 30, 2003. Also, in that same proposed rule, we proposed to revise this adjustment factor in this final rule based on the best available data.

In this final rule, based on the best available data for 194 LTCHs, we estimated that LTCH prospective payment system payments would be approximately $1.960 billion for the 2004 LTCH PPS rate year. As we proposed in the March 7, 2003, proposed rule (68 FR 11248), the proposed change to the annual update of the FY 2003 factors and rates from a rate year beginning October 1, 2003, to a rate year beginning July 1, 2003, would be budget neutral because, as we noted above, total estimated LTCH PPS payments in FY 2003 must equal estimated payments that would have been made under the reasonable cost-based principles, if the LTCH PPS were not implemented. Therefore, in order to maintain budget neutrality for the change in the rate update cycle, in this final rule based on updated data and the final policies discussed in this final rule, under § 412.523(c)(3)(ii), we have adjusted the 2004 LTCH PPS rate year standard Federal rate by a factor of 0.997 (($1.960 billion − $5.68 million)/$1.960 billion) or − 0.003 to account for the resulting additional cost of $5.68 million to the FY 2003 Federal budget that we estimated based on the most recent data for the 3-month period from July 1, 2003, through September 30, 2003, for 194 LTCHs.

In the March 7, 2003, proposed rule (68 FR 11248), we proposed to update the current standard Federal rate ($34,956.15) established in the August 30, 2002, final rule (67 FR 56033) by 2.2 percent (2.5 percent minus 0.3 percent) for discharges paid under the LTCH PPS that occur on or after July 1, 2003, through June 30, 2004. The proposed update represented the most recent estimate of the increase in the excluded hospital with capital market basket for the proposed 2004 LTCH PPS rate year, adjusted by the above described factor to transition to the proposed change in the rate update cycle to July 1, and is based on the best available data for 194 LTCHs.

Comment: One commenter stated that the proposed 2.2 percent increase in the LTCH PPS standard Federal rate from $34.956.15 to $35,726.64 does not reflect the inflation of input hospital costs.

Response: As noted above, the proposed update of 2.2 percent was based on the most recent estimate of the increase in the proposed excluded hospital with capital market basket for the proposed 2004 LTCH PPS rate year, adjusted as explained above to transition to the proposed change in the rate update cycle to July 1. The proposed update and adjustment were based on the best available data for 194 LTCHs contained in our database. The most recent estimate of the increase in the excluded hospital with capital market basket for the 2004 LTCH PPS rate year was determined in a manner that is consistent with our historical practice of estimating market basket increases for other Medicare prospective payment systems (inpatient acute care hospitals, IRFs, SNFs, and HHAs), that is, using Global Insights' (formerly DRI-WEFA) most recent forecast of the applicable PPS market basket. Furthermore, we believe it is appropriate to adjust the most recent estimate of the 12-month increase in the LTCH PPS market basket for July 1, 2003, through June 30, 2004, because as we explained above, the FY 2003 standard Federal rate ($34,956.15) already includes inflation for the 3-month period from July 1, 2003, through September 30, 2003. Thus, the projected market basket increase for this 3-month period needs to be deducted from the projected market basket increase for the 12-month period of July 1, 2003, through June 30, 2004.

In addition, as we explained above, it is necessary that the market basket increase be further adjusted so that the proposed change in updating the FY 2003 rate 3 months early (July 1, 2003, instead of October 1, 2003) be budget neutral, as mandated by section 123 of Public Law 106–113 (that is, total estimated LTCH PPS payments in FY 2003 will equal estimated payments that would have been made under the reasonable cost-based principles if the LTCH PPS were not implemented). Therefore, we believe that the proposed methodology for determining the proposed 2.2 percent update for the 2004 LTCH PPS rate year is appropriate.

Comment: A few commenters stated that the proposed 2004 LTCH PPS rate year standardized amount of $35,726.64 is based on the identification of costs related to short-stay outlier cases which have been derived from cost-to-charge ratios that do not account for the proposed change to the short-stay outlier policy under proposed § 412.529. Specifically, in the March 7, 2003,

proposed rule (68 FR 11253), we proposed that fiscal intermediaries would use either the most recently settled cost report or most recent tentative settled cost report, whichever is later, in determining a LTCH's cost-to-charge ratio used in determining short-stay outlier payments. We also proposed, in that same proposed rule, that the applicable statewide average cost-to-charge ratio would only be applied when a LTCH's cost-to-charge ratio exceeds the ceiling (but not when a LTCH's cost-to-charge ratio falls below the floor). The commenters express concern that the proposed change to the short-stay outlier policy is not reflected in the proposed 2004 LTCH PPS rate year standard Federal rate and, therefore, CMS fails to maintain budget neutrality.

In addition, one of the commenters noted that the cost-to-charge ratio data posted on the web for the 2004 rate year proposed rule (published on March 7, 2003, in the **Federal Register**) differed for many LTCHs from the cost-to-charge ratio data posted on the web for the FY 2003 final rule (published August 30, 2002, in the **Federal Register**). The commenter believes that the observed change in the LTCHs' cost-to-charge ratios is due to the proposed change to allow fiscal intermediaries to use either the most recently settled cost report or most recent tentative settled cost report, whichever is later, in computing a LTCH's cost-to-charge ratio used to determine both short-stay outlier and high-cost outlier payments.

Response: The commenters have raised concerns that we have not taken into account the proposed changes to the policies for determining short-stay and high-cost outlier payments in calculating the proposed update to the standard Federal rate for the proposed 2004 LTCH PPS rate year. As we discuss in greater detail below in section VII.B.3. of this preamble, at this time, the finalized changes to the proposed high-cost outlier and short-stay outlier policies presented in the March 7, 2003, proposed rule (68 FR 11250–11253) are not yet effective. Accordingly, in establishing the final update factor for the 2004 LTCH PPS rate year in this final rule, we used the high-cost outlier and short-stay outlier policies established in the August 30, 2002, final rule (67 FR 55995–56000 and 56022–56027).

Nevertheless, based on the comments, there appears to be a misconception among the commenters regarding the methodology for updating the LTCH PPS standard Federal rate. While we are not finalizing the proposed changes to the outlier policies in this final rule, we believe that it is important to clarify the methodology used in the March 7, 2003, proposed rule to determine the proposed update factor for the proposed 2004 LTCH PPS rate year.

In the August 30, 2002, final rule, we established at § 412.523(c)(3)(ii) that for fiscal years after FY 2003, we update the standard Federal rate annually to adjust for the most recent estimate of the projected increases in prices for LTCH inpatient hospital services. That is, for years after FY 2003, the annual update to the LTCH PPS standard Federal rate will be equal to the percentage change in the excluded hospital with capital market basket.

In determining the proposed update for the proposed 2004 LTCH PPS rate year, we adjusted the projected proposed LTCH market basket increase in order to maintain budget neutrality (in addition to an adjustment to account for the transition to the proposed change in the LTCH PPS rate year) by accounting for the estimated increase in payments during the remainder of FY 2003 (July 1, 2003, through September 30, 2003) that would result from updating the factors and rates 3 months early (July 1, 2003, instead of October 1, 2003). This budget neutrality adjustment to the proposed rate update included the effect of the proposed increase in the LTCH PPS standard Federal rate, the effect of proposed change in the wage index values, and the effect of the proposed change in the short-stay outlier policy and high-cost outlier policy (specifically the elimination of assigning the statewide average cost-to-charge ratio when a LTCH's cost-to-charge ratio falls below the floor).

As we discussed in the March 7, 2003, proposed rule (68 FR 11251), in calculating short-stay outlier and high-cost outlier payments we currently use cost-to-charge ratios based on the latest available cost report data from HCRIS and corresponding MedPAR claims data from FYs 1998, 1999, and 2000. In some cases the latest available cost report data from HCRIS is from settled cost reports; however, in other instances, the latest available cost report data from HCRIS is from ''as submitted'' cost reports. Since the universe of LTCHs is relatively small and the substantial increase in the number of LTCHs is fairly recent, due to the lag time in the cost report settlement and the availability of cost report data in HCRIS, we used cost-to-charge ratios based on as submitted cost report data if settled cost report data were not available. Since, as we noted above, the data used to compute LTCH cost-to-charge ratios was generated prior to the implementation of the LTCH PPS (when the use of charges was not as germane), we believe that the difference between a LTCH's cost-to-charge ratio computed from the latest settled cost report and a LTCH's cost-to-charge ratio computed from the latest tentative settled cost report is immaterial for most LTCHs, and, therefore, would not have a significant impact on payment estimates.

The commenter is mistaken as to the reason behind the change in the cost-to-charge ratio data posted on the web from the FY 2003 final rule (published August 30, 2002, in the **Federal Register**) to the 2004 LTCH PPS rate year proposed rule (published on March 7, 2003, in the **Federal Register**). As discussed above, this change in LTCHs' cost-to-charge ratios is not a result of applying the proposed change to allow fiscal intermediaries to use either the most recently settled cost report or most recent tentative settled cost report, whichever is later, in determining a LTCH's cost-to-charge ratio. We note instead that the change in the LTCH cost-to-charge ratios observed by the commenter is a result of using more updated data between the development of the August 30, 2002, final rule and the March 7, 2003, proposed rule. For example, LTCHs that previously only had FY 1998 data available for the FY 2003 final rule may now have FY 1999 or FY 2000 data available. Similarly, LTCHs that previously only had as submitted cost report data available for the FY 2003 final rule may now have settled cost report data available. Therefore, we do not believe that a change in our methodology for updating the standard Federal rate for the 2004 LTCH PPS rate year is warranted.

In this final rule, we updated the current standard Federal rate ($34,956.15) established in the August 30, 2002, final rule (67 FR 56033) by 2.2 percent (2.5 percent minus 0.3 percent) for discharges paid under the LTCH PPS that occur on or after July 1, 2003, through June 30, 2004. This update represents the most recent estimate of the increase in the excluded hospital with capital market basket for the 2004 LTCH PPS rate year, adjusted to account for the change in the rate update cycle to July 1, and is based on the best available data for 194 LTCHs.

2. Standard Federal Rate for the 2004 LTCH PPS Rate Year

In the August 30, 2002, LTCH PPS final rule (67 FR 56033), we established a standard Federal rate of $34,956.15 based on the best available data and policies established in that final rule. In the March 7, 2003, proposed rule (68 FR 11248), for the proposed 2004 LTCH

PPS rate year, we proposed a standard Federal rate of $35,726.64. Since the proposed standard Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, and high-cost outlier payments, we did not propose any additional adjustments in the proposed standard Federal rate for these factors.

In this final rule, we are establishing a standard Federal rate of $35,726.18 for the 2004 LTCH PPS rate year. Since the 2004 LTCH PPS rate year standard Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, and high-cost outlier payments, we did not make any additional adjustments in the standard Federal rate for these factors.

C. Calculation of LTCH Prospective Payments for the 2004 LTCH PPS Rate Year

The basic methodology for determining prospective payment rates for LTCH inpatient operating and capital-related costs is set forth in § 412.515 through § 412.532. In accordance with § 412.515, we assign appropriate weighting factors to each LTC–DRG to reflect the estimated relative cost of hospital resources used for discharges within that group as compared to discharges classified within other groups. The amount of the prospective payment is based on the standard Federal rate, established under § 412.523, and adjusted for the LTC–DRG relative weights, differences in area wage levels, cost-of-living in Alaska and Hawaii, high-cost outliers, and other special payment provisions (short-stay outliers under § 412.529 and interrupted stays under § 412.531). In accordance with § 412.533, during the 5-year transition period, payment is based on the applicable transition blend percentage of the adjusted Federal rate and the reasonable cost-based payment rate unless the LTCH makes a one-time election to receive payment based on 100 percent of the Federal rate. A LTCH defined as ''new'' under § 412.23(e)(4) is paid based on 100 percent of the Federal rate with no blended transition payments (§ 412.533(d)). As discussed in the August 30, 2002, final rule and in accordance with § 412.533(a), the applicable transition blends are as follows:

Cost reporting periods beginning on or after	Federal rate percentage	Reasonable cost-based payment rate percentage
October 1, 2002	20	80
October 1, 2003	40	60
October 1, 2004	60	40
October 1, 2005	80	20
October 1, 2006	100	0

Accordingly, for cost reporting periods that begin during FY 2003 (that is, on or after October 1, 2002, and before September 30, 2003), blended payments under the transition methodology are based on 80 percent of the LTCH's reasonable cost-based payment rate and 20 percent of the adjusted Federal rate. For cost reporting periods that begin during FY 2004 (that is, on or after October 1, 2003, and before September 30, 2004), blended payments under the transition methodology will be based on 60 percent of the LTCH's reasonable cost-based principles rate and 40 percent of the adjusted Federal rate.

1. Adjustment for Area Wage Levels

Under the authority of section 307(b) of Public Law 106–554, we established an adjustment to account for differences in LTCH area wage levels under § 412.525(c) using the labor-related share estimated by the excluded hospital market basket with capital and wage indices that were computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act. Furthermore, as we discussed in the August 30, 2002, final rule (67 FR 56015–56019), we established a 5-year transition to the full wage adjustment. For cost reporting periods beginning on or after October 1, 2002, and before September 30, 2003 (FY 2003), the applicable LTCH wage index value is one-fifth of the full FY 2002 acute care hospital inpatient wage index data, without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act.

In that same final rule (67 FR 56018), we stated that we would continue to reevaluate LTCH data as they become available and would propose to adjust the phase-in if subsequent data support a change. As we stated in the March 7, 2003, proposed rule (68 FR 11249), because the LTCH PPS was only recently implemented, sufficient new data have not been generated that would enable us to conduct a comprehensive reevaluation of the appropriateness of adjusting the phase-in. However, we reviewed the most recent data available and did not find any evidence to support a change in the 5-year phase-in of the wage index. Therefore, in the March 7, 2003, proposed rule, we did not propose to adjust the phase-in of the wage index adjustment at this time.

Comment: One commenter requested that we reconsider accelerating the phase-in of the wage index adjustment.

Response: As we stated above, because the LTCH PPS was only recently implemented, sufficient new data have not been generated that would enable us to conduct a comprehensive reevaluation of the appropriateness of adjusting the phase-in. For this final rule, we reviewed the most recent data available again and still did not find any evidence to support a change in the 5-year phase-in of the wage index. Therefore, in this final rule, we are not revising the phase-in of the wage index adjustment.

In addition, as we discussed in the March 7, 2003, proposed rule (68 FR 11249), the 5-year phase-in of the wage index would not be affected by the proposed establishment of a LTCH PPS rate year of July 1 to June 30. Instead, the 5-year phase-in of the wage index established in the August 30, 2002 final rule (67 FR 56018) will continue to follow the Federal fiscal year. That is, for cost reporting periods beginning on or after October 1, 2003, and before September 30, 2004 (FY 2004; the second year of the phase-in), the applicable LTCH wage index will be two-fifths of the applicable LTCH PPS index values discussed below. However, as we stated in that same proposed rule, we will reevaluate LTCH data as they become available and propose to adjust the phase-in if subsequent data support a change.

As we noted above, we have not found any evidence to support a change in the 5-year phase-in of the wage index adjustment at this time. Therefore, we are not adopting the commenter's

recommendation and we are not revising the phase-in to the wage index adjustment in this final rule.

Section 412.525(c) provides that the adjustment to account for differences in area wage levels is made by multiplying the labor-related portion of the Federal rate by the appropriate wage index value for the area in which the LTCH is physically located. In the August 30, 2002, final rule (67 FR 56018), based on the best available data at that time, we stated that the wage index adjustment is based on the FY 2002 inpatient acute care hospital wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. In the March 7, 2003, proposed rule, for the 2004 LTCH PPS rate year, we proposed that the wage index adjustment provided for under § 412.525(c) be based on the most recent available acute care hospital inpatient wage data, that is, the same data used to compute the FY 2003 acute care hospital inpatient wage index without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. As we noted above, we proposed that the 5-year phase-in of the wage index adjustment would not be affected by the proposed change in the LTCH PPS rate update cycle and will continue to be based on the Federal fiscal year. However, we proposed to update the data used to compute the annual wage index values on the 2004 LTCH PPS rate year cycle (July through June).

Comment: A few commenters stated that our proposal to update the data used to compute wage index values according to the LTCH PPS rate year (July 1st) would cause LTCHs whose cost reporting periods do not align with the LTCH rate year to have to make two wage index changes per year during the 5-year phase-in of the wage index adjustment. In addition to increasing provider burden, the commenters stated that two wage index changes per year would also introduce the potential for payment calculation errors. Thus, the commenters recommend that we align the phase-in of the wage index adjustment and the update of the data used to compute the wage index values to coincide with the LTCH PPS rate year.

Response: Adopting the recommendation of the commenters to align the phase-in of the wage index adjustment with the LTCH PPS rate year (July 1st) would advance the 5-year phase-in of the wage index adjustment. For instance, if the phase-in of the wage index adjustment were to change for all LTCHs on July 1st (rather than, as required under current language, for cost-reporting periods beginning on or after October 1st each year during the 5-year phase-in period), LTCH's with an April 1st cost reporting period would receive payments based on ⅕th of the wage index value for only 3 months (April 1, 2003, through June 30, 2003) before changing to ⅖th of the wage index on July 1, 2003. As we discussed in the August 30, 2002, final rule (67 FR 56018), based on the latest available LTCH data, we did not find any statistical evidence that showed a significant relationship between LTCHs' costs and their geographic location, therefore, we believed that it was appropriate to transition to a full wage index adjustment over a 5-year period.

As we discussed in the March 7, 2003, proposed rule and as we noted above, because the LTCH PPS was only recently implemented, sufficient new data have not been generated that would enable us to conduct a comprehensive reevaluation of the appropriateness of adjusting the phase-in. However, for this final rule we again reviewed the most recent data available and we still did not find any evidence to support a change in the 5-year phase-in of the wage index. Therefore, as stated above, we are not revising the phase-in of the wage index adjustment.

Moreover, we believe it is inappropriate to accelerate the phase-in of the wage index adjustment by adopting the commenters' recommendation to align the phase-in of the wage index adjustment with the LTCH PPS rate year. As we noted above, in accordance with § 412.525(c), the labor-related portion of the Federal rate is adjusted by the applicable wage index value. Because the proposed labor-related share (72.612 percent) is lower then the existing labor-related share (72.885 percent) established in the August 30, 2002, final rule, LTCHs with a wage index of less than 1.0 would be disadvantaged by the acceleration of the phase-in of the wage index adjustment that would result if we were to align the phase-in of the wage index adjustment with the LTCH PPS rate year.

In addition, we do not believe that the application of two wage index changes per year during the 5-year phase-in of the wage index adjustment, for those LTCHs whose cost reporting periods do not align with the LTCH rate year, would result in an additional burden or in payment errors to LTCHs. We do not believe LTCHs would be additionally burdened because they are not required to provide any additional information due to the change in the wage index adjustment during their cost reporting period. Also, we do not believe payment errors will occur because both the wage index data and the phase-in of the wage index adjustment are automatically performed in the PRICER software used by fiscal intermediaries to price each LTCH claim based on the date of service.

Therefore, we are not adopting the commenters' suggestion to align the phase-in of the wage index adjustment and the update of the data used to compute the wage index values to coincide with the LTCH PPS rate year. The phase-in of the wage index adjustment will continue to remain linked to each LTCH's cost reporting period beginning on or after October 1st each year during the 5-year phase-in period and the update of the data used to compute the wage index values will correspond with the LTCH PPS rate year (that is, effective beginning on July 1st each year).

For example, for a LTCH with a cost reporting period from January 1, 2003, through December 31, 2003, the LTCH will be paid using one-fifth of the wage index value for its entire cost reporting period. For the first 6 months of that period (January 1, 2003, through June 30, 2003), the one-fifth wage index value will be based on the same data used to compute the FY 2002 acute care hospital inpatient wage index without taking into account geographic reclassifications under sections 1886(d)(8) and (d)(10) of the Act as established in the August 30, 2002, final rule (67 FR 56018) and shown in Tables 1 and 2 of the Addendum to that same final rule (67 FR 56057–56075). Under the policy we are establishing in this final rule to update the data used to compute the LTCH PPS wage index values for July 1, 2003, through June 30, 2004, for the next 6 months (July 1, 2003, through December 31, 2003) that LTCH will still be paid using one-fifth of the wage index value, but the wage index value will now be computed using the same data used to compute the FY 2003 acute care hospital inpatient wage index without taking into account geographic reclassifications under sections 1886(d)(8) and (d)(10) of the Act (as shown in Tables 1 and 2 of the Addendum to this final rule). In this example, for that LTCH's subsequent cost reporting period from January 1, 2004, through December 31, 2004, that LTCH will be paid using the two-fifth wage index value. For the first 6 months of that period (January 1, 2004, through June 30, 2004), the two-fifths wage index value will be based on the same data used to compute the FY 2003 acute care hospital inpatient wage index without taking into account geographic reclassifications under sections

1886(d)(8) and (d)(10) of the Act, as shown in Tables 1 and 2 of the Addendum to this final rule.

In the August 30, 2002, final rule (67 FR 56018), for FY 2003 we used the same data used to compute the FY 2002 acute care hospital inpatient wage index without taking into account geographic reclassifications under sections 1886(d)(8) and (d)(10) of the Act. The same data is also used in the IRF PPS and the SNF PPS. As we discussed in the August 30, 2002, final rule (67 FR 56019), since hospitals that are excluded from the IPPS are not required to provide wage-related information on the Medicare cost report and we would need to establish instructions for the collection of such LTCH data in order to establish a geographic reclassification adjustment under the LTCH PPS, the wage adjustment established under the LTCH PPS is based on a LTCH's actual location without regard to the urban or rural designation of any related or affiliated provider. In this final rule, we are establishing that for the 2004 LTCH PPS rate year, the same data used to compute the FY 2003 acute care hospital inpatient wage index without taking into account geographic reclassifications under sections 1886(d)(8) and (d)(10) of the Act will be used to determine the applicable wage index values under the LTCH PPS, because it is the most recent available complete data. This is the same wage data that were used to compute the FY 2003 wage indices currently used under the IPPS. The final LTCH wage index values for July 1, 2003, through June 30, 2004, are shown in Table 1 (for urban areas) and Table 2 (for rural areas) in the Addendum to this final rule.

As noted above, for cost reporting periods beginning on or after October 1, 2002, and before September 30, 2003 (FY 2003), the labor portion of the standard Federal rate is adjusted by one-fifth of the applicable wage index value (that is, for LTCH PPS discharges on or after July 1, 2003, through June 30, 2004, one-fifth of the full FY 2003 acute care hospital inpatient wage index data, without taking into account geographic reclassifications under sections 1886(d)(8) and (d)(10) of the Act). For cost reporting periods beginning on or after October 1, 2003, and before October 1, 2004 (FY 2004), the LTCH wage index is two-fifths of the applicable wage index value. Therefore, for LTCHs with cost reporting periods beginning on or after October 1, 2003, through September 30, 2004, for discharges occurring on or after July 1, 2003, through June 30, 2004, the labor portion of the standard Federal rate is adjusted by two-fifths of the full FY 2003 acute care hospital inpatient wage index data, without taking into account geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act.

In conjunction with our proposal to revise and rebase the excluded hospital with capital market basket from an FY 1992 to an FY 1997 base year (as discussed above in section VII.B.1.a. of this preamble), in the March 7, 2003, proposed rule (68 FR 11249–11250), we also proposed to use a labor-related share that is determined based on the FY 1997-based excluded hospital with capital market basket. In the August 30, 2002, final rule (67 FR 56016), we established a labor-related share of 72.885 percent based on the relative importance of the labor-related share of operating and capital costs of the excluded hospital with capital market basket with an FY 1992 base-year. In the March 7, 2003, proposed rule, we proposed a labor-related share of 72.612 percent based on the relative importance of the labor-related share of operating costs (wages and salaries, employee benefits, professional fees, postal services, and all other labor-intensive services) and capital costs in the proposed FY 1997 rebased excluded hospital with capital market basket. (For further details on the development of the proposed labor share of 72.612 percent, refer to the March 7, 2003, proposed rule (68 FR 11249–11250).)

Comment: Two commenters noted that the proposed revising and rebasing of the LTCH PPS market basket coincided with the revisions made to the IPPS market basket for FY 2003 where FY 1992 data was replaced with FY 1997 data and other proxies used to measure changes in costs were replaced (*see* the August 1, 2002, IPPS final rule; 67 FR 50041–50042). While we received no comments on the effect of the proposed revising and rebasing of the LTCH PPS market basket on the LTCH PPS update factor, the commenters noted that the proposed change under the LTCH PPS, resulted in a decrease to the labor share from 72.885 percent to 72.612 percent, while under the IPPS, the use of this new data resulted in an increase in the labor share. However, under the IPPS, CMS decided not to use the updated data pending further analysis. Thus, the commenters believe that a change in the labor share under the LTCH PPS should be delayed, pending the results of the analysis being performed under the IPPS.

Response: The methodology used to determine the labor-related share presented in the March 7, 2003, proposed rule is consistent with our historical methodology of determining the labor-related share in the past for the IPPS market basket and the excluded hospital market basket, which is the summation of cost categories from the market basket deemed to vary with the local labor market. The concerns expressed by the commenters regarding the proposed revising of the LTCH PPS labor-related share are the same concerns expressed by commenters in the August 1, 2002, IPPS final rule (67 FR 50041–50042) when we proposed to revise the IPPS market basket and the excluded hospital market basket. In response to those comments in that same IPPS final rule, we stated that we are in the process of conducting further analysis to determine the most appropriate methodology for determining the labor-related share.

In the May 19, 2003, IPPS proposed rule (68 FR 27226), we explain that we have not yet completed our research into the appropriateness of this measure. In that same IPPS proposed rule, we discuss two ways that we are currently reviewing for establishing the labor-related share—(1) updating the regression analysis that was done when the IPPS was originally developed and (2) reevaluating the methodology we currently use for determining the labor-related share using the hospital market basket. While each of these alternatives have strengths and weaknesses, it is not clear at this point that any one alternative is superior to the current methodology. Thus, we want to continue researching these alternatives, in part, because changing from the current labor share methodology would impact the labor-related shares for other Medicare prospective payment systems, since they use a similar methodology.

Therefore, we agree with the commenter that it would be inappropriate to change the LTCH PPS labor share until the results of this research and analysis are complete. Accordingly, we are adopting the commenters' recommendation and the labor share for the 2004 LTCH PPS rate year will remain 72.885 percent.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Under § 412.525(b), we make a cost-of-living adjustment (COLA) for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. In the March 7, 2003, proposed rule (68 FR 11250), for the proposed 2004 LTCH PPS rate year, we proposed to make a COLA to payments for LTCHs located in Alaska and Hawaii by multiplying the standard Federal payment rate by the appropriate factor listed in Table V. below. These factors are obtained from the U.S. Office of

Personnel Management (OPM). In addition, in that same proposed rule we stated that if OPM releases revised COLA factors before May 1, 2003, we proposed to use them for the development of payments and publish them in this final rule.

The OPM has not released revised COLA factors for Alaska and Hawaii since the publication of the March 7, 2003, proposed rule. We received no comments on the proposed COLA factors for Alaska and Hawaii for the 2004 LTCH PPS rate year. Therefore, under § 412.525(b), we are finalizing the COLA factors for Alaska and Hawaii shown below in Table V. for the 2004 LTCH PPS rate year.

TABLE V.—COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS FOR THE 2004 LTCH PPS RATE YEAR

Alaska:	
All areas	1.25
Hawaii:	
Honolulu County	1.25
Hawaii County	1.165
Kauai County	1.2325
Maui County	1.2375
Kalawao County	1.2375

3. Adjustment for High-Cost Outliers

Under § 412.525(a), we make an adjustment for additional payments for outlier cases that have extraordinarily high costs relative to the costs of most discharges. Providing additional payments for outliers strongly improves the accuracy of the LTCH PPS in determining resource costs at the patient and hospital level. These additional payments reduce the financial losses that would otherwise be caused by treating patients who require more costly care and, therefore, reduce the incentives to underserve these patients. We set the outlier threshold before the beginning of the applicable rate year so that total outlier payments are projected to equal 8 percent of total payments under the LTCH PPS.

Under § 412.525(a), we make outlier payments for any discharges if the estimated cost of a case exceeds the adjusted LTCH PPS payment for the LTC–DRG plus a fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that a hospital will incur under an outlier policy. This results in Medicare and the LTCH sharing financial risk in the treatment of extraordinarily costly cases. The LTCH's loss is limited to the fixed-loss amount and the percentage of costs above the marginal cost factor. We calculate the estimated cost of a case by multiplying the overall hospital cost-to-charge ratio by the Medicare allowable covered charge. In accordance with § 412.525(a), we pay outlier cases 80 percent of the difference between the estimated cost of the patient case and the outlier threshold (the sum of the adjusted Federal prospective payment for the LTC–DRG and the fixed-loss amount).

We determine a fixed-loss amount, that is, the maximum loss that a LTCH can incur under the LTCH PPS for a case with unusually high costs before the LTCH will receive any additional payments. We calculate the fixed-loss amount by simulating aggregate payments with and without an outlier policy. The fixed loss amount would result in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments.

Outlier payments under the LTCH PPS are determined consistent with the IPPS outlier policy. Currently, under the IPPS, a floor and a ceiling are applied to an acute care hospital's cost-to-charge ratio and if the acute care hospital's cost-to-charge ratio is either below the floor or above the ceiling, the applicable statewide average cost-to-charge ratio is assigned to the acute care hospital. Similarly, if a LTCH's cost-to-charge ratio is below the floor or above the ceiling, currently the applicable statewide average cost-to-charge ratio is assigned to the LTCH. In addition, for LTCHs for which we are unable to compute a cost-to-charge ratio, we also assign the applicable statewide average. Currently, MedPAR claims data and cost-to-charge ratios based on the latest available cost report data from HCRIS and corresponding MedPAR claims data are used to establish a fixed-loss threshold amount under the LTCH PPS.

For FY 2003, based on FY 2001 MedPAR claims data and cost-to-charge ratios based on the latest available data from HCRIS and corresponding MedPAR claims data from FYs 1998 and 1999, we established a fixed-loss amount of $24,450. In the March 7, 2003, proposed rule (68 FR 11251), for the proposed 2004 LTCH PPS rate year, we proposed to continue to use the March 2002 update of the FY 2001 MedPAR claims data to determine a fixed-loss threshold that would result in outlier payments projected to be equal to 8 percent of total payments, based on the policies described in that proposed rule, because these data are the best data available. We would calculate cost-to-charge ratios for determining the proposed fixed-loss amount based on the latest available cost report data in HCRIS and corresponding MedPAR claims data from FYs 1998, 1999, and 2000.

In the March 7, 2003, proposed rule (68 FR 11251), consistent with the proposed outlier policy changes for acute care hospitals under the IPPS discussed in the March 5, 2003, IPPS high-cost outlier proposed rule (68 FR 10424), we proposed to no longer assign the applicable statewide average cost-to-charge ratio when a LTCH's cost-to-charge ratio falls below the floor. We proposed this policy change because, as is the case for acute care hospitals, we believe LTCHs could arbitrarily increase their charges in order to maximize outlier payments. Even though this arbitrary increase in charges should result in a lower cost-to-charge ratio in the future (due to the lag time in cost report settlement), currently when a LTCH's actual cost-to-charge ratio falls below the floor, the LTCH's cost-to-charge ratio would be raised to the applicable statewide average. This application of the statewide average would result in inappropriately higher outlier payments. Accordingly, we proposed to apply the LTCH's actual cost-to-charge ratio to determine the cost of the case, even where the LTCH's actual cost-to-charge ratio falls below the floor.

Also, in the March 7, 2003, proposed rule (68 FR 11251), consistent with the proposed policy change for acute care hospitals under the IPPS, we proposed under § 412.525(a)(4), by cross-referencing proposed § 412.84(i), to continue to apply the applicable statewide average cost-to-charge ratio when a LTCH's cost-to-charge ratio exceeds the ceiling by adopting the proposed policy at proposed § 412.84(i)(1)(ii). As we stated in that same proposed rule, cost-to-charge ratios above this range are probably due to faulty data reporting or entry, and, therefore, should not be used to identify and make payments for outlier cases because such data are clearly errors and should not be relied upon. In addition, we also proposed to make a similar change to the short-stay outlier policy at § 412.529. Since cost-to-charge ratios are also used in determining short-stay outlier payments, the rationale for that proposed change mirrors that for high-cost outliers.

Therefore, in the March 7, 2003, proposed rule (68 FR 11251), consistent with the proposed changes to the IPPS outlier policy, in determining the proposed fixed-loss amount for the proposed 2004 LTCH PPS rate year, we proposed to use only the current combined operating and capital cost-to-charge ratio ceiling under the IPPS of 1.421 (as explained in the IPPS final rule (67 FR 50125, August 1, 2002)). We believe that using the current combined

IPPS operating and capital cost-to-charge ratio ceiling for LTCHs is appropriate since, as we explained in the August 30, 2002, final rule (67 FR 55960), LTCHs are certified as acute care hospitals that meet the criteria set forth in section 1861(e) of the Act to participate as a hospital in the Medicare program, and in general, hospitals are paid as a LTCH only because their Medicare average length of stay is greater than 25 days in accordance with § 412.23(e). In the March 7, 2003, proposed rule (68 FR 11251), we also explained that prior to qualifying as a LTCH under § 412.23(e)(2)(i), the hospitals generally are paid as acute care hospitals under the IPPS during the period in which they demonstrate that they have an average length of stay of greater than 25 days. Accordingly, if a LTCH's cost-to-charge ratio is above this ceiling, we proposed to assign the applicable IPPS statewide average cost-to-charge ratio. We also proposed to assign the applicable statewide average for LTCHs for which we are unable to compute a cost-to-charge ratio, such as for new LTCHs. Therefore, based on the proposed methodology and data described above, in the March 7, 2003, proposed rule (68 FR 11251), for the proposed 2004 LTCH PPS rate year, we proposed a fixed-loss amount of $19,978. Thus, we proposed to pay an outlier case 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted Federal LTCH payment for the LTC–DRG and the proposed fixed-loss amount of $19,978).

We received numerous comments on the proposed changes to the LTCH PPS high-cost outlier policy under proposed § 412.525(a) (and short-stay outlier policy under § 412.529(c)). Because many features of the proposed LTCH PPS high-cost outlier policy are based upon the proposed policy changes to the IPPS high-cost outlier policy, we believe it is appropriate to finalize the proposed changes to the LTCH PPS high-cost outlier policy together with the final policy decisions on the IPPS high-cost outlier policy. Because the existing LTCH PPS outlier policy and proposed outlier policy changes are modeled after the IPPS outlier policy, we include the summary of public comments submitted on behalf of LTCHs, which in many cases mirror the comments we received on the proposed changes to the IPPS outlier policy, and the responses to those comments in the IPPS high-cost outlier final rule. Please refer to that final rule for a full discussion of the comments and responses, as well as any other final policy decisions concerning LTCH PPS high-cost outlier policy under § 412.525(a) (and the short-stay outlier policy under § 412.529(c)).

Therefore, in this final rule in calculating the final fixed-loss amount for the 2004 LTCH PPS rate year since the finalized changes to the high-cost outlier policy (and short-stay outlier policy) are not yet effective, we applied the existing outlier policy; that is, we assigned the statewide average to LTCHs whose cost-to-charge ratios fell below the floor or exceeded the ceiling. Accordingly, we used the current IPPS combined operating and capital cost-to-charge ratio floor of 0.206 and cost-to-charge ratio ceiling of 1.421 (as explained in the IPPS final rule (67 FR 50125, August 1, 2002)). We believe that using the current combined IPPS operating and capital cost-to-charge ratio floor and ceiling for LTCHs is appropriate for the same reasons we stated above regarding the use of the current combined operating and capital cost-to-charge ratio ceiling under the IPPS.

In this final rule, for the 2004 LTCH PPS rate year, we continue to use the March 2002 update of the FY 2001 MedPAR claims data to establish a fixed-loss threshold that would result in outlier payments projected to be equal to 8 percent of total payments, based on the policies described in this final rule, because these data are the best LTCH data available. We also computed cost-to-charge ratios for establishing the fixed-loss amount for the 2004 LTCH PPS rate year based on the latest available cost report data in HCRIS and corresponding MedPAR claims data from FYs 1998, 1999, and 2000. As we explained above, the applicable IPPS statewide average cost-to-charge ratios were applied when a LTCH's cost-to-charge ratio exceeded the ceiling (1.421) or fell below the floor (0.206). Also, we assigned the applicable statewide average to LTCHs for which we were unable to compute a cost-to-charge ratio. (Currently, the applicable IPPS statewide averages can be found in Tables 8A and 8B of the August 1, 2002, IPPS final rule (67 FR 50263).)

Accordingly, based on updated data and the final rates and policies established in this final rule (including the existing cost-to-charge ratio policy described above), we are establishing a fixed-loss amount of $19,590 for the FY 2004 LTCH PPS rate year. Thus, we will pay an outlier case 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted Federal LTCH payment for the LTC–DRG and the fixed-loss amount of $19,590).

As we discussed in the March 7, 2003, proposed rule (68 FR 11251–11252), the IPPS standard Federal rate and relative weights are updated simultaneously, effective October 1 of each year, when the new GROUPER with the final DRGs and the new relative weights are implemented for that fiscal year. The LTCH PPS utilizes the same DRGs and Medicare GROUPER program as the IPPS. The GROUPER in effect on July 1, 2003, will be version 20.0. Although we proposed to update the LTCH PPS standard Federal rate on July 1, 2003, version 21.0 of the GROUPER will not be available at the time this final rule is published. Therefore, as we explained in the March 7, 2003, proposed rule (68 FR 11242), we are not proposing an update to the LTC–DRG weights for the period of July 1, 2003, through September 30, 2003, and the LTCH PPS will continue to use version 20.0 of the GROUPER and the LTC–DRG relative weights published in Table 3 of the Addendum to the August 30, 2002, final rule (reprinted in Table 3 of the Addendum to the March 7, 2003, proposed rule) for the period from July 1, 2003, through September 30, 2003.

The calculation of the fixed-loss amount is dependent in part on the LTC–DRG relative weights because the fixed-loss amount is set so that estimated total outlier payments are estimated to be equal to 8 percent of total LTCH PPS payments. We proposed to calculate a fixed-loss amount that would result in total estimated outlier payments being equal to 8 percent of total LTCH PPS payments for the proposed 2004 LTCH PPS rate year, using the LTC–DRG relative weights based on the version 20.0 GROUPER. We proposed to use the version 20.0 GROUPER in determining the fixed-loss amount for the period of July 1, 2003, through June 30, 2004, as it contains the best available data at the time the fixed-loss amount is determined.

As we discuss below, we did not propose to change the fixed-loss amount to account for changes in the version 21.0 GROUPER, because we believe implementing two fixed-loss amounts during the proposed LTCH PPS rate year may be administratively burdensome. Implementing a single fixed-loss amount which would be in effect for a full 12 months (July through June) would be consistent with other components of the LTCH PPS, such as the standard Federal rate and the wage index, both of which would be in effect for a full 12-month period (July through June). Similarly, the relative weights and the GROUPER program are in effect for 12 months (October through September). However, because the

update to the ICD–9–CM codes is effective at the beginning of the Federal fiscal year, as described in section IV.E.2. of the March 7, 2003, proposed rule (68 FR 11241), we explained in that same proposed rule (68 FR 11252) that we would continue to update the LTCH PPS GROUPER and the relative weights on October 1.

In addition, in the March 7, 2003, proposed rule (68 FR 11252), we also stated that we do not anticipate that the fixed-loss amount calculated using the relative weights based on the version 20.0 GROUPER would be significantly different from a fixed-loss amount calculated using the relative weights based on the version 21.0 GROUPER. We believe this based on the fact that the LTCH PPS outlier policy, one component of which is a fixed-loss amount, is modeled after the IPPS outlier policy. The annual reclassification and recalibration of DRGs under the IPPS generally does not result in a significant impact on the IPPS fixed-loss amount (although this impact would vary from year to year depending on the actual DRG changes). Therefore, we proposed to calculate a single fixed-loss amount for each LTCH PPS rate year based on the version of the GROUPER that is in effect as of July 1 of that year.

Since the proposed effective date of the updated LTCH PPS standard Federal rate would be July 1, while the updated GROUPER would not be effective until October 1, we stated in the March 7, 2003, proposed rule (68 FR 12252) that we did consider an alternative proposal that would establish two separate fixed-loss amounts during the proposed LTCH PPS rate year—one for July through September based on the current GROUPER and another for October through June based on the updated GROUPER. As we explained in that same proposed rule, we decided not to propose this alternative because, as we discussed above, calculating and implementing two fixed-loss amounts in one proposed LTCH PPS rate year is administratively burdensome.

We received no comments on our proposal to calculate a single fixed-loss amount for each LTCH PPS rate year based on the version of the GROUPER that is in effect as of July 1 of that year. Therefore, for the 2004 LTCH PPS rate year, we are establishing a single fixed-loss amount based on the version 20.0 of the GROUPER, which is in effect at the start of the 2004 LTCH PPS rate year (July 1, 2003). As we stated above, the fixed-loss amount for the 2004 LTCH PPS rate year is $19,590. As we stated in the August 30, 2002, final rule (67 FR 56026), under some rare circumstances, a LTCH discharge could qualify as a short-stay outlier case (as defined under § 412.529 and discussed in section VII.B.4.b. of this preamble) and also as a high-cost outlier case. In such a scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific LTC–DRG, and yet incur extraordinarily high treatment costs. If the costs exceeded the outlier threshold (that is, the short-stay outlier payment plus the fixed-loss amount), the discharge would be eligible for payment as a high-cost outlier. Thus, for a short-stay outlier in the 2004 LTCH PPS rate year, the high-cost outlier payment will be 80 percent of the difference between the estimated cost of the case plus the outlier threshold (the sum of the final fixed-loss amount of $19,590 and the amount paid under the short-stay outlier policy).

Under existing regulations at § 412.525(a), we specify that no retroactive adjustment will be made to the outlier payments upon cost report settlement to account for differences between the estimated cost-to-charge ratios and the actual cost-to-charge ratios for outlier cases. This policy is consistent with the existing outlier payment policy for acute care hospitals under the IPPS. However, we note that in the March 5, 2003, IPPS high-cost outlier proposed rule (68 FR 10424), we proposed to revise the methodology for determining cost-to-charge ratios for acute care hospitals under the IPPS because, as we discussed in that notice, we became aware that payment vulnerabilities exist in the current IPPS outlier policy.

Because the LTCH PPS high-cost outlier and short-stay policies are modeled after the outlier policy in the IPPS, we believe they are susceptible to the same payment vulnerabilities and, therefore, merit revision. As proposed for acute care hospitals under the IPPS at proposed § 412.84(m) in the March 5, 2003, IPPS high-cost outlier proposed rule (68 FR 10429), we proposed in the March 7, 2003, proposed rule (68 FR 11252) under § 412.525(a)(4)(ii), by cross-referencing proposed § 412.84(m), that for LTCHs any reconciliation of outlier payments would be made upon cost report settlement to account for differences between the estimated cost-to-charge ratio for the period during which the discharge occurs. As is the case with the proposed changes to the outlier policy for acute care hospitals under the IPPS, we are still assessing the procedural changes that would be necessary to implement this change. In addition, in that same proposed rule (68 FR 11252), we proposed to make a similar change to the short-stay outlier policy at proposed § 412.529(c)(4)(ii).

We also stated in the March 7, 2003, proposed rule (68 FR 11252), that because we currently use cost-to-charge ratios based on the latest settled cost report, any dramatic increases in charges during the payment year are not reflected in the cost-to-charge ratios when making outlier payments. Consistent with the proposed policy change for acute care hospitals under the IPPS at proposed § 412.84(i) discussed in the March 5, 2003, IPPS high-cost outlier proposed rule (68 FR 10424–10426), because a LTCH has the ability to increase its outlier payments through a dramatic increase in charges and because of the lag time in the data used to calculate cost-to-charge ratios, in the March 7, 2003, proposed rule (68 FR 11252), we proposed that fiscal intermediaries would use more recent data when determining a LTCH's cost-to-charge ratio. Therefore, by cross-referencing proposed § 412.84(i) under proposed § 412.525(a)(4)(ii) in the March 7, 2003, proposed rule (68 FR 11252), we proposed that fiscal intermediaries would use either the most recent settled cost report or the most recent tentative settled cost report, whichever is later. In addition, in that same proposed rule, we proposed to make a similar change to the short-stay outlier policy at proposed § 412.529(c)(4)(ii).

As we noted above, we received numerous comments on the proposed reconciliation of outlier payments at cost report settlement and the proposed policy to allow fiscal intermediaries to use either the most recent settled cost report or the most recent tentative settled cost report, whichever is later, in computing LTCH's cost-to-charge ratios for determining high-cost outlier payments under proposed § 412.525(a) (and short-stay outlier payments under proposed § 412.529(c)). As we also noted previously, because many features of the proposed LTCH PPS high-cost outlier policy are based upon the proposed policy changes to the IPPS high-cost outlier policy, we believe it is appropriate to finalize the proposed changes to the LTCH PPS high-cost outlier together with the final policy decisions on the IPPS outlier policy. Because, however, the LTCH PPS outlier policy and proposed outlier policy changes are modeled after the IPPS outlier policy, we include the summary of public comments submitted on behalf of LTCHs, which in many cases mirror the comments we received on the proposed IPPS outlier policy, and the responses to those comments in the IPPS high-cost outlier final rule. Please

refer to that final rule for a full discussion of the comments and responses, as well as any other final policy decisions concerning LTCH PPS high-cost outlier policy under § 412.525(a) (and the short-stay outlier policy under § 412.529(c)).

In conclusion, the summary of public comments on the proposed changes presented in the March 7, 2003, proposed rule regarding the high-cost outlier policy under proposed § 412.525(a) (and the short-stay outlier policy under proposed § 412.529(c)), and the responses to those comments are presented in the IPPS high-cost outlier final rule. Therefore, in this final rule, based on the data and existing methodology described above, we are establishing a fixed-loss amount of $19,590 for the FY 2004 LTCH PPS rate year. Accordingly, we will pay an outlier case 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted Federal LTCH payment for the LTC–DRG and the fixed-loss amount of $19,590).

4. Adjustments for Special Cases

a. General

As discussed in the August 30, 2002, final rule (67 FR 55995), under section 123 of Public Law 106–113, the Secretary generally has broad authority in developing the PPS for LTCHs, including whether (and how) to provide for adjustments to reflect variations in the necessary costs of treatment among LTCHs.

Generally, LTCHs, as described in section 1886(d)(1)(B)(iv) of the Act, are distinguished from other inpatient hospital settings by maintaining an average length of stay of greater than 25 days. However, LTCHs may have cases that have stays of considerably less than the average length of stay and that receive significantly less than the full course of treatment for a specific LTC–DRG. As we explained in the August 30, 2002, final rule (67 FR 55995), such cases would be paid inappropriately if the hospital were to receive the full LTC–DRG payment. While we did not propose any changes to the payment policy for special cases at this time, below we discuss the payment methodology for these special cases as implemented in the August 30, 2002, final rule (67 FR 55955–56010).

b. Short-Stay Outlier Cases

A short-stay outlier case may occur when a beneficiary receives less than the full course of treatment at the LTCH before being discharged. These patients may be discharged to another site of care or they may be discharged and not readmitted because they no longer require treatment. Furthermore, patients may expire early in their LTCH stay.

As noted above, generally LTCHs are defined by statute as having an average length of stay of greater than 25 days. We believe that a payment adjustment for short-stay outlier cases results in more appropriate payments, because these cases most likely would not receive a full course of treatment in such a short period of time and a full LTC–DRG payment may not always be appropriate. Payment-to-cost ratios simulated for LTCHs, for the cases described above, show that if LTCHs receive a full LTC–DRG payment for those cases, they would be significantly ''overpaid'' for the resources they have actually expended.

Under § 412.529, we adjust the per discharge payment to the least of 120 percent of the cost of the case, 120 percent of the LTC–DRG specific per diem amount multiplied by the length of stay of that discharge, or the full LTC–DRG payment, for all cases with a length of stay up to and including five-sixths of the geometric average length of stay of the LTC–DRG.

As we discussed in the March 7, 2003, proposed rule (68 FR 12252), in the March 5, 2003, IPPS high-cost outlier proposed rule (68 FR 10424), we proposed to revise the methodology for determining cost-to-charge ratios for acute care hospitals under the IPPS because, as we discussed in that March 7, 2003, proposed rule, we became aware that payment vulnerabilities exist in the current IPPS outlier policy. As we also explained in that March 7, 2003, proposed rule, because the LTCH PPS high-cost outlier and short-stay outlier policies are modeled after the outlier policy in the IPPS, we believe they are susceptible to the same payment vulnerabilities and, therefore, merit revision. As proposed for acute care hospitals under the IPPS at proposed § 412.84(i) and (m) in the March 5, 2003, IPPS high-cost outlier proposed rule (68 FR 10429), and as we proposed above for high-cost outlier payments at § 412.525(a)(4)(ii), we proposed under § 412.529(c) that short-stay outlier payments would be subject to the proposed provisions in the regulations at proposed § 412.84(i) and (m). Therefore, consistent with the proposed changes to the high-cost outlier policy discussed in the March 7, 2003, proposed rule (68 FR 11251), we proposed, by cross-referencing proposed § 412.84(i), that fiscal intermediaries would use either the most recent settled cost report or the most recent tentative settled cost report, whichever is later, in determining a LTCH's cost-to-charge ratio.

In the March 7, 2003, proposed rule (68 FR 11253), we also proposed, by cross-referencing proposed § 412.84(i), that the applicable statewide average cost-to-charge ratio would only be applied when a LTCH's cost-to-charge ratio exceeds the ceiling. Thus, the applicable statewide average cost-to-charge ratio would not be applied if a LTCH's cost-to-charge ratio falls below the floor. Finally, in that same proposed rule, by cross-referencing proposed § 412.84(m), we proposed that any reconciliation of payments for short-stay outliers would be made upon cost report settlement to account for differences between the estimated cost-to-charge ratio and the actual cost-to-charge ratio for the period during which the discharge occurs. We also noted that, as is the case with the proposed changes to the outlier policy for acute care hospitals under the IPPS, we are still assessing the procedural changes that would be necessary to implement this change.

As we discussed above in section VII.B.3 of this preamble, we received numerous comments on the proposed changes to the short-stay outlier policy under proposed § 412.529(c) (and the high-cost outlier policy under proposed § 412.525(a)). Because many features of the proposed LTCH PPS outlier policies are based upon the proposed policy changes to the IPPS high-cost outlier policy, we believe it is appropriate to finalize the proposed changes to the LTCH PPS short-stay outlier policy (and high-cost outlier policy) together with the final policy decisions on the IPPS high-cost outlier policy. Because the LTCH PPS outlier policy and proposed outlier policy changes are modeled after the IPPS outlier policy, we include the summary of public comments submitted on behalf of LTCHs, which in many cases mirror the comments we received on the proposed IPPS outlier policy, and the responses to those comments in the IPPS high-cost outlier final rule. Please refer to that final rule for a full discussion of the comments and responses, as well as any other final policy decisions concerning LTCH PPS (the short-stay outlier policy under § 412.529(c) and the high cost outlier policy under § 412.525(a)). Therefore, in this final rule, we are not making the changes to the short-stay outlier policy at § 412.529 based on the changes proposed in the March 7, 2003, proposed rule (68 FR 11252).

As noted above, we will be responding to all comments on the proposed outlier policies for the LTCH PPS and presenting any changes in

existing policy in the IPPS high-cost outlier final rule. We believe that it is appropriate, however, to respond to three commenters that submitted comments regarding the impact of our short-stay outlier policy on certain hospitals which qualify as LTCHs under section 1886(d)(1)(B)(iv)(II) of the Act (''subclause (II)'' LTCHs) as added by section 4417(b) of Public Law 105–33, and implemented in § 412.23(e)(2)(ii).

Comment: Three commenters, two hospital associations and the other, a hospital that qualifies as a LTCH under section 1886(d)(1)(B)(iv)(II) of the Act, expressed great concern that since becoming subject to the LTCH PPS, the LTCH is experiencing considerable financial losses which it anticipates will continue to increase during the 5-year transition period. The commenters assert that these mounting losses will substantially threaten the LTCH's ability to continue to offer services in accordance with its unique mission of primarily treating cancer patients. The commenters identify our payment policy for short-stay outliers as creating the most damaging shortfall, given this ''subclause (II)'' LTCH's case mix. In order to ameliorate this situation, all three commenters suggest that we exempt ''subclause (II)'' LTCHs, from the short-stay outlier policy and establish a hospital-specific standard Federal rate to reflect this change, which would also result in a lower average payment amount for all of those LTCHs' cases and a higher high-cost outlier threshold. We were urged, by one of the commenters to make these suggested policy modifications retroactive to the start of the hospital's first cost reporting period under the LTCH PPS and also to suspend the timing requirements of § 412.533(c), which would allow this LTCH to elect fully prospective payments as of that date. A suggestion from one of the hospital associations also advanced the possibility that the necessity for any adjustment to the short-stay outlier policy would end with the completion of the 5-year transition because with implementation of the full wage index adjustment and no budget neutrality adjustment (to account for the costs incurred by the Medicare program during the transition), Medicare payments for the ''subclause (II)'' LTCH would be more in line with the costs of delivering care.

Response: By enacting section 4417(b) of Public Law 105–33, and adding the provision at section 1886(d)(1)(B)(iv)(II) of the Act, the Congress provided an exception to the general definition of LTCH as set forth in section 1886(d)(1)(B)(iv)(I) of the Act (''subclause (I)'' LTCHs), intending, we believe, to recognize the existence and importance of a distinct category of LTCHs that might not otherwise warrant exclusion from the IPPS under subclause (I), but which, nonetheless, fulfills a unique and vital role in serving a particular subset of Medicare patients. Under this provision, which we implemented at § 412.23(e)(2)(ii), to qualify as a LTCH, a hospital must have first been excluded as a LTCH in 1986, have an average inpatient length of stay of greater than 20 days, and demonstrate that 80 percent of its annual Medicare inpatient discharges in the 12-month reporting period ending in Federal fiscal year 1997 have a principal diagnosis that reflects a finding of neoplastic disease (62 FR 46016 and 46026, August 29, 1997). Moreover, we believe the Congress assumed ''subclause (II)'' LTCHs would continue to serve this population after FY 1997. Acknowledging the distinction between hospitals qualifying as LTCHs under section 1886(d)(1)(B)(iv)(I) of the Act, and those qualifying under section 1886(d)(1)(B)(iv)(II) of the Act when we developed the LTCH PPS, we revised the greater than 25 day average length of stay criteria to include only Medicare patients for these ''subclause (I)'' LTCHs. However, for LTCHs described in section 1886(d)(1)(B)(iv)(II) of the Act, no change was made to the methodology for calculating the LTCH's average length of stay, since ''we have no reason to believe that the change in methodology for determining the average inpatient length of stay would better identify the hospitals that the Congress intended to exclude under subclause (II)'' (67 FR 55974, August 30, 2002). Consistent with existing policies that differentiate ''subclause (II)'' LTCHs from other LTCHs, we agree with the commenters that it is appropriate for us to consider whether or not a policy that applies to LTCHs designated under subclause I, can reasonably and equitably be applied to ''subclause (II)'' LTCHs without some measure of adjustment. We also believe that the specificity of section 4417(b) of Public Law 105–33, which states that 80 percent or more of the annual Medicare inpatient discharges, in such a ''subclause (II)'' LTCH, in the 12-month reporting period ending in Federal fiscal year 1997 would have had a principal diagnosis that reflects a finding of neoplastic disease, indicates to us that the Congress determined that hospitals fitting this description fulfilled a unique and vital service for certain Medicare beneficiaries. Furthermore, we believe the Congress assumed that not only would a ''subclause (II)'' LTCH have at least 80 percent of its Medicare inpatient discharges with a diagnosis of neoplastic disease in FY 1997, but this type of LTCH would continue to serve this patient case-mix in years subsequent to FY 1997.

The theoretical foundations of a DRG-based PPS are that while the costs of one case may exceed its payment, the opposite is also likely to happen, and that where some types of cases are always very expensive for a hospital to treat, others are, in general, not costly. It is assumed that hospitals under a DRG-based system, therefore, can typically exercise some influence over their case-mix and their services in order to achieve fiscal stability. This is not generally the case for ''subclause (II)'' LTCHs because they continue to primarily treat patients with neoplastic diseases (97.4 percent of patients at a ''subclause (II)'' LTCH had primary diagnosis of neoplastic disease, according to data from FY 2001 MedPAR files.). According to our claims data for January 1, 2001, through December 31, 2001, at a ''subclause (II)'' LTCH, more than 93 percent of its Medicare patients expired, over half of the patients at this hospital would qualify as short-stay outliers (97 percent of those short-stay outliers expired), and 30 percent of its patient days were for high-cost outlier patients with an average length of stay of 109 days.

We have analyzed our data as well as information supplied by the commenters in order to better understand the financial impact on a ''subclause (II)'' LTCH of the payment policies established for LTCHs that will be in place during the 5-year transition to the full LTCH PPS. In identifying this category of LTCHs, Congress required that ''in the 12-month cost reporting period ending in fiscal year 1997'' the Medicare patient population would be comprised of at least 80 percent with ''* * * a principal diagnosis that reflects a finding of neoplastic disease.'' As noted above, our data indicates that the treatment of neoplastic diseases continues to be the mission of a ''subclause (II)'' LTCH. Accordingly we believe that the patient census at a ''subclause (II)'' LTCH will, by its very nature, be comprised of unusually high percentages of both short-stay cases as well as high-cost outliers. Data projections further reveal that the significant losses that are being incurred will gradually decline throughout the 5-year transition, as the percentage of payments based on the Federal rate increase and the effect of the wage index adjustment is fully transitioned. Our analyses lead us to believe that until the

full wage index is phased-in in 2006 and the transition period budget neutrality adjustments cease, the survival of such a ''subclause (II)'' LTCH is in serious jeopardy.

By establishing ''subclause (II)'' LTCHs, the Congress provided an exception to the general definition of LTCH under subclause (I), and, therein, we believe, endorsed the unique mission of a particular type of hospital. We do not believe that the Congress intended for policies that equitably apply to LTCHs described under subclause (I) to potentially undermine the viability of a LTCH described under subclause (II).

In the August 30, 2003, final rule (67 FR 55954), we stated that we believed that in establishing the short-stay outlier policy under the LTCH PPS, we were recognizing that LTCHs, as a provider category under Medicare, should not be admitting patients whose stay were considerably less than the average length of stay at a LTCH and who could otherwise receive care at an acute care hospital subject to the IPPS. Data from the FY 1999 MedPAR files revealed that 52 percent of cases being treated at LTCHs were for stays of less than two-thirds of the average length of stay for the LTC–DRG and 20 percent had a length of stay of even less than 8 days (67 FR 55970, August 30, 2002). We noted, however, that short-stay outliers could also result from a legitimate admission to a LTCH when a change in the patient's condition dictated that another treatment or care setting would be more clinically appropriate or if the patient expired early in the LTCH stay. In these situations, the patient would still not have received the full course of treatment at the LTCH and paying a full LTC–DRG would result in significant overpayment. Therefore, we created the short-stay outlier category as a feature of the LTCH PPS, so that Medicare would be rendering fair, but not excessive payment for patients who could have received treatment at an acute care hospital as well as for patients who, for valid clinical reasons, did not stay long enough at a LTCH to receive the course of treatment for which the full LTC–DRG payments were calibrated. We further believed that implementing the short-stay policy could encourage LTCHs to adopt admission policies that, for the most part, would work to limit the number of short-stay patients since there would be no inappropriate financial incentive for admitting such cases.

As we evaluate the short-stay outlier policy with regard to ''subclause (II)'' LTCHs, we believe that a LTCH in this category may not be able to readily address the length of stay of patients and the costs it incurs for those patients as would LTCHs described under subclause (I) because a ''subclause (II)'' LTCH continues to primarily serve patients with neoplastic diseases. In fact, as previously noted, FY 2001 MedPAR data demonstrate that 97.4 percent of the patients at a ''subclause (II)'' LTCH have a primary diagnosis of neoplastic disease. Accordingly, we believe that it is necessary to adjust the short-stay policy for ''subclause (II)'' LTCHs during the 5-year transition period, so that a LTCH of this type can continue to serve its community, as we believe was assumed by the Congress when it established this category of LTCHs.

All three commenters suggested that we abrogate the entire short-stay outlier policy for ''subclause (II)'' LTCHs, which would result in a revised hospital-specific standard Federal rate and high-cost outlier threshold. We do not believe that such a radical departure from the general LTCH PPS policies is either necessary or appropriate to address the problems that we have noted.

In the August 30, 2002, final rule (67 FR 55995–56000), we describe the simulations that resulted in our short-stay outlier policy of the lesser of 120 percent of the cost, 120 percent of the per diem amount of the LTC–DRG, or the full LTC–DRG. Since these simulations were established by analyzing costs and payments of a LTCH with a greater than 25 day average length of stay, we are instead providing an adjustment to the short-stay outlier payment policy for a ''subclause (II)'' LTCH, which is held to a greater than 20 day average length of stay criterion and not to the greater than 25 day average length of stay criterion which applies to ''subclause (I)'' LTCHs. Furthermore, this adjustment to the short-stay payment policy will be in place during ''subclause (II)'' LTCHs'' 5-year transition to full LTCH PPS in the form of percentages, corresponding to the 120 percent for ''subclause (I)'' LTCHs, and it will be ''phased out'' gradually as the percentage of payments under the LTCH PPS are increased, the full wage index adjustment is phased-in, and the budget neutrality adjustment is decreased. The adjustment, described below, was derived based on payment simulations using the same methodology on ''subclause (II)'' LTCH data that we used in arriving at the 120 percent for ''subclause (I)'' LTCHs. (67 FR 55995–56000, August 30, 2002)

We are establishing this formula with the expectation that an adjustment to the short-stay payments during the transition will result in reducing the difference between payments and costs for a ''subclause (II)'' LTCH for the period of July 1, 2003, through the end of the transition period, when the LTCH PPS will be fully phased-in. Therefore, for example, a ''subclause (II)'' LTCH, which became subject to the LTCH PPS for their first cost reporting period which began on January 1, 2003 (and did not elect payment based on 100% of the Federal rate), 80 percent of Medicare payments would still be based on what would have been paid under the TEFRA system and only 20 percent would be based on the Federal rate (and subject to payments under the short-stay outlier policy established in the August 30, 2002, final rule). Effective for discharges from a ''subclause (II)'' LTCH occurring on or after July 1, 2003, and based on the payment simulations described above, we have revised the short-stay outlier percentage to 195 percent during the first year of the hospital's 5-year transition. For the second cost reporting period, the short-stay outlier percentage will be 193 percent; for the third cost reporting period, the percentage will be 165 percent; for the fourth cost reporting period, the percentage will be 136 percent; and for the final cost reporting period of the 5-year transition, the short-stay outlier percentage for ''subclause (II)'' LTCHs, will be 120 percent, that is, the same as it is for all other LTCHs under the LTCH PPS. We have set forth this policy by redesignating the existing paragraph (c)(4) as (c)(5) and adding a new paragraph (c)(4) to § 412.529.

We also expect that during this 5-year period, ''subclause (II)'' LTCHs will make every attempt to adopt the type of efficiency enhancing policies that generally result from the implementation of prospective payment systems in other health care settings.

