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3. The important elements of typical Federal Register documents.

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

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

WHEN: Tuesday, February 7, 2006
9:00 a.m.–Noon

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

RESERVATIONS: (202) 741–6008

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Contents

Federal Register

Vol. 71, No. 10

Tuesday, January 17, 2006

Agency for Healthcare Research and Quality
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2550–2551

Agriculture Department
See Food Safety and Inspection Service
See Forest Service
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2512–2513

Arts and Humanities, National Foundation
See National Foundation on the Arts and the Humanities

Centers for Medicare & Medicaid Services
See Inspector General Office, Health and Human Services Department
RULES
Medicare:
Hospital outpatient prospective payment system and 2006 CY payment rates; correction, 2617

Coast Guard
NOTICES
Merchant mariner credentials: temporary procedures:
Credential validity; expiration dates extended, 2559

Commerce Department
See Industry and Security Bureau
See International Trade Administration
See National Institute of Standards and Technology
See National Oceanic and Atmospheric Administration
See Patent and Trademark Office
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2513–2516

Commodity Futures Trading Commission
NOTICES
Meetings; Sunshine Act, 2529

Comptroller of the Currency
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2614–2615

Customs and Border Protection Bureau
RULES
Organization and functions; field organization, ports of entry, etc.:
Rockford, IL; port limits extension, 2457–2458

Defense Department
See Navy Department
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2529–2530
Servicemembers Civil Relief Act:
Housing price inflation adjustment, 2530

Employment and Training Administration
NOTICES
Adjustment assistance; applications, determinations, etc.:
Cabot Corp., 2566
Capital City Press, Inc., 2566–2567
Nicholson Manufacturing Co. et al, 2567
Spartacraft, Inc., et al, 2567–2569
Tri-Mountain Machining, 2569

Environmental Protection Agency
RULES
Air pollution control; new motor vehicles and engines:
Light-duty vehicles, light-duty trucks, and heavy-duty vehicles; emission durability procedures, 2810–2842
Air programs; State authority delegations:
Various States, 2472–2482
PROPOSED RULES
Air pollution control; new motor vehicles and engines:
Light-duty vehicles, light-duty trucks, and heavy-duty vehicles; emission durability procedures, 2843–2855
Air programs:
Ambient air quality standards, national—
Particulate matter, 2620–2708, 2710–2808
Air programs; State authority delegations:
Various States, 2509–2510
NOTICES
Confidential business information and data transfer, 2531
Grants and cooperative agreements; availability, etc.:
Clean Water Act; Tribal nonpoint source pollution programs; guidelines, 2531–2543
Pesticide registration, cancellation, etc.:
Ferbam; correction, 2543–2544

Executive Office of the President
See Management and Budget Office
See Trade Representative, Office of United States

Federal Aviation Administration
RULES
Airworthiness directives:
Airbus, 2455–2457
Pacific Aerospace Corp. Ltd., 2453–2455
PROPOSED RULES
Airworthiness directives:
International Aero Engines, 2491–2493

Federal Highway Administration
NOTICES
Pennsylvania; final action on proposed highway, 2612

Federal Housing Finance Board
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2544–2547

Federal Reserve System
NOTICES
Banks and bank holding companies:
Change in bank control, 2548
Formations, acquisitions, and mergers, 2548
Permissible nonbanking activities, 2549

Fish and Wildlife Service
NOTICES
Comprehensive conservation plans; availability, etc.:
Mackay Island National Wildlife Refuge, NC and VA, 2560–2561
Upper Mississippi River National Wildlife and Fish Refuge; IL, IA, MN, and WI, 2561–2562
Endangered and threatened species permit applications, 2562–2563
Environmental statements; availability, etc.:
Incidental take permits—
Volusia County, FL; Florida scrub-jay, 2563–2564
Marine mammal permit determinations, etc., 2564

Food and Drug Administration
RULES
Human drugs:
Current good manufacturing practices—
Investigational new drugs; Phase 1 drugs exemption, 2458–2462
PROPOSED RULES
Human drugs:
Current good manufacturing practices—
Investigational new drugs; Phase 1 drugs exemption, 2494–2496
Institutional review boards:
Sponsors and investigators; requirement to inform IRBs of prior IRB reviews; withdrawn, 2493–2494
NOTICES
Reports and guidance documents; availability, etc.:
Exploratory Investigational New Drug Studies; industry guidance, 2551–2552
Investigational new drugs; approaches to complying with current good manufacturing practice during Phase 1; industry guidance, 2552–2554

Food Safety and Inspection Service
PROPOSED RULES
Meat and poultry inspection:
Accredited laboratory program, 2483–2491

Forest Service
NOTICES
Appealable decisions; legal notice:
Northern Region, 2513
Meetings:
National Urban and Community Forestry Advisory Council, 2513

Health and Human Services Department
See Agency for Healthcare Research and Quality
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See Health Resources and Services Administration
See Inspector General Office, Health and Human Services Department
NOTICES
Grants.gov; electronic submission of grant applications for Federal funding opportunities; early registration, 2549–2550

Health Resources and Services Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2554

Homeland Security Department
See Coast Guard
See Customs and Border Protection Bureau
See U.S. Citizenship and Immigration Services

Industry and Security Bureau
NOTICES
Meetings:
Sensors and Instrumentation Technical Advisory Committee, 2516

Inspector General Office, Health and Human Services Department
NOTICES
Program exclusions; list, 2554–2559

Interior Department
See Fish and Wildlife Service
See Land Management Bureau

Internal Revenue Service
RULES
Income taxes:
Partnerships; treatment of controlled foreign corporation's distributive share of partnership income; guidance under subpart F, 2462–2464
PROPOSED RULES
Income taxes:
Deferred compensation plans; application of section 409A; correction, 2496
Partnerships: treatment of controlled foreign corporation's distributive share of partnership income; guidance under subpart F, 2496–2497
Procedure and administration:
Collection due process procedures relating to notice upon filing notice of tax lien; hearing canceled, 2498
Substitute for return; cross-reference; public hearing, 2497–2498

International Trade Administration
NOTICES
Antidumping:
Silicomanganese from—
Brazil, 2516–2517
Tapered roller bearings and parts, finished and unfinished, from—
China, 2517–2524

International Trade Commission
NOTICES
Import investigations:
Digital processors and digital processing systems, components, and products containing same, 2565–2566
Meetings; Sunshine Act, 2566

Labor Department
See Employment and Training Administration

Land Management Bureau
NOTICES
Meetings:
Resource Advisory Councils—
New Mexico, 2564
Survey plat filings:
Idaho, 2565

Management and Budget Office
NOTICES
Reports and guidance documents; availability, etc.:
Information disseminated by Federal agencies; quality, objectivity, utility, and integrity guidelines; risk assessment bulletins, 2600

Maritime Administration
NOTICES
Coastwise trade laws; administrative waivers:
TRIPLE TROUBLE, 2612–2613

National Aeronautics and Space Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2569–2570

National Credit Union Administration
NOTICES
Meetings; Sunshine Act, 2571

National Foundation on the Arts and the Humanities
NOTICES
Meetings:
International Exhibitions Federal Advisory Committee, 2571

National Institute of Standards and Technology
NOTICES
Meetings:
Radiation detection instruments testing for Homeland Security applications; workshop, 2524–2525
National Voluntary Laboratory Accreditation Program:
Radiation detection instruments testing used in homeland security applications, 2525

National Oceanic and Atmospheric Administration
PROPOSED RULES
Fishery conservation and management:
West Coast States and Western Pacific fisheries—
Coastal pelagic species, 2510–2511
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2525–2526
Environmental statements; availability, etc.:
Alaska Coastal Zone Management Program, 2526–2527
Marine mammal permit determinations, etc., 2527
Meetings:
North Pacific Fishery Management Council, 2527–2528

National Science Foundation
NOTICES
Meetings:
International Science and Engineering Advisory Committee, 2571

Navy Department
NOTICES
Inventions, Government-owned; availability for licensing, 2530–2531

Nuclear Regulatory Commission
NOTICES
Operating licenses; amendments; no significant hazards considerations; biweekly notices, 2586–2600
Applications, hearings, determinations, etc.:
Geisen, David, 2571–2576
Goyal, Prasoon, 2576–2578
Miller, Dale, 2579–2581
Moffitt, Steven, 2581–2585
Southern Nuclear Operating Co., Inc., 2585–2586

Office of Management and Budget
See Management and Budget Office

Office of United States Trade Representative
See Trade Representative, Office of United States

Patent and Trademark Office
PROPOSED RULES
Practice and procedure:
Trademark Trial and Appeal Board rules; miscellaneous changes, 2498–2509
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2528–2529

Pension Benefit Guaranty Corporation
NOTICES
Employee Retirement Income Security Act:
Sale of assets by employer who contributes to multiemployer plan; bond/escrow requirement; exemption request, 2600–2601

Pipeline and Hazardous Materials Safety Administration
NOTICES
Pipeline safety:
Advisory bulletins—
Gas transmission lines; integrity management notification, 2613–2614

Postal Rate Commission
RULES
Practice and procedure:
Postal service definition, 2464–2472

Railroad Retirement Board
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2601–2602

Securities and Exchange Commission
NOTICES
Securities Exchange Act:
National securities exchange registration; receipt acknowledgment, 2603–2604
Self-regulatory organizations; proposed rule changes:
American Stock Exchange LLC, 2604
Chicago Board Options Exchange, Inc., 2605–2606
National Association of Securities Dealers, Inc., 2607–2610
Applications, hearings, determinations, etc.:
Aquacell Technologies, Inc., 2602–2603
Sony Corp., 2603

Social Security Administration
NOTICES
Meetings:
Ticket to Work and Work Inventives Advisory Panel, 2610–2611

State Department
NOTICES
Meetings:
Industry Advisory Panel, 2611

Trade Representative, Office of United States
NOTICES
Trade Act of 1974:
Identification of countries under Section 182; special 301 review, 2611–2612

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See Maritime Administration
See Pipeline and Hazardous Materials Safety Administration

Treasury Department
See Comptroller of the Currency
See Internal Revenue Service
NOTICES
Bonds, Treasury:
13-7/8 percent bonds (2006-2011); call for redemption, 2614

U.S. Citizenship and Immigration Services
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 2559–2560

Veterans Affairs Department
RULES
Medical benefits:
Elimination of copayment for smoking cessation counseling, 2464
NOTICES
Reports and guidance documents; availability, etc.:
VA Directive and Handbook 5021, Employee/Management Relations; Disciplinary Appeals Board procedures, 2615–2616

Separate Parts In This Issue

Part II
Environmental Protection Agency, 2620–2708

Part III
Environmental Protection Agency, 2710–2808

Part IV
Environmental Protection Agency, 2810–2855

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.

9 CFR

Proposed Rules:

318 2483
381 2483
439 2483

14 CFR

39 (2 documents) 2453, 2455

Proposed Rules:

39 2491

19 CFR

101 2457

21 CFR

210 2458

Proposed Rules:

56 2493
210 2494

26 CFR

1 2462

Proposed Rules:

1 (2 documents) 2496
301 (2 documents) 2497, 2498

37 CFR

Proposed Rules:

2 2498

38 CFR

17 2464

39 CFR

3001 2464

40 CFR

60 2472
61 2472
86 2810

Proposed Rules:

50 (2 documents) 2620
53 2710
58 2710
60 2509
61 2509
86 2843

42 CFR

419 2617

50 CFR

Proposed Rules:

660 2510

Rules and Regulations

Federal Register

Vol. 71, No. 10

Tuesday, January 17, 2006

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

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–23473; Directorate Identifier 2005–CE–54–AD; Amendment 39–14451; AD 2005–26–53]

RIN 2120–AA64

Airworthiness Directives; Pacific Aerospace Corporation Ltd. Model 750XL Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Pacific Aerospace Corporation (PAC) Ltd. Model 750XL airplanes. This AD contains the same information as emergency AD 2005–26–53 and publishes the action in the **Federal Register**. This AD requires you to insert text into the Limitations Section of the Airplane Flight Manual (AFM) that reduces the maximum takeoff weight from 7,500 pounds to 7,125 pounds. This AD results from mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for New Zealand. We are issuing this AD to reduce the maximum takeoff weight that will allow wing ultimate load requirements to be met. If wing ultimate load requirements are not met, wing failure could result and subsequent loss of control of the airplane.

DATES: This AD becomes effective on January 16, 2006, to all affected persons who did not receive emergency AD 2005–26–53, issued December 22, 2005. Emergency AD 2005–26–53 contained the requirements of this amendment and became effective immediately upon receipt.

We must receive any comments on this AD by February 14, 2006.

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

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001.
- *Fax:* 1–202–493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

To get the service information identified in this proposed AD, contact Pacific Aerospace Corporation Ltd., Hamilton Airport, Private Bag HN 3027, Hamilton, New Zealand.

To view the comments to this AD, go to *http://dms.dot.gov*. The docket number is FAA–2005–23473; Directorate Identifier 2005–CE–54–AD.

FOR FURTHER INFORMATION CONTACT: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4146; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

What events have caused this AD? The Civil Aviation Authority (CAA), which is the airworthiness authority for New Zealand, recently notified FAA that an unsafe condition may exist on all PAC Ltd. Model 750XL airplanes. The CAA reports that the wings of these airplanes may not meet the ultimate load requirements for a maximum takeoff weight of 7,500 pounds. PAC found the condition on a production wing during an ultimate load test. Investigation is not complete, but indications show that some critical rivets were not fully age-hardened. PAC is developing a modification that will replace the critical rivets with ''AN'' bolts. In the interim, PAC is reducing the maximum takeoff weight from 7,500 pounds to 7,125 pounds. The maximum takeoff weight reduction will allow the airplane to meet the ultimate load requirements for an airplane certificated in the Normal Category.

The CAA issued emergency New Zealand AD Number DCA/750XL/7, dated December 22, 2005, to ensure the continued airworthiness of these airplanes in New Zealand. These PAC Model 750XL airplanes are manufactured in New Zealand and are type-certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement.

Under this bilateral airworthiness agreement, the CAA of New Zealand has kept us informed of the situation described above.

On December 22, 2005, FAA issued emergency AD 2005–26–53 to require incorporating information into the Limitations Section of the Airplane Flight Manual (AFM) on the affected airplanes that are registered in the United States. The AFM limitation reduces the maximum takeoff weight from 7,500 pounds to 7,125 pounds.

Why is it important to publish this AD? The FAA found that immediate corrective action was required, that notice and opportunity for prior public comment were impracticable and contrary to the public interest, and that good cause existed to make the AD effective immediately by individual letters issued on December 23, 2005, to all known U.S. operators of PAC Ltd. Model 750XL airplanes. These conditions still exist, and the AD is published in the **Federal Register** as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective to all persons.

Comments Invited

Will I have the opportunity to comment before you issue the rule? This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any written relevant data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES**. Include the docket number, ''FAA–2005–23473; Directorate Identifier 2005–CE–54–AD'' at the beginning of your comments. We will post all comments we receive, without change, to *http://dms.dot.gov*, including

any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD.

Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). This is docket number FAA–2005–23473; Directorate Identifier 2005–CE–54–AD. You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://dms.dot.gov*.

Are there any specific portions of this AD I should pay attention to? We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. If you contact us through a nonwritten communication and that contact relates to a substantive part of this 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 this AD in light of those comments and contacts.

Docket Information

Where can I go to view the docket information? You may view the AD docket that contains the AD, any comments received, and any final disposition in person at the DMS Docket Offices between 9 a.m. and 5 p.m. (eastern standard time), Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5227) is located on the plaza level of the Department of Transportation NASSIF Building at the street address stated in **ADDRESSES**. You may also view the AD docket on the Internet at *http://dms.dot.gov*. The comments will be available in the AD docket shortly after the DMS receives them.

Authority for This Rulemaking

What authority does FAA have for issuing this rulemaking action? Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

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

Regulatory Findings

Will this AD impact various entities? We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Will this AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a summary of the costs to comply with this AD (and other information as included in the Regulatory Evaluation) 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 ''Docket No. FAA–2005–23473; Directorate Identifier 2005–CE–54–AD'' in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

2005–26–53 Pacific Aerospace Corporation Ltd.: Amendment 39–14451; Docket No. FAA–2005–23473; Directorate Identifier 2005–CE–54–AD.

When Does This AD Become Effective?

(a) This AD becomes effective on January 16, 2006, to all affected persons who did not receive emergency AD 2005–26–53, issued December 22, 2005. Emergency AD 2005–26–53 contained the requirements of this amendment and became effective immediately upon receipt.

Are Any Other ADs Affected by This Action?

(b) None.

What Airplanes Are Affected by This AD?

(c) This AD affects Model 750XL airplanes, all serial numbers, that are certificated in any category.

What Is the Unsafe Condition Presented in This AD?

(d) This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for New Zealand. We are issuing this AD to reduce the maximum takeoff weight that will allow wing ultimate load requirements to be met. If wing ultimate load requirements are not met, wing failure could result and subsequent loss of control of the airplane.

What Must I Do To Address This Problem?

(e) To address this problem, you must do the following:

Actions	Compliance	Procedures
Insert the following information into the Limitations Section of the Airplane Flight Manual (AFM). You may do this by inserting a copy of this AD into the Limitations Section of the AFM. ''The maximum takeoff weight is reduced from 7,500 pounds to 7,125 pounds.''	Prior to further flight after January 16, 2006 (the effective date of this AD), except for those who received emergency AD 2005–26–53, issued December 22, 2005, unless already done. Emergency AD 2005–26–53 contained the requirements of this amendment and became effective immediately upon receipt.	The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may do the flight manual changes requirement of this AD. Make an entry in the aircraft records showing compliance with this portion of the AD following section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

May I Request an Alternative Method of Compliance?

(f) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Standards Office, Small Airplane Directorate, FAA. For information on any already approved alternative methods of compliance, contact Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4146; facsimile: (816) 329–4090.

Is There Other Information That Relates to This Subject?

(g) Civil Aviation Authority airworthiness directive DCA/750XL/7, dated December 22, 2005, also addresses the subject of this AD.

Issued in Kansas City, Missouri, on January 5, 2006.

John R. Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–260 Filed 1–13–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–22035; Directorate Identifier 2005–NM–016–AD; Amendment 39–14442; AD 2006–01–03]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300 B2 and B4 Series Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Model A300 B2 and B4 series airplanes. This AD requires repetitive replacement of the angle of attack (AOA) sensors with new or overhauled AOA sensors. This AD also provides an optional terminating action for the repetitive replacements. This AD results from reports of several false stall warnings associated with stick-shaker activation, occurring during take-off. We are issuing this AD to prevent false stall warnings associated with stick-shaker activation, which could result in increased pilot workload as the pilot tries to determine the cause of the stall warning and possible reduction in the pilot's ability to control the airplane.

DATES: This AD becomes effective February 21, 2006.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of February 21, 2006.

ADDRESSES: You may examine the AD docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC.

Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Tom Stafford, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1622; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Examining the Docket

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

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to all Airbus Model A300 B2 and B4 series airplanes. That NPRM was published in the **Federal Register** on August 8, 2005 (70 FR 45592). That NPRM proposed to require an inspection to determine the part number of all angle of attack (AOA) sensors, and repetitive replacement of the AOA sensors with new or overhauled AOA sensors if necessary.

Relevant Service Information

After the NPRM was issued, we received Airbus Service Bulletin A300–34–0092, Revision 04, dated April 25, 2005. Revision 03, dated November 2, 2004, was referenced as the appropriate source of service information for accomplishing the optional terminating action specified in paragraph (g) of the NPRM. We have reviewed Revision 04 of the service bulletin and have determined that the procedures for replacing the Honeywell AOA sensors with ''vane type'' AOA sensors and replacing the current detectors in relay boxes 252VU and 107VU with new current detectors are identical to the procedures in Revision 03 of the service bulletin. Therefore, we have revised paragraph (g) of this AD to reference Revision 04 of the service bulletin as the appropriate source of service information for accomplishing the optional terminating action. We have also moved reference to Revision 03 of the service bulletin to paragraph (k) of this AD to give credit for actions done in accordance with Revision 03 before the effective date of this AD.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments received.

Request To Revise the Applicability

One commenter, the airplane manufacturer, requests that we limit the applicability of the NPRM to certain Airbus Model A300 B2 and B4 series airplanes equipped with Honeywell angle of attack (AOA) sensors having part number 965–4020–007. The commenter states that this matches the applicability of French airworthiness directive F–2003–457 R1, dated December 22, 2004. As justification for limiting the applicability, the commenter asserts that operators can easily trace the affected part on their airplanes. The commenter also states that limiting the applicability will relieve operators from inspecting airplanes, which are not equipped with the affected AOA sensor.

We do not agree to revise the applicability of this AD. Even if operators could easily trace AOA sensors installed on an airplane, this AD must be applicable to all Model A300 B2 and B4 series airplanes to ensure that an affected AOA sensor is not installed on an airplane after the effective date of this AD. However, we have added a provision to paragraph (f) of this AD to relieve operators of the inspection requirement. Operators may conduct a review of airplane maintenance records, instead of doing an inspection, if the part numbers of the AOA sensors can positively be determined from that review.

Request To Delete Compliance Time

The same commenter requests that we delete the compliance time for replacing the AOA sensor before further flight, as specified in paragraph (f) of the NPRM. The commenter states that it is not possible to comply with this compliance time because Airbus Service Bulletin A300–34–0176, Revision 01, dated

February 3, 2004, recommends replacing an affected AOA sensor with an overhauled AOA sensor, which would require operators to return the affected AOA sensor to the parts manufacturer for overhaul.

We do not agree. In developing an appropriate compliance time for this action, we considered the safety implications, parts availability, and normal maintenance schedules for the timely accomplishment of the replacement. In consideration of these items, we have determined that replacing an affected AOA sensors before further flight after inspecting to the determine its part number will ensure an acceptable level of safety and allow the replacement to be done during scheduled maintenance intervals for most affected operators. Also, we point out that paragraph (g) of this AD provides an optional terminating action to the repetitive replacements required by paragraph (f) of this AD. This terminating action allows operators to replace the affected AOA sensors with ''vane type'' AOA sensors and does not require returning an affected AOA sensor to the parts manufacturer for overhaul. According to the manufacturer, an ample number of ''vane type'' AOA sensors will be available to modify the U.S. fleet within the proposed compliance time. Furthermore, according to the provisions of paragraph (l) of this AD, we may approve requests to adjust the compliance time if the request includes data that prove that the new compliance time would provide an acceptable level of safety.

Request To Reduce the Compliance Time

One commenter states that a compliance time of 4,500 flight hours or 36 months is too long given that the unsafe condition could result in increased pilot workload as the pilot tries to determine the cause of the stall warning and possible reduction in the pilot's ability to control the airplane. We infer the commenter would like us to reduce the compliance time.

We disagree. After considering all the available information, we have determined that the compliance time, as proposed, represents an appropriate interval of time for accomplishing the required actions in a timely manner within the affected fleet, while still maintaining an adequate level of safety. In developing an appropriate compliance time, we considered the safety implications, parts availability, and normal maintenance schedules for timely accomplishment of the inspection. Furthermore, we arrived at the compliance time of 4,500 flight hours or 36 months, whichever is first, with concurrence from the manufacturer and the Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France. Reducing the compliance time would necessitate (under the provisions of the Administrative Procedure Act) reissuing the notice, reopening the period for public comment, considering additional comments subsequently received, and eventually issuing a final rule. That procedure could take as long as four months. We have determined that further delay of this AD is inappropriate. However, if additional data are presented that would justify a shorter compliance time, we may consider further rulemaking on this issue.

Clarification of Alternative Method of Compliance (AMOC) Paragraph

We have revised this AD to clarify the appropriate procedure for notifying the principal inspector before using any approved AMOC on any airplane to which the AMOC applies.

Conclusion

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

Costs of Compliance

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

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection	1	$65	None	$65	20	$1,300.
Replacement, per replacement cycle.	2	65	$3,300 ($1,100 per sensor)	3,430	20	$68,600, per replacement cycle.
Optional terminating action	7	65	$8,780	9,235	20	$184,700.

Authority for This Rulemaking

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

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

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2006–01–03 Airbus: Amendment 39–14442. Docket No. FAA–2005–22035; Directorate Identifier 2005–NM–016–AD.

Effective Date

(a) This AD becomes effective February 21, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Airbus Model A300 B2–1A, B2–1C, B2K–3C, and B2–203 airplanes; and Model A300 B4–2C, B4–103, and B4–203 airplanes; certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports of several false stall warnings associated with stick-shaker activation, occurring during take-off. We are issuing this AD to prevent false stall warnings associated with stick-shaker activation, which could result in increased pilot workload as the pilot tries to determine the cause of the stall warning and possible reduction in the pilot's ability to control the airplane.

Compliance

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

Repetitive Replacements

(f) Within 4,500 flight hours or 36 months after the effective date of this AD, whichever is first: Inspect zone 120 to determine the part numbers (P/Ns) of all three angle of attack (AOA) sensors, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–34–0176, Revision 01, dated February 3, 2004. Instead of inspecting zone 120 to determine the P/Ns of the AOA sensors, a review of airplane maintenance records is acceptable if the P/Ns of the AOA sensors can be conclusively determined from that review. If no Honeywell AOA sensor having part number (P/N) 965–4020–007 is found, then no further action is required by this paragraph. If any Honeywell AOA sensor having P/N 965–4020–007 is found, before further flight, replace the AOA sensor with a new or overhauled AOA sensor having P/N 965–4020–007, in accordance with the service bulletin. Repeat the replacement thereafter at intervals not to exceed 8,000 flight hours or 96 months, whichever is first. Accomplishing the actions specified in paragraph (g) of this AD terminates the repetitive replacements.

Optional Terminating Action

(g) Replacement of all Honeywell AOA sensors having P/N 965–4020–007 between frame (FR)18 and FR19 with ''vane type'' AOA sensors; and replacement of the current detectors in relay boxes 252VU and 107VU with new current detectors; in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–34–0092, Revision 04, dated April 25, 2005; terminate the repetitive replacements required by paragraph (f) of this AD.

No Reporting Requirement

(h) Although Airbus Service Bulletin A300–34–0176, Revision 01, dated February 3, 2004, specifies to submit certain information to the manufacturer, this AD does not include that requirement.

Parts Installation

(i) As of the effective date of this AD, no person may install an AOA sensor having P/N 965–4020–007 on any airplane, unless it is new or overhauled. Thereafter repetitively replace the new or overhauled AOA sensor in accordance with paragraph (f) of this AD.

Credit for Previously Accomplished Actions

(j) Actions done before the effective date of this AD in accordance with Airbus Service Bulletin A300–34–0176, dated July 9, 2003, are acceptable for compliance with the corresponding requirements of paragraph (f) of this AD.

Credit for Optional Terminating Action

(k) Actions done before the effective date of this AD in accordance with Airbus Service Bulletin A300–34–092, Revision 2, dated July 18, 1985, or Airbus Service Bulletin A300–34–0092, Revision 03, dated November 2, 2004, are acceptable for compliance with the requirements of paragraph (g) of this AD.

Alternative Methods of Compliance (AMOCs)

(l)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with 14 CFR 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(m) French airworthiness directive F–2003–457 R1, dated December 22, 2004, also addresses the subject of this AD.

Material Incorporated by Reference

(n) You must use Airbus Service Bulletin A300–34–0176, Revision 01, excluding Appendix 01, dated February 3, 2004, to perform the actions that are required by this AD, unless the AD specifies otherwise. The optional terminating action provided by paragraph (g) of this AD, if accomplished, must be done in accordance with Airbus Service Bulletin A300–34–0092, Revision 04, dated April 25, 2005. The Director of the Federal Register approved the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Nassif Building, Washington, DC; on the Internet at *http://dms.dot.gov;* or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on January 5, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–315 Filed 1–13–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

19 CFR Part 101

[CBP Dec. 05–38]

Extension of Port Limits of Rockford, IL

AGENCY: Customs and Border Protection; Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This rule amends the Department of Homeland Security regulations pertaining to the field organization of the Bureau of Customs and Border Protection by extending the geographical limits of the port of entry at Rockford, Illinois, to include the City of Rochelle, Illinois. The extension of the port is necessary to accommodate the Union Pacific Railroad Company's new intermodal facility in Rochelle. This change is part of the Bureau of

Customs and Border Protection's continuing program to utilize more efficiently its personnel, facilities, and resources, and to provide better service to carriers, importers, and the general public.

DATES: *Effective Date:* February 16, 2006.

FOR FURTHER INFORMATION CONTACT: Dennis Dore, Office of Field Operations, 202–344–2776.

SUPPLEMENTARY INFORMATION:

Background

The Union Pacific Railroad Company has a new state-of-the-art intermodal rail facility that is located 25 miles south of Rockford in Rochelle, Illinois. This facility provides the capacity necessary to support the efficient interchange of shipments to and from rail connections and to expedite the operation of trains and containers. In order to accommodate this new facility, and provide better service to carriers, importers, and the public, the Bureau of Customs and Border Protection (CBP) is extending the port limits of the port of Rockford, Illinois, to include the City of Rochelle, Illinois.

A Notice of Proposed Rulemaking concerning this extension was published in the **Federal Register** (69 FR 50107) on August 13, 2004. No comments were received in response to the Notice of Proposed Rulemaking. As CBP believes that the extension of the Port of Rockford, Illinois, to include the City of Rochelle, will improve service to importers and the rail transportation industry in Illinois, CBP is expanding the limits of the port of Rockford as proposed.

New Port Limits of Rockford, Illinois

CBP extends the limits of the port of Rockford, Illinois, to include the City of Rochelle, Illinois, so that the description of the limits of port reads as follows:

Bounded to the north by the Illinois/Wisconsin border; bounded to the west by Illinois State Route 26; bounded to the south by Interstate Route 88; bounded to the east by Illinois State Route 23 to the Wisconsin/Illinois border.

Authority

This change is being made under the authority of 5 U.S.C. 301 and 19 U.S.C. 2, 66 and 1624, and the Homeland Security Act of 2002, Public Law 107–296 (November 25, 2002).

The Regulatory Flexibility Act and Executive Order 12866

With DHS approval, CBP establishes, expands, and consolidates CBP ports of entry throughout the United States to accommodate the volume of CBP-related activity in various parts of the country. It also will not have significant economic impact on a substantial number of small entities. Accordingly, it is certified that this document is not subject to the additional requirements of the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

In addition, DHS and the Office of Management and Budget have determined that this final rule does not constitute a significant regulatory action as defined under Executive Order 12866.

Signing Authority

The signing authority for this document falls under 19 CFR 0.2(a). Accordingly, the final rule is signed by the Secretary of Homeland Security.

List of Subjects in 19 CFR Part 101

Customs ports of entry, Exports, Imports, Organization and functions (Government Agencies).

Amendment to the Regulations

■ For the reasons set forth above, 19 CFR part 101 is amended as set forth below.

PART 101—GENERAL PROVISIONS

■ 1. The general authority citation for part 101 is revised and the specific authority provision for § 101.3 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1623, 1624, 1646a.

Sections 101.3 and 101.4 also issued under 19 U.S.C. 1 and 58b;

* * * * *

§ 101.3 [Amended]

■ 2. In the list of ports in § 101.3(b)(1), under the state of Illinois, the ''Limits of port'' column adjacent to ''Rockford'' in the ''Ports of entry'' column is amended by removing the citation ''T.D. 95–62'' and adding in its place ''CBP Dec. 05–38''.

Dated: January 3, 2006.

Michael Chertoff,

Secretary.