We consider the above adjustment to be a reasonable, equitable and sufficient response to the particular situation of a ''subclause (II)'' LTCH under the LTCH PPS and, therefore, we will not address at any length the other two suggestions regarding retroactive adjustments to the start of a LTCH's first cost reporting period under the LTCH PPS and the disregarding of timing requirements established in § 412.533(c) for election not to be paid under the transition period methodology. In this final rule, therefore, we are making a temporary adjustment to payments under the short-stay outlier policy for LTCHs designated under section 1886(d)(1)(B)(iv)(II) of the Act and § 412.23(e)(2)(ii) that will end upon full implementation of the LTCH PPS, at the beginning of their fifth cost reporting period in the 5-year transition period.

c. Interrupted Stay

In § 412.531(a), we define an ''interruption of a stay'' as a stay at a LTCH during which a Medicare inpatient is admitted upon discharge from the LTCH to an acute care hospital, an IRF, or a SNF for treatment or services that are not available in the LTCH and returns to the same LTCH within applicable fixed day periods. For a discharge to an acute care hospital, the applicable fixed-day period is 9 days. For a discharge to an IRF, the applicable fixed-day period is 27 days. For a discharge to a SNF, the applicable fixed-day period is 45 days. The counting of the days begins on the day of discharge from the LTCH and ends on the 9th, 27th, or 45th day for an acute care hospital, an IRF, or a SNF, respectively. (We refer readers to section VII.C.4.e. of this preamble for a discussion of application of this interrupted stay policy to Medicare-participating providers with approved swing beds.)

If the patient's length of stay away from the LTCH does not exceed the fixed-day thresholds, the return to the LTCH is considered part of the first admission and only a single LTCH PPS payment will be made. (From the standpoint of implementing this policy, in the event that a Medicare inpatient is discharged from a LTCH and is readmitted and the stay qualifies as an interrupted stay, the provider should cancel the claim generated by the original stay in the LTCH and submit one claim for the entire stay. For further details, see Program Memorandum Transmittal A–02–093, September 2002.) On the other hand, if the patient stay exceeds the total fixed-day threshold outside of the LTCH at another facility before being readmitted, two separate LTC–DRG payments will be made, one based on the principal diagnosis for the first admittance and the other based on the principal diagnosis for the second admittance. Moreover, if the principal diagnoses are the same for both admissions, the hospital could receive two similar payments. (See section VII.C.4.e. of this final rule for application of the interrupted stay policy to transfers to swing bed hospitals.)

d. Onsite Discharges and Readmittances

Under § 412.532, generally, if a LTCH readmits more than 5 percent of its Medicare patients who are discharged to an onsite SNF, IRF, or psychiatric facility, or to an onsite acute care hospital, only one LTC–DRG payment will be made to the LTCH for discharges and readmittances during the LTCH's cost reporting period. Therefore, payment for the entire stay will be paid either as one full LTC–DRG payment or a short-stay outlier, depending on the duration of the entire LTCH stay.

In applying the 5-percent threshold, we apply one threshold for discharges and readmittances with a co-located acute care hospital. There is also a separate 5-percent threshold for all discharges and readmittances with co-located SNFs, IRFs, and psychiatric facilities. In the case of a LTCH that is co-located with an acute care hospital, an IRF, or a SNF, the interrupted stay policy at § 412.531 applies until the 5-percent threshold is reached. However, once the applicable threshold is reached, all such discharges and readmittances to the applicable site(s) for that cost reporting period are paid as one discharge. This means that even if a discharged LTCH Medicare patient was readmitted to the LTCH following a stay in an acute care hospital of greater than 9 days, if the facilities share a common location and the 5-percent threshold were exceeded, the subsequent discharge from the LTCH will not represent a separate hospitalization for payment purposes. Only one LTC–DRG payment will be made for all such discharges during a cost reporting period to the acute care hospital, regardless of the length of stay at the acute care hospital, that are followed by readmittances to the onsite LTCH.

Similarly, if the LTCH has exceeded its 5-percent threshold for all discharges to an onsite IRF, SNF, or psychiatric hospital or unit, with readmittances to the LTCH, the subsequent LTCH discharge for patients from any of those sites for the entire cost reporting period will not be treated as a separate discharge for Medicare payment purposes. (As under the interrupted stay policy, payment to an acute care hospital under the IPPS, to an IRF under the IRF PPS, and to a SNF under the SNF PPS, will not be affected. Payments to the psychiatric facility also will not be affected.)

e. Treatment of Swing Beds Under the Interrupted Stay and Onsite Discharge and Readmittance Policies

A swing-bed hospital is defined at § 413.114(b) as a hospital or critical access hospital (CAH) participating in Medicare that has an approval from CMS to provide post-hospital SNF care as defined in § 409.20 and meets the requirements specified in § 482.66 or § 485.645. Swing beds are otherwise licensed hospital beds that may, under certain circumstances, be used temporarily as SNF beds. Under § 413.114(a)(2), post-hospital SNF care furnished in general routine inpatient beds in rural hospitals (other than CAHs) is paid in accordance with the provisions of the SNF PPS for services furnished for cost reporting periods beginning on or after July 1, 2002. Since it is possible for a Medicare beneficiary to be discharged from a LTCH for post-hospital SNF care that is being provided by another hospital-level Medicare provider with swing beds, such a discharge would be considered the same as if it were to an individual SNF. We interpret the extension of the SNF PPS to swing beds to require that all payment policy determinations regarding patient movement between LTCHs and SNFs, including the onsite policy described above, also apply to swing beds.

In the March 7, 2003, proposed rule (68 FR 11254), we stated that we want to emphasize that our inclusion of swing beds in payment policy determinations for all patient movement between LTCHs and SNFs (*see* section VII.C.4.c. of this preamble) would mean that a readmission to a LTCH from post-hospital SNF care being provided in a swing bed that is located either in the LTCH itself or in another onsite Medicare provider would have the same policy consequences as would a readmission to the LTCH from an onsite SNF. We received no comments on this clarification.

5. Other Payment Adjustments

As indicated earlier, we had broad authority under section 123 of Public Law 106–113, including whether (and how) to provide for adjustments to reflect variations in the necessary costs of treatment among LTCHs. Thus, in the August 30, 2002, final rule (67 FR 56014–56027), we discussed our extensive data analysis and rationale for not implementing an adjustment for geographic reclassification, rural location, treating a disproportionate share of low-income patients (DSH), or indirect medical education (IME) costs. In that same final rule, we stated that we would collect data and reevaluate the appropriateness of these adjustments in the future once more LTCH data become available after the LTCH PPS is implemented. As we stated in the March 7, 2003, proposed rule (68 FR 11254), because the LTCH PPS was only recently implemented, sufficient new data have not yet been generated that would enable us to conduct a comprehensive reevaluation of these payment adjustments. Therefore, in that same proposed rule, we did not propose an adjustment for geographic reclassification, rural location, DSH, or IME at this time. Additionally, we stated

that we would continue to collect and interpret new data as they become available in the future to determine if these data support proposing any additional payment adjustments.

Comment: Two commenters objected to our proposal not to include an adjustment to account for a hospital's treatment of a disproportionate share of low-income patients (a DSH adjustment) or an adjustment to account for indirect teaching costs (an IME adjustment). One commenter stated that given that LTCHs are a heterogeneous group of facilities with widely varying costs and patient populations, it is particularly important to provide adjustments to compensate for the differences where possible. The other commenter stated that the LTCH regression analysis was among a diverse set of facilities, thus weakening CMS' conclusions not to include adjustments for DSH and IME. Accordingly, both commenters urged for the inclusion of a DSH adjustment and an IME adjustment in the LTCH PPS.

Response: As we discussed in the August 30, 2002, final rule (67 FR 56020–56022), we examined the appropriateness of an adjustment for LTCHs serving a disproportionate share of low-income patients. In that same final rule, we explained that in examining the most recent LTCH data available to us, we determined that a DSH adjustment consistent with the DSH adjustment under the IPPS for acute care hospitals (set forth at section 1886(d)(5)(F) of the Act) would reduce the ability of the LTCH PPS to predict cost per case while lowering the base payment rate. We also evaluated alternative methods to provide some type of DSH adjustment. Specifically, using regression analysis that took into account both the Medicaid patients receiving SSI and the percentage of Medicaid patients not entitled to Medicare, we found no significant empirical relationship between these variables and LTCHs' costs. Therefore, we did not establish a DSH adjustment under the LTCH PPS.

Also, in the August 30, 2002, final rule (67 FR 56022), we explained that based on a double log regression, we found that the indirect teaching cost variable was negative and not significant. In addition, we looked at different specifications for the teaching variable, including resident-to-bed ratio and resident-to-average daily census, to measure teaching intensity. In all of our payment regressions it was determined that the teaching variable was not significant; that is, no empirical evidence exists to show that LTCHs' cost per case would vary with teaching costs.

In the March 7, 2003, proposed rule (68 FR 11254), we explained that because the LTCH PPS was only recently implemented, sufficient new data have not yet been generated that would enable us to conduct a comprehensive reevaluation of these payment adjustments. Therefore, since we still do not have empirical evidence to support a DSH adjustment or an IME adjustment, we continue to believe that it would be inappropriate to establish such adjustments at this time. Accordingly, in this final rule, we are not adopting the commenters' suggestion to include a DSH adjustment and an IME adjustment in the LTCH PPS. As we stated in the March 7, 2003, proposed rule (68 FR 11254), we will continue to collect and interpret new data as they become available in the future to determine if these data support proposing any additional payment adjustments.

6. Budget Neutrality Offset To Account for the Transition Methodology

In the August 30, 2002, final rule (67 FR 56038) under § 412.533, we implemented a 5-year transition period from reasonable cost-based payment to prospective payment, during which a LTCH will be paid an increasing percentage of the LTCH PPS rate and a decreasing percentage of its payments under the reasonable cost-based principles for each discharge. Furthermore, we allow a LTCH to elect to be paid based on 100 percent of the standard Federal rate in lieu of the blend methodology.

As we discussed in further detail in the August 30, 2002, final rule (67 FR 56032–56037), the standard Federal rate was determined as if all LTCHs will be paid based on 100 percent of the standard Federal rate. As stated earlier, we provide for a 5-year transition period methodology that allows LTCHs to receive payments based partially on reasonable cost-based principles. In order to maintain budget neutrality as required by section 123(a)(1) of the Public Law 106–113 and § 412.523(d)(2) during the 5-year transition period, we reduce all LTCH Medicare payments (whether a LTCH elects payment based on 100 percent of the Federal rate or whether a LTCH is being paid under the transition blend methodology). Specifically, we reduce all LTCH Medicare payments during the 5-year transition by a factor that is equal to 1 minus the ratio of the estimated TEFRA reasonable cost-based payments that would have been made if the LTCH PPS had not been implemented, to the projected total Medicare program PPS payments (that is, payments made under the transition methodology and the option to elect payment based on 100 percent of the Federal rate).

For FY 2003, based on a comparison of the estimated FY 2003 payments to each LTCH based on 100 percent of the standard Federal rate and the transition blend methodology, we projected that approximately 49 percent of LTCHs would elect to be paid based on 100 percent of the standard Federal rate rather than receive payment based on the transition blend methodology. This projection was based on our estimate that those 49 percent of LTCHs would receive higher payments based on 100 percent of the standard Federal rate compared to the payments they would receive under the transition blend methodology. Similarly, we projected that the remaining 51 percent of LTCHs would choose to be paid based on the transition blend methodology (80 percent of reasonable cost-based payments and 20 percent of payments based on the Federal rate) in FY 2003, because those payments would be higher than if they were paid based on 100 percent of the standard Federal rate.

In the August 30, 2002, final rule (67 FR 56034), we projected that the full effect of the 5-year transition period and the election option would result in a cost to the Medicare program of $240 million as follows: For FY 2003, $50 million; for FY 2004, $80 million; for FY 2005, $60 million; for FY 2006, $40 million; for FY 2007, $10 million. Thus, in order to maintain budget neutrality, we applied a 6.6 percent reduction (0.934) to all LTCHs' payments in FY 2003 to account for the estimated cost of $50 million for FY 2003. Furthermore, in order to maintain budget neutrality, we indicated that, in the future, we would propose a budget neutrality offset for each of the remaining years of the transition period to account for the estimated payments for the respective fiscal year. Based on the data available at that time, in the August 30, 2002, final rule (67 FR 56037) we estimated the following budget neutrality offsets to LTCH payments during the remainder of the transition period: 5.0 percent (0.950) in FY 2004; 3.4 percent (0.966) in FY 2005; and 1.7 percent (0.983) in FY 2006. We also stated that no budget neutrality offset is necessary in the 5th year of the transition period (FY 2007) because under the transition methodology at § 412.533, all LTCHs will be paid based on 100 percent of the standard Federal rate and zero percent of the reasonable cost-based principles.

As stated in the March 7, 2003, proposed rule (68 FR 11254–11256), for the proposed 2004 LTCH PPS rate year,

based on the best available data and the policies presented in that proposed rule, we projected that approximately 49 percent of LTCHs would be paid based on 100 percent of the proposed standard Federal rate rather than receive payment under the transition blend methodology. Using the same methodology in the August 30, 2002, final rule (67 FR 56034) described above, this projection, which uses updated data and inflation factors, is based on our estimate that these LTCHs would receive higher payments based on 100 percent of the proposed standard Federal rate compared to the payments they would receive under the transition blend methodology. Similarly, we project that the remaining 51 percent of LTCHs would choose to be paid based on the transition blend methodology (80 percent of reasonable cost-based payments and 20 percent of Federal rate payments for cost reporting periods that begin during FY 2003; and 60 percent of reasonable cost-based payments and 40 percent of Federal rate payments for cost reporting periods that begin during FY 2004 (in accordance with § 412.533(a))) because they would receive higher payments than if they were paid based on 100 percent of the proposed standard Federal rate.

In the March 7, 2003, proposed rule (68 FR 11255), based on the best available data and the proposed policy revisions described in that proposed rule, we projected that the full effect of the remaining 4 years of the transition period (including the election option) would result in a cost to the Medicare program of $300 million as follows: $120 million in the 2004 LTCH PPS rate year; $90 million in the 2005 LTCH PPS rate year; $60 million in the 2006 LTCH PPS rate year; and $30 million in the 2007 LTCH PPS rate year. Therefore, we proposed a 5.7 percent reduction (0.943) to all LTCHs' payments for discharges occurring on or after July 1, 2003, and through June 30, 2004, to account for the estimated cost of the $120 million for the proposed 2004 LTCH PPS rate year.

As we stated above, in order to maintain budget neutrality, we indicated that we would propose a budget neutrality offset for each of the remaining years of the transition period to account for the estimated costs for the respective fiscal year. In the March 7, 2003, proposed rule (68 FR 11255), based on the best available data at that time, we proposed the following budget neutrality offsets to LTCH payments during the transition period: 4.4 percent (0.956) in proposed 2005 LTCH PPS rate year; 2.9 percent (0.971) in proposed 2006 LTCH PPS rate year; and 1.2 percent (0.988) in proposed 2007 LTCH PPS rate year.

Comment: One commenter recommended that the budget neutrality offsets to LTCH payments during the transition period be updated periodically and adjusted to reflect any change in the percentage of LTCHs electing to receive payments during the transition period based on 100 percent of the Federal rate as provided for under § 412.533(c).

Response: As we stated in the March 7, 2003, proposed rule, the proposed budget neutrality offsets to LTCH payments during the transition period are determined using the best available data. Moreover, as we stated above, we proposed to revise the estimated budget neutrality offsets to LTCH payments during the transition period for future years annually along with the update to the Federal rate based on updated data. Therefore, in determining the budget neutrality offsets to LTCH payments during the transition period in future rate years, we will use the latest data available, including data on actual elections made by LTCHs to receive payments during the transition period based on 100 percent of the Federal rate as provided for under § 412.533(c). To update the budget neutrality offsets to LTCH payments during the transition period more often than in conjunction with the annual rate update would be an administrative burden to LTCHs and us.

Comment: A few commenters requested clarification on how we derived the estimate that 49 percent of LTCHs would elect payment based on 100 percent of the Federal rate in the proposed 2004 LTCH PPS rate year. Additionally, the commenters requested an explanation of how the estimate that 49 percent of LTCHs would elect payment based on 100 percent of the Federal rate in the 2004 LTCH PPS rate year can be determined from the proposed rule data posted on the CMS Web site. Some commenters also requested that the data files posted on the CMS Web site be consistent in the future, that is, provide the same information and title headings. One commenter, requested that the data files posted on the CMS Web site contain an indicator of which LTCHs have elected to receive payments based on 100 percent of the standard Federal rate as provided for under § 412.533(c).

Response: As we discussed above, the proposed estimate that 49 percent of LTCHs would elect payment based on 100 percent of the standard Federal rate in the proposed 2004 LTCH PPS rate year was based on our estimate that those 49 percent of LTCHs (96 out of 194) would receive higher payments based on 100 percent of the proposed standard Federal rate compared to the payments they would receive under the transition blend methodology. As we also noted above, this projection was based on the best available data and the policies presented in that proposed rule. Accordingly, in the March 7, 2003, proposed rule, when we simulated payments for each LTCH under the LTCH PPS for the proposed 2004 LTCH PPS rate year based on 100 percent of the proposed standard Federal rate, we incorporated the proposed policy changes, including the proposed standard Federal rate of $35,726.64, the proposed fixed loss amount of $19,978, the proposed labor-share of 72.612 percent, the proposed update of the wage index data, and the proposed elimination of the assignment of the applicable statewide average cost-to-charge ratio when a LTCH's cost-to-charge ratio fell below the floor. In estimating the payments that LTCHs would receive under the transition blend methodology, we projected the payments that each LTCH would receive during the proposed 2004 LTCH PPS rate year, if the LTCH PPS were not implemented. That is, we estimated payments based on reasonable cost-based principles in accordance with the methodology set forth in § 1886(b) of the Act.

Based on the LTCH's cost reporting period, we applied the applicable transition blend percentages for each LTCH during the proposed 2004 LTCH PPS rate year. For example, as we noted in the March 7, 2003, proposed rule (68 FR 11261), based on the transition blend percentages set forth in § 412.533(a), some providers may experience a change in the transition blend percentage during the proposed 2004 LTCH PPS rate year, such that a LTCH with an October 1, 2002, cost reporting period would have 3 months (July 1, 2003, through September 30, 2003) under the 80/20 transition blend (that is, 80 percent of payments based on reasonable cost-based principles and 20 percent based on the Federal rate) and 9 months (October 1, 2003, through June 30, 2004) of payment under the 60/40 transition blend (60 percent of payments based on reasonable cost-based principles and 40 based on the Federal rate).

If a LTCH's estimated LTCH PPS payments for the proposed 2004 LTCH PPS rate year were greater than its estimated payments under the transition period methodology for the proposed 2004 LTCH PPS rate year, then we assumed that the LTCH would elect payment based on 100 percent of the standard Federal rate for the proposed

2004 LTCH PPS rate year. Conversely, if a LTCH's estimated payments under the transition period methodology for the proposed 2004 LTCH PPS rate year were greater than its estimated LTCH PPS payments for the proposed 2004 LTCH PPS rate year, then we assumed that the LTCH would receive payment based on the transition blend methodology set forth in § 412.533(a) for the proposed 2004 LTCH PPS rate year. However, regardless of the comparison of a LTCH's estimated LTCH PPS payments and estimated payments under the transition period methodology for the proposed 2004 LTCH PPS rate year, we also took into account whether we had previously projected that a LTCH would elect payment based on 100 percent of the standard Federal rate in the August 30, 2002, final rule. Specifically, because LTCHs subject to the LTCH PPS with cost reporting periods that began prior to start of the proposed 2004 LTCH PPS rate year (July 1, 2003) would have already notified their fiscal intermediary of their election to receive payment based on 100 percent of the Federal rate in accordance with § 412.533(c)(2), and once a LTCH makes this election it cannot revert to the transition blend (§ 412.533(a)), in our proposed rule projection, we took into account our previous projection from the August 30, 2003, final rule.

Based on the clarification of how we derived the estimate that 49 percent of LTCHs would elect payment based on 100 percent of the Federal rate in the 2004 LTCH PPS rate year provided above, the March 7, 2003, proposed rule data posted on our website could be combined with the August 30, 2002, final rule data also posted on our website to derive the estimate that that 49 percent of LTCHs would elect payment based on 100 percent of the Federal rate in the proposed 2004 LTCH PPS rate year. Specifically, the variables ''Total TEFRA Payments for Impact'' and ''Total PPS Payments'' in the August 30, 2002, final rule data file posted on our website and the variables ''Estimated Total TEFRA Payment'' and ''Estimated Total PPS Payments (DRG + High-Cost Outlier)'' in the March 7, 2003, proposed rule data file posted on our website can be used to derive the estimate that 49 percent of LTCHs would elect payment based on 100 percent of the Federal rate in the 2004 LTCH PPS rate year.

In the future, we will make every attempt possible to provide the same information and title headings in the data file posted on our Web site. However, changes may be necessary in the future to reflect current policy and to more accurately reflect the data used. For example, the August 30, 2002, final rule data files posted on our website contained the variable ''Total TEFRA Payment for Budget Neutrality.'' As described in the corresponding file layout also posted on our Web site, in accordance with section 307 of Public Law 106–554, this variable used to determine the budget neutral standard Federal rate does not contain the increases to LTCHs' payments provided for under section 122 of Public Law 106–113 and section 307 of Public Law 106–554. However, that variable is no longer necessary since we are not required to determine the LTCH PPS Federal rate based on payments made under the reasonable cost-based methodology once the LTCH PPS is implemented (that is, for years beyond FY 2003). Since this variable was not required to determine the proposed rate and factors discussed in the March 7, 2003, proposed rule, there is no corresponding variable in the data files posted on our Web site. Additionally, as data on which LTCHs have elected to receive payments based on 100 percent of the standard Federal rate as provided for under § 412.533(c) become available in the future, we will incorporate that data in the LTCH PPS data files posted on the CMS' Web site.

Comment: One commenter requested clarification on why the proposed budget neutrality offsets for the transition period were increased for ''fiscal years'' 2004 through 2007, despite the fact the assumptions appear the same. The commenter recommends that the budget neutrality offsets for the transition period remain unchanged from those published in the August 30, 2002, final rule.

Response: Although the budget neutrality offsets presented in the August 30, 2002, final rule were applicable on a fiscal year basis, this is no longer true for the proposed budget neutrality offsets included in the March 7, 2003, proposed rule. The proposed budget neutrality offsets for the transition period were estimated to apply for the proposed LTCH PPS rate years 2004 through 2007, not ''fiscal years'' 2004 through 2007 as the commenter stated. The change in the period of time for which the proposed budget neutrality offsets for the transition period would be applicable is the primary reason why we determined the proposed budget neutrality offset for the transition period to be 5.7 percent for the proposed 2004 LTCH PPS rate year, beginning July 1, 2003, as compared to the previous estimate of 5.0 percent for FY 2004, beginning October 1, 2003 (presented in the August 30, 2002, final rule). Therefore, the change in the budget neutrality offsets for the transition period is primarily due to moving from the Federal FY (October 1st) rate cycle to the LTCH PPS rate year (July 1st) rate cycle. As we stated in the August 30, 2002, final rule, future budget neutrality offsets for the transition period in the proposed rule will be based on the best available data. Accordingly, in determining the proposed budget neutrality offsets for the transition period, we also took into account updated data.

Therefore, we believe that the proposed budget neutrality offset for the transition period for the proposed 2004 LTCH PPS rate year is appropriate based on the data available at that time, and we are not adopting the commenter's recommendation that the budget neutrality offsets for the transition period remain unchanged from those published in the August 30, 2002, final rule. Instead, in this final rule, we are revising the budget neutrality offsets for the transition period for the 2004 LTCH PPS rate year based on the same methodology established in the August 30, 2002, final rule, while using the best available data, and applying the offset to the 2004 LTCH PPS rate year.

In this final rule, for the 2004 LTCH PPS rate year, based on the best available data and the policies established in this final rule, we project that approximately 49 percent of LTCHs will be paid based on 100 percent of the proposed standard Federal rate rather than receive payment under the transition blend methodology. Using the same methodology described in the August 30, 2002, final rule (67 FR 56034), this projection, which uses updated data and inflation factors, is based on our estimate that either—(1) a LTCH has already elected payment based on 100 percent of the Federal rate prior to July 1, 2003, or (2) a LTCH will receive higher payments based on 100 percent of the 2004 LTCH PPS rate year standard Federal rate compared to the payments it would receive under the transition blend methodology. Similarly, we project that the remaining 51 percent of LTCHs will choose to be paid based on the transition blend methodology (80 percent of reasonable cost-based payments and 20 percent of the Federal rate for cost reporting periods beginning during FY 2003 and 60 percent of reasonable cost-based payments and 40 percent of the Federal rate for cost reporting periods beginning during FY 2004 in accordance with § 412.533(a)) because they will receive higher payments than if they were paid based on 100 percent of the 2004 LTCH PPS rate year standard Federal rate. We note that, as discussed in the March 7,

2003, proposed rule (68 FR 11256–11257), we did not propose to change the 5-year transition period set forth in § 412.533(a) in conjunction with the proposed change in the proposed 2004 LTCH PPS rate year update. Therefore, the applicable transition blend percentage will apply for a LTCH's entire cost reporting period beginning on or after October 1 (unless the LTCH elects payment based on 100 percent of the Federal rate).

In this final rule, based on the best available data and the final policy revisions described above, we projected that the full effect of the remaining 4 years of the transition period (including the election option) will result in a cost to the Medicare program of $310 million as follows:

LTCH PPS rate year	Estimated cost (in millions)
2004	$120
2005	100
2006	60
2007	30

Therefore, using the methodology established in the August 30, 2002, final rule (67 FR 56034) based on updated data and the final policies and rates established in this final rule, we are establishing a 6.0 percent reduction (0.940) to all LTCHs' payments for discharges subject to the LTCH PPS occurring on or after July 1, 2003, and through June 30, 2004, to account for the estimated cost of the election of the $120 million for the proposed 2004 LTCH PPS rate year. This offset has increased slightly over the estimate in the proposed rule (5.7 percent) primarily due to slightly higher projections of reasonable cost-based payment based on the latest available data. In addition, as we stated in the March 7, 2003, proposed rule (68 FR 12255), we emphasize that the budget neutrality offset to account for the transition methodology is calculated based on and effective for payments made for discharges occurring during the 2004 LTCH PPS rate year of July 1, 2003, through June 30, 2004, not the Federal FY 2004 of October 1, 2003, through September 30, 2004.

As we discussed in the August 30, 2002, final rule (67 FR 56036), consistent with the statutory requirement for budget neutrality in section 123(a)(1) of Public Law 106–113, we intended for estimated aggregate payments under the LTCH PPS to equal the estimated aggregate payments that would be made if the LTCH PPS was not implemented. Our methodology for estimating payments for purposes of the budget neutrality calculations use the best available data at that time and necessarily reflect assumptions. As the LTCH PPS progresses, we are monitoring payment data and will evaluate the ultimate accuracy of the assumptions used in the budget neutrality calculations (for example, inflation factors, intensity of services provided, or behavioral response to the implementation of the LTCH PPS) described in the August 30, 2002, final rule (67 FR 56027–56037). To the extent these assumptions significantly differ from actual experience, the aggregate amount of actual payments may turn out to be significantly higher or lower than the estimates on which the budget neutrality calculations were based.

Section 123 of Public Law 106–113 and section 307 of Public Law 106–554 provides broad authority to the Secretary in developing the LTCH PPS, including the authority for appropriate adjustments. Under this broad authority, as implemented in the regulations at § 412.523(d)(3), we have provided for the possibility of making a one-time prospective adjustment to the LTCH PPS rates by October 1, 2006, so that the effect of any significant difference between actual payments and estimated payments for the first year of the LTCH PPS would not be perpetuated in the LTCH PPS rates for future years.

In the August 30, 2002, final rule (67 FR 56037), we estimated that total Medicare program payments for LTCH services over 5 years would be $1.59 billion for FY 2003; $1.69 billion for FY 2004; $1.79 billion for FY 2005; $1.90 billion for FY 2006; and $2.00 billion for FY 2007. In the March 7, 2003, proposed rule (68 FR 12255), based on the best available data, we estimated that total Medicare program payments for LTCH services for the proposed LTCH PPS rate years of 2004 through 2008 would be:

LTCH PPS rate year	Estimated payments ($ in billion)
2004	$2.17
2005	2.29
2006	2.42
2007	2.56
2008	2.71

At this time, based on the most recent and best available data, these estimates of Medicare program payments for LTCH services for the LTCH PPS rate years of 2004 through 2008 remain unchanged from those estimates presented in the proposed rule. Therefore, in this final rule, we continue to estimate that Medicare program payments for LTCH services for the LTCH PPS rate years of 2004 through 2008 will be approximately $12.2 billion as shown above.

In accordance with the methodology established in the August 30, 2002, final rule (67 FR 56037), these estimates are based on the projection that 49 percent of LTCHs will elect to be paid based on 100 percent of the 2004 LTCH PPS rate year standard Federal rate rather than the transition blend, and an update of our estimate of 2004 LTCH PPS rate year payments to LTCHs using our Office of the Actuary's most recent estimate (based on updated data) of the excluded hospital with capital market basket of 2.5 percent for the 2004 LTCH PPS rate year (adjusted to account for the proposed change in the rate update cycle discussed in section VII.B.1.b. of this preamble), 3.2 percent for the 2005 LTCH PPS rate year, 3.1 percent for the 2006 and 2007 LTCH PPS rate years, and 3.0 percent for the 2008 LTCH PPS rate year. We also took into account our Office of the Actuary's projection that there would be an increase in Medicare beneficiary enrollment of 1.3 percent in the 2004 LTCH PPS rate year, 1.6 percent in the 2005 LTCH PPS rate year, 1.9 percent in the 2006 LTCH PPS rate year, 2.0 percent in the 2007 LTCH PPS rate year, and 2.1 percent in the 2008 LTCH PPS rate year.

Because the LTCH PPS was only recently implemented, sufficient new data have not been generated that would enable us to conduct a comprehensive reevaluation of our budget neutrality calculations. Therefore, in the March 7, 2003, proposed rule (68 FR 11256), we did not propose an adjustment for budget neutrality under § 412.523(d)(3) at this time. However, we stated that we will continue to collect and interpret new data as the data become available in the future to determine if such an adjustment should be proposed.

Comment: A few commenters expressed concern that the retroactive one-time budget neutrality adjustment at § 412.523(d)(3) would wrongly penalize LTCHs for a CMS calculation error, thereby, weakening the intent and value of the PPS design. The commenters believe that the proposed rule lacks detail about the methodology CMS will use to implement this adjustment and requests that CMS publish the data and methodology used to assess compliance with the budget neutrality mandate under section 123 of Public Law 106–113 established in regulations at § 412.523(d)(3). In addition, one commenter states that if the Congress intended CMS to ''reduce'' future payments based on a one-time budget neutrality adjustment, the Congress would have specified this

intent more clearly in the statutory or report language.

Response: As we discussed in greater detail in the August 30, 2002, final rule, section 123(a)(1) of Public Law 106–113 requires the Secretary to develop a DRG-based PPS for LTCHs and ''shall maintain budget neutrality.'' As we stated in that same final rule (67 FR 56036), in implementing the LTCH PPS in FY 2003 we intended for estimated aggregate payments under the LTCH PPS to equal the estimated aggregate payments that would have been made if the LTCH PPS had not been implemented. Moreover, section 123 of Public Law 106–113 and section 307 of Public Law 106–554 provide broad authority to the Secretary in developing the LTCH PPS, including the authority for appropriate adjustments. Under this broad authority, as implemented in the regulations at § 412.523(d)(3), we have provided for the possibility of making a one-time prospective adjustment to the LTCH PPS rates by October 1, 2006, so that the effect of any significant difference between actual payments and estimated payments of the LTCH PPS would not be perpetuated in the LTCH PPS rates for future years. This adjustment would not be ''retroactive'' as stated by the commenters; therefore, we do not believe that the one-time budget neutrality adjustment at § 412.523(d)(3) would wrongly penalize LTCHs for any calculation errors. Instead, as noted above, this adjustment is necessary so that any errors in the original budget neutrality calculations would not be perpetuated in the LTCH PPS rates for future years.

Furthermore, as we stated in the August 30, 2002, final rule (67 FR 56036–56037), if a one-time budget neutrality adjustment were proposed in the future under § 412.523(d)(3), the standard Federal rate may either increase or decrease depending on the difference between actual payments and estimated payments under the LTCH PPS.

As we also stated in the August 30, 2002, final rule (67 FR 56036–56037), when estimating payments for the purposes of the budget neutrality calculations in implementing the LTCH PPS for FY 2003, we used the best available data and any assumptions. As we explained in that same final rule, the actual data and the assumptions include inflation factors, intensity of services provided, and behavioral responses to the implementation of the LTCH PPS. To the extent that these data or assumptions significantly differ from actual experience, actual payments under the LTCH PPS may be higher *or* lower than the estimates on which the budget neutrality calculations were based, and a one-time prospective budget neutrality adjustment may be necessary to prevent perpetuating any errors in the budget neutrality calculations in future years. If in the future (but prior to October 1, 2006) after monitoring LTCH PPS payment data we believe that the assumptions used to determine the budget neutrality calculations differ significantly from actual experience, we would first propose an appropriate adjustment and publish the details of our findings in a future **Federal Register** document. At that time, we would also discuss the data and methodology used to determine the proposed one-time budget neutrality offset provided for under § 412.523(d)(3).

As we stated in the March 7, 2003, proposed rule, because the LTCH PPS was only recently implemented, sufficient new data have not been generated that would enable us to conduct a comprehensive reevaluation of our budget neutrality calculations. Therefore, in the March 7, 2003, proposed rule (68 FR 11256), we did not propose a one-time prospective adjustment for budget neutrality under § 412.523(d)(3) at that time. However, we will continue to collect and interpret new data as the data becomes available in the future to determine if such an adjustment should be proposed. Therefore, at this time we are not making a one-time prospective adjustment for budget neutrality as provided for under § 412.523(d)(3).

VIII. Computing the Adjusted Federal Prospective Payments

In accordance with § 412.525 and as discussed in section VII. of this final rule, the standard Federal rate is adjusted to account for differences in area wages by multiplying the labor-related share of the standard Federal rate by the appropriate LTCH PPS wage index. The standard Federal rate is also adjusted to account for the higher costs of hospitals in Alaska and Hawaii by multiplying the nonlabor-related share of the standard Federal rate by the appropriate adjustment factor shown in Table V in section VII.C.2. of this preamble. In the March 7, 2003, proposed rule (68 FR 11248), we proposed a standard Federal rate of $35,726.64 for the proposed 2004 LTCH PPS rate year. In this final rule, based on the best available data and the finalized policies present in this final rule, we are establishing a standard Federal rate of $35,892.41 for the 2004 LTCH PPS rate year. We illustrate the methodology used to adjust the Federal prospective payments in the following example:

During the 2004 LTCH PPS rate year, a Medicare patient is in a LTCH located in Chicago, Illinois (MSA 1600) with a two-fifths wage index value of 1.0418 (see Table 1 in the Addendum to this final rule). The Medicare patient is classified into LTC–DRG 4 (Spinal Procedures), which has a relative weight of 1.2493 (see Table 3 of the Addendum to this final rule). To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient, we compute the wage-adjusted Federal prospective payment amount by multiplying the unadjusted standard Federal rate ($35,892.41) by the labor-related share (72.885 percent) and the wage index (1.0418). This wage-adjusted amount is then added to the nonlabor-related portion of the unadjusted standard Federal rate (27.115 percent) to determine the adjusted Federal rate, which is then multiplied by the LTC–DRG relative weight (1.2493) to calculate the total adjusted Federal prospective payment for the 2004 LTCH PPS rate year ($45,992.49). In addition, as discussed in section VII.C.6. of this preamble, for the 2004 LTCH PPS rate year, we are reducing the LTCH PPS payment by 6.0 percent for the budget neutrality offset to account for the costs of the transition methodology. The following illustrates the components of the calculations in this example:

Unadjusted Standard Federal Prospective Payment Rate		$35,726.18
Labor-Related Share		0.72885
Labor-Related Portion of the Federal Rate	=	$26,039.03
2/5th Wage Index (MSA 1600)		1.0418
Wage-Adjusted Labor Share	=	$27,127.46
Nonlabor-Related Portion of the Federal Rate (adjusted for COLA if applicable)	+	$9,687.15
Adjusted Federal Rate	=	$36,814.61
LTC–DRG 4 Relative Weight	×	1.2493
Total Adjusted Federal Prospective Payment (Before the Budget Neutrality Offset)	=	$45,992.49
Budget Neutrality Offset	×	0.940
Total Federal Prospective Payment (With the Budget Neutrality Offset)	=	$43,232.94

IX. Transition Period

To provide a stable fiscal base for LTCHs, under § 412.533, we implemented a 5-year transition period from reasonable cost-based reimbursement under the TEFRA system to a prospective payment based

on industry-wide average operating and capital-related costs. Under the average pricing system, payment is not based on the experience of an individual hospital. As discussed in the August 30, 2002, final rule (67 FR 56038), we believe that a 5-year phase-in will provide LTCHs time to adjust their operations and capital financing to the new LTCH PPS, which is based on prospectively determined Federal payment rates. Furthermore, we believe that the 5-year phase-in of the LTCH PPS allows LTCH personnel to develop proficiency with the LTC–DRG coding system, resulting in improvement in the quality of the data used for generating our annual determination of relative weights and payment rates.

In accordance with § 412.533, the transition period for all hospitals subject to the LTCH PPS begins with the hospital's first cost reporting period beginning on or after October 1, 2002, and extends through the hospital's last cost reporting period beginning before October 1, 2007. During the 5-year transition period, a LTCH's total payment under the LTCH PPS is based on two payment percentages—one based on reasonable cost-based (TEFRA) payments and the other based on the standard Federal prospective payment rate. The percentage of payment based on the LTCH PPS Federal rate increases by 20 percentage points each year, while the reasonable cost-based payment rate percentage decreases by 20 percentage points each year, for the next 4 fiscal years. For cost reporting periods beginning on or after October 1, 2006, Medicare payment to LTCHs will be determined entirely under the Federal PPS methodology. The blend percentages as set forth in § 412.533(a) are as follows:

Cost reporting periods beginning on or after	Federal rate percentage	Reasonable cost principles rate percentage
October 1, 2002	20	80
October 1, 2003	40	60
October 1, 2004	60	40
October 1, 2005	80	20
October 1, 2006	100	0

For a cost reporting period that began on or after October 1, 2002, and before October 1, 2003 (FY 2003), the total payment for a LTCH is 80 percent of the amount calculated under reasonable cost principles for that specific LTCH and 20 percent of the Federal prospective payment amount. For cost reporting periods beginning on or after October 1, 2003, and before October 1, 2004 (Federal FY 2004), the total payment for a LTCH will be 60 percent of the amount calculated under reasonable cost principles for that specific LTCH and 40 percent of the Federal prospective payment amount. As we noted in the March 7, 2003, proposed rule (68 FR 11257), the change in the effective date of the annual LTCH PPS rate update discussed in section IV. of this preamble has no effect on the LTCH PPS transition period as set forth in § 412.533(a). That is, LTCHs paid under the transition blend under § 412.533(a), will receive those blend percentages for the entire 5-year transition period (unless they elect payments based on 100 percent of the Federal rate). Furthermore, LTCHs paid under the transition blend will receive the appropriate blend percentages of the Federal and reasonable cost-based rate for their entire cost reporting period as prescribed in § 412.533(a)(1) through (a)(5). For example, a LTCH with a cost reporting period beginning on July 1, 2003 (which is the LTCH's first cost reporting period since the implementation of the LTCH PPS), will receive payments based on 80 percent of the reasonable cost-based rate and 20 percent of the Federal rate for its discharges occurring on or after July 1, 2003, through June 30, 2004 (if the LTCH does not elect payment based on 100 percent of the Federal rate).

The reasonable cost-based rate percentage is a LTCH specific amount that is based on the amount that the LTCH would have been paid (under TEFRA) if the PPS were not implemented. As we discussed in the August 30, 2002, final rule (67 FR 56040), Medicare fiscal intermediaries will continue to compute the LTCH reasonable cost-based payment amount according to § 412.22(b) of the regulations and sections 1886(d) and (g) of the Act. We note that several reasonable cost-based payment provisions that were previously in effect are no longer effective, starting with cost reporting periods beginning in FY 2003. For instance, the caps on the target amounts for ''existing'' LTCHs provided for under section 4414 of the BBA (see § 413.40(c)(4)(iii)) for FYs 1998 through 2002 are no longer applicable for cost reporting periods beginning in FY 2003. Thus, a LTCH's target amount for FYs 2003 and beyond will be determined by updating its prior year's target amount (which for FY 2003 was subject to the FY 2002 cap). In addition, the 15-percent reduction to payments to LTCHs for capital-related costs provided for under section 4412 of Public Law 105–33 (§ 413.40(j)) is only applicable for portions of cost reporting periods occurring in FYs 1998 through FY 2002. This reduction is no longer applicable for cost reporting periods beginning in FY 2003. Therefore, the TEFRA portion of a LTCH's payment for capital-related costs during the LTCH PPS transition period is based on 100 percent of its Medicare allowable capital costs.

As we discussed in the August 30, 2002, final rule (67 FR 56038), in implementing the PPS for LTCHs, one of our goals is to transition hospitals to full prospective payments as soon as appropriate. Therefore, under § 412.533(c), we allow a LTCH, which is subject to a blended rate, to elect payment based on 100 percent of the Federal rate at the start of any of its cost reporting periods during the 5-year transition period rather than incrementally shifting from reasonable cost-based payments to prospective payments. Once a LTCH elects to be paid based on 100 percent of the Federal rate, it will not be able to revert to the transition blend. For cost reporting periods beginning on or after December 1, 2002, and for the remainder of the 5-year transition period, a LTCH must notify its fiscal intermediary in writing of its election on or before the 30th day prior to the start of the LTCH's next cost reporting period. For example, a LTCH with a cost report period that begins on May 1, 2004, must notify its fiscal intermediary in writing of an election before April 1, 2004.

Under § 412.533(c)(2)(i), the notification by the LTCH to make the election must be made in writing to the Medicare fiscal intermediary. Under § 412.533(c)(2)(ii) and (iii), the intermediary must receive the request on or before the specified date (that is, on or before the 30th day before the applicable cost reporting period begins for cost reporting periods beginning on or after December 1, 2002, through September 30, 2006), regardless of any postmarks or anticipated delivery dates.

Notifications received, postmarked, or delivered by other means after the specified date will not be accepted. If the specified date falls on a day that the postal service or other delivery sources are not open for business, the LTCH will be responsible for allowing sufficient time for the delivery of the request before the deadline. If a LTCH's notification is not received timely, payment will be based on the transition period blend percentages.

X. Payments to New LTCHs

Under § 412.23(e)(4), for purposes of Medicare payment under the LTCH PPS, we define a new LTCH as a provider of inpatient hospital services that otherwise meets the qualifying criteria for LTCHs, set forth in § 412.23(e)(1)

and (e)(2) and, under present or previous ownership (or both), and its first cost reporting period as a LTCH begins on or after October 1, 2002. We also specify in § 412.500 that the LTCH PPS is applicable to hospitals with a cost reporting period beginning on or after October 1, 2002.

As we discussed in the August 30, 2002, final rule (67 FR 56040), this definition of new LTCHs should not be confused with those LTCHs first paid under the TEFRA payment system for discharges occurring on or after October 1, 1997, described in section 1886(b)(7)(A) of the Act, added by section 4416 of Public Law 105–33. As stated in § 413.40(f)(2)(ii), for cost reporting periods beginning on or after October 1, 1997, the payment amount for a ''new'' (post-FY 1998) LTCH is the lower of the hospital's net inpatient operating cost per case or 110 percent of the national median target amount payment limit for hospitals in the same class for cost reporting periods ending during FY 1996, updated to the applicable cost reporting period (*see* 62 FR 46019, August 29, 1997). Under the LTCH PPS, those ''new'' LTCHs that meet the definition of ''new'' under § 413.40(f)(2)(ii) and that have their first cost reporting period as a LTCH beginning prior to October 1, 2002, will be paid under the transition methodology described in § 412.533.

As noted above and in accordance with § 412.533(d), new LTCHs will not participate in the 5-year transition from reasonable cost-based reimbursement to prospective payment. The transition period is intended to provide existing LTCHs time to adjust to payment under the new system. Since these new LTCHs with cost reporting periods beginning on or after October 1, 2002, would not have received payment under reasonable cost-based reimbursement for the delivery of LTCH services prior to the effective date of the LTCH PPS, we do not believe that those new LTCHs require a transition period in order to make adjustments to their operations and capital financing, as will LTCHs that have been paid under reasonable cost-based.

For example, a ''new'' LTCH (post-FY 1998) that first began receiving payment as a LTCH on October 1, 2001, will be subject to the 110 percent of the median target amount payment limit for LTCHs (in accordance with § 413.40(f)(2)(ii)) for both its FY 2002 (October 1, 2001, through September 30, 2002) and FY 2003 (October 1, 2002, through September 30, 2003) cost reporting periods. Assuming the hospital has not elected to be paid 100 percent of the Federal rate for its cost reporting period beginning on October 1, 2002 (the first cost reporting period when the LTCH will be subject to the PPS), the hospital will be paid under the transition methodology whereby the LTCH's reasonable cost-based portion of its payment for operating costs (80 percent) is limited by the 110 percent of the median target amount payment limit for LTCHs under § 413.40(f)(2)(ii). For its cost reporting period beginning on October 1, 2003 (which is the hospital's third cost reporting period), under the transition methodology, that LTCH's reasonable cost-based portion of its payment for operating costs (60 percent) will be limited to its target amount as determined under § 413.40(c)(4)(v). Furthermore, if a hospital is designated as a LTCH on September 1, 2002, it will not be considered a new LTCH under § 412.23(e)(4), even if it had not discharged any patients or received any payments as of the implementation date of the LTCH PPS on October 1, 2002, because its first cost reporting period did not begin on or after October 1, 2002. Thus, it will be paid according to § 413.40(f)(2)(ii) from September 1, 2002, through August 30, 2003. This LTCH will not be subject to payments under the LTCH PPS until the start of its next cost reporting period on September 1, 2003. At the beginning of its second cost reporting period as a LTCH (that is, September 1, 2003), this LTCH will be subject to the transition period methodology in § 412.533(a)(1), because this provision applies to cost reporting periods beginning on or after October 1, 2002, and before October 1, 2003. Under the blended payments of the transition period in § 412.533(a)(1), 80 percent of payments for operating costs would be paid under the reasonable cost principles, as described in § 413.40(f)(2)(ii). (This hospital could also elect to be paid 100 percent of the Federal rate for its cost reporting period beginning September 1, 2003.)

XI. Method of Payment

Under § 412.513, a Medicare LTCH patient is classified into a LTC–DRG based on the principal diagnosis, up to eight additional (secondary) diagnoses, and up to six procedures performed during the stay, as well as age, sex, and discharge status of the patient. The LTC–DRG is used to determine the Federal prospective payment that the LTCH will receive for the Medicare-covered part A services the LTCH furnished during the Medicare patient's stay. Under § 412.541(a), the payment is based on the submission of the discharge bill. The discharge bill also provides data to allow for reclassifying the stay from payment at the full LTC–DRG rate to payment for a case as a short-stay outlier (under § 412.529) or as an interrupted stay (under § 412.531), or to determine if the case will qualify for a high-cost outlier payment (under § 412.525(a)).

Accordingly, the ICD–9–CM codes and other information used to determine if an adjustment to the full LTC–DRG payment is necessary (for example, length of stay or interrupted stay status) are recorded by the LTCH on the Medicare patient's discharge bill and submitted to the Medicare fiscal intermediary for processing. The payment represents payment in full, under § 412.521(b), for inpatient operating and capital-related costs, but not for the costs of an approved medical education program, bad debts, blood clotting factors, anesthesia services by hospital-employed nonphysician anesthetists or obtained under arrangement, or the costs of photocopying and mailing medical records requested by a QIO, which are costs paid outside the LTCH PPS.

As under the previous reasonable cost-based payment system, under § 412.541(b) a LTCH may elect to be paid using the periodic interim payment (PIP) method described in § 413.64(h) and may be eligible to receive accelerated payments as described in § 413.64(g).

For those LTCHs that are paid during the 5-year transition based on the blended transition methodology in § 412.533(a) for cost reporting periods beginning on or after October 1, 2002, and before October 1, 2006, the PIP amount is based on the transition blend. For those LTCHs that are paid based on 100 percent of the standard Federal rate, the PIP amount is based on the estimated prospective payment for the year rather than on the estimated reasonable cost-based reimbursement. We exclude high-cost outlier payments that are paid upon submission of a discharge bill from the PIP amounts. In addition, part A costs that are not paid for under the LTCH PPS, including Medicare costs of an approved medical education program, bad debts, blood clotting factors, anesthesia services by hospital-employed nonphysician anesthetists or obtained under arrangement, and the costs of photocopying and mailing medical records requested by a QIO, are subject to the interim payment provisions (§ 412.541(c)).

Under § 412.541(d), LTCHs with unusually long lengths of stay and that are not receiving payment under the PIP method may bill on an interim basis (60 days after an admission and at intervals of at least 60 days after the date of the

first interim bill) and should include any high-cost outlier payment determined as of the last day for which the services have been billed.

XII. Monitoring

In the August 30, 2002, final rule (67 FR 56014), we discussed our intent to develop a monitoring system that will assist us in evaluating the LTCH PPS. Specifically, we discussed the monitoring of the various policies that we believe would provide equitable payment for stays that reflect less than the full course of treatment and reduce the incentives for inappropriate admissions, transfers, or premature discharges of patients that are present in a discharge-based prospective payment system. We also stated our intent to collect and interpret data on changes in average lengths of stay under the LTCH PPS for specific LTC–DRGs and the impact of these changes on the Medicare program. We stated that if our data indicate that changes might be warranted, we may revisit these issues and consider proposing revisions to these policies in the future. To this end, we have designed systems features utilizing MedPAR data that will enable CMS and the fiscal intermediary to track beneficiary movement to and from a LTCH and to and from another Medicare provider. The Medicare Payment Advisory Commission (MedPac) has endorsed this monitoring activity and is pursuing an independent research initiative that will evaluate all aspects of LTCHs, including the accuracy of data reporting, provision of equivalent services by other providers, growth in the number of LTCHs, and clinical outcomes.

Also, in the August 30, 2002, final rule (67 FR 56014), we explained that, given that the only unique requirement that distinguishes a LTCH from other inpatient acute care hospitals is an average length of stay of greater than 25 days, we continue to be concerned about the extent to which LTCH services and patients differ from those services and patients treated in other Medicare covered settings (for example, SNFs and IRFs) and how the LTCH PPS will affect the access, quality, and costs across the health care continuum. Thus, we will monitor trends in the supply and utilization of LTCHs and Medicare's costs in LTCHs relative to other Medicare providers. For example, we may conduct medical record reviews of Medicare patients to monitor changes in service use (for example, ventilator use) over a LTCH episode of care and to assess patterns in the average length of stay at the facility level. We will consider future changes to LTCH coverage and payment policy based upon the results of such analyses.

XIII. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

XIV. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act (the Act), the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4), and Executive Order 13132.

1. Executive Order 12866

Executive Order 12866 (as amended by Executive Order 13258, which merely assigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). We have determined that this final rule will not be a major rule within the meaning of Executive Order 12866 because the redistributive effects do not constitute a shift of $100 million in any one year. As we discuss in further detail below, and in section VII.B.1.b. of this preamble, the change to the LTCH PPS rate update cycle will be budget neutral. Therefore, we estimate that there will be no budgetary impact for the Medicare program as a result of the change to the LTCH PPS rate update cycle. Based on the best available data for 194 LTCHs, we estimate that the 2.2 percent increase in the standard Federal rate for the 2004 LTCH PPS rate year will result in an increase in payments of $32.4 million and there are no significant redistributive effects among any groups of hospitals. (Section VII.C.6. of this preamble includes an estimate of Medicare program payments for LTCH services.)

2. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $26 million or less in any 1 year. For purposes of the RFA, all hospitals are considered small entities according to the Small Business Administration's latest size standards with total revenues of $26 million or less in any 1 year (for further information, *see* 65 FR 69432, November 17, 2000). Medicare fiscal intermediaries are not considered to be small entities. Individuals and States are not included in the definition of a small entity. We certify that this final rule will not have a significant impact on a substantial number of small entities, in accordance with RFA.

3. Impact on Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. For a final rule, this analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As discussed in detail below, the rates and policies set forth in this final rule will not have a substantial impact on the seven rural hospitals for which data were available that have fewer than 100 beds and that are located in rural areas.

4. Unfunded Mandates

Section 202 of the UMRA requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million or more. This final rule will not mandate any requirements for State, local, or tribal governments, nor would it result in expenditures by the private sector of $110 million or more in any one year.

5. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined this final rule under the criteria set forth in Executive Order 13132 and have determined that, based on the 9 State and local LTCHs in our database, this final rule will not have any significant impact on the rights, roles, and responsibilities of State, local, or tribal governments or preempt State law.

B. Anticipated Effects

We discuss the impact of this final rule below in terms of its fiscal impact on the Medicare budget and on LTCHs.

1. Budgetary Impact

Section 123(a)(1) of Medicare, Medicaid and State Child Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) requires us to set the payment rates contained in this final rule such that total payments under the LTCH PPS are projected to equal the amount that would have been paid if this PPS had not been implemented. However, as discussed in greater detail in the August 30, 2002, final rule (67 FR 56033–56036), the FY 2003 standard Federal rate ($34,956.15) was calculated as though all LTCHs will be paid based on 100 percent of the standard Federal rate in FY 2003. As discussed in section VII.C.6 of this final rule, we are applying a budget neutrality offset to payments to account for the monetary effect of the 5-year transition period and the policy to permit LTCHs to elect to be paid based on 100 percent of the standard Federal rate rather than a blend of Federal prospective payments and reasonable cost-based payments during the transition. The amount of the offset is equal to 1 minus the ratio of the estimated reasonable cost-based payments that would have been made if the LTCH PPS had not been implemented, to the projected total Medicare program payments that will be made under the transition methodology and the option to elect payment based on 100 percent of the Federal prospective payment rate.

Our Office of the Actuary computed an update factor to update LTCH PPS payments from the current rate period (Federal FY 2003) to the new 2004 LTCH PPS rate year (July 1, 2003, through June 30, 2004). The 2004 LTCH PPS rate year overlaps the current rate period by 3 months (July 1, 2003, through September 30, 2003). The market basket increase for Federal FY 2003 is currently estimated at 3.7 percent and the most recent estimate of the LTCH PPS market basket increase for the 2004 LTCH PPS rate year is estimated at 2.5 percent (as discussed in section VII.B.1.b of this preamble). Therefore, over the period from FY 2002 through the 2004 LTCH PPS rate year (June 30, 2004), the cumulative increase would be 6.0 percent (1.037 * 1.025 = 1.063). This cumulative increase matches (within rounding) the cumulative increase calculated by using the index level in the new effective period and the index level in FY 2002, such that having two separate updates result in the same cumulative update as if we had used a single update for the entire 21-month period (October 1, 2002, through June 30, 2004). Thus, the change to the 2004 LTCH PPS rate update cycle will not result in a higher or lower update than would have been the case (except due to rounding) if no change had been made to the LTCH PPS update cycle. In addition, as discussed in section VII.B.1.b. of the preamble of this final rule, we apply a budget neutrality adjustment of 0.997 in determining the standard Federal rate to account for the estimated $5.68 million budgetary impact for the Medicare program in FY 2003 as a result of the change to the 2004 LTCH PPS rate year cycle.

2. Impact on Providers

The basic methodology for determining a LTCH PPS payment is set forth in the regulations at § 412.515 through § 412.525. In addition to the basic LTC–DRG payment (standard Federal rate × LTC–DRG relative weight), we make adjustments for differences in area wage levels, cost-of-living adjustment for Alaska and Hawaii, and short-stay outliers. In addition, LTCHs may also receive high-cost outlier payments for those cases that qualify under the threshold established each rate year. Section 412.533 provides for a 5-year transition to fully prospective payments from payment based on reasonable cost-based principles. During the 5-year transition period, payments to LTCHs are based on an increasing percentage of the LTCH PPS Federal rate and a decreasing percentage of payment based on reasonable cost-based principles. Section 412.533(c) provides for a one-time opportunity for LTCHs to elect payments based on 100 percent of the LTCH PPS Federal rate.

In order to understand the impact of the changes to the LTCH PPS discussed in this final rule on different categories of LTCHs for the 2004 LTCH PPS rate year, it is necessary to estimate payments per discharge under the current (Federal FY 2003) LTCH PPS rates and factors (*see* the August 30, 2002, final rule) and payments per discharge that will be made under the LTCH PPS rates and factors for the 2004 LTCH PPS rate year (July 1, 2003, through June 30, 2004). We also evaluated the percent change in payments per discharge of estimated FY 2003 prospective payments to estimated 2004 LTCH PPS rate year payments for each category of LTCHs.

Hospital groups were based on characteristics provided in OSCAR data and FYs 1998 through 2000 cost report data from HCRIS. Hospitals with incomplete characteristics were grouped into the ''unknown'' category. Hospital groups include:

—Location: Large Urban/Other Urban/ Rural
—Participation Date
—Ownership Control
—Census Region
—Bed Size

To estimate the impacts among the various categories of providers during the transition period, it is imperative that reasonable cost-based principle payments and prospective payments contain similar inputs. More specifically, in the impact analysis showing the impact reflecting the applicable transition blend percentages of prospective payments and reasonable cost-based principle payments and the option to elect payment based on 100 percent of the Federal rate (Table VII below), we estimated payments only for those providers for whom we are able to calculate payments based on reasonable cost-based principles. For example, if we did not have FYs 1996 through 1999 cost data for a LTCH, we were unable to determine an update to the LTCH's target amount to estimate payment under the current reasonable cost-based principles.

Using LTCH cases from the FY 2001 MedPAR file and cost data from FYs 1996 through 2000 in HCRIS to estimate payments under the current reasonable cost-based principles, we have both case-mix and cost data for 194 LTCHs. Thus, for the impact analyses reflecting the applicable transition blend percentages of prospective payments and reasonable cost-based principle payments and the option to elect payment based on 100 percent of the Federal rate (*see* Table VI below), we used data from 194 LTCHs. While currently there are approximately 280 LTCHs, the most recent growth is predominantly in for-profit LTCHs that provide respiratory and ventilator-dependent patient care. We believe that the discharges from the MedPAR data for the 194 LTCHs in our database provide sufficient representation in the LTC–DRGs containing discharges for patients that received respiratory and ventilator-dependent care. However,

using cases from the FY 2001 MedPAR file, we had case-mix data for 250 LTCHs. Cost data to determine current payments under reasonable cost-based principle payments are not needed to simulate payments based on 100 percent of the Federal rate. Therefore, for the impact analyses reflecting fully phased-in prospective payments (*see* Table VII below), we used data from 250 LTCHs.

These impacts reflect the estimated ''losses'' or ''gains'' among the various classifications of providers for the 12-month period from October 1, 2002, through September 30, 2003 (Federal FY 2003), compared to the 12-month period from July 1, 2003, through June 30, 2004 (2004 LTCH PPS rate year). Prospective payments for the 2004 LTCH rate year were based on the standard Federal rate of $35,726.18 and the hospital's estimated case-mix based on FY 2001 claims data. Prospective payments for Federal FY 2003 were based on the standard Federal rate of $34,956.15 and the same FY 2001 claims data.

3. Calculation of Prospective Payments

To estimate payments under the LTCH PPS, we simulated payments on a case-by-case basis by applying the payment policy for short-stay outliers (as described in section VII.C.4.b of this final rule) and the adjustments for area wage differences (as described in section VII.C.1 of this final rule) and for the cost-of-living for Alaska and Hawaii (as described in section VII.C.2 of this final rule). Additional payments would also be made for high-cost outlier cases (as described in section VII.C.3 of this final rule). As noted in section VII.C.5 of this final rule, we are not making adjustments for rural location, geographic reclassification, indirect medical education costs, or a disproportionate share of low-income patients.

We adjusted for area wage differences for estimated FY 2003 payments by using the applicable LTCH PPS wage index (one-fifth of the full FY 2002 acute care hospital inpatient wage index data, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (*see* August 30, 2002, 67 FR 56057–56075). For the estimated 2004 LTCH PPS rate year payments, we used a weighted average of a LTCH's applicable wage index during the period from July 1, 2003, through June 30, 2004, since some providers may experience a change in the wage index phase-in percentage during the period from July 1, 2003, through June 30, 2004. For cost reporting periods beginning on or after October 1, 2002, and before September 30, 2003, the labor portion of the Federal rate is adjusted by one-fifth of the applicable LTCH PPS wage index. For cost reporting periods beginning on or after October 1, 2003, and before September 30, 2004, the labor portion of the Federal rate is adjusted by two-fifths of the applicable LTCH PPS wage index. The applicable LTCH PPS wage index values are computed using the same data to compute the acute care hospital inpatient wage index data, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (as discussed in section VII.C.1. of this final rule). Therefore, a provider with a cost reporting period beginning October 1, 2003, will have 3 months of payments under the one-fifth wage index value and 9 months of payment under the two-fifths wage index value. For this provider, we computed a blended wage index of 25 percent (3 months/12 months) of the one-fifth wage index value and 75 percent (9 months/12 months) of the two-fifths wage index value.

We also calculated payments using the applicable transition blend percentages. For FY 2003, the applicable transition blend percentage is 80 percent of payment based on reasonable cost-based principles and 20 percent of payment under the LTCH PPS. For the 2004 LTCH PPS rate year based on the transition blend percentages set forth in § 412.533(a), some providers may experience a change in the transition blend percentage during the period from July 1, 2003, through June 30, 2004. For example during the 12-month period from July 1, 2003, through June 30, 2004, a provider with a cost reporting period beginning on October 1, 2002 (which is paid under the 80/20 transition blend (80 percent of payments based on reasonable cost-based principles and 20 percent of payments under the LTCH PPS), beginning October 1, 2002) will have 3 months (July 1, 2003, through September 30, 2003) under the 80/20 blend and 9 months (October 1, 2003, through June 30, 2004) of payment under the 60/40-transition blend (60 percent of payments based on reasonable cost-based principles and 40 percent of payments under the LTCH PPS). (The 60 percent/40 percent blend would continue until the provider's cost report period beginning on October 1, 2004.) In estimating blended transition payments, we estimated payments based on reasonable cost-based principles in accordance with the methodology in section 1886(b) of the Act. We compared the estimated blended transition payment to the LTCH's estimated payment if it would elect payment based on 100 percent of the Federal rate. If we estimated that a LTCH would be paid more based on 100 percent of the Federal rate, we assumed that it would elect to bypass the transition methodology and to receive immediate prospective payments.

Then we applied the 6.6 percent reduction to payment to account for the effect of the 5-year transition methodology and election of payment based on 100 percent of the Federal rate on Medicare program payments established in the August 30, 2002, final rule (67 FR 56034) to each LTCH's estimated payments under the LTCH PPS for FY 2003. Similarly, we applied the 6.0 percent reduction to payment to account for the effect of the 5-year transition methodology and election of payment based on 100 percent of the Federal rate on Medicare program payments (see section VII.C.6 of this final rule) to each LTCH's estimated payments under the LTCH PPS for the 2004 LTCH PPS rate year. The impact based on our projection of whether a LTCH will be paid based on the transition blend methodology or will elect payment based on 100 percent of the Federal rate is shown below in Table VI.

In Table VII below, we also show the impact if the LTCH PPS were fully implemented; that is, as if there were an immediate transition to fully Federal prospective payments under the LTCH PPS for Federal FY 2003 and the 2004 LTCH PPS rate year. Accordingly, the 6.0 percent reduction to account for the 5-year transition methodology on LTCHs' Medicare program payments for the 2004 LTCH PPS rate year and the 6.6 percent reduction to account for the 5-year transition methodology on LTCHs' Medicare program payments established for FY 2003 were not applied to LTCHs' estimated payments under the PPS.

Tables VI and VII below illustrate the aggregate impact of the payment system among various classifications of LTCHs.

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of long-term care cases.
- The fourth column shows the estimated payment per discharge for FY 2003.
- The fifth column shows the estimated payment per discharge for the 2004 LTCH PPS rate year.

• The sixth column shows the percent change of FY 2003 compared to the 2004 LTCH PPS rate year.

TABLE VI.—PROJECTED IMPACT REFLECTING APPLICABLE TRANSITION BLEND PERCENTAGES OF PROSPECTIVE PAYMENTS AND REASONABLE COST-BASED (TEFRA) PAYMENTS AND OPTION TO ELECT PAYMENT BASED ON 100 PERCENT OF THE FEDERAL RATE [1]

[FY 2003 payments compared to 2004 LTCH prospective payment system rate year]

LTCH classification	Number of LTCHs	Number of LTCH cases	Average federal FY 2003 payment per case [2]	Average 2004 LTCH prospective payment system rate year payment per case [3]	Percent change
All Providers	194	71,861	26,751	27,202	1.7
By Location:					
Rural	7	2,153	20,381	20,807	2.1
Urban	187	69,708	26,947	27,400	1.7
Large	113	47,743	27,232	27,695	1.7
Other	74	21,965	26,329	26,757	1.6
By Participation Date:					
After October 1993	129	42,973	27,983	28,452	1.7
Before October 1983	16	7,846	20,204	20,262	0.3
October 1983–September 1993	48	20,810	26,531	27,063	2.0
Unknown	1	232	39,515	42,895	8.6
By Ownership Control:					
Voluntary	48	17,741	24,561	25,032	1.9
Proprietary	136	51,655	27,562	27,980	1.5
Government	10	2,465	25,513	26,531	4.0
By Census Region:					
New England	14	9,499	20,371	20,286	-0.4
Middle Atlantic	9	3,282	28,390	28,069	–1.1
South Atlantic	20	6,573	30,805	31,580	2.5
East North Central	33	9,061	28,862	29,454	2.1
East South Central	10	2,863	26,516	26,163	–1.3
West North Central	11	2,906	26,278	26,940	2.5
West South Central	71	30,262	25,842	26,464	2.4
Mountain	15	2,495	28,049	28,611	2.0
Pacific	11	4,920	34,011	34,566	1.6
By Bed Size:					
Beds: 0–24	17	2,456	28,815	29,591	2.7
Beds: 25–49	88	21,734	28,129	28,507	1.3
Beds: 50–74	24	8,214	28,780	28,592	–0.7
Beds: 75–124	34	16,310	26,821	27,673	3.2
Beds: 125–199	21	13,838	24,430	24,558	0.5
Beds: 200+	9	9,228	24,671	25,559	3.6
Unknown	1	81	7,668	7,937	3.5

[1] These calculations take into account that some providers may experience a change in the blend percentage changes during the July 1, 2003, through June 30, 2004, rate year. For example, during the 12-month period of July 1, 2003, through June 30, 2004, a provider with a cost reporting period beginning October 1 would have 3 months (July 1, 2003, through September 30, 2003) of payments under the 80/20 blend and 9 months (October 1, 2003, through June 30, 2004) of payment under the 60/40 blend.

[2] Average payment per case for the 12-month period of October 1, 2002, through September 30, 2003.

[3] Average payment per case for the 12-month period of July 1, 2003, through June 30, 2004.

TABLE VII.—PROJECTED IMPACT REFLECTING THE FULLY PHASED-IN PROSPECTIVE PAYMENTS

[FY 2003 payments compared to 2004 LTCH prospective payment system rate year payments]

LTCH classification	Number of LTCHs	Number of LTCH cases	Average Federal FY 2003 payment per case [1]	Average 2004 LTCH prospective payment system rate year payment per case [2]	Percent change
All Providers	250	82,625	26,357	26,951	2.2
By Location:					
Rural	16	4,674	20,851	21,013	0.8
Urban	234	77,951	26,687	27,307	2.3
Large	135	52,256	27,027	27,651	2.3
Other	99	25,695	25,996	26,607	2.3
By Participation Date:					
After October 1993	182	53,246	27,178	27,740	2.1

TABLE VII.—PROJECTED IMPACT REFLECTING THE FULLY PHASED-IN PROSPECTIVE PAYMENTS—Continued

[FY 2003 payments compared to 2004 LTCH prospective payment system rate year payments]

LTCH classification	Number of LTCHs	Number of LTCH cases	Average Federal FY 2003 payment per case [1]	Average 2004 LTCH prospective payment system rate year payment per case [2]	Percent change
Before October 1983	17	7,897	20,826	20,881	0.3
October 1983—September 1993	49	21,257	26,230	27,138	3.5
Unknown	2	743	25,318	26,537	4.8
By Ownership Control:					
Voluntary	55	19,853	24,314	24,833	2.1
Proprietary	148	54,269	27,490	28,052	2.0
Government	47	8,503	23,893	24,864	4.1
By Census Region:					
New England	16	9,609	21,094	21,009	−0.4
Middle Atlantic	15	4,162	28,982	28,607	−1.3
South Atlantic	23	7,051	30,441	31,289	2.8
East North Central	48	12,145	28,356	29,074	2.5
East South Central	14	3,722	28,561	28,496	−0.2
West North Central	16	3,769	26,347	27,245	3.4
West South Central	87	33,971	24,560	25,384	3.4
Mountain	19	2,993	26,529	27,567	3.9
Pacific	12	5,203	33,836	34,323	1.4
By Bed Size:					
Beds: 0–24	21	3,073	27,130	28,221	4.0
Beds: 25–49	98	24,386	27,954	28,222	1.0
Beds: 50–74	27	9,310	27,556	27,610	0.2
Beds: 75–124	35	16,432	26,222	27,475	4.8
Beds: 125–199	21	13,838	24,945	25,148	0.8
Beds: 200+	11	9,518	25,041	26,054	4.0
Unknown	37	6,068	23,354	24,284	4.0

[1] Average payment per case for the 12-month period of October 1, 2002, through September 30, 2003.
[2] Average payment per case for the 12-month period of July 1, 2003, through June 30, 2004.

4. Results

We have prepared the following summary of the impact (as shown in Table VI) of the LTCH PPS set forth in this proposed rule.

a. Location. The majority of LTCHs are in urban areas. Approximately 3 percent of the LTCHs are identified as being located in a rural area, and approximately 3 percent of all LTCH cases are treated in these rural hospitals. Impact analysis in Table VI shows that the percent change in estimated payments per discharge for FY 2003 compared to the 2004 LTCH PPS rate year for rural LTCHs will be 2.1 percent, and will be 1.7 percent for urban LTCHs. Large urban LTCHs are projected to experience a 1.7 percent increase in payments per discharge percent from FY 2003 compared to the 2004 LTCH PPS rate year, while other urban LTCHs projected to experience a 1.6 percent increase in payments per discharge percent from FY 2003 compared to the 2004 LTCH PPS rate year. (*See* Table VI.)

b. Participation Date. LTCHs are grouped by participation date into three categories: (1) Before October 1983; (2) between October 1983 and September 1993; and (3) after October 1993. We did not have sufficient OSCAR data on 1 LTCH, which we labeled as an ''Unknown'' category. The majority, approximately 60 percent, of the LTCH cases are in hospitals that began participating after October 1993 and are projected to experience a 1.7 percent increase in payments per discharge from FY 2003 compared to the 2004 LTCH PPS rate year. Approximately 11 percent of the cases are in LTCHs that began participating in Medicare before October 1983 and are projected to experience a 0.3 percent increase in payments per discharge percent from FY 2003 compared to the 2004 LTCH PPS rate year. LTCHs that began participating between October 1983 and September 1993 are projected to experience a 2.0 percent increase in payments per discharge from FY 2003 compared to the 2004 LTCH PPS rate year. (*See* Table VI.)

c. Ownership Control. LTCHs are grouped into three categories based on ownership control type—(1) Voluntary; (2) proprietary; and (3) government.

Approximately 5 percent of LTCHs are government run and we expect that they will ''gain'' the most from the changes based on our projection that they will experience a 4.0 percent increase in payments per discharge from FY 2003 compared to the 2004 LTCH PPS rate year. Voluntary and proprietary LTCHs are projected to experience a 1.9 percent and 1.5 percent increase in payments per discharge percent from FY 2003 compared to the 2004 LTCH PPS rate year, respectively. (*See* Table VI.)

d. Census Region. LTCHs located in most regions are expected to experience an increase in payments per discharge percent from FY 2003 compared to the 2004 LTCH PPS rate year. Specifically, of the nine census regions, we expect that LTCHs in the South Atlantic and West North Central regions will experience the largest percent increase in payments per discharge percent from FY 2003 compared to the 2004 LTCH PPS rate year (2.5 percent). We expect LTCHs in the Pacific region will experience the smallest percent increase in payments per discharge percent from FY 2003 compared to the 2004 LTCH PPS rate year (1.6 percent). (*See* Table VI.)

e. Bed Size. LTCHs were grouped into six categories based on bed size—0–24 beds, 25–49 beds, 50–74 beds, 75–124 beds, 125–199 beds, and 200+ beds. We did not have sufficient OSCAR data on

1 LTCH, which we labeled as an ''Unknown'' category.

The percent increase in payments per discharge percent from FY 2003 compared to the 2004 LTCH PPS rate year are projected to increase for all bed size categories. Most LTCHs were in bed size categories where the percent increase in payments per discharge from FY 2003 compared to the 2004 LTCH PPS rate year is estimated to be greater than 1.0 percent. Other than the LTCH whose bed size is unknown, LTCHs with 200 or more beds have the highest estimated percent change in payments per discharge percent from FY 2003 compared to the 2004 LTCH PPS rate year (3.6 percent), while LTCHs with 125–199 beds have the lowest projected increase in the percent change in payments per discharge percent from FY 2003 compared to the 2004 LTCH PPS rate year (0.5 percent). (*See* Table VI.)

5. Effect on the Medicare Program

Based on actuarial projections resulting from our experience with other prospective payment systems, we estimate that Medicare spending (total Medicare program payments) for LTCH services over the next 5 years will be as follows:

LTCH PPS rate year	Estimated payments ($ in billions)
2004	$2.17
2005	2.29
2006	2.42
2007	2.56
2008	2.71

These estimates are based on the current estimate of increase in the excluded hospital market with capital basket of 2.5 percent for 2004 LTCH PPS rate year (adjusted to account for the change in the rate update cycle discussed in section VII.B.1.b of the preamble of this final rule), 3.2 percent for the 2005 LTCH PPS rate year, 3.1 percent for the 2006 and 2007 LTCH PPS rate years, and 3.0 percent for the 2008 LTCH PPS rate year. We currently estimate that there will be an increase in Medicare beneficiary enrollment of 1.3 percent in 2004 LTCH PPS rate year, 1.6 percent in 2005 LTCH PPS rate year, 1.9 percent in 2006 LTCH PPS rate year, 2.0 percent in 2007 LTCH PPS rate year, 2.1 percent in 2008 LTCH PPS rate year, and an estimated increase in the total number of LTCHs.

Consistent with the statutory requirement for budget neutrality, we intend for estimated aggregate payments under the LTCH PPS in FY 2003 to equal the estimated aggregate payments that will be made if the LTCH PPS were not implemented. Our methodology for estimating payments for purposes of the budget neutrality calculations uses the best available data and necessarily reflects assumptions. As we collect data from LTCHs, we will monitor payments and evaluate the ultimate accuracy of the assumptions used to calculate the budget neutrality calculations (that is, inflation factors, intensity of services provided, or behavioral response to the implementation of the LTCH PPS). To the extent the assumptions significantly differ from actual experience, the aggregate amount of actual payments may turn out to be significantly higher or lower than the estimates on which the budget neutrality calculations are based.

Section 123 of BBRA and section 307 of BIPA provide the Secretary with extremely broad authority in developing the LTCH PPS, including the authority for appropriate adjustments. In accordance with this broad authority, we may discuss in a future proposed rule a possible one-time prospective adjustment to the LTCH PPS rates to maintain budget neutrality so that the effect of the difference between actual payments and estimated payments for the first year of LTCH PPS is not perpetuated in the PPS rates for future years. Because the LTCH PPS was only implemented for cost reporting periods beginning on or after October 1, 2002, we do not yet have sufficient data to determine whether such an adjustment is warranted.

6. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals will receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries under the LTCH PPS, but we expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

C. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

■ In accordance with the discussion in this preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, part 412, as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 412.22 is amended by revising paragraph (h)(2) introductory text and adding a new paragraph (h)(6) to read as follows:

§ 412.22 Excluded hospitals and hospital units: General rules.

* * * * *

(h) *Satellite facilities.* * * *

(2) Except as provided in paragraphs (h)(3) and (h)(6) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the prospective payment systems for any period:

* * * * *

(6) The provisions of paragraph (h)(2)(i) of this section do not apply to any long-term care hospital that is subject to the long-term care hospital prospective payment system under Subpart O of this part, effective for cost reporting periods occurring on or after October 1, 2002, and that elects to be paid based on 100 percent of the Federal prospective payment rate as specified in § 412.533(c), beginning with the first cost reporting period following that election, or when the LTCH is fully transitioned to 100 percent of the Federal prospective rate, or to a new long-term care hospital, as defined in § 412.23(e)(4).

■ 3. Section 412.503 is amended by adding a definition of ''long-term care hospital prospective payment system rate year'' in alphabetical order to read as follows:

§ 412.503 Definitions.

* * * * *

Long-term care hospital prospective payment system rate year means the 12-month period of July 1 through June 30.

* * * * *

■ 4. Section 412.523 is amended by revising paragraphs (c)(3) and (d)(3) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) *Computation of the standard Federal rate.* The standard Federal rate is computed as follows:

(i) *For FY 2003.* Based on the updated costs per discharge and estimated

payments for FY 2003 determined in paragraph (c)(2) of this section, CMS computes a standard Federal rate for FY 2003 that reflects, as appropriate, the adjustments described in paragraph (d) of this section. The FY 2003 standard Federal rate is effective for discharges occurring in cost reporting periods beginning on or after October 1, 2002 through June 30, 2003.

(ii) *For long-term care hospital prospective payment system rate years beginning July 1, 2003 and after.* The standard Federal rate for long-term care hospital prospective payment system rate years beginning July 1, 2003 and after will be the standard Federal rate for the previous long-term care hospital prospective payment system rate year, updated by the increase factor described in paragraph (a)(2) of this section, and adjusted, as appropriate, as described in paragraph (d) of this section. For the rate year from July 1, 2003 through June 30, 2004, the updated and adjusted standard Federal rate will be offset by a budget neutrality factor to account for updating the FY 2003 standard Federal rate on July 1 rather than October 1.

* * * * *

(d) * * *

(3) *One-time prospective adjustment.* The Secretary will review payments under this prospective payment system and may make a one-time prospective adjustment to the long-term care hospital prospective payment system rates by October 1, 2006, so that the effect of any significant difference between actual payments and estimated payments for the first year of the long-term care hospital prospective payment system is not perpetuated in the prospective payment rates for future years.

* * * * *

■ 5. Section 412.525 is amended by revising paragraph (a) to read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

(a) *Adjustments for high-cost outliers.*

(1) CMS provides for an additional payment to a long-term care hospital if its estimated costs for a patient exceed the adjusted LTC–DRG payment plus a fixed-loss amount. For each long-term care hospital rate year, CMS determines a fixed-loss amount that is the maximum loss that a hospital can incur under the prospective payment system for a case with unusually high costs.

(2) The fixed-loss amount is determined for the long-term care hospital rate year using the LTC–DRG relative weights that are in effect on July 1 of the rate year.

(3) The additional payment equals 80 percent of the difference between the estimated cost of the patient care (determined by multiplying the hospital-specific cost-to-charge ratios by the Medicare allowable covered charge) and the sum of the adjusted Federal prospective payment for the LTC–DRG prospective payment system payment and the fixed-loss amount.

(4) No retroactive adjustments will be made to outlier payments upon cost report settlement to account for differences between the estimated cost-to-charge ratio and the actual cost-to-charge ratio of the case.

* * * * *

■ 6. Section 412.529 is amended by:

■ A. Revising paragraph (c)(1) introductory text.

■ B. Redesignating paragraph (c)(4) as paragraph (c)(5) and removing the term ''LTCH's'' and adding the term ''long-term care hospital's'' in its place.

■ C. Adding a new paragraph (c)(4).

§ 412.529 Special payment provision for short-stay outliers.

* * * * *

(c) *Method for determining the payment amount.*

(1) Subject to the provisions of paragraph (c)(4) of this section, the adjusted payment amount for a short-stay outlier is the least of the following amounts:

* * * * *

(4) Effective for discharges occurring on or after July 1, 2003, for long-term care hospitals described under § 412.23(e)(2)(ii), the adjusted payment amount for a short-stay outlier is determined under the formula set forth in paragraph (c)(1) of this section with the following substitution of the percentages specified for the LTG-DRG specific per diem amount and the cost of the case under paragraphs (c)(1)(i) and (c)(1)(ii) of this section:

(i) For the 1st year of the transition period, as specified at § 412.533(a)(1), the percentage is 195 percent.

(ii) For the 2nd year of the transition period, as specified at § 412.533(a)(2), the percentage is 193 percent;

(iii) For the 3rd year of the transition period, as specified at § 412.533(a)(3), the percentage is 165 percent;

(iv) For the 4th year of the transition period, as specified at § 412.533(a)(4), the percentage is 136 percent;

(v) For the 5th year of the transition period and after, as specified at § 412.533(a)(5), the percentage is 120 percent.

* * * * *

■ 7. Section 412.535 is revised to read as follows:

§ 412.535 Publication of the Federal prospective payment rates.

CMS publishes information pertaining to the long-term care hospital prospective payment system effective for each annual update in the **Federal Register**.

(a) Information on the unadjusted Federal payment rates and a description of the methodology and data used to calculate the payment rates are published on or before May 1 prior to the start of each long-term care hospital prospective payment system rate year which begins July 1, unless for good cause it is published after May 1, but before June 1.

(b) Information on the LTC–DRG classification and associated weighting factors is published on or before August 1 prior to the beginning of each Federal fiscal year.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: May 28, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: May 28, 2003.

Tommy G. Thompson,

Secretary.

Addendum

This addendum contains the tables referred to throughout the preamble to this final rule. The tables presented below are as follows:

Table 1.—Long-Term Care Hospital Wage Index for Urban Areas for Discharges Occurring from July 1, 2003, through June 30, 2004.

Table 2.—Long-Term Care Hospital Wage Index for Rural Areas for Discharges Occurring from July 1, 2003, through June 30, 2004.

Table 3.—LTC–DRG Relative Weights, Geometric Mean Length of Stay, and Short-Stay Five-Sixths Average Length of Stay for the Period of July 1, 2003, through September 30, 2003.

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
0040	Abilene, TX	0.7792	0.9558	0.9117
	Taylor, TX			
0060	Aguadilla, PR	0.4587	0.8917	0.7835
	Aguada, PR			
	Aguadilla, PR			
	Moca, PR			
0080	Akron, OH	0.9600	0.9920	0.9840
	Portage, OH			
	Summit, OH			
0120	Albany, GA	1.0594	1.0119	1.0238
	Dougherty, GA			
	Lee, GA			
0160	Albany-Schenectady-Troy, NY	0.8384	0.9677	0.9354
	Albany, NY			
	Montgomery, NY			
	Rensselaer, NY			
	Saratoga, NY			
	Schenectady, NY			
	Schoharie, NY			
0200	Albuquerque, NM	0.9315	0.9863	0.9726
	Bernalillo, NM			
	Sandoval, NM			
	Valencia, NM			
0220	Alexandria, LA	0.7859	0.9572	0.9144
	Rapides, LA			
0240	Allentown-Bethlehem-Easton, PA	0.9735	0.9947	0.9894
	Carbon, PA			
	Lehigh, PA			
	Northampton, PA			
0280	Altoona, PA	0.9225	0.9845	0.9690
	Blair, PA			
0320	Amarillo, TX	0.9034	0.9807	0.9614
	Potter, TX			
	Randall, TX			
0380	Anchorage, AK	1.2358	1.0472	1.0943
	Anchorage, AK			
0440	Ann Arbor, MI	1.1103	1.0221	1.0441
	Lenawee, MI			
	Livingston, MI			
	Washtenaw, MI			
0450	Anniston, AL	0.8044	0.9609	0.9218
	Calhoun, AL			
0460	Appleton-Oshkosh-Neenah, WI	0.8997	0.9799	0.9599
	Calumet, WI			
	Outagamie, WI			
	Winnebago, WI			
0470	Arecibo, PR	0.4337	0.8867	0.7735
	Arecibo, PR			
	Camuy, PR			
	Hatillo, PR			
0480	Asheville, NC	0.9876	0.9975	0.9950
	Buncombe, NC			
	Madison, NC			
0500	Athens, GA	1.0211	1.0042	1.0084
	Clarke, GA			
	Madison, GA			
	Oconee, GA			
0520	Atlanta, GA	0.9991	0.9998	0.9996
	Barrow, GA			
	Bartow, GA			
	Carroll, GA			
	Cherokee, GA			
	Clayton, GA			
	Cobb, GA			
	Coweta, GA			
	DeKalb, GA			
	Douglas, GA			
	Fayette, GA			
	Forsyth, GA			
	Fulton, GA			

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Gwinnett, GA			
	Henry, GA			
	Newton, GA			
	Paulding, GA			
	Pickens, GA			
	Rockdale, GA			
	Spalding, GA			
	Walton, GA			
0560	Atlantic-Cape May, NJ	1.1017	1.0203	1.0407
	Atlantic, NJ			
	Cape May, NJ			
0580	Auburn-Opelika, AL	0.8325	0.9665	0.9330
	Lee, AL			
0600	Augusta-Aiken, GA-SC	1.0264	1.0053	1.0106
	Columbia, GA			
	McDuffie, GA			
	Richmond, GA			
	Aiken, SC			
	Edgefield, SC			
0640	Austin-San Marcos, TX	0.9637	0.9927	0.9855
	Bastrop, TX			
	Caldwell, TX			
	Hays, TX			
	Travis, TX			
	Williamson, TX			
0680	Bakersfield, CA	0.9877	0.9975	0.9951
	Kern, CA			
0720	Baltimore, MD	0.9929	0.9986	0.9972
	Anne Arundel, MD			
	Baltimore, MD			
	Baltimore City, MD			
	Carroll, MD			
	Harford, MD			
	Howard, MD			
	Queen Anne's, MD			
0733	Bangor, ME	0.9664	0.9933	0.9866
	Penobscot, ME			
0743	Barnstable-Yarmouth, MA	1.3202	1.0640	1.1281
	Barnstable, MA			
0760	Baton Rouge, LA	0.8294	0.9659	0.9318
	Ascension, LA			
	East Baton Rouge, LA			
	Livingston, LA			
	West Baton Rouge, LA			
0840	Beaumont-Port Arthur, TX	0.8324	0.9665	0.9330
	Hardin, TX			
	Jefferson, TX			
	Orange, TX			
0860	Bellingham, WA	1.2282	1.0456	1.0913
	Whatcom, WA			
0870	Benton Harbor, MI	0.8965	0.9793	0.9586
	Berrien, MI			
0875	Bergen-Passaic, NJ	1.2150	1.0430	1.0860
	Bergen, NJ			
	Passaic, NJ			
0880	Billings, MT	0.9022	0.9804	0.9609
	Yellowstone, MT			
0920	Biloxi-Gulfport-Pascagoula, MS	0.8757	0.9751	0.9503
	Hancock, MS			
	Harrison, MS			
	Jackson, MS			
0960	Binghamton, NY	0.8341	0.9668	0.9336
	Broome, NY			
	Tioga, NY			
1000	Birmingham, AL	0.9222	0.9844	0.9689
	Blount, AL			
	Jefferson, AL			
	St. Clair, AL			
	Shelby, AL			
1010	Bismarck, ND	0.7972	0.9594	0.9189

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Burleigh, ND			
	Morton, ND			
1020	Bloomington, IN	0.8907	0.9781	0.9563
	Monroe, IN			
1040	Bloomington-Normal, IL	0.9109	0.9822	0.9644
	McLean, IL			
1080	Boise City, ID	0.9310	0.9862	0.9724
	Ada, ID			
	Canyon, ID			
1123	Boston-Worcester-Lawrence-Lowell-Brockton, MA-NH (NH Hospitals)	1.1229	1.0246	1.0492
	Bristol, MA			
	Essex, MA			
	Middlesex, MA			
	Norfolk, MA			
	Plymouth, MA			
	Suffolk, MA			
	Worcester, MA			
	Hillsborough, NH			
	Merrimack, NH			
	Rockingham, NH			
	Strafford, NH			
1125	Boulder-Longmont, CO	0.9689	0.9938	0.9876
	Boulder, CO			
1145	Brazoria, TX	0.8535	0.9707	0.9414
	Brazoria, TX			
1150	Bremerton, WA	1.0944	1.0189	1.0378
	Kitsap, WA			
1240	Brownsville-Harlingen-San Benito, TX	0.8880	0.9776	0.9552
	Cameron, TX			
1260	Bryan-College Station, TX	0.8821	0.9764	0.9528
	Brazos, TX			
1280	Buffalo-Niagara Falls, NY	0.9365	0.9873	0.9746
	Erie, NY			
	Niagara, NY			
1303	Burlington, VT	1.0052	1.0010	1.0021
	Chittenden, VT			
	Franklin, VT			
	Grand Isle, VT			
1310	Caguas, PR	0.4371	0.8874	0.7748
	Caguas, PR			
	Cayey, PR			
	Cidra, PR			
	Gurabo, PR			
	San Lorenzo, PR			
1320	Canton-Massillon, OH	0.8932	0.9786	0.9573
	Carroll, OH			
	Stark, OH			
1350	Casper, WY	0.9690	0.9938	0.9876
	Natrona, WY			
1360	Cedar Rapids, IA	0.9056	0.9811	0.9622
	Linn, IA			
1400	Champaign-Urbana, IL	1.0635	1.0127	1.0254
	Champaign, IL			
1440	Charleston-North Charleston, SC	0.9235	0.9847	0.9694
	Berkeley, SC			
	Charleston, SC			
	Dorchester, SC			
1480	Charleston, WV	0.8898	0.9780	0.9559
	Kanawha, WV			
	Putnam, WV			
1520	Charlotte-Gastonia-Rock Hill, NC-SC	0.9875	0.9975	0.9950
	Cabarrus, NC			
	Gaston, NC			
	Lincoln, NC			
	Mecklenburg, NC			
	Rowan, NC			
	Stanly, NC			
	Union, NC			
	York, SC			
1540	Charlottesville, VA	1.0438	1.0088	1.0175

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Albemarle, VA			
	Charlottesville City, VA			
	Fluvanna, VA			
	Greene, VA			
1560	Chattanooga, TN-GA	0.8976	0.9795	0.9590
	Catoosa, GA			
	Dade, GA			
	Walker, GA			
	Hamilton, TN			
	Marion, TN			
1580	Cheyenne, WY	0.8628	0.9726	0.9451
	Laramie, WY			
1600	Chicago, IL	1.1044	1.0209	1.0418
	Cook, IL			
	DeKalb, IL			
	DuPage, IL			
	Grundy, IL			
	Kane, IL			
	Kendall, IL			
	Lake, IL			
	McHenry, IL			
	Will, IL			
1620	Chico-Paradise, CA	0.9745	0.9949	0.9898
	Butte, CA			
1640	Cincinnati, OH-KY-IN	0.9381	0.9876	0.9752
	Dearborn, IN			
	Ohio, IN			
	Boone, KY			
	Campbell, KY			
	Gallatin, KY			
	Grant, KY			
	Kenton, KY			
	Pendleton, KY			
	Brown, OH			
	Clermont, OH			
	Hamilton, OH			
	Warren, OH			
1660	Clarksville-Hopkinsville, TN-KY	0.8406	0.9681	0.9362
	Christian, KY			
	Montgomery, TN			
1680	Cleveland-Lorain-Elyria, OH	0.9670	0.9934	0.9868
	Ashtabula, OH			
	Cuyahoga, OH			
	Geauga, OH			
	Lake, OH			
	Lorain, OH			
	Medina, OH			
1720	Colorado Springs, CO	0.9916	0.9983	0.9966
	El Paso, CO			
1740	Columbia, MO	0.8496	0.9699	0.9398
	Boone, MO			
1760	Columbia, SC	0.9307	0.9861	0.9723
	Lexington, SC			
	Richland, SC			
1800	Columbus, GA-ALRussell, AL	0.8374	0.9675	0.9350
	Chattahoochee, GA			
	Harris, GA			
	Muscogee, GA			
1840	Columbus, OH	0.9751	0.9950	0.9900
	Delaware, OH			
	Fairfield, OH			
	Franklin, OH			
	Licking, OH			
	Madison, OH			
	Pickaway, OH			
1880	Corpus Christi, TX	0.8729	0.9746	0.9492
	Nueces, TX			
	San Patricio, TX			
1890	Corvallis, OR	1.1453	1.0291	1.0581
	Benton, OR			

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
1900	Cumberland, MD-WV (WV Hospital)	0.7847	0.9569	0.9139
	Allegany, MD			
	Mineral, WV			
1920	Dallas, TX	0.9998	1.0000	0.9999
	Collin, TX			
	Dallas, TX			
	Denton, TX			
	Ellis, TX			
	Henderson, TX			
	Hunt, TX			
	Kaufman, TX			
	Rockwall, TX			
1950	Danville, VA	0.8859	0.9772	0.9544
	Danville City, VA			
	Pittsylvania, VA			
1960	Davenport-Moline-Rock Island, IA-IL	0.8835	0.9767	0.9534
	Scott, IA			
	Henry, IL			
	Rock Island, IL			
2000	Dayton-Springfield, OH	0.9282	0.9856	0.9713
	Clark, OH			
	Greene, OH			
	Miami, OH			
	Montgomery, OH			
2020	Daytona Beach, FL	0.9071	0.9814	0.9628
	Flagler, FL			
	Volusia, FL			
2030	Decatur, AL	0.8973	0.9795	0.9589
	Lawrence, AL			
	Morgan, AL			
2040	Decatur, IL	0.8055	0.9611	0.9222
	Macon, IL			
2080	Denver, CO	1.0601	1.0120	1.0240
	Adams, CO			
	Arapahoe, CO			
	Denver, CO			
	Douglas, CO			
	Jefferson, CO			
2120	Des Moines, IA	0.8791	0.9758	0.9516
	Dallas, IA			
	Polk, IA			
	Warren, IA			
2160	Detroit, MI	1.0448	1.0090	1.0179
	Lapeer, MI			
	Macomb, MI			
	Monroe, MI			
	Oakland, MI			
	St. Clair, MI			
	Wayne, MI			
2180	Dothan, AL	0.8137	0.9627	0.9255
	Dale, AL			
	Houston, AL			
2190	Dover, DE	0.9356	0.9871	0.9742
	Kent, DE			
2200	Dubuque, IA	0.8795	0.9759	0.9518
	Dubuque, IA			
2240	Duluth-Superior, MN-WI	1.0368	1.0074	1.0147
	St. Louis, MN			
	Douglas, WI			
2281	Dutchess County, NY	1.0684	1.0137	1.0274
	Dutchess, NY			
2290	Eau Claire, WI	0.8952	0.9790	0.9581
	Chippewa, WI			
	Eau Claire, WI			
2320	El Paso, TX	0.9265	0.9853	0.9706
	El Paso, TX			
2330	Elkhart-Goshen, IN	0.9722	0.9944	0.9889
	Elkhart, IN			
2335	Elmira, NY	0.8416	0.9683	0.9366
	Chemung, NY			

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
2340	Enid, OK	0.8376	0.9675	0.9350
	Garfield, OK			
2360	Erie, PA	0.8925	0.9785	0.9570
	Erie, PA			
2400	Eugene-Springfield, OR	1.0944	1.0189	1.0378
	Lane, OR			
2440	Evansville-Henderson, IN-KY (IN Hospitals)	0.8177	0.9635	0.9271
	Posey, IN			
	Vanderburgh, IN			
	Warrick, IN			
	Henderson, KY			
2520	Fargo-Moorhead, ND-MN	0.9684	0.9937	0.9874
	Clay, MN			
	Cass, ND			
2560	Fayetteville, NC	0.8889	0.9778	0.9556
	Cumberland, NC			
2580	Fayetteville-Springdale-Rogers, AR	0.8100	0.9620	0.9240
	Benton, AR			
	Washington, AR			
2620	Flagstaff, AZ-UT	1.0682	1.0136	1.0273
	Coconino, AZ			
	Kane, UT			
2640	Flint, MI	1.1135	1.0227	1.0454
	Genesee, MI			
2650	Florence, AL	0.7792	0.9558	0.9117
	Colbert, AL			
	Lauderdale, AL			
2655	Florence, SC	0.8780	0.9756	0.9512
	Florence, SC			
2670	Fort Collins-Loveland, CO	1.0066	1.0013	1.0026
	Larimer, CO			
2680	Ft. Lauderdale, FL	1.0297	1.0059	1.0119
	Broward, FL			
2700	Fort Myers-Cape Coral, FL	0.9680	0.9936	0.9872
	Lee, FL			
2710	Fort Pierce-Port St. Lucie, FL	0.9823	0.9965	0.9929
	Martin, FL			
	St. Lucie, FL			
2720	Fort Smith, AR-OK	0.7895	0.9579	0.9158
	Crawford, AR			
	Sebastian, AR			
	Sequoyah, OK			
2750	Fort Walton Beach, FL	0.9693	0.9939	0.9877
	Okaloosa, FL			
2760	Fort Wayne, IN	0.9457	0.9891	0.9783
	Adams, IN			
	Allen, IN			
	De Kalb, IN			
	Huntington, IN			
	Wells, IN			
	Whitley, IN			
2800	Forth Worth-Arlington, TX	0.9446	0.9889	0.9778
	Hood, TX			
	Johnson, TX			
	Parker, TX			
	Tarrant, TX			
2840	Fresno, CA	1.0169	1.0034	1.0068
	Fresno, CA			
	Madera, CA			
2880	Gadsden, AL	0.8505	0.9701	0.9402
	Etowah, AL			
2900	Gainesville, FL	0.9871	0.9974	0.9948
	Alachua, FL			
2920	Galveston-Texas City, TX	0.9465	0.9893	0.9786
	Galveston, TX			
2960	Gary, IN	0.9584	0.9917	0.9834
	Lake, IN			
	Porter, IN			
2975	Glens Falls, NY	0.8281	0.9656	0.9312
	Warren, NY			

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Washington, NY			
2980	Goldsboro, NC	0.8892	0.9778	0.9557
	Wayne, NC			
2985	Grand Forks, ND-MN	0.8897	0.9779	0.9559
	Polk, MN			
	Grand Forks, ND			
2995	Grand Junction, CO	0.9456	0.9891	0.9782
	Mesa, CO			
3000	Grand Rapids-Muskegon-Holland, MI	0.9525	0.9905	0.9810
	Allegan, MI			
	Kent, MI			
	Muskegon, MI			
	Ottawa, MI			
3040	Great Falls, MT	0.8950	0.9790	0.9580
	Cascade, MT			
3060	Greeley, CO	0.9237	0.9847	0.9695
	Weld, CO			
3080	Green Bay, WI	0.9502	0.9900	0.9801
	Brown, WI			
3120	Greensboro-Winston-Salem-High Point, NC	0.9282	0.9856	0.9713
	Alamance, NC			
	Davidson, NC			
	Davie, NC			
	Forsyth, NCGuilford, NC			
	Randolph, NC			
	Stokes, NC			
	Yadkin, NC			
3150	Greenville, NC	0.9100	0.9820	0.9640
	Pitt, NC			
3160	Greenville-Spartanburg-Anderson, SC	0.9122	0.9824	0.9649
	Anderson, SC			
	Cherokee, SC			
	Greenville, SC			
	Pickens, SC			
	Spartanburg, SC			
3180	Hagerstown, MD	0.9268	0.9854	0.9707
	Washington, MD			
3200	Hamilton-Middletown, OH	0.9418	0.9884	0.9767
	Butler, OH			
3240	Harrisburg-Lebanon-Carlisle, PA	0.9223	0.9845	0.9689
	Cumberland, PA			
	Dauphin, PA			
	Lebanon, PA			
	Perry, PA			
3283	Hartford, CT	1.1549	1.0310	1.0620
	Hartford, CT			
	Litchfield, CT			
	Middlesex, CT			
	Tolland, CT			
3285	Hattiesburg, MS	0.7659	0.9532	0.9064
	Forrest, MS			
	Lamar, MS			
3290	Hickory-Morganton-Lenoir, NC	0.9028	0.9806	0.9611
	Alexander, NC			
	Burke, NC			
	Caldwell, NC			
	Catawba, NC			
3320	Honolulu, HI	1.1457	1.0291	1.0583
	Honolulu, HI			
3350	Houma, LA	0.8317	0.9663	0.9327
	Lafourche, LA			
	Terrebonne, LA			
3360	Houston, TX	0.9892	0.9978	0.9957
	Chambers, TX			
	Fort Bend, TX			
	Harris, TX			
	Liberty, TX			
	Montgomery, TX			
	Waller, TX			
3400	Huntington-Ashland, WV-KY-OH	0.9636	0.9927	0.9854

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Boyd, KY Carter, KY Greenup, KY Lawrence, OH Cabell, WV Wayne, WV			
3440	Huntsville, AL Limestone, AL Madison, AL	0.8903	0.9781	0.9561
3480	Indianapolis, IN Boone, IN Hamilton, IN Hancock, IN Hendricks, IN Johnson, IN Madison, IN Marion, IN Morgan, IN Shelby, IN	0.9717	0.9943	0.9887
3500	Iowa City, IA Johnson, IA	0.9587	0.9917	0.9835
3520	Jackson, MI Jackson, MI	0.9532	0.9906	0.9813
3560	Jackson, MS Hinds, MS Madison, MS Rankin, MS	0.8607	0.9721	0.9443
3580	Jackson, TN Madison, TN Chester, TN	0.9275	0.9855	0.9710
3600	Jacksonville, FL Clay, FL Duval, FL Nassau, FL St. Johns, FL	0.9381	0.9876	0.9752
3605	Jacksonville, NC Onslow, NC	0.8239	0.9648	0.9296
3610	Jamestown, NY Chautauqua, NY	0.7976	0.9595	0.9190
3620	Janesville-Beloit, WI Rock, WI	0.9849	0.9970	0.9940
3640	Jersey City, NJ Hudson, NJ	1.1190	1.0238	1.0476
3660	Johnson City-Kingsport-Bristol, TN-VA Carter, TN Hawkins, TN Sullivan, TN Unicoi, TN Washington, TN Bristol City, VA Scott, VA Washington, VA	0.8268	0.9654	0.9307
3680	Johnstown, PA Cambria, PA Somerset, PA	0.8329	0.9666	0.9332
3700	Jonesboro, AR Craighead, AR	0.7749	0.9550	0.9100
3710	Joplin, MO Jasper, MO Newton, MO	0.8613	0.9723	0.9445
3720	Kalamazoo-Battlecreek, MI Calhoun, MI Kalamazoo, MI Van Buren, MI	1.0595	1.0119	1.0238
3740	Kankakee, IL Kankakee, IL	1.0790	1.0158	1.0316
3760	Kansas City, KS-MO Johnson, KS Leavenworth, KS Miami, KS	0.9736	0.9947	0.9894

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Wyandotte, KS Cass, MO Clay, MO Clinton, MO Jackson, MO Lafayette, MO Platte, MO Ray, MO			
3800	Kenosha, WI Kenosha, WI	0.9686	0.9937	0.9874
3810	Killeen-Temple, TX Bell, TX Coryell, TX	1.0399	1.0080	1.0160
3840	Knoxville, TN Anderson, TN Blount, TN Knox, TN Loudon, TN Sevier, TN Union, TN	0.8970	0.9794	0.9588
3850	Kokomo, IN Howard, IN Tipton, IN	0.8971	0.9794	0.9588
3870	La Crosse, WI-MN Houston, MN La Crosse, WI	0.9400	0.9880	0.9760
3880	Lafayette, LA Acadia, LA Lafayette, LA St. Landry, LA St. Martin, LA	0.8452	0.9690	0.9381
3920	Lafayette, IN Clinton, IN Tippecanoe, IN	0.9278	0.9856	0.9711
3960	Lake Charles, LA Calcasieu, LA	0.7965	0.9593	0.9186
3980	Lakeland-Winter Haven, FL Polk, FL	0.9357	0.9871	0.9743
4000	Lancaster, PA Lancaster, PA	0.9078	0.9816	0.9631
4040	Lansing-East Lansing, MI Clinton, MI Eaton, MI Ingham, MI	0.9726	0.9945	0.9890
4080	Laredo, TX Webb, TX	0.8472	0.9694	0.9389
4100	Las Cruces, NM Dona Ana, NM	0.8745	0.9749	0.9498
4120	Las Vegas, NV-AZ Mohave, AZ Clark, NV Nye, NV	1.1521	1.0304	1.0608
4150	Lawrence, KS Douglas, KS	0.8323	0.9665	0.9329
4200	Lawton, OK Comanche, OK	0.8315	0.9663	0.9326
4243	Lewiston-Auburn, ME Androscoggin, ME	0.9179	0.9836	0.9672
4280	Lexington, KY Bourbon, KY Clark, KY Fayette, KY Jessamine, KY Madison, KY Scott, KY Woodford, KY	0.8581	0.9716	0.9432
4320	Lima, OH Allen, OH Auglaize, OH	0.9483	0.9897	0.9793
4360	Lincoln, NE	0.9892	0.9978	0.9957

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Lancaster, NE			
4400	Little Rock-North Little Rock, AR	0.9097	0.9819	0.9639
	Faulkner, AR			
	Lonoke, AR			
	Pulaski, AR			
	Saline, AR			
4420	Longview-Marshall, TX	0.8629	0.9726	0.9452
	Gregg, TX			
	Harrison, TX			
	Upshur, TX			
4480	Los Angeles-Long Beach, CA	1.2001	1.0400	1.0800
	Los Angeles, CA			
4520	Louisville, KY-IN	0.9276	0.9855	0.9710
	Clark, IN			
	Floyd, IN			
	Harrison, IN			
	Scott, IN			
	Bullitt, KY			
	Jefferson, KY			
	Oldham, KY			
4600	Lubbock, TX	0.9646	0.9929	0.9858
	Lubbock, TX			
4640	Lynchburg, VA	0.9219	0.9844	0.9688
	Amherst, VA			
	Bedford, VA			
	Bedford City, VA			
	Campbell, VA			
	Lynchburg City, VA			
4680	Macon, GA	0.9204	0.9841	0.9682
	Bibb, GA			
	Houston, GA			
	Jones, GA			
	Peach, GA			
	Twiggs, GA			
4720	Madison, WI	1.0467	1.0093	1.0187
	Dane, WI			
4800	Mansfield, OH	0.8900	0.9780	0.9560
	Crawford, OH			
	Richland, OH			
4840	Mayaguez, PR	0.4914	0.8983	0.7966
	Anasco, PR			
	Cabo Rojo, PR			
	Hormigueros, PR			
	Mayaguez, PR			
	Sabana Grande, PR			
	San German, PR			
4880	McAllen-Edinburg-Mission, TX	0.8428	0.9686	0.9371
	Hidalgo, TX			
4890	Medford-Ashland, OR	1.0498	1.0100	1.0199
	Jackson, OR			
4900	Melbourne-Titusville-Palm Bay, FL	1.0253	1.0051	1.0101
	Brevard, Fl			
4920	Memphis, TN-AR-MS	0.8920	0.9784	0.9568
	Crittenden, AR			
	DeSoto, MS			
	Fayette, TN			
	Shelby, TN			
	Tipton, TN			
4940	Merced, CA	0.9742	0.9948	0.9897
	Merced, CA			
5000	Miami, FL	0.9802	0.9960	0.9921
	Dade, FL			
5015	Middlesex-Somerset-Hunterdon, NJ	1.1213	1.0243	1.0485
	Hunterdon, NJ			
	Middlesex, NJ			
	Somerset, NJ			
5080	Milwaukee-Waukesha, WI	0.9893	0.9979	0.9957
	Milwaukee, WI			
	Ozaukee, WI			
	Washington, WI			

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Waukesha, WI			
5120	Minneapolis-St. Paul, MN-WI	1.0903	1.0181	1.0361
	Anoka, MN			
	Carver, MN			
	Chisago, MN			
	Dakota, MN			
	Hennepin, MN			
	Isanti, MN			
	Ramsey, MN			
	Scott, MN			
	Sherburne, MN			
	Washington, MN			
	Wright, MN			
	Pierce, WI			
	St. Croix, WI			
5140	Missoula, MT	0.9157	0.9831	0.9663
	Missoula, MT			
5160	Mobile, AL	0.8108	0.9622	0.9243
	Baldwin, AL			
	Mobile, AL			
5170	Modesto, CA	1.0498	1.0100	1.0199
	Stanislaus, CA			
5190	Monmouth-Ocean, NJ	1.0674	1.0135	1.0270
	Monmouth, NJ			
	Ocean, NJ			
5200	Monroe, LA	0.8137	0.9627	0.9255
	Ouachita, LA			
5240	Montgomery, AL	0.7734	0.9547	0.9094
	Autauga, AL			
	Elmore, AL			
	Montgomery, AL			
5280	Muncie, IN	0.9284	0.9857	0.9714
	Delaware, IN			
5330	Myrtle Beach, SC	0.8976	0.9795	0.9590
	Horry, SC			
5345	Naples, FL	0.9754	0.9951	0.9902
	Collier, FL			
5360	Nashville, TN	0.9578	0.9916	0.9831
	Cheatham, TN			
	Davidson, TN			
	Dickson, TN			
	Robertson, TN			
	Rutherford TN			
	Sumner, TN			
	Williamson, TN			
	Wilson, TN			
5380	Nassau-Suffolk, NY	1.3357	1.0671	1.1343
	Nassau, NY			
	Suffolk, NY			
5483	New Haven-Bridgeport-Stamford-Waterbury-	1.2408	1.0482	1.0963
	Danbury, CT			
	Fairfield, CT			
	New Haven, CT			
5523	New London-Norwich, CT	1.1767	1.0353	1.0707
	New London, CT			
5560	New Orleans, LA	0.9046	0.9809	0.9618
	Jefferson, LA			
	Orleans, LA			
	Plaquemines, LA			
	St. Bernard, LA			
	St. Charles, LA			
	St. James, LA			
	St. John The Baptist, LA			
	St. Tammany, LA			
5600	New York, NY	1.4414	1.0883	1.1766
	Bronx, NY			
	Kings, NY			
	New York, NY			
	Putnam, NY			
	Queens, NY			

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Richmond, NY			
	Rockland, NY			
	Westchester, NY			
5640	Newark, NJ	1.1381	1.0276	1.0552
	Essex, NJ			
	Morris, NJ			
	Sussex, NJ			
	Union, NJ			
	Warren, NJ			
5660	Newburgh, NY-PA	1.1387	1.0277	1.0555
	Orange, NY			
	Pike, PA			
5720	Norfolk-Virginia Beach-Newport News, VA-NC	0.8574	0.9715	0.9430
	Currituck, NC			
	Chesapeake City, VA			
	Gloucester, VA			
	Hampton City, VA			
	Isle of Wight, VA			
	James City, VA			
	Mathews, VA			
	Newport News City, VA			
	Norfolk City, VA			
	Poquoson City, VA			
	Portsmouth City, VA			
	Suffolk City, VA			
	Virginia Beach City VA			
	Williamsburg City, VA			
	York, VA			
5775	Oakland, CA	1.5072	1.1014	1.2029
	Alameda, CA			
	Contra Costa, CA			
5790	Ocala, FL	0.9402	0.9880	0.9761
	Marion, FL			
5800	Odessa-Midland, TX	0.9397	0.9879	0.9759
	Ector, TX			
	Midland, TX			
5880	Oklahoma City, OK	0.8900	0.9780	0.9560
	Canadian, OK			
	Cleveland, OK			
	Logan, OK			
	McClain, OK			
	Oklahoma, OK			
	Pottawatomie, OK			
5910	Olympia, WA	1.0960	1.0192	1.0384
	Thurston, WA			
5920	Omaha, NE-IA	0.9978	0.9996	0.9991
	Pottawattamie, IA			
	Cass, NE			
	Douglas, NE			
	Sarpy, NE			
	Washington, NE			
5945	Orange County, CA	1.1474	1.0295	1.0590
	Orange, CA			
5960	Orlando, FL	0.9640	0.9928	0.9856
	Lake, FL			
	Orange, FL			
	Osceola, FL			
	Seminole, FL			
5990	Owensboro, KY	0.8344	0.9669	0.9338
	Daviess, KY			
6015	Panama City, FL	0.8865	0.9773	0.9546
	Bay, FL			
6020	Parkersburg-Marietta, WV-OH	0.8127	0.9625	0.9251
	Washington, OH			
	Wood, WV			
6080	Pensacola, FL	0.8610	0.9722	0.9444
	Escambia, FL			
	Santa Rosa, FL			
6120	Peoria-Pekin, IL	0.8739	0.9748	0.9496
	Peoria, IL			

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Tazewell, IL			
	Woodford, IL			
6160	Philadelphia, PA-NJ	1.0713	1.0143	1.0285
	Burlington, NJ			
	Camden, NJ			
	Gloucester, NJ			
	Salem, NJ			
	Bucks, PA			
	Chester, PA			
	Delaware, PA			
	Montgomery, PA			
	Philadelphia, PA			
6200	Phoenix-Mesa, AZ	0.9820	0.9964	0.9928
	Maricopa, AZ			
	Pinal, AZ			
6240	Pine Bluff, AR	0.7962	0.9592	0.9185
	Jefferson, AR			
6280	Pittsburgh, PA	0.9365	0.9873	0.9746
	Allegheny, PA			
	Beaver, PA			
	Butler, PA			
	Fayette, PA			
	Washington, PA			
	Westmoreland, PA			
6323	Pittsfield, MA	1.0235	1.0047	1.0094
	Berkshire, MA			
6340	Pocatello, ID	0.9372	0.9874	0.9749
	Bannock, ID			
6360	Ponce, PR	0.5169	0.9034	0.8068
	Guayanilla, PR			
	Juana Diaz, PR			
	Penuelas, PR			
	Ponce, PR			
	Villalba, PR			
	Yauco, PR			
6403	Portland, ME	0.9794	0.9959	0.9918
	Cumberland, ME			
	Sagadahoc, ME			
	York, ME			
6440	Portland-Vancouver, OR-WA	1.0667	1.0133	1.0267
	Clackamas, OR			
	Columbia, OR			
	Multnomah, OR			
	Washington, OR			
	Yamhill, OR			
	Clark, WA			
6483	Providence-Warwick-Pawtucket, RI	1.0854	1.0171	1.0342
	Bristol, RI			
	Kent, RI			
	Newport, RI			
	Providence, RI			
	Washington, RI			
6520	Provo-Orem, UT	0.9984	0.9997	0.9994
	Utah, UT			
6560	Pueblo, CO	0.8820	0.9764	0.9528
	Pueblo, CO			
6580	Punta Gorda, FL	0.9218	0.9844	0.9687
	Charlotte, FL			
6600	Racine, WI	0.9334	0.9867	0.9734
	Racine, WI			
6640	Raleigh-Durham-Chapel Hill, NC	0.9990	0.9998	0.9996
	Chatham, NC			
	Durham, NC			
	Franklin, NC			
	Johnston, NC			
	Orange, NC			
	Wake, NC			
6660	Rapid City, SD	0.8846	0.9769	0.9538
	Pennington, SD			
6680	Reading, PA	0.9295	0.9859	0.9718

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Berks, PA			
6690	Redding, CA	1.1135	1.0227	1.0454
	Shasta, CA			
6720	Reno, NV	1.0648	1.0130	1.0259
	Washoe, NV			
6740	Richland-Kennewick-Pasco, WA	1.1491	1.0298	1.0596
	Benton, WA			
	Franklin, WA			
6760	Richmond-Petersburg, VA	0.9477	0.9895	0.9791
	Charles City County, VA			
	Chesterfield, VA			
	Colonial Heights City, VA			
	Dinwiddie, VA			
	Goochland, VA			
	Hanover, VA			
	Henrico, VA			
	Hopewell City, VA			
	New Kent, VA			
	Petersburg City, VA			
	Powhatan, VA			
	Prince George, VA			
	Richmond City, VA			
6780	Riverside-San Bernardino, CA	1.1365	1.0273	1.0546
	Riverside, CA			
	San Bernardino, CA			
6800	Roanoke, VA	0.8614	0.9723	0.9446
	Botetourt, VA			
	Roanoke, VA			
	Roanoke City, VA			
	Salem City, VA			
6820	Rochester, MN	1.2139	1.0428	1.0856
	Olmsted, MN			
6840	Rochester, NY	0.9194	0.9839	0.9678
	Genesee, NY			
	Livingston, NY			
	Monroe, NY			
	Ontario, NY			
	Orleans, NY			
	Wayne, NY			
6880	Rockford, IL	0.9625	0.9925	0.9850
	Boone, IL			
	Ogle, IL			
	Winnebago, IL			
6895	Rocky Mount, NC	0.9228	0.9846	0.9691
	Edgecombe, NC			
	Nash, NC			
6920	Sacramento, CA	1.1500	1.0300	1.0600
	El Dorado, CA			
	Placer, CA			
	Sacramento, CA			
6960	Saginaw-Bay City-Midland, MI	0.9650	0.9930	0.9860
	Bay, MI			
	Midland, MI			
	Saginaw, MI			
6980	St. Cloud, MN	0.9700	0.9940	0.9880
	Benton, MN			
	Stearns, MN			
7000	St. Joseph, MO	0.9544	0.9909	0.9818
	Andrew, MO			
	Buchanan, MO			
7040	St. Louis, MO-IL	0.8855	0.9771	0.9542
	Clinton, IL			
	Jersey, IL			
	Madison, IL			
	Monroe, IL			
	St. Clair, IL			
	Franklin, MO			
	Jefferson, MO			
	Lincoln, MO			
	St. Charles, MO			

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	St. Louis, MO			
	St. Louis City, MO			
	Warren, MO			
7080	Salem, OR	1.0500	1.0100	1.0200
	Marion, OR			
	Polk, OR			
7120	Salinas, CA	1.4623	1.0925	1.1849
	Monterey, CA			
7160	Salt Lake City-Ogden, UT	0.9945	0.9989	0.9978
	Davis, UT			
	Salt Lake, UT			
	Weber, UT			
7200	San Angelo, TX	0.8374	0.9675	0.9350
	Tom Green, TX			
7240	San Antonio, TX	0.8753	0.9751	0.9501
	Bexar, TX			
	Comal, TX			
	Guadalupe, TX			
	Wilson, TX			
7320	San Diego, CA	1.1131	1.0226	1.0452
	San Diego, CA			
7360	San Francisco, CA	1.4142	1.0828	1.1657
	Marin, CA			
	San Francisco, CA			
	San Mateo, CA			
7400	San Jose, CA	1.4145	1.0829	1.1658
	Santa Clara, CA			
7440	San Juan-Bayamon, PR	0.4741	0.8948	0.7896
	Aguas Buenas, PR			
	Barceloneta, PR			
	Bayamon, PR			
	Canovanas, PR			
	Carolina, PR			
	Catano, PR			
	Ceiba, PR			
	Comerio, PR			
	Corozal, PR			
	Dorado, PR			
	Fajardo, PR			
	Florida, PR			
	Guaynabo, PR			
	Humacao, PR			
	Juncos, PR			
	Los Piedras, PR			
	Loiza, PR			
	Luguillo, PR			
	Manati, PR			
	Morovis, PR			
	Naguabo, PR			
	Naranjito, PR			
	Rio Grande, PR			
	San Juan, PR			
	Toa Alta, PR			
	Toa Baja, PR			
	Trujillo Alto, PR			
	Vega Alta, PR			
	Vega Baja, PR			
	Yabucoa, PR			
7460	San Luis Obispo-Atascadero-Paso Robles, CA	1.1271	1.0254	1.0508
	San Luis Obispo, CA			
7480	Santa Barbara-Santa Maria-Lompoc, CA	1.0481	1.0096	1.0192
	Santa Barbara, CA			
7485	Santa Cruz-Watsonville, CA	1.3646	1.0729	1.1458
	Santa Cruz, CA			
7490	Santa Fe, NM	1.0712	1.0142	1.0285
	Los Alamos, NM			
	Santa Fe, NM			
7500	Santa Rosa, CA	1.3046	1.0609	1.1218
	Sonoma, CA			
7510	Sarasota-Bradenton, FL	0.9425	0.9885	0.9770

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
	Manatee, FL			
	Sarasota, FL			
7520	Savannah, GA	0.9376	0.9875	0.9750
	Bryan, GA			
	Chatham, GA			
	Effingham, GA			
7560	Scranton--Wilkes-Barre--Hazleton, PA	0.8599	0.9720	0.9440
	Columbia, PA			
	Lackawanna, PA			
	Luzerne, PA			
	Wyoming, PA			
7600	Seattle-Bellevue-Everett, WA	1.1474	1.0295	1.0590
	Island, WA			
	King, WA			
	Snohomish, WA			
7610	Sharon, PA	0.7869	0.9574	0.9148
	Mercer, PA			
7620	Sheboygan, WI	0.8697	0.9739	0.9479
	Sheboygan, WI			
7640	Sherman-Denison, TX	0.9255	0.9851	0.9702
	Grayson, TX			
7680	Shreveport-Bossier City, LA	0.8987	0.9797	0.9595
	Bossier, LA			
	Caddo, LA			
	Webster, LA			
7720	Sioux City, IA-NE	0.9046	0.9809	0.9618
	Woodbury, IA			
	Dakota, NE			
7760	Sioux Falls, SD	0.9257	0.9851	0.9703
	Lincoln, SD			
	Minnehaha, SD			
7800	South Bend, IN	0.9802	0.9960	0.9921
	St. Joseph, IN			
7840	Spokane, WA	1.0852	1.0170	1.0341
	Spokane, WA			
7880	Springfield, IL	0.8659	0.9732	0.9464
	Menard, IL			
	Sangamon, IL			
7920	Springfield, MO	0.8424	0.9685	0.9370
	Christian, MO			
	Greene, MO			
	Webster, MO			
8003	Springfield, MA	1.0927	1.0185	1.0371
	Hampden, MA			
	Hampshire, MA			
8050	State College, PA	0.8941	0.9788	0.9576
	Centre, PA			
8080	Steubenville-Weirton, OH-WV (WV Hospitals)	0.8804	0.9761	0.9522
	Jefferson, OH			
	Brooke, WV			
	Hancock, WV			
8120	Stockton-Lodi, CA	1.0506	1.0101	1.0202
	San Joaquin, CA			
8140	Sumter, SC	0.8273	0.9655	0.9309
	Sumter, SC			
8160	Syracuse, NY	0.9714	0.9943	0.9886
	Cayuga, NY			
	Madison, NY			
	Onondaga, NY			
	Oswego, NY			
8200	Tacoma, WA	1.0940	1.0188	1.0376
	Pierce, WA			
8240	Tallahassee, FL	0.8504	0.9701	0.9402
	Gadsden, FL			
	Leon, FL			
8280	Tampa-St. Petersburg-Clearwater, FL	0.9065	0.9813	0.9626
	Hernando, FL			
	Hillsborough, FL			
	Pasco, FL			
	Pinellas, FL			

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
8320	Terre Haute, IN	0.8599	0.9720	0.9440
	Clay, IN			
	Vermillion, IN			
	Vigo, IN			
8360	Texarkana,AR-Texarkana, TX	0.8088	0.9618	0.9235
	Miller, AR			
	Bowie, TX			
8400	Toledo, OH	0.9810	0.9962	0.9924
	Fulton, OH			
	Lucas, OH			
	Wood, OH			
8440	Topeka, KS	0.9199	0.9840	0.9680
	Shawnee, KS			
8480	Trenton, NJ	1.0432	1.0086	1.0173
	Mercer, NJ			
8520	Tucson, AZ	0.8911	0.9782	0.9564
	Pima, AZ			
8560	Tulsa, OK	0.8332	0.9666	0.9333
	Creek, OK			
	Osage, OK			
	Rogers, OK			
	Tulsa, OK			
	Wagoner, OK			
8600	Tuscaloosa, AL	0.8130	0.9626	0.9252
	Tuscaloosa, AL			
8640	Tyler, TX	0.9521	0.9904	0.9808
	Smith, TX			
8680	Utica-Rome, NY	0.8465	0.9693	0.9386
	Herkimer, NY			
	Oneida, NY			
8720	Vallejo-Fairfield-Napa, CA	1.3354	1.0671	1.1342
	Napa, CA			
	Solano, CA			
8735	Ventura, CA	1.1096	1.0219	1.0438
	Ventura, CA			
8750	Victoria, TX	0.8756	0.9751	0.9502
	Victoria, TX			
8760	Vineland-Millville-Bridgeton, NJ	1.0031	1.0006	1.0012
	Cumberland, NJ			
8780	Visalia-Tulare-Porterville, CA	0.9418	0.9884	0.9767
	Tulare, CA			
	Tulare, CA			
8800	Waco, TX	0.8073	0.9615	0.9229
	McLennan, TX			
8840	Washington, DC-MD-VA-WV	1.0851	1.0170	1.0340
	District of Columbia, DC			
	Calvert, MD			
	Charles, MD			
	Frederick, MD			
	Montgomery, MD			
	Prince Georges, MD			
	Alexandria City, VA			
	Arlington, VA			
	Clarke, VA			
	Culpeper, VA			
	Fairfax, VA			
	Fairfax City, VA			
	Falls Church City, VA			
	Fauquier, VA			
	Fredericksburg City, VA			
	King George, VA			
	Loudoun, VA			
	Manassas City, VA			
	Manassas Park City, VA			
	Prince William, VA			
	Spotsylvania, VA			
	Stafford, VA			
	Warren, VA			
	Berkeley, WV			
	Jefferson, WV			

TABLE 1.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

MSA	Urban Area (Constituent Counties)	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
8920	Waterloo-Cedar Falls, IA Black Hawk, IA	0.8069	0.9614	0.9228
8940	Wausau, WI Marathon, WI	0.9782	0.9956	0.9913
8960	West Palm Beach-Boca Raton, FL Palm Beach, FL	0.9939	0.9988	0.9976
9000	Wheeling, WV-OH Belmont, OH Marshall, WV Ohio, WV	0.7670	0.9534	0.9068
9040	Wichita, KS Butler, KS Harvey, KS Sedgwick, KS	0.9520	0.9904	0.9808
9080	Wichita Falls, TX Archer, TX Wichita, TX	0.8498	0.9700	0.9399
9140	Williamsport, PA Lycoming, PA	0.8544	0.9709	0.9418
9160	Wilmington-Newark, DE-MD New Castle, DE Cecil, MD	1.1173	1.0235	1.0469
9200	Wilmington, NC New Hanover, NC Brunswick, NC	0.9640	0.9928	0.9856
9260	Yakima, WA Yakima, WA	1.0569	1.0114	1.0228
9270	Yolo, CA Yolo, CA	0.9434	0.9887	0.9774
9280	York, PA York, PA	0.9026	0.9805	0.9610
9320	Youngstown-Warren, OH Columbiana, OH Mahoning, OH Trumbull, OH	0.9358	0.9872	0.9743
9340	Yuba City, CA Sutter, CA Yuba, CA	1.0276	1.0055	1.0110
9360	Yuma, AZ Yuma, AZ	0.8589	0.9718	0.9436

[1] Prereclassification wage index from Federal FY 2003 based on fiscal year 1999 audited acute care hospital inpatient wage data that excludes wages for services provided by teaching physicians, interns and residents, and nonphysician anesthetists under Part B of the Medicare program.