[FR Doc. 06–359 Filed 1–13–06; 8:45 am]

BILLING CODE 9110–06–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 210

[Docket No. 2005N–0285]

Current Good Manufacturing Practice Regulation and Investigational New Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its current good manufacturing practice (CGMP) regulations for human drugs, including biological products, to exempt most investigational ''Phase 1'' drugs from complying with the requirements in FDA's regulations. FDA will instead exercise oversight of production of these drugs under the agency's general statutory CGMP authority and investigational new drug application (IND) authority. In addition, FDA is making available simultaneously with the publication of this direct final rule, a guidance document setting forth recommendations on approaches to CGMP compliance for the exempted Phase 1 drugs.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comments and withdraws this direct final rule. The companion proposed rule and direct final rule are substantively identical.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled ''INDs—Approaches to Complying With CGMP During Phase 1'' to provide further guidance on the subject.

DATES: This rule is effective June 1, 2006. Submit written or electronic comments on or before April 3, 2006. If FDA receives no significant adverse comments within the specified comment period, the agency will publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the agency will publish a notice of significant adverse comment in the **Federal Register** withdrawing this direct final rule before May 2, 2006.

ADDRESSES: Submit written comments on the direct final rule to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Monica Caphart, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9047; or Christopher Joneckis, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–1), 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

SUPPLEMENTARY INFORMATION:

I. Discussion

This action is intended to streamline and promote the drug development process while ensuring the safety and quality of the earliest stage investigational drug products, those intended for use in Phase 1 clinical trials. Together with its companion guidance, this rule represents a significant step in the agency's plan to formally lay out an approach to aid manufacturers in implementing manufacturing controls that are appropriate for this stage of development.

As defined in 21 CFR 312.21, a Phase 1 clinical trial includes the initial introduction of an investigational new drug into humans. Such studies are aimed at establishing basic safety and are designed to determine the metabolism and pharmacologic actions of the drug in humans. The total number of subjects in a Phase 1 study is limited—generally no more than 80 subjects. This is in contrast to Phase 2 and Phase 3 trials, which may involve substantially greater numbers of subjects being exposed to the drug product, and which aim to test the effectiveness of the drug product. During Phase 2 or 3, drug products may be made available for treatment use through one of several mechanisms for expanded access to investigational drugs.

FDA's general CGMP regulations for human drugs are set forth in parts 210 and 211 (21 CFR parts 210 and 211). Although the preamble to the September 1978 final rule issuing these regulations expressly stated that the CGMP regulations applied to investigational drug products, it also raised the possibility of proposing an additional CGMP regulation to cover drugs being used in research:

> The Commissioner finds that, as stated in § 211.1, these CGMP regulations apply to the preparation of any drug product for administration to humans or animals, including those still in investigational stages. It is appropriate that the process by which a drug product is manufactured in the development phase be well documented and controlled in order to assure the reproducibility of the product for further testing and for ultimate commercial production. The Commissioner is considering proposing additional CGMP regulations to cover drugs in research stages (43 FR 45014 at 45029, September 29, 1978).

Such additional regulations have never been issued.

In 1991, the agency issued a ''Guideline on the Preparation of Investigational New Drug Products (Human and Animal).'' That document, however, did not discuss all manufacturing scenarios, and did not clearly address small- or laboratory-scale production of drug products for use in Phase 1 clinical trials. Additionally, the 1991 guidance did not fully discuss the agency's expectations on appropriate approaches to manufacturing controls for batches produced during drug development.

For several reasons, FDA believes that production of human drug products, including biological drug products, intended for use in Phase 1 clinical trials should be exempted from complying with the specific regulatory requirements set forth in parts 210 and 211. First, even if exempted from the requirements of parts 210 and 211, investigational drugs remain subject to the statutory requirement that deems a drug adulterated:

> if * * * the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of * * * [the Federal Food, Drug, and Cosmetic] Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess (21 U.S.C. 351(a)(2)(B)).

Second, FDA oversees drugs for use in Phase 1 trials through its existing IND authority. Every IND must contain, among other things, a section on chemistry, manufacturing, and control information that describes the composition, manufacture, and control of the investigational drug product (21 CFR 312.23(a)(7)). Submission of this information, along with other information required in the IND, informs the agency of the steps that the manufacturer is taking to ensure the safety and quality of the investigational drug. Under this IND authority, FDA has the option to place an IND on clinical hold if the study subjects would be exposed to an unreasonable and significant risk or if the IND does not contain sufficient information to assess the risks to subjects (21 CFR 312.42). FDA also may terminate an IND if the methods, facilities, and controls used for the manufacturing, processing, and packing of the investigational drug are inadequate to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for subject safety (21 CFR 312.44(b)(iii)).

Thus, even though FDA is exempting Phase 1 drug products from compliance with the specific requirements of the CGMP regulations, the agency retains the ability to take appropriate actions to address manufacturing issues. For example, in addition to the authority to put an IND on clinical hold or terminate an IND, FDA may initiate an action to seize an investigational drug or enjoin its production if its production does not occur under conditions sufficient to ensure the identity, strength, quality, and purity of the drug, which may adversely affect its safety.

FDA believes this change in the CGMP regulations (parts 210 and 211) is appropriate because many of the issues presented by the production of investigational drugs intended for use in the relatively small Phase 1 clinical trials are different from issues presented by the production of drug products for use in the larger Phase 2 and Phase 3 clinical trials or for commercial marketing. We are considering additional guidance and regulations to clarify the agency's expectations with regard to fulfilling CMGP requirements when producing investigational drugs for Phase 2 and Phase 3 clinical studies.

Additionally, many of the specific requirements in the regulations in part 211 do not apply to the conditions under which many drugs for use in Phase 1 clinical trials are produced. For example, the concerns underlying the regulations' requirement for fully validated manufacturing processes, rotation of the stock for drug product containers, the repackaging and relabeling of drug products, and separate packaging and production areas are generally not concerns for these very limited production investigational drug products used in Phase 1 clinical trials. Consequently, in this direct final rule, FDA is amending the scope section of the drug CGMP regulations in 21 part

210 to make clear that production of investigational drugs for use in Phase 1 studies conducted under an IND does not need to comply with the regulations in part 211. However, once an investigational drug product has been manufactured by, or for, a sponsor and is available for use in a Phase 2 or Phase 3 study thus demonstrating an intent to expose more subjects to the investigational drug and requiring that the regulations' CGMP requirements be met, the same investigational drug product used in any subsequent Phase 1 study by the same sponsor must be manufactured in compliance with part 211. In addition to drug products that, if eventually approved, would be approved under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), this rule would apply to investigational biological products that are subject to the CGMP requirements of section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)). Examples of such products include recombinant and nonrecombinant therapeutic products, vaccine products, allergenic products, in vivo diagnostics, plasma derivative products, blood and blood products, gene therapy products, and somatic cellular therapy products (including xenotransplantation products) that are subject to the CGMP requirements of section 501(a)(2)(B).

To convey the agency's current thinking on the possible approaches to manufacturing controls for the production of Phase 1 drugs, FDA is issuing simultaneously with this direct final rule a draft guidance titled ''INDs—Approaches to Complying With CGMP During Phase 1,'' which sets forth recommendations on approaches to statutory compliance. Comments on that guidance can be submitted to the public docket identified in that document.

II. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. This direct final rule adds § 210.2(c) to make clear that production of an investigational drug for use in a Phase 1 study conducted under an IND, when the drug has not yet been, or is not being, manufactured for use in Phase 2 or 3 studies or for an already approved use, is not subject to the requirements in part 211. Additionally, the rule states that once an investigational drug product has already been manufactured and is available for use in Phase 2 or Phase 3 studies or for an already approved use, the investigational drug product used in any subsequent Phase 1 investigational studies must comply with part 211.

Because of the small batch size for these drugs, many of the issues implicated in larger scale production, which occurs late in the drug development process, or in commercial manufacture are not present during production of drugs for use in Phase 1 studies. The action taken should be noncontroversial, and the agency does not anticipate receiving any significant adverse comment on this rule.

If FDA does not receive significant adverse comment the agency will publish a document in the **Federal Register** confirming the effective date of the final rule. The agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the **Federal Register**. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment also states why this rule would be ineffective without the additional change.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, identical in substance to the direct final rule, that provides a procedural framework from which to proceed with standard notice-and-comment rulemaking should the direct final rule be withdrawn because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding this direct final rule and vice versa. FDA will not provide additional opportunity for comment on the companion proposed rule. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. Legal Authority

Under section 501(a)(2)(B) of the act (21 U.S.C. 201 *et seq.*) a drug is deemed adulterated if the methods used in, or the facilities, or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated in conformity with CGMP to ensure that such drug meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. The rulemaking authority conferred on FDA by Congress under the act permits the agency to amend its regulations as contemplated by this direct final rule. Section 701(a) of the act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the act. We refer readers to the legal authority section of the preamble of the 1978 CGMP regulations for a fuller discussion (43 FR 45014 at 45020–45026).

IV. Environmental Impact

The agency has determined that under 21 CFR 25.30(h) 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.

V. Analysis of Impacts

FDA has examined the impacts of the direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. Because exempting production of drugs for use in Phase 1 studies from compliance with specific regulatory requirements does not add any burden, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold

after adjustment for inflation is $115 million using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The purpose of this direct final rule is to amend our current CGMP regulations to exempt the manufacture of Phase 1 drugs from compliance with the regulatory requirements in part 211. The rule will affect drug manufacturers, chemical manufacturers, and laboratories that manufacture drugs on a small scale for use in Phase 1 clinical trials.

For drug manufacturers that produce Phase 1 drug products in-house and also produce approved drug products, this direct final rule is expected to reduce the amount of documentation they produce and maintain when they manufacture a Phase 1 drug. In some cases, it should also reduce the amount of component and product testing.

Because they have far less experience with pharmaceutical CGMPs, some chemical manufacturers and laboratories may experience a slight increase in documentation if they currently do not have written standard operating procedures (SOPs), or if they need to modify existing methods of documentation. Although formats may be different, the rule should not require more information than is already collected as part of standard laboratory practices.

Because the actual SOPs and manufacturing requirements are different for each new drug product and manufacturing facility, the procedures to comply with the statutory CGMP requirements for Phase 1 production are generated as part of product development. The savings or costs would be incurred on a per-IND and not per-facility basis.

This rule is intended to clarify requirements of the statutory CGMPs that are necessary for Phase 1 products and to exempt certain drugs produced under INDs from other CGMP requirements. Some manufacturers may realize savings because they no longer must meet certain requirements. The savings to drug manufacturers that produce the phase 1 drugs in-house will vary greatly from product to product. FDA lacks data to estimate the extent of cost savings. Some examples where substantial savings may be realized are the level of testing and analyzing components and in-process materials. These costs can typically range from $50 to $1,200 per component tested. The extent of the need for SOPs and methods validation may also be greatly reduced. We estimate that large drug manufacturers that produce Phase 1 drugs in-house could potentially save between 24 to 40 hours per IND. In addition, the clarifications we have made could lead some large firms to produce future drugs for Phase 1 trials in-house, rather than contracting the work out.

For chemical manufacturers and laboratories, the requirements in this rule may increase the time required for developing SOPs for quality, process, and procedural controls and will be incurred on a recurring basis for each new product produced. There may also be an incremental increase in training costs to educate employees on the CGMP requirements. We estimate that an additional 12 to 24 hours may be required for these activities depending on the experience of the entity and its employees with our current CGMP rule.

The facility that manufactures the drug for the Phase 1 trials is identified in the IND. We do not keep a database of these facilities and, therefore, we do not have a precise number of entities that might be affected by this final rule. To estimate the economic impact, we derived an estimate of the number affected annually based on the number of INDs we receive.

In 2003, we received about 350 research and 500 commercial INDs. However, this rule would not apply to the majority of these INDs because they are for drug products that already have approvals and thus are subject to part 211. To derive an estimate of the percentage of INDs that would be affected by this rule, we used the percentage of total new drug applications (NDAs) that were for new molecular entities (NMEs) and applied that percentage to the number of annual IND applications. Historically, about 30 percent of NDAs are for NMEs each year. Assuming the relationship would be the same for the INDs and that the number of INDs will remain at about 850, this rule would affect about 255 INDs per year. A firm may produce multiple drug products for Phase 1 trials in a given year and use different companies to produce each of these drugs. Therefore, we do not know how many individual entities would be affected by this rule each year.

The Small Business Administration (SBA) defines manufacturers of biologic drugs as small entities if they employ fewer than 500 people and other drug manufacturers as small if they employ fewer than 750 people. FDA estimates that about 65 percent of the entities that submit NDAs and biologics license applications to the agency meet SBA's definition of a small entity. We assume that the distribution of large to small entities that submit INDs would be about the same. Although many of the entities that produce drug products for Phase 1 trials are laboratories, they are usually part of much larger institutions and are not considered small under SBA's definition. All of the entities affected by this rule have personnel with the skills necessary to comply with the requirements.

Because we do not know the experience levels the affected entities have with our current CGMP requirements, we used the midpoint of the estimated ranges to estimate the potential recurring savings or costs.

Savings to large manufacturers from reduced SOP and validation requirements for Phase 1 drug production in-house, assuming a time savings of 32 hours per application, a fully loaded wage rate of $45 and 90 INDs per year (approximately 35 percent of 255) would total $129,600 per year or $1,440 per IND. This would be in addition to any other savings from decreased component testing.

The incremental average annual cost to chemical manufacturers and laboratories, assuming all would incur costs and assuming an average increase of 18 hours per application for writing SOPs and training, a fully loaded wage rate of $45, and 165 INDs (approximately 65 percent of 255) affected per year, would total $133,650 per year or $810 per IND.

Although we do not know the number and size distribution of the entities affected by this rule, FDA believes that the impact on them will be negligible and should actually reduce the compliance burden for some. To clarify the requirements for the manufacture of drugs for Phase 1 trials, we have prepared a draft guidance document with recommendations for compliance.

VI. Paperwork Reduction Act of 1995

This direct final rule contains no new information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Under the direct final rule, the production of human drug products, including biological drug products, intended for use in Phase 1 clinical trials will be exempted from complying with the specific regulatory requirements set forth in parts 210 and 211. Parts 210 and 211 contain information collection requirements that have been approved by OMB under control number 0910–0139. As explained in the following paragraph, the information collection requirements

in parts 210 and 211 will be reduced under this direct final rule.

The OMB-approved hourly burden to comply with the information collection requirements in parts 210 and 211 (control number 0910–0139) is 848,625 hours. FDA estimates that, under the direct final rule, approximately 7,315 drugs will be exempted from complying with the specific regulatory requirements set forth in parts 210 and 211. Based on this number and the total number of drugs that are subject to parts 210 and 211, FDA estimates that the burden hours approved under control number 0910–0139 will be reduced by approximately 50,493 hours. Thus, as a result of the direct final rule, the amended burden hours in control number 0910–0139 will be approximately 798,132 hours.

VII. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 210

Drugs, Packaging and containers.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 210 is amended as follows:

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

■ 1. The authority citation for 21 CFR part 210 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 2. Section 210.2 is amended by adding paragraph (c) to read as follows:

§ 210.2 Applicability of current good manufacturing practice regulations.

* * * * *

(c) An investigational drug for use in a Phase 1 study, as defined in § 312.21(a) of this chapter, is subject to the statutory requirements set forth at 21 U.S.C. 351(a)(2)(B). The production of such drug is exempt from compliance with the regulations in part 211 of this chapter. However, this exemption does not apply to an investigational drug for use in a Phase 1 study once the investigational drug has been made available for use by or for the sponsor in a Phase 2 or Phase 3 study, as defined in § 312.21(b) and (c) of this chapter, or the drug has been lawfully marketed. If the investigational drug has been made available in a Phase 2 or 3 study or the drug has been lawfully marketed, the drug for use in the Phase 1 study must comply with part 211.

Dated: January 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–353 Filed 1–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9240]

RIN 1545–BF15

Guidance Under Subpart F Relating to Partnerships

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations providing guidance under subpart F relating to partnerships. The temporary regulations add rules for determining whether a controlled foreign corporation's (CFC's) distributive share of partnership income is excluded from foreign personal holding company income under the exception contained in section 954(i). These temporary regulations will affect CFCs that are qualified insurance companies, as defined in section 953(e)(3), that have an interest in a partnership and U.S. shareholders of such CFCs. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective January 17, 2006.