[2] One-fifth of the full wage index value, applicable for LTCH's cost reporting period beginning on or after October 1, 2002 through September 30, 2003 (Federal FY 2203). For example, for a LTCH's cost reporting period begins during Federal in FY 2003 and located in Chicago, Illinois (MSA 1600), the 1/5th of the wage index value is computed as (1.1044 + 4)/5 = 1.0209. For further details on the 5-year phase-in of the wage index, see section VI.C.1. of this final rule.

[3] Two-fifths of the full wage index value, applicable for LTCH's cost reporting period beginning on or after October 1, 2003 through September 30, 2003 (Federal FY 2004). For example, for a LTCH's cost reporting period begins during Federal in FY 2004 and located in Chicago, Illinois (MSA 1600), the 2/5th of the wage index value is computed as ((2*1.1044) + 3))/5 = 1.0418. For further details on the 5-year phase-in of the wage index, see section VI.C.1. of this final rule.

TABLE 2.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR RURAL AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004

Nonurban Area	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
Alabama	7660	9532	9064
Alaska	2293	0459	0917
Arizona	8493	9699	9397
Arkansas	7666	9533	9066
California	9899	9980	9960
Colorado	9015	9803	9606
Connecticut	2394	0479	0958
Delaware	9128	9826	9651
Florida	8827	9765	9531
Georgia	8230	9646	9292
Hawaii	0255	0051	0102
Idaho	8747	9749	9499
Illinois	8204	9641	9282

TABLE 2.—LONG-TERM CARE HOSPITAL WAGE INDEX FOR RURAL AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2003 THROUGH JUNE 30, 2004—Continued

Nonurban Area	Full Wage Index [1]	1/5th Wage Index [2]	2/5th Wage Index [3]
Indiana	8755	9751	9502
Iowa	8315	9663	9326
Kansas	7900	9580	9160
Kentucky	8079	9616	9232
Louisiana	7580	9516	9032
Maine	8874	9775	9550
Maryland	8946	9789	9578
Massachusetts	1288	0258	0515
Michigan	9009	9802	9604
Minnesota	9151	9830	9660
Mississippi	7680	9536	9072
Missouri	7881	9576	9152
Montana	8481	9696	9392
Nebraska	8204	9641	9282
Nevada	9577	9915	9831
New Hampshire	9839	9968	9936
New Jersey [4]	.....	.....	.....
New Mexico	8872	9774	9549
New York	8542	9708	9417
North Carolina	8669	9734	9468
North Dakota	7788	9558	9115
Ohio	8613	9723	9445
Oklahoma	7590	9518	9036
Oregon	0259	0052	0104
Pennsylvania	8462	9692	9385
Puerto Rico	4356	8871	7742
Rhode Island [4]	.....	.....	.....
South Carolina	8607	9721	9443
South Dakota	7815	9563	9126
Tennessee	7877	9575	9151
Texas	7821	9564	9128
Utah	9312	9862	9725
Vermont	9345	9869	9738
Virginia	8504	9701	9402
Washington	0179	0036	0072
West Virginia	7975	9595	9190
Wisconsin	9162	9832	9665
Wyoming	9007	9801	9603

[1] Pre-reclassification wage index from Federal FY 2003 based on fiscal year 1999 audited acute care hospital inpatient wage data that exclude wages for services provided by teaching physicians, residents, and nonphysician anesthetists under Part B of the Medicare program.

[2] One-fifth of the full wage index value, applicable for LTCH's cost reporting period beginning on or after October 1, 2002 through September 30, 2003 (Federal FY 2203). For example, for a LTCH's cost reporting period begins during Federal in FY 2003 and located in rural Illinois, the 1/5th of the wage index value is computed as (0.8204 + 4)/5 = 0.9641. For further details on the 5-year phase-in of the wage index, see section VI.C.1. of this final rule.

[3] Two-fifths of the full wage index value, applicable for LTCH's cost reporting period beginning on or after October 1, 2003 through September 30, 2003 (Federal FY 2004). For example, for a LTCH's cost reporting period begins during Federal in FY 2004 and located in rural Illinois, the 2/5th of the wage index value is computed as ((2*0.8204) + 3))/5 = 0.9282. For further details on the 5-year phase-in of the wage index, see section VI.C.1. of this final rule.

[4] All counties within the State are classified as urban.

TABLE 3.—LTC–DRG RELATIVE WEIGHTS, GEOMETRIC MEAN LENGTH OF STAY, AND SHORT-STAYS OF FIVE-SIXTHS AVERAGE LENGTH OF STAY FOR THE PERIOD OF JULY 1, 2003 THROUGH SEPTEMBER 30, 2003

LTC–DRG	Description	Relative Weight	Geo-metric Mean Length of Stay	Short-Stays of 5/6th Aver-age Length of Stay
1	CRANIOTOMY AGE >17 W CC [5]	1.8783	46.3	38.5
2	CRANIOTOMY AGE > 17 W/O CC [5]	1.8783	46.3	38.5
3	CRANIOTOMY AGE 0-17 *	1.8783	46.3	38.5
4	SPINAL PROCEDURES [4]	1.2493	31.3	26.0
5	EXTRACRANIAL VASCULAR PROCEDURES [4]	1.2493	31.3	26.0
6	CARPAL TUNNEL RELEASE *	0.4055	16.8	14.0
7	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W CC	1.7829	43.8	36.5
8	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W/O CC [4]	1.2493	31.3	26.0
9	SPINAL DISORDERS & INJURIES	1.4118	34.6	28.8
10	NERVOUS SYSTEM NEOPLASMS W CC [7]	0.8537	24.5	20.4
11	NERVOUS SYSTEM NEOPLASMS W/O CC [7]	0.8537	24.5	20.4

TABLE 3.—LTC–DRG RELATIVE WEIGHTS, GEOMETRIC MEAN LENGTH OF STAY, AND SHORT-STAYS OF FIVE-SIXTHS AVERAGE LENGTH OF STAY FOR THE PERIOD OF JULY 1, 2003 THROUGH SEPTEMBER 30, 2003—Continued

LTC–DRG	Description	Relative Weight	Geo-metric Mean Length of Stay	Short-Stays of 5/6th Average Length of Stay
12	DEGENERATIVE NERVOUS SYSTEM DISORDERS	0.7773	27.1	22.5
13	MULTIPLE SCLEROSIS & CEREBELLAR ATAXIA	0.7207	25.6	21.3
14	INTERCRANIAL HEMORRHAGE & STROKE W INFARCT	0.8816	26.6	22.1
15	NONSPECIFIC CVA & PRECEREBRAL OCCULUSION W/O INFARCT	0.9053	29.4	24.5
16	NONSPECIFIC CEREBROVASCULAR DISORDERS W CC	0.8864	27.0	22.5
17	NONSPECIFIC CEREBROVASCULAR DISORDERS W/O CC[2]	0.6655	21.9	18.2
18	CRANIAL & PERIPHERAL NERVE DISORDERS W CC	0.7770	24.9	20.7
19	CRANIAL & PERIPHERAL NERVE DISORDERS W/O CC	0.5486	22.0	18.3
20	NERVOUS SYSTEM INFECTION EXCEPT VIRAL MENINGITIS	1.2331	29.3	24.4
21	VIRAL MENINGITIS[1]	0.4055	16.8	14.0
22	HYPERTENSIVE ENCEPHALOPATHY[2]	0.6655	21.9	18.2
23	NONTRAUMATIC STUPOR & COMA	0.9623	27.2	22.6
24	SEIZURE & HEADACHE AGE >17 W CC	0.8831	24.8	20.6
25	SEIZURE & HEADACHE AGE >17 W/O CC	0.4830	20.4	17.0
26	SEIZURE & HEADACHE AGE 0-17*	0.4055	16.8	14.0
27	TRAUMATIC STUPOR & COMA, COMA >1 HR	1.1126	31.6	26.3
28	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE >17 W CC	1.1507	29.0	24.1
29	TRAUMATIC STUPOR & COMA, COMA >1 HR AGE >17 W/O CC	0.9268	27.2	22.6
30	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE 0-17*	0.8284	23.3	19.4
31	CONCUSSION AGE >17 W CC[2]	0.6655	21.9	18.2
32	CONCUSSION AGE >17 W/O CC*	0.4055	16.8	14.0
33	CONCUSSION AGE 0-17*	0.4055	16.8	14.0
34	OTHER DISORDERS OF NERVOUS SYSTEM W CC	0.8385	25.1	20.9
35	OTHER DISORDERS OF NERVOUS SYSTEM W/O CC	0.6561	25.3	21.0
36	RETINAL PROCEDURES*	0.4055	16.8	14.0
37	ORBITAL PROCEDURES*	0.4055	16.8	14.0
38	PRIMARY IRIS PROCEDURES*	0.4055	16.8	14.0
39	LENS PROCEDURES WITH OR WITHOUT VITRECTOMY*	0.4055	16.8	14.0
40	EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE >17*	0.4055	16.8	14.0
41	EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE 0-17*	0.4055	16.8	14.0
42	INTRAOCULAR PROCEDURES EXCEPT RETINA, IRIS & LENS*	0.4055	16.8	14.0
43	HYPHEMA[3]	0.8284	23.3	19.4
44	ACUTE MAJOR EYE INFECTIONS[2]	0.6655	21.9	18.2
45	NEUROLOGICAL EYE DISORDERS[1]	0.4055	16.8	14.0
46	OTHER DISORDERS OF THE EYE AGE >17 W CC[2]	0.6655	21.9	18.2
47	OTHER DISORDERS OF THE EYE AGE >17 W/O CC[1]	0.4055	16.8	14.0
48	OTHER DISORDERS OF THE EYE AGE 0-17*	0.4055	16.8	14.0
49	MAJOR HEAD & NECK PROCEDURES*	1.8783	46.3	38.5
50	SIALOADENECTOMY*	0.6655	21.9	18.2
51	SALIVARY GLAND PROCEDURES EXCEPT SIALOADENECTOMY*	0.6655	21.9	18.2
52	CLEFT LIP & PALATE REPAIR*	0.6655	21.9	18.2
53	SINUS & MASTOID PROCEDURES AGE >17*	0.6655	21.9	18.2
54	SINUS & MASTOID PROCEDURES AGE 0-17*	0.6655	21.9	18.2
55	MISCELLANEOUS EAR, NOSE, MOUTH & THROAT PROCEDURES[2]	0.6655	21.9	18.2
56	RHINOPLASTY*	0.6655	21.9	18.2
57	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17*	0.6655	21.9	18.2
58	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0-17*	0.6655	21.9	18.2
59	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17*	0.6655	21.9	18.2
60	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0-17*	0.6655	21.9	18.2
61	MYRINGOTOMY W TUBE INSERTION AGE >17[5]	1.8783	46.3	38.5
62	MYRINGOTOMY W TUBE INSERTION AGE 0-17*	0.6655	21.9	18.2
63	OTHER EAR, NOSE, MOUTH & THROAT O.R. PROCEDURES[5]	1.8783	46.3	38.5
64	EAR, NOSE, MOUTH & THROAT MALIGNANCY	1.0447	25.5	21.2
65	DYSEQUILIBRIUM	0.5056	19.8	16.5
66	EPISTAXIS[1]	0.4055	16.8	14.0
67	EPIGLOTTITIS[1]	0.4055	16.8	14.0
68	OTITIS MEDIA & URI AGE >17 W CC[3]	0.8284	23.3	19.4
69	OTITIS MEDIA & URI AGE >17 W/O CC[3]	0.8284	23.3	19.4
70	OTITIS MEDIA & URI AGE 0-17*	0.4055	16.8	14.0
71	LARYNGOTRACHEITIS*	0.4055	16.8	14.0
72	NASAL TRAUMA & DEFORMITY[1]	0.4055	16.8	14.0
73	OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE >17	0.8097	23.7	19.7
74	OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE 0-17*	0.4055	16.8	14.0
75	MAJOR CHEST PROCEDURES[5]	1.8783	46.3	38.5
76	OTHER RESP SYSTEM O.R. PROCEDURES W CC	2.7674	50.6	42.1
77	OTHER RESP SYSTEM O.R. PROCEDURES W/O CC[5]	1.8783	46.3	38.5
78	PULMONARY EMBOLISM	0.6348	20.5	17.0

TABLE 3.—LTC–DRG RELATIVE WEIGHTS, GEOMETRIC MEAN LENGTH OF STAY, AND SHORT-STAYS OF FIVE-SIXTHS AVERAGE LENGTH OF STAY FOR THE PERIOD OF JULY 1, 2003 THROUGH SEPTEMBER 30, 2003—Continued

LTC–DRG	Description	Relative Weight	Geo-metric Mean Length of Stay	Short-Stays of 5/6th Average Length of Stay
79	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W CC	0.8916	22.2	18.5
80	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W/O CC	0.7947	22.8	19.0
81	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE 0-17*	0.4055	16.8	14.0
82	RESPIRATORY NEOPLASMS	0.7976	20.9	17.4
83	MAJOR CHEST TRAUMA W CC	0.7384	24.8	20.6
84	MAJOR CHEST TRAUMA W/O CC[1]	0.4055	16.8	14.0
85	PLEURAL EFFUSION W CC	0.8207	23.6	19.6
86	PLEURAL EFFUSION W/O CC	0.6194	21.1	17.5
87	PULMONARY EDEMA & RESPIRATORY FAILURE	1.6597	32.3	26.9
88	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	0.7532	20.9	17.4
89	SIMPLE PNEUMONIA & PLEURISY AGE >17 W CC	0.8533	23.6	19.6
90	SIMPLE PNEUMONIA & PLEURISY AGE >17 W/O CC	0.7921	23.0	19.1
91	SIMPLE PNEUMONIA & PLEURISY AGE 0-17*	0.8284	23.3	19.4
92	INTERSTITIAL LUNG DISEASE W CC	0.7251	19.1	15.9
93	INTERSTITIAL LUNG DISEASE W/O CC	0.5573	18.5	15.4
94	PNEUMOTHORAX W CC	0.7885	22.7	18.9
95	PNEUMOTHORAX W/O CC[1]	0.4055	16.8	14.0
96	BRONCHITIS & ASTHMA AGE >17 W CC	0.8173	24.2	20.1
97	BRONCHITIS & ASTHMA AGE >17 W/O CC	0.5940	17.9	14.9
98	BRONCHITIS & ASTHMA AGE 0-17*	0.4055	16.8	14.0
99	RESPIRATORY SIGNS & SYMPTOMS W CC	1.1164	27.3	22.7
100	RESPIRATORY SIGNS & SYMPTOMS W/O CC	1.0015	25.4	21.1
101	OTHER RESPIRATORY SYSTEM DIAGNOSES W CC	0.9763	23.4	19.5
102	OTHER RESPIRATORY SYSTEM DIAGNOSES W/O CC	0.9313	24.5	20.4
103	HEART TRANSPLANT[6]	0.0000	0.0	0.0
104	CARDIAC VALVE & OTHER MAJOR CARDIOTHORACIC PROC W CARDIAC CATH*	1.8783	46.3	38.5
105	CARDIAC VALVE & OTHER MAJOR CARDIOTHORACIC PROC W/O CARDIAC CATH*	1.8783	46.3	38.5
106	CORONARY BYPASS W PTCA*	1.8783	46.3	38.5
107	CORONARY BYPASS W CARDIAC CATH*	1.8783	46.3	38.5
108	OTHER CARDIOTHORACIC PROCEDURES[2]	0.6655	21.9	18.2
109	CORONARY BYPASS W/O PTCA OR CARDIAC CATH*	1.8783	46.3	38.5
110	MAJOR CARDIOVASCULAR PROCEDURES W CC[5]	1.8783	46.3	38.5
111	MAJOR CARDIOVASCULAR PROCEDURES W/O CC[5]	1.8783	46.3	38.5
113	AMPUTATION FOR CIRC SYSTEM DISORDERS EXCEPT UPPER LIMB & TOE	1.4103	36.9	30.7
114	UPPER LIMB & TOE AMPUTATION FOR CIRC SYSTEM DISORDERS	1.3377	40.2	33.5
115	PRM CARD PACEM IMPL W AMI,HRT FAIL OR SHK,OR AICD LEAD OR GNRTR P[5]	1.8783	46.3	38.5
116	OTH PERM CARD PACEMAK IMPL OR PTCA W CORONARY ARTERY STENT IMPLNT[3]	0.8284	23.3	19.4
117	CARDIAC PACEMAKER REVISION EXCEPT DEVICE REPLACEMENT*	0.4055	16.8	14.0
118	CARDIAC PACEMAKER DEVICE REPLACEMENT[1]	0.4055	16.8	14.0
119	VEIN LIGATION & STRIPPING*	0.6655	21.9	18.2
120	OTHER CIRCULATORY SYSTEM O.R. PROCEDURES	1.4091	36.4	30.3
121	CIRCULATORY DISORDERS W AMI & MAJOR COMP, DISCHARGED ALIVE	0.7167	21.6	18.0
122	CIRCULATORY DISORDERS W AMI W/O MAJOR COMP, DISCHARGED ALIVE	0.5144	19.0	15.8
123	CIRCULATORY DISORDERS W AMI, EXPIRED	0.9412	20.9	17.4
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG[3]	0.8284	23.3	19.4
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG[5]	1.8783	46.3	38.5
126	ACUTE & SUBACUTE ENDOCARDITIS	0.7689	24.8	20.6
127	HEART FAILURE & SHOCK	0.7616	22.4	18.6
128	DEEP VEIN THROMBOPHLEBITIS	0.6042	20.8	17.3
129	CARDIAC ARREST, UNEXPLAINED	1.0534	20.9	17.4
130	PERIPHERAL VASCULAR DISORDERS W CC	0.7914	24.8	20.6
131	PERIPHERAL VASCULAR DISORDERS W/O CC	0.7081	23.7	19.7
132	ATHEROSCLEROSIS W CC	0.8183	21.8	18.1
133	ATHEROSCLEROSIS W/O CC	0.5484	18.5	15.4
134	HYPERTENSION	0.6985	24.0	20.0
135	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE >17 W CC	0.7331	20.3	16.9
136	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE >17 W/O CC	0.7075	21.0	17.5
137	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE 0-17*	0.6655	21.9	18.2
138	CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS W CC	0.7187	23.4	19.5
139	CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS W/O CC	0.6482	20.4	17.0
140	ANGINA PECTORIS	0.7690	20.1	16.7
141	SYNCOPE & COLLAPSE W CC	0.6252	23.2	19.3
142	SYNCOPE & COLLAPSE W/O CC	0.5452	21.5	17.9
143	CHEST PAIN	0.7316	22.7	18.9
144	OTHER CIRCULATORY SYSTEM DIAGNOSES W CC	0.7870	21.9	18.2
145	OTHER CIRCULATORY SYSTEM DIAGNOSES W/O CC	0.7637	25.0	20.8
146	RECTAL RESECTION W CC[4]	1.2493	31.3	26.0

TABLE 3.—LTC–DRG RELATIVE WEIGHTS, GEOMETRIC MEAN LENGTH OF STAY, AND SHORT-STAYS OF FIVE-SIXTHS AVERAGE LENGTH OF STAY FOR THE PERIOD OF JULY 1, 2003 THROUGH SEPTEMBER 30, 2003—Continued

LTC–DRG	Description	Relative Weight	Geo-metric Mean Length of Stay	Short-Stays of 5/6th Average Length of Stay
147	RECTAL RESECTION W/O CC*	1.2493	31.3	26.0
148	MAJOR SMALL & LARGE BOWEL PROCEDURES W CC	2.8488	47.6	39.6
149	MAJOR SMALL & LARGE BOWEL PROCEDURES W/O CC[2]	0.6655	21.9	18.2
150	PERITONEAL ADHESIOLYSIS W CC[1]	0.4055	16.8	14.0
151	PERITONEAL ADHESIOLYSIS W/O CC*	0.4055	16.8	14.0
152	MINOR SMALL & LARGE BOWEL PROCEDURES W CC[4]	1.2493	31.3	26.0
153	MINOR SMALL & LARGE BOWEL PROCEDURES W/O CC*	0.8284	23.3	19.4
154	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W CC[4]	1.2493	31.3	26.0
155	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W/O CC*	0.8284	23.3	19.4
156	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE 0-17*	0.8284	23.3	19.4
157	ANAL & STOMAL PROCEDURES W CC[1]	0.4055	16.8	14.0
158	ANAL & STOMAL PROCEDURES W/O CC*	0.4055	16.8	14.0
159	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W CC[4]	1.2493	31.3	26.0
160	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W/O CC*	0.6655	21.9	18.2
161	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W CC*	0.6655	21.9	18.2
162	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W/O CC*	0.6655	21.9	18.2
163	HERNIA PROCEDURES AGE 0-17*	0.6655	21.9	18.2
164	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W CC*	0.8284	23.3	19.4
165	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W/O CC*	0.8284	23.3	19.4
166	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W CC*	0.6655	21.9	18.2
167	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W/O CC*	0.6655	21.9	18.2
168	MOUTH PROCEDURES W CC[3]	0.8284	23.3	19.4
169	MOUTH PROCEDURES W/O CC*	0.6655	21.9	18.2
170	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W CC	1.5543	35.0	29.1
171	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/O CC[3]	0.8284	23.3	19.4
172	DIGESTIVE MALIGNANCY W CC	0.8553	24.2	20.1
173	DIGESTIVE MALIGNANCY W/O CC	0.5513	18.9	15.7
174	G.I. HEMORRHAGE W CC	0.8741	23.6	19.6
175	G.I. HEMORRHAGE W/O CC	0.8359	25.6	21.3
176	COMPLICATED PEPTIC ULCER	0.7661	24.4	20.3
177	UNCOMPLICATED PEPTIC ULCER W CC[3]	0.8284	23.3	19.4
178	UNCOMPLICATED PEPTIC ULCER W/O CC[2]	0.6655	21.9	18.2
179	INFLAMMATORY BOWEL DISEASE	1.0975	23.4	19.5
180	G.I. OBSTRUCTION W CC	0.8457	22.8	19.0
181	G.I. OBSTRUCTION W/O CC	0.5638	19.5	16.2
182	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE >17 W CC	0.8829	25.9	21.5
183	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE >17 W/O CC	0.6913	21.5	17.9
184	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE 0-17*	0.6655	21.9	18.2
185	DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE >17[3]	0.8284	23.3	19.4
186	DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE 0-17*	0.8284	23.3	19.4
187	DENTAL EXTRACTIONS & RESTORATIONS*	0.8284	23.3	19.4
188	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE >17 W CC	1.0490	24.2	20.1
189	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE >17 W/O CC	0.5852	17.4	14.5
190	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE 0-17*	0.6655	21.9	18.2
191	PANCREAS, LIVER & SHUNT PROCEDURES W CC[5]	1.8783	46.3	38.5
192	PANCREAS, LIVER & SHUNT PROCEDURES W/O CC*	1.2493	31.3	26.0
193	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W CC[4]	1.2493	31.3	26.0
194	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W/O CC*	0.8284	23.3	19.4
195	CHOLECYSTECTOMY W C.D.E. W CC*	0.8284	23.3	19.4
196	CHOLECYSTECTOMY W C.D.E. W/O CC*	0.8284	23.3	19.4
197	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W CC[5]	1.8783	46.3	38.5
198	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W/O CC[5]	1.8783	46.3	38.5
199	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR MALIGNANCY[3]	0.8284	23.3	19.4
200	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR NON-MALIGNANCY[4]	1.2493	31.3	26.0
201	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES[5]	1.8783	46.3	38.5
202	CIRRHOSIS & ALCOHOLIC HEPATITIS	0.5736	18.4	15.3
203	MALIGNANCY OF HEPATOBILIARY SYSTEM OR PANCREAS	0.5897	18.2	15.1
204	DISORDERS OF PANCREAS EXCEPT MALIGNANCY	0.9444	22.1	18.4
205	DISORDERS OF LIVER EXCEPT MALIG,CIRR,ALC HEPA W CC	0.6825	21.5	17.9
206	DISORDERS OF LIVER EXCEPT MALIG,CIRR,ALC HEPA W/O CC[2]	0.6655	21.9	18.2
207	DISORDERS OF THE BILIARY TRACT W CC	0.6979	21.5	17.9
208	DISORDERS OF THE BILIARY TRACT W/O CC[1]	0.4055	16.8	14.0
209	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY[5]	1.8783	46.3	38.5
210	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W CC[4]	1.2493	31.3	26.0
211	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W/O CC*	0.8284	23.3	19.4
212	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE 0-17*	0.8284	23.3	19.4
213	AMPUTATION FOR MUSCULOSKELETAL SYSTEM & CONN TISSUE DISORDERS	1.2591	33.0	27.5

TABLE 3.—LTC–DRG RELATIVE WEIGHTS, GEOMETRIC MEAN LENGTH OF STAY, AND SHORT-STAYS OF FIVE-SIXTHS AVERAGE LENGTH OF STAY FOR THE PERIOD OF JULY 1, 2003 THROUGH SEPTEMBER 30, 2003—Continued

LTC–DRG	Description	Relative Weight	Geo-metric Mean Length of Stay	Short-Stays of 5/6th Average Length of Stay
216	BIOPSIES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE[4]	1.2493	31.3	26.0
217	WND DEBRID & SKN GRFT EXCEPT HAND,FOR MUSCSKELET & CONN TISS DIS	1.3602	38.8	32.3
218	LOWER EXTREM & HUMER PROC EXCEPT HIP,FOOT,FEMUR AGE >17 W CC[3]	0.8284	23.3	19.4
219	LOWER EXTREM & HUMER PROC EXCEPT HIP,FOOT,FEMUR AGE >17 W/O CC*	0.8284	23.3	19.4
220	LOWER EXTREM & HUMER PROC EXCEPT HIP,FOOT,FEMUR AGE 0-17*	0.8284	23.3	19.4
223	MAJOR SHOULDER/ELBOW PROC, OR OTHER UPPER EXTREMITY PROC W CC[4]	1.2493	31.3	26.0
224	SHOULDER,ELBOW OR FOREARM PROC,EXC MAJOR JOINT PROC, W/O CC[1]	0.4055	16.8	14.0
225	FOOT PROCEDURES[4]	1.2493	31.3	26.0
226	SOFT TISSUE PROCEDURES W CC[4]	1.2493	31.3	26.0
227	SOFT TISSUE PROCEDURES W/O CC[3]	0.8284	23.3	19.4
228	MAJOR THUMB OR JOINT PROC,OR OTH HAND OR WRIST PROC W CC*	0.6655	21.9	18.2
229	HAND OR WRIST PROC, EXCEPT MAJOR JOINT PROC, W/O CC[2]	0.6655	21.9	18.2
230	LOCAL EXCISION & REMOVAL OF INT FIX DEVICES OF HIP & FEMUR[1]	0.4055	16.8	14.0
231	LOCAL EXCISION & REMOVAL OF INT FIX DEVICES EXCEPT HIP & FEMUR[5]	1.8783	46.3	38.5
232	ARTHROSCOPY*	0.4055	16.8	14.0
233	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W CC[4]	1.2493	31.3	26.0
234	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC[1]	0.4055	16.8	14.0
235	FRACTURES OF FEMUR	0.7540	28.5	23.7
236	FRACTURES OF HIP & PELVIS	0.7381	27.2	22.6
237	SPRAINS, STRAINS, & DISLOCATIONS OF HIP, PELVIS & THIGH[2]	0.6655	21.9	18.2
238	OSTEOMYELITIS	0.8275	27.5	22.9
239	PATHOLOGICAL FRACTURES & MUSCULOSKELETAL & CONN TISS MALIGNANCY	0.6689	21.9	18.2
240	CONNECTIVE TISSUE DISORDERS W CC	0.9260	26.0	21.6
241	CONNECTIVE TISSUE DISORDERS W/O CC	0.5805	22.7	18.9
242	SEPTIC ARTHRITIS	0.7725	26.3	21.9
243	MEDICAL BACK PROBLEMS	0.6596	23.4	19.5
244	BONE DISEASES & SPECIFIC ARTHROPATHIES W CC	0.5756	20.6	17.1
245	BONE DISEASES & SPECIFIC ARTHROPATHIES W/O CC	0.4426	17.5	14.5
246	NON-SPECIFIC ARTHROPATHIES	0.6053	21.4	17.8
247	SIGNS & SYMPTOMS OF MUSCULOSKELETAL SYSTEM & CONN TISSUE	0.5590	20.4	17.0
248	TENDONITIS, MYOSITIS & BURSITIS	0.7288	23.9	19.9
249	AFTERCARE, MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE	0.8005	27.1	22.5
250	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W CC	0.8373	31.8	26.5
251	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W/O CC	0.6904	26.0	21.6
252	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE 0-17*	0.4055	16.8	14.0
253	FX, SPRN, STRN & DISL OF UPARM,LOWLEG EX FOOT AGE >17 W CC	0.8054	28.0	23.3
254	FX, SPRN, STRN & DISL OF UPARM,LOWLEG EX FOOT AGE >17 W/O CC	0.6999	26.4	22.0
255	FX, SPRN, STRN & DISL OF UPARM,LOWLEG EX FOOT AGE 0-17*	0.4055	16.8	14.0
256	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE DIAGNOSES	0.8002	25.1	20.9
257	TOTAL MASTECTOMY FOR MALIGNANCY W CC[2]	0.6655	21.9	18.2
258	TOTAL MASTECTOMY FOR MALIGNANCY W/O CC*	0.6655	21.9	18.2
259	SUBTOTAL MASTECTOMY FOR MALIGNANCY W CC*	0.6655	21.9	18.2
260	SUBTOTAL MASTECTOMY FOR MALIGNANCY W/O CC*	0.6655	21.9	18.2
261	BREAST PROC FOR NON-MALIGNANCY EXCEPT BIOPSY & LOCAL EXCISION*	0.4055	16.8	14.0
262	BREAST BIOPSY & LOCAL EXCISION FOR NON-MALIGNANCY[1]	0.4055	16.8	14.0
263	SKIN GRAFT &/OR DEBRID FOR SKN ULCER OR CELLULITIS W CC	1.5388	45.0	37.5
264	SKIN GRAFT &/OR DEBRID FOR SKN ULCER OR CELLULITIS W/O CC	1.1645	38.8	32.3
265	SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W CC	1.6569	45.6	38.0
266	SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W/O CC[3]	0.8284	23.3	19.4
267	PERIANAL & PILONIDAL PROCEDURES*	0.4055	16.8	14.0
268	SKIN, SUBCUTANEOUS TISSUE & BREAST PLASTIC PROCEDURES[4]	1.2493	31.3	26.0
269	OTHER SKIN, SUBCUT TISS & BREAST PROC W CC	1.3915	41.7	34.7
270	OTHER SKIN, SUBCUT TISS & BREAST PROC W/O CC	1.3879	41.6	34.6
271	SKIN ULCERS	0.9714	31.1	25.9
272	MAJOR SKIN DISORDERS W CC	0.6846	21.0	17.5
273	MAJOR SKIN DISORDERS W/O CC[2]	0.6655	21.9	18.2
274	MALIGNANT BREAST DISORDERS W CC[7]	0.7872	22.0	18.3
275	MALIGNANT BREAST DISORDERS W/O CC[7]	0.7872	22.0	18.3
276	NON-MALIGANT BREAST DISORDERS[2]	0.6655	21.9	18.2
277	CELLULITIS AGE >17 W CC	0.7704	24.4	20.3
278	CELLULITIS AGE >17 W/O CC	0.6353	22.4	18.6
279	CELLULITIS AGE 0-17*	0.6655	21.9	18.2
280	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE >17 W CC	1.0097	30.9	25.7
281	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE >17 W/O CC	0.7363	27.4	22.8
282	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE 0-17*	0.6655	21.9	18.2
283	MINOR SKIN DISORDERS W CC	0.8574	24.8	20.6
284	MINOR SKIN DISORDERS W/O CC[1]	0.4055	16.8	14.0

TABLE 3.—LTC–DRG RELATIVE WEIGHTS, GEOMETRIC MEAN LENGTH OF STAY, AND SHORT-STAYS OF FIVE-SIXTHS AVERAGE LENGTH OF STAY FOR THE PERIOD OF JULY 1, 2003 THROUGH SEPTEMBER 30, 2003—Continued

LTC–DRG	Description	Relative Weight	Geo-metric Mean Length of Stay	Short-Stays of 5/6th Average Length of Stay
285	AMPUTAT OF LOWER LIMB FOR ENDOCRINE,NUTRIT,& METABOL DISORDERS	1.3692	31.7	26.4
286	ADRENAL & PITUITARY PROCEDURES*	1.2493	31.3	26.0
287	SKIN GRAFTS & WOUND DEBRID FOR ENDOC, NUTRIT & METAB DISORDERS	1.3195	39.6	33.0
288	O.R. PROCEDURES FOR OBESITY[5]	1.8783	46.3	38.5
289	PARATHYROID PROCEDURES*	0.4055	16.8	14.0
290	THYROID PROCEDURES[1]	0.4055	16.8	14.0
291	THYROGLOSSAL PROCEDURES*	0.4055	16.8	14.0
292	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W CC[4]	1.2493	31.3	26.0
293	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/O CC*	0.6655	21.9	18.2
294	DIABETES AGE >35	0.7678	25.1	20.9
295	DIABETES AGE 0-35[3]	0.8284	23.3	19.4
296	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W CC	0.7710	24.3	20.2
297	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W/O CC	0.6321	21.1	17.5
298	NUTRITIONAL & MISC METABOLIC DISORDERS AGE 0-17*	0.6655	21.9	18.2
299	INBORN ERRORS OF METABOLISM[3]	0.8284	23.3	19.4
300	ENDOCRINE DISORDERS W CC	0.8670	23.3	19.4
301	ENDOCRINE DISORDERS W/O CC[1]	0.4055	16.8	14.0
302	KIDNEY TRANSPLANT[6]	0.0000	0.0	0.0
303	KIDNEY,URETER & MAJOR BLADDER PROCEDURES FOR NEOPLASM[5]	1.8783	46.3	38.5
304	KIDNEY,URETER & MAJOR BLADDER PROC FOR NON-NEOPL W CC[4]	1.2493	31.3	26.0
305	KIDNEY,URETER & MAJOR BLADDER PROC FOR NON-NEOPL W/O CC[2]	0.6655	21.9	18.2
306	PROSTATECTOMY W CC[3]	0.8284	23.3	19.4
307	PROSTATECTOMY W/O CC[1]	0.4055	16.8	14.0
308	MINOR BLADDER PROCEDURES W CC[3]	0.8284	23.3	19.414.0
309	MINOR BLADDER PROCEDURES W/O CC*	0.4055	16.8	26.0
310	TRANSURETHRAL PROCEDURES W CC[4]	1.2493	31.3	14.0
311	TRANSURETHRAL PROCEDURES W/O CC[1]	0.4055	16.8	38.5
312	URETHRAL PROCEDURES, AGE >17 W CC[5]	1.8783	46.3	14.0
313	URETHRAL PROCEDURES, AGE >17 W/O CC*	0.4055	16.8	14.0
314	URETHRAL PROCEDURES, AGE 0-17*	0.4055	16.8	14.0
315	OTHER KIDNEY & URINARY TRACT O.R. PROCEDURES	1.5800	39.5	32.9
316	RENAL FAILURE	0.9308	24.1	20.0
317	ADMIT FOR RENAL DIALYSIS[4]	1.2493	31.3	26.0
318	KIDNEY & URINARY TRACT NEOPLASMS W CC	0.8075	21.5	17.9
319	KIDNEY & URINARY TRACT NEOPLASMS W/O CC[2]	0.6655	21.9	18.2
320	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W CC	0.7424	23.9	19.9
321	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W/O CC	0.6123	20.4	17.0
322	KIDNEY & URINARY TRACT INFECTIONS AGE 0-17*	0.6655	21.9	18.2
323	URINARY STONES W CC, &/OR ESW LITHOTRIPSY[2]	0.6655	21.9	18.2
324	URINARY STONES W/O CC[2]	0.6655	21.9	18.2
325	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W CC	0.8123	26.7	22.2
326	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W/O CC[2]	0.6655	21.9	18.2
327	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE 0-17*	0.4055	16.8	14.0
328	URETHRAL STRICTURE AGE >17 W CC*	0.6655	21.9	18.2
329	URETHRAL STRICTURE AGE >17 W/O CC[1]	0.4055	16.8	14.0
330	URETHRAL STRICTURE AGE 0-17*	0.4055	16.8	14.0
331	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE >17 W CC	0.9267	24.6	20.5
332	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE >17 W/O CC	0.6393	20.9	17.4
333	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE 0-17*	0.4055	16.8	14.0
334	MAJOR MALE PELVIC PROCEDURES W CC*	1.2493	31.3	26.0
335	MAJOR MALE PELVIC PROCEDURES W/O CC*	0.8284	23.3	19.4
336	TRANSURETHRAL PROSTATECTOMY W CC[3]	0.8284	23.3	19.4
337	TRANSURETHRAL PROSTATECTOMY W/O CC*	0.6655	21.9	18.2
338	TESTES PROCEDURES, FOR MALIGNANCY*	0.6655	21.9	18.2
339	TESTES PROCEDURES, NON-MALIGNANCY AGE >17[1]	0.4055	16.8	14.0
340	TESTES PROCEDURES, NON-MALIGNANCY AGE 0-17*	0.4055	16.8	14.0
341	PENIS PROCEDURES[2]	0.6655	21.9	18.2
342	CIRCUMCISION AGE >17[4]	1.2493	31.3	26.0
343	CIRCUMCISION AGE 0-17	0.4055	16.8	14.0
344	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES FOR MALIGNANCY[4]	1.2493	31.3	26.0
345	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROC EXCEPT FOR MALIGNANCY[3]	0.8284	23.3	19.4
346	MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W CC	0.7070	21.6	18.0
347	MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W/O CC[2]	0.6655	21.9	18.2
348	BENIGN PROSTATIC HYPERTROPHY W CC[1]	0.4055	16.8	14.0
349	BENIGN PROSTATIC HYPERTROPHY W/O CC*	0.4055	16.8	14.0
350	INFLAMMATION OF THE MALE REPRODUCTIVE SYSTEM	0.6058	19.9	16.5
351	STERILIZATION, MALE*	0.4055	16.8	14.0

TABLE 3.—LTC–DRG RELATIVE WEIGHTS, GEOMETRIC MEAN LENGTH OF STAY, AND SHORT-STAYS OF FIVE-SIXTHS AVERAGE LENGTH OF STAY FOR THE PERIOD OF JULY 1, 2003 THROUGH SEPTEMBER 30, 2003—Continued

LTC–DRG	Description	Relative Weight	Geo-metric Mean Length of Stay	Short-Stays of 5/6th Average Length of Stay
352	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES [3]	0.8284	23.3	19.4
353	PELVIC EVISCERATION, RADICAL HYSTERECTOMY & RADICAL VULVECTOMY *	1.8783	46.3	38.5
354	UTERINE,ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIG W CC *	1.2493	31.3	26.0
355	UTERINE,ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIG W/O CC *	1.2493	31.3	26.0
356	FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES *	1.2493	31.3	26.0
357	UTERINE & ADNEXA PROC FOR OVARIAN OR ADNEXAL MALIGNANCY *	1.2493	31.3	26.0
358	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W CC [5]	1.8783	46.3	38.5
359	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W/O CC [1]	0.4055	16.8	14.0
360	VAGINA, CERVIX & VULVA PROCEDURES [1]	0.4055	16.8	14.0
361	LAPAROSCOPY & INCISIONAL TUBAL INTERRUPTION *	0.6655	21.9	18.2
362	ENDOSCOPIC TUBAL INTERRUPTION *	0.6655	21.9	18.2
363	D&C, CONIZATION & RADIO-IMPLANT, FOR MALIGNANCY *	0.8284	23.3	19.4
364	D&C, CONIZATION EXCEPT FOR MALIGNANCY *	0.6655	21.9	18.2
365	OTHER FEMALE REPRODUCTIVE SYSTEM O.R. PROCEDURES [5]	1.8783	46.3	38.5
366	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W CC	0.9654	23.9	19.9
367	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W/O CC [3]	0.8284	23.3	19.4
368	INFECTIONS, FEMALE REPRODUCTIVE SYSTEM [4]	1.2493	31.3	26.0
369	MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS [2]	0.6655	21.9	18.2
370	CESAREAN SECTION W CC *	0.8284	23.3	19.4
371	CESAREAN SECTION W/O CC *	0.6655	21.9	18.2
372	VAGINAL DELIVERY W COMPLICATING DIAGNOSES *	0.6655	21.9	18.2
373	VAGINAL DELIVERY W/O COMPLICATING DIAGNOSES *	0.4055	16.8	14.0
374	VAGINAL DELIVERY W STERILIZATION &/OR D&C *	0.4055	16.8	14.0
375	VAGINAL DELIVERY W O.R. PROC EXCEPT STERIL &/OR D&C *	0.4055	16.8	14.0
376	POSTPARTUM & POST ABORTION DIAGNOSES W/O O.R. PROCEDURE *	0.4055	16.8	14.0
377	POSTPARTUM & POST ABORTION DIAGNOSES W O.R. PROCEDURE *	0.4055	16.8	14.0
378	ECTOPIC PREGNANCY *	0.6655	21.9	18.2
379	THREATENED ABORTION *	0.4055	16.8	14.0
380	ABORTION W/O D&C *	0.4055	16.8	14.0
381	ABORTION W D&C, ASPIRATION CURETTAGE OR HYSTEROTOMY *	0.4055	16.8	14.0
382	FALSE LABOR *	0.4055	16.8	14.0
383	OTHER ANTEPARTUM DIAGNOSES W MEDICAL COMPLICATIONS *	0.4055	16.8	14.0
384	OTHER ANTEPARTUM DIAGNOSES W/O MEDICAL COMPLICATIONS *	0.4055	16.8	14.0
385	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY *	0.4055	16.8	14.0
386	EXTREME IMMATURITY *	0.6655	21.9	18.2
387	PREMATURITY W MAJOR PROBLEMS *	0.6655	21.9	18.2
388	PREMATURITY W/O MAJOR PROBLEMS *	0.4055	16.8	14.0
389	FULL TERM NEONATE W MAJOR PROBLEMS [4]	1.2493	31.3	26.0
390	NEONATE W OTHER SIGNIFICANT PROBLEMS *	0.6655	21.9	18.2
391	NORMAL NEWBORN *	0.4055	16.8	14.0
392	SPLENECTOMY AGE >17 *	0.8284	23.3	19.4
393	SPLENECTOMY AGE 0-17 *	0.6655	21.9	18.2
394	OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS [5]	1.8783	46.3	38.5
395	RED BLOOD CELL DISORDERS AGE >17	0.8584	25.1	20.9
396	RED BLOOD CELL DISORDERS AGE 0-17 *	0.4055	16.8	14.0
397	COAGULATION DISORDERS	0.7567	19.4	16.1
398	RETICULOENDOTHELIAL & IMMUNITY DISORDERS W CC	0.9008	23.4	19.5
399	RETICULOENDOTHELIAL & IMMUNITY DISORDERS W/O CC)[1]	0.4055	16.8	14.0
400	LYMPHOMA & LEUKEMIA W MAJOR O.R. PROCEDURE [3]	0.8284	23.3	19.4
401	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W CC [4]	1.2493	31.3	26.0
402	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W/O CC *	0.8284	23.3	19.4
403	LYMPHOMA & NON-ACUTE LEUKEMIA W CC	0.9651	23.9	19.9
404	LYMPHOMA & NON-ACUTE LEUKEMIA W/O CC	0.8980	19.1	15.9
405	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE 0-17 *	0.6655	21.9	18.2
406	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R.PROC W CC [5]	1.8783	46.3	38.5
407	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R.PROC W/O CC *	0.8284	23.3	19.4
408	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W OTHER O.R.PROC [4]	1.2493	31.3	26.0
409	RADIOTHERAPY	0.5220	19.5	16.2
410	CHEMOTHERAPY W/O ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS [1]	0.4055	16.8	14.0
411	HISTORY OF MALIGNANCY W/O ENDOSCOPY *	0.4055	16.8	14.0
412	HISTORY OF MALIGNANCY W ENDOSCOPY *	0.4055	16.8	14.0
413	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W CC [7]	0.9061	23.7	19.7
414	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W/O CC [7]	0.9061	23.7	19.7
415	O.R. PROCEDURE FOR INFECTIOUS & PARASITIC DISEASES	1.4933	38.7	32.2
416	SEPTICEMIA AGE >17	0.9612	25.9	21.5
417	SEPTICEMIA AGE 0-17 *	0.8284	23.3	19.4
418	POSTOPERATIVE & POST-TRAUMATIC INFECTIONS	0.8771	25.8	21.5

TABLE 3.—LTC–DRG RELATIVE WEIGHTS, GEOMETRIC MEAN LENGTH OF STAY, AND SHORT-STAYS OF FIVE-SIXTHS AVERAGE LENGTH OF STAY FOR THE PERIOD OF JULY 1, 2003 THROUGH SEPTEMBER 30, 2003—Continued

LTC–DRG	Description	Relative Weight	Geo-metric Mean Length of Stay	Short-Stays of 5/6th Average Length of Stay
419	FEVER OF UNKNOWN ORIGIN AGE >17 W CC	0.5948	20.5	17.0
420	FEVER OF UNKNOWN ORIGIN AGE >17 W/O CC[1]	0.4055	16.8	14.0
421	VIRAL ILLNESS AGE >17[4]	1.2493	31.3	26.0
422	VIRAL ILLNESS & FEVER OF UNKNOWN ORIGIN AGE 0-17*	0.4055	16.8	14.0
423	OTHER INFECTIOUS & PARASITIC DISEASES DIAGNOSES	0.8701	24.7	20.5
424	O.R. PROCEDURE W PRINCIPAL DIAGNOSES OF MENTAL ILLNESS[5]	1.8783	46.3	38.5
425	ACUTE ADJUSTMENT REACTION & PSYCHOLOGICAL DYSFUNCTION	0.6177	26.0	21.6
426	DEPRESSIVE NEUROSES	0.5739	26.9	22.4
427	NEUROSES EXCEPT DEPRESSIVE[2]	0.6655	21.9	18.2
428	DISORDERS OF PERSONALITY & IMPULSE CONTROL[4]	1.2493	31.3	26.0
429	ORGANIC DISTURBANCES & MENTAL RETARDATION	0.5466	25.0	20.8
430	PSYCHOSES	0.4479	22.9	19.0
431	CHILDHOOD MENTAL DISORDERS	0.4345	22.7	18.9
432	OTHER MENTAL DISORDER DIAGNOSES[2]	0.6655	21.9	18.2
433	ALCOHOL/DRUG ABUSE OR DEPENDENCE, LEFT AMA	0.2489	13.1	10.9
439	SKIN GRAFTS FOR INJURIES	1.3200	42.5	35.4
440	WOUND DEBRIDEMENTS FOR INJURIES	1.3567	40.1	33.4
441	HAND PROCEDURES FOR INJURIES*	0.6655	21.9	18.2
442	OTHER O.R. PROCEDURES FOR INJURIES W CC	1.6442	39.7	33.0
443	OTHER O.R. PROCEDURES FOR INJURIES W/O CC[2]	0.6655	21.9	18.2
444	TRAUMATIC INJURY AGE >17 W CC	0.9614	30.7	25.5
445	TRAUMATIC INJURY AGE >17 W/O CC	0.8448	27.3	22.7
446	TRAUMATIC INJURY AGE 0-17*	0.8284	23.3	19.4
447	ALLERGIC REACTIONS AGE >17[2]	0.6655	21.9	18.2
448	ALLERGIC REACTIONS AGE 0-17*	0.4055	16.8	14.0
449	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W CC[3]	0.8284	23.3	19.4
450	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W/O CC[2]	0.6655	21.9	18.2
451	POISONING & TOXIC EFFECTS OF DRUGS AGE 0-17*	0.4055	16.8	14.0
452	COMPLICATIONS OF TREATMENT W CC	0.9596	25.5	21.2
453	COMPLICATIONS OF TREATMENT W/O CC	0.6666	23.1	19.2
454	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W CC[3]	0.8284	23.3	19.4
455	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W/O CC[1]	0.4055	16.8	14.0
461	O.R. PROC W DIAGNOSES OF OTHER CONTACT W HEALTH SERVICES	1.3383	38.0	31.6
462	REHABILITATION	0.6469	23.5	19.5
463	SIGNS & SYMPTOMS W CC	0.7618	26.8	22.3
464	SIGNS & SYMPTOMS W/O CC	0.6234	24.3	20.2
465	AFTERCARE W HISTORY OF MALIGNANCY AS SECONDARY DIAGNOSIS[3]	0.8284	23.3	19.4
466	AFTERCARE W/O HISTORY OF MALIGNANCY AS SECONDARY DIAGNOSIS	0.8119	23.9	19.9
467	OTHER FACTORS INFLUENCING HEALTH STATUS[2]	0.6655	21.9	18.2
468	EXTENSIVE O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS	2.2177	45.5	37.9
469	PRINCIPAL DIAGNOSIS INVALID AS DISCHARGE DIAGNOSIS[6]	0.0000	0.0	0.0
470	UNGROUPABLE[6]	0.0000	0.0	0.0
471	BILATERAL OR MULTIPLE MAJOR JOINT PROCS OF LOWER EXTREMITY*	1.8783	46.3	38.5
473	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE >17	0.8047	17.1	14.2
475	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT	2.0906	35.5	29.5
476	PROSTATIC O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS[5]	1.8783	46.3	38.5
477	NON-EXTENSIVE O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS	1.6791	39.7	33.0
478	OTHER VASCULAR PROCEDURES W CC	1.6244	37.8	31.5
479	OTHER VASCULAR PROCEDURES W/O CC[2]	0.6655	21.9	18.2
480	LIVER TRANSPLANT[6]	0.0000	0.0	0.0
481	BONE MARROW TRANSPLANT*	1.8783	46.3	38.5
482	TRACHEOSTOMY FOR FACE,MOUTH & NECK DIAGNOSES*	0.6655	21.9	18.2
483	TRACH W MECH VENT 96+ HRS OR PDX EXCEPT FACE,MOUTH & NECK DIAG	3.2319	4.6	45.5
484	CRANIOTOMY FOR MULTIPLE SIGNIFICANT TRAUMA*	1.8783	46.3	38.5
485	LIMB REATTACHMENT, HIP AND FEMUR PROC FOR MULTIPLE SIGNIFICANT TR*	1.8783	46.3	38.5
486	OTHER O.R. PROCEDURES FOR MULTIPLE SIGNIFICANT TRAUMA[3]	0.8284	23.3	19.4
487	OTHER MULTIPLE SIGNIFICANT TRAUMA	1.0885	29.5	24.5
488	HIV W EXTENSIVE O.R. PROCEDURE[5]	1.8783	46.3	38.5
489	HIV W MAJOR RELATED CONDITION	0.8846	22.9	19.0
490	HIV W OR W/O OTHER RELATED CONDITION	0.6952	20.4	17.0
491	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF UPPER EXTREMITY*	1.8783	46.3	38.5
492	CHEMOTHERAPY W ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS[3]	0.8284	23.3	19.4
493	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W CC[3]	0.8284	23.3	19.4
494	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W/O CC[1]	0.4055	16.8	14.0
495	LUNG TRANSPLANT[6]	0.0000	0.0	0.0
496	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION*	1.2493	31.3	26.0
497	SPINAL FUSION W CC[5]	1.8783	46.3	38.5

TABLE 3.—LTC–DRG RELATIVE WEIGHTS, GEOMETRIC MEAN LENGTH OF STAY, AND SHORT-STAYS OF FIVE-SIXTHS AVERAGE LENGTH OF STAY FOR THE PERIOD OF JULY 1, 2003 THROUGH SEPTEMBER 30, 2003—Continued

LTC–DRG	Description	Relative Weight	Geo-metric Mean Length of Stay	Short-Stays of 5/6th Aver-age Length of Stay
498	SPINAL FUSION W/O CC[3]	0.8284	23.3	19.4
499	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W CC[5]	1.8783	46.3	38.5
500	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W/O CC*	0.8284	23.3	19.4
501	KNEE PROCEDURES W PDX OF INFECTION W CC[5]	1.8783	46.3	38.5
502	KNEE PROCEDURES W PDX OF INFECTION W/O CC*	0.8284	23.3	19.4
503	KNEE PROCEDURES W/O PDX OF INFECTION[5]	1.8783	46.3	38.5
504	EXTENSIVE 3RD DEGREE BURNS W SKIN GRAFT*	1.8783	46.3	38.5
505	EXTENSIVE 3RD DEGREE BURNS W/O SKIN GRAFT[4]	1.2493	31.3	26.0
506	FULL THICKNESS BURN W SKIN GRAFT OR INHAL INJ W CC OR SIG TRAUMA[5]	1.8783	46.3	38.5
507	FULL THICKNESS BURN W SKIN GRFT OR INHAL INJ W/O CC OR SIG TRAUMA*	0.8284	23.3	19.4
508	FULL THICKNESS BURN W/O SKIN GRFT OR INHAL INJ W CC OR SIG TRAUMA[3]	0.8284	23.3	19.4
509	FULL THICKNESS BURN W/O SKIN GRFT OR INH INJ W/O CC OR SIG TRAUMA[3]	0.8284	23.3	19.4
510	NON-EXTENSIVE BURNS W CC OR SIGNIFICANT TRAUMA	1.0734	32.2	26.8
511	NON-EXTENSIVE BURNS W/O CC OR SIGNIFICANT TRAUMA[3]	0.8284	23.3	19.4
512	SIMULTANEOUS PANCREAS/KIDNEY TRANSPLANT[6]	0.0000	0.0	0.0
513	PANCREAS TRANSPLANT[6]	0.0000	0.0	0.0
514	CARDIAC DEFIBRILATOR IMPLANT W CARDIAC CATH*	0.8284	23.3	19.4
515	CARDIAC DEFIBRILATOR IMPLANT W/O CARDIAC CATH[4]	1.2493	31.3	26.0
516	PERCUTANEOUS CARDIVASCULAR PROCEDURE W AMI*	0.8284	23.3	19.4
517	PERCUTANEOUS CARDIVASCULAR PROC W NON-DRUG ELUTING STENT W/O AMI[5]	1.8783	46.3	38.5
518	PERCUTANEOUS CARDIVASCULAR PROC W/O CORONARY ARTERY STENT OR AMI[4]	1.2493	31.3	26.0
519	CERVICAL SPINAL FUSION W CC[3]	0.8284	23.3	19.4
520	CERVICAL SPINAL FUSION W/O CC[2]	0.6655	21.9	18.2
521	ALCOHOL/DRUG ABUSE OR DEPENDENCE W CC	0.3755	18.6	15.5
522	ALCOHOL/DRUG ABUSE OR DEPENDENCE W REHABILITATION THERAPY W/O CC[1]	0.4055	16.8	14.0
523	ALCOHOL/DRUG ABUSE OR DEPENDENCE W/O REHABILITATION THERAPY W/O CC	0.3860	21.2	17.6
524	TRANSIENT ISCHEMIA	0.6250	23.1	19.2
525	HEART ASSIST SYSTEM IMPLANT*	1.8783	46.3	38.5
526	PERCUTANEOUS CARVIOVASCULAR PROC W DRUG-ELUTING STENT W AMI*	0.8284	23.3	19.4
527	PERCUTANEOUS CARVIOVASCULAR PROC W DRUG-ELUTING STENT W/O AMI*	0.8284	23.3	19.4

* Relative weights for these LTC–DRGs were determined by assigning these cases to the appropriate low volume quintile because they had no LTCH cases in the FY 2001 MedPAR.

[1] Relative weights for these LTC–DRGs were determined by assigning these cases to low volume quintile 1.
[2] Relative weights for these LTC–DRGs were determined by assigning these cases to low volume quintile 2.
[3] Relative weights for these LTC–DRGs were determined by assigning these cases to low volume quintile 3.
[4] Relative weights for these LTC–DRGs were determined by assigning these cases to low volume quintile 4.
[5] Relative weights for these LTC–DRGs were determined by assigning these cases to low volume quintile 5.
[6] Relative weights for these LTC–DRGs were assigned a value of 0.0.
[7] Relative weights for these LTC–DRGs were determined after adjusting to account for nonmonotonically (see step 5 above).

[FR Doc. 03–14078 Filed 5–30–03; 3:28 pm]

BILLING CODE 4120–01–P

Federal Register

Friday,
June 6, 2003

Part IV

Department of Commerce

Bureau of Industry and Security

15 CFR Parts 744 and 772

Department of the Treasury

Office of Foreign Assets Control

31 CFR Part 594

Imposition and Expansion of Controls on Designated Terrorists; Global Terrorism Sanctions Regulation; Final Rules

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 744 and 772

[Docket No. 020912210–2210–01]

RIN 0694–AC60

Imposition and Expansion of Controls on Designated Terrorists

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule amends the Export Administration Regulations (EAR) by imposing a license requirement on the export and reexport of any item subject to the EAR by a U.S. person or non-U.S. person to persons designated in or pursuant to Executive Order 13224 of September 23, 2001. In response to grave acts of terrorism and threats of terrorism, Executive Order 13224 blocks the property and interests in property of persons listed in an Annex to the order and persons designated by the Secretary of State or the Secretary of the Treasury pursuant to criteria set forth in the order. Executive Order 13224 also prohibits U.S. persons from engaging in any transactions with such blocked persons. The Department of the Treasury's Office of Foreign Assets Control (OFAC) announces the names of persons designated pursuant to Executive Order 13224 in the **Federal Register** and includes such persons in a listing of persons subject to various sanctions programs administered by OFAC. The Department of State also announces the names of foreign persons designated pursuant to Executive Order 13224 in the **Federal Register**. All persons designated in or pursuant to Executive Order 13224 are identified by the bracketed initials [SDGT] in the Department of Treasury listing and are also known as Specially Designated Global Terrorists (SDGTs). This rule also amends the EAR by expanding reexport controls on Specially Designated Terrorists (SDTs) and Foreign Terrorist Organizations (FTOs). OFAC also includes SDTs and FTOs in the Department of Treasury listing and identifies them by the bracketed initials [SDT] and [FTO], respectively.

DATES: This rule is effective June 6, 2003.

Comment Dates: Comments on this rule must be received on or before July 21, 2003.

ADDRESSES: Written comments on this rule should be sent to Sheila Quarterman, Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, P.O. Box 273, Washington, DC 20044, or to E-mail address *squarter@bis.doc.gov.*

FOR FURTHER INFORMATION CONTACT: Joan Roberts, Director, Foreign Policy Controls Division, Office of Strategic Trade and Foreign Policy Controls, Bureau of Industry and Security, Department of Commerce. Telephone: (202) 482–0171, E-mail *jroberts@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Imposition of Controls on Specially Designated Global Terrorists (SDGTs)

President Bush issued Executive Order 13224 (E.O. 13224) (Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism) on September 23, 2001, in response to grave acts of terrorism and threats of terrorism. On September 28, 2001, the United Nations Security Council (UNSC) adopted Resolution 1373, requiring all member states, among other things, to refrain from providing any form of support to persons involved in terrorist acts and to prohibit their nationals from making economic resources available to persons who commit, attempt to commit, facilitate or participate in the commission of terrorist acts. In addition, on January 28, 2002, the UNSC adopted Resolution 1390, which requires all member states to freeze funds and other financial assets or economic resources of Usama bin Laden, members of the Al-Qaida organization and the Taliban and other individuals, groups, undertakings and entities associated with them, as referred to in the list created pursuant to UNSC Resolutions 1267 (October 15, 1999) and 1333 (December 19, 2000). UNSC Resolution 1455 (January 17, 2003) continued and improved the measures provided in UNSC Resolution 1390. The Bureau of Industry and Security (BIS) is taking action consistent with E.O. 13224 and UNSC Resolutions 1267, 1390, 1452 (December 20, 2002), and 1455, as well as 1373, by imposing a license requirement on all exports and reexports to persons designated in or pursuant to E.O. 13224. Persons designated pursuant to criteria set forth in E.O. 13224 by the Secretary of State or the Secretary of the Treasury are announced in the **Federal Register** and listed in Appendix A to 31 CFR chapter V, which lists persons subject to various sanctions programs administered by OFAC (''Blocked Persons list''). Persons designated in or pursuant to E.O. 13224 are identified in Appendix A by the bracketed initials [SDGT] and are also known as Specially Designated Global Terrorists (SDGTs). Provisions that implement BIS controls on SDGTs are included in new section 744.12 of the EAR.

Expansion of Reexport Controls on SDTs and FTOs

Specially Designated Terrorists (SDTs) are designated in or pursuant to Executive Order 12947 issued on January 23, 1995 (Prohibiting Transactions with Terrorists Who Threaten to Disrupt the Middle East Peace Process), as amended by Executive Order 13099 of August 20, 1998. Foreign Terrorist Organizations (FTOs) are designated pursuant to the 1996 Anti-Terrorism and Effective Death Penalty Act (Pub. L. 104–132). SDTs and FTOs are included on the Blocked Persons list maintained by OFAC in Appendix A to 31 CFR chapter V and identified by the bracketed initials [SDT] and [FTO], respectively.

On January 8, 1999, BIS issued a rule imposing foreign policy controls on exports and certain reexports of items subject to the EAR to individuals and groups designated as SDTs and groups designated as FTOs. The January 1999 rule imposed a license requirement on the following exports and reexports to a designated SDT or FTO:

(1) The export from the United States of any item subject to the EAR;

(2) The export or reexport by a U.S. person, wherever located, of any item subject to the EAR; and

(3) The export from abroad or reexport by a non-U.S. person of any item subject to the EAR on the Commerce Control List.

The January 1999 rule did not impose a license requirement on the export from abroad or reexport by a non-U.S. person of EAR99 items. The action BIS is now taking, effective June 6, 2003, expands current controls by requiring a license for the export from abroad or reexport to a designated SDT or FTO by a non-U.S. person of any item subject to the EAR, whether such item is on the Commerce Control List or is classified as EAR99. Provisions that expand BIS controls on SDTs and FTOs are found in revised sections 744.13 and 744.14 of the EAR, respectively.