Applicability Date: For dates of applicability, see § 1.954–2T(a)(5)(v).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Kate Y. Hwa, (202) 622–3840 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR part 1 relating to the rules under section 954(i) of the Internal Revenue Code (Code) for determining whether a controlled foreign corporation's (CFC's) distributive share of partnership income is excluded from foreign personal holding company income under the exception contained in section 954(i).

Need for Changes

On July 23, 2002, the IRS and the Treasury Department published in the **Federal Register** (TD 9008, 67 FR 48020) final regulations under section 702 and subpart F. Since the publication of TD 9008, the IRS and the Treasury Department have received several comments relating to the rule in the final regulations regarding the application of section 954(i) (special rule for income derived in the active conduct of an insurance business). These temporary regulations modify this rule in response to these comments.

Explanation of Revisions

Section 1.954–2(a)(5)(ii) sets forth special rules for determining the extent to which a CFC's distributive share of an item of income of a partnership is foreign personal holding company income. Section 1.954–2(a)(5)(ii)(C) addresses the exception contained in section 954(i) for income derived in the active conduct of an insurance business. Investment income that is excluded from insurance income as exempt insurance income under section 953(e) may nevertheless be treated as subpart F income if it falls within the definition of foreign personal holding company income under section 954(c) and the exception contained in section 954(i) is

not satisfied. Section 1.954–2(a)(5)(ii)(C) provides that a CFC's distributive share of partnership income is excluded from foreign personal holding company income under the exception contained in section 954(i) only if the CFC is a qualifying insurance company, generally as defined in section 953(e)(3), and the partnership, of which the CFC is a partner, generates qualified insurance income within the meaning of section 954(i)(2), taking into account only the income of the partnership. Qualified insurance income is defined under section 954(i)(2) as income of a qualifying insurance company that is derived from investment of certain of its reserves or surplus if certain other requirements are satisfied.

Commentators expressed concern that § 1.954–2(a)(5)(ii)(C) would never permit a CFC's distributive share of partnership income to qualify for the exclusion under section 954(i). Section 7701(a)(3) and the regulations provide that any entity that is an insurance company is treated as a corporation for Federal tax purposes. See Rev. Rul. 83–132 (1983–2 C.B. 270). Thus, any entity engaged in an active insurance business generally would be treated as a corporation and therefore would not be subject to the rule in § 1.954–2(a)(5)(ii)(C).

Commentators also distinguished section 954(i) from the other exceptions to foreign personal holding company income in section 954, arguing that those exceptions do not provide the appropriate model for section 954(i). The special rules in the regulations regarding the exception to foreign personal holding company income contained in section 954(c), or the exception for income derived from the active conduct of a banking or similar business contained in section 954(h), turn on whether the income was generated from certain active business activities. In contrast, income that is excluded under section 954(i) may be generated from purely passive investments as long as the amount of the investments satisfies the requirements set forth in section 954(i). Commentators asked for clarification of the regulations to take into account the purposes of section 954(i).

In response to these comments, these temporary regulations provide that a CFC's distributive share of partnership income will qualify for the exception contained in section 954(i) if the CFC is a qualifying insurance company and the income of the partnership would have been qualified insurance income under section 954(i) if received by the CFC directly. Thus, whether the CFC partner's distributive share of partnership income is qualified insurance income is determined at the CFC partner level.

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 has also been determined that section 553(b) of the Administrative Procedures Act (5 U.S.C. chapter 5) does not apply to these regulations and, because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this temporary regulation will be submitted 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 Kate Y. Hwa of the Office of the Associate Chief Counsel (International), IRS. However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for 26 CFR part 1 continues to read, in part, as follows:

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

■ **Par. 2.** Section 1.954–2 is amended by revising paragraphs (a)(5)(ii)(C) and (a)(5)(iii) *Example 2*, to read as follows:

§ 1.954–2 Foreign personal holding company income.

(a) * * *

(5) * * *

(C) [Reserved]. For further guidance, see § 1.954–2T(a)(5)(ii)(C).

* * * * *

(iii) * * *

Example 2. [Reserved]. For further guidance, see § 1.954–2T(a)(5)(iii) Example 2.

* * * * *

■ **Par. 3.** Section 1.954–2T is added as follows:

§ 1.954–2T Foreign personal holding company income (temporary).

(a)(1) through (5)(ii)(B) [Reserved]. For further guidance, see § 1.954–2(a)(1) through (5)(ii)(B).

(C) A controlled foreign corporation's distributive share of partnership income will not be excluded from foreign personal holding company income under the exception contained in section 954(i) unless the controlled foreign corporation is a qualifying insurance company, as defined in section 953(e)(3), and the income of the partnership would have been qualified insurance income, as defined in section 954(i)(2), if received by the controlled foreign corporation directly. See § 1.952–1(g)(1).

(iii) *Examples.* [Reserved] For further guidance, see § 1.954–2(a)(5)(iii).

Example 1. [Reserved] For further guidance, see § 1.954–2(a)(5)(iii) *Example 1.*

Example 2. D Corp, a Country F corporation, is a controlled foreign corporation within the meaning of section 957(a). D Corp is a qualifying insurance company, within the meaning of section 953(e)(3), that is engaged in the business of issuing life insurance contracts. D Corp has reserves of $100x, all of which are allocable to exempt contracts, and $10x of surplus, which is equal to 10 percent of the reserves allocable to exempt contracts. D Corp contributed the $100x of reserves and $10x of surplus to DJ Partnership in exchange for a 40-percent partnership interest. DJ Partnership is an entity organized under the laws of Country G and is treated as a partnership under the laws of Country G and Country F. DJ Partnership earns $30x of investment income during the taxable year that is received from persons who are not related persons with respect to D Corp, within the meaning of section 954(d)(3). D Corp's distributive share of this investment income is $12x. This income is treated as earned by D Corp in Country F under the tax laws of Country F and meets the definition of exempt insurance income in section 953(e)(1). This $12x of investment income would be qualified insurance income, under section 954(i)(2), if D Corp had received the income directly, because the $110x invested by D Corp in DJ Partnership is equal to D Corp's reserves allocable to exempt contracts under section 954(i)(2)(A) and allowable surplus under section 954(i)(2)(B)(ii). Thus, D Corp's distributive share of DJ Partnership's income will be excluded from foreign personal holding company income under section 954(i).

(iv) [Reserved].

(v) *Effective date.* [Reserved]. See § 1.954–2(a)(5)(v).

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Eric Solomon,

Acting Deputy Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 06–355 Filed 1–13–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AM11

Elimination of Copayment for Smoking Cessation Counseling

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This rule adopts as final, without change, the interim final rule published in the **Federal Register** (70 FR 22595) on May 2, 2005. The Department of Veterans Affairs (VA) is publishing this final rule to designate smoking cessation counseling (individual and group sessions) as a service that is not subject to copayment requirements.

DATES: *Effective Date:* January 17, 2006.

FOR FURTHER INFORMATION CONTACT: Eileen P. Downey, Program Analyst, Policy Development, Chief Business Office (16), (202) 254–0347 or Dr. Kim Hamlet-Berry, Director, Public Health National Prevention Program, Veterans Health Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8929. (These are not toll-free numbers).

SUPPLEMENTARY INFORMATION: An interim final rule amending VA's medical regulations to set forth a rule designating smoking cessation counseling (individual and group sessions) as a service that is not subject to copayment requirements was published in the **Federal Register** on May 2, 2005 (70 FR 22595).

We provided a 60-day comment period that ended July 1, 2005. Twelve comments were received and all supported the rule. Based on the rationale set forth in the interim final rule, we now adopt the interim final rule as a final rule.

Administrative Procedure Act

In the May 2, 2005, **Federal Register** notice, we determined that there was a basis under the Administrative Procedure Act for issuing the interim final rule with immediate effect. We invited and received public comment on the interim final rule. This document merely affirms the interim final rule as a final rule without change.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule will not directly affect any small entities. Only individuals could be directly affected. Accordingly, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: November 22, 2005

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

PART 17—MEDICAL

Accordingly, the interim final rule amending 38 CFR part 17, which was published at 70 FR 22595 on May 2, 2005, is adopted as a final rule without change.

[FR Doc. 06–373 Filed 1–13–06; 8:45 am]

BILLING CODE 8320–01–P

POSTAL RATE COMMISSION

39 CFR Part 3001

[Docket No. RM2004–1; Order No. 1449]

Definition of Postal Service

AGENCY: Postal Rate Commission.

ACTION: Final rule.

SUMMARY: This document addresses adding a definition of the term ''postal service'' to the rules of practice. This change is prompted by the Postal Service's action with respect to nonpostal initiatives. There is often controversy and uncertainty regarding the postal character of the services provided under those initiatives. The definition provides guidance to the Postal Service and the general public concerning services that are subject to sections 3622 and 3623 of the Postal Reorganization Act.

DATES:

1. *Effective Date:* February 16, 2006.
2. Deadline for (optional) Postal Service motion to dismiss Docket No. C2004–1: January 17, 2006.
3. Deadline for (optional) Postal Service update on 14 services identified in Consumer Action petition: February 17, 2006.
4. Deadline for Postal Service updates on postal and nonpostal services: June 1, 2006.

ADDRESSES: File all documents referred to in this order electronically via the Commission's Filing Online system at *http://www.prc.gov.*

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, 202–789–6818.

SUPPLEMENTARY INFORMATION:

Regulatory History

69 FR 3288, January 23, 2004.
69 FR 11353, March 10, 2004.
69 FR 67514, November 12, 2004.

I. Introduction and Summary

The Commission initiated this rulemaking to consider amending its Rules of Practice and Procedure, 39 CFR 3001.1 *et seq.*, to include a definition of the term ''postal service.'' [1] As a result of comments received in response to Order No. 1389 as well as further consideration of the issues presented, the Commission proposed a revised definition, which read as follows: ''*Postal service*'' means the receipt, transmission, or delivery by the Postal Service of correspondence, including, but not limited to, letters, printed matter, and like materials; mailable packages; or other services supportive or ancillary thereto.'' [2] The revised definition differed from that originally proposed in two principal respects. First, it made the Service's statutory ''postal service'' duties the touchstone of the definition rather than any specific activities the Postal Service may or may not perform. Second, in response to comments,[3] the accompanying discussion made clear what had been implied—that electronic communication services offered by the Postal Service to the public fell within the scope of the definition.

Order No. 1424 provided interested persons an opportunity to comment on the revised definition. The proposal is supported by mailing and consumer interests, as well as by a competitor of the Postal Service. It is opposed by two commenters, albeit on entirely different grounds.

Parcel Shippers Association (PSA), Pitney Bowes Inc., and the Office of the Consumer Advocate and Consumer Action (OCA/CA), endorse the revised definition as is.[4] United Parcel Service (UPS) supports the proposed rule, but suggests that the definition be modified to delete the reference to correspondence.[5] The Association for Postal Commerce (PostCom) argues that the Postal Service is not authorized to offer purely electronic services unrelated to physical mail delivery whether on a regulated or unregulated basis. In the alternative, based on the assumption that the Commission will proceed with defining postal service, PostCom suggests modifications to more closely track the statute.[6] The Postal Service restates its earlier contention that the Commission lacks the authority to determine the scope of its own jurisdiction, contending that the definition may only restate the ''prevailing law,'' which it defines by reference to two court opinions.[7]

The Commission finds the comments of the parties to be helpful and, upon review, has revised the definition in minor respects in the final rule. The Postal Service is alone in its view that the Commission lacks authority to determine the scope of its own jurisdiction. While it reiterates that position in its comments, it fails to address the substance of Order No. 1424, which discussed in detail the merits of the Postal Service's arguments and the basis for the Commission's conclusions.[8] In the instant order, the Commission rejects the Postal Service's contention that it is limited simply to restating ''prevailing law'' as the Postal Service would define it, finding it both contrived and myopic. The final rule imposes no restrictions on the types of service, postal or otherwise, that the Postal Service may wish to offer. It remains free to offer whatever services or products management may wish to offer subject to the requirements of the Act. For those that fall within the meaning of the final rule, however, the Postal Service has an obligation to obtain a recommended decision before commencing a service or charging the public. Procedures are established herein to address existing services unilaterally begun by the Postal Service which meet the definition of the term postal service.

The rule is supported by mailers, private industry in competition with the Postal Service, and consumer interests. The final rule comports with the statute, legislative history, and case law. It is in the public interest and is necessary and proper for the Commission to carry out its responsibilities under the Act.

Having thoroughly considered the record, including the parties' comments, in this proceeding, the Commission finds it appropriate to adopt as its final rule new paragraph (s) to § 3001.5 of its Rules of Practice and Procedure, 39 CFR 3001.1, as follows: ''*Postal service* means the receipt, transmission, or delivery by the Postal Service of correspondence, including, but not limited to, letters, printed matter, and like materials; mailable packages; or other services incidental thereto.'' The amendment is effective 30 days after publication in the **Federal Register**.

II. The Unsettled Nature of New Services

This proceeding was precipitated by a petition filed by Consumer Action, which requested the Commission to commence proceedings concerning 14 services offered by the Postal Service without prior Commission approval.[9] It also was precipitated by a number of other recent proceedings in which the ''postal'' character of a new service was squarely at issue. In Order No. 1389, the Commission discussed the relatively few proceedings in which it was called upon to consider, for jurisdictional purposes, the meaning of the term ''postal service,'' following the decision in *Associated Third Class Mail Users* v. *U.S. Postal Service (ATCMU)*,[10] which vested the Commission with jurisdiction over special services.[11] Following the Commission's review of special services in Docket No. R76–1 and Docket No. MC78–3, involving the Postal Service's request for a recommended decision to establish an Electronic Computer Originated Mail subclass, nearly 20 years elapsed before the Commission had occasion again to consider the issue as presented in a series of dockets commencing in 1995.

The first two dockets in this series, Docket Nos. C95–1 and C96–1, raised

[1] *See* Proposed Rulemaking Concerning Amendment to the Rules of Practice and Procedure, PRC Order No. 1389, January 16, 2004.

[2] Notice and Order Concerning Proposed Amendment to the Commission's Rules of Practice and Procedure, PRC Order No. 1424, November 12, 2004, at 3–4, 49.

[3] *See, e.g.*, Comments of United Parcel Service in Support of Proposed Rule, March 9, 2004, at 3–4; and Office of the Consumer Advocate and Consumer Action Comments on Proposed Amendment to the Commission's Rules of Practice and Procedure, March 15, 2004, at 4–6; *see also* PostCom Comments on Proposed Rulemaking Concerning Amendment to the Rules of Practice and Procedure, March 1, 2004, at 3, 4.

[4] *See* Comments of the Parcel Shippers Association to the Proposed Rule Concerning the Definition of ''Postal Service,'' January 11, 2005; Comments of Pitney Bowes Inc., February 1, 2005; and Office of the Consumer Advocate and Consumer Action Comments on Proposed Amendment to the Commission's Rules, February 1, 2005, at 2 (OCA/CA Initial Comments). OCA/CA also suggest procedures by which the Commission can monitor the commercial activities of the Postal Service for compliance with the Postal Reorganization Act. *Id.* at 9–19.

[5] Reply Comments of United Parcel Service on Revised Proposed Amendment to the Commission's Rule, March 1, 2005, at 2–3 (UPS Reply Comments).

[6] PostCom Comments on Proposed Rulemaking Concerning the Definition of ''Postal Service'', February 1, 2005 (PostCom Initial Comments).

[7] Initial Comments of the United States Postal Service in Response to Order No. 1424, February 1, 2005, at 4–6 (Postal Service Initial Comments).

[8] *See* Order No. 1424, *supra*, at 6–39.

[9] *See* PRC Order No. 1388, Docket *2003, January 16, 2004.