Note that certain persons designated in or pursuant to E.O. 13224 also have been designated as SDTs or FTOs or both, and are appropriately identified by more than one of the bracketed acronyms in Appendix A to 31 CFR chapter V. As such, section 744.1 is also revised to add a new subsection (a)(2), which provides that when controls set forth under more than one section of

part 744 apply to a person, the license requirements for such a person will be determined based on the requirements of all applicable sections, and license applications will be reviewed under all applicable licensing policies. For example, if an entity on the Entity List in Supplement No. 4 to part 744 is also designated in or pursuant to E.O. 13224, the provisions set forth in Supplement No. 4 to part 744 as well as the provisions set forth in section 744.12 will apply, and the denial policy for the export or reexport of all items subject to the EAR will be the operative policy. Also note that paragraph 744.1(a) is updated to reflect the controls in sections 744.9–744.16.

Allocation of Agency Licensing Responsibility To Avoid Dual Licensing Requirements

Exports by U.S. Persons

OFAC requires a license for all exports from the United States and all exports and reexports by a U.S. person to any SDT or SDGT. To avoid duplication, if OFAC authorizes a transaction involving an export from the United States or an export or reexport by a U.S. person of an item subject to the EAR to a designated SDT or SDGT, no separate authorization from BIS is necessary, even if the SDT or SDGT is also an FTO. However, authorization from BIS is required for an export from the United States or an export from abroad or reexport of an item subject to the EAR by a U.S. person to an FTO that is not also an SDT or SDGT.

Exports From Abroad and Reexports by Non-U.S. Persons

Authorization from BIS is required for exports from abroad and reexports by non-U.S. persons of items subject to the EAR to SDGTs, SDTs, or FTOs.

Licensing Policy

License applications for exports or reexports to SDGTs, SDTs, or FTOs are subject to a policy of denial.

OFAC announces in the **Federal Register** and incorporates into the Blocked Persons list on an on-going basis the frequent changes or additions to the three lists of persons subject to sanctions who are identified by the bracketed initials [SDGT], [SDT] or [FTO] in Appendix A to 31 CFR chapter V. To obtain additional information regarding the Blocked Persons list maintained by OFAC, contact OFAC at telephone number 202/622–2520. Additional information also may be found at OFAC's Web site at *www.treas.gov/ofac.*

A foreign policy report on the new and expanded controls imposed by this rule on designated terrorist entities and individuals was submitted to the Congress on March 18, 2003.

Rulemaking Requirements

1. This interim rule has been determined not to be significant for purposes of E.O. 12866.

2. Notwithstanding any other provision of law, no person is required to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the Paperwork Reduction Act (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves a collection of information approved by the OMB under control number 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 40 minutes per electronic submission and 45 minutes for a manual submission. Send comments regarding this burden estimate or any other aspect of these collections of information, including suggestions for reducing the burden, to OMB Desk Officer, New Executive Office Building, Washington, DC 20503; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, P.O. Box 273, Washington, DC 20044.

3. This rule does not contain policies with federalism implications as this term is defined under Executive Order 13132.

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

However, because of the importance of the issues raised by these regulations, this rule is being issued in interim form and BIS will consider comments in the development of the final regulations.

Accordingly, the Department of Commerce (the Department) encourages interested persons who wish to comment to do so at the earliest possible time to permit the fullest consideration of their views.

The period for submission of comments will close July 21, 2003. The Department will consider all comments received before the close of the comment period in developing final regulations. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept public comments accompanied by a request that a part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the persons submitting the comments and will not consider them in the development of final regulations. All public comments on these regulations will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, the Department requires comments in written form.

Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying. Communications from agencies of the United States Government or foreign governments will not be available for public inspection.

The Office of Administration, Bureau of Industry and Security, U.S. Department of Commerce, displays these public comments on BIS's Freedom of Information Act (FOIA) Web site at *http://www.bis.doc.gov/foia.* This office does not maintain a separate public inspection facility. If you have technical difficulties accessing this Web site, please call BIS's Office of Administration, at (202) 482–0637, for assistance.

List of Subjects

15 CFR Part 744

Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Part 772

Exports, Foreign trade.

■ Accordingly, parts 744 and 772 of the Export Administrations Regulations (15 CFR parts 730–799) are amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for part 744 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994

Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; notice of November 9, 2001, 66 FR 56965, 3 CFR, 2001 Comp., p. 917; notice of August 14, 2002, 67 FR 53721, August 16, 2002.

■ 2. Section 744.1 is amended by revising paragraph (a) to read as follows:

§ 744.1 General Provisions.

(a)(1) *Introduction.* In this part, references to the EAR are references to 15 CFR chapter VII, subchapter C. This part contains prohibitions against exports, reexports, and selected transfers to certain end-users and end-uses as introduced under General Prohibition Five (End-use/End-users) and Nine (Orders, Terms, and Conditions), unless authorized by BIS. Sections 744.2, 744.3, 744.4 and 744.5 prohibit exports and reexports of items subject to the EAR to defined nuclear, missile, chemical and biological activities and nuclear maritime end-uses. Section 744.6 prohibits certain activities by U.S. persons in support of certain nuclear, missile, chemical, or biological end-uses regardless of whether that support involves the export or reexport of items subject to the EAR. Sections 744.7 and 744.8 prohibit exports and reexports of certain items for certain aircraft and vessels. Section 744.9 prohibits U.S. persons from providing technical assistance to certain foreign persons seeking to develop or manufacture certain encryption commodities or software. Section 744.10 prohibits exports and reexports of any item subject to the EAR to Russian entities, included in Supplement No. 4 of this part. Sections 744.12, 744.13 and 744.14 prohibit exports and reexports of any item subject to the EAR to persons designated as Specially Designated Global Terrorists, Specially Designated Terrorists, or Foreign Terrorist Organizations, respectively. Section 744.15 describes restrictions on exports and reexports to persons named in general orders. Section 744.16 prohibits exports and reexports by U.S. persons of items subject to the EAR to persons designated pursuant to Executive Order 13088, as amended by Executive Order 13192, including Slobodan Milosevic, his close associates, and persons determined to be under open indictment by the International Criminal Tribunal for the former Yugoslavia. In addition, these sections include license review standards for export license applications submitted as required by these sections. It should also be noted that part 764 of the EAR prohibits exports, reexports and certain in-country transfers of items subject to the EAR to denied parties.

(2) If controls set forth under more than one section of part 744 apply to a person, the license requirements for such a person will be determined based on the requirements of all applicable sections of part 744, and license applications will be reviewed under all applicable licensing policies.

* * * * *

■ 3. Section 744.12 is added to read as follows:

§ 744.12 Restrictions on exports and reexports to persons designated in or pursuant to Executive Order 13224 (Specially Designated Global Terrorist) (SDGT).

BIS maintains restrictions on exports and reexports to persons designated in or pursuant to Executive Order 13224 of September 23, 2001 (Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism). These persons include individuals and entities listed in the Annex to Executive Order 13224, as well as persons subsequently designated by the Secretary of State or Secretary of the Treasury pursuant to criteria set forth in the Order. Pursuant to Executive Order 13224, the Department of the Treasury's Office of Foreign Assets Control (OFAC) maintains 31 CFR part 594, the Global Terrorism Sanctions Regulations. OFAC announces the names of persons designated pursuant to Executive Order 13224 in the **Federal Register** and includes such persons in Appendix A to 31 CFR Chapter V, which lists persons subject to various sanctions programs administered by OFAC. The Department of State also announces the names of foreign persons designated pursuant to Executive Order 13224 in the **Federal Register**. All persons designated in or pursuant to Executive Order 13224 are identified in Appendix A to 31 CFR Chapter V by the bracketed initials [SDGT] and are also known as Specially Designated Global Terrorists (SDGTs).

(a) *License requirement(s).* (1) A license requirement applies to the export or reexport to an SDGT of any item subject to the EAR.

(2) To avoid duplication, U.S. persons are not required to seek separate authorization for an export or reexport to an SDGT of an item subject to both the EAR and OFAC's regulatory authority pursuant to Executive Order 13224. Therefore, if OFAC authorizes an export from the United States or an export or reexport by a U.S. person to an SDGT, no separate authorization from BIS is necessary.

(3) U.S. persons must seek authorization from BIS for the export or reexport to an SDGT of any item subject to the EAR that is not subject to OFAC's Global Terrorism Sanctions Regulations in 31 CFR part 594.

(4) Non-U.S. persons must seek authorization from BIS for any export from abroad or reexport to an SDGT of any item subject to the EAR.

(5) Any export or reexport to an SDGT of any item subject to both the EAR and OFAC's regulatory authority pursuant to Executive Order 13224 and not authorized by OFAC is a violation of the EAR.

(6) Any export or reexport by a U.S. person to an SDGT of any item subject to the EAR that is not subject to regulation by OFAC and not authorized by BIS is a violation of the EAR. Any export from abroad or reexport by a non-U.S. person to an SDGT of any item subject to the EAR and not authorized by BIS is a violation of the EAR.

(7) These licensing requirements supplement any other requirements set forth elsewhere in the EAR.

(b) *Exceptions.* No License Exceptions or other BIS authorization are available for any export or reexport to an SDGT of any item subject to the EAR.

(c) *Licensing policy.* Applications for licenses for the export or reexport to an SDGT of any item subject to the EAR generally will be denied. You should consult with OFAC concerning transactions subject to OFAC licensing requirements.

(d) *Contract sanctity.* Contract sanctity provisions are not available for license applications reviewed under this section.

Note to § 744.12: This section does not implement, construe, or limit the scope of any criminal statute, including (but not limited to) 18 U.S.C. 2339B(a)(1) and 2339A, and does not excuse any person from complying with any criminal statute, including (but not limited to) 18 U.S.C. 2339B(a)(1) and 18 U.S.C. 2339A.

■ 4. Section 744.13 is revised to read as follows:

§ 744.13 Restrictions on exports and reexports to persons designated pursuant to Executive Order 12947 (Specially Designated Terrorist) (SDT).

Consistent with the purpose of Executive Order 12947 of January 23, 1995, BIS maintains restrictions on exports and reexports to Specially Designated Terrorists (SDTs). Executive Order 12947 prohibits transactions by U.S. persons with terrorists who threaten to disrupt the Middle East peace process. Pursuant to the Executive Order, the Department of the Treasury, Office of Foreign Assets Control

(OFAC), maintains 31 CFR part 595, the Terrorism Sanctions Regulations. In Appendix A to 31 CFR Chapter V, pursuant to 31 CFR part 595, these Specially Designated Terrorists are identified by the bracketed suffix initials [SDT]. The requirements set forth below further the objectives of Executive Order 12947.

(a) *License requirement(s).* (1) A license requirement applies to the export or reexport to an SDT of any item subject to the EAR.

(2) To avoid duplication, U.S. persons are not required to seek separate authorization for an export or reexport to an SDT of an item subject both to the EAR and to OFAC's Terrorism Sanctions Regulations in 31 CFR part 595. Therefore, if OFAC authorizes an export or reexport of an item by a U.S. person to a SDT, no separate authorization from BIS is necessary.

(3) U.S. persons must seek authorization from BIS for the export or reexport to an SDT of an item subject to the EAR but not subject to OFAC's Terrorism Sanctions Regulations in 31 CFR part 595.

(4) Non-U.S. persons must seek authorization from BIS for the export from abroad or reexport to an SDT of any item subject to the EAR.

(5) Any export or reexport to an SDT by a U.S. person of any item subject both to the EAR and OFAC's Terrorism Sanctions Regulations in 31 CFR part 595 and not authorized by OFAC is a violation of the EAR.

(6) Any export or reexport by a U.S. person to an SDT of any item subject to the EAR that is not subject to OFAC's Terrorism Sanctions Regulations in 31 CFR part 595 and not authorized by BIS is a violation of the EAR. Any export from abroad or reexport by a non-U.S. person to an SDT of any item subject to the EAR and not authorized by BIS is a violation of the EAR.

(7) These licensing requirements supplement any other requirements set forth elsewhere in the EAR.

(b) *Exceptions.* No License Exceptions or other BIS authorization are available for export or reexport to an SDT of any item subject to the EAR.

(c) *Licensing policy.* Applications for licenses for the export or reexport to an SDT of any item subject to the EAR generally will be denied. You should consult with OFAC concerning transactions subject to OFAC licensing requirements.

(d) *Contract sanctity.* Contract sanctity provisions are not available for license applications reviewed under this section.

Note to § 744.13: This section does not implement, construe, or limit the scope of any criminal statute, including (but not limited to) 18 U.S.C. 2339B(a)(1) and 2339A, and does not excuse any person from complying with any criminal statute, including (but not limited to) 18 U.S.C. 2339B(a)(1) and 18 U.S.C. 2339A.

■ 5. Section 744.14 is revised to read as follows:

§ 744.14 Restrictions on exports and reexports to designated Foreign Terrorist Organizations (FTOs).

Consistent with the objectives of section 219 of the Immigration and Nationality Act, as amended (INA) (8 U.S.C. 1189), and section 303 of the Antiterrorism and Effective Death Penalty Act 1996, as amended (Anti-Terrorism Act) (18 U.S.C. 2339B) (Public Law 104–132. 110 Stat. 1214–1319), BIS maintains restrictions on exports and reexports to organizations designated as Foreign Terrorist Organizations (FTOs) pursuant to section 219 of the INA. The Department of the Treasury, Office of Foreign Assets Control, maintains 31 CFR part 597, the Foreign Terrorist Organizations Sanctions Regulations, requiring U.S. financial institutions to block all financial transactions involving assets of designated FTOs within the possession or control of such U.S. financial institutions. Section 303 of the Anti-Terrorism Act prohibits persons within the United States or subject to U.S. jurisdiction from knowingly providing material support or resources to a designated FTO and makes violations punishable by criminal penalties under title 18, United States Code. These designated FTOs are listed in Appendix A to 31 CFR Chapter V and identified by the bracketed initials [FTO]. A designation of a foreign organization determined to meet the criteria of section 219 of the INA takes effect upon publication in the **Federal Register** by the Secretary of State, or the Secretary's designee.

(a) *License requirement(s).* (1) A license requirement applies to the export or reexport to an FTO of any item subject to the EAR.

(2) U.S. persons must seek authorization from BIS for the export or reexport to an FTO of any item subject to the EAR.

(3) Non-U.S. persons must seek authorization from BIS for the export from abroad or reexport to an FTO of any item subject to the EAR.

(4) Any export or reexport to an FTO by any person of any item subject to the EAR and not authorized by BIS is a violation of the EAR.

(5) These licensing requirements supplement any other requirements set forth elsewhere in the EAR.

(b) *Exceptions.* No License Exceptions or other BIS authorization for items described by paragraph (a) of this section are available for exports or reexports to FTOs.

(c) *Licensing policy.* Applications for exports and reexports to FTOs of all items identified by paragraph (a) of this section will generally be denied, to the extent they constitute material support or resources, as defined in 18 U.S.C. 2339A(b).

(d) *Contract sanctity.* Contract sanctity provisions are not available for license applications reviewed under this section.

(e) *FTOs also designated as SDTs or SDGTs.* In cases in which an FTO is also an SDT, as described in § 744.13, or an SDGT, as described in § 744.12, the license requirements and licensing policy set forth in § 744.13 or § 744.12 will apply.

Note to § 744.14: This section does not implement, construe, or limit the scope of any criminal statute, including (but not limited to) 18 U.S.C. 2339B(a)(1) and 2339A, and does not excuse any person from complying with any criminal statute, including (but not limited to) 18 U.S.C. 2339B(a)(1) and 18 U.S.C. 2339A.

PART 772—[AMENDED]

■ 6. The authority citation for part 772 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; notice of August 14, 2002, 67 FR 53721, August 16, 2002.

■ 7. Section 772.1 is amended by revising the definition of ''U.S. Person'' to read as follows:

§ 772.1 Definitions of terms as used in the Export Administration Regulations.

* * * * *

U.S. Person. (a) For purposes of §§ 744.6, 744.10, 744.11, 744.12, 744.13 and 744.14 of the EAR, the term U.S. person includes:

(1) Any individual who is a citizen of the United States, a permanent resident alien of the United States, or a protected individual as defined by 8 U.S.C. 1324b(a)(3);

(2) Any juridical person organized under the laws of the United States or any jurisdiction within the United States, including foreign branches; and

(3) Any person in the United States.

(b) *See also* § 740.9 and parts 746 and 760 of the EAR for definitions of ''U.S. person'' that are specific to those parts.

* * * * *

Dated: May 28, 2003.

James J. Jochum,

Assistant Secretary for Export Administration.

[FR Doc. 03–14253 Filed 6–3–03; 8:50 am]

BILLING CODE 3510–33–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 594

Global Terrorism Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Interim final rule.

SUMMARY: The Office of Foreign Assets Control of the U.S. Department of the Treasury is adding new part 594 to chapter V of 31 CFR to carry out the purposes of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism.''

DATES: *Effective Date:* June 6, 2003.

Comments: Written comments must be received no later than August 5, 2003.

ADDRESSES: Comments may be sent either via regular mail to the attention of Chief, Policy Planning and Program Management Division, rm. 2176, Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Ave., NW., Annex—2d Floor, Washington, DC 20220, or via OFAC's Web site (*http://www.treas.gov/ofac*).

FOR FURTHER INFORMATION CONTACT: Chief of Licensing, tel.: 202/622–2480, or Chief Counsel, tel.: 202/622–2410, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document is available as an electronic file on The Federal Bulletin Board the day of publication in the **Federal Register**. By modem, dial 202/512–1387 and type ''/GO FAC,'' or call 202/512–1530 for disk or paper copies. This file is available for downloading without charge in ASCII and Adobe Acrobat7 readable (*.PDF) formats. For Internet access, the address for use with the World Wide Web (home page), Telnet, or FTP protocol is: *fedbbs.access.gpo.gov*. This document and additional information concerning the programs of the Office of Foreign Assets Control are available for downloading from the Office's Internet home page: *http://www.treas.gov/ofac,* or in fax form through the Office's 24-hour fax-on-demand service: call 202/622–0077 using a fax machine, fax modem, or (within the United States) a touch-tone telephone.

Background

On September 23, 2001, the President, invoking the authority, *inter alia,* of the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) (''IEEPA'') and the United Nations Participation Act (22 U.S.C. 287c), issued Executive Order 13224 (66 FR 49079, September 25, 2001), effective at 12:01 a.m. eastern daylight time on September 24, 2001. In the order, the President found that ''grave acts of terrorism and threats of terrorism committed by foreign terrorists, including the terrorist attacks in New York, Pennsylvania, and the Pentagon committed on September 11, 2001 * * * and the continuing and immediate threat of further attacks on United States nationals or the United States'' constituted an unusual and extraordinary threat to the national security, foreign policy and economy of the United States, and declared a national emergency with respect to that threat. The order was amended by Executive Order 13268 (67 FR 44751, July 3, 2001) and Executive Order 13284 (68 FR 4075, January 28, 2003).

These regulations are promulgated to implement Executive Order 13224. They are in addition to and do not take the place of other parts of 31 CFR chapter V relating to terrorism, including, but not limited to, the Terrorism Sanctions Regulations (part 595), implementing Executive Order 12947, ''Prohibiting Transactions With Terrorists Who Threaten To Disrupt the Middle East Peace Process'' (60 FR 5079, January 25, 1995); the Terrorism List Government Sanctions Regulations (part 596), implementing section 321 of the Antiterrorism and Effective Death Penalty Act of 1996 (18 U.S.C. 2332d); and the Foreign Terrorist Organizations Sanctions Regulations (part 597), implementing sections 302 and 303 of the Antiterrorism and Effective Death Penalty Act of 1996 (8 U.S.C. 1189, 18 U.S.C. 2339B). (Detailed information regarding each of those other parts is available on OFAC's Web site (*http://www.treas.gov/ofac*).) Certain persons designated pursuant to the regulations now being promulgated may also be designated pursuant to those other parts, and transactions related to those persons are subject to the requirements of those parts and other sanctions under U.S. law. These new regulations also do not in any way modify the criminal prohibition, set forth at 18 U.S.C. 2339B, against providing material support or resources to foreign terrorist organizations designated pursuant to section 219 of the Immigration and Nationality Act, as amended.

Specifically, these regulations are promulgated in furtherance of the sanctions set forth in Executive Order 13224. Section 1 of the order blocks, with certain exceptions, all property and interests in property of foreign persons listed in an Annex to the order and persons designated by the Secretary of State or the Secretary of the Treasury pursuant to criteria set forth in the order. Section 2 of the order prohibits any transaction or dealing by a United States person or within the United States in property or interests in property blocked pursuant to the order, including but not limited to the making or receiving of any contribution of funds, goods, or services to or for the benefit of a person designated in or pursuant to the order. Section 2 of the order also prohibits any transaction by a United States person or within the United States that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in the order, as well as any conspiracy formed to violate such prohibitions. Section 7 of the order authorizes the Secretary of the Treasury, in consultation with the Secretary of State, the Secretary of Homeland Security and the Attorney General, to take such actions, including the promulgation of rules and regulations, as may be necessary to carry out the purposes of the order. Acting under authority delegated by the Secretary of the Treasury, the Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is promulgating these Global Terrorism Sanctions Regulations, 31 CFR part 594 (the ''Regulations'').

Subpart B of the Regulations sets forth the prohibitions contained in sections 1 and 2 of the order. See §§ 594.201, 594.204, and 594.205. Persons identified in the Annex to the order or designated by or under the authority of the Secretary of State or the Secretary of the Treasury pursuant to the order are referred to throughout the Regulations as ''persons whose property or interests in property are blocked pursuant to § 594.201(a).'' Their names are or will be published on OFAC's website, announced in the **Federal Register** and incorporated on an ongoing basis into appendix A to 31 CFR chapter V, which lists persons subject to various sanctions programs administered by OFAC.

Sections 594.202 and 594.203 of subpart B detail the effect of transfers of

blocked property in violation of the Regulations and the requirement to hold blocked property in interest-bearing blocked accounts. Section 594.206 of subpart B provides that all expenses incident to the maintenance of blocked physical property shall be the responsibility of the owners and operators of such property, and that such expenses shall not be met from blocked funds. The section further provides that blocked property may, in the discretion of the Director of OFAC, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

Subpart C of the Regulations defines key terms used throughout the Regulations, and subpart D sets forth interpretive sections regarding the general prohibitions contained in subpart B. Certain transactions otherwise prohibited under the Regulations but found to be consistent with U.S. policy are authorized by one of the general licenses contained in subpart E or may be authorized by a specific license issued pursuant to the procedures described in subpart D of part 501 of 31 CFR chapter V.

Subpart F of the Regulations refers to subpart C of part 501 for applicable recordkeeping and reporting requirements. Subpart G of the Regulations describes the civil and criminal penalties applicable to violations of the Regulations, as well as the procedures governing the potential imposition of a civil monetary penalty.

Subpart H of the Regulations refers to subpart D of part 501 for applicable provisions relating to administrative procedures. Subpart I of the Regulations sets forth a Paperwork Reduction Act notice.

Request for Comments; Procedural Requirements

Because the Regulations involve a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) (the ''APA'') requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. However, because of the importance of the issues addressed in these regulations, this rule is being issued in interim form and comments will be considered in the development of final regulations. Accordingly, the Department encourages interested persons who wish to comment to do so at the earliest possible time to permit the fullest consideration of their views. Comments may address the impact of the Regulations on the submitter's activities, whether of a commercial, non-commercial or humanitarian nature, as well as changes that would improve the clarity and organization of the Regulations.

The period for submission of comments will close August 5, 2003. The Department will consider all comments received before the close of the comment period in developing final regulations. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept public comments accompanied by a request that a part or all of the submission be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such submission to the originator without considering them in the development of final regulations. In the interest of accuracy and completeness, the Department requires comments in written form.

All public comments on these Regulations will be a matter of public record. Copies of the public record concerning these Regulations will be made available not sooner than September 4, 2003, and will be obtainable from OFAC's Web site (*http://www.treas.gov/ofac*). If that service is unavailable, written requests for copies may be sent to: Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Ave., NW., Washington, DC 20220, Attn: Chief, Records Division.

Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the ''Reporting and Procedures Regulations''). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been previously approved by the Office of Management and Budget under control number 1505–0164. 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.

List of Subjects in 31 CFR Part 594

Administrative practice and procedure, Banks, Banking, Blocking of assets, Penalties, Reporting and recordkeeping requirements, Specially designated global terrorist, Terrorism, Transfer of assets.

■ 1. For the reasons set forth in the preamble, part 594 is added to 31 CFR chapter V to read as follows:

PART 594—GLOBAL TERRORISM SANCTIONS REGULATIONS

Subpart A—Relation of This Part to Other Laws and Regulations

Sec.

Subpart B—Prohibitions

Subpart C—General Definitions

Subpart D—Interpretations

Subpart E—Licenses, Authorizations and Statements of Licensing Policy

Authority: 3 U.S.C. 301; 22 U.S.C. 287c; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; E.O. 13224, 66 FR 49079, September 25, 2001; E.O. 13268, 67 FR 44751, July 3, 2002, 3 CFR, 2002 Comp., p. 240; E.O. 13284, 64 FR 4075, January 28, 2003.

Subpart A—Relation of This Part to Other Laws and Regulations

§ 594.101 Relation of this part to other laws and regulations.

This part is separate from, and independent of, the other parts of this chapter, with the exception of part 501 of this chapter, the recordkeeping and reporting requirements and license application and other procedures of which apply to this part. Actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. Differing foreign policy and national security circumstances may result in differing interpretations of similar language among the parts of this chapter. No license or authorization contained in or issued pursuant to those other parts authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to any other provision of law or regulation authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to this part relieves the involved parties from complying with any other applicable laws or regulations.

Subpart B—Prohibitions

§ 594.201 Prohibited transactions involving blocked property.

(a) Except as authorized by statutes, regulations, orders, directives, rulings, instructions, licenses or otherwise, and notwithstanding any contracts entered into or any license or permit granted prior to the effective date, property and interests in property of the following persons that are in the United States, that hereafter come within the United States, or that hereafter come within the possession or control of U.S. persons, including their overseas branches, are blocked and may not be transferred, paid, exported, withdrawn or otherwise dealt in:

(1) Foreign persons listed in the Annex to Executive Order 13224 of September 23, 2001, as may be amended;

(2) Foreign persons determined by the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of Homeland Security and the Attorney General, to have committed, or to pose a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States;

(3) Persons determined by the Secretary of the Treasury, in consultation with the Secretary of State, the Secretary of Homeland Security and the Attorney General, to be owned or controlled by, or to act for or on behalf of, any person whose property or interests in property are blocked pursuant to paragraphs (a)(1), (a)(2), (a)(3), or (a)(4)(i) of this section; or

(4) Except as provided in section 5 of Executive Order 13224, any person determined by the Secretary of the Treasury, in consultation with the Secretary of State, the Secretary of Homeland Security and the Attorney General:

(i) To assist in, sponsor, or provide financial, material, or technological support for, or financial or other services to or in support of:

(A) Acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States, or

(B) Any person whose property or interests in property are blocked pursuant to paragraph (a) of this section; or

(ii) To be otherwise associated with any person whose property or interests in property are blocked pursuant to paragraphs (a)(1), (a)(2), (a)(3), or (a)(4)(i) of this section.

Note 1 to paragraph (a). Section 5 of Executive Order 13224, as amended, provides that, with respect to those persons designated pursuant to paragraph (a)(4) of this section, the Secretary of the Treasury, in the exercise of his discretion and in consultation with the Secretary of State, the Secretary of Homeland Security and the Attorney General, may take such other actions than the complete blocking of property or interests in property as the President is authorized to take under the International Emergency Economic Powers Act and the United Nations Participation Act if the Secretary of the Treasury, in consultation with the Secretary of State, the Secretary of Homeland Security and the Attorney General, deems such other actions to be consistent with the national interests of the United States, considering such factors as he deems appropriate.

Note 2 to paragraph (a). The names of persons whose property or interests in property are blocked pursuant to § 594.201(a) are published on OFAC's website, announced in the **Federal Register** and incorporated on an ongoing basis with the identifier [SDGT] in appendix A to 31 CFR chapter V.

Note 3 to paragraph (a). Section 501.807 of this chapter V sets forth the procedures to be followed by persons seeking administrative reconsideration of their designation pursuant to § 594.201(a)(2), (a)(3), or (a)(4) or who wish to assert that the circumstances resulting in designation no longer apply. Similarly, when a transaction results in the blocking of funds at a financial institution pursuant to this section and a party to the transaction believes the funds to have been blocked due to mistaken identity, that party may seek to have such funds unblocked pursuant to the administrative procedures set forth in § 501.806 of this chapter.

(b) Unless otherwise authorized by this part or by a specific license expressly referring to this section, any dealing in any security (or evidence thereof) held within the possession or control of a U.S. person and either registered or inscribed in the name of or known to be held for the benefit of any person whose property or interests in property are blocked pursuant to § 594.201(a) is prohibited. This prohibition includes but is not limited to the transfer (including the transfer on the books of any issuer or agent thereof), disposition, transportation, importation, exportation, or withdrawal of any such security or the endorsement or guaranty of signatures on any such security. This prohibition applies irrespective of the fact that at any time (whether prior to, on, or subsequent to the effective date) the registered or inscribed owner of any such security may have or might appear to have assigned, transferred, or otherwise disposed of the security.

Note 1 to § 594.201. Section 106 of the USA PATRIOT Act of 2001 (Pub. L. 107–56, Oct. 26, 2001) amended section 203 of the International Emergency Economic Powers Act (50 U.S.C. 1702) to authorize explicitly the blocking of property and interests in property of a person or entity during the pendency of an investigation. The name of any person or entity whose property or interests in property are blocked pursuant to this authority appears on the Office of

Foreign Assets Control's (OFAC) blocked persons list with the descriptor ''[BPI–PA].'' The scope of the property or interests in property blocked during the pendency of an investigation may be more limited than the scope of the blocking set forth in § 594.201(a). Inquiries regarding the scope of any such blocking should be directed to OFAC's Compliance Division at 202/622–2490.

Note 2 to § 594.201. The prohibitions set forth in this part are separate from and in addition to other parts of 31 CFR chapter V, including but not limited to the Terrorism Sanctions Regulations (part 595), the Terrorism List Government Sanctions Regulations (part 596), and the Foreign Terrorist Organizations Sanctions Regulations (part 597). The prohibitions set forth in this part also are separate and apart from the criminal prohibition, set forth at 18 U.S.C. 2339B, against providing material support or resources to foreign terrorist organizations designated pursuant to section 219 of the Immigration and Nationality Act, as amended.

§ 594.202 Effect of transfers violating the provisions of this part.

(a) Any transfer after the effective date that is in violation of any provision of this part or of any regulation, order, directive, ruling, instruction, or license issued pursuant to this part, and that involves any property or interest in property blocked pursuant to § 594.201(a), is null and void and shall not be the basis for the assertion or recognition of any interest in or right, remedy, power, or privilege with respect to such property or property interests.

(b) No transfer before the effective date shall be the basis for the assertion or recognition of any right, remedy, power, or privilege with respect to, or any interest in, any property or interest in property blocked pursuant to § 594.201(a), unless the person with whom such property is held or maintained, prior to that date, had written notice of the transfer or by any written evidence had recognized such transfer.

(c) Unless otherwise provided, an appropriate license or other authorization issued by or pursuant to the direction or authorization of the Director of the Office of Foreign Assets Control before, during, or after a transfer shall validate such transfer or make it enforceable to the same extent that it would be valid or enforceable but for the provisions of the International Emergency Economic Powers Act, this part, and any regulation, order, directive, ruling, instruction, or license issued pursuant to this part.

(d) Transfers of property that otherwise would be null and void or unenforceable by virtue of the provisions of this section shall not be deemed to be null and void or unenforceable as to any person with whom such property was held or maintained (and as to such person only) in cases in which such person is able to establish to the satisfaction of the Director of the Office of Foreign Assets Control each of the following:

(1) Such transfer did not represent a willful violation of the provisions of this part by the person with whom such property was held or maintained;

(2) The person with whom such property was held or maintained did not have reasonable cause to know or suspect, in view of all the facts and circumstances known or available to such person, that such transfer required a license or authorization issued pursuant to this part and was not so licensed or authorized, or, if a license or authorization did purport to cover the transfer, that such license or authorization had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained; and

(3) The person with whom such property was held or maintained filed with the Office of Foreign Assets Control a report setting forth in full the circumstances relating to such transfer promptly upon discovery that:

(i) Such transfer was in violation of the provisions of this part or any regulation, ruling, instruction, license, or other direction or authorization issued pursuant to this part;

(ii) Such transfer was not licensed or authorized by the Director of the Office of Foreign Assets Control; or

(iii) If a license did purport to cover the transfer, such license had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained.

Note to paragraph (d). The filing of a report in accordance with the provisions of paragraph (d)(3) of this section shall not be deemed evidence that the terms of paragraphs (d)(1) and (d)(2) of this section have been satisfied.

(e) Except to the extent otherwise provided by law or unless licensed pursuant to this part, any attachment, judgment, decree, lien, execution, garnishment, or other judicial process is null and void with respect to any property in which on or since the effective date there existed an interest of a person whose property or interests in property are blocked pursuant to § 594.201(a).

§ 594.203 Holding of funds in interest-bearing accounts; investment and reinvestment.

(a) Except as provided in paragraph (c) or (d) of this section, or as otherwise directed by the Office of Foreign Assets Control, any U.S. person holding funds, such as currency, bank deposits, or liquidated financial obligations, subject to § 594.201(a) shall hold or place such funds in a blocked interest-bearing account located in the United States.

(b)(1) For purposes of this section, the term *blocked interest-bearing account* means a blocked account:

(i) In a federally-insured U.S. bank, thrift institution, or credit union, provided the funds are earning interest at rates that are commercially reasonable; or

(ii) With a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934, provided the funds are invested in a money market fund or in U.S. Treasury bills.

(2) For purposes of this section, a rate is commercially reasonable if it is the rate currently offered to other depositors on deposits or instruments of comparable size and maturity.

(3) Funds held or placed in a blocked account pursuant to this paragraph (b) may not be invested in instruments the maturity of which exceeds 180 days. If interest is credited to a separate blocked account or subaccount, the name of the account party on each account must be the same.

(c) Blocked funds held in instruments the maturity of which exceeds 180 days at the time the funds become subject to § 594.201(a) may continue to be held until maturity in the original instrument, provided any interest, earnings, or other proceeds derived therefrom are paid into a blocked interest-bearing account in accordance with paragraph (b) or (d) of this section.

(d) Blocked funds held in accounts or instruments outside the United States at the time the funds become subject to § 594.201(a) may continue to be held in the same type of accounts or instruments, provided the funds earn interest at rates that are commercially reasonable.

(e) This section does not create an affirmative obligation for the holder of blocked tangible property, such as chattels or real estate, or of other blocked property, such as debt or equity securities, to sell or liquidate such property at the time the property becomes subject to § 594.201(a). However, the Office of Foreign Assets Control may issue licenses permitting or directing such sales or liquidation in appropriate cases.

(f) Funds subject to this section may not be held, invested, or reinvested in a manner that provides immediate financial or economic benefit or access to any person whose property or interests in property are blocked pursuant to § 594.201(a), nor may their holder cooperate in or facilitate the pledging or other attempted use as collateral of blocked funds or other assets.

§ 594.204 Prohibited transaction or dealing in property; contributions of funds, goods, or services.

Except as otherwise authorized, no U.S. person may engage in any transaction or dealing in property or interests in property of persons whose property or interests in property are blocked pursuant to § 594.201(a), including but not limited to the making or receiving of any contribution of funds, goods, or services to or for the benefit of persons whose property or interests in property are blocked pursuant to § 594.201(a).

§ 594.205 Evasions; attempts; conspiracies.

(a) Except as otherwise authorized, and notwithstanding any contract entered into or any license or permit granted prior to the effective date, any transaction by any U.S. person or within the United States on or after the effective date that evades or avoids, has the purpose of evading or avoiding, or attempts to violate any of the prohibitions set forth in this part is prohibited.

(b) Except as otherwise authorized, and notwithstanding any contract entered into or any license or permit granted prior to the effective date, any conspiracy formed for the purpose of engaging in a transaction prohibited by this part is prohibited.

§ 594.206 Expenses of maintaining blocked property; liquidation of blocked property.

(a) Except as otherwise authorized, and notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or contract entered into or any license or permit granted before the effective date, all expenses incident to the maintenance of physical property blocked pursuant to § 594.201(a) shall be the responsibility of the owners or operators of such property, which expenses shall not be met from blocked funds.

(b) Property blocked pursuant to § 594.201(a) may, in the discretion of the Director, Office of Foreign Assets Control, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

Subpart C—General Definitions

§ 594.301 Blocked account; blocked property.

The terms *blocked account* and *blocked property* shall mean any account or property subject to the prohibition in § 594.201 held in the name of a person whose property or interests in property are blocked pursuant to § 594.201(a), or in which such person has an interest, and with respect to which payments, transfers, exportations, withdrawals, or other dealings may not be made or effected except pursuant to an authorization or license from the Office of Foreign Assets Control expressly authorizing such action.

§ 594.302 Effective date.

The term *effective date* refers to the effective date of the applicable prohibitions and directives contained in this part as follows:

(a) With respect to a person whose property or interests in property are blocked pursuant to § 594.201(a)(1), 12:01 a.m. eastern daylight time, September 24, 2001;

(b) With respect to a person whose property or interests in property are blocked pursuant to § 594.201(a)(2), (a)(3), or (a)(4), the earlier of the date on which is received actual or constructive notice of such person's designation by the Secretary of State or the Secretary of the Treasury.

§ 594.303 Entity.

The term *entity* means a partnership, association, corporation, or other organization, group, or subgroup.

§ 594.304 Foreign person.

The term *foreign person* means any citizen or national of a foreign state (including any such individual who is also a citizen or national of the United States), or any entity not organized solely under the laws of the United States or existing solely in the United States, but does not include a foreign state.

§ 594.305 Information or informational materials.

(a) For purposes of this part, the term *information or informational materials* includes, but is not limited to, publications, films, posters, phonograph records, photographs, microfilms, microfiche, tapes, compact disks, CD ROMs, artworks, and news wire feeds.

Note to paragraph (a). To be considered information or informational materials, artworks must be classified under chapter heading 9701, 9702, or 9703 of the Harmonized Tariff Schedule of the United States.

(b) The term *information or informational materials,* with respect to United States exports, does not include items:

(1) That were, as of April 30, 1994, or that thereafter became, controlled for export pursuant to section 5 of the Export Administration Act of 1979, 50 U.S.C. App. 2401–2420 (1979) (the ''EAA''), or section 6 of the EAA to the extent that such controls promote the nonproliferation or antiterrorism policies of the United States; or

(2) With respect to which acts are prohibited by 18 U.S.C. chapter 37.

§ 594.306 Interest.

Except as otherwise provided in this part, the term *interest* when used with respect to property (*e.g.,* ''an interest in property'') means an interest of any nature whatsoever, direct or indirect.

§ 594.307 Licenses; general and specific.

(a) Except as otherwise specified, the term *license* means any license or authorization contained in or issued pursuant to this part.

(b) The term *general license* means any license or authorization the terms of which are set forth in subpart E of this part.

(c) The term *specific license* means any license or authorization not set forth in subpart E of this part but issued pursuant to this part.

Note to § 594.307. *See* § 501.801 of this chapter on licensing procedures.

§ 594.308 Person.

The term *person* means an individual or entity.

§ 594.309 Property; property interest.

The terms *property* and *property interest* include, but are not limited to, money, checks, drafts, bullion, bank deposits, savings accounts, debts, indebtedness, obligations, notes, guarantees, debentures, stocks, bonds, coupons, any other financial instruments, bankers acceptances, mortgages, pledges, liens or other rights in the nature of security, warehouse receipts, bills of lading, trust receipts, bills of sale, any other evidences of title, ownership or indebtedness, letters of credit and any documents relating to any rights or obligations thereunder, powers of attorney, goods, wares, merchandise, chattels, stocks on hand, ships, goods on ships, real estate mortgages, deeds of trust, vendors' sales agreements, land contracts, leaseholds, ground rents, real estate and any other interest therein, options, negotiable

instruments, trade acceptances, royalties, book accounts, accounts payable, judgments, patents, trademarks or copyrights, insurance policies, safe deposit boxes and their contents, annuities, pooling agreements, services of any nature whatsoever, contracts of any nature whatsoever, and any other property, real, personal, or mixed, tangible or intangible, or interest or interests therein, present, future or contingent.

§ 594.310 Specially designated global terrorist; SDGT.

The term *specially designated global terrorist* or *SDGT* means any foreign person or person listed in the Annex or designated pursuant to Executive Order 13224 of September 23, 2001.

§ 594.311 Terrorism.

The term *terrorism* means an activity that:

(a) Involves a violent act or an act dangerous to human life, property, or infrastructure; and

(b) Appears to be intended:

(1) To intimidate or coerce a civilian population;

(2) To influence the policy of a government by intimidation or coercion; or

(3) To affect the conduct of a government by mass destruction, assassination, kidnapping, or hostage-taking.

§ 594.312 Transfer.

The term *transfer* means any actual or purported act or transaction, whether or not evidenced by writing, and whether or not done or performed within the United States, the purpose, intent, or effect of which is to create, surrender, release, convey, transfer, or alter, directly or indirectly, any right, remedy, power, privilege, or interest with respect to any property and, without limitation upon the foregoing, shall include the making, execution, or delivery of any assignment, power, conveyance, check, declaration, deed, deed of trust, power of attorney, power of appointment, bill of sale, mortgage, receipt, agreement, contract, certificate, gift, sale, affidavit, or statement; the making of any payment; the setting off of any obligation or credit; the appointment of any agent, trustee, or fiduciary; the creation or transfer of any lien; the issuance, docketing, filing, or levy of or under any judgment, decree, attachment, injunction, execution, or other judicial or administrative process or order, or the service of any garnishment; the acquisition of any interest of any nature whatsoever by reason of a judgment or decree of any foreign country; the fulfillment of any condition; the exercise of any power of appointment, power of attorney, or other power; or the acquisition, disposition, transportation, importation, exportation, or withdrawal of any security.

§ 594.313 United States.

The term *United States* means the United States, its territories and possessions, and all areas under the jurisdiction or authority thereof.

§ 594.314 U.S. financial institution.

The term *U.S. financial institution* means any U.S. person (including its foreign branches) that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, or purchasing or selling foreign exchange, securities, commodity futures or options, or procuring purchasers and sellers thereof, as principal or agent; including but not limited to, depository institutions, banks, savings banks, trust companies, securities brokers and dealers, commodity futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, and U.S. holding companies, U.S. affiliates, or U.S. subsidiaries of any of the foregoing. This term includes those branches, offices and agencies of foreign financial institutions that are located in the United States, but not such institutions' foreign branches, offices, or agencies.

§ 594.315 United States person; U.S. person.

The term *United States person* or *U.S. person* means any United States citizen, permanent resident alien, entity organized under the laws of the United States (including foreign branches), or any person in the United States.

Subpart D—Interpretations

§ 594.401 Reference to amended sections.

Except as otherwise specified, reference to any provision in or appendix to this part or chapter or to any regulation, ruling, order, instruction, direction, or license issued pursuant to this part refers to the same as currently amended.

§ 594.402 Effect of amendment.

Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part or chapter or of any order, regulation, ruling, instruction, or license issued by or under the direction of the Director of the Office of Foreign Assets Control does not affect any act done or omitted, or any civil or criminal suit or proceeding commenced or pending prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such order, regulation, ruling, instruction, or license continue and may be enforced as if such amendment, modification, or revocation had not been made.

§ 594.403 Setoffs prohibited.

A setoff against blocked property (including a blocked account), whether by a U.S. bank or other U.S. person, is a prohibited transfer under §§ 594.201 and 594.204 if effected after the effective date.

§ 594.404 Termination and acquisition of an interest in blocked property.

(a) Whenever a transaction licensed or authorized by or pursuant to this part results in the transfer of property (including any property interest) away from a person, such property shall no longer be deemed to be property blocked pursuant to § 594.201(a), unless there exists in the property another interest that is blocked pursuant to § 594.201(a) or any other part of this chapter, the transfer of which has not been effected pursuant to license or other authorization.

(b) Unless otherwise specifically provided in a license or authorization issued pursuant to this part, if property (including any property interest) is transferred or attempted to be transferred to a person whose property or interests in property are blocked pursuant to § 594.201(a), such property shall be deemed to be property in which that person has an interest and therefore blocked.

§ 594.405 Transactions incidental to a licensed transaction.

Any transaction ordinarily incident to a licensed transaction and necessary to give effect thereto is also authorized, except:

(a) An incidental transaction, not explicitly authorized within the terms of the license, by or with a person whose property or interests in property are blocked pursuant to § 594.201(a); or

(b) An incidental transaction, not explicitly authorized within the terms of the license, involving a debit to a blocked account or a transfer of blocked property.

§ 594.406 Provision of services.

(a) Except as provided in § 594.207, the prohibitions on transactions or dealings involving blocked property contained in §§ 594.201 and 594.204

apply to services performed in the United States or by U.S. persons, wherever located, including by an overseas branch of an entity located in the United States:

(1) On behalf of or for the benefit of a person whose property or interests in property are blocked pursuant to § 594.201(a); or

(2) With respect to property interests subject to §§ 594.201 and 594.204.

(b) Example: U.S. persons may not, except as authorized by or pursuant to this part, provide legal, accounting, financial, brokering, freight forwarding, transportation, public relations, educational, or other services to a person whose property or interests in property are blocked pursuant to § 594.201(a).

Note to § 594.406. *See* §§ 594.506 and 594.507, respectively, on licensing policy with regard to the provision of certain legal or medical services.

§ 594.407 Offshore transactions.

The prohibitions in §§ 594.201 and 594.204 on transactions or dealings involving blocked property apply to transactions or dealings by any U.S. person in a location outside the United States with respect to property that the U.S. person knows, or has reason to know, is held in the name of a person whose property or interests in property are blocked pursuant to § 594.201(a) or in which the U.S. person knows, or has reason to know, a person whose property or interests in property are blocked pursuant to § 594.201(a) has or has had an interest since the effective date.

§ 594.408 Payments from blocked accounts to satisfy obligations prohibited.

Pursuant to §§ 594.201 and 594.204, no debits may be made to a blocked account to pay obligations to U.S. persons or other persons, except as authorized pursuant to this part.

§ 594.409 Charitable contributions.

Unless otherwise specifically authorized by the Office of Foreign Assets Control by or pursuant to this part, no charitable contribution or donation of funds, goods, services, or technology, including those to relieve human suffering, such as food, clothing, or medicine, may be made to or for the benefit of a person whose property or interests in property are blocked pursuant to § 594.201(a). For purposes of this part, a contribution or donation is made to or for the benefit of a person whose property or interests in property are blocked pursuant to § 594.201(a) if made to or in the name of such a person; if made to or in the name of an entity or individual acting for or on behalf of, or owned or controlled by, such a person; or if made in an attempt to violate, to evade or to avoid the bar on the provision of contributions or donations to such a person.

§ 594.410 Credit extended and cards issued by U.S. financial institutions.

The prohibitions in §§ 594.201 and 594.204 on engaging in transactions or dealings in property subject to those sections prohibits U.S. financial institutions from performing under any existing credit agreements, including, but not limited to, charge cards, debit cards, or other credit facilities issued by a U.S. financial institution to a person whose property or interests in property are blocked pursuant to § 594.201(a).

Subpart E—Licenses, Authorizations and Statements of Licensing Policy

§ 594.501 General and specific licensing procedures.

For provisions relating to licensing procedures, see part 501, subpart D, of this chapter. Licensing actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part.

§ 594.502 Effect of license or authorization.

(a) No license or other authorization contained in this part, or otherwise issued by or under the direction of the Director of the Office of Foreign Assets Control, authorizes or validates any transaction effected prior to the issuance of the license, unless specifically provided in such license or authorization.

(b) No regulation, ruling, instruction, or license authorizes any transaction prohibited under this part unless the regulation, ruling, instruction or license is issued by the Office of Foreign Assets Control and specifically refers to this part. No regulation, ruling, instruction, or license referring to this part shall be deemed to authorize any transaction prohibited by any provision of this chapter unless the regulation, ruling, instruction, or license specifically refers to such provision.

(c) Any regulation, ruling, instruction, or license authorizing any transaction otherwise prohibited under this part has the effect of removing a prohibition contained in this part from the transaction, but only to the extent specifically stated by its terms. Unless the regulation, ruling, instruction, or license otherwise specifies, such an authorization does not create any right, duty, obligation, claim, or interest in, or with respect to, any property which would not otherwise exist under ordinary principles of law.

§ 594.503 Exclusion from licenses and other authorizations.

The Director of the Office of Foreign Assets Control reserves the right to exclude any person, property, or transaction from the operation of any license or from the privileges conferred by any license. The Director of the Office of Foreign Assets Control also reserves the right to restrict the applicability of any license to particular persons, property, transactions, or classes thereof. Such actions are binding upon all persons receiving actual or constructive notice of the exclusions or restrictions.

§ 594.504 Payments and transfers to blocked accounts in U.S. financial institutions.

Any payment of funds or transfer of credit in which a person whose property or interests in property are blocked pursuant to § 594.201(a) has any interest, that comes within the possession or control of a U.S. financial institution, must be blocked in an account on the books of that financial institution. A transfer of funds or credit by a U.S. financial institution between blocked accounts in its branches or offices is authorized, provided that no transfer is made from an account within the United States to an account held outside the United States, and further provided that a transfer from a blocked account may only be made to another blocked account held in the same name.

Note to § 594.504. Please refer to § 501.603 of this chapter for mandatory reporting requirements regarding financial transfers. *See also* § 594.203 concerning the obligation to hold blocked funds in interest-bearing accounts.

§ 594.505 Entries in certain accounts for normal service charges authorized.

(a) A U.S. financial institution is authorized to debit any blocked account held at that financial institution in payment or reimbursement for normal service charges owed it by the owner of that blocked account.

(b) As used in this section, the term *normal service charge* shall include charges in payment or reimbursement for interest due; cable, telegraph, internet, or telephone charges; postage costs; custody fees; small adjustment charges to correct bookkeeping errors; and, but not by way of limitation, minimum balance charges, notary and protest fees, and charges for reference books, photocopies, credit reports, transcripts of statements, registered mail, insurance, stationery and supplies, and other similar items.

§ 594.506 Provision of certain legal services authorized.

(a) The provision of the following legal services to or on behalf of persons whose property or interests in property are blocked pursuant to § 594.201(a) is authorized, provided that all receipts of payment of professional fees and reimbursement of incurred expenses must be specifically licensed:

(1) Provision of legal advice and counseling on the requirements of and compliance with the laws of any jurisdiction within the United States, provided that such advice and counseling are not provided to facilitate transactions in violation of this part;

(2) Representation of persons when named as defendants in or otherwise made parties to domestic U.S. legal, arbitration, or administrative proceedings;

(3) Initiation and conduct of domestic U.S. legal, arbitration, or administrative proceedings in defense of property interests subject to U.S. jurisdiction;

(4) Representation of persons before any federal or state agency with respect to the imposition, administration, or enforcement of U.S. sanctions against such persons; and

(5) Provision of legal services in any other context in which prevailing U.S. law requires access to legal counsel at public expense.

(b) The provision of any other legal services to persons whose property or interests in property are blocked pursuant to § 594.201(a), not otherwise authorized in this part, requires the issuance of a specific license.

(c) Entry into a settlement agreement affecting property or interests in property or the enforcement of any lien, judgment, arbitral award, decree, or other order through execution, garnishment, or other judicial process purporting to transfer or otherwise alter or affect property or interests in property blocked pursuant to § 594.201(a) is prohibited except to the extent otherwise provided by law or unless specifically licensed in accordance with § 594.202(e).

§ 594.507 Authorization of emergency medical services.

The provision of nonscheduled emergency medical services in the United States to persons whose property or interests in property are blocked pursuant to § 594.201(a) is authorized, provided that all receipt of payment for such services must be specifically licensed.

§ 594.508 Transactions related to telecommunications authorized.

All transactions ordinarily incident to the receipt or transmission of telecommunications involving persons whose property or interests in property are blocked pursuant to § 594.201(a) are authorized, provided that any payment owed to any such person is paid into a blocked account in a U.S. financial institution. This section does not authorize the provision, sale, or lease to persons whose property or interests in property are blocked pursuant to § 594.201(a) of telecommunications equipment or technology; nor does it authorize the provision, sale, or leasing of capacity on telecommunications transmission facilities (such as satellite or terrestrial network connectivity).

§ 594.509 Transactions related to mail authorized.

All transactions by U.S. persons, including payment and transfers to common carriers, incident to the receipt or transmission of mail between a U.S. person and a person whose property or interests in property are blocked pursuant to § 594.201(a) are authorized, provided the mail is limited to personal communications not involving a transfer of anything of value and not exceeding 12 ounces in weight.

Subpart F—Reports

§ 594.601 Records and reports.

For provisions relating to required records and reports, *see* part 501, subpart C, of this chapter. Recordkeeping and reporting requirements imposed by part 501 of this chapter with respect to the prohibitions contained in this part are considered requirements arising pursuant to this part.

Subpart G—Penalties

§ 594.701 Penalties.

(a) Attention is directed to section 206 of the International Emergency Economic Powers Act (the ''Act'') (50 U.S.C. 1705), which is applicable to violations of the provisions of any license, ruling, regulation, order, direction, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the Act. Section 206 of the Act, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, as amended, 28 U.S.C. 2461 note), provides that:

(1) A civil penalty not to exceed $11,000 per violation may be imposed on any person who violates or attempts to violate any license, order, or regulation issued under the Act;

(2) Whoever willfully violates or willfully attempts to violate any license, order, or regulation issued under the Act, upon conviction, shall be fined not more than $50,000, and if a natural person, may also be imprisoned for not more than 10 years; and any officer, director, or agent of any corporation who knowingly participates in such violation may be punished by a like fine, imprisonment, or both.

(b) The criminal penalties provided in the Act are subject to increase pursuant to 18 U.S.C. 3571.

(c) Attention is directed to section 5 of the United Nations Participation Act (22 U.S.C. 287c(b)), which provides that any person who willfully violates or evades or attempts to violate or evade any order, rule, or regulation issued by the President pursuant to the authority granted in that section, upon conviction, shall be fined not more than $10,000 and, if a natural person, may also be imprisoned for not more than 10 years; and the officer, director, or agent of any corporation who knowingly participates in such violation or evasion shall be punished by a like fine, imprisonment, or both and any property, funds, securities, papers, or other articles or documents, or any vessel, together with her tackle, apparel, furniture, and equipment, or vehicle, or aircraft, concerned in such violation shall be forfeited to the United States. The criminal penalties provided in the United Nations Participation Act are subject to increase pursuant to 18 U.S.C. 3571.

(d) Attention is also directed to 18 U.S.C. 1001, which provides that whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device, a material fact, or makes any materially false, fictitious, or fraudulent statement or representation or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry shall be fined under title 18, United States Code, or imprisoned not more than five years, or both.

(e) Violations of this part may also be subject to relevant provisions of other applicable laws.

§ 594.702 Prepenalty notice.

(a) *When required.* If the Director of the Office of Foreign Assets Control has reasonable cause to believe that there has occurred a violation of any provision of this part or a violation of the provisions of any license, ruling, regulation, order, direction, or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to

this part or otherwise under the International Emergency Economic Powers Act, and the Director determines that further proceedings are warranted, the Director shall notify the alleged violator of the agency's intent to impose a monetary penalty by issuing a prepenalty notice. The prepenalty notice shall be in writing. The prepenalty notice may be issued whether or not another agency has taken any action with respect to the matter.

(b) *Contents of notice*—(1) *Facts of violation.* The prepenalty notice shall describe the violation, specify the laws and regulations allegedly violated, and state the amount of the proposed monetary penalty.

(2) *Right to respond.* The prepenalty notice also shall inform the respondent of the respondent's right to make a written presentation within the applicable 30-day period set forth in § 594.703 as to why a monetary penalty should not be imposed or why, if imposed, the monetary penalty should be in a lesser amount than proposed.

(c) *Informal settlement prior to issuance of prepenalty notice.* At any time prior to the issuance of a prepenalty notice, an alleged violator may request in writing that, for a period not to exceed sixty (60) days, the agency withhold issuance of the prepenalty notice for the exclusive purpose of effecting settlement of the agency's potential civil monetary penalty claims. In the event the Director grants the request, under terms and conditions within his discretion, the Office of Foreign Assets Control will agree to withhold issuance of the prepenalty notice for a period not to exceed 60 days and will enter into settlement negotiations of the potential civil monetary penalty claim.

§ 594.703 Response to prepenalty notice; informal settlement.

(a) *Deadline for response.* The respondent may submit a response to the prepenalty notice within the applicable 30-day period set forth in this paragraph. The Director may grant, at his discretion, an extension of time in which to submit a response to the prepenalty notice. The failure to submit a response within the applicable time period set forth in this paragraph shall be deemed to be a waiver of the right to respond.

(1) *Computation of time for response.* A response to the prepenalty notice must be postmarked or date-stamped by the U.S. Postal Service (or foreign postal service, if mailed abroad) or courier service provider (if transmitted to OFAC by courier) on or before the 30th day after the postmark date on the envelope in which the prepenalty notice was mailed. If the respondent refused delivery or otherwise avoided receipt of the prepenalty notice, a response must be postmarked or date-stamped on or before the 30th day after the date on the stamped postal receipt maintained at the Office of Foreign Assets Control. If the prepenalty notice was personally delivered to the respondent by a non-U.S. Postal Service agent authorized by the Director, a response must be postmarked or date-stamped on or before the 30th day after the date of delivery.

(2) *Extensions of time for response.* If a due date falls on a federal holiday or weekend, that due date is extended to include the following business day. Any other extensions of time will be granted, at the Director's discretion, only upon the respondent's specific request to the Office of Foreign Assets Control.

(b) *Form and method of response.* The response must be submitted in writing and may be handwritten or typed. The response need not be in any particular form. A copy of the written response may be sent by facsimile, but the original also must be sent to the Office of Foreign Assets Control Civil Penalties Division by mail or courier and must be postmarked or date-stamped, in accordance with paragraph (a) of this section.

(c) *Contents of response.* A written response must contain information sufficient to indicate that it is in response to the prepenalty notice.

(1) A written response must include the respondent's full name, address, telephone number, and facsimile number, if available, or those of the representative of the respondent.

(2) A written response should either admit or deny each specific violation alleged in the prepenalty notice and also state if the respondent has no knowledge of a particular violation. If the written response fails to address any specific violation alleged in the prepenalty notice, that alleged violation shall be deemed to be admitted.

(3) A written response should include any information in defense, evidence in support of an asserted defense, or other factors that the respondent requests the Office of Foreign Assets Control to consider. Any defense or explanation previously made to the Office of Foreign Assets Control or any other agency must be repeated in the written response. Any defense not raised in the written response will be considered waived. The written response also should set forth the reasons why the respondent believes the penalty should not be imposed or why, if imposed, it should be in a lesser amount than proposed.

(d) *Default.* If the respondent elects not to submit a written response within the time limit set forth in paragraph (a) of this section, the Office of Foreign Assets Control will conclude that the respondent has decided not to respond to the prepenalty notice. The agency generally will then issue a written penalty notice imposing the penalty proposed in the prepenalty notice.

(e) *Informal settlement.* In addition to or as an alternative to a written response to a prepenalty notice, the respondent or respondent's representative may contact the Office of Foreign Assets Control as advised in the prepenalty notice to propose the settlement of allegations contained in the prepenalty notice and related matters. However, the requirements set forth in paragraph (f) of this section as to oral communication by the representative must first be fulfilled. In the event of settlement at the prepenalty stage, the claim proposed in the prepenalty notice will be withdrawn, the respondent will not be required to take a written position on allegations contained in the prepenalty notice, and the Office of Foreign Assets Control will make no final determination as to whether a violation occurred. The amount accepted in settlement of allegations in a prepenalty notice may vary from the civil penalty that might finally be imposed in the event of a formal determination of violation. In the event no settlement is reached, the time limit specified in paragraph (a) of this section for written response to the prepenalty notice will remain in effect unless additional time is granted by the Office of Foreign Assets Control.

(f) *Representation.* A representative of the respondent may act on behalf of the respondent, but any oral communication with the Office of Foreign Assets Control prior to a written submission regarding the specific allegations contained in the prepenalty notice must be preceded by a written letter of representation, unless the prepenalty notice was served upon the respondent in care of the representative.

§ 594.704 Penalty imposition or withdrawal.

(a) *No violation.* If, after considering any response to the prepenalty notice and any relevant facts, the Director of the Office of Foreign Assets Control determines that there was no violation by the respondent named in the prepenalty notice, the Director shall notify the respondent in writing of that determination and of the cancellation of the proposed monetary penalty.

(b) *Violation.* (1) If, after considering any written response to the prepenalty

notice, or default in the submission of a written response, and any relevant facts, the Director of the Office of Foreign Assets Control determines that there was a violation by the respondent named in the prepenalty notice, the Director is authorized to issue a written penalty notice to the respondent of the determination of the violation and the imposition of the monetary penalty.

(2) The penalty notice shall inform the respondent that payment or arrangement for installment payment of the assessed penalty must be made within 30 days of the date of mailing of the penalty notice by the Office of Foreign Assets Control.

(3) The penalty notice shall inform the respondent of the requirement to furnish the respondent's taxpayer identification number pursuant to 31 U.S.C. 7701 and that such number will be used for purposes of collecting and reporting on any delinquent penalty amount.

(4) The issuance of the penalty notice finding a violation and imposing a monetary penalty shall constitute final agency action. The respondent has the right to seek judicial review of that final agency action in a federal district court.

§ 594.705 Administrative collection; referral to United States Department of Justice.

In the event that the respondent does not pay the penalty imposed pursuant to this part or make payment arrangements acceptable to the Director of the Office of Foreign Assets Control within 30 days of the date of mailing of the penalty notice, the matter may be referred for administrative collection measures by the Department of the Treasury or to the United States Department of Justice for appropriate action to recover the penalty in a civil suit in a federal district court.

Subpart H—Procedures

§ 594.801 Procedures.

For license application procedures and procedures relating to amendments, modifications, or revocations of licenses; administrative decisions; rulemaking; and requests for documents pursuant to the Freedom of Information and Privacy Acts (5 U.S.C. 552 and 552a), *see* part 501, subpart D, of this chapter.

§ 594.802 Delegation by the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to Executive Order 13224 of September 23, 2001 (66 FR 49079, September 25, 2001), and any further Executive orders relating to the national emergency declared therein, may be taken by the Director of the Office of Foreign Assets Control or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

Subpart I—Paperwork Reduction Act

§ 594.901 Paperwork Reduction Act notice.

For approval by the Office of Management and Budget (''OMB'') under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) of information collections relating to recordkeeping and reporting requirements, licensing procedures (including those pursuant to statements of licensing policy), and other procedures, *see* 501.901 of this chapter. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

Dated: May 13, 2003.

R. Richard Newcomb,

Director, Office of Foreign Assets Control.

Approved: May 22, 2003.

Juan C. Zarate,

Deputy Assistant Secretary (Terrorist Financing and Financial Crimes), Department of the Treasury.

[FR Doc. 03–14251 Filed 6–3–03; 8:50 am]

BILLING CODE 4810–25–P

Federal Register

Friday,
June 6, 2003

Part V

Department of Agriculture

Food Safety and Inspection Service

9 CFR Part 430

Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products; Final Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 430

[Docket No. 97–013F]

RIN 0583–AC46

Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its regulations to require that official establishments that produce certain ready-to-eat (RTE) meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes.* In particular, under these regulations, establishments that produce RTE meat and poultry products that are exposed to the environment after lethality treatments and that support the growth of *L. monocytogenes* will be required to have, in their hazard analysis and critical control point (HACCP) plans, or in their sanitation standard operating procedures or other prerequisite programs, controls that prevent product adulteration by *L. monocytogenes.* The establishments must share with FSIS data and information relevant to their controls for *L. monocytogenes.* The establishments also must furnish FSIS with information on the production volume of products affected by the regulations. The establishments may make claims on the labels of their RTE products regarding the processes they use to eliminate or reduce *L. monocytogenes* or suppress or limit its growth in the products.

DATES: This interim final rule is effective on October 6, 2003.

Comments on the information presented under ''Paperwork Reduction Act'' must be received by August 5, 2003.

Recognizing, however, that some approaches to *L. monocytogenes* control set out in this interim final rule are novel, FSIS will accept comments on the rule until December 8, 2004, for the purpose of reviewing and evaluating the effectiveness of these approaches.

ADDRESSES: One original and two copies of each comment should be sent to FSIS Docket #97–013F, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102 Cotton Annex, 300 12th Street, SW., Washington, DC 20250–3700. Comments will be available for public inspection in the Docket Clerk's Office between 8:30 and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Acting Assistant Deputy Administrator, Policy Analysis and Formulation, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 205–0495. Copies of references cited in this document are available in the FSIS Docket Clerk's Office, Room 102, Cotton Annex, 300 12th Street, SW., Washington DC 20250–3700. The Office is open 8:30 a.m. to 4:30 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

The Food Safety and Inspection Service (FSIS) administers the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 *et seq.*) to ensure that meat, poultry, and egg products prepared for distribution in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. The FMIA and PPIA prohibit anyone from selling, transporting, offering for sale or transportation, or receiving for transportation in commerce, any adulterated or misbranded meat or poultry product (21 U.S.C. 610, 458).

Under the Acts, a meat or poultry product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m)(1), 453(g)(1)); if it is for any reason unsound, unhealthful, unwholesome, or unfit for human food (21 U.S.C. 601(m)(3), 453(g)(3); or if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health (21 U.S.C. 601(m)(4), 453(g)(4). Such a product is misbranded if, among other circumstances, it fails to bear directly or on its container the official inspection legend (*e.g.*, for meat products, ''U.S. Inspected and Passed'' plus the official establishment number) prescribed in the regulations (21 U.S.C. 601(n)(12), 453(h)(12)). The Acts require FSIS to carry out an inspection of meat, meat food products, and poultry products to ensure that the products are not adulterated (21 U.S.C. 606, 455), and if the products are found upon inspection to be not adulterated, they must bear directly or on their containers the official inspection legend (21 U.S.C. 606, 607, 457).

The Acts give FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the Acts (21 U.S.C. 621, 463). The Acts require FSIS to prescribe rules and regulations governing the sanitary conditions under which the establishments that produce these products are to be operated (21 U.S.C. 608, 456).

On February 27, 2001, FSIS proposed (66 FR 12589) to establish several new requirements for the processing of ready-to-eat (RTE) and other meat and poultry products. The Agency proposed food safety performance standards for all RTE and all partially heat-treated meat and poultry products. The proposed performance standards set both levels of pathogen reduction and limits on pathogen growth that official meat and poultry establishments must achieve in order to produce products that are not adulterated. FSIS also proposed to allow the use of customized, plant-specific processing procedures and to eliminate its regulations that require that both RTE and not-ready-to eat pork and products containing pork be treated to destroy trichina (*Trichinella spiralis*).

Finally, FSIS proposed environmental testing requirements intended to verify measures to reduce the incidence of *L. monocytogenes* in RTE meat and poultry products. Specifically, FSIS proposed to

require establishments that produce RTE meat and poultry products to test food contact surfaces for *Listeria* species to verify that establishments were controlling the presence of *L. monocytogenes* within their processing environments. Under the proposal, establishments that developed and implemented HACCP controls for *L. monocytogenes* would be exempt from these testing requirements because the HACCP regulations require on-going monitoring and verification to demonstrate that the food safety system is working.

In this interim final rule, FSIS is amending its regulations only in regard to the control of *L. monocytogenes* in RTE products. FSIS plans to address the other proposed provisions in future **Federal Register** publications. In view of recent outbreaks of foodborne listeriosis, as well as recent recalls of meat and poultry products adulterated by *L. monocytogenes,* the Agency has decided to adopt these regulations before completing action on the other provisions of the proposal.

II. Listeria monocytogenes

L. monocytogenes is a pathogenic bacterium found in the environment (*e.g.*, in soil, water, and vegetation and on the surfaces of equipment, floors, and walls) and is often carried by healthy animals (including humans). *L. monocytogenes* is spread very easily by direct food contact with a contaminated surface, and it can survive and grow in a refrigerated, packaged RTE product.

L. monocytogenes grows under low-oxygen conditions and at low refrigeration temperatures and survives for long periods of time in the environment, on foods, in processing plants, and in household refrigerators. Although frequently present in raw foods of both plant and animal origin, it also can be present in cooked foods because of post-processing contamination. Consumption of food contaminated with *L. monocytogenes* can cause listeriosis. Listeriosis is a potentially fatal disease in newborns, the elderly, and persons with weakened immune systems, such as those with chronic disease or human immunodeficiency virus (HIV) infection or those taking chemotherapy for cancer. Listeriosis is also a major concern in pregnant women. Even though symptoms may be relatively mild in the mother, the illness can be transmitted to the fetus, causing illness or fetal death.

Each year, according to the Centers for Disease Control and Prevention (CDC), *L. monocytogenes* causes an estimated 2,493 cases of listeriosis. Of these, 2,298 persons are hospitalized, and 499 persons die. The case-fatality rate is high across the whole population—20 deaths per 100 cases of illness. Epidemiologic surveillance data show that the case-fatality rate varies by age, with a higher case-fatality rate among newborns and the elderly.[1]

L. monocytogenes is one of several foodborne pathogens that have been a special focus of public health strategies, such as Healthy People 2010. Organized by the Department of Health and Human Services (HHS), Healthy People 2010 is a comprehensive, nationwide health promotion and disease prevention agenda for increasing the quality and years of healthy life. The food safety objectives of Healthy People 2010 include infection reduction targets for pathogens of concern. The 2010 target for *L. monocytogenes* is to reduce by 50 percent the rate of illnesses below the 2001 level of 0.5 cases per 100,000 population.

A number of factors can cause or contribute to *L. monocytogenes* contamination of RTE meat and poultry products in a meat or poultry processing establishment. First, if the pathogen is already present in product ingredients, a processing error, such as incorrect formulation or inadequate processing time or temperature, can result in the production of products containing live organisms. Second, a product that has undergone a successful lethality treatment can be contaminated by biofilms on food-contact surfaces of equipment used for processing, handling, or packaging the product. The product can also be exposed to environmental contamination or cross-contamination in the post-lethality processing environment. One cause of cross-contamination can be plant construction in the post-lethality area of the establishment, unless precautions are taken to protect the products during the period of construction. Serious outbreaks of listeriosis have occurred because of the failure to take such precautions during facilities construction or remodeling.

Additional causes of contamination or cross contamination can be poor facilities design or plant equipment layout. Cross-contamination can occur if the flow paths of raw product and finished products cross or if vehicle or personnel traffic from outside the plant or from a raw-product area of the plant enters an area where exposed finished products are handled. Contamination or cross-contamination also can occur if processing equipment has not been designed for easy cleaning, or if equipment or facilities have hard-to-reach niches that can harbor *L. monocytogenes* or other pathogens.

III. Events Leading Up to the Proposed Rule

Outbreaks and Recalls

During the 1980's, *L. monocytogenes* began to emerge as a problem in processed meat and poultry products. FSIS and FDA worked with processing plants to improve their procedures and emphasized a ''zero tolerance''—no detectable levels of viable pathogens—for the organism in RTE products. Between 1989 and 1993, the rate of illness from *L. monocytogenes* declined 44 percent.

In the fall of 1998, State health departments and the CDC investigated an outbreak of foodborne illness in which hotdogs and, possibly deli (luncheon) meats, were implicated. CDC and FSIS investigators isolated the outbreak strain, a strain of *L. monocytogenes*, from an opened and previously unopened package of hotdogs manufactured by a single plant. CDC eventually reported 101 illnesses, 15 adult deaths, and 6 stillbirths or miscarriages associated with the outbreak.

Another outbreak of listeriosis occurred between May and December 2000 and was spread over 10 States. CDC linked a strain of *L. monocytogenes* to 29 illnesses—8 perinatal and 21 non-perinatal—resulting in 4 deaths and 3 in miscarriages or stillbirths. Subtyping by pulsed-field gel electrophoresis (PFGE) showed the *L. monocytogenes* strains to be indistinguishable from one another.

The outbreak was linked to eating turkey deli meat. Thirteen stores and delicatessens where patients reported purchasing turkey meat obtained their turkey meat from at least 27 federally inspected establishments. Two establishments were linked to 10 of 11 patients. FSIS traced the implicated turkey meat to a Texas poultry processor.

1999 Reassessment Notice

In 1999, with the emergence of an especially virulent strain of *L. monocytogenes*, the Agency concluded that many establishments should reassess their HACCP plans. FSIS published in the **Federal Register** a Notice (64 FR 28351; May 26, 1999) advising manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to ensure that the plans were, in fact, adequately

[1] Mead, P. S., L. Slutsker, V. Dietz, L. F. McCraig, S. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe. 1999. Food-related illness and death in the United States. *Emerging Infectious Diseases* 5:607–625.

addressing *L. monocytogenes*. If the reassessment revealed that *L. monocytogenes* was a hazard reasonably likely to occur in an establishment's production process, the establishment would have to address the hazard in its HACCP plan.

The same month, FDA and FSIS announced plans to conduct a quantitative microbial risk assessment to determine the extent of consumer exposure to foodborne *L. monocytogenes* in RTE foods (64 FR 24661; May 7, 1999).

FSIS Action Plan

A May 5, 2000, Presidential directive on *L. monocytogenes* in RTE foods revised the Healthy People 2010 target date for reducing illnesses caused by the pathogen up to 2005 and set other objectives. HHS and USDA responded to this directive with an eight-point action plan providing for consumer, health-care provider, and industry education; redirection of enforcement strategies, including increased microbial sampling; enhanced disease surveillance; coordinated research activities; and proposing new regulations. For its part, FSIS announced its intention to publish a proposed rule that would, among other things, require establishments to conduct environmental testing for *Listeria* species in order to verify the effectiveness of their sanitation standard operating procedures (Sanitation SOPs).

FDA/FSIS Draft Risk Ranking

FDA and FSIS made public a preliminary draft of a risk ranking in January 2001 (66 FR 5515; January 19, 2001). The risk ranking (*see http://www.foodsafety.gov/dms/lmrisk.html*) estimated the relative risks of serious illness and death from listeriosis that may be associated with consumption of different types of RTE foods. The risk ranking did not cover listerial gastroenteritis, a less serious infection with mild flu-like symptoms. The risk ranking (1) estimated the potential level of exposure of three age-based U.S. population groups to *L. monocytogenes* contaminated foods in 20 food categories and (2) related this exposure to public health consequences. The food categories studied included foods with a history of *L. monocytogenes* contamination. The models used in the risk ranking provided a means of predicting the likelihood that severe illness or death will result from consuming foods contaminated with this pathogen. Estimates were made of the relative risks posed by the food categories, but the risk ranking did not predict the precise public health consequences attributable to any particular contaminated food.

The foods considered in this risk ranking were RTE foods that are generally eaten without being cooked (*e.g.*, cheese) or are typically reheated (*e.g.*, frankfurters) before consumption. The main categories considered were seafood, produce, dairy, meat, and combination foods. The population groups evaluated were: (1) perinatal, including fetuses and neonates from 16 weeks after fertilization to 30 days postpartum. These are pregnancy-associated cases where exposure occurs most often *in utero* as a result of foodborne *L. monocytogenes* infections of the mothers during pregnancy and may result in spontaneous abortions, stillbirths, and neonatal infections; (2) elderly, that is, individuals who are 60 or more years of age; and (3) the intermediate-age group, including the remaining population, both healthy individuals (with very low risk of severe illness or death from *L. monocytogenes*) and certain susceptible population groups.

The population groups included individuals with increased susceptibility to listeriosis, such as acquired immune deficiency syndrome (AIDS) patients or individuals taking drugs that suppress the immune systems (*e.g.*, cancer or transplant drugs). Individuals within these susceptible population groups account for most of the cases of listeriosis within the intermediate-age group. The risk ranking focused on the overall burden of listeriosis on public health and includes the occurrence of both sporadic illnesses (*i.e.*, illnesses not associated with a documented outbreak) and outbreak illnesses.

The results of the risk ranking indicated that certain RTE meat and poultry products presented a relatively moderate to high risk for listeriosis. These included pâtés and meat spreads, deli meats, hotdogs, and deli salads containing meat or poultry products. Further, there was a significant opportunity for recontamination of RTE meat and poultry products in the processing establishment.

IV. Proposed Rule Provisions on *L. monocytogenes*

The Agency concluded that many establishments were not effectively implementing HACCP plans and Sanitation SOPs to prevent *L. monocytogenes* from contaminating the RTE product in the post-lethality processing environment. The Agency therefore resolved to proceed to rulemaking to correct the problem. In February 2001, FSIS issued a proposed rule that would require that establishments that produce post-lethality exposed RTE meat or poultry products conduct testing of food contact surfaces for *Listeria* species in areas of the establishments into which the products are routed after undergoing lethality treatment and before final product packaging. All establishments would be required to do this unless they had incorporated one or more controls validated to prevent, reduce to an acceptable level, or eliminate the *L. monocytogenes* from their products into their HACCP systems.

The proposed testing was intended to verify that the establishment's Sanitation SOP was preventing direct product contamination by *L. monocytogenes* after the products had undergone a lethality treatment. FSIS recognized that there is a significant risk for RTE meat and poultry products to become re-contaminated by *L. monocytogenes* if they came into contact with the pathogen, and that testing was necessary to verify that the procedures conducted under the Sanitation SOP had killed or eliminated the pathogen.

Under the proposal, if an establishment found that a food contact surface had tested positive for *Listeria* species, the establishment would have to take the corrective action necessary to properly clean the surfaces and to prevent product that may have become contaminated through contact with the surface from entering commerce.

Under the proposal, an establishment that had identified *L. monocytogenes* as a hazard reasonably likely to occur in its HACCP plan, and that had established CCPs for *L. monocytogenes*, was exempt from the proposed mandatory testing frequency requirement because HACCP regulations already require monitoring and verification, including testing frequency, as validated in the HACCP plan. An establishment that did not explicitly identify *L. monocytogenes* as a hazard reasonably likely to occur, but whose HACCP controls for biological hazards effectively prevented, eliminated, or reduced product contamination by the pathogen, would have had to make only minor amendments in its HACCP plan and supporting documentation to reflect that *L. monocytogenes* had been identified as a hazard addressed by the HACCP plan. In any case, if HACCP controls were implemented, the establishment would have to develop and validate the monitoring and verification procedures used to document the on-going effectiveness of the system. FSIS did not specify minimum monitoring and verification requirements for these processors.

The Agency has made it clear that, in its view, contamination with *L. monocytogenes* is a hazard reasonably likely to occur in all RTE meat and poultry products that are exposed to the processing environment post-lethality. Significant concerns about such contamination underlay the Agency's May 26, 1999, **Federal Register** Notice advising manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to determine whether the plans were appropriately addressing *L. monocytogenes*. In the proposal, however, the Agency acknowledged that, even though *L. monocytogenes* was a significant concern in RTE products, it may not be necessary to address this pathogen in the HACCP plan itself. FSIS acknowledged that this pathogen may be present but not necessarily likely to occur because the establishment had measures in place, such as Sanitation SOPs, that effectively prevented contamination by the pathogen in the food processing environment. An establishment might have incorporated the controls in its Sanitation SOP and thereby prevented the pathogen from posing a contamination hazard in the processing environment.

Consequently, to verify that such plants were effectively preventing environmental contamination, FSIS proposed to require that establishments without HACCP controls for *L. monocytogenes* test food contact surfaces for *Listeria* species at a frequency that was based on the relative size of the establishments. FSIS proposed that large establishments subject to the requirement conduct at least four such tests per line per month; small establishments at least two per line per month; and very small establishments at least once per line per month. A large establishment was one employing more than 500 employees; a small establishment from 10 to 499 employees; and a very small establishment one employing fewer than 10 employees and grossing less than $2.5 million in sales. These are the same size criteria the Agency had used in its 1996 final rule on HACCP systems (61 FR 38806).

The Agency solicited information on the proposed rule, including the efficacy of the testing frequencies, their potential cost to industry, the relationship between *Listeria* species on food contact surfaces and *L. monocytogenes* in product, and the various factors that might be important in devising effective testing protocols.

FSIS also proposed that establishments take certain actions after obtaining a positive food contact surface test result for *Listeria* species. An establishment with such a result would have to take the corrective action defined in its Sanitation SOP. The establishment would have to have in place procedures to determine which lots of product might be affected; to hold, sample, and test that product; and to dispose of affected product appropriately. FSIS acknowledged that some establishments would have to modify their Sanitation SOP corrective actions to include such elements.

FSIS requested comment on whether *Listeria*-positive test results on different food contact surfaces (such as surfaces that had been treated with a bactericide versus those that had not) should be treated differently; whether the Agency should establish more specific requirements on product sampling following a *Listeria*-positive test on a food contact surface; and whether an establishment should have to determine whether a *Listeria*-positive sample is *L. monocytogenes* before having to initiate product testing.

FSIS stated in the preamble of the proposal that if a sampled lot is found to be positive for *L. monocytogenes*, and the product from the lot is already in commerce, the Agency would request that the product be recalled. Further, the Agency stated, if product is found to be positive for *L. monocytogenes*, the establishment that produced it would likely have to establish controls for the pathogen within its HACCP plan.

FSIS noted that the two provisions addressing *Listeria* contamination contained in the proposed rule, HACCP and Sanitation SOPs, required specific daily action to ensure that product is not adulterated. FSIS stated that, as of the time of the proposal, it did not consider programs outside of Sanitation SOPs and HACCP to be sufficient to prevent the hazards associated with post-lethality contamination with *Listeria* in the manufacture of RTE products. For one thing, the Agency noted, documentation of corrective and preventive actions taken in such programs, known as GMPs (good manufacturing practices) or prerequisite programs, generally was not being provided to the Agency.

Compliance guidance: In the proposal, FSIS made a commitment to provide compliance guidance to establishments on testing frequencies and methodologies and appropriate corrective actions to take following positive tests on samples from food contact surfaces. FSIS also said it would publish guidance on available interventions (techniques for killing *L. monocytogenes*) establishments can implement as CCP's. FSIS made the draft compliance guidance available on its Web site after publication of the proposal.

Opportunity for Public Comment

FSIS provided a 90-day comment period. On April 13, 2001, FSIS published a **Federal Register** notice (66 FR 19102) extending the comment period an additional 30 days, through June 28, 2001, to provide opportunity for the public to comment on issues raised at a technical conference and public meetings that the Agency held May 8–10, 2001, on the proposed regulations. After the extended comment period expired, the Agency announced, in a July 3, 2001, **Federal Register** notice (66 FR 35112), that at the request of a consortium of trade associations, the Agency was reopening the comment period for an additional 30 days, until September 10, 2001. The consortium had said that it needed the additional time to review the large amount of scientific and economic data presented at the May 8–10 meetings, FSIS's draft compliance guidelines, and the draft FDA/FSIS risk ranking on the relationship between foodborne *L. monocytogenes* in RTE foods and human health.

Public Meetings on Listeria

During the development both of the proposal and this interim final rule, FSIS held a series of meetings with constituents and with technical and scientific experts on the problem of *L. monocytogenes* and how to control it. Some meetings were prompted by large-scale product recalls due to contamination with the pathogen or actual outbreaks of listeriosis.

In February 1999, following the late-1998 listeriosis outbreak and a recall of hotdogs and deli meats that had been contaminated with *L. monocytogenes*, FSIS held a public meeting on the food safety issues related to *L. monocytogenes* in meat and poultry products. At the meeting, industry and government procedures were discussed, including sampling programs for RTE products and the best ways to educate ''at risk'' populations about *Listeria*.

On May 15, 2000, FSIS held a public meeting to discuss current Agency initiatives to prevent human illness from *L. monocytogenes* in RTE meat and poultry products; the use of *Listeria* species as an indicator organism for *L. monocytogenes*; and the efficacy of environmental testing for *Listeria* species.

On May 8, 2001, FSIS held a public meeting to discuss scientific research and new technologies for detecting and controlling *L. monocytogenes* in RTE

meat and poultry products. At this meeting, FSIS requested data relevant to the proposed regulation regarding frequencies of testing for environmental *Listeria* species and the correlation of potential product contamination with production volume.

On November 18, 2002, FSIS held a public meeting to provide a forum for experts from government, academia, industry, and elsewhere to discuss current research and information related to improving the safety of RTE products. The topics discussed included the role of environmental and product testing, decontamination strategies, and consumer behaviors related to RTE foods. At the meeting, FSIS released a new draft directive (Directive 10,240.3, discussed below) on FSIS microbiological testing of RTE products for a number of organisms, including *L. monocytogenes*.

An additional public meeting was held February 26, 2003, to discuss an FSIS draft risk assessment which had been conducted to determine the likelihood that *L. monocytogenes* may contaminate RTE meat and poultry products during production and packaging processes. The Agency's draft risk assessment was released February 14, 2003, and was posted on the FSIS Web site (at *http://www.fsis.usda.gov/OPHS/lmrisk/DraftLm22603.pdf*). Copies also were made available in the FSIS Docket Room. Public and peer reviewer comments on the risk assessment and the Agency's response to the comments also can be viewed in the Docket Room and on the Web site.

V. FSIS Risk Assessment of *L. monocytogenes* in RTE Meat and Poultry Products

The FSIS risk assessment and the FDA/FSIS risk ranking on *L. monocytogenes* in RTE foods sold at retail provided a framework for evaluation of, and data on, risk mitigation strategies, including in-plant measures, to inform the Agency in this rulemaking as it considered the need to address potential contamination of RTE products by the pathogen.

FSIS initiated its *Listeria* risk assessment in February 2002 in response to public comments on the proposed rule that suggested the need for a stronger scientific basis for provisions requiring the testing of food contact surfaces for *Listeria* species. The risk assessment was developed: (1) To provide insight into the relationship between *Listeria* species on food contact surfaces and *L. monocytogenes* in RTE meat and poultry products exposed to the environment after the lethality treatment (post-lethality exposure); and (2) to evaluate the effectiveness of food contact surface testing and sanitation regimes, pre- and post-packaging interventions, growth inhibitors, and combinations of these interventions to mitigate contamination of RTE meat and poultry products that are post-lethality exposed, and to reduce the subsequent risk of illness or death from *L. monocytogenes*.

FSIS risk managers asked that the FSIS risk assessors evaluate the effect of various food contact surface testing and sanitation regimes in reducing *L. monocytogenes* contamination of products and the effect of other pre- or post-packaging antimicrobial interventions and of growth inhibitors in reducing such contamination. The risk managers also sought guidance from the risk assessors on testing and sanitation of food contact surfaces for *Listeria* species.

Given the available data and the fact that deli meats comprised about 80 percent of the listeriosis cases associated with ready-to-eat product, the FSIS risk assessment addressed only deli products. In order to evaluate the specific FSIS risk management questions, the risk assessment assumed that all *L. monocytogenes* on RTE product comes from the food contact surfaces and not from inadequate lethality treatment.

Using available data, the FSIS risk assessors developed a dynamic in-plant Monte Carlo simulation model (referred to as the in-plant model) quantitatively characterizing the relationship between *Listeria* species in the in-plant environment and *L. monocytogenes* in a production lot of RTE product at retail.

The outputs of the in-plant model (*e.g.*, concentration of *L. monocytogenes* on deli meats at retail) were used as inputs into the two major components of the FDA/FSIS risk ranking model discussed earlier: the exposure assessment and the associated dose-response relationship for deli meats.

In the FDA/FSIS risk ranking, the retail-to-table exposure assessment for deli meats and the associated dose-response relationship were developed to identify which RTE foods pose the greatest risk for causing listeriosis. Two components of the FDA/FSIS risk ranking model, the exposure assessment for deli meats and the dose-response relationship, were later updated with data and information provided during the public comment period on the draft FDA/FSIS risk ranking. The updated exposure assessment is used to track the level of *L. monocytogenes* in deli meat from retail to table and, using the updated dose-response relationship for *L. monocytogenes*, provides estimates of the subsequent risk of illness or death from consuming deli meats.

The outputs of the FSIS risk assessment model were calibrated to the *L. monocytogenes* concentration in deli meats at retail in the updated FDA/FSIS exposure assessment. That is, the FSIS output data were statistically compared with standard data on *L. monocytogenes* from a reputable third-party to determine whether the output data deviated from the standard data. Calibration of risk assessment models is intended to ensure the accuracy of risk estimates.

By modeling changes in in-plant practices, such as the frequency of testing and sanitation of food contact surfaces, the FSIS risk assessment model provides insight into the effects of these practices on the annual risk of illness or death from *L. monocytogenes* in RTE meat and poultry products. The risk assessment model was designed to provide numerous outputs that depended on the selection of in-plant practices, such as ''test and hold,'' responding after an initial positive food contact surface sample, or alternatively, after consecutive positive samples, and that were based on various plant characteristics (*e.g.*, plant size or production volume).

The most significant findings of the risk assessment model are: (1) The proposed minimal frequency of testing and sanitation of food contact surfaces (66 FR 12589, February 27, 2001) results in a small reduction in the levels of *L. monocytogenes* on deli meats at retail; and (2) combinations of interventions (*e.g.*, sanitation/testing of food contact surfaces, pre- and post-packaging lethality interventions, and growth inhibitors) appear to be much more effective than any single intervention in mitigating the potential contamination of finished RTE products with *L. monocytogenes* and reducing the subsequent risk of illness or death.

Specific model outputs relating to *L. monocytogenes* concentrations in deli products at retail and the resulting public health impacts of various interventions were developed and were presented at a public meeting on February 26, 2003. FSIS accepted comments on its draft risk assessment at the public meeting and afterward, until March 14, 2003 (68 FR 6109; February 6, 2003). The comments received have been included in the record of this rulemaking proceeding. An analysis of comments and responses is available in the FSIS Docket Clerk's Office and on the FSIS Web site at: *http://www.fsis.usda.gov*.

VI. Comments on the Proposal and FSIS Response

On the proposed requirements for controlling *Listeria* in RTE products in the February 27, 2001, **Federal Register** document, FSIS received 28 comments. Comment summaries, grouped by topic, and Agency responses follow.

Support for the Proposal

Comment: Three comments supported the proposed rule and favored even more stringent requirements. They said that manufacturers of RTE products should be required to implement programs for detecting and eliminating *L. monocytogenes* harborages and should perform tests for *L. monocytogenes* and *Listeria* species. All establishments that produce such products should have control programs that include environmental testing. The Agency should require establishments that have CCPs for *L. monocytogenes* to conduct testing. Also, the proposed required sampling frequencies should be increased and the intervals between tests specified. FSIS should mandate specific testing frequencies for product testing to be conducted following an environmental test that is positive for *Listeria.* Two of the commenters suggested that *Listeria* species is an appropriate indicator for *L. monocytogenes*.

The commenters said that FSIS should require even more intensive environmental and product testing than that proposed. Final product testing as well as environmental testing should be required; eventually, continuous product testing should be performed. One commenter opposed the notion of adopting food irradiation as a solution for potential contamination of RTE products.

One commenter said that the Agency should require establishments to test a statistically significant amount of RTE product for *L. monocytogenes*. The establishments also should conduct environmental testing for the organism. If the products are produced by an establishment that does not conduct RTE product testing as part of its HACCP plan, the products should carry warning labels.

Commenters said that FSIS should maintain its ''zero tolerance'' for *L. monocytogenes* in RTE products rather than setting a minimum colony-forming-unit (CFU) level for the organism in the products, as some have suggested.

A commenter said that official establishments should identify sources of *L. monocytogenes* in their Sanitation SOP.

Response: FSIS agrees with comments that supported establishment use of effective process controls combined with environmental testing to verify the effectiveness of sanitation programs. The Agency also agrees with the comment that establishments should address sources of *L. monocytogenes* either in their HACCP plans or in their Sanitation SOPs or other appropriate procedures. This interim final rule provides a framework within which establishments must meet this objective and provides flexibility for doing so.

FSIS does not agree that it is necessary to mandate *Listeria* testing for establishments that have a CCP for *L. monocytogenes*. Such establishments are already required to validate and verify the CCP's, and microbiological testing is an important means of validation and verification.

FSIS also believes that, if it mandated a high frequency of environmental or product testing, the Agency would be foreclosing unnecessarily the use of effective control programs or strategies adopted by establishments that might require testing at frequencies different from those mandated. In this interim final rule, FSIS is not adopting the proposed frequency requirements. Instead, the Agency is requiring establishments to adopt one of several alternatives that are appropriate for their products and process controls that are effective in addressing *L. monocytogenes*.

On the question of a ''zero tolerance'' for *L. monocytogenes* and particularly with respect to RTE products that support growth of the pathogen, FSIS currently regards any amount of the organism as a product adulterant. As stated above, because the product is RTE, it is likely to be consumed without any effort to kill the pathogen, and the presence of the pathogen may render the product injurious to health (21 U.S.C. 601(m)(1), 453(g)(1)) and would cause the product to be unhealthful.

General Comments on the Proposal and Its Scientific Basis

Comment: A number of commenters said that the proposed testing requirements are arbitrary, unsupported by the FDA/FSIS risk ranking, and generally unscientific (*i.e.*, they were not based on the relative risk posed by establishments, products, or processes).

Response: FSIS agrees, in principle, that mandating a testing frequency is not well founded. In this interim final rule, FSIS is not adopting the proposed provisions for testing food contact surfaces at specified frequencies. Under the interim final rule, establishments will have to implement effective controls for *L. monocytogenes*. The interim final rule is based on the Agency's conclusion that establishments that process post-lethality exposed RTE products must address *L. monocytogenes* in their food safety systems. Those establishments that rely only on sanitation procedures to control the pathogen should carry out more intensive verification procedures, such as food contact surface testing, to ensure that the procedures are effective, and that products are not contaminated, than establishments that controls the pathogen through their HACCP plans.

Severity of Effects

Comment: In framing the rule, FSIS should consider the relative risk of illness posed by RTE products and the severity of effects.

Response: FSIS has taken into account the relative risk of illness and death posed by the processes and products addressed by this interim final rule as reported in the FDA/FSIS risk ranking of RTE foods sold at retail and the FSIS risk assessment.

Success of Industry Efforts

Comment: The industry has been successful in lowering the incidence of foodborne listeriosis. The industry's efforts will help the country achieve the Department of Health and Human Service's ''Healthy People 2010'' goals for lowering the incidence of listeriosis in the population within the timeframe established in the May 5, 2000, Presidential directive. Thus, the Agency's proposal to require environmental testing is unjustified, especially in view of the fact that HACCP was intended to obviate the need for this type of prescriptive requirement.

Response: Although it is early to determine whether the ''Healthy People 2010'' goals for reducing listeriosis (to 0.25 cases per 100,000 population) will be achieved, recent data from CDC indicate that from 1996 to 2002 there was a 38-percent decline in the number of cases per 100,000 population (to .27 overall). Nonetheless, meat and poultry products have been implicated in a substantial proportion (nearly half) of listeriosis cases. FSIS believes that the meat and poultry industry, together with other segments of the food industry, is capable of contributing significantly to the achievement of the Nation's goals for *Listeria* control, particularly by focusing on higher-risk meat and poultry products and on mandatory control procedures—the approach taken in this interim final rule. This interim final rule does not, however, mandate specific testing frequencies.

Effectiveness of Industry Controls

Comment: Some commenters stated that the current HACCP and Sanitation SOP requirements are adequate for ensuring control of *Listeria.* Therefore, the need for regulatory change in this area is questionable.

Response: It is true that validated HACCP plans and effective Sanitation SOPs should be sufficient to address the *Listeria* hazard. The continuing occurrence of product contamination and of significant outbreaks of illness in which meat and poultry products are implicated, however, suggest that establishments have not appropriately addressed the hazard in their HACCP plans, and that the effectiveness of establishment Sanitation SOPs used to control *L. monocytogenes* contamination is not being ensured. The Agency has therefore concluded that it is necessary to require establishments to take specific steps to control the *Listeria* hazard.

Ubiquity of L. monocytogenes and Difficulty of Controlling It

Comment: Several commenters stated that it is important to recognize how ubiquitous *L. monocytogenes* is in the environment and that elimination of *L. monocytogenes* from all food is probably impossible. Thus, the commenters believe, it is not appropriate to require product testing on the basis of a single positive test for *Listeria* spp. on a food contact surface. Some commenters said that environmental testing results should not lead to enforcement actions.

Response: While FSIS does not think that the ubiquity of an organism in the environment argues against regulations requiring control of the organism, the Agency agrees that a more flexible approach to *L. monocytogenes* control than that taken in the proposal is warranted and desirable. FSIS is not adopting the proposed requirement to test product after the first positive test on a food contact surface. Although a positive test for *Listeria* species on a food contact surface does not necessarily mean that product is adulterated, or that enforcement action should be taken, such a finding does suggest the need for corrective action. FSIS inspection program personnel are instructed to verify that the establishment takes the corrective actions it has developed, whether as part of a HACCP plan or of a Sanitation SOP or other prerequisite program.

On the other hand, FSIS regards a positive test for *L. monocytogenes* on a food contact surface as evidencing an insanitary condition that may render product injurious to health. RTE product that comes into contact with the sampled surface at the time it was contaminated with the pathogen and is not subject to any further lethality treatment is adulterated, and FSIS inspection program personnel will take the appropriate action in response to such a finding as set out in Agency directives.

Incentives and Disincentives

Comment: The proposed testing requirements are a disincentive to control *L. monocytogenes* and may actually increase risk of foodborne listeriosis. Establishments might test for the organism at a lower rate than they currently do lest positive tests lead to unwarranted enforcement actions by FSIS. Many small and very small establishments have already implemented *L. monocytogenes* control measures (GMPs, Sanitation SOPs, and testing) in excess of the proposed requirements.

Response: FSIS agrees that mandating testing at a fixed frequency might discourage some establishments that are making strong efforts at *Listeria* control that include regular testing. This recognition factored into the Agency's decision not to adopt the proposed testing frequencies in this interim final rule.

Comment: FSIS should provide incentives for finding harborages, taking corrective actions, and preventing the recurrence of contamination.

Response: FSIS agrees with the comment. When the interim final rule becomes effective, FSIS verification testing will be more intensive in establishments where controls are less rigorous. (*See* discussion of new Directive 10,240.4 below.) Whether FSIS takes an enforcement action will depend on whether establishments are correcting insanitary conditions that may result in product adulteration.

FSIS believes that this interim final rule gives establishments the flexibility to adopt innovative and effective *Listeria* control methods. Moreover, the interim final rule includes a provision enabling establishments to declare on their product labels their use of *Listeria* control measures, provided that the establishments can validate the declarations.

HACCP, Sanitation SOPs, Prerequisite Programs, Directives or Performance Standards

Listeria Controls in HACCP Plans

Comment: Some commenters favored using equipment design, GMPs, and facilities management techniques to control *L. monocytogenes.* They stated that FSIS should recognize that enhanced and focused sanitation and employee behavior programs can be effective preventive and corrective actions. These commenters argued that contamination occurring in a post-lethality processing area is a sanitation, and not a HACCP, issue.

Others argued, to the contrary, that *L. monocytogenes* should be controlled by CCPs in an establishment's HACCP plan.

Response: FSIS is persuaded that *L. monocytogenes* contamination is being prevented in many establishments by Sanitation SOPs and other prerequisite programs. Where these programs are effective, an establishment may conclude in its hazard analysis that *L. monocytogenes* is not a hazard reasonably likely to occur. Of course, in the Agency's view, it is also appropriate to address this hazard in a HACCP plan. Thus, the Agency is allowing establishments the latitude to include *L. monocytogenes* control measures in HACCP plans or to address potential contamination by this pathogen in Sanitation SOPs or other prerequisite programs. It is important to note that if an establishment is applying a post-lethality treatment to an RTE product, the establishment must have concluded that *L. monocytogenes* is a hazard reasonably likely to occur in the product. For this reason, the establishment must include that treatment as a CCP in its HACCP plan.

Comment: Since no technology exists to completely eliminate *L. monocytogenes* from products, a CCP for controlling *L. monocytogenes* is infeasible. Establishments should focus their resources on sanitation and plant improvement projects rather than on HACCP CCPs. Allowing plants to develop CCPs instead of testing, they said, would result in decreased consumer protection.

Response: FSIS disagrees. A CCP in a HACCP plan is a point, step, or procedure in a food process where the occurrence of an identified hazard can be prevented, eliminated, or reduced to an acceptable level. Various methods are available to prevent, eliminate, or reduce *L. monocytogenes* in the RTE products that are subject to this interim final rule and their effectiveness can be validated. For example, a post-lethality heat treatment of a packaged product can eliminate the pathogen. Thus, establishments that use post-lethality treatments for this purpose should include the treatments in their HACCP plans. But establishments may use other methods, including the addition of antimicrobial agents, that have the effect of limiting or suppressing growth of *L.*

monocytogenes in the products. These methods need not be in the establishments' HACCP plans, so long as the plant is regularly ensuring that these methods are working effectively and is making its records that relate to these methods available to FSIS inspection personnel.

Use of Process Controls and Technologies to Control Listeria

Comment: FSIS should encourage establishments to adopt effective process controls, such as food irradiation and high-pressure processing, rather than imposing testing requirements. Relying solely on Sanitation SOPs or GMPs would fail to control *L. monocytogenes*. Further, products that are subject to an in-package lethality treatment before being shipped should be exempt from both environmental and product testing requirements.

Response: FSIS has designed the interim final rule to be sufficiently flexible that establishments will be able to implement a variety of technologies to address *L. monocytogenes*. Of course, before establishments can take advantage of food irradiation for the types of products covered by this interim final rule, FDA approval will be necessary.

FSIS agrees that effective process controls will yield more beneficial results than testing requirements of the kind proposed and that establishments may use various methods to prevent or control *L. monocytogenes* contamination. Therefore, FSIS is not adopting the proposed testing frequency requirements. The Agency is permitting establishments that produce RTE products to implement the type of HACCP or sanitation program that is most appropriate for their production situation and is not imposing uniform testing requirements of the kind proposed. FSIS recognizes that different validation or verification testing regimes are appropriate for different types of products or process control programs, and that a combination of interventions, including post-lethality treatments, sanitation and testing, processing, and the use of growth inhibitors, appears to be most effective in controlling *L. monocytogenes*.

Resource Allocation to Testing or Process Controls

Comment: FSIS has not shown how the proposed, prescriptive, environmental testing will reduce the incidence of *L. monocytogenes* in RTE products. If plants devote resources to environmental testing rather than to effective sanitation activities, consumer protection would decrease. Also, FSIS should let establishments use prerequisite programs instead of CCPs in the HACCP plan to control *L. monocytogenes*.

Response: FSIS acknowledges that testing by itself is insufficient to control *L. monocytogenes* but needs to be a part of a sanitation control program. FSIS regards testing as an essential means of verifying the effectiveness of sanitation procedures to control *L. monocytogenes*, whether the procedures are incorporated in a HACCP plan, a Sanitation SOP, or another prerequisite program. Devoting resources to a testing program developed for this purpose actually supports the control measures.

The proposed *Listeria* testing requirements, which would have mandated specific testing frequencies, were intended for Sanitation SOP verification. Although this interim final rule does not adopt the proposed testing frequency requirements, establishments that do not apply post-lethality treatments to their post-lethality exposed RTE products will have to include at least some food-contact surface testing in their sanitation programs. Such testing is intended to ensure that their measures for controlling, or preventing contamination by, *L. monocytogenes*, whether in HACCP plans or in Sanitation SOPs or other prerequisite programs, are effective.

Comment: FSIS should set a performance standard for *L. monocytogenes* as it has for other pathogens of concern. The Agency should also give establishments the flexibility to meet the standard. Thus, the Agency should consider the problem of pathogen growth after processing and give plants maximum flexibility in testing for *L. monocytogenes*.

Response: FSIS considered the option of adopting a process performance standard for controlling *L. monocytogenes* but determined that there was insufficient scientific information on which to base such a standard. Nonetheless, the Agency has given the establishments flexibility in deciding how to address this pathogen.

FSIS Directive on Microbial Sampling Procedures for RTE Products

Comment: Some commenters said that the Agency should continue to have its personnel use FSIS Directive 10,240.2, which sets out the procedures to be followed when Agency personnel conduct microbiological sampling in establishments that produce RTE products, rather than issuing new regulations. They said that FSIS could revise the Directive and conduct some food contact surface testing, either in all establishments that produce RTE products or just in establishments that do not conduct their own sampling.

Response: FSIS disagrees with the assertion that a regulation is not necessary to ensure effective control of *L. monocytogenes* in RTE products. As noted, with respect to the risk ranking, there is a significant opportunity for recontamination of RTE products in establishments. Many establishments are not implementing HACCP, Sanitation SOPs, or prerequisite programs in a manner that is effective in eliminating *L. monocytogenes* in RTE products. It should also be noted that FSIS replaced its Directive 10,240.2 in December 2002 with a new directive (10,240.3) with updated inspection verification activities. This new directive will be further revised to reflect the requirements of this interim final rule.

Inspection and Enforcement

Comments: FSIS inspectors should be trained to understand *Listeria* testing and the evaluation of the testing results because the considerations involved are complex. FSIS should make compliance guidance materials available for industry review before final regulations take effect.

Response: FSIS will be training its field inspection personnel to ensure that the interim final rule is properly implemented. FSIS's Food Safety Regulatory Essentials training, which addresses RTE products, is being given to all consumer safety inspectors. Regarding guidance materials, FSIS will provide comprehensive guidance to facilitate implementation of this interim final rule by all affected establishments. FSIS will make this guidance material available on its Web site well before this interim final rule takes effect.

Correlation Between Testing and Establishment Size and Production Volume

Comments: There is no evidence that the testing frequencies proposed, which are based on establishment size, will lead to reductions in the rate of listeriosis.

Also, requiring a large establishment to test more frequently than a small one because that establishment manufactured more product is not supportable. The Agency's preliminary economic impact analysis indicated that a small establishment could produce more product than a large establishment because factors other than employees were involved.

Response: FSIS agrees that there is no necessary correspondence between

establishment size and the rate of listeriosis or the degree of risk posed by the products the establishment manufactures. This is one reason why the Agency is not adopting the food contact-surface testing frequencies it proposed. Instead, the Agency is allowing establishments flexibility in designing measures to address *L. monocytogenes*, including appropriate testing and hold-and-test strategies for their products.

FSIS also understands that production volume does not necessarily correspond to establishment size. The Agency has concluded that having better and more comprehensive information about the production volume of RTE products will help it to more efficiently target its resources in verifying establishment *L. monocytogenes* controls.

Hold and Test

Comments: Some commenters stated that requirements for establishments to hold and test product after initial positive tests from environmental sampling would be complicated and likely to result in errors. Such regulation would therefore prove ineffective.

Other commenters insisted that, after an environmental positive, it would be appropriate for an establishment to follow hold-and-test procedures. They said that establishments should regard positive tests for *Listeria* from a non-food contact surface as indicating a sanitation or *Listeria* control problem and that if the positive test were from a food contact surface, all product from the shift represented by the sample should be held and tested before release.

Response: FSIS proposed requirements for food contact-surface testing rather than tests from the general plant environment. In this interim final rule, with the exception of one provision, FSIS is allowing the industry flexibility in designing procedures to be carried out following positive tests for an indicator organism, such as *Listeria* species. However, if a product has been in contact with a food contact surface that has tested positive for *L. monocytogenes*, it is considered adulterated and must be withheld from commerce. FSIS believes that this flexibility should result in the adoption of hold-and-test procedures that are not needlessly complicated and do not result in errors.

Costs and Benefits

Comments: Some commenters stated that the proposed regulations that require establishments to hold and test product after positive environmental test results would impose significant costs that would be especially burdensome to small businesses. Further, it was asserted that establishments unable to hold product because of customer demand or lack of storage facilities would run the risk of incurring the costs associated with increased product recalls.

Commenters argued that FSIS provided little justification for its *Listeria* testing policies in its proposal. They stated that it is difficult to estimate the number of listeriosis cases that might arise from contamination of meat and poultry products and discrepancies in the Agency's proposal illustrated this fact. For example, there is a significant data gap in the relationship between a product contact surface that tests positive for *Listeria*-like, *Listeria* species, and *L. monocytogenes* and whether the product will be positive and the risk to consumers. Commenters suggested that FSIS estimate the reductions in foodborne illness that would result from the regulation and provide further analysis or quantification of costs and benefits.

Response: FSIS agrees that the proposed testing frequency requirements would not be without cost and is interested in ensuring the accuracy of its estimates. To this end, the Agency has accepted data that were submitted by several commenters on this matter and has used the data in preparing the final regulatory impact analysis.

FSIS agrees that the costs associated with product recalls may far exceed those associated with hold-and-test procedures.

On the effect of *Listeria* control regulations on small businesses, FSIS agrees that a relatively large proportion of small establishments will be affected by this interim final rule. FSIS has prepared compliance guidance for such establishments, including guidance specifically intended to assist them in HACCP plan validation with respect to *L. monocytogenes* control, and is making this guidance available with this interim final rule in the FSIS Docket Room and on the Agency's Web site. Also, FSIS will mail the guidance material to all RTE operations before the effective date of this interim final rule.

FSIS agrees with the comments on the difficulties involved in determining the relationship between listeriosis cases and meat and poultry product contamination and with the suggestion that FSIS estimate the reductions in foodborne illness that could result from the regulation. FSIS initiated a risk assessment of in-plant processing of RTE products to determine the relationship between various food contact surface testing and sanitation regimes and other pre- and post-packaging interventions in mitigating contamination of RTE products with *L. monocytogenes* and in reducing the subsequent risk of illness or death and has further analyzed the costs and benefits. FSIS considered the results of the risk assessment in developing this interim final rule. In the final regulatory impact analysis, the Agency analyzes the effect of the interim final rule in terms of the reduction of illness and death from listeriosis.

Definition of RTE and Relative Risk of Different RTE Products

Comments: Commenters expressed concern about the terminology that the Agency used in its proposal. These concerns were related to the scope and effects of the regulation. The commenters said that FSIS should more clearly define RTE products. Some of them stated that frozen products ought not to be considered RTE for the purposes of the rule. To include such products in the RTE category, they argued, would be contrary to previous FSIS policy (Agency directives), the FDA's model food code, and the FDA/FSIS risk ranking model for *Listeria* in RTE foods. The commenters argued that another category of products, dried meat and fermented products, also should not be considered RTE for the purposes of the rule, for their water activity (a_w) puts them at low risk as a medium for growth of *L. monocytogenes*.

The commenters suggested that instead FSIS should define RTE products as ''refrigerated foods of extended shelf life (>10 days) that can support the growth of *L. monocytogenes* and that will be consumed without further listericidal treatment.'' The commenters added that FSIS should base *L. monocytogenes* control requirements on risks posed by specific types of products.

Response: The Agency has revised the definition of RTE to be consistent with the definition of RTE used in the 2001 Food Code. FSIS does not believe that frozen foods, as a broad category, can be excluded from the definition of RTE for this rule. Rather, the Agency will continue to follow its existing practice of determining whether foods should be considered RTE because of the manner of processing and the handling instructions provided to consumers. Some instructions direct that the product must receive further preparation for safety purposes.

Several labeling features or statements are used exclusively on RTE products or non-RTE products, but not on both. RTE products often include phrases indicating that they do not require

further preparation for safety, *i.e.*, ''fully cooked,'' ''Ready-to-eat,'' and ''Heat and Serve.'' Features that are used exclusively on non-RTE products to inform consumers that the products must be cooked to be safe for consumption include the Safe Handling Instructions, which indicate that the meat or poultry portion have not received an adequate lethality treatment and such phrases as, ''Raw,'' ''Uncooked,'' ''Not Ready-to-Eat,'' and ''Ready-to-Cook.''

Cooking instructions alone, however, are not a reliable labeling feature for consumers to determine whether a product requires cooking for safety. Phrases such as ''Cook and Serve,'' ''See cooking instructions,'' and ''Cook thoroughly'' have been used interchangeably on both RTE and NRTE meat and poultry products.

FSIS will continue to consider frozen foods that provide clear instructions to consumers about safe handling and cooking requirements as not-RTE and therefore not subject to this regulation. Frozen products that do not meet these requirements will be considered RTE.

The Agency does not agree that either frozen foods or dried meat and fermented products should be excluded from the definition just because they pose a low risk for *L. monocytogenes*. In both cases, the products are lower in risk because they have undergone a process that is either lethal to or suppresses or limits the growth of pathogens, including *L. monocytogenes*. For this reason, FSIS believes that establishments producing these products should also be required to incorporate in their operations measures addressing *L. monocytogenes* to ensure that the products can be consumed safely without further preparation.

Tolerance for L. monocytogenes and Food Safety Objectives (FSO's)

Comments: Some commenters recommended that FSIS establish a tolerance for *L. monocytogenes* in certain products that do not support growth of the organism. The commenters suggested that a FSO would be consistent with the concepts favored by the Codex Alimentarius Commission and the standards applied by some of this Nation's trading partners. A more rigorous standard could be applied to product that is intended for vulnerable populations.

Response: Establishing a tolerance for *L. monocytogenes* is outside the scope of this rulemaking. The Agency is not in a position to set a regulatory tolerance for *L. monocytogenes* in RTE products, for a number of reasons, including the fact that the Agency is unable routinely to identify the end users of the products.

Absent a conclusive demonstration to the contrary, the Agency must regard any amount of *L. monocytogenes* in a RTE product as an adulterant under the FMIA or PPIA (21 U.S.C. 601(m), 453(g)).

Labeling and Consumer Education

Comments: Some commenters said that development of meaningful ''use-by'' dating that reflects the safety of the product is a practical impossibility. They said that ''use-by'' dates would only be effective for products that are ''refrigerated foods of extended shelf life (>10 days) that can support the growth of *L. monocytogenes* and that will be consumed without further listericidal treatment.''

Other commenters maintained that FSIS should require RTE products to have a uniform expiration dating system to identify product that should be frozen or not consumed after a specified number of days. Some commenters said that RTE products should carry warning labels if they are produced by a plant that does not conduct product testing for *L. monocytogenes* as a feature of its HACCP system. Also, they said, because of the possibility that RTE products might be contaminated with *L. monocytogenes*, the products should carry safe-handling labels until testing is required.

Response: FSIS proposed some revisions to the special-handling label requirements that are not addressed in this interim final rule. The Agency did not propose use-by labeling but requested comment on the feasibility of requiring such labeling, including the most effective way to implement it, the assumptions retailers and consumers should be expected to make in using it, scientific and economic data on the shelf-life and safety of RTE meat and poultry products, the kinds of post-lethality interventions that should be expected for products bearing use-by labeling, and the content of the labeling (66 FR 12635). FSIS notes that the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is currently addressing safety-based use-by dates. FSIS will consider the NACMCF findings and other information of the kind requested in the proposal before any further rulemaking on the issue.

VII. The Interim Final Rule: Control of *L. monocytogenes*

FSIS has considered the information presented in comments on the proposal, public meetings, the FDA/FSIS risk ranking, and the FSIS risk assessment. Given the pathogenicity of *L. monocytogenes*, the opportunity for it to contaminate RTE product in the post-lethality environment, and the significant consequences that this contamination can have, FSIS is amending its regulations. The Agency is adding provisions that require establishments that produce post-lethality exposed RTE product to include in their HACCP plans or in their Sanitation SOPs or other prerequisite programs measures that prevent product adulteration by *L. monocytogenes*.

FSIS is adding several definitions (9 CFR 430.1) to the regulations. FSIS is defining ''deli product'' and ''hotdog product,'' which are a particular focus of the regulations because of the risks they pose. The Agency is also adding several definitions relating to conditions affecting RTE products after the products have undergone a process that destroys *L. monocytogenes* (9 CFR 430.1).

The first definition in 9 CFR 430.1 is for ''antimicrobial agent,'' which FSIS is defining to mean a substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism or of suppressing or limiting its growth throughout the shelf life of the product. In the context of this regulation, an antimicrobial agent may be added to a post-lethality exposed product (also defined) after its initial lethality treatment. An antimicrobial agent, such as acid from fermentation, may also be an inherent component of the product or a result of its formulation. In any case, the effect of the use of the antimicrobial agent is to limit or suppress growth of *L. monocytogenes*.

''Antimicrobial process'' is defined to mean an operation, such as freezing, that is applied to an RTE product and that has the effect of suppressing or limiting the growth of a microorganism. In the context of this regulation, the process is typically applied to a post-lethality exposed product after its initial lethality treatment, and the effect of the process in limiting or suppressing growth of *L. monocytogenes* continues throughout the shelf life of the product. If a product were frozen, the effect of freezing the product could only continue throughout the shelf life of the product if the product were maintained continuously in a frozen state.

The Agency is defining ''post-lethality exposed product'' as RTE product that comes into direct contact with a food contact surface after undergoing a lethality treatment that is a usual and necessary step in the production of the product, *e.g.*, the cooking step for a hotdog or other cooked sausage. A

definition of ''lethality treatment'' is provided. The ''post-lethality processing environment'' is defined as the area of an establishment into which product is routed after undergoing a lethality treatment.

''Post-lethality treatment'' is defined as a lethality treatment applied to a product after post-lethality exposure. A post-lethality treatment might be an additional heat step or other pasteurization process, such as high-pressure processing. A ''post-lethality treatment'' to reduce or eliminate *L. monocytogenes* is to be distinguished from the use of an antimicrobial agent or process that suppresses or limits the growth of the pathogen. Antimicrobial agents include lactic acid in certain types of sausage products or ingredients of growth-limiting packaging (*e.g.*, cellulose containing an antimicrobial substance). An example of a growth suppressing or limiting process is freezing.

FSIS is defining ''prerequisite program'' as a procedure or set of procedures designed to provide the basic environmental or operating conditions necessary for the production of safe, wholesome food. The definition is adapted from ''Hazard Analysis and Critical Control Point Principles and Application Guidelines,'' which was adopted August 14, 1997, by the National Advisory Committee on Microbiological Criteria for Foods and has wide currency in the food industry. Prerequisite programs are a part of the decision-making documentation that is associated with the hazard identification and selection of CCPs in a HACCP plan. An establishment is required by 9 CFR 417.5 to maintain such documentation because the existence of an effective Sanitation SOP or other prerequisite program affects the outcome of an establishment's hazard analysis.

The definition of a ''prerequisite program'' is being provided, and the use of such a program in the new regulations is being permitted, in response to industry comments on the proposal emphasizing the importance of prerequisite programs in preventing *L. monocytogenes* contamination. One commenter stated that post-processing contamination by *L. monocytogenes* is best controlled through prerequisite programs.

Finally, FSIS is adopting the definition of a ''ready-to-eat'' product that, although similar to the one proposed, conforms with the 2001 Model Food Code. Thus, an RTE meat or poultry product is one that is ''in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.''

In a new section on control of *L. monocytogenes* in post-lethality exposed RTE products, 9 CFR 430.4, FSIS first states its basic finding that *L. monocytogenes* is a hazard in such products, and that establishments must control this hazard through their HACCP plans or prevent it in the processing environment through Sanitation SOPs or other prerequisite programs. FSIS is making this finding, as it states in 9 CFR 430.4(a), based on the fact that RTE products that have been subjected to a lethality treatment but then exposed to the environment may be recontaminated with *L. monocytogenes.*

An establishment may determine that recontamination is not reasonably likely to occur in its post-lethality exposed RTE products because it has an effective Sanitation SOP or some other prerequisite program that effectively prevents *L. monocytogenes* contamination. If an establishment makes this determination, under 9 CFR 417.5(a)(2), the regulation requiring establishments to keep documentation supporting the selection of CCPs or critical limits, the basis for this determination must be documented and made available to the Agency. FSIS is aware that, in their hazard analyses, establishments have been taking their Sanitation SOPs and other prerequisite programs into consideration. Thus, an establishment that produces RTE products may not identify *L. monocytogenes* as such a hazard to be addressed in its HACCP plan, it must nonetheless effectively address this pathogen in its food safety system.

The Agency is requiring, in 9 CFR 430.4(b), that an establishment that produces post-lethality exposed RTE product must meet the specific requirements of one of three alternative programs for addressing *L. monocytogenes*. In the view of FSIS, any situation involving establishment measures to address post-lethality contamination of RTE products by *L. monocytogenes* is covered by one of the alternatives. Under this interim final rule, the first alternative relies largely on control though HACCP and an antimicrobial agent or process that suppresses or limits the growth of the pathogen. Each successive alternative places a greater reliance on the rigor of sanitation procedures, including verification testing, than on post-lethality treatments, to control *L. monocytogenes*. Consequently, the frequency and intensity of FSIS verification is likely to be greater for Alternatives 2 and 3, as more reliance is placed on sanitation.

Alternative 1. In the first alternative, an establishment controls *L. monocytogenes* by using a post-lethality treatment of the product *and* an antimicrobial agent or process that suppresses or limits the growth of the pathogen. As mentioned previously, the use of the post-lethality treatment to reduce or eliminate *L. monocytogenes* reflects a determination that the pathogen may be present in the product—in other words, that it is a hazard reasonably likely to occur. Therefore, the establishment must include the post-lethality treatment in its HACCP plan. The point in the process at which the treatment is applied is, by definition, a ''critical control point'' under 9 CFR 417.1 in that it is a step in a process at which control is applied to prevent, eliminate, or reduce to acceptable levels a food safety hazard, *L. monocytogenes*. The post-lethality treatment incorporated in the HACCP plan must be validated in accordance with 9 CFR 417.4 as being effective in reducing or eliminating *L. monocytogenes*.

The use of an antimicrobial agent or growth suppressing or limiting process may not in practice have the *L. monocytogenes* reduction effect of a post-lethality treatment, but still be an effective measure because it inhibits growth of the pathogen, thus, limiting the possibility that any *L. monocytogenes* that survives the post-lethality treatment will grow out and presents a food safety hazard. In Alternative 1, FSIS is giving the establishment the choice of including the antimicrobial agent or process in its Sanitation SOP or other prerequisite program or as a CCP in its HACCP plan.

FSIS recognizes that an establishment electing to adopt Alternative 1 may employ an antimicrobial agent or process as part of its initial lethality treatment and that the agent or process may have a continuing bactericidal effect on *L. monocytogenes* that persists even through post-lethality exposure and distribution. In such a case, the antimicrobial agent or process could serve as both a post-lethality treatment and growth inhibitor. Thus, neither an additional post-lethality treatment nor an additional antimicrobial agent or process is necessary to qualify for Alternative 1. The establishment would need to have documentation on file to demonstrate that the conditions of Alternative 1 are being met through the application of the initial antimicrobial agent or process.

As with the post-lethality treatment, if the antimicrobial agent or process is

included as a CCP in the HACCP plan, it must be validated as effective in suppressing or limiting growth of the pathogen. The establishment must also verify the effectiveness of the control measures in accordance with 9 CFR 417.4. If the agent or process is included in the establishment's sanitation program, it must be in compliance with the general sanitation regulations and the Sanitation SOP requirements in 9 CFR part 416. The control measures, if included in the HACCP plan, must be validated as effective. The establishment's regular monitoring of its operation must be verified. Sanitation procedures must be in compliance with the general sanitation regulations and the Sanitation SOP requirements, as applicable.

In addition, the establishment is required to make the results of its verification measures, under whichever program—HACCP, Sanitation SOP, or other prerequisite program—available upon request to FSIS inspection personnel.

FSIS has concluded, and this conclusion is informed by the FSIS risk assessment, that Alternative 1, which involves a combination of interventions that includes a post-lethality treatment and the application of an antimicrobial agent or process, is likely to be among the most effective means of reducing the risk of *L. monocytogenes* contamination and hence of listeriosis mortality among vulnerable populations.

Alternative 2. An establishment may choose to address *L. monocytogenes* by using a post-lethality treatment *or* an antimicrobial agent or process that suppresses or limits the growth of the pathogen. As with Alternative 1, the post-lethality treatment, if used, must be included as a CCP in the establishment's HACCP plan. The application of the antimicrobial agent or the growth suppressing or limiting process must be included in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. Whichever program includes the application of the antimicrobial agent or the growth suppressing or limiting process, the establishment must have documentation to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting the growth of *L. monocytogenes*.

In addition, FSIS is providing that if the establishment chooses Alternative 2 and chooses to use only a post-lethality treatment of product, it would likely be subject to more frequent verification testing than if it chose Alternative 1. FSIS has concluded that multiple steps are more likely to reduce the risk of *L. monocytogenes* contamination of RTE products and subsequent adverse public health effects. Without an antimicrobial to suppress or limit the growth of *L. monocytogenes* that may survive the post-lethality treatment, it becomes more important to verify the effectiveness of that treatment.

The establishment may choose not to rely on a post-lethality treatment to reduce or eliminate *L. monocytogenes*, but to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. If so, it becomes extremely important to minimize any possibility of post-lethality contamination. The establishment's sanitation program must, therefore, provide for the testing of food contact surfaces in the post-lethality processing environment to ensure that the establishment's sanitation program is effective in keeping those surfaces sanitary and free of *L. monocytogenes* or of indicator organisms that would reflect the presence of *L. monocytogenes*. The program must delineate the frequency with which testing will be done, state the size and location of the sample sites (so that the area represented by a sample can be known), and provide an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or the indicator organism is being maintained. The program also must identify the conditions under which the establishment will implement hold-and-test procedures after a positive test for *L. monocytogenes* or indicator organisms.

As under the Alternative 1, the establishment must make the verification results of the effectiveness of its controls from its HACCP, Sanitation SOP, or other prerequisite program available upon request to FSIS inspection personnel.

For Alternative 2, if the measures for addressing *L. monocytogenes* are in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment's documentation of its program and of its results and its implementation of the program must be sufficient to support a finding, during validation or reassessment, under 9 CFR 417.4, that the HACCP plan is adequate and that the HACCP plan in operation is not inadequate within the meaning of 9 CFR 417.

Alternative 3. An establishment that processes RTE products may control *L. monocytogenes* in the post-lethality processing environment through sanitation procedures only. If incorporated in the HACCP plan, the sanitation procedures followed in this alternative must be validated and verified in accordance with 9 CFR 417.4. Also, sanitation in the post-lethality processing area must be maintained in accordance with 9 CFR 416.

As in Alternative 2, FSIS is requiring that the sanitation procedures in the post-lethality processing environment include testing of food contact surfaces to ensure that the surfaces are sanitary and free of *L. monocytogenes* or an indicator organism. The procedures must delineate the frequency of testing; state the size and location of sample sites; and provide an explanation of why the testing is sufficient to ensure that the establishment's sanitation procedures are effectively keeping *L. monocytogenes* or indicator organisms from contaminating product. The establishment must identify in its procedures the conditions under which it will implement hold-and-test procedures to ensure that *L. monocytogenes* or indicator organisms are not contaminating product.

Establishments that adopt Alternative 3 will need to address in their decisionmaking documents why the sanitation procedures they employ, the frequency of testing they carry out, and the circumstances in which they test the product and hold it pending receipt of test results are appropriate and adequate to prevent the contamination of their product by *L. monocytogenes* and to ensure that contamination is discovered if it has occurred.