[10] *Associated Third Class Mail Users* v. *U.S. Postal Service*, 405 F.Supp. 1109 (D. D.C. 1975); *National Association of Greeting Card Publishers* v. *U.S. Postal Service*, 569 F.2d 570 (D.C. Cir. 1976); *vacated on other grounds*, 434 U.S. 884 (1977).

[11] *See* PRC Order No. 1389, January 16, 2004, at 1–9.

the issue of the meaning of the term ''postal service,'' and are distinguishable from subsequent proceedings in that neither involved new technology.[12] Docket No. C95–1 concerned shipping and handling charges for orders placed with the Postal Service Philatelic Service Fulfillment Center,[13] while Docket No. C96–1 concerned fees for a new packaging service (Pack & Send).[14] Docket No. C99–1 introduced a novel element to the controversy involving the Postal Service's offering new services to the public without first requesting a recommended decision from the Commission, namely, the use of new technology to provide the service; indeed this has been central to virtually all subsequent disputes over the Postal Service's unilateral offering of new services.[15]

The complaint in Docket No. C99–1 concerned Post Electronic Courier Service (Post E.C.S.), an all-electronic means of transmitting documents securely via the Internet.[16] This proceeding was distinguishable from the earlier complaints because it involved an all-electronic service, and also because the Commission never reached the question whether Post E.C.S. was or was not a postal service, as the complaint was subsequently dismissed as moot.[17] Notably, however, the Commission did not find it dispositive that service did not entail hard-copy mail.[18]

In Docket No. R2001–1, a discovery dispute ensued over various services offered by the Postal Service, e.g., Post E.C.S., USPS eBillPay, and USPS Send Money. The Postal Service objected to these interrogatories, characterizing the services as nonpostal and irrelevant to the rate proceeding. The Postal Service was directed to respond to certain interrogatories; however, this ruling was suspended as a result of a settlement filed in that proceeding.[19]

The petition filed by Consumer Action, which became the springboard for this rulemaking, requested the Commission to initiate proceedings concerning 14 services offered by the Postal Service without prior Commission approval. The 14 services ranged from electronic services, such as online payment services and electronic postmark, to miscellaneous other services, such as retail merchandise and the Unisite Antenna Program. The Postal Service argued that all of the services identified in the petition were nonpostal.[20]

Subsequent to the commencement of this proceeding, DigiStamp, Inc. filed a complaint which, among other things, contends that the Postal Service is offering a postal service, Electronic Postmark, without first obtaining a recommended decision from the Commission.[21] As an element of its complaint, DigiStamp alleges competitive harm.[22] The Postal Service submitted an answer to the complaint as well as a motion to dismiss, arguing, inter alia, that the Commission ''lacks authority to resolve the claims that DigiStamp has made.'' [23] DigiStamp submitted a reply to the Postal Service's motion, challenging the Postal Service's authority to implement Electronic Postmark unilaterally.[24] The matter is pending before the Commission.

Finally, the dispute over the status of various services offered by the Postal Service continued in the latest omnibus rate proceeding, Docket No. R2005–1. During discovery, OCA sought relatively detailed data about every domestic service or product sold by the Postal Service that is not contained in the Domestic Mail Classification Schedule. The Postal Service provided some information but objected to the interrogatories arguing, among other things, lack of relevance, *i.e.,* that nonpostal services are outside the Commission's jurisdiction. Following motion practice, the Postal Service was directed to file certain additional information in response to the interrogatories.[25]

III. The Commission Has Authority to Determine Its Own Jurisdiction

Section 3603 of the Postal Reorganization Act, 39 U.S.C. 101 et seq., authorizes the Commission to adopt ''rules and regulations and establish procedures, subject to chapters 5 and 7 of title 5, and take any other action [it] deem[s] necessary and proper to carry out [its] functions and obligations to the Government of the United States and the people as prescribed under this chapter.'' 39 U.S.C 3603. No party disputes the Commission's authority to adopt a definition of the term ''postal service.'' The Postal Service, however, argues that the Commission is limited simply to restating ''prevailing law,'' which it defines as the *ATCMU* opinion as affirmed by *NAGCP* I.[26]

The Postal Service concept of ''prevailing law'' is contrived. On the one hand, it would limit those precedents to the factual situation prevailing 30 years ago. On the other hand, the Postal Service ignores ''prevailing law'' establishing that the Commission's interpretation, not the Postal Service's, is entitled to deference regarding rate and classification matters.

While *ATCMU* and *NAGCP I* provide a standard for evaluating analogous services, it is indisputable that those opinions addressed a narrow question, *i.e.*, whether certain long-established, traditional special services were postal

[12] Since this is the third order in this proceeding, it will be assumed that the reader is familiar with the background of this proceeding, including the Commission's institutional history involving jurisdictional determinations. Hence, the following discussion will be somewhat abbreviated. For a more complete discussion, *see* Order No. 1389, *supra*, at 1–9.

[13] The Commission dismissed the complaint, finding that the handling and shipping of catalog orders placed with the Philatelic Fulfillment Service Center were not closely related to the delivery of mail and, thus, charges for those services did not constitute fees for postal services under 39 U.S.C. 3662. PRC Order No. 1075, Docket No. C95–1, September 11, 1995.

[14] The Commission found Pack & Send to be a postal service because, among other things, it represented ''an entirely new form of access'' to parcel services and because of its potential public effect, particularly on the Commercial Mailing Receiving Agency industry. PRC Order No. 1145, Docket No. C96–1, December 16, 1996, at 12, 17–18. Following this finding, the Commission held further proceedings in Docket No. C96–1 in abeyance pending a filing by the Postal Service requesting a recommended decision concerning Pack & Send service, or the filing of a notice by the Service indicating that the packaging service was discontinued. *Id.* at 25. Further proceedings proved unnecessary as the Postal Service chose to discontinue Pack & Send service. PRC Order No. 1171, Docket No. C96–1, April 25, 1997.

[15] The sole exception is Docket No. C2004–3 involving stamped stationery.

[16] In its motion to dismiss, the Postal Service argued that the Commission lacked the authority to determine the status of the service as either postal or nonpostal. The Commission denied the motion, finding that its mail classification authority empowered it to review the status of services proposed or offered by the Postal Service. Nor was the Commission persuaded, based on the record developed to that point, that the service did not include domestic operations or that it was nonpostal. PRC Order No. 1239, Docket No. C99–1, May 3, 1999, at 12–21.

[17] PRC Order No. 1352, Docket No. C99–1, November 6, 2002.

[18] PRC Order No. 1239, *supra*, at 17–21.

[19] *See* P.O. Ruling R2001–1/42, January 29, 2002, at 5–11, 13.

[20] For a complete discussion of issues concerning the petition, *see* PRC Order No. 1388, Docket *2003, January 16, 2004.

[21] *See* Complaint of DigiStamp, Docket No. C2004–2, February 25, 2004.

[22] *Id.* at 3 and 7.

[23] Motion of the United States Postal Service to Dismiss, Docket No. C2004–2, April 26, 2004, at 5. In the alternative, the Postal Service argues that the complaint should be dismissed because Electronic Postmark is a nonpostal service. *Id.* at 6 et seq. *See also* Answer of the United States Postal Service, Docket No. C2004–2, April 26, 2004.

[24] Digistamp Answer in Response to Motion of the United States Postal Service to Dismiss, Docket No. C2004–2, May 3, 2004.

[25] *See* P.O. Ruling R2005–1/58 and P.O. Ruling R2005–1/70.

[26] *National Association of Greeting Card Publishers* v. *U.S. Postal Service*, 569 F.2d 570 (D.C. Cir. 1976) (*NAGCP I*), *vacated on other grounds*, 434 U.S. 884 (1977). *See* Postal Service Initial Comments at 3.

services or not.[27] Those opinions did not address or even consider the potential impact of the profound technological changes that have occurred in the nearly 30 years since they were issued and which have been central to many of the new services offered unilaterally by the Postal Service. The ''prevailing law'' is simply not the prevailing factual situation; rather it is the standards which are to be used to evaluate and resolve controversies wrought by wholly new technologies not envisioned when the opinions were issued.[28]

The Postal Service takes the position that the Commission lacks authority to determine the scope of its own jurisdiction under Chapter 36 of the Act.[29] The Postal Service further contends that it cannot be bound by any definition that extends beyond its interpretation of prevailing law.[30] Under its theory, its unilateral declaration of whether any service or product is or is not postal is determinative. Thus, under the Postal Service's theory, the Commission's jurisdiction is based not on its own consideration of the facts as applicable to policies and the rate and classification factors of the Act, but rather on what the Postal Service unilaterally determines to be postal.

In Order No. 1424, the Commission rejected this claim, explaining in some detail the basis of its conclusion that it has the primary responsibility for interpreting whether services offered by the Postal Service are subject to Chapter 36 of the Act.[31] Nothing in the Postal Service's comments warrants altering that conclusion. The Postal Service's interpretation remains wholly unconvincing.

The Postal Service's view of the ''prevailing law'' ignores a series of cases, including *NAGCP I,* holding that the Commission's interpretation of rate and classification matters is due deference.[32]

The Supreme Court has affirmed this principle:

> Although the Postal Reorganization Act divides ratemaking responsibility between two agencies, the legislative history demonstrates 'that ratemaking * * * authority [was] vested primarily in [the] Postal Rate Commission.' S. Rep. No. 91–912, p. 4 (1970) (Senate Report); *see Time, Inc.* v. *USPS,* 685 F. 2d 760, 771 (CA2 1982); *Newsweek, Inc.* v. U*SPS,* 663 F. 2d, at 1200–1201; *NAGCP III,* 197 U.S. App. D.C., at 87, 607 F. 2d, at 401. The structure of the Act supports this view. While the Postal Service has final responsibility for guaranteeing that total revenues equal total costs, the Rate Commission determines the proportion of the revenue that should be raised by each class of mail. In so doing, the Rate Commission applies the factors listed in § 3622(b). Its interpretation of that statute is due deference. *See Time, Inc.* v. *USPS,* 685 F. 2d, at 771; *United Parcel Service, Inc.* v. *USPS,* 604 F. 2d 1370, 1381 (CA3 1979), *cert. denied,* 446 U.S. 957 (1980).

National Association of Greeting Card Publishers v. *U.S. Postal Service,* 462 U.S. 810, 821 (1983).

The Court of Appeals for the D.C. Circuit specifically resolved any suggestion that the Commission lacked the implicit authority to assert jurisdiction: ''[A]ny reasonable examination of the purposes of the Act discloses Congress' implicit design that the distinct functions of service provision and rate adjustment be divided between the Postal Service and the Rate Commission.'' *NAGCP I* at 597.[33]

Criticizing the Postal Service's jurisdictional argument as ''wholly unconvincing,'' [34] the Court noted that the Commission ''advances an interpretation of the Act quite at odds with that of the Service and fully in accord with the conclusion reached by the district court.'' In light of this, the Court of Appeals stated that ''[t]he district court, in short, without expressly stating so might simply have deferred to the long-held and reasonable interpretation given the statute by the very agency whose jurisdiction is at issue.'' [35]

The 3rd Circuit Court of Appeals reaffirmed the principle succinctly: ''[I]t was recognized there, [in *NAGCP* v. *USPS,* 569 F.2d 570 (D.C. Cir. 1976)] as we do here, that the agency entitled to deference in the interpretation of 39 U.S.C. 3622–24 is the Rate Commission—not the Postal Service—as it is the Rate Commission which is charged with making recommended decisions on changes in rates and mail classification.'' [36]

In sum, it is clear that ''rate and classification supervision [vests] in the Postal Rate Commission.'' [37]

Furthermore, the deference afforded the agency is particularly compelling regarding challenges to rules adopted under notice and comment rulemaking.[38] In such a situation, if Congress has not directly addressed a matter and if the agency's answer is based upon a permissible construction of the statute, the agency's interpretation will be upheld by a reviewing court.[39] This is especially

[27] The Postal Service has concluded similarly. In their decision in Docket No. C96–1, the Governors characterized *ATCMU* as the ''one case which attempted a definition of postal versus nonpostal *as applied to specific services then offered.*'' Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on the Complaint of the Coalition Against Unfair USPS Competition, Docket No. C96–1, April 8, 1997, at 11 (Governors' Decision Docket No. C96–1) (emphasis added).

[28] In an effort to bolster its contention that the legal standard for the term ''postal service'' has been definitively determined, the Postal Service quotes a passage from Order No. 1145 paraphrasing *NAGCP I.* Postal Service Initial Comments at 2. The attempt is unavailing. The Commission's reliance on that precedent to frame the jurisdictional issue in Docket No. C96–1 was entirely appropriate since Pack & Send service had the earmarks of service traditionally offered by the Postal Service, notably without any reliance on new technology. In contrast, in Docket No. C99–1, the Commission found existing precedent inadequate to resolve the jurisdictional dispute regarding Post E.C.S. service, an all-electronic means of transmitting documents securely via the Internet. PRC Order No. 1239, May 3, 1999, at 18. As noted above, the Commission did not find it dispositive that Post E.C.S. service did not entail hard-copy mail. *Id.* at 15–21.

[29] *See* Initial Comments of the United States Postal Service, March 15, 2004, at 1–2.

[30] Postal Service Initial Comments at 4. This is similar to its claim in earlier comments that it ''would not in any way be bound by the definition which the Commission is now proposing [in Order No. 1389] to incorporate into its rules.'' Initial Comments of the United States Postal Service, March 15, 2004, at 3.

[31] PRC Order No. 1424, *supra,* at 2; *see also id.* at 6–9. This has been a consistent long-held position by the Commission. *See, e.g.*, PRC Op. R74–1, Vol. 2, Appendix F; PRC Op. R76–1, Vol. 1, at 263 *et seq.*, and Vol. 2, Appendix F; PRC Order No. 1239, May 3, 1999, at 9–14; *see also United Parcel Service* v. *U.S. Postal Service,* 604 F.2d 1370, 1381 (3rd Cir. 1979), *cert. denied,* 446 U.S. 957 (1980).

[32] Furthermore, the Postal Service's interpretation is contrary to the well-settled principle that an agency's interpretation of its own jurisdiction is entitled to deference. *See Chevron U.S.A., Inc.* v. *Natural Resources Defense Council,* 467 U.S. 837, 842–44 (1984) (*Chevron*); *Transmission Access Policy Study Group* v. *Federal Energy Regulatory Commission,* 225 F.3d 667, 694 (D.C. Cir. 2000) (''It is the law of this circuit that the deferential standard of [*Chevron*] applies to an agency's interpretation of its own statutory jurisdiction.''); and *Oklahoma Natural Gas Company* v. *Federal Energy Regulatory Commission,* 28 F.3d 1281, 1283 (D.C. Cir. 1994).

[33] The court's holding answers the Postal Service's misplaced claim that the Act excludes ''an implicit delegation of authority to the Commission to define postal and nonpostal services.'' Postal Service Initial Comments at 6–7. Moreover, the Postal Service's statement misreads the order. The Commission has not asserted or even suggested that it has authority to define nonpostal services.

[34] *NAGCP I* at 597.

[35] *Id.* at 595, n.110.

[36] *United Parcel Service* v. *U.S. Postal Service,* 604 F.2d 1370, 1381 (3d Cir. 1979), *cert. denied,* 446 U.S. 957 (1980).

[37] *United Parcel Service* v. *U.S. Postal Service,* 455 F. Supp. 857, 869 (E.D. Pa. 1978), *aff'd,* 604 F.2d 1370 (3d Cir. 1979), *cert. denied,* 446 U.S. 957 (1980).

[38] *U.S.* v. *Mead Corp.,* 533 U.S. 218, 229–31 (2001). (clarifying that *Chevron* deference is afforded to rules issued with procedural safeguards such as notice and comment). *See generally Chevron, supra,* 467 U.S. at 842–44 (1984), concerning the high degree of deference afforded to agencies.

[39] *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council,* 467 U.S. 837, 842–44 (1984).

true when the agency is using the rulemaking to clarify the extent of its jurisdiction.[40] Courts give strong deference to agency regulations that have undergone strict notice and comment rulemaking because:[41]

> The rulemaking process, by its very design, encourages public scrutiny of an agency's proposed course of action. By giving notice of the proposed rule, the agency provides interested parties with the opportunity to express their views and bring their political influence to bear on the process.

These procedural safeguards give all interested parties the ability to influence the rulemaking and agency process in a meaningful way.[42] Accordingly, a rule promulgated and vetted through the formal rulemaking process by the Commission on matters clarifying its jurisdiction is entitled to significant deference, whereas ad hoc, unilateral, unchecked Postal Service decisions on services it believes are not subject to Commission review are not.[43]

IV. The Meaning of the Term ''Postal Service'' Is Not Frozen in Time

In its comments, the Postal Service contends that the meaning of the term ''postal service'' has been, for all intents and purposes, settled since the mid-1970s, following the District Court's *ATCMU* opinion as affirmed in *NAGCP I*.[44] It argues that both the Commission and it have employed the ''resulting legal standard since that time[,]'' quoting, as affirmation, the Commission's order in Docket No. C96–1 involving the complaint regarding Pack & Send service.[45]

The Postal Service's premise, that the meaning of the term ''postal service'' was resolved in the 1970s, is flawed. First, the question before the *ATCMU* court was a narrow one, namely whether or not certain special services were subject to the Commission's jurisdiction. In affirming the Commission's jurisdiction, neither the *ATCMU* nor the *NAGCP I* courts addressed the jurisdictional status of services not before them, let alone completely new forms of service.

As a general matter, each of the services then at issue, *e.g.*, forwarding and return, registry, insurance, collect on delivery, and money orders, was a long-time, traditional service offered by the Postal Service and its predecessor, the Post Office Department. Significantly, each involved some form of hard-copy service. Thus, there was no reason for the court to engage in a broader inquiry.

Secondly, the Postal Service's argument rests on an implicit assumption that the absence of controversy renders the matter settled. In fact, the absence of controversy is merely an indication of inactivity, a manifestation of the status quo, not an indication that the matter is settled. As discussed above, during the 20 years following the *ATCMU* opinion, there was simply little occasion or need to revisit the issue. The absence of controversy is of no import in determining whether the term ''postal service'' applies to the spate of new services introduced by the Postal Service, some of which entail the use of electronic communications not in existence at the time of the *ATCMU* opinion.

Finally, the Postal Service overreaches in characterizing the matter as settled based on the *ATCMU* opinion. The Governors' remarks in Docket No. C96–1 cast that opinion in the correct light. While expressing various policy concerns with the Commission's conclusion in that proceeding that ''Pack & Send'' was a postal service, the Governors note that, ''[v]irtually the only judicial assistance for the task has come from one case, litigated more than 23 years ago, early in the history of the reorganized Postal Service.''[46] The *ATCMU* opinion remains instructive in evaluating proposed services that exhibit characteristics similar to those at issue in that case, and for identifying the agency responsible for applying Chapter 36 to entirely new services based on technologies not extant at the time of that decision. Contrary to the Postal Service's contention, *ATCMU* is not dispositive of matters it never considered, let alone addressed.

The Governors' decision is pertinent for a separate reason. In discussing its policy concerns with the Commission's order, the Governors lament the lack of clarity surrounding what is or is not a postal service. ''It would be far better if the legal standards were clear, well settled, and universally understood, so that full attention could be given to meeting the real needs of the public.'' *Id.* at 16. ''With the benefit of additional years of experience, perhaps it is now time to revisit the drawing of the relevant lines.'' Id. at 17. The Commission does not disagree with these sentiments and, indeed, as noted in prior orders, they are consistent with the purpose of this proposed rulemaking.

In amending its Rules of Practice to include a definition of the term ''postal service,'' the Commission's intent is ''to provide guidance to the Postal Service and the public for evaluating what falls within the scope of sections 3622 and 3623 of the Postal Reorganization Act.''[47] The need to develop a definition became apparent because, as evident from the discussion above, the jurisdictional status of various services offered unilaterally by the Postal Service had become increasingly controversial. Accordingly, the Commission concluded that ''it would be administratively most efficacious to clarify [the term] by rule rather than on an ad hoc basis.''[48] The Commission's decision to proceed in this fashion is well within its discretion.[49]

It has also become apparent that the uncertainty is exacerbated by a lack of transparency. Service may be offered (and subsequently terminated) by the Postal Service without an opportunity for any public input or review. Illustratively, many of the services at the heart of Consumer Action's petition are no longer offered by the Postal Service or are offered in reconstituted form. Some may have had or continue to have substantial public effect.

The Postal Service's status as a government entity supports the need for Commission review of new postal products. Services provided include those subject to its statutory monopoly as well as those in competition with the private sector. The potential for harm is significant, raising issues of possible undue discrimination/preference and unfair competition. The need to prevent this is acute and the statute provides a means for affected parties to be heard. 39 U.S.C. 3624(a). The Commission fully appreciates the Postal Service's

[40] *National Ass'n of Greeting Card Publishers* v. *U.S. Postal Service,* 462 U.S. 810, 820–21 (1983) (Upholding the Commission's position that the Act does not dictate or exclude the use of any method of attribution of costs method and stating that: ''[a]n agency's interpretation of its enabling statute must be upheld unless the interpretation is contrary to the statutory mandate or frustrates Congress' policy objectives.''); *see also Federal Election Commission* v. *Democratic Senatorial Campaign Committee,* 454 U.S. 27, 32 (1981).

[41] *Fior d'Italia, Inc.* v. *United States,* 242 F.3d 844, 852 (9th Cir. 2001), *rev'd on other grounds,* 536 U.S. 238 (2002).

[42] *See Ohio Dep't of Human Servs.* v. *U.S. Dep't of Health and Human Servs.,* 862 F.2d 1228, 1236 (6th Cir. 1988).

[43] *See U.S.* v. *Mead Corp.,* 533 U.S. 218, 229–31 (2001). Even assuming that the Postal Service's unilateral determinations were entitled any deference, it would be minimal since its determinations are not pursuant to APA's rulemaking or adjudicatory procedures. *See also Skidmore* v. *Swift & Co.,* 323 U.S. 134 (1984).

[44] Postal Service Initial Comments, *supra,* at 1–2.

[45] *Id.* at 2.

[46] Governors' Decision Docket No. C96–1, *supra,* at 17.

[47] PRC Order No. 1424, November 12, 2004, at 1.

[48] PRC Order No. 1389, January 16, 2004, at 8; *see also* PRC Order No. 1424, *supra,* at 3.

[49] *See NLRB* v. *Bell Aerospace Co.,* 416 U.S. 267, 290–95 (1974); *see also SEC* v. *Chenery Corp.,* 332 U.S. 194, 199–204 (1947).

need to grow revenues.[50] The Commission, however, has a concomitant duty to consider, among other things, the effect of establishing new postal services and their rates on the general public and on competitive enterprises in the private sector.

None of the foregoing is intended to suggest that any specific existing, but unreviewed service, or any new service offered by the Postal Service would necessarily be considered a postal service. But for those that fall reasonably within the meaning of the rule, it is imperative that the Postal Service follow the requirements of the statute, *i.e.*, by requesting a recommended decision from the Commission thereby allowing affected members of the public an opportunity to present facts and argument before an expert, independent agency.

V. The Rule Does Not Limit Services the Postal Service May Wish to Offer

In Order No. 1424, responding to a Postal Service argument that a Commission definition of the term ''postal service'' imposes no limit on its authority under the Act, the Commission made it clear that the rule in no way limits the types of service, postal or otherwise, that the Postal Service may wish to offer.

> The Postal Service is free to offer whatever services or products it wishes subject to the strictures of the Act. However, for those that are postal services, as defined by the Commission, the Postal Service has an obligation to obtain a recommended decision before commencing a service or charging the public.'' [51]

The Postal Service quotes this passage and argues that it is the *Commission's belief* that ''however it expands its definition of postal services, the Postal Service would be required to seek its approval prior to offering any service that the Commission had defined to be a postal service.'' [52] It then offers conjecture suggesting that the Commission may act arbitrarily, changing the definition capriciously over time.[53]

The Postal Service's representation of the Commission's belief is a red herring; and its conjecture that the Commission will redefine the term ''postal service'' without regard to the statute or the facts is not well-founded. The Commission has thoroughly documented its reasons for initiating this rulemaking.[54]

The final rule is a product of a long, deliberative process. Interested persons, including the Postal Service, have been afforded multiple opportunities to comment. The Commission has reviewed those comments thoroughly. In fact, based on that review, the Commission revised the proposed rule and gave parties a further opportunity to comment. At the same time, the Commission explained in detail the basis for its conclusions. Thus, this rulemaking does not represent a case of the Commission ''changing its thinking'' (*see* Postal Service Initial Comments at 6), but rather is the Commission's de novo review of its authority under Chapter 36 of the Act for purposes of providing guidance to the Postal Service and the public as to what constitutes postal services.

Although the Postal Service may chafe under the requirements of the Act,[55] it should respect the existing law. Under the Act, the Postal Service must submit a request to the Commission for a recommended decision on changes in the mail classification schedule to the extent it wishes to provide a postal service. Management's initial characterization of a service as postal or not neither deprives the Commission of jurisdiction over postal services nor precludes Commission review, on complaint or otherwise, for purposes of determining its statutory jurisdiction. Such review does not encroach on management's prerogatives in a manner not contemplated by the Act. The *United Parcel Service* court addressed this very point: [56]

> Management was vested in the Postal Service, rate and classification supervision in the Postal Rate Commission. We recognize and weigh heavily the congressional goal of greater managerial flexibility, but also recognize another congressional purpose that finds its incarnation in the Postal Rate Commission. The Commission's existence insures that an agency independent of the Postal Service will provide for public notice and hearing input of those affected by the proposed action and full and on the record, *see* 39 U.S.C. 3624(a), consideration of pertinent factors and congressionally imposed goals before certain types of decisions are made.

* * * * *

> The very existence and function of the Postal Rate Commission bespeaks a limitation on postal management's freedom.

Moreover, the Commission has adopted rules specifically to accommodate requests for expeditious consideration of experimental classifications. *See* 39 CFR 3001.67. If the Postal Service believes that the current rules are inadequate for its purposes, it may petition for appropriate relief.

In the final analysis, the Commission properly is acting to clarify the scope of its own jurisdiction. The proposed rule is consistent with the Act, its legislative history, and precedent. It concerns only the provision of postal services. The Postal Service remains free to offer whatever services are consistent with its statutory mandate. Nothing in the rule affects the lawfulness of the Postal Service initiatives that are not postal. The lawfulness of the Postal Service's nonpostal activities is not an issue for resolution by the Commission.[57] However, the prices for services within the ambit of the rule adopted herein must be set in accordance with section 3624.

VI. Substantive Comments

A. PostCom

PostCom reiterates its claim that the Postal Service is not authorized to offer electronic services unless they are ''directly related to the delivery of 'written and printed matter, parcels, and like materials.' '' [58] Consequently, it contends that what it labels ''purely electronic services'' cannot be within the Commission's jurisdiction.[59] PostCom argues that the only technological advances contemplated by Congress in passing the Postal Reorganization Act in 1970 ''are those that contribute to the efficient physical carriage of mail.'' [60]

PostCom fails to support its suggestion that Congress contemplated that the Postal Service's use of new technology would be limited to physical deliveries with more than supposition. It argues that postal services ''cannot include all manner of technological innovations affecting communications'' such as facsimile, Voice-Over-Internet-Protocol (VOIP), and video

[50] *See* Report on Nonpostal Initiatives, Docket *2003, March 10, 2003, at 1 (''To fulfill its universal service mandate and mission, the Postal Service must find ways to use existing resources to generate new revenue.'')

[51] PRC Order No. 1424, *supra* at 7–8.

[52] Postal Service Initial Comments at 5.

[53] *Id.* at 5–6.

[54] *See, e.g.,* PRC Order No. 1389, *supra* at 1–12; and PRC Order No. 1424, *supra,* at 1–6.

[55] *See, e.g.,* Governors' Decision, Docket No. C96–1, (''The Postal Service should be able, quickly and efficiently, to test the viability and design of service offerings that provide service of value to the general public, and that have already been established in the marketplace.'')

[56] *United Parcel Service* v. *U.S. Postal Service, aff'd,* 604 F.2d 1370 (3d Cir. 1979), *cert. denied,* 446 U.S. 957 (1980).

[57] *See, e.g.,* PRC Order No. 724, December 2, 1986, at 11; PRC Order No. 1239, May 3, 1999, at 13.

[58] PostCom Initial Comments, PostCom initial Comments, *supra.* at 1.

[59] *Ibid.; see* PostCom Reply Comments on the Proposed Rulemaking Concerning the Definition of ''Postal Service,'' April 15, 204, at 2.

[60] PostCom Initial Comments at 2.

conferencing, for to do so ''would open a Pandora's box of confusing federal jurisdictional issues.'' [61] As OCA/CA note, PostCom reads Order No. 1424 too broadly.[62] The Commission's jurisdiction is restricted to domestic services provided by the Postal Service and further to the panoply of ''postal services'' offered by the Postal Service, including those used to ''bind the Nation together through the personal, educational, literary, and business correspondence of the people.'' 39 U.S.C. 101(a). Thus, there is no federal jurisdictional controversy.[63]

In concluding that the Postal Service may avail itself of technological advances to provide postal services, the Commission relies on Congress' own words that it intended to: ''[c]reate a lasting foundation for a modern, dynamic, and viable postal institution that is both equipped and empowered at all times to satisfy the postal requirements of the future technological, economic, cultural, and social growth of the Nation.'' [64] That Congress intended a ''modern, dynamic, and viable postal institution'' did not require it to envision particular future technological advances, but only that it contemplated that the Postal Service would be ''equipped and empowered'' to use them in meeting the ''postal requirements'' of the Nation. As the Commission has observed: ''The Act does not require the Postal Service to ignore innovations, and to remain, in essence, the equivalent to the best buggy whip manufacturer it can be.'' [65]

Under PostCom's theory, the Postal Service may employ new technology, but only if related to physical mail delivery. PostCom would permit the Postal Service to modernize to a limited degree, *e.g.*, electronic return receipt and tracking services, but preclude it from employing technological advances that affect its principal duties of receiving, transmitting, and delivering mail services, as they may evolve over time, to postal patrons.[66] The distinction is arbitrary and without support.

PostCom takes issue with the Commission's description of Airmail and Express Mail as new forms of postal service, arguing that ''these services are a new means to deliver the same written and printed matter, and parcels.'' [67] While that characterization is not incorrect, the quality that gave rise to the new form of postal service is the transmission, not the delivery, which, in any event, remained the same.[68]

In the alternative to its legal position, PostCom expresses general support for the proposed definition, but suggests that it be revised in two ways.[69] First, noting that the terms ''ancillary and supportive'' lack a statutory predicate, PostCom suggests substituting the term ''incidental thereto'', which is found in section 403(a).[70] The Commission finds this suggestion reasonable and adopts it, albeit not for reasons advanced by PostCom. In suggesting the change, PostCom contends that ''it is these very terms that over-extend the definition of 'postal services' to encompass electronic communications services unrelated to physical mail delivery.'' [71] The Commission rejects this contention.

The phrase ''supportive or ancillary thereto'' has been used by the Commission for nearly 30 years to describe jurisdictional special services that support or are ancillary to the collection, transmission, or delivery of mail.[72] Elaborating, the Commission noted that such services ''enhance the value of service rendered under one of the substantive mail classes by providing such features as added security, added convenience or speed, indemnity against loss, correct information as to the current address of a recipient, etc.'' [73] PostCom describes ''incidental services'' in virtually the same terms, *i.e.*, as services which enhance the value of mail.[74] Thus, while adopting this change, the Commission does not perceive it as substantively altering the scope of its long-held views of supportive or ancillary services.