Because establishments using Alternative 3 are relying only on sanitation procedures and because verification activities are so important to ensuring the on-going effectiveness of such measures, FSIS has concluded that establishments electing to adopt Alternative 3 are likely to be subject to a higher frequency of testing by FSIS than establishments using Alternative 1 or 2. As is the case with establishments adopting the other alternatives, an establishment that has adopted Alternative 3 must make the verification results obtained from its own food contact surface testing available on request to FSIS inspection personnel.

Under Alternative 3, more stringent requirements apply to an establishment that processes deli meats or hotdogs. These products were shown in the FDA/FSIS risk ranking to pose a relatively high risk of listeriosis, in terms of cases per annum. Thus, in order to provide the assurance that comes from increased verification, FSIS expects the frequency of its own testing, as well as the establishment's testing, to be higher

than that for other products produced under the Alternative 3 approach.

Under Alternative 3, for establishments producing deli meats and hotdogs, FSIS is requiring specific procedures for holding and testing product to minimize the risk of contaminated product entering commerce. These procedures are to be followed if an establishment has had a positive test for an indicator organism, such as *Listeria* species, on a food contact surface in the post-lethality processing environment.

After the establishment takes corrective action to clean the food contact surface, the establishment must verify that the corrective action has been effective through follow-up testing in the post-lethality processing area. This testing is to include targeting the specific site on the food contact surface area that was the most likely source of contamination by the organism and must include such additional tests of the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective action. (If the initial positive test was for *L. monocytogenes*, the product is considered adulterated and must be withheld from commerce even before the results of further testing are available.)

If, during this follow-up testing, the establishment obtains a second positive test result for the indicator organism on a sample from the previously tested area, the establishment must hold lots of product produced between the second positive test result and completion of the corrective action until samples from the food contact surfaces in the same area test negative for *L. monocytogenes* or the indicator organism. The establishment may sample and test the held product, using a sampling method that will provide a level of statistical confidence that is sufficient to establish that the product is not adulterated with *L. monocytogenes*, and it can release the product into commerce if the results are negative.

For Alternative 3, if the measures for addressing *L. monocytogenes* are in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment's documentation of its program and of its results and its implementation of the program must be sufficient to support a finding, during validation or reassessment, under 9 CFR 417.4, that the HACCP plan is adequate and that the HACCP plan in operation is not inadequate within the meaning of 9 CFR 417 part 1.

Estimates of annual production volume. As previously stated in this document, some commenters observed that a large establishment may not necessarily produce more RTE product than a small establishment. FSIS agrees and regards production volume as a more important risk factor than establishment size. FSIS intends to target its inspection resources on the higher volume operations. To do this effectively, FSIS will need data on the annual production volume of post-lethality exposed RTE products produced, by product, and by *L. monocytogenes* control alternative (1, 2, or 3), and other related information (such as the establishment's own testing procedures). The affected establishments will have to provide FSIS with this information at least annually. The Agency expects to have an electronic form available for this purpose (9 CFR 430.4(f)).

Labeling Incentive

Finally, FSIS is allowing establishments that use post-lethality treatments or antimicrobial agents or processes that are effective in destroying *L. monocytogenes* or in limiting its growth to declare this fact on the labels of their products. The purpose of the labeling is to inform consumers about measures that have been taken to ensure the safety of the products and thus to enable the consumers to select such products in preference to others. This provision is entirely voluntary, but FSIS believes that labeling claims about treatments that eliminate, suppress, or limit the growth of *L. monocytogenes* can be of value to consumers, especially those in groups most vulnerable to foodborne infection.

For example, products with antimicrobial agents can be viewed as containing substances that reduce the presence of pathogens or the likelihood of foodborne illness, provided that the products are appropriately handled throughout the distribution chain and prepared safely by the consumer. Thus, a label statement should identify the presence of ingredients and their purpose of use but not claim that the product is somehow ''safer than'' other untreated products.

Examples of statements that can be made are: ''Sprayed with a solution of sodium lactate to prevent the growth of *L. monocytogenes*'' or ''Contains sodium diacetate and sodium lactate to prevent the growth of *Listeria monocytogenes*.''

New and Existing Regulatory Requirements

The regulations promulgated in this interim final rule include new requirements and reiterate for clarity certain existing regulations. The definitions in § 430.1 are new, as are the provisions in § 430.4 specifying the three permissible alternatives for addressing *L. monocytogenes*. Similarly, the provisions in this interim final rule requiring that measures included in the establishment's Sanitation SOP or other prerequisite program are new. The provision requiring that RTE establishments report at least annually the volume of production by type of RTE product and by alternative for controlling or addressing *L. monocytogenes* is new. Also new are the sanitation procedure requirements that include hold-and-test provisions.

Although the use by industry and the Agency's acceptance of prerequisite programs is not new, the provisions on prerequisite programs in this interim final rule constitute explicit recognition, for the first time in the codified regulations, of such programs. The requirement that documentation of prerequisite programs and the results of such programs be available to the Agency also makes explicit an implied requirement in the HACCP regulations.

Also, the requirement that a post-lethality treatment be included in an establishment's HACCP plan is made explicit for the first time in this interim final rule. The requirement to maintain documentation on Sanitation SOPs or other prerequisite programs that are used to support a decision not to identify *L. monocytogenes* as a hazard reasonably likely to occur that must be controlled makes explicit a requirement in the HACCP regulations (9 CFR 417.5). The provision for validation of controls included in a HACCP plan just reiterates existing requirements of 9 CFR 417.4. Similarly, the requirement that Sanitation SOPs be evaluated routinely to ensure their effectiveness reiterates the requirements in 9 CFR 416.14.

The requirement to verify, that is, to evaluate routinely and maintain, the effectiveness of the Sanitation SOP, is already a regulation (at 9 CFR 416.14). Also, the requirement to follow existing sanitation requirements in the post-lethality processing environment simply reiterates the general sanitation regulations (9 CFR 416) that are applicable everywhere in an official establishment.

Finally, the provision for RTE product labeling that declares the fact of an *L. monocytogenes* control treatment or ingredient is new, but permissive. RTE product labeling may, under current regulations, bear such statements if the statements are valid.

VIII. Implementation

Implementation Strategy

FSIS has designed this interim final rule to recognize that there are alternative, effective ways to ensure that post-lethality exposed RTE products do not become contaminated with *L. monocytogenes*. While each approach can be effective in preventing such contamination, Alternatives 1 and 2 present a greater opportunity for mitigating the risk of RTE product contamination than does Alternative 3 because under Alternatives 1 and 2, products are formulated or processed in a manner either to eliminate *L. monocytogenes* or to limit its growth, should it be present.

Hence, in implementing this interim final rule, FSIS plans to conduct verification activities, including testing, that focus most intensively on Alternative 3 establishments and, within that group, on establishments that produce deli meats and hotdogs to verify that the total food safety system under which these products are produced is working properly.

FSIS is aware that the regulated industry is using antimicrobial agents at levels that provide some limitation of growth, that some establishments use these agents at levels that allow no more than 2-$\log_{10}$ growth throughout the shelf-life of the product, and that other establishments are using the agents at levels that more severely limit growth. FSIS believes that the majority of products formulated with the higher levels of antimicrobial agents are cured products because they better tolerate the agents, and the products do not have unacceptable organoleptic qualities. For this reason, the FSIS verification testing program for Alternative 2 will cover establishments that produce products formulated with antimicrobial agents but will focus on establishments using lower levels of antimicrobial agents because there is some potential for pathogen growth in the products. However, FSIS does not intend to conduct its verification testing at such establishments at a rate that is any higher than that for establishments in Alternative 3 and certainly not at a rate as high as that for establishments using Alternative 3 and producing deli meats or hotdogs.

FSIS intends to collect information about the RTE products produced by establishments using Alternatives 1 through 3. The information will include estimates of production volume for post-lethality exposed products, so that the Agency can develop annual sampling frequencies for the establishments and the products. FSIS will make the sampling frequency information available to the establishments so that they will have some indication of how the risk of *L. monocytogenes* contamination is tied to FSIS verification testing.

FSIS is continuing to model scenarios in its risk assessment model and will use this information in determining where to direct its verification testing resources to ensure that such products are not adulterated. In the meantime, FSIS will continue to use currently available production volume figures in directing these resources.

The Agency expects to weight its sample scheduling process so that a large-volume establishment will be targeted more frequently than an establishment with a lower volume of production. Because, under this interim final rule, all establishments must have written programs that address *Listeria* and share their testing results with FSIS, FSIS believes that there will be no need to phase in the implementation of the interim final rule for establishments of different sizes or of different production volume capacity. The effective date will be October 6, 2003, for all establishments. During the 120 days before the interim final rule becomes effective, FSIS will issue a new directive (Directive 10,240.4, discussed below). The Agency is now making available new compliance guidelines that will contain information about the effects of sanitation and testing, as well as the effectiveness of various levels of antimicrobials.

New Directive for FSIS Inspection Program Employees

Through a new directive replacing FSIS Directive 10,240.3 that issued in December 2002, FSIS will conduct a risk-based verification testing program to assess the effectiveness of RTE operations in controlling *L. monocytogenes*. FSIS will identify the general features of the design of its verification testing program. Each fiscal year, FSIS identifies the general number of samples that it expects to collect throughout the year associated with RTE products. In order to implement this interim final rule, FSIS expects to apportion the types of products sampled with an emphasis on deli meats and hotdogs produced under Alternative 3. All RTE products are subject to being tested.

Until FSIS has actual production volume and associated data obtained through the reports required by 9 CFR 430.4(f), FSIS likely will continue sampling in the same manner currently employed by the Agency. FSIS intends to build in the production volume feature, as soon as possible, in order to ensure that larger volume production is verified more frequently than smaller volume production. In addition, FSIS will continue to assess information about sanitation non-compliances and other plant performance indicators when determining which operations should be tested, but with an emphasis on products that allow for growth of *L. monocytogenes.*

As FSIS obtains information on the effectiveness of establishment process controls for *L. monocytogenes*, the Agency should be able to reduce the intensiveness of verification testing at establishments with more effective controls.

Generally, FSIS expects to collect for *L. monocytogenes* testing just one sample unit of RTE product from a production lot at an establishment selected for sampling. FSIS is considering taking more than one product sample from an establishment that produces product without post-lethality treatments or growth inhibitors, particularly deli meat and hotdog operations. Finally, FSIS expects to collect food contact surface samples and environmental samples mainly from operations that have a history of problems associated with the proper control for *L. monocytogenes*, or that produce RTE products, particularly deli meats and hotdogs, that allow for the growth of *L. monocytogenes.*

IX. Consumer Outreach Effort

Food safety education is one risk management strategy FSIS uses to reduce the incidence of illness associated with *L. monocytogenes* in RTE meat and poultry products. Safe handling, storage and preparation of RTE meat and poultry products can help reduce the risk of illness, particularly for those populations most at risk of contracting listeriosis: pregnant women, newborns, older adults, people with weakened immune systems caused by cancer treatment, AIDS, diabetes, kidney disease, and organ transplants. FSIS reaches these audiences through printed materials, the FSIS Web site, electronic communication, the media, and other information multipliers, in collaboration with other Federal agencies, educators, and healthcare professionals, and through the USDA Meat and Poultry Hotline.

For example, FSIS has worked with the Association of Women's Health, Obstetric and Neonatal Nurses, the International Food Information Council Foundation, FDA, and CDC to produce a patient education sheet, ''Listeriosis and Pregnancy: What is Your Risk?'' targeted to both pregnant women and

their healthcare providers. The Spanish version will be printed in spring 2003. In addition, FSIS is completing a low literacy flyer aimed at pregnant women entitled, ''Protect Your Baby and Yourself from Listeriosis'' with input from WIC nutritionists, public health nurses, and extension food safety specialists. To reach other vulnerable groups, discussions are underway with transplant organizations, community health clinics, geriatric organizations, dialysis centers, and AIDS/HIV care organizations to determine how best to reach these individuals. Through the newly launched Food Safety Education Mobile, informational materials will be distributed as the vehicle travels throughout the country.

In addition to providing education on safe food handling, FSIS will provide information to consumers regarding new labels that processors may voluntarily use under this regulation to inform consumers of interventions used to reduce contamination.

X. Executive Order 12866 and Effect on Small Entities

This interim final rule has been reviewed by the Office of Management and Budget under E.O. 12866 and has been determined to be economically significant. FSIS is amending the Federal meat and poultry inspection regulations by adding requirements for establishments that produce certain RTE meat and poultry products to take measures to prevent product adulteration by the pathogen *L. monocytogenes.* Establishments that produce RTE meat and poultry products that are exposed to the environment after lethality treatments must include in their HACCP plans or their Sanitation SOPs or other prerequisite programs measures designed to prevent product adulteration by *L. monocytogenes.* The establishments also must share with FSIS all data relevant to the validation, operation, and verification of their controls for *L. monocytogenes.*

This action is compelled by outbreaks of foodborne illness in which RTE meat and poultry products contaminated with *L. monocytogenes* were implicated, coupled with information on the pathogenicity of the organism and the findings of the risk assessment and risk ranking conducted by FDA and FSIS. Although FSIS now routinely conducts food contact surface and environmental sampling in select establishments that produce such products, and performs product testing in nearly all RTE establishments for the presence of this pathogen before the products are distributed, until now there have been no specific regulatory requirements for controlling the pathogen. Appendix A, published at the end of this interim final rule in this issue of the **Federal Register**, contains the final regulatory analysis required by E.O. 12866 and the Regulatory Flexibility Act (at 5 U.S.C. 604), including a discussion of the need for the regulations, regulatory alternatives considered by FSIS, and a cost-benefit analysis. This interim final rule provides affected small and very small establishments with the flexibility to minimize the costs associated with this rule by implementing Sanitation SOPs or other prerequisite programs. FSIS is providing compliance guidance for these establishments in accordance with the Small Business Regulatory Enforcement Fairness Act. In addition, in verifying compliance with this interim final rule, the Agency plans to conduct testing at modulated frequencies, taking into account all relevant factors, including the alternative employed to address *L. monocytogenes*, production volume by type of RTE product produced, and the establishment's compliance history.

Summary of Final Regulatory Impact Analysis (FRIA)

Benefits

FSIS has estimated the benefits of this interim final rule in terms of averted deaths and illnesses resulting from actions taken by establishments that produce RTE meat and poultry products so far with respect to only one product group: Deli meats. FSIS has concentrated on this product group for several reasons: The FDA/FSIS risk ranking identified deli meats as posing the most overall risk to public health. The FSIS in-plant risk assessment tied risk mitigation actions to possible reductions in deaths and illnesses from listeriosis when the FSIS risk assessment model was calibrated with the FDA/FSIS risk ranking model, and when containment strategies for *Listeria* contamination of RTE meat and poultry products were simulated. The FSIS risk assessment model has been presented to the public, along with estimates of reduced listeriosis mortality resulting from actions taken by establishments that prepare or process the products.

The FRIA relies on results from the FSIS in-plant risk assessment model and considers the adoption by large, small, and very small deli-meat producing establishments of stratagems of varying rigor for controlling *L. monocytogenes.* The analysis shows that adoption of *L. monocytogenes* mitigation measures induced by this interim final rule results in a total median reduction of deaths from listeriosis of 27.3; with 8.9 deaths averted at the 5th percentile and 31.2 at the 95th percentile. These gains are attributable to an expected shift—discussed in detail in Appendix A—of establishments from sanitation-only to ''Alternative 1'' and ''Alternative 2'' methods of addressing *L. monocytogenes.* The corresponding reductions in illnesses are 136.7 at the median, with 44.6 at the 5th percentile, and 156.0 at the 95th percentile.

Using a method used by USDA's Economic Research Service (ERS) for estimating the human health benefits of reduced listeriosis, the benefits of the reduction in illness-related losses due to the interim final rule are estimated to be $3.7 million at the median ((.05 x 136.7 x $10,300) + (.95 x 136.7 x $28,300)) and $1.3 million at the 5th and $4.4 million at the 95th percentile.

ERS estimated the value of statistical life at $4.8 million [7] as a proxy for the cost of one fatality. Based on this estimate, the annual human health benefits from implementation of the interim final rule are $134.9 million at the median (the $3.7 million above plus $27.3 \times $4.8 million) and $44.0 million at the 5th percentile and $154.0 million at the 95th percentile.

Given the limitations in data and the fact that the risk assessment addresses only deli meats, FSIS believes that this estimate may be overstated by at least 50 percent. If so, the adjusted annual net benefits then become $50.8 million at the median, $5.4 million at the 5th percentile, and $60.4 million at the 95th percentile. FSIS performed a sensitivity analysis on the benefits estimates. Given the cost estimates, the total benefits of this rule would have to be 85 percent lower than estimated for the net benefits to lower to zero.

Cost Impacts

FSIS estimated the cost impacts of this interim final rule on all affected establishments. The FRIA adds several cost impacts in addition to those considered in the preliminary regulatory impact analysis (PRIA). The PRIA identified major cost impacts from mandatory food contact surface testing, HACCP plan modification, and production adjustments. In addition to these and in response to comments, the FRIA considers the costs, both fixed and recurring, associated with the installation by establishments of post-lethality treatments; the costs, both fixed and recurring, associated with product formulation or process changes to include antimicrobial agents or processes that limit the growth of *L. monocytogenes*; and the costs to establishments required to hold and test products pending confirmation of

positive food contact-surface tests for *Listeria* species.

FSIS estimates that the interim final rule will have combined one-time and recurring costs to large establishments totaling about $15.9 million, to small establishments about $55.3 million, and to very small establishments about $1.7 million. FSIS assumes a 10-year useful life for the changes (*e.g.*, post-lethality treatment validation, installation, antimicrobial agent or process alteration, and production adjustments) for which establishments incur one-time costs and, using a 7-percent discount rate, the Agency annualizes these one-time costs over the useful life of the changes. Adding these to the annual recurring costs, FSIS obtains annualized industry-wide costs of the interim final rule to large establishments of about $3.6 million, to small establishments about $12.5 million, and to very small establishments about $613,000.

The grand total of industry-wide annualized costs is $16.6 million. With the 50 percent downward adjustment discussed above, net benefits of $50.8 million at the median and ranging from $5.4 million at the 5th percentile to $60.4 million at the 95th percentile are to be derived from the interim final rule.

Paperwork Reduction Act

FSIS has reviewed the paperwork and recordkeeping requirements in this interim final rule in accordance with the Paperwork Reduction Act and has determined that the paperwork requirements respecting the regulations that may cause establishments to evaluate and revise their Sanitations SOPS, HACCP plans, and prerequisite programs have already been accounted for in the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Systems information collection approved by the Office of Management and Budget (OMB). The OMB approval number for the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Systems information collection is 0583–0103.

The requirement that may cause establishments to test for *L. monocytogenes*, to document their testing protocols and their hold-and-test procedures, and the requirement for establishments that produce RTE products to provide FSIS with production volume information by product type and *L. monocytogenes* control alternative are new information collections.

Title: Listeria.

Type of Collection: New.

The paperwork and recordkeeping requirements in this interim final rule are awaiting approval by the Office of Management and Budget.

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this interim final rule in accordance with the Paperwork Reduction Act. Under this interim final rule, FSIS is requiring an information collection activity. FSIS is requiring that establishments that produce ready to eat product annually report the estimated production volume by product type and *Listeria* control alternative employed. FSIS is also publishing requirements for RTE establishments to conduct, and plans to ask them to report on, food-contact surface sampling. In addition, FSIS is establishing requirements that may cause some RTE establishments to hold and test product for *L. monocytogenes* and other indicator organisms.

Estimate of Burden: FSIS estimates that the time to collect and report the required information on the estimated volume of RTE product by product type and *Listeria* control method is one hour. The Agency estimates that it will take establishments 50 minutes to collect the information necessary to make the required estimates and 10 minutes to report the information by form.

FSIS estimates that it will take 25 hours to develop a microbiological sampling and testing plan to support the efficacy of the sanitation controls, including the development of test-and-hold procedures. The Agency estimates that it will take two hours to revise microbiological sampling and testing plans. And FSIS estimates that it will take an average of 30 minutes to conduct a food contact surface test and an average of 30 minutes to collect information on product samples for test and hold procedures.

Respondents: Meat and poultry product establishments that produce Ready to Eat product.

Estimated Number of Respondents: 4,975.

Estimated Number of Responses per Respondent: 10.

Estimated Total Annual Burden on Respondents: 154,243 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th Street, SW., Washington DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' 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; 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 may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

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

Government Paperwork Elimination Act (GPEA)

FSIS is committed to achieving the goals of the GPEA, which requires Government agencies, in general, to provide the public with the option of submitting information or transacting business electronically to the maximum possible extent. FSIS is making available to establishments affected by this interim final rule an electronic form by which they may provide the required production volume information. The form will be accessible on a special page on the FSIS Web site at *http://www.fsis.usda.gov*; log-on and authentication instructions will be provided. Each establishment's submission will be treated as confidential. Provision of this electronic form is expected to enable the Agency more efficiently to gather, and affected establishments to report, the needed information.

This electronic data collection is intended to meet Goal 4 of the e-Government strategy in the President's Management Agenda. The electronic filing option is provided to reduce data collection time and information processing and handling for the regulated industry and FSIS.

This electronic data collection is intended to be consistent with Goal 2 (enhancing collaboration with public and private sector organizations to develop and deliver USDA's mission) and Objective 2.4 of the Department's e-Government Strategic Plan in that it reduces time necessary for information collection and processing for both regulated establishments and FSIS. A further, related initiative, providing for use of electronic signatures and authentication, will be consistent with the Department-wide strategies and

policies to develop and implement e-signature and e-Authentication policies.

1. The interim final rule on *L. monocytogenes* control in ready-to-eat meat and poultry products contains a requirement for official establishments that prepare post-lethality exposed ready-to-eat meat and poultry products to provide FSIS at least annually with data on the volume of production of products they prepare in processes that are covered by the interim final rule. FSIS is developing a form by which to collect the data. The form will be made available to establishments in both paper and electronic formats. The electronic form will be available for use by affected establishments at all times after the rule becomes effective.

2. FSIS can use its existing information technology resources in the electronic data collection. That is, the Agency plans to use its existing database applications and server storage to house the data collection form and associated databases. FSIS estimates that no more than $1,000 in materials and 0.25 FTE annually at the level of a GS–13 or equivalent staff officer grade in FSIS'S Data Analysis Systems and Support Staff, Office of Policy and Program Development, will be required to administer the data collection.

FSIS is developing a centralized system known as the FSIS Automated Corporate Technology Suite (FACTS) for which approximately $15 million has been earmarked. The system will provide, among other things, facilities for accessing Agency electronic forms and for processing the data collected through such forms. The new production volume form can be integrated with FACTS.

3. FSIS plans to use e-signature and e-Authentication methods that are consistent with Department e-Authentication policy.

4. Regarding information security, FSIS plans to provide ordinary levels of protection for the production volume information obtained. Establishment-linked information will be treated as confidential and stored in password-protected databases and electronic systems to which only authorized personnel have access. Information in paper format will be stored under lock and key in file boxes or cabinets to which only authorized personnel have access. FSIS does not envision a need for sophisticated security or encryption systems to protect this information.

5. For the purpose of this information collection, FSIS does not foresee a need for telecommunications systems additional to those already operated by the Agency.

6. The interim final rule does not specifically address recordkeeping by establishments but only data reporting. The data collected will be stored in a protected database managed by FSIS.

XII. E. O. 12988 Civil Justice Reform

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jursidicitons are preempted by the FMIA and the PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, that are not at such an establishment, after their entry into the United States. This proposed rule is not intended to have retroactive effect.

Administrative proceedings will not be required before parties may file suit in court challenging this interim final rule. However, the administrative procedures specified in 9 CFR 306.6 and 381.35 must be exhausted before any judicial challenge of the application of the provisions of this interim final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

XIII. Additional Public Notification

Public awareness of all segments of policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this interim final rule, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update.

The Constituent Update provides information on FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. These include industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. The Constituent Update is available on-line through the FSIS Web page located at *http://www.fsis.usda.gov/OA/update/update.htm.*

The FSIS Constituent Update is issued via the USDA-FSISConstituentsListserv to over 400 organizations and individuals on a weekly basis. FSIS also issues other communications on the Listserv, including news releases, recall notices, and Constituent Alerts on important issues. Persons interested in subscribing to the Listserv can do so by completing a form at *http://www.fsis.usda.gov/OA/update/subscribe.asp.*

XIV. Final Regulations

List of Subjects in 9 CFR Part 430

Food labeling, Meat inspection, Poultry and poultry products inspection.

■ Accordingly, title 9, chapter III, of the Code of Federal Regulations is amended as follows:

■ 1. A new part 430 is added to read as follows:

PART 430—REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

Sec.

Authority: 7 U.S.C. 450; 7 U.S.C. 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

§ 430.1 Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes,* or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes,* in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an

antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called ''prerequisite'' because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

§ 430.4 Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products.

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface which is contaminated with *L. monocytogenes.*

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) *Alternative 1.* Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product *and* an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes.* If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with § 417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes.*

(2) *Alternative 2.* Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product *or* an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes.* If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with § 417.4. The establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes.*

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes,* its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) *Alternative 3.* Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an

indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) Further, in order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes,* the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes.* The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with § 417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with § 416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section.

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

Done in Washington, DC: June 2, 2003.

Garry L. McKee,

Administrator.

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

Appendix A

Final Regulatory Impact Analysis

FSIS is amending its regulations to require that official establishments that produce certain ready-to-eat (RTE) meat and poultry products (MPPs) take measures to prevent product adulteration by *L. monocytogenes (Lm).* These amended regulations primarily affect establishments that produce RTE MPPs that are exposed to the environment following lethality treatment and that support the growth of *Lm.*

The final rule takes into account the differences in the risk of *Lm* contamination by type of RTE MPP product and by the manner in which the pathogen is controlled in the production process. It takes into account these differences by identifying four alternative *Lm* control approaches applying to RTE MPPs that are exposed to the plant environment after undergoing a process that is lethal to the pathogen. Each alternative involves a different level of pathogen control and to each there corresponds a preferred level of monitoring and verification, based on science and the nature of the product.

Need for the Rule

This action is compelled by recent outbreaks of food borne illness related to the consumption of adulterated RTE meat and poultry products, coupled with information on the pathogenicity of the organism and the findings of the risk assessment and risk ranking conducted by FDA and FSIS. *Lm* contamination is often a result of post processing contamination or growth of the organism after it leaves the Federal establishment. FSIS concluded before beginning this rulemaking that many establishments were not effectively implementing HACCP plans and Sanitation SOPs to prevent *L. monocytogenes* from contaminating the RTE product in the post-lethality processing environment.

Given the pathogenicity of *L. monocytogenes*, the opportunity for it to contaminate RTE product in the post-lethality environment, and the significant consequences that this contamination can have, FSIS is amending its regulations. The Agency is adding provisions that require establishments that produce post-lethality exposed RTE product to include in their HACCP plans or in their Sanitation SOPs or other prerequisite programs measures that prevent product adulteration by *L. monocytogenes*.

Market Failure. This final rule addresses a market failure. Market failures occur when resources are misallocated or allocated inefficiently. Markets fail, in the current case, because processors may not always be provided with sufficient incentives to allocate the additional resources and efforts needed to provide effective prevention methods for pathogen contamination in their products. These incentives are lacking because consumers cannot identify (and reward) those firms that produce RTE MPPs and are implementing the desired food safety safeguards. Therefore, consumers are unable to distinguish these products from those produced by lower cost firms that are applying less effective pathogen prevention methods. The lack of information on the safety of the products produced by the establishments in this latter group is a major concern of this rule. The recent FSIS risk assessment clearly indicates that products from establishments that are not taking these precautions can lead to illness or death.

The provisions of this final rule are designed to provide establishments a choice of selected, proven technologies to minimize the presence of *Listeria* in their processing

environment. The use of these technologies and documentation of records on the environment of these establishments, brought about by this final rule, will provide the kind of information, and needed food safety assurance, that is lacking for consumers.

Rationale for the Approach Taken

The economic rationale for the requirements of the final rule is that it recognizes that a combination of interventions have been shown to be more effective that a single intervention and builds this into the framework of regulation. Second, the requirements recognize that the level of risk varies by product and how it is produced. Third, the requirements provide incentives for the establishment to adopt sanitation and testing practices that are most suitable for its products and processes. And lastly, these incentives for establishments have been shown to be preferable over mandatory requirements.

The FDA/FSIS risk ranking [1] found that RTE MPPs posed a moderate to high human health risk, particularly among vulnerable populations. These products include deli meats, hotdogs, meat spreads, pâté, and deli salads that include RTE meat or poultry products as components. The risk ranking indicates that among the RTE MPPs, deli meats pose an especially high risk.

The *FSIS Risk Assessment for L. monocytogenes in Ready-to-Eat Deli Meats* [2] (FSIS *Lm* risk assessment) estimated the reduction in fatalities among vulnerable populations from consuming contaminated deli meats that might be achieved through in-plant sanitation with verification testing regimes of increasing intensity. These results were compared with estimates for similar fatality reductions that might be achieved by applying post-lethality treatments or growth inhibiting additives or processes. Based on the finding of the FSIS *Lm* risk assessment, the Agency concluded that a combination of interventions, including sanitation coupled with verification testing, and the use of growth inhibitors, appears to be more effective in controlling *Lm* than a single intervention in these operations.

FSIS considered the findings of the FDA/FSIS risk ranking and the Agency's *Lm* risk assessment and the public comments that had been submitted on the Agency's proposed rule regarding control of *Lm* in RTE products. Many of the comments expressed opposition to proposed mandatory testing frequencies—either the frequencies themselves or the fact that they would be mandated. Instead of mandatory testing requirements, the Agency is requiring that establishments incorporate appropriate verification methods into their HACCP plan, Sanitation SOP, or prerequisite program. This approach provides establishments with incentives to test for *Lm* and the flexibility to implement control measures that are appropriate for the types of products produced and processing methods at the establishment.

The final rule sets out four alternative *Lm* control approaches. For the purposes of this analysis, FSIS has grouped the affected establishments according to their use of these *Lm* control approaches.

Changes Between the Proposed and the Final Rule

FSIS considered four regulatory options for this final rule that had been generated from comments on the proposed rule. The options were: (1) No action; (2) a sanitation performance standard for reduction of *Lm* in RTE MPPs; (3) mandatory testing frequencies for *Listeria* species on food contact surfaces different from the frequencies proposed; and (4) a warning label to inform consumers in vulnerable groups of the potential for *Lm* contamination.

FSIS determined that: (1) Comments supported a final rule; (2) scientific support for a sanitation performance standard was lacking; (3) mandatory testing frequencies were objectionable for reasons given in the comments; (4) a warning label would be inappropriate because, under the law, all RTE meat and poultry products must be not adulterated and thus safe for all consumers.

FSIS adopted a modification of the third option. It will require establishments to describe their testing programs in their HACCP plans or in their Sanitation SOPs or other prerequisite programs, as appropriate for products and processing technologies. It will also require establishments to set the frequency of their verification tests for *Lm* on food contact surfaces, but will not mandate a specific frequency. The *Lm* control alternative influences the frequency of verification testing at an establishment. Verification testing is expected to be most frequent for establishments that produce post-lethality exposed deli meats and hotdogs and rely exclusively on sanitation and verification testing to control *Lm*.

The final rule identifies four *Lm* control alternatives that are typical of industry practices. The purpose of these control alternatives is to link the usage of HACCP or sanitation procedures with the risk of *Lm* contamination based on the FDA/FSIS risk ranking and the FSIS *Lm* risk assessment. The control approaches are: (1) A HACCP-based post-lethality treatment plus *Lm* growth limiting measures; (2) a HACCP-based post-lethality treatment or *Lm* growth limiting measures; (3) solely sanitation and verification control measures in its post-lethality treatment and no *Lm* growth inhibiting measures—and producing a class of post-lethality exposed product that is not a deli product or a hotdog product; and (4) solely sanitation and verification control measures in its post-lethality treatment and no *Lm* growth inhibiting measures—and producing a class of post-lethality exposed product that is a deli product or a hotdog product. For the purposes of this analysis, FSIS has grouped all establishments producing RTE MPPs that are exposed post-lethality according to their current and expected use of these *Lm* control approaches and this analysis will refer to these establishment groups as establishment group (EG) 1 through 4.

The proposed rule would have required RTE MPP establishments to control *Lm* either in their HACCP plans or their Sanitation SOPs. The final rule requires establishments to include post-lethality treatments in their HACCP plans and allows them to have other types of *Lm* contamination controls in their HACCP plans or in their Sanitation SOPs or other prerequisite programs. This modification of the proposal is based on the finding that the establishment's use of a post-lethality treatment represents a determination by the establishment that *Lm* is a hazard reasonably likely to occur.

The prerequisite program provisions in the final rule respond to comments that the Agency should provide establishments with greater flexibility in implementing *Lm* contamination controls. In particular, RTE MPP establishments usually do not control post-processing contamination through HACCP alone, but through a variety of prerequisite programs.

In response to public comments, the final rule also does not mandate food contact surface (FCS) testing frequencies. Instead, the final rule sets out specific requirements, for Alternatives 2 and 3 for sanitation procedures that are included in HACCP plans, or in Sanitation SOPs or other prerequisite programs. Establishments are allowed to choose their own testing methods and frequencies for verifying the effectiveness of their procedures.

The sanitation procedure requirements for Alternative 3 establishments that process hotdog and deli meat products and control for *Lm* using sanitation procedures only, include hold-and-test provisions. These procedures are invoked when follow-up testing to verify corrective actions in response to *Listeria*-positive FCS test results. A second positive FCS test for *L. monocytogenes* or an indicator organism entails withholding from commerce product that was in contact with the contaminated surface. Shipments can resume when subsequent tests in the same area of the plant are negative. The product can be tested under a sampling plan that provides sufficient confidence to enable the product to be released into commerce. The requirements for Alternative 3 establishments that process deli meats and hotdogs represent a modification of the hold-and-test procedures that the proposal would have required (proposed § 430.4(b)) but imposes this requirement only on establishments producing hotdog and deli-meat type products. This particular change from the proposal is responsive to comments opposing mandatory testing frequencies and the proposed hold-and-test requirements, which would have applied to all RTE MPPs. The requirements for Alternative 3 establishments that process deli meats and hotdogs are also responsive to the FDA/FSIS risk ranking which identified hot dog and deli-meat products as posing a moderate to high risk for listeriosis on a per annum basis (as opposed to a per serving basis), and the FSIS *Lm* risk assessment which evaluated the risk-reduction effectiveness of various

[1] FDA, FSIS, CDC. ''Draft Assessment of the Relative Risk to public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods''. The document is available at *www.foodsafety.gov.*

[2] USDA, FSIS. ''Draft Risk Assessment for Listeria Monocytogenes in Ready-to-eat Deli Meat Products''. FSIS. March 2003. The risk assessment is available at *www.fsis.usda.gov.*

combinations of in-plant interventions, including FCS testing, with and without test and hold actions.

The final rule also differs from the proposal by requiring RTE MPP establishments to furnish FSIS with at-least-annual estimates of production volume by type of RTE MPP and by alternative *Lm* control program used. This change responds to comments on the proposed rule indicating opposition to the use of establishment size criteria in determining verification testing intensity and to information provided in the public comments indicating that there may not be a connection between establishment size and volume of production. These comments noted that production volume is dependent on factors other than establishment size, such as technology.

Finally, the rule allows labels on RTE MPPs to show that the products were processed in a manner to eliminate, reduce, or limit the growth of *Lm*, provided that the claim is validated. This provision is not a regulatory requirement in that it does not mandate such labeling, but is intended to encourage the industry to implement effective *Lm* controls and to provide useful information to consumers, especially vulnerable subpopulations.

Coverage

FSIS found that that the final rule will affect 2,930 federally inspected RTE MPP establishments and about 2,046 State-inspected establishments. About 144 of these establishments are considered large, 1,276 small and 3,556 very small, using the size criteria adopted by FSIS in implementing the HACCP regulations. FSIS was able to determine that the baseline numbers of federally and State-inspected establishments in the respective *Lm* control groups 1 through 4 are, respectively: 49; 2,297; 1,864; and 766. These numbers are expected to change as a result of this rule.

FSIS was further able to determine that, because of the intensity of verification testing that sanitation-and-testing establishments would have to implement to ensure that product contaminated with *Lm* is not shipped, a certain percentage of establishments in this group are likely to decide to put their *Lm* controls in their HACCP plans or to adopt *Lm* growth suppressing or limiting methods. They would decide, therefore, to ''move or migrate'' into the grouping of establishments that take either the first or the second *Lm* control approach. The number of establishments in establishment groups 1 through 4 is expected to be 95, 2,363, 1,864, and 654, respectively, after the final rule goes into effect. The expected movement among establishment groups is discussed in detail in a later section.

The numbers of establishments in each of these *Lm* control groupings will determine the allocation of FSIS inspection resources for *Lm* control verification. FSIS will verify that establishments that produce RTE products are carrying out *Lm* control procedures in their post-lethality processing areas as described in their HACCP plans or their Sanitation SOPs or other prerequisite programs, and that they are complying with the requirements of this final rule. In addition to verifying establishment *Lm* controls, the Agency will verify that any label claims regarding *Lm* control have been validated. The frequency of FSIS verification testing of establishment *Lm* controls is expected to be higher for each successive *Lm* control alternative. In other words, the frequency will be lowest for establishments that use control Alternative 1 and highest for establishments that use control alternative 3 and that produce deli meats and hotdogs.

Establishment Groups

Grouping by Control Method. For the purposes of this analysis, four establishment groups can be identified in the final rule. The four groups are composed respectively of the establishments choosing *L. monocytogenes* control Alternatives 1 through 3, and the deli meat- and hotdog-producing establishments choosing Alternative 3 (9 CFR 430.4(b)(1), (b)(2), (b)(3)(i) and (b)(3)(ii)):

Establishment Group One (9 CFR 430.4(b)(1)): Establishments apply a post-lethality (PL) treatment to their products or process and use a *Lm* growth inhibiting agent or process. Products produced by establishments in EG 1 are expected to present the least risk of possible *Lm* contamination of products because they use a combination of intervention measures. EG 1's HACCP, Sanitation SOP or other prerequisite program controls and FSIS's ''normal'' verification procedures are expected to provide information that is adequate to assure the establishment and FSIS inspection personnel that an adulterated product is not being produced.

Establishment Group Two (9 CFR 430.4(b)(2)): Establishments apply either a post-lethality treatment to their products or use a *Lm* growth inhibiting agent or process. Because establishments in EG 2 apply a PL treatment to their products or use a growth inhibiting agent or process, but not both, this group's products present a somewhat higher level of risk. They still would be considered ''safe'' with a high degree of certainty, but this final rule will provide additional assurance that the products are not adulterated by requiring EG 2 establishments to test food contact surfaces (FCSs) and make the test results available to FSIS.

Establishment Group Three (9 CFR 430.4(b)(3)(i)): Establishments use neither a PL treatment nor a growth inhibiting agent or process, but has Sanitation standard operating procedures (Sanitation SOP) or other prerequisite programs and produce a class of post-lethality exposed product that is not a deli product or a hotdog product.

Establishment Group Four (9 CFR 430.4(b)(3)(ii)): Establishments use neither PL treatments nor *Lm* growth inhibiting agents or processes in their RTE MPP production, but have Sanitation SOP or other prerequisite programs and produce a class of post-lethality exposed product that is a deli product or a hotdog product. Establishments in EG 4 produce RTE MPPs that have been identified in recent risk assessments as posing significant risk of *Lm* contamination in their post-processing environment and significantly contribute to illnesses and deaths. The *Lm* control measures for establishments in EG 4 are similar to those of EG 3, but FSIS feels that specific holding action requirements are justified to ensure that no adulterated product enters commerce when a second consecutive positive FCS test in the post-lethality processing environment of a EG 4 is found. A guide to the final rule requirements by establishment group is given in Table 1.

BILLING CODE 3410–DM–P

Table 1. Summary of final rule requirements by establishment group.

Item	Establishment Group			
	1	2	3	4
(1) Inclusion of a PL treatment to their product or process as a CCP in the establishment's HACCP plan.	R	R	NR	NR
(2) Validation of (1) as being effective in eliminating L. monocytogenes.	R	R	NR	NR
(3) Verification of (1) to be effective in accordance with 417.4 on a continuous basis and provision of them to FSIS.	R	R OR	NR	NR
(4) Apply a bacteriostatic agent or process that eliminates L. monocytogenes growth in the product.	R	R	NR	NR
(5) Validation of (4) as being effective in eliminating L. monocytogenes.	R	R	NR	NR
(6) Verification of (4) to be effective in accordance with 417.4 on a continuous basis and provision of them to FSIS.	R	R	NR	NR
(7) FCS testing with a frequency determined by the establishment to be effective.	NR	R	R	R
(8) Provision of FCS testing results to FSIS.	NR	R	R	R
(9) Establishment's sanitation plan explains how FCS is kept sanitary and free of L. monocytogenes.	NR	R	R	R
(10) Specific requirements on holding of each lot of product associated with two consecutive FCS positives, until two consecutive FCS negatives.	NR	NR	NR	R
NR = Not required; R = Required.				

BILLING CODE 3410–DM–C

Analysis of Costs

Number of Establishments. The preliminary regulatory impact analysis relied on the 1997 Census of Manufacturers for an initial count of RTE MPP establishment numbers. 1,630 establishments were identified as producing a RTE MPP. The estimated number of establishments affected by the proposed rule was expected to be fewer than the actual number total for many reasons, but chiefly because the Census classifies businesses according to their principal activity. In some cases, the production of RTE MPP might be a secondary activity. This undercounting was a major deficiency in the preliminary regulatory impact analysis (PRIA). FSIS has corrected this problem and is estimating the impacts of the final rule considering both federally and State-inspected establishments producing RTE MPPs.

Basing the analysis on a more realistic estimate of the number and types of establishments affected by the rule provides a better estimate of industry impacts. However, using this approach, the product-specific information, such as the value of production, that was available through Census data, cannot be used. Also, certain assumptions must be made in manipulating the data for both federally and State-inspected establishments to avoid double counting and to estimate HACCP process categories for RTE MPPs at State-inspected establishments.

FSIS used the 2001 Performance-Based Inspection System (PBIS) databases to identify Federal-inspected establishments that have at least one HACCP process category code (actually, the pertinent procedure code from FSIS's inspection system procedure guide) associated with a RTE MPP. The 2001 PBIS database showed that there were 2,930 federally inspected establishments with 3,556 HACCP process category codes associated with RTE MPPs. Establishments were grouped into HACCP establishment size categories by cross tabulating this data with the 2001 Enhanced Facilities Database (EFD). (HACCP establishment size categories have been defined since the publication of the PR/HACCP rule (61 FR 38806; July 25, 1996) as large: more than 500 employees; small: between 499 and 10 employees; and very small: Fewer than 10 employees or less than $2.5 million in annual sales.) To obtain the number of unique establishments in each HACCP process category code, the number of HACCP plans for each HACCP process code was divided by the average number of HACCP plans per establishment in each size category (bottom of Table 2).

The EFD identified 2,046 State-inspected RTE MPP establishments comprised of 1,992 very small establishments and 54 small establishments. To obtain an estimate of the product types produced at State-inspected plants, the total number of State-inspected establishments was distributed across the four HACCP process category codes in the same proportion that was found in federally inspected establishments (Table 3).

BILLING CODE 3410–DM–P

Table 2. Federally inspected RTE MPP establishments by HACCP process category code, 2002.				
Item	HACCP Establishment Size Category			Total
	L	S	VS	
O3E- Not heat-treated, shelf-stable	5	68	88	161
O3F- Heat-treated, self-stable	41	238	405	684
O3G-Fully cooked, not shelf-stable	122	1,079	1,319	2,520
O3I-Product w/ secondary inhibitors	9	68	72	149
Total HACCP plans	177	1,453	1,884	3,514
Total Unique Federally inspected Establishments	144	1,222	1,564	2,930
HACCP plans/establishment	1.23	1.19	1.20	1.20
"Adjusted" number of federally-inspected establishments by HACCP Process Category Code (Number of HACCP Process Category Codes by Size Category divided by HACCP plans/establishment)				
Item	L	S	VS	Total
O3E- Not heat-treated, shelf-stable	4	57	73	134
O3F- Heat-treated, self-stable	33	200	336	570
O3G-Fully cooked, not shelf-stable	99	907	1,095	2,101
O3I-Product w/ secondary inhibitors	7	57	60	124
Total Federal-inspected RTE MPP establishments	144	1,222	1,564	2,930

Table 3. State-inspected RTE MPP establishments by HACCP process category code, 2002.

Item	Distribution of federally-inspected establishments			
HACCP Process Category Code	HACCP Establishment Size Category			Total
	L	S	VS	
	Percent			
O3E- Not heat-treated, shelf-stable	2.8	4.7	4.7	4.6
O3F- Heat-treated, self-stable	23.2	16.4	21.5	19.5
O3G-Fully cooked, not shelf-stable	68.9	74.3	70.0	71.7
O3I-Product w/ secondary inhibitors	5.1	4.7	3.8	4.2
Total Federal-inspected RTE MPP establishments	100	100	100	100
Item	"Adjusted" number of State-inspected establishments			
O3E- Not heat-treated, shelf-stable	0	3	93	96
O3F- Heat-treated, self-stable	0	9	428	437
O3G-Fully cooked, not shelf-stable	0	40	1,395	1,435
O3I-Product w/ secondary inhibitors	0	3	76	79
Total State-inspected RTE MMP establishments	0	54	1,992	2,046

Table 4. Total number of RTE MPP Federally and State-inspected establishments by HACCP process category code, 2002.

Item	HACCP Establishment Size Category			Total
HACCP Process Category Codes	L	S	VS	
O3E- Not heat-treated, shelf-stable	4	60	166	230
O3F- Heat-treated, self-stable	33	209	764	1,007
O3G-Fully cooked, not shelf-stable	99	948	2,490	3,536
O3I-Product w/ secondary inhibitors	7	60	136	203
Total RTE MPP establishments	144	1,276	3,556	4,976

BILLING CODE 3410–DM–C

The total number of establishments producing RTE MPP products is estimated to be 4,976: 59 percent federally inspected and 41 percent State-inspected. Of the total, 4.6 percent are associated with the O3E HACCP code; 20.2 percent with the O3F code; 71.1 percent with the O3G code; and, 4.1 percent with the O3I code (Table 4). Further analysis of HACCP size categories shows that 71.5 percent of all RTE MPP establishments are very small; 25.6 percent are small; and, 2.9 percent are large.

Product groups. The PRIA classified RTE MPP establishments by the expected range of potential cost impact on those establishments: Those likely to incur the greatest costs, moderate costs, minor costs, and no likely costs (Table 3 in **Federal Register**, Vol. 66, No. 39). This grouping was based on the likely impact from both the proposed testing programs as well as the proposed changes in lethality and stabilization performance standards. The final rule concerns only that section of the proposed rule dealing strictly with FSIS's desire to increase safeguards with respect to possible *Lm* contamination. Because of this and also because products and production processes vary across the same product classification, it is not feasible to disaggregate in the fashion of the PRIA. However, it appears that the largest impact will be on establishments producing cooked RTE MPP products—those products associated with HACCP process code O3G. There is little likelihood that there will be any cost impact on RTE MPP establishments producing products in the O3E, O3F and O3I HACCP process codes, except for costs attributable to a possible increase in FCS testing mandated by the rule. These costs are expected to be minor because many of the establishments in the HACCP process category codes already apply an agent or process that inhibits *Lm* growth so many of these establishments ''qualify'' to be classified in EG 2.

Establishments associated with the O3G HACCP process category code produce cooked RTE MPPs which may or may not be able to apply post-lethality treatment to products, apply antimicrobial agents, or include procedures in either Sanitation SOPs or prerequisite programs. In some cases, FCS testing and disclosure of those results to FSIS may result in minor cost increases similar to those for 03E, 03F, and 03I HACCP process category codes. For other products in the 03G HACCP process code, they could be produced under any of the four alternative post-lethality *Lm* control regimes identified in this final rule. In those cases, the costs could be significantly higher. Accordingly, the cost impact discussion is presented by each establishment group, type of products produced, and their associated establishment numbers and size distribution.

Impacts according to establishment group. The Agency anticipates that the measures taken by establishments will differ by establishment group. The following describes the major types of responses expected to be taken in response to the final rule for those establishments switching establishment groups and/or validating current *Lm* controls.

EG 1 EG 2 Impacts

(1) *Incorporation of post-lethality treatments and/or their validation for FSIS:* Many establishments are currently using post-lethality measures to address possible *Lm* contamination. These actions may have been taken in response to client requirements, the recent FSIS *Lm* intensified verification program, or in anticipation of further FSIS action. The costs of these actions taken by establishments are not attributed to the final rule. However, measures taken to satisfy this requirement or to validate these measures to FSIS are attributed to the final rule. These measures include: Post-lethality heating (may not be feasible for many products, especially those with a high fat content); high-pressure systems, which may be limited to a few specialty items and usually have a low throughput; and irradiation, which is not permitted to be applied to RTE MPPs at present. FSIS expects establishments using post-lethality treatments to verify that their treatments are effective and also to monitor FCSs to assure that the treatment is effective. This level of verification FCS testing for establishments in EG 1 is expected to be about twice yearly.

(2) *Use of agent in product formulation or change in processes to inhibit* Lm *growth in product:* FSIS has recently permitted the use of certain food additives that inhibit *Lm* growth (65 FR 17128, March 31, 2000). These additives include lactate and diacetates that have been applied increasingly to cooked and cured RTE MPPs such as hotdogs. The cost to establishments of taking measures involving the use of these additives is not attributable to the final rule. The Agency estimates that up to 70 percent of all hotdog manufacturers have recently changed their product formulations to incorporate one of the recently permitted food additives. Changes in a process that would help inhibit the *Lm* growth in the product include: lowering the pH or water activity levels and refrigerating or freezing the product following processing. Growth inhibiting processes uses antimicrobial agents to control growth in post-lethality exposed products such as many hotdogs and certain other kinds of sausages. Verification FCS testing for establishments in EG 2 would be expected at least once per quarter. This level of testing would be expected whether the establishment administered a PL treatment or applied a *Lm* growth inhibiting agent or included a process in either a Sanitation SOP or prerequisite program.

EG 3 and EG 4 Impacts

(1) *FCS testing frequencies:* For the purpose of this analysis, the minimum level of FCS testing expected for establishments in EG 3 is at least once per month: once a month for high, once a month for small, and once a month for very small establishments. Also, the minimal level of FCS testing for EG 4 is: at least weekly for high-volume establishments, semi-monthly for small volume establishments, and monthly for very small (or low volume) establishments (4–2–1). These testing frequencies are illustrative in that the actual testing frequencies incorporated into final compliance guidelines may differ.

A potential unintended impact of the rule for establishments in EG 4 might be the incentive to reduce their current level of FCS testing if results are to be shared with FSIS. An establishment in this group may conduct fewer tests if results could lead to costly hold-and-test actions. This potential unintended impact was not be quantified in this analysis.

EG 4 Impacts

(1) *Hold and Test:* EG 4 establishments may be unable to (1) apply a post-lethality treatment or (2) apply an agent or include a process in either the Sanitation SOP or prerequisite program for a variety of reasons. Product from these establishments can be held on the basis of FCS testing results shared with the Agency. Multiple episodes of holding product may be incurred in the case of two consecutive positive FCS test results.

Baseline

Establishment Types. The compliance cost impacts of the rule differ significantly among establishment groups and by HACCP size category. The current distribution of establishments by group and size serves as the baseline for determining the distribution of compliance cost and also the starting point for the expected establishment shifts among establishment groups discussed below.

Table 4 indicates that 1,440 establishments produced RTE MPPs in the O3E, O3F, and O3I HACCP process category codes. For purposes of this analysis, these establishments are distributed 90 percent in EG 2 and 10 percent in EG 3. The high proportion in EG 2 is a result of the use of growth inhibitors in most of these products which include cured and salted products. These products have not been associated with listeriosis outbreaks.

The remaining 3,536 establishments in O3G produce cooked RTE MPPs that may be produced by any of the four Lm control methods. These establishments were partitioned into the four establishment groups as follows:

(1) From a December 2002 FSIS hotdog and deli meat survey, we know that there are 1,712 operations producing hotdogs and/or deli meats. Given that 38 percent of these operations produce both hotdogs and deli meats, the actual number of unique establishments involved is 1,061 ((1 − .38) × 1,712).

(2) The number of establishments producing cooked products other than hotdogs and/or deli meats was estimated by subtracting the number of single establishments producing hotdogs and/or deli meats from the total number of establishments producing cooked products (3,536 − 1,061 = 2,475).

(3) FSIS inspection program personnel were contacted to estimate the proportion of establishments producing hotdog/deli meat and other cooked products in each of the establishment groups. These estimates, provided in Tables 5 and 6, were used to partition the establishments producing hotdog and deli meats and the other cooked RTE MPPs by establishment group (Table 7).

BILLING CODE 3410–DM–P

Table 5. Percentage of hotdog and deli meat establishments by establishment group, 2002

Item	HACCP Establishment Size Category		
Establishment group	L	S	VS
1	0.15	0.05	0.03
2	0.65	0.30	0.12
3	0.00	0.00	0.00
4	0.20	0.65	0.85

Source: FSIS Hotdog and deli meat industry survey, December 2002.

Table 6. Percentage of remaining establishments in O3G Code by establishment group, 2002

Item	HACCP Establishment Size Category		
Establishment group	L	S	VS
1	0.00	0.00	0.00
2	0.75	0.50	0.25
3	0.25	0.50	0.75
4	0.00	0.00	0.00

Source: FSIS inspection program personnel, January 2003.

Table 7. Total number of RTE MPP Federally and State-inspected establishments by establishment group, 2002.

Item	HACCP Establishment Size Category			
Establishment Group	L	S	VS	Total
1	9	24	16	49
2	108	675	1514	2297
3	13	269	1581	1864
4	13	308	445	766
Total RTE MPP establishments	143	1276	3556	4976

BILLING CODE 3410–DM–C

Health Consequences. The baseline for comparing human health benefits associated with the rule is established by the ''Draft FSIS Risk Assessment for *Listeria Monocytogenes* in Ready-to-eat Deli Meat Products''[3] (*Lm* Risk Assessment). The *Lm* Risk Assessment concludes that 320 deaths are attributable to RTE deli meats. It is not possible at this time to identify the number or deaths attributable to RTE MPPs, which in addition to deli meats includes hotdogs, fermented sausages, and related products.

The FDA/FSIS risk ranking model[4] estimates that there are about 340 billion servings of all RTE products consumed per year. RTE MPPs are contained within the following classes: reheated franks, non-reheated franks, deli meats, fermented sausages, pâté, and deli-salads. These classes comprise about 43 billions servings. The deli meat class is responsible for 49 percent of the 43 billion servings of RTE MPP. The two hotdog classes are together responsible for 15 percent of the servings of RTE MPP. Based on these estimates, there could be as many 375 annual fatalities associated with RTE MPPs.

The *Lm* Risk Assessment, because of its focus on deli meats, is only able to estimate the human health benefits associated with the rule as it affects this category of products. For purposes of establishing a baseline for potential human health benefits, deli meats are divided into two categories: Products sliced and packaged at the establishment; and retail sliced product. Pre-packed products are post-lethality exposed and the focus of the regulation. Retail-sliced products are not post-lethality exposed until prepared for use or sale at a retail location. The human health exposure to each type of product is a function of its share of total RTE deli meats consumed and the level of contamination in each type of product. Actions by FSIS can reduce the exposure to some, but not all RTE deli meat.

The Economic Research Service estimates that pre-packaged product accounts for 46 percent ($11.6 billion) of total sales of RTE deli meats ($25.2 billion) and retail sliced product the remaining 54 percent ($13.6 billion).[5] Volume of product in the categories would provide a more suitable basis for establishing a baseline level.

There is considerable uncertainty about the level of contamination in each type of product when purchased. A recent study by Gombas, Chen, Clavero, and Scott[6] finds that there is a 0.4 percent prevalence rate for *Lm* in pre-packaged product and a 2.7 percent prevalence rate for *Lm* in retail sliced product at the retail level. If 0.4 percent of pre-packaged product was found to be contaminated at the processing plant, it follows that 0.4 percent of the 2.7 percent prevalence rate at retail might be due to contamination at the processing site. That means that the prevalence of product solely contaminated during retail slicing is 2.3 percent (the observed 2.7 percent minus the 0.4 percent that was contaminated at the processor site). Using this information and the relative market share weights for pre-packaged and retail sliced deli meats from ERS provides a weighted average exposure rate for deli meats: .004(0.46) + 0.004(0.54) + .027 (.54) = .0164 or, .004 + .01242 = .01642

The pre-packaged product share of the weighted average exposure rate is 24.4 percent (.004/.01642 = 0.2436) and the retail sliced product share is the remaining 75.6 percent. Therefore, the human health baseline risk which the FSIS can affect at federally inspected establishments is a potential maximum 78 deaths (24.4×320).

The Agency has several concerns about this approach to establish a baseline level of human health risk. The prevalence levels estimated by Gombas, *et al.* and based on National Food Processing Association (NFPA) Survey data, taken at retail establishments, are significantly lower than those found by FSIS and reported in the *Lm* Risk Assessment Model. Levine, *et al.*[7] reported 1999 prevalence levels of *Lm* at 2.71 percent for cooked, roast, and corned beef and 4.58 percent in sliced ham and other pork luncheon meats. All samples were collected at production facilities, not at retail. The prevalence levels from the NFPA and FSIS studies are not entirely comparable, but they do seem to be inconsistent, even after taking into account basic limitations in the data used in both studies. The NFPA survey data describe the difference in prevalence between product contaminated at processing and product contaminated at retail. It is important to recognize that some of the product found contaminated at retail was contaminated at the processor but was only detected at retail. It is difficult to reconcile FSIS product sampling which finds 2.7–4.6 percent of RTE meats positive for *Lm,* with the finding based on the NFPA survey data that only 0.4 percent of packaged RTE meats are positive at retail outlets. Some net growth, not dying off, of *Lm* within contaminated packages between processor and retail is expected. The Agency concludes that there is much uncertainty about the true proportion of products contaminated at the processor and at the retail facility and among products affected by the rule and not affected by the rule.

All things considered, the Agency concludes that it is appropriate to make at least a 50-percent reduction in the potential deaths and illnesses averted due to *Lm* control measures taken by RTE MPP establishments as a result of this rule (versus the 24.4 percent based on the estimate presented). This percentage takes into account the study by Gombas, *et al.*, and discussions with FSIS industry experts, risk assessors, and microbiologists. Consequently, the maximum potential reduction in fatalities achieved through Agency measures for RTE deli meat products is 180 ($320 \times .5$). This level would be somewhat higher if hotdogs, fermented sausage, and related products were included in the *Lm* Risk Assessment.

Expected Movement Among Establishment Groups

There are six major industry cost impacts that are expected with the final rule. Most of these impacts arise because some establishments are expected to shift into establishment groups that entail different technologies than they currently employ. These shifts are attributed to compliance with requirements of the rule. Costs are estimated on the basis of such shifts among the establishment groups. The movements among establishment groups are based on the experience and judgment of FSIS personnel which were pooled together to produce certain guidelines to estimate the expected movement of establishments across establishment groups, depending on their establishment size. For large establishments, it is expected that, based on this collective judgment, 20 percent of the establishments in EG 2 (that were already applying a PL treatment and referred to as EG 2A) would move into EG 1 (Table 8). These seven establishments already had the necessary equipment for these treatments, but simply had not validated their use. Therefore, only very little additional cost was involved for these establishments to move into EG 1 (along with the adoption of applying a *Lm* inhibiting agent or process). A 10-percent shift in establishments in EG 2B and EG 4 is expected because these establishments have not incurred the high initial costs of the post lethality equipment, resulting in a shift of seven establishments from EG 2B and two from EG 4. No establishment shifts in EG 3 are anticipated. In total, the application of these guidelines produced an increase of 16 establishments in EG 1 (Table 9).

BILLING CODE 3410–DM–P

[3] USDA, FSIS. ''Draft Risk Assessment for Listeria Monocytogenes in Ready-to-eat Deli Meat Products''. FSIS. March 2003. The risk assessment is available at *www.fsis.usda.gov.*

[4] FDA, FSIS, CDC. ''Draft Assessment of the Relative Risk to Public Health from Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods''. The document is available at *www.foodsafety.gov.*

[5] The estimate is based on information from the A.C. Nielson Co. 2001 Consumer Expenditures Study as reported in *Progressive Grocer,* September, 2002. The data sources are: supermarket checkout scanner data from a representative sample of 10,000 U.S. supermarkets, a representative consumer panel consisting of 55,000 households, and *Progressive Grocer* estimates.

[6] ''Survey of Listeria monocytogenes in Ready-to-Eat Foods'', *Journal of Food Protection* 66 (H): 559–569.

[7] Levine P, Rose B, Green S, Ransom G, and Hill W (2001). Pathogen testing of ready-to-eat meat and poultry products collected at federally-inspected establishments in the United States, 1990 to 1999. Journal of Food Protection 64(8):188–1193.

Table 8.Rules employed in estimating large establishment shifts across establishment groups.

	Went to:				Came from:		
Estab. Group	1	2A	2B	4	2A	2B	4
1	NA	--------	----------	--------	20% of 34	10% of 74	10% of 13
2A /1	2A-1 above.	NA	----------	--------	----------	----------	----------
2B /1	2B-1 above.	--------	NA	--------	----------	----------	25% of 13
3	----------	--------	----------	--------	----------	----------	----------
4	4-1 above.	--------	4-2B above.	NA	----------	----------	----------

/1 2A refers to those establishments applying only a PL treatment; 2B refers to those establishments applying only a Lm inhibiting agent or process to their product or process.

Table 9. Absolute levels and changes in large establishments across establishment groups.

Item	Start and End Levels			Went to:					Came from:			
Estab. Group	Old	New	Change	1	2A	2B	4	Total	2A	2B	4	Total
1	9	25	16	0	0	0	0	0	7	7	2	16
2A /1	34	27	-7	-7	0	0	0	-7	0	0	0	0
2B /1	74	70	-4	-7	0	0	0	-7	0	0	3	3
3	14	14	0	0	0	0	0	0	0	0	0	0
4	13	8	-5	-2	0	-3	0	-5	0	0	0	0
All Estab.	144	144	0	-16	0	-3	0	-19	7	7	5	19

/1 2A refers to those establishments applying only a PL treatment; 2B refers to those establishments applying only a Lm inhibiting agent or process to their product or process.

BILLING CODE 3410–DM–C

For small establishments, the combination of the high cost of technologies involved in EG 1 and/or EG 2 plus their limited volume of production is expected to lower their propensity for establishments to shift to another establishment group. Also, characteristics of their products and their production are expected to limit establishment shifts. Because of these constraints, it is expected that only 31 establishments (or 10 percent of the small establishments in EG 4) are likely to migrate to EG 1 as a result of the final rule (Table 10). Recall that all such movement involves the purchase and use of new technology. For most of these establishments, the option of adding a *Lm* inhibiting agent or process is probably a more attractive, least-cost option. As a result, 25 percent of the existing number of small establishments in EG 4 (or 77 establishments) is expected to shift into EG 2. No small establishments in EG 3 are expected to shift establishment groups. In total, 108 small establishments are expected to shift from EG 4 into either EG 1 or EG 2 (Table 11).

BILLING CODE 3410–DM–P

Table 10. Rules employed in estimating small establishment shifts across establishment groups.