Second, PostCom suggests that the phrase ''including, but not limited to'' be deleted, noting that it is not found in section 403 and contending that it is redundant to the phrase ''and like materials'' which is. This suggestion will not be adopted.

The two phrases serve different purposes. The phrase ''and like materials'' takes into account changes in postal services required by ''the future technological, economic, cultural, and social growth of the Nation.'' [75] The phrase ''including, but not limited to,'' was employed to make it plain that the term ''correspondence'' was intended to encompass all forms of written communications. This is consistent with section 101(a), that the Postal Service be ''operated as a basic communications service,'' [76] and section 403(a), the requirement that it receive, transmit, and deliver written and printed matter, parcels, and like materials.

B. United Parcel Service

UPS contends that many non-package items, such as catalogs and printed advertisements, ''are arguably not 'correspondence.' '' [77] Because such items are undeniably postal services, UPS suggests that potential controversy would be avoided by substituting the phrase ''letters, other written and printed matter, and like materials'' for ''correspondence, including, but not limited to, letters, printed matter, and like materials.'' [78]

The Commission will not adopt the suggestion, but will clarify that ''correspondence,'' as used in the rule, includes all manner of non-package materials, *e.g.*, advertisements, catalogs, solicitations, newspapers, magazines, etc. In short, ''non-package items'' are covered by the term ''printed matter.'' The Commission includes the term ''correspondence'' in the rule because that is the means by which the Postal Service fulfills its basic function,

[61] *Ibid.*

[62] OCa/CA Reply Comments at 5–6.

[63] PostCom's concern over opening Pandora's box appears to be overblown for another reason. It is not the purpose of this order to attempt to foresee how future technological change may affect the Postal Service. On more than one occasion, however, the Commission has dealt with possibly competing federal jurisdictional issues with comity and dispatch. *See, e.g.,* PRC Op. Docket Nos. MC76–1 *et al.,* June 15, 1977; PRC Op. Docket Nos. MC78–3, December 17, 1979.

[64] *See* PRC Order No. 1424, *supra,* at 32, quoting H.R. Rep. No. 1104, 91st Cong., 2nd Sess. 2 (1970), *reprinted in* 1970 U.S. Code Cong. & Admin. News, Vol. 2, at 3650; (hereinafter H.R. Rep. No. 91–1104 with page cites to U.S.C.C.A.N.).

[65] PRC Order No. 1424 at 32.

[66] H.R. Rep. No. 91–1104, *supra*, at 3671. (''[T]he United States Postal Service shall be operated as a basic communications service provided to all the people by the Government of the United States[.]'')

[67] PostCom Initial Comments at 3–5.

[68] In its initial comments in this proceeding, PostCom appears to recognize that transmission connotes something more than vehicular transportation. PostCom Comments on Proposed Rulemaking Concerning Amendment to the Rules of Practice and Procedure, March 1, 2004, at 4. The concept is not new. As early as Docket No. MC78–3, involving Electronic Computer Originated Mail, the Postal Service characterized electronic communications as a form of transportation. PRC Op., Docket No. MC78–3, December 17, 1979, at 59.

[69] PostCom Initial Comments at 3–5. The Postal Service views PostCom's suggestions as preferable to the proposed rule. Reply Comments of the United States Postal Service in Response to Order No. 1424, March 1, 2005, at 2.

[70] PostCom Initial Comments at 5.

[71] *Id.* at 4.

[72] *See* PRC Op. R76–1, Vol. 1, at 266–67 (footnote omitted); *id.*, Vol. 2, Appendix F.

[73] PRC Op. R76–1, Vol. 1, at 267.

[74] PostCom Initial Comments at 4.

[75] H.R. Rep. No. 1104, *supra,* at 3650.

[76] *Id.* at 3671.

[77] UPS Reply Comments, *supra,* at 2.

[78] *Ibid.* UPS's suggestion does not reply to any parties' comments and as such is more properly considered as initial comments. Since no party objected to the suggestion or sought to file a reply, the Commission will address it.

namely ''to provide postal services to bind the Nation together through the * * * correspondence of the people.'' Section 101(a). As used in section 101(a), correspondence includes all forms of written communications between and among ''the people,'' running the gamut from personal to business to cultural. UPS's suggested alternative language would forego use of this term and, therefore, the Commission does perceive it as an improvement over the proposed rule.

C. OCA/CA

OCA/CA, who support the proposed rule, characterize the Commission's findings and suggest procedures for reviewing the Postal Service's unclassified commercial activities. In discussing the Commission's ''jurisdictional findings,'' OCA/CA make several statements that appear to be problematic in certain respects. For example, they state that ''[t]he Commission's order accepts the OCA and CA interpretation that § 404(a)(6) only relates to Postal Service activities undertaken on behalf of other government agencies.'' [79] The Commission did not adopt OCA/CA's ''narrow definition,'' [80] a conclusion seemingly acknowledged elsewhere in their comments.[81] However, other than illustratively, the Commission finds it unnecessary to address these statements since the order speaks for itself and, moreover, OCA/CA do not seek any modification to the proposed rule.

OCA/CA propose procedures for reviewing all Postal Service activities for compliance with the Act.[82] First, they request that the Commission initiate classification proceedings pursuant to section 3623 to review the current commercial services provided by the Postal Service.[83] They suggest that if the Commission concludes that no classification is warranted, whether a postal service or not, it should issue a declaratory order finding the service to be inappropriate or unauthorized.[84]

Second, OCA/CA suggest that, upon complaint, the Commission may review commercial activities pursuant to section 3662. For services found to be postal, they suggest that the Commission issue findings via a declaratory order; for services found not to be postal, they suggest that the Commission issue ''a public report advising the Postal Service to desist from continuing to offer such services.'' [85]

The procedures suggested by OCA/CA are premature and thus needlessly confrontational. The Commission believes that the Postal Service should take the lead in assuring that current services comply with the rule and the procedures discussed below are intended to facilitate that approach. It is the Commission's hope and expectation that those procedures will bring an end to the uncertainty regarding the postal status of ongoing services unilaterally offered by the Postal Service.

VII. Procedures

The Commission had no predetermined outcome in mind when it initiated this proceeding. Its goal was to provide guidance to the Postal Service and the public concerning services that are subject to sections 3622 and 3623 of the Act. All interested persons have had ample opportunity to comment on the proposed rule. The proposed rule is supported by mailer, competitor, and consumer interests. Notably, no party supports the Postal Service's position.

The Commission has carefully considered the comments, as evidenced by both Order No. 1424 and this order issuing the final rule. In particular, recognizing that the Postal Service maintained a different legal theory, the Commission took great pains to address its arguments thoroughly. *See, e.g.*, Order No. 1424, *supra*, at 18–39. The final rule is a product of painstaking analyses and is fully consistent with the Act, the legislative history, and precedent.

The Commission comes with an open mind to the next step in this process, classifying services as postal or not. Those services or products that satisfy the definition are subject to the rule. There may be some contentious issues and ''hard'' choices. Nonetheless, in a reasonable period of time, controversy and confusion associated with such services will be eliminated.

It is the Commission's expectation that the Postal Service will exercise good faith in complying with procedures outlined below. Since the genesis of this rulemaking is the Consumer Action petition, the Postal Service is requested to submit an update of each of the 14 services referenced in the petition, briefly describing its current status. The successor, if any, to each service no longer offered or otherwise terminated should be described. The Postal Service is requested to file the update by no later than February 17, 2006.

For each current unreviewed service (or product) that fairly falls within the meaning of the final rule, the Postal Service shall file, not later than June 1, 2006, a request for a recommended decision to establish such service as a permanent or experimental classification with rates and fees consistent with 39 U.S.C. 3622(b).[86] The request should conform to the Commission's rules for such requests. Five months is provided to afford the Postal Service sufficient time to prepare the requisite filings. To the extent practicable, however, the Postal Service should endeavor to file such requests as they are prepared.

Finally, the Postal Service shall file a list identifying and providing a brief description of each current unreviewed service that, in its opinion, falls outside the meaning of the final rule. In a series of interrogatory responses in Docket No. R2005–1, the Postal Service provided a description of its nonpostal services offered during the base year.[87] It should be a relatively easy matter to update this material as needed. This material should be filed no later than June 1, 2006.

The Commission has before it two complaints alleging that the Postal Service is providing ''postal service'' without first obtaining a recommended decision from the Commission. *See* Docket No. C2004–2, Complaint on Electronic Postmark and Docket No. C2004–3, Complaint on Stamped Stationery. A motion to dismiss is pending in Docket No. C2004–2. It is the Commission's intent to address the threshold issue whether or not to hear these complaints in orders to be issued relatively early in the New Year.[88]

It is ordered:

1. The Commission amends its Rules of Practice and Procedure by inserting new paragraph 5(s), 39 CFR 3001.5(s) as follows: ''*Postal service* means the receipt, transmission, or delivery by the Postal Service of correspondence,

[79] OCA/CA Initial Comments, *supra*, at 5.

[80] PRC Order No. 1424, *supra*, at 17. The Commission's view is that appropriate courts must resolve what nonpostal services the Postal Service may or may not offer.

[81] *See* OCA/CA Initial Comments at 12.

[82] *Id.* at 11, 12–13.

[83] *Id.* at 11. Separately, CA requests the Commission to initiate a classification proceeding regarding the services that were the subject of its petition in Docket No. * 2003. *Id.* at 10.

[84] *Id.* at 14. For activities found not to be postal, they suggest that the Commission order that they be terminated as *ultra vires. Id.* at 15.

[85] *Id.* at 18.

[86] ''Unreviewed'' is intended to apply to services (or products) currently offered by the Postal Service that have not been established through the procedures of §§ 3622–3625.

[87] *See, e.g.*, Tr. 8D/4730–42.

[88] In its answer to the complaint in Docket No. C2004–3, the Postal Service indicated its intent to file a motion to dismiss. Answer of United States Postal Service, Docket No. C2004–3, August 31, 2004, at 8. Apparently, none was filed. If the Postal Service wishes to submit a motion to dismiss, it should do so by no later than January 17, 2006.

including, but not limited to, letters, printed matter, and like materials; mailable packages; or other services incidental thereto.'' effective 30 days after publication in the **Federal Register**.

2. For each current unreviewed service (or product) that fairly falls within the meaning of the final rule, the Postal Service shall file, not later than June 1, 2006, a request for a recommended decision to establish such service as a permanent or experimental classification.

3. The Postal Service shall file, not later than June 1, 2006, a list identifying and providing a brief description of each current unreviewed service that, in its opinion, falls outside the meaning of the final rule.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Steven W. Williams,

Secretary.

List of Subjects in 39 CFR Part 3001

Administrative practice and procedure, Postal service.

■ For the reasons discussed above, the Commission amends 39 CFR part 3001 as follows:

PART 3001—RULES OF PRACTICE AND PROCEDURE

■ 1. The authority citation for part 3001 continues to read as follows:

Authority: 39 U.S.C. 404(b); 3603; 3622–24; 3661, 3663.

Subpart A—Rules of General Applicability

■ 2. Amend § 3001.5 by adding new paragraph (s) to read as follows:

§ 3001.5 Definitions.

* * * * *

(s) *Postal service* means the receipt, transmission, or delivery by the Postal Service of correspondence, including, but not limited to, letters, printed matter, and like materials; mailable packages; or other services incidental thereto.

[FR Doc. 06–180 Filed 1–13–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 61

[AZ, CA, HI, NV–075–NSPS; FRL–8013–4]

Delegation of New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants for States of Arizona, California, Hawaii, and Nevada

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is finalizing updates for delegation of certain federal standards to state and local agencies in Region IX. This document is addressing general authorities mentioned in the regulations for New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants, updating the delegations tables and clarifying those authorities that are retained by EPA.

DATES: This rule is effective on March 20, 2006 without further notice, unless EPA receives adverse comments by February 16, 2006. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number [Docket Number], by one of the following methods:

1. Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions.

2. E-mail: *steckel.andrew@epa.gov*.

3. Mail or deliver: Andrew Steckel (Air–4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or e-mail. *Http://www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. 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.

Docket: The index to the docket for this action is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Cynthia G. Allen at (415) 947–4120, U.S. Environmental Protection Agency, Region IX, Rulemaking Office (AIR–4), 75 Hawthorne Street, San Francisco, California 94105.

SUPPLEMENTARY INFORMATION: The supplementary information is organized in the following order:

What Is the Purpose of This Document?
Who Is Authorized To Delegate These Authorities?
What Does Delegation Accomplish?
What Authorities Are Not Delegated by EPA?
Does EPA Keep Some Authority?
Administrative Requirements

What Is the Purpose of This Document?

Today's action will update the delegation tables in 40 CFR parts 60 and 61, to allow easier access by the public to the status of delegations in various state or local jurisdictions. We are following the general procedures described in 67 FR 20652 (April 26, 2002). The updated delegation tables will include the delegations approved in response to recent requests, as well as those previously granted. Those tables are shown at the end of this document.

Recent requests for delegation that will be incorporated into the CFR tables are identified below. Each individual submittal identifies the specific NSPS and NESHAPS for which delegation was requested. All of these requests have already been approved by letter and simply need to be included in the CFR.

Agency	Date of request
Hawaii Department of Health.	April 20, 2004.
Nevada Division of Environmental Protection.	December 27, 2004, June 22, 2005, and August 17, 2005.
Pima County Department of Environmental Quality.	November 8, 2004.
San Joaquin Valley Air Pollution Control District.	September 28, 2004.

Who Is Authorized To Delegate These Authorities?

Sections 111(c)(1) and 112(l) of the Clean Air Act, as amended in 1990, authorize the Administrator to delegate his or her authority for implementing and enforcing standards in 40 CFR parts 60 and 61.

What Does Delegation Accomplish?

Delegation grants a state or local agency the primary authority to implement and enforce federal standards. All required notifications and reports should be sent to the delegated state or local agency, as appropriate, with a copy to EPA Region IX. Acceptance of delegation constitutes agreement by the state or local agency to follow 40 CFR parts 60 and 61, and EPA's test methods and continuous monitoring procedures.

What Authorities Are Not Delegated by EPA?

In general, EPA does not delegate to state or local agencies the authority to make decisions that are likely to be nationally significant, or alter the stringency of the underlying standards. For a more detailed description of the authorities in 40 CFR parts 60 and 61 that are retained by EPA, please see the proposed rule published on January 14, 2002 (67 FR 1676).

As additional assurance of national consistency, state and local agencies must send to EPA Region IX Air Division's Enforcement Office Chief a copy of any written decisions made pursuant to the following delegated authorities:

- Applicability determinations that state a source is not subject to a rule or requirement;
- Approvals or determination of construction, reconstruction or modification;
- Minor or intermediate site-specific changes to test methods or monitoring requirements; or
- Site-specific changes or waivers of performance testing requirements.

For decisions that require EPA review and approval (for example, major changes to monitoring requirements), EPA intends to make determinations in a timely manner.

In some cases, the standards themselves specify that specific provisions cannot be delegated. State and local agencies should review each individual standard for this information.

Does EPA Keep Some Authority?

EPA retains independent authority to enforce the standards and regulations of 40 CFR parts 60 and 61.

Administrative Requirements

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 delegation requests, 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 delegation request for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a request for delegation, to use VCS in place of a 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 March 20, 2006. 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 Parts 60 and 61

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: November 21, 2005.

Kerry Drake,

Acting Director, Air Division, Region IX.

■ For the reasons set out in the preamble, title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 60—[AMENDED]

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart A—General Provisions

■ 2. Section 60.4 is amended by revising paragraphs (d)(1), (d)(2)(vii), (d)(3), and (d)(4) to read as follows:

§ 60.4 Address.