	Went to:				Came from:		
Estab. Group	1	2A	2B	4	2A	2B	4
1	NA	--------	----------	--------	----------	----------	10% of 308
2A /1	----------	NA	----------	--------	----------	----------	----------
2B /1	----------	--------	NA	--------	----------	----------	25% of 308
3	----------	--------	----------	--------	----------	----------	----------
4	4-1 above.	--------	4-2B above.	NA	----------	----------	----------

/1 2A refers to those establishments applying only a PL treatment; 2B refers to those establishments applying only a Lm inhibiting agent or process to their product or process.

Table 11. Absolute levels and changes in small establishments across establishment groups.

Item	Start and End Levels			Went to:					Came from:			
Estab. Group	Old	New	Change	1	2A	2B	4	Total	2A	2B	4	Total
1	24	55	31	0	0	0	0	0	0	0	31	31
2A /1	114	114	0	0	0	0	0	0	0	0	0	0
2B /1	561	638	77	0	0	0	0	0	0	0	77	77
3	269	269	0	0	0	0	0	0	0	0	0	0
4	308	200	-108	-31	0	-77	0	-108	0	0	0	0
All Estab.	1276	1276	0	-31	0	-77	0	-108	7	7	108	108

/1 2A refers to those establishments applying only a PL treatment; 2B refers to those establishments applying only a Lm inhibiting agent or process to their product or process.

BILLING CODE 3410–DM–C

For very small establishments, the combination of high costs associated with technologies necessary to "qualify" for EG 1 or EG 3 and the nature of their product or production is expected to make it highly unlikely that any establishment will move into a different establishment group as a result of this final rule. The total expected establishment movements expected as a result of this final rule are given in the table below (Table 12).

Table 12. Changes in all establishments across establishment groups.

Item	Establishment Size			
Establishment Group	Large	Small	Very Small	Total
1	16	31	0	+47
2A /1	-7	0	0	-7
2B /1	-4	77	0	+73
3	0	0	0	0
4	-5	-108	0	-113
All Establishments	0	0	0	0

/1 2A refers to those establishments applying only a PL treatment; 2B refers to those establishments applying only a Lm inhibiting agent or process to their product or process.

Cost to validate a post-lethality treatment for establishments in EG 1 and EG 2. It is expected that 43 HACCP plans of 35 establishments (of the original 49 establishments in EG 1) will need to be validated (Table 13). This represents only

about 15 percent of all the HACCP plan validations that will occur as a result of the final rule. This number of HACCP plan validations is based on a 50-percent validation rate currently being attained by large establishments, 30-percent rate by small, and a 10-percent rate by very small establishments. These rates are based on information that FSIS obtained from industry sources and in its public meetings related to the proposed rule and Lm risk assessment. Given the high relative numbers of small and very small establishments whose HACCP plans require validation, the total number of establishments affected is 35.

The major impact of the need for HACCP plan validation occurs in establishments already in EG 2 that have an unvalidated PL treatment (60 percent of all expected validation expenses incurred by establishments that already apply a PL treatment). To calculate this impact, establishments in EG 2 are grouped by the same validation rate used for EG 1 establishments above. To the extent that PL treatments are validated by the manufacturer, validation costs would be lower.

Some validation costs are incurred by establishments in EG 2 that are expected to move into EG 1 (20 percent of the large establishments that currently have a PL treatment and 10 percent of those that do not have a PL treatment in EG 2) and some establishments in EG 4 that are expected to move into EG 1 (10 percent of the large and small establishments currently in EG 4).

Table 13. Costs for validation of PL treatments as CCPs in HACCP plans

Item	HACCP Establishment Size Category			
	L	S	VS	Total
	$thousand			
Cost per Plan	20	10	5	
Existing EG 1 HACCP plans				
Number of plans	6	20	17	43
Number of establishments	5	17	14	35
	$thousand			
Cost	$116.6	197.4	85.2	399.2
Establishments in EG 2 moving to EG 1 incurred by establishments that already apply a PL treatment				
Number of plans	13	0	0	13
Number of establishments	10	0	0	10
	$thousand			
Cost	266.5	0	0	266.5
Establishments in EG 4 moving to EG 1				
Number of plans	2	37	0	39
Number of establishments	1	31	0	32
	$thousand			
Cost	31.1	366.6	0	397.7
Cost for existing EG 2 HACCP plans				
Number of plans	17	95	60	171
Number of establishments	14	80	50	143
	$thousand			
Cost	334.9	946.2	300.5	1,581.5
Total Number of HACCP Plan Validations and Cost				
Number of plans	37	151	77	266
Number of establishments	30	127	64	222
	$thousand			
Total Cost, EG 1 and EG 2	749.1	1,510.1	385.7	2,644.8

BILLING CODE 3410–DM–C

Cost to install a post-lethality (PL) treatment. Establishments in EG 1 and about half in EG 2 already have a PL treatment by virtue of being classified in that establishment group. Establishments in EG 4 and those in EG 2 that use an agent or have a process to control *Lm* do not necessarily have a PL treatment. Seven large establishments are expected to move from EG 2 to EG 1 and 1 large establishment moving from EG 4 will need to install PL treatments. 31 small establishments are expected to move from EG 4 to EG 1 and will make similar adjustments.

The Agency received comments to the proposed rule indicated that such investments, like high pressure processing units, cost up to $1.0 million to $1.5 million per unit. FSIS is using $1.5 million and $1.25 million as the expected capital costs of such equipment for large and small establishments, respectively. FSIS received comments regarding per-pound operating expenses for various post-pasteurization processes, but was unable to use this information because of the lack of data on average production per establishment. FSIS assumes annual operating expenses are 10 percent of the initial capital cost.

The changes in the industry (movement among establishment groups) reflected by the installation of post-lethality treatments are given in Table 14.

BILLING CODE 3410–DM–P

Table 14. Costs for post-lethality treatments, equipment and annual operating.

Item	HACCP Establishment Size Category			
	L	S	VS	Total
	$thousand			
PL Equipment Cost per Establishment	1,500.0	1,250.0	NA	NA
Establishments moving from EG 2 to EG 1				
Number of establishments	7	0	0	7
	$thousand			
Equipment cost	11,149.4	0	0	11,149.4
Establishments moving from EG 4 to EG 1				
Number of establishments	1	31	0	32
	$thousand			
Equipment cost	1,897.2	38,536.9	0	40,434.1
Total establishment movements to EG 1				
Number of establishments	8	31	0	39
	$thousand			
Total equipment costs	13,046.6	38,536.9	0	51,583.5
Annual operating costs	1,304.7	3,853.7	0	5,158.4
Total first year costs	14,351.3	42,390.6	0	56,741.9

BILLING CODE 3410–DM–C

Cost to add agent or alter process to inhibit Listeria growth in the final product. One of the major impacts of the rule is that it encourages establishments in EG 4 to move into EG 2 by adding an agent or altering their production processes to inhibit *Lm* growth in the product. Adding such treatments would eliminate the need for more frequent verification testing. It is expected that 25 percent of the large and small establishments in EG 4 will move to EG 2 by doing so—3 large and 77 small establishments. The costs associated with this impact are subject to several factors. They include each establishment's unique situation with respect to product type, facility size, and equipment. Assuming that the cost to add agents or alter a process includes a one-time cost of installing equipment to add agents or alter production processes of $150,000 for a large, $125,000 for a small, and $100,000 for a very small establishment, the initial treatment cost totals $10.1 million. Using an operating cost of 10 percent of the initial cost produces a corresponding annual outlay of about $1 million (Table 15).

Table 15. Costs for Lm growth inhibiting treatments or processes, initial and annual operating.

Item	HACCP Establishment Size Category			
	L	S	VS	Total
	$thousand			
Initial cost per establishment	150.0	125.0	100.0	
	Number of Establishments			
Establishments in EG 4 moving to EG 2	3	77	0	80
	$thousand			
Initial cost	474.3	9,634.2	0	10,108.5
Annual operating costs	47.4	963.4	0	1,010.9
Total costs	521.7	10,597.6	0	11,119.4

Cost of FCS testing for Listeria species. As with the third impact discussed above, the testing provisions of the rule encourage establishments to move from EG 4 into EG 1 and EG 2 (Table 16). These establishments are expected to be mostly small establishments attempting to avoid frequent FCS verification testing requirements for EG 4 establishments and the potential exposure to holding product upon two consecutive positive FCS verification test results. Almost half of the large establishments that were previously in EG 4 are expected to migrate either to EG 1 or to EG 2.

The costs of testing for the remaining 2,518 establishments in EG 3 and EG 4 are based on several assumptions. They include: the actual level of FCS verification testing being conducted at the present time, the percentage of establishments conducting this level of verification testing, the number of production lines by establishment size, and the costs of testing. The assumptions used in this analysis are supported by observations by FSIS inspection personnel and by various recent surveys conducted by FSIS and the industry. For example, in the recent FSIS hotdog and deli-meat survey, about 20 percent of large, 26 percent of small, and about 5 percent of very small establishments stated that they conducted FCS verification testing for *Listeria* spp. The *Lm* growth inhibiting processes and ingredients used in producing these products probably lowers the level of verification testing being conducted by establishments producing other RTE MPPs. Therefore, FSIS believes that the actual proportion of establishments in EG 3 and EG 4 that conduct FCS tests is probably double the proportions reported in the recent hotdog and deli-meat survey for the small and very small establishments. That is, FSIS assumes that the current FCS verification testing levels for large, small, and very small RTE MPP producing establishments are 100 percent, 50 percent, and 10 percent, respectively (*See* middle rows in Table 17).

BILLING CODE 3410–DM–P

Table 16. Number of Federally and State-inspected RTE MPP establishments by establishment group resulting from FCS testing provisions. (Numbers in parenthesis are baseline numbers from Table 7).

Item	HACCP Establishment Size Category			
Establishment Group	L	S	VS	Total
1	25 (9)	55 (24)	16 (16)	95 (49)
2	97 (108)	752 (675)	1514 (1514)	2363 (2297)
3	13 (13)	269 (269)	1581 (1581)	1864 (1864)
4	8 (13)	200 308)	445 (445)	654 (766)
Total establishments	143	1276	3556	4976

Table 17. Assumptions concerning FCS testing in EG3 and EG4

Item	HACCP Establishment Size Category			
Assumption	L	S	VS	Total
Assumed lines/establishment	6	4	2	
Observed average testing frequencies for those that conduct FCS testing (number of times per month)				
EG 3	1	1	1	
EG 4	4	2	1	
Proportion of establishments conducting FCS testing at above frequencies				
EG 3	1.00	0.50	0.10	
EG 4	0.90	0.50	0.10	
Number of tests not conducted by establishments not testing at the above frequencies				
EG 3	0	539	2846	3385
EG 4	20	802	802	1623
Total	20	1341	3647	5007
Cost of testing shortfall by EG 3 and EG 4 at above frequencies, ($35/test):	$thousand			
EG 3	0.0	18.9	99.6	118.5
EG 4	0.7	28.1	28.1	56.8
Total cost for increased FCS testing	0.7	47.0	127.7	175.3

BILLING CODE 3410–DM–C

Cost of Production Adjustments. As was discussed in the PRIA, it is expected that a series of *Lm* contamination events may occur in some establishments. The PRIA expected that most—about 85 percent—of the establishments that obtain one positive FCS test result could remedy the cause of the *Lm* contamination at no additional cost through more stringent sanitation and handling techniques. The remaining 15 percent of establishments are expected to encounter a greater degree of difficulty. Some of these establishments (as discussed in the PRIA) will probably encounter *Lm* contamination problems that could be remedied at a cost of $2,000 per line (these establishments consist of 7 percent of the establishments experiencing at least one positive FCS verification test result); another 7 percent are expected to encounter more serious contamination problems that would need to be remedied by actions costing up to about 1/10 of one percent of gross sales; and a final group made up of 1 percent of the establishments that discover that they have a chronic *Lm* contamination problem and have to cease their RTE MPP production altogether. No comments were received that would either support or refute this scenario or the set of assumptions needed in describing it. Some commented at the May 2001 public meeting that inclusion of these possible eventualities would help complete the analysis. These results are expected to only apply to establishments in EG 4 who face the highest level of FCS verification testing. The underlying assumptions and resultant cost implications are given in Table 18.

Some explanation of the cost estimates of this impact is needed. First, the calculations for cost estimates for minor remedies are the same as in the PRIA. That is, the number of firms in each establishment group is faced with a $2000 per line cost times the number of lines in the establishment for production adjustments. Second, the cost estimates for major repairs are slightly different from those in the PRIA. In the PRIA, the value of shipments for the 1,479 establishments was available and estimated by Census at $25.2 billion for 1999. In the PRIA, this value of shipments was distributed across the 133 large establishments, 840 small ones and 506 very small ones using an average distribution for value of shipments by those size categories of 80-percent (for large), 15-percent (for small), and 5-percent for very small). This average distribution was derived from averages across broad categories of agricultural commodities. A much different distribution of value of production was found in the Fall 2002 FSIS survey of hotdog and deli meat establishments. It found a value of production distribution of 48-percent (large), 48-percent (small), and 4-percent (very small). The final regulatory impact analysis uses a distribution of 65, 35, and 5 in conjunction with the original $25.2 billion for total value of shipments. This calculation produced average per establishment value of shipment estimates of $123 million for large establishments, $9 million for small establishments, and $2 million for very small establishments. This estimate is important because it serves as the basis for calculating the costs to remedy the major cases of *Lm* contamination. As in the PRIA it is expected that a small number of establishments whose contamination problems will be perceived to be prohibitively costly to ''fix'' and/or not feasible to undertake without complete modernization or renovation. Without making these needed capital improvements, their only option is to either partially or entirely cease RTE MPP production. FSIS expects that up to two small and four very small establishments may be in this situation.

BILLING CODE 3410–DM–P

Table 18. Assumptions about production adjustments to eliminate L. monocytogenes contamination and associated costs

Item	HACCP Establishment Size Category			
	L	S	VS	Total
Lines per establishment	6	4	2	NA
Proportion of establishments with no major L. monocytogenes contamination problems by establishment group:				
EG 3	0.95	0.95	0.9	NA
EG 4	0.85	0.85	0.85	NA
Number of establishments				
EG 3	1	13	158	172
EG 4	1	30	67	98
Total	2	44	225	270
Number of establishments incurring a $2,000 per line costs				
EG 3	0	0	158	158
EG 4	1	14	31	46
Total	1	14	189	204
Number of establishments incurring a major L. monocytogenes contamination problem				
EG 3	0	0	0	0
EG 4	1	14	31	46
Total	1	14	31	46
Number of establishments incurring a severe L. monocytogenes contamination problem				
EG 3	0	0	0	0
EG 4	0	2	4	6
Total	0	2	4	6
Production adjustment Costs	$thousand			
EG 3	0	0	632.4	632.4
EG 4	77.9	238.7	202.4	519.0
Costs of production adjustments	77.9	238.7	834.8	1,151.4

BILLING CODE 3410–DM–C

Costs related to possible hold-and-test actions. Hold-and-test actions are expected to be taken by establishments in EG 4 and to a lesser extent in EG 3. For purposes of this analysis, 50 percent of the EG 3 and 95 percent of the EG 4 establishments that are expected to have some problems with *Lm* contamination are also expected to be faced with one or more hold and test events annually. This calculation suggested that seven small and 79 very small establishments in EG 3 and one large establishment and 29 small and 63 very small establishments in EG 4 are expected to take one or more hold-and-test actions over a typical year. In addition to the number of establishments affected, there are five other factors that affect this cost impact. These are: (1) The amount of production likely affected (based on the number of lines times number of shifts and production per shift estimates); (2) the pounds per pallet that will need to be handled and placed into storage; (3) the average number of days that the product will be held in storage; (4) the number of times per year that a hold-and-test action occurs; and, (5) the cost per day per pallet in handling and storage. Also, the amount of existing available storage will influence any expected burden placed on establishments. The recent FSIS hotdog and deli-meat survey found that up to 40 percent of establishments have sufficient storage to hold product, but for only one to two days of production. Even though this finding only reflects the capacity of hotdog and deli-meat establishments, FSIS does not anticipate any serious problems with establishments finding available storage for holding product under possible increased hold-and-test situations on their premises or at other locations. FSIS bases its estimate for expected industry-wide costs of hold-and-test on parameters stated in Table 19. These costs are intended to include the transportation, handling and storage costs associated with product that has been tested and may or may not prove to be contaminated with *Lm.* For example, the $119,500 cost calculation for hold and test expected to be incurred by very small establishments was made by multiplying the expected number of affected establishments (79) times the number of expected hold and test occurrences per year (3) times the daily cost of holding (5 days times 5.6 pallets times $18 per pallet per day). Similar calculations were made for other affected establishments in the other HACCP establishment size categories and establishment groups. FSIS does not consider that the costs associated with the handling and eventual disposition of contaminated product, including its possible destruction, should be attributed to this final rule. It is believed that this product would have or should have been discovered and appropriately disposed of under current good manufacturing practices had they been followed by the establishment. Also to the extent that some of these products are normally refrigerated, these holding cost estimates would over-estimate the impact on the industry.

Table 19. Cost of hold-and-test actions

Item	HACCP Establishment Size Category			
Assumption	L	S	VS	Total
	Pounds			
Production affected	228,000	28,400	5,600	
	Number of:			
Pallets (1000 lbs. per pallet)	228	28	6	
Average days in storage	5	5	5	
Hold and test frequencies				
EG 3	3	3	3	
EG 4	6	6	6	
	Dollars			
Handling and storage cost per day ($/pallet)	18	18	18	
Handling and storage costs				
	$thousands			
EG 3	20.7	51.7	119.5	191.9
EG 4	144.2	437.9	191.9	774.1
Cost of hold and test	164.9	489.6	311.4	966.0

Analysis of Alternatives

For purposes of the analysis, the expected frequency of FCS verification testing for *Listeria* spp. for establishments in EG 2 is once per line per quarter; for EG 3, at least once per line per month; and for EG 4, once per line per month for very small establishments; semi-monthly for small producing establishments and weekly for high volume producing establishments (4–2–1). These testing frequencies are to be considered minimum expected levels for the purposes of estimating costs and benefits. Conditions may warrant a higher frequency of FCS verification testing to assure FSIS that establishments' sanitation or prerequisite plans are adequately addressing the risk of possible contamination in its products. As an additional precaution, FSIS is requiring that after a second positive *Listeria* spp. FCS test result in an EG 4 establishment, hold and test actions are taken until such time that FSIS is assured that this action is no longer needed.

The FSIS *Lm* Risk Assessment found an increase in median lives saved as FCS verification testing frequencies increase relative to the baseline. The minimum FCS verification testing frequency for EG 4 (4–2–1) results in 25 deaths averted if there is 100 percent adoption of this testing frequency by all establishments producing deli meats.

An alternative FCS verification testing frequency could be 40–20–10 for EG 4. In this case, the reduction in human health risk increases to 89 deaths averted, given 100 percent adoption. At an extremely high level of testing, such as 60–60–60 (for either FCS verification testing for *Listeria* spp. or product testing for *Lm*), 153 deaths are averted given 100 percent adoption. Also, at these high levels of FCS verification testing, hold and test protocols were shown to reduce the level of *Lm* contamination at retail.

Extremely high FCS verification testing levels may not be required to assure adequate sanitation. Nor are they necessarily effective from an economic perspective. Costly hold and test actions increase with FCS verification testing frequency. As such costs increase, establishments producing RTE MPPs, especially small and very small establishments, may eliminate product lines or cease production entirely. FSIS recognizes, however, that FCS verification testing frequencies higher than 4–2–1 may be appropriate for establishments with a history of poor sanitation controls or evidence of producing adulterated product.

Another concern about high FCS verification testing frequencies is the likelihood that many establishments that produce RTE MPPs using traditional methods will no longer produce such products. To the extent that this reduces the amount of adulterated product, this rule and its emphasis on FCS verification testing is appropriate. It may be inappropriate for any product that FCS testing for *Listeria* species is not a reliable indicator for *Lm* product contamination. FSIS believes that its establishment categorization in this final rule will place only those products in EG 4 where intense sanitation and verification testing is most appropriate. However, extremely high verification testing frequencies in most cases may be unnecessary and burdensome.

The risk assessment clearly shows that a combination of post-lethality treatment or *Lm* growth inhibition along with sanitation and FCS verification testing and other measures is more effective than a ''sanitation coupled with FCS verification testing only'' strategy. This result also reinforces the observed industry practice of maintaining a series of adequate precautions throughout slaughter and processing, and of not exclusively relying on verification of sanitation through FCS testing alone to assure that products are not adulterated. FCS verification testing of sanitation procedures for *Listeria* species can compliment these other measures, *e.g.* post processing pasteurization, the addition of *Lm* growth inhibiting packaging. To the extent that establishments take a series of steps to address their possible *Lm* contamination, the need for higher FCS verification testing frequencies, and its impact of inspection personnel to review these data, is reduced.

Summary of Direct Industry Costs

The PRIA identified three major possible industry-wide impacts from mandatory FCS verification testing: HACCP plan modification costs ($1.28 million); direct testing costs ($1.75 million); and, production adjustments ($2.5 million). The total first-year cost of these impacts was $5.53 million—$3.8 million in one-time outlays and $1.75 million in recurring annual costs associated with testing.

The Final Regulatory Impact Analysis (FRIA) reflects many comments received in the public comment period. In addition to the impacts identified in the PRIA, the FRIA estimates (1) the cost of PL treatments (initial and annual operating); (2) the cost of using an agent or process to inhibit *Lm* growth (initial and annual operating); and, (3) the costs of holding product while awaiting confirmation of FCS verification testing.

The validation of PL treatments and related HACCP plan modifications results in a one-time cost of $2.6 million. The estimated cost in the FRIA is higher than that in the PRIA due to an increase in the number of establishments affected. The FRIA estimate may be conservative as it does not take into account the use of validation studies conducted by PL equipment manufacturers. Direct testing costs are substantially lower than estimated in the PRIA ($175,260 versus $1.75 million) because the expected movement of establishments out of EG 4 and into the other establishment groups where higher FCS verification testing is not expected. Production adjustments are estimated at $1.15 million in one-time costs in the FRIA compared to $2.5 million in the PRIA. The difference is due mainly to fewer expected cases where establishments are not able to overcome their *Lm* contamination problem. More establishments adopt PL treatments and move into EG 1 or EG 2. The total of the two, one-time cost components (production adjustments and use of PL treatments) is the same as that estimated in the PRIA ($3.8 million as opposed to $3.75 million estimated in the PRIA). Verification testing costs, as noted above, are substantially lower than that estimated in the PRIA.

The additional costs associated with the installation of PL treatments and/or altering their production to incorporate an agent or process to inhibit *Lm* growth introduces potentially large cost outlays, especially for the initial, one-time investments in plant and equipment (Table 20). The initial industry-wide, one-time cost outlays for equipment associated with production adjustments and PL treatments are expected to be as high as $51.6 and $10.1 million, respectively. The annual operating (recurring) costs of $5.2 and $1 million, respectively, make first-year costs for these two technologies, $56.7 and $11.1 million, respectively.

Table 20. Total Expected Industry-wide Costs				
Item	HACCP Establishment Size Category			Total
	L	S	VS	
	$thousand			
PL validation	749.1	1,510.1	385.7	2,644.8
PL Equipment & operations	14,351.3	42,390.6	0	56,741.
Growth inhibiting agent or process	521.7	10,597.6	0	11,119.4
FCS testing	.7	46.9	127.7	175.3
Production adjustments	77.9	238.7	834.8	1,151.4
Product handling and storage	165.0	489.6	311.4	966.0
Total Costs	15,865.7	55,273.5	1,659.5	72,798.7

Converting initial costs into an annual equivalent cost of capital recovery provides a more accurate measure of economic impacts.[8] Using a 7-percent discount rate over ten years results in annualized cost of $9.3 million for PL validation, installation, agent and/or process alteration cost, and production adjustments. The annual operating (recurring) costs are estimated at $7.3 million. Combining these two estimates produces a total annual cost of the final rule of $16.6 million (bottom of Table 21).

Table 21. Total Annualized Industry-wide Cost Impact, by establishment size.				
Item	HACCP Establishment Size Category			
	L	S	VS	Total
	$thousand			
Initial	14,347.9	49,919.9	1,220.5	65,488.2
Recurring	1,517.8	5,353.5	439.1	7,310.4
Total	15,865.6	55,273.5	1,659.5	72,798.6
	22%	76%	2%	100%
Annualized Cost	10 year, 7-percent			
Initial	2,042.8	7,107.5	173.8	9,324.0
Recurring	1,517.8	5,353.6	439.1	7,310.4
Total	3,560.6	12,461.1	612.8	16,634.5
	21%	75%	4%	100%

Possible Indirect and Unintended Cost Impacts

The focus of the cost discussion thus far was mainly on industry-wide direct compliance costs: These costs, on an annual basis, were estimated at $16.6 million, roughly one-half of one percent of the total annual value of industry sales ($16.6 million divided by $25.2 billion). In addition, some discussion was made of the possible impacts that the final rule may have on lowering product quality, reducing current FCS testing frequencies in some establishments, and forcing some establishments to exit the industry. However, these impacts were not quantified. Two other possible indirect cost impacts are on consumers and other sectors of the economy.

No market product quantity and price data are available to calculate the possible consumer price implications brought about by the higher compliance costs identified in this analysis. This information, plus an estimation of any reduction in market supplies, could be used to calculate the social costs of shifts in supply and demand in a consumer- and producer-surplus framework. Also, a complicating factor in estimating possible market supply reductions is to what extent imported product could be substituted for any U.S. RTE MPP production cutback. Without such information, one can only say that higher industry compliance

[8] Lynn E. Bussey, *The Economic Analysis of Industrial Projects*, Engelwood Cliffs, New Jersey, 1978.

costs and lower market supplies would be expected to raise consumer prices to some extent. From the information provided in this analysis (the expected small cost impacts relative to total value of production and the likely small quantity cut-backs), it is expected that these impacts would be minimal.

A related issue is the possible impact on other sectors of the economy. Census data show that swine, beef, dairy, and poultry industries supply significant amounts of raw product to the RTE MPP industry. Because, however, the quantity effect is expected to be minimal, these upstream suppliers of raw material are not expected to be significantly affected by the final rule.

Analysis of Benefits

The analysis of benefits resulting from the final rule examines the reduction in human health risk (deaths and illnesses caused by listeriosis) from actions taken as a result of this final rule by RTE MPP establishments in only one product group: deli meats (primarily sliced luncheon meats). This analysis of benefits thus differs from that in the PRIA which examined the reduction in human health risk from all RTE MPPs.

FSIS is focusing on deli products for several reasons. First, the FDA–FSIS risk assessment identified this product group as having the highest risk of all food classes and the cause of a large share of listeriosis deaths and illnesses. Second, the FSIS *Lm* Risk Assessment, when calibrated to a revised version of FDA–FSIS risk assessment, tied risk mitigation actions at deli-meat producing establishments to potentially lower rates of listeriosis death and illnesses. FSIS plans to modify the model to capture the dynamics of *Lm* contamination and containment in other RTE MPP products, such as hotdogs, along with the impact of production volume. Third, the FSIS *Lm* Risk Assessment, having been presented to the public for comment, has been revised to the extent possible at this time.

The analysis of benefits uses the FSIS *Lm* Risk Assessment to evaluate the human health risk reduction effects of sanitation coupled with FCS verification testing, the use of growth inhibiting packaging (GIP); and the use of PL treatments. The likely reduction in listeriosis deaths from a 100-percent adoption of these practices and treatments by the industry is given in Table 22. FSIS is reporting three values for the possible benefits derived from this rule: The median, the 5th percentile, and the 95th percentile for each scenario (baseline, sanitation/FCS verification testing, *Lm* growth-inhibiting packaging (GIP) and post-lethality processing (PP) + GIP). This range of values represents the uncertainty in the true number of averted number of deaths per year. The reported results imply 90 percent certainty that the true value lies between the 5th and 95th percentiles. Each uncertainty distribution is the result of three hundred computer simulations, each simulation consisting of 100,000 iterations, of the FDA–FSIS risk ranking model. The risk characterization portion of that model comprises 4,000 combinations of the exposure distributions for the 23 different food groups in the FDA–FSIS risk ranking model. The median reports the mid-point value of deaths averted from these multiple computer simulations for each scenario. The median is reported because it is the preferred measure of central tendency in the FDA–FSIS risk ranking. Furthermore, the distribution of results suggests that the mean, as an alternative measure of central tendency, is less informative about the shape of the distribution because of the influence of outliers in its calculation. Illnesses are estimated using the standard .20 case-fatality rate commonly reported in the literature.

Table 22. Incremental Reductions in Deaths Due to Various Interventions (assuming 100% industry-wide adoption)

	Averted Deaths			Averted Illnesses		
Scenario	Median	5%	95%	Median	5%	95%
FCS testing /1	25 (24)	8 (8)	25 (24)	125 (120)	42 (40)	125 (120)
GIP	141 (135)	48 (45)	165 (158)	707 (675)	240 (225)	823 (790)
PP & GIP	238 (227)	77 (72)	272 (261)	1188 (1135)	384 (360)	1360 (1305)
/1 FCS testing at a 4-2-1 rate.						
/2 Numbers in parentheses exclude reductions in neonate deaths.						

The greatest reduction in listeriosis deaths and illnesses would occur if all establishments used both PP and GIP. However, 100 percent adoption is not possible for a variety of reasons, including technical—not all products are amenable to the use of PL or GIP—and economic—the costs are prohibitive in relation to the value of the product.

The analysis of costs described movements among establishment groups that are likely to occur as a result of the final rule. These movements are the basis for estimating the human health benefits of the final rule. Establishment group net movements are placed on a percentage basis of establishments in each size class (Table 23). The absolute changes in establishment numbers are converted into percentage increases by dividing the number establishments estimated to adopt one or more measures by the total number of establishments in that size class. For example, 2 of the 42 large establishments producing deli meats (4.8 percent) are estimated to adopt PL and GIP measures. Next, the percentage change in establishments is weighted by the relative volume of deli meats produced by that size class. The two large establishments are estimated to account for 2.3 percent of deli-meat production (4.8 times 0.48). The summation of these weighted percentages produces the percentage increase in that technology which is adopted as a result of the final rule. Thus, deli-meat producing establishments adopting PL and GIP represent a 5.4-percent increase in the amount of deli-meat production that is produced using this technology. Likewise, the percent increase in the amount of production using GIP and FCS sanitation/verification testing is 8.9 and 13.3 percent, respectively.

Table 23. Number of establishments adopting various interventions				
	HACCP Establishment Size Category			Average
Item	L	S	VS	
Product Volume Weights	0.48	0.48	0.04	
Deli-meat producing stab.	42	311	340	
Mitigation Measure	Number of Establishments			
Establishments adopting PL and GIP	2	20	0	
	Percent			
Establishments	4.8	6.4	0.0	
Product	2.3	3.1	0.0	5.4
Mitigation Measure	Number of Establishments			
Establishments adopting GIP	1	50	0	
	Percent			
Establishments	2.4	16.1	0.0	
Product	1.2	7.7	0.0	8.9
Mitigation Measure	Number of Establishments			
Establishments adopting FCS Testing at a 4-2-1 rate	0	66	260	
	Percent			
Establishments	0.0	21.2	76.5	
Product	0.0	10.2	3.1	13.3

The results in Tables 22 and 23 are used to estimate the possible reduction in listeriosis deaths that may be attributed to actions taken be deli-meat producing establishments as a result of the final rule (Table 24).

This analysis excludes neonate deaths estimated by the FSIS risk assessment because of concerns about using the standard values for a statistical life, which are derived from adult lives. Of course, it is obvious that averting such neonate losses is a potentially significant benefit. However, excluding these losses does not substantially affect the conclusions of this analysis.

Calculations combining information from Tables 22 and 23 are fairly straightforward: for example, the 13.3 percent increase in adoption rates of sanitation coupled with FCS verification testing translates into 3.1 fewer listeriosis deaths at the median (0.133 from Table 23 times 24 from Table 22); 1.0 fewer at the 5th percentile (0.133×8.0); and, 3.1 fewer at the 95th percentile (0.133×24). Similar calculations for the other two mitigation measures result in a total reduction of 27.3 at the median; 8.9 at the 5th percentile; and, 31.2 at the 95th percentile. The corresponding reductions in illnesses are 136.7 at the median, 44.6 at the 5th percentile, and 156.0 at the 95th percentile, respectively.

Table 24. Reduction in listeriosis deaths due to various interventions			
	Averted Deaths		
Interventions	Median	5th percentile	95th percentile
FCS Testing (4-2-1)	3.1	1.0	3.2
GIP	12.0	4.0	14.0
PL & GIP	12.2	3.9	14.0
Total Reduction	27.3	8.9	31.2

The Economic Research Service of USDA presented a method for estimating the human health benefits of reduced listeriosis at a public meeting on the proposed rule held in May 2001. To estimate the benefits, it was assumed that 5 percent of the cases were moderate, and that moderate cases resulted in hospital costs of $10,300 per case. The remaining 95 percent of the illness were severe, resulting in hospital costs of $28,300 per case.[9] Using these assumptions and excluding the loss in productivity of those affected and any pain and suffering, the benefits of the reduction in illness-related losses due to the final rule are estimated to be $3.7 million at the median (0.05 × 136.7 × $10,300) + (0.95 × 136.7 × $28,300)) and $1.2 million at the 5th and $4.3 million at the 95th percentile.

ERS estimated the value of statistical life at $4.8 million[7] as a proxy for the cost of one fatality. Based on this estimate, the annual human health benefits from the implementation of the final rule are $134.9 million at the median (the $3.7 million above plus 27.3 × $4.8 million) and $44.0 million at the 5th percentile and $154.0 million at the 95th percentile.

Given the limitations in data and the output of the risk assessment dealing only with deli meats and as per the discussion found earlier concerning the estimates of health consequences, FSIS believes that this estimate may be overstated by as much as 50 percent. If so, the adjusted annual net benefits then become $50.8 million, $5.4 million and $60.4 million at the median, 5th and 95th percentile levels, respectively (Table 25). It appears that a downward adjustment in total benefits of 85 percent would be necessary to lower net benefits to near zero.

Table 25. Summary of Annual Total and Net Benefits

Item	No adjustment	Benefits reduced 50 percent	Benefits at Breakeven (15%)
	$million		
Total Benefits			
Median	134.9	67.5	20.2
5th percentile	44.0	22.0	6.6
95th percentile	154.0	77.0	23.1
Net Benefits			
Median	118.3	50.8	3.6
5th percentile	27.4	5.4	-10.0
95th percentile	137.4	60.4	6.5
Net benefits hold industry-wide compliance cost of this regulation constant at $16.6 million.			

Compliance With Regulatory Flexibility Act of 1996

The Administrator has determined that for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–612), this rule will have a significant economic impact on a substantial number of small entities. As discussed above, FSIS estimates that the *Lm* sanitation coupled with FCS verification testing provisions of this final rule may result in annual costs to small and very small producers of post-lethality exposed RTE MPPs of $12.5 and $0.6 million, respectively. These establishments incur about 79 percent of the total industry-wide costs of compliance with the sanitation coupled with FCS verification testing provisions of this final rule.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) requires, among other things, that for each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis under section 604 of title 5, United States Code, the agency must publish one or more guides to assist small entities in complying with the rule, and must designate such publications as ''small entity compliance guides''. The guides must explain the actions a small entity is required to take to comply with a rule or group of rules. FSIS is developing guidance to assist small and very small establishments in fulfilling their responsibilities under the final rule. The guides will include instructions on how establishments that produce post-lethality exposed RTE MPPs can conduct sanitation coupled with FCS and product verification testing. Establishments that wish to use the guides may incorporate their features into their HACCP plans, Sanitation SOPs or other prerequisite programs. Because FSIS is basing its guidance on existing research and industry practices that are known to be effective, the Agency also will consider the processing instructions to be already validated. That is, an establishment may follow the guidance without contracting for or conducting additional validation of the content of the materials.

FSIS is examining other options to minimize the potential negative economic effects of these proposed regulations on small businesses, including encouraging research that would facilitate validation of pathogen lethality in many products, especially those produced by traditional methods by small and very small establishments.

Types of Entities and Production Affected by the Final Regulations. The preliminary RIA found that small and very small establishments made up about 91 percent of the number of establishments in the U.S. RTE MPP industry and were expected to incur up to 69 percent of the cost of complying with the requirements of the proposed rule. The FRIA finds that small and very small establishments make up about 97 percent of the number of establishments in the industry and are expected to incur nearly 80 percent of total cost impact on the industry. As was also stated in the FRIA, the final rule only involves that part of the original proposal dealing with FCS verification testing for *Lm* or indicator organism and also uses a more accurate baseline for the number of establishments affected by the final rule.

An important note to consider throughout this analysis is that much of the projected impacts originate from expected movements of establishments from one establishment group to another. As was stated in the

[9] Stephen Crutchfield, ''The Benefits of Reducing Listeria in Ready to Eat Products.'' 2001. Presented at public meeting, ''Performance Standards for the Production of processed Meat and Poultry Products,'' May 9–10, 2001. FSIS–USDA Washington, D.C. Roberts, Tanya, and Robert Pinner. Economic Impact of Disease Caused by Listeria monocytogenes.'' In Miller, AJ, Smith JL, and Somkuti GA, (Eds.) *Foodborne Listeriosis.* Amsterdam, the Netherlands: Elsevier Science Publishing Co., 1990, pp. 137–144.

preliminary RIA, ''mandatory *Listeria* testing is the most difficult provision in the proposed rule to analyze because of the uncertainty of current practices and how establishments will react to the proposed rule. Major uncertainties include: the degree to which firms will switch to a *Listeria*-related CCP in their HACCP plan, the degree to which firms will be able to resolve their *Listeria*-related problems if they present themselves, and the degree to which they must increase their testing.'' This problem is further compounded in this analysis because the final rule is not limited to whether establishments either elect to incorporate a *Lm*-related CCP in their HACCP plan or face mandatory testing. In this analysis, it is possible for establishments to address possible *Lm* contamination in their operations through a variety of methods.

A large share of the cost impact is on small establishments, which are expected to absorb nearly 75 percent of the total industry-wide cost impact (Tables 26 and 27). These establishments have the same incentives to move to new post-pasteurization technologies as do very small establishments, but their production volumes more easily justify the associated high capital and recurring expenditures. Very small establishments will likely have to increase sanitation coupled with FCS verification testing to comply with this final rule. Large establishments are likely to complete the process of adopting new technologies. The expected impacts on large, small, and very small establishments are discussed below.

Large Establishments

As discussed in the ''Baseline'' section of this analysis, most (131 out of 144 large establishments) already fall into either establishment group 1, 2 or 3. This number is expected to increase by 5 establishments as a result of the final rule, leaving only 8 establishments in the establishment group 4: those establishments required to conduct more intense sanitation coupled with FCS *L. spp.* verification testing than establishments producing product in the other establishment groups. Many of these firms already employ post-pasteurization technologies, but need them validated to comply with the final rule. In fact, six of the existing establishments in EG 1 and four of the establishments from EG 2 already employ the technology, but simply have not validated their processes. It is expected that total validation costs will run about $749,000 in first-year costs for these establishments.

The remaining establishments are likely to have high enough product volume levels to justify the acquisition of new post-pasteurization technologies and/or to alter product formulations and packaging. The remaining eight establishments (seven of the 10 establishments from EG 2 (or 10 percent of the establishments in EG 2 that do not apply a post-pasteurization step)); and one from EG 4 (or 10 percent of the establishments in EG 4) all are expected to need post-pasteurization equipment and have their processes validated. The resulting large initial cost outlays plus the estimated recurring annual operating costs are expected to total $14.3 million in first-year costs. This cost represents about 90 percent of all the costs that are expected to be incurred by large establishments as a result of this final rule. The remaining costs are incurred by those establishments electing to add an inhibiting agent or process in their production or to a lesser degree, as a result of sanitation coupled with FCS verification testing and possible subsequent actions related to hold and test and finding remedies to possible persistent *Lm* contamination problems.

Small Establishments

It is estimated that there are 1,276 small establishments producing RTE MPPs. FSIS estimates that 108 small establishments will migrate to other establishment categories as a result of the final rule. This is a costly undertaking, especially for those establishments that elect to migrate into EG 1. Due to the high cost of both technologies (post-lethality processing and adding an agent or process to the product) and because their products must conform to both process adjustments, it is expected that only 31 establishments (or 10 percent of the small establishments that were formally in EG 4) migrate to EG 1 as a result of the final rule. All movement involves the purchase and use of new technology which is expected to cost these establishments over $42 million. About twice the number of establishments that is expected to migrate to EG 1 is expected to migrate to EG 2. This move is less costly and it is expected that more RTE MPPs lead themselves to the addition of an inhibiting agent or process. These 77 establishments are expected to incur $10.6 million in first-year, total direct and recurring costs. All of the 108 establishments are expected to migrate from EG 4.

Very Small Establishments

It is estimated that there are 3,556 very small establishments producing RTE MPPs. The preliminary RIA had an estimate of only 524 establishments, acknowledging that that estimate severely underestimated the true number of very small establishments. Due to the combination of high costs and technical difficulties faced by very small establishments, FSIS projects that no very small establishments will shift into a different establishment group. Consequently, FSIS does not expect that very small establishments will incur any costs associated with the adoption of post lethality treatment methods or by incorporating an inhibiting agent or process in their production. Instead, most of the entire cost impact of this final rule on very small establishments is expected to originate from sanitation coupled with FCS verification testing and the possible production adjustments and additional handling and storage associated with increased testing and the higher likelihood of incurring *Listeria* species positive FCS test results. A small amount of costs are expected to be incurred by those very small establishments that currently employ un-validated post-lethality processing technologies.

Summary

Small establishments make up 26 percent of the establishments, yet are expected to incur up to 75 percent of the aggregate cost burden. Much of these expected costs are in large capital expenditures in post lethality processing equipment and in changing their production process to incorporate *Lm* growth inhibiting agents or processes. This cost impact would be reduced to the extent that these cost estimates over-estimate the actual costs of acquiring these technologies or over-estimate the establishment movements. It is unlikely that actual cost impacts would exceed those estimated in this analysis. Very small establishments make up 71 percent of the number of establishments in the industry and yet are expected to incur only 4 percent of the total costs of this final rule. This estimate may under-estimate their exposure to cost increases related to FCS testing. Thus, it is unlikely that actual cost impacts would be lower than those estimated in this analysis. The estimates for large establishments are highly contingent on their movement into EG1 and EG2. To the degree that actual movements into these establishment groups occur, the estimates in this analysis should reflect these expected cost outlays.

BILLING CODE 3410–DM–P

Table 26. Potential First-Year Total Direct and Recurring Cost Impacts Across HACCP Establishment Size Categories.

Cost Component	HACCP Establishment Size Category			
	L	S	VS	Total 2/
	$thousand			
PL Validation	749.0	1,510.1	385.7	2,644.8
PL Installation	14,351.3	42,390.6	0	56,741.9
Growth Inhibitor	521.7	10,597.6	0	11,119.3
FCS testing	0	46.8	127.5	175.3
Production Adjustments	77.9	238.7	834.8	1,151.4
Handling & Storage	165.0	489.6	311.4	966.0
Total Costs Above	15,865.6	55,273.5	1,659.5	72,798.6
Total Costs broken into one-time, initial year costs and recurring costs.				
One-time, initial year	14,347.9	49,919.9	1,220.4	65,488.2
Recurring	1,517.8	5,353.6	439.0	7,310.4

Table 27. Estimated Total Cost Impact of Final Rule, Annualized.

Annualized Cost	10 year, 7-percent			
	HACCP Establishment Size Category			
	L	S	VS	Total
	$thousand			
One-time costs	2,042.8	7,107.5	173.8	9,324.0
Recurring	1,517.8	5,353.6	439.1	7,310.4
Total	3,560.6	12,461.1	612.8	16,634.5
	Percent			
Total Costs	21	75	4	100
	Percent			
Establishments	3	26	71	100

[FR Doc. 03–14173 Filed 6–5–03; 8:45 am]
BILLING CODE 3410–DM–P

Federal Register

Friday,
June 6, 2003

Part VI

Department of Transportation

Federal Aviation Administration

14 CFR Part 36

Harmonization of Noise Certification Standards for Propeller-Driven Small Airplanes; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 36

[Docket No. FAA–2003–15279; Notice No. 03–09]

RIN 2120–AH42

Harmonization of Noise Certification Standards for Propeller-Driven Small Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to amend two technical items to harmonize them with international standards and provide uniform noise certification standards for airplanes certificated in the United States and Joint Aviation Authorities (JAA) countries. This will help to simplify airworthiness approvals for import and export purposes. The revisions to these two items would apply only to a small number of older-technology airplanes.

DATES: Send your comments by July 7, 2003.

ADDRESSES: Address your comments to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2003–15279 at the beginning of your comments, and you should send two copies of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard. You may also send comments through the Internet to *http://dms.dot.gov.* You may review the public docket containing comments on these proposed regulations in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Dockets Office is on the plaza level of the NASSIF Building at the Department of Transportation at the address in this section. Also, you may review public dockets on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Mehmet Marsan, AEE–100, Office of Environment and Energy, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–7703; facsimile (202) 267–5594.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested individuals to take part in this rulemaking by sending written comments, data, or views. We also invite comments about the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain why you want to make any recommended change, and include supporting data. We ask that you send us two copies of your written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel about this proposed rulemaking. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also review the docket using the Internet at the web address in the **ADDRESSES** section.

Before acting on this proposal, we will consider all comments we receive by the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change this proposal because of the comments we receive.

If you want the FAA to acknowledge receipt of your comments on this proposal, include with your comments a preaddressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it to you.

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) web page (*http://dms.dot.gov/search*);

(2) Visiting the Office of Rulemaking's web page at *http://www.faa.gov/avr/armhome.htm*; or

(3) Accessing the Federal Register's web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html*.

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the docket number, or notice number of this rulemaking.

Background

Under 49 U.S.C. 44715, the Administrator of the FAA is directed to prescribe ''standards to measure aircraft noise and sonic boom; * * * and regulations to control and abate aircraft noise and sonic boom.'' Title 14, part 36 of the Code of Federal Regulations (CFR) contains the FAA's noise standards and regulations that apply to the issuance of type certificates for all types of aircraft. The standards and requirements that apply to propeller-driven small airplanes and propeller-driven commuter category airplanes are found in § 36.501 and Appendix G to part 36. Appendix G addresses takeoff noise requirements for propeller-driven small airplanes and propeller-driven commuter category airplane certification tests conducted on or after December 22, 1988. The FAA added this appendix to part 36 in 1988 to require takeoff noise tests, instead of the level flyover test formerly required under Appendix F, for airplanes that had certification tests completed before December 22, 1988. Appendix F is no longer used.

On October 13, 1999, the FAA published a final rule (64 FR 55598) amending the noise certification standards for propeller-driven small airplanes. The rule, which harmonized the U.S. noise certification regulations and the European Joint Aviation Requirements for propeller-driven small airplanes, is based on the joint effort of the FAA, the JAA, and the Aviation Rulemaking Advisory Committee. However, two technical items, which appear in Appendix G to part 36, were left unharmonized with Annex 16, Volume 1, Chapter 10 of the International Civil Aviation Organization (ICAO) because we were not aware of the possible effect on exported older airplanes. These older airplanes predated current noise certification requirements or have already been noise certificated. On rare occasions, these airplanes may be required to perform a new noise test if they undergo a modification that could increase their noise level.

The two unharmonized technical items were filed with the ICAO. The ICAO includes these items in the national variances list for Annex 16, Volume I. These differences could result in foreign regulators conducting additional reviews, which the FAA and U.S. manufacturers must support, of any U.S.-made, propeller-driven small airplane noise certifications when the airplanes are exported. In practice, the existence of these differences means that all aircraft must undergo additional review by a foreign authority since it is

not clear which airplanes encompass the differences in their noise certifications. This proposed rule would harmonize the two technical items to eliminate the differences and the need for the additional reviews.

The two unharmonized items, which are the subject of this proposed rule, are as follows:

(1) The use of ''maximum continuous power'' during the second segment of the noise certification test flight path is allowed under current section G36.111. However, the ''power'' definition in Annex 16, Chapter 10, section 10.5.2 for the second segment is defined as ''maximum power''. Since the ''maximum continuous power'' is typically lower than the maximum or takeoff power described in ICAO, the two items are not considered harmonized.

(2) For fixed pitch type propellers, current section G36.201 specifies a simplified data correction procedure if the engine test power is within 5 percent of the reference power. The ICAO Annex 16, Volume 1, Chapter 10 does not have a corresponding simplified data correction procedure.

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is the FAA's policy to comply with ICAO Standards and Recommended Practices to the maximum extent practicable. We propose to revise the two unharmonized technical items in Appendix G to part 36 to make them the same as ICAO Annex 16, Volume I, Chapter 10, regarding propeller-driven small airplane noise certification regulation. The proposed revisions better represent the intent of the original noise certification standards, which was to certify propeller-driven small airplanes at takeoff power. This proposed rule would complete harmonization between current Appendix G to part 36 of 14 CFR and Annex 16.

Section-by-Section Analysis

Appendix G To Part 36—Takeoff Noise Requirements for Propeller-Driven Small Airplane and Propeller-Driven, Commuter Category Airplane Certification Tests on or After December 22, 1988

Section G36.111 Flight Procedures

Current section G36.111 allows the use of maximum continuous power during the second segment of the flight path. However, the power definition in Annex 16, Chapter 10, section 10.5.2 for the second segment is defined as maximum or takeoff power. The maximum continuous power described in Appendix G is typically lower than the takeoff power and is applicable only to older engines. This proposed rule specifies that takeoff power must be used in the second segment of the flight profile and describes a method to perform the test if the test airplane is equipped with an engine that can operate at takeoff power for only a short time.

The FAA conducted an informal survey to determine whether any recent noise certification tests have been conducted on airplanes equipped with time-limited engines. The FAA found no noise measurements of airplanes with old-technology engines that may be affected by this proposal. If testing were required for an airplane, which was previously noise certificated at maximum continuous power, rather than at takeoff power as proposed in this NPRM, the noise levels could be slightly higher or lower, depending on the height gained over the microphone by operating at the higher engine power. The amount of height gained is a function of the performance of the particular airplane. The noise increase caused by the engine at takeoff power will be canceled or reduced by the height gained over the microphone since the sound propagation distance from the airplane to the microphone increases as the airplane flies higher. Hence, the sound reaches the microphone at a lower level.

Section G36.201 Corrections to Test Results

This section prescribes that corrections made to test results must account for the effects of differences between the conditions referenced in the prescribed procedures in Appendix G and the actual test conditions.

Under current section G36.201(c)(1), helical tip Mach number and power corrections must be made if (1) the propeller is a variable pitch type, or (2) the propeller is a fixed pitch type and the actual power is not within 5 percent of the reference power. The 1999 rule change includes an additional helical tip Mach number correction exception for all types of propellers by stating that a correction is not necessary if the helical tip Mach number meets criteria listed in current section G36.201(c)(2). This proposal (1) removes the exception provided for fixed pitch propellers if the test power is within 5 percent of the reference power and (2) requires helical tip Mach number and power corrections for all types of propellers, depending on which criteria of current section G36.201(c)(2) are being used.

Fixed pitch propellers rotate at less than their maximum speed during takeoff because the pitch angle cannot be adjusted to match the loading on the propeller blade. As the propeller slows down, the dominant noise generation shifts from the propeller to the engine exhaust. The lack of a correction exception for slower rotating propellers is provided not just as a simplification to the procedure, but to avoid correcting the engine noise using the propeller speed. Current section G36.201(c)(2) provides either no correction exception or a small correction for slow rotating propellers, if the test power is not within 5 percent of the reference power. These requirements coincide with the exception in section G36.201(c)(1)(ii) proposed to be removed in this NPRM. Accordingly, the proposed change is not expected to affect test results.

Economic Evaluation

Proposed changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency must propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, make them the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation).

However, for regulations with an expected minimal impact, the above-specified analyses are not required. The Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If it is determined that the expected impact is so minimal that the proposal does not warrant a full evaluation, a statement to that effect and the basis for it are included in proposed regulation.

This proposed rule would revise two technical items, which are the only remaining unharmonized items between part 36 Appendix G and the ICAO Annex 16, Volume I, Chapter 10,

regarding the noise certification of small propeller-driven airplanes. The FAA has determined that the expected cost impact would be minimal because these two items affect only airplanes with older technology engines, that are not required to undergo new noise certification or are already noise certificated. On rare occasions, these airplanes may be required to perform a new noise test if they go through a modification that may increase their noise level. As a result, the FAA does not foresee any circumstances in which these older airplanes would need to re-certify for noise.

The two unharmonized technical items were filed with the ICAO. The ICAO includes these items in the national variances list for Annex 16, Volume I. These differences could result in foreign regulators conducting additional reviews, which the FAA and U.S. manufacturers must support, of any U.S.-made, propeller-driven small airplane noise certifications when the airplanes are exported. In practice, only a small number of the exported airplanes might encompass the two unharmonized items in their noise certifications.

The FAA has determined that this proposed rule would increase the harmonization of the U.S. Federal regulations with the ICAO Standards and Recommended Practices and would impose, at most, negligible costs.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 directs the FAA to fit regulatory requirements to the scale of the business, organizations, and governmental jurisdictions subject to the regulation. We are required to determine whether a proposed or final action will have a ''significant economic impact on a substantial number of small entities'' as they are defined in the Act. If we find that the action will have a significant impact, we must do a ''regulatory flexibility analysis''.

Because of the minimal cost impact of this proposed rule, the FAA has determined that it would, at most, impose negligible costs on small aircraft manufacturers. Therefore, the FAA certifies that this proposal would not have a significant economic impact on a substantial number of small entities.

Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. This proposed rule is a direct action to respond to these statutory requirements.

In addition, the FAA has determined that this proposed rule would generate cost savings for foreign regulators in the form of reductions in their administrative expenses. Their administrative expenses may be reduced because a review of the U.S. propeller-driven small airplane noise certifications for exported airplanes will no longer be necessary.

Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (the Act) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action''.

This NPRM does not contain such a mandate. The requirements of Title II of the Act, therefore, do not apply.

Executive Order 13132, Federalism

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action 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, and therefore would not have federalism implications.

Plain English

Executive Order 12866 (58 FR 51735, Oct. 4, 1993) requires each agency to write regulations that are simple and easy to understand. We invite your comments on how to make these proposed regulations easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulations clearly stated?
- Do the proposed regulations contain unnecessary technical language or jargon that interferes with their clarity?
- Would the regulations be easier to understand if they were divided into more (but shorter) sections?
- Is the description in the preamble helpful in understanding the proposed regulations?

Please send your comments to the address specified in the **ADDRESSES** section.

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act environmental impact statement. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), this proposed rulemaking action qualifies for a categorical exclusion.

Energy Impact

The energy impact of the notice has been assessed in accordance with the Energy Policy and Conservation Act (EPCA), Public Law 94–163, as amended (42 U.S.C. 6362) and FAA Order 1053.1. We have determined that the notice is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 14 CFR Part 36

Aircraft, Noise control.

The Proposed Amendments

In consideration of the foregoing the Federal Aviation Administration proposes to amend Chapter I of Title 14 Code of Federal Regulations as follows:

PART 36—NOISE STANDARDS: AIRCRAFT TYPE AND AIRWORTHINESS CERTIFICATION

1. The authority citation for part 36 continues to read as follows:

Authority: 42 U.S.C. 4321 *et seq.* 49 U.S.C. 106(g), 40113, 44701–44702, 44704, 44715, sec. 305, Pub. L. 96–193, 94 Stat. 50, 57; E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970 Comp., p. 902.

2. Revise section G36.111(c)(2)(iv) of Appendix G to read as follows:

Appendix G to Part 36—Takeoff Noise Requirements for Propeller-Driven Small Airplane and Propeller-Driven, Commuter Category Airplane Certification Tests on or After December 22, 1988

Sec. G36.111 Flight Procedures.

* * * * *

(c) * * *

(2) * * *

(iv) For airplanes equipped with fixed pitch propellers, takeoff power must be maintained throughout the second segment. For airplanes equipped with variable pitch or constant speed propellers, takeoff power and rpm must be maintained throughout the second segment. If airworthiness limitations do not allow the application of takeoff power and rpm up to the reference point, then takeoff power and rpm must be maintained

for as long as is permitted by such limitations; thereafter, maximum continuous power and rpm must be maintained. Maximum time allowed at takeoff power under the airworthiness standards must be used in the second segment. The reference height must be calculated assuming climb gradients appropriate to each power setting used.

3. In G36.201 of Appendix G, revise paragraph (c) as follows:

Sec. G36.201 Corrections to Test Results

* * * * *

(c) No corrections for helical tip Mach number variation need to be made if the propeller helical tip Mach number is:

(1) At or below 0.70 and the test helical tip Mach Number is within 0.014 of the reference helical tip Mach number.

(2) Above 0.70 and at or below 0.80 and the test helical tip Mach number is within 0.007 of the reference helical tip Mach number.

(3) Above 0.80 and the test helical tip Mach number is within 0.005 of the reference helical tip Mach number. For mechanical tachometers, if the helical tip Mach number is above 0.8 and the test helical tip Mach number is within 0.008 of the reference helical tip Mach number.

* * * * *

Issued in Washington, DC on June 2, 2003.

Carl E. Burleson,

Director, Office of Environment and Energy.

[FR Doc. 03–14310 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–13–P

Reader Aids

Federal Register

Vol. 68, No. 109

Friday, June 6, 2003

CUSTOMER SERVICE AND INFORMATION

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **http://www.access.gpo.gov/nara**

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: **info@fedreg.nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, JUNE

CFR PARTS AFFECTED DURING JUNE

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.

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 JUNE 6, 2003

COMMERCE DEPARTMENT

Industry and Security Bureau

Designated terrorists; control imposition and expansion; published 6-6-03

COMMERCE DEPARTMENT

National Institute of Standards and Technology

National Construction Safety Team Act; implementation; published 5-7-03

ENVIRONMENTAL PROTECTION AGENCY

Air quality implementation plans; approval and promulgation; various States; air quality planning purposes; designation of areas:

California; published 5-7-03

Air quality implementation plans; approval and promulgation; various States:

Pennsylvania; published 4-7-03

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Pesticide tolerance processing fees; annual adjustment; published 5-7-03

Thymol and eucalyptus oil; published 6-6-03

GENERAL ACCOUNTING OFFICE

Public availability of General Accounting Office records; published 6-6-03

HEALTH AND HUMAN SERVICES DEPARTMENT

Food and Drug Administration

Animal drugs, feeds, and related products:

Acepromazine maleate injection; published 6-6-03

Human drugs:

Ingrown toenail relief products (OTC); published 5-7-03

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

Boeing; published 5-2-03

TREASURY DEPARTMENT

Foreign Assets Control Office

Global terrorism; sanctions regulations; published 6-6-03

TREASURY DEPARTMENT

Internal Revenue Service

Procedure and administration:

Agriculture Department; return information disclosure; published 6-6-03

RULES GOING INTO EFFECT JUNE 7, 2003

HOMELAND SECURITY DEPARTMENT

Coast Guard

Ports and waterways safety:

Lake Michigan—

Chicago, IL; safety zone; published 5-20-03

Willamette River, Portland, OR; safety zone; published 5-6-03

Regattas and marine parades:

Harvard-Yale Regatta; published 5-14-03

RULES GOING INTO EFFECT JUNE 8, 2003

HOMELAND SECURITY DEPARTMENT

Coast Guard

Regattas and marine parades:

Chesapeake Bay Bridges Swim Races; published 5-20-03

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Nectarines and peaches grown in—

California; comments due by 6-9-03; published 4-9-03 [FR 03-08650]

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Onions (sweet) grown in—

Washington and Oregon; comments due by 6-9-03; published 4-9-03 [FR 03-08648]

AGRICULTURE DEPARTMENT

Animal and Plant Health Inspection Service

Animal welfare:

Medical records maintenance; comments due by 6-10-03; published 4-11-03 [FR 03-08928]

Viruses, serums, toxins, etc.:

Veterinary biological products; actions by licensees and permitees to stop preparation, distribution, sale, etc.; comments due by 6-9-03; published 4-9-03 [FR 03-08599]

AGRICULTURE DEPARTMENT

Farm Service Agency

Special programs:

Farm Security and Rural Investment Act of 2002; implementation—

Loan eligibility provisions; comments due by 6-9-03; published 4-9-03 [FR 03-08646]

Minor Program loans; comments due by 6-9-03; published 4-9-03 [FR 03-08597]

AGRICULTURE DEPARTMENT

Rural Business-Cooperative Service

Program regulations:

Farm Security and Rural Investment Act of 2002; implementation—

Loan eligibility provisions; comments due by 6-9-03; published 4-9-03 [FR 03-08646]

Minor Program loans; comments due by 6-9-03; published 4-9-03 [FR 03-08597]

AGRICULTURE DEPARTMENT

Rural Housing Service

Program regulations:

Farm Security and Rural Investment Act of 2002; implementation—

Loan eligibility provisions; comments due by 6-9-03; published 4-9-03 [FR 03-08646]

Minor Program loans; comments due by 6-9-03; published 4-9-03 [FR 03-08597]

AGRICULTURE DEPARTMENT

Rural Utilities Service

Program regulations:

Farm Security and Rural Investment Act of 2002; implementation—

Loan eligibility provisions; comments due by 6-9-03; published 4-9-03 [FR 03-08646]

Minor Program loans; comments due by 6-9-03; published 4-9-03 [FR 03-08597]

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:

Northeastern United States fisheries—

Northeast multispecies; comments due by 6-10-03; published 5-23-03 [FR 03-13013]

West Coast States and Western Pacific fisheries—

Pacific Coast groundfish; comments due by 6-13-03; published 5-16-03 [FR 03-12315]

DEFENSE DEPARTMENT

Acquisition regulations:

Tangible item marking and valuing; contractor possession of government property; comments due by 6-9-03; published 5-12-03 [FR 03-11726]

ENERGY DEPARTMENT

Polygraph Examination Regulations; counterintelligence polygraph program; comments due by 6-13-03; published 4-14-03 [FR 03-09009]

ENVIRONMENTAL PROTECTION AGENCY

Air pollution control:

Federal operating permit programs—

California agricultural sources; fee payment deadlines; comments due by 6-12-03; published 5-13-03 [FR 03-11910]

ENVIRONMENTAL PROTECTION AGENCY

Air pollution control:

Federal operating permit programs—

California agricultural sources; fee payment deadlines; comments due by 6-12-03; published 5-13-03 [FR 03-11911]

Air pollution; standards of performance for new stationary sources:

Stationary gas turbines; comments due by 6-13-03; published 5-28-03 [FR 03-13416]

ENVIRONMENTAL PROTECTION AGENCY

Air programs; approval and promulgation; State plans

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.nara.gov/fedreg/plawcurr.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.access.gpo.gov/nara/nara005.html*. Some laws may not yet be available.

S. 243/P.L. 108–28
Concerning participation of Taiwan in the World Health Organization. (May 29, 2003; 117 Stat. 769)

S. 330/P.L. 108–29
Veterans' Memorial Preservation and Recognition Act of 2003 (May 29, 2003; 117 Stat. 772)

S. 870/P.L. 108–30
To amend the Richard B. Russell National School Lunch Act to extend the availability of funds to carry out the fruit and vegetable pilot program. (May 29, 2003; 117 Stat. 774)

Last List May 30, 2003

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.