(d) * * *

(1) Arizona. The following table identifies delegations as of October 21, 2004:

DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR ARIZONA

	Subpart	Air Pollution Control Agency			
		Arizona DEQ	Maricopa County	Pima County	Pinal County
A	General Provisions	X	X	X	X
D	Fossil-Fuel Fired Steam Generators Constructed After August 17, 1971	X	X	X	X
Da	Electric Utility Steam Generating Units Constructed After September 18, 1978.	X	X	X	X
Db	Industrial-Commercial-Institutional Steam Generating Units	X	X	X	X
Dc	Small Industrial Steam Generating Units	X	X	X	X
E	Incinerators	X	X	X	X
Ea	Municipal Waste Combustors Constructed After December 20, 1989 and On or Before September 20, 1994.	X	X	X	X
Eb	Municipal Waste Combustors Constructed After September 20, 1994	X	.....	X	.....
Ec	Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996.	.....	.....	X	.....
F	Portland Cement Plants	X	X	X	X
G	Nitric Acid Plants	X	X	X	X
H	Sulfuric Acid Plant	X	X	X	X
I	Hot Mix Asphalt Facilities	X	X	X	X
J	Petroleum Refineries	X	X	X	X
K	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After June 11, 1973, and Prior to May 19, 1978.	X	X	X	X
Ka	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978, and Prior to July 23, 1984.	X	X	X	X
Kb	Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984.	X	X	X	X
L	Secondary Lead Smelters	X	X	X	X
M	Secondary Brass and Bronze Production Plants	X	X	X	X
N	Primary Emissions from Basic Oxygen Process Furnaces for Which Construction is Commenced After June 11, 1973.	X	X	X	X
Na	Secondary Emissions from Basic Oxygen Process Steelmaking Facilities for Which Construction is Commenced After January 20, 1983.	X	X	X	X
O	Sewage Treatment Plants	X	X	X	X
P	Primary Copper Smelters	X	X	X	X
Q	Primary Zinc Smelters	X	X	X	X
R	Primary Lead Smelters	X	X	X	X
S	Primary Aluminum Reduction Plants	X	X	X	X
T	Phosphate Fertilizer Industry: Wet Process Phosphoric Acid Plants	X	X	X	X
U	Phosphate Fertilizer Industry: Superphosphoric Acid Plants	X	X	X	X
V	Phosphate Fertilizer Industry: Diammonium Phosphate Plants	X	X	X	X
W	Phosphate Fertilizer Industry: Triple Superphosphate Plants	X	X	X	X
X	Phosphate Fertilizer Industry: Granular Triple Superphosphate Storage Facilities.	X	X	X	X
Y	Coal Preparation Plants	X	X	X	X
Z	Ferroalloy Production Facilities	X	X	X	X
AA	Steel Plants: Electric Arc Furnaces Constructed After October 21, 1974 and On or Before August 17, 1983.	X	X	X	X
AAa	Steel Plants: Electric Arc Furnaces and Argon-Oxygen Decarburization Vessels Constructed After August 7, 1983.	X	X	X	X
BB	Kraft pulp Mills	X	X	X	X
CC	Glass Manufacturing Plants	X	X	X	X
DD	Grain Elevators	X	X	X	X
EE	Surface Coating of Metal Furniture	X	X	X	X
FF	(Reserved)	.....	.....	.....	.....
GG	Stationary Gas Turbines	X	X	X	X
HH	Lime Manufacturing Plants	X	X	X	X
KK	Lead-Acid Battery Manufacturing Plants	X	X	X	X
LL	Metallic Mineral Processing Plants	X	X	X	X
MM	Automobile and Light Duty Trucks Surface Coating Operations	X	X	X	X
NN	Phosphate Rock Plants	X	X	X	X
PP	Ammonium Sulfate Manufacture	X	X	X	X
QQ	Graphic Arts Industry: Publication Rotogravure Printing	X	X	X	X
RR	Pressure Sensitive Tape and Label Surface Coating Operations	X	X	X	X

DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR ARIZONA—Continued

	Subpart	Air Pollution Control Agency			
		Arizona DEQ	Maricopa County	Pima County	Pinal County
SS	Industrial Surface Coating: Large Appliances	X	X	X	X
TT	Metal Coil Surface Coating	X	X	X	X
UU	Asphalt Processing and Asphalt Roofing Manufacture	X	X	X	X
VV	Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry.	X	X	X	X
WW	Beverage Can Surface Coating Industry	X	X	X	X
XX	Bulk Gasoline Terminals	X	X	X	X
AAA	New Residential Wool Heaters	X	X	X	X
BBB	Rubber Tire Manufacturing Industry	X	X	X	X
CCC	(Reserved)				
DDD	Volatile Organic Compounds (VOC) Emissions from the Polymer Manufacturing Industry.	X	X	X	X
EEE	(Reserved)				
FFF	Flexible Vinyl and Urethane Coating and Printing	X	X	X	X
GGG	Equipment Leaks of VOC in Petroleum Refineries	X	X	X	X
HHH	Synthetic Fiber Production Facilities	X	X	X	X
III	Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes.	X	X	X	X
JJJ	Petroleum Dry Cleaners	X	X	X	X
KKK	Equipment Leaks of VOC From Onshore Natural Gas Processing Plants	X	X	X	X
LLL	Onshore Natural Gas Processing: SO_2 Emissions	X	X	X	X
MMM	(Reserved)	X	X	X	X
NNN	Volatile Organic Compound (VOC) Emissions From Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations.	X	X	X	X
OOO	Nonmetallic Mineral Processing Plants	X	X	X	X
PPP	Wool Fiberglass Insulation Manufacturing Plants	X	X	X	X
QQQ	VOC Emissions From Petroleum Refinery Wastewater Systems	X	X	X	X
RRR	Volatile Organic Compound Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes.	X		X	
SSS	Magnetic Tape Coating Facilities	X	X	X	X
TTT	Industrial Surface Coating: Surface Coating of Plastic Parts for Business Machines.	X	X	X	X
UUU	Calciners and Dryers in Mineral Industries	X		X	
VVV	Polymeric Coating of Supporting Substrates Facilities	X	X	X	X
WWW	Municipal Solid Waste Landfills	X		X	
AAAA	Small Municipal Waste Combustion Units for Which Construction is Commenced After August 30, 1999 or for Which Modification or Reconstruction is Commended After June 6, 2001.	X			
CCCC	Commercial and Industrial Solid Waste Incineration Units for Which Construction Is Commenced After November 30, 1999 or for Which Modification or Reconstruction Is Commenced on or After June 1, 2001.	X			

(2) * * *

(vii) Delegations for San Diego County Air Pollution Control District, San Joaquin Valley Unified Air Pollution Control District, San Luis Obispo County Air Pollution Control District, and Santa Barbara County Air Pollution Control District are shown in the following table:

DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR SAN DIEGO COUNTY AIR POLLUTION CONTROL DISTRICT, SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT, SAN LUIS OBISPO COUNTY AIR POLLUTION CONTROL DISTRICT, AND SANTA BARBARA COUNTY AIR POLLUTION CONTROL DISTRICT

	Subpart	Air Pollution Control Agency			
		San Diego County APCD	San Joaquin Valley Unified APCD	San Luis Obispo County APCD	Santa Barbara County APCD
A	General Provisions	X	X	X	X
D	Fossil-Fuel Fired Steam Generators Constructed After August 17, 1971	X	X	X	X
Da	Electric Utility Steam Generating Units Constructed After September 18, 1978.	X	X	X	X
Db	Industrial-Commercial-Institutional Steam Generating Units		X	X	X
Dc	Small Industrial Steam Generating Units	X	X		X
E	Incinerators	X	X	X	X
Ea	Municipal Waste Combustors Constructed After December 20, 1989 and On or Before September 20, 1994.		X	X	X

DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR SAN DIEGO COUNTY AIR POLLUTION CONTROL DISTRICT, SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT, SAN LUIS OBISPO COUNTY AIR POLLUTION CONTROL DISTRICT, AND SANTA BARBARA COUNTY AIR POLLUTION CONTROL DISTRICT—Continued

	Subpart	Air Pollution Control Agency			
		San Diego County APCD	San Joaquin Valley Unified APCD	San Luis Obispo County APCD	Santa Barbara County APCD
Eb	Municipal Waste Combustors Constructed After September 20, 1994			X	
Ec	Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996.				
F	Portland Cement Plants		X	X	X
G	Nitric Acid Plants		X	X	X
H	Sulfuric Acid Plants		X	X	X
I	Hot Mix Asphalt Facilities	X	X	X	X
J	Petroleum Refineries	X	X	X	X
K	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After June 11, 1973, and Prior to May 19, 1978.	X	X	X	X
Ka	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978, and Prior to July 23, 1984.	X	X	X	X
Kb	Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984.	X	X	X	X
L	Secondary Lead Smelters	X	X	X	X
M	Secondary Brass and Bronze Production Plants	X	X	X	X
N	Primary Emissions from Basic Oxygen Process Furnaces for Which Construction is Commenced After June 11, 1973.		X	X	X
Na	Secondary Emissions from Basic Oxygen Process Steelmaking Facilities for Which Construction is Commenced After January 20, 1983.		X	X	X
O	Sewage Treatment Plants	X	X	X	X
P	Primary Copper Smelters		X	X	X
Q	Primary Zinc Smelters		X	X	X
R	Primary Lead Smelters		X	X	X
S	Primary Aluminum Reduction Plants		X	X	X
T	Phosphate Fertilizer Industry: Wet Process Phosphoric Acid Plants		X	X	X
U	Phosphate Fertilizer Industry: Superphosphoric Acid Plants		X	X	X
V	Phosphate Fertilizer Industry: Diammonium Phosphate Plants		X	X	X
W	Phosphate Fertilizer Industry: Triple Superphosphate Plants		X	X	X
X	Phosphate Fertilizer Industry: Granular Triple Superphosphate Storage Facilities.		X	X	X
Y	Coal Preparation Plants		X	X	X
Z	Ferroalloy Production Facilities		X	X	X
AA	Steel Plants: Electric Arc Furnaces Constructed After October 21, 1974 and On or Before August 17, 1983.		X	X	X
AAa	Steel Plants: Electric Arc Furnaces and Argon-Oxygen Decarburization Vessels Constructed After August 7, 1983.		X	X	X
BB	Kraft pulp Mills		X	X	X
CC	Glass Manufacturing Plants	X	X	X	X
DD	Grain Elevators	X	X	X	X
EE	Surface Coating of Metal Furniture		X	X	X
FF	(Reserved)				
GG	Stationary Gas Turbines	X	X	X	X
HH	Lime Manufacturing Plants		X	X	X
KK	Lead-Acid Battery Manufacturing Plants		X	X	X
LL	Metallic Mineral Processing Plants		X	X	X
MM	Automobile and Light Duty Trucks Surface Coating Operations		X	X	X
NN	Phosphate Rock Plants		X	X	X
PP	Ammonium Sulfate Manufacture		X	X	X
QQ	Graphic Arts Industry: Publication Rotogravure Printing		X	X	X
RR	Pressure Sensitive Tape and Label Surface Coating Operations		X	X	X
SS	Industrial Surface Coating: Large Appliances		X	X	X
TT	Metal Coil Surface Coating		X	X	X
UU	Asphalt Processing and Asphalt Roofing Manufacture		X	X	X
VV	Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry.		X	X	X
WW	Beverage Can Surface Coating Industry		X	X	X
XX	Bulk Gasoline Terminals				
AAA	New Residential Wool Heaters		X	X	X
BBB	Rubber Tire Manufacturing Industry		X	X	X
CCC	(Reserved)				

DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR SAN DIEGO COUNTY AIR POLLUTION CONTROL DISTRICT, SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT, SAN LUIS OBISPO COUNTY AIR POLLUTION CONTROL DISTRICT, AND SANTA BARBARA COUNTY AIR POLLUTION CONTROL DISTRICT—Continued

	Subpart	Air Pollution Control Agency			
		San Diego County APCD	San Joaquin Valley Unified APCD	San Luis Obispo County APCD	Santa Barbara County APCD
DDD	Volatile Organic Compounds (VOC) Emissions from the Polymer Manufacturing Industry.		X		X
EEE	(Reserved)				
FFF	Flexible Vinyl and Urethane Coating and Printing		X	X	X
GGG	Equipment Leaks of VOC in Petroleum Refineries		X	X	X
HHH	Synthetic Fiber Production Facilities		X	X	X
III	Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes.		X		X
JJJ	Petroleum Dry Cleaners		X	X	X
KKK	Equipment Leaks of VOC From Onshore Natural Gas Processing Plants		X	X	X
LLL	Onshore Natural Gas Processing: SO_2 Emissions		X	X	X
MMM	(Reserved)				
NNN	Volatile Organic Compound (VOC) Emissions From Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations.		X		X
OOO	Nonmetallic Mineral Processing Plants	X	X	X	X
PPP	Wool Fiberglass Insulation Manufacturing Plants		X	X	X
QQQ	VOC Emissions From Petroleum Refinery Wastewater Systems		X	X	X
RRR	Volatile Organic Compound Emissions From Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes.		X	X	X
SSS	Magnetic Tape Coating Facilities		X	X	X
TTT	Industrial Surface Coating: Surface Coating of Plastic Parts for Business Machines.		X	X	X
UUU	Calciners and Dryers in Mineral Industries	X	X	X	X
VVV	Polymeric Coating of Supporting Substrates Facilities		X	X	X
WWW	Municipal Solid Waste Landfills	X	X	X	X

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(3) Hawaii. The following table identifies delegations as of October 21, 2004:

DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR HAWAII

	Subpart	Hawaii
A	General Provisions	X
D	Fossil-Fuel Fired Steam Generators Constructed After August 17, 1971	X
Da	Electric Utility Steam Generating Units Constructed After September 18, 1978	X
Db	Industrial-Commercial-Institutional Steam Generating Units	X
Dc	Small Industrial Steam Generating Units	X
E	Incinerators	X
Ea	Municipal Waste Combustors Constructed After December 20, 1989 and On or Before September 20, 1994	X
Eb	Municipal Waste Combustors Constructed After September 20, 1994	X
Ec	Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 19	X
F	Portland Cement Plants	X
G	Nitric Acid Plants	
H	Sulfuric Acid Plants	
I	Hot Mix Asphalt Facilities	X
J	Petroleum Refineries	X
Ka	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978, and Prior to July 23, 1984.	X
Kb	Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984.	X
L	Secondary Lead Smelters	
M	Secondary Brass and Bronze Production Plants	
N	Primary Emissions from Basic Oxygen Process Furnaces for Which Construction is Commenced After June 11, 1973	
Na	Secondary Emissions from Basic Oxygen Process Steelmaking Facilities for Which Construction is Commenced After January 20, 1983.	
O	Sewage Treatment Plants	X
P	Primary Copper Smelters	
Q	Primary Zinc Smelters	
R	Primary Lead Smelters	
S	Primary Aluminum Reduction Plants	

DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR HAWAII—Continued

	Subpart	Hawaii
T	Phosphate Fertilizer Industry: Wet Process Phosphoric Acid Plants	
U	Phosphate Fertilizer Industry: Superphosphoric Acid Plants	
V	Phosphate Fertilizer Industry: Diammonium Phosphate Plants	
W	Phosphate Fertilizer Industry: Triple Superphosphate Plants	
X	Phosphate Fertilizer Industry: Granular Triple Superphosphate Storage Facilities	
Y	Coal Preparation Plants	X
Z	Ferroalloy Production Facilities	
AA	Steel Plants: Electric Arc Furnaces Constructed After October 21, 1974 and On or Before August 17, 1983	X
AAa	Steel Plants: Electric Arc Furnaces and Argon-Oxygen Decarburization Vessels Constructed After August 7,1983	X
BB	Kraft pulp Mills	
CC	Glass Manufacturing Plants	
DD	Grain Elevators	
EE	Surface Coating of Metal Furniture	
FF	(Reserved)	
GG	Stationary Gas Turbines	X
HH	Lime Manufacturing Plants	
KK	Lead-Acid Battery Manufacturing Plants	
LL	Metallic Mineral Processing Plants	
MM	Automobile and Light Duty Trucks Surface Coating Operations	
NN	Phosphate Rock Plants	
PP	Ammonium Sulfate Manufacture	
QQ	Graphic Arts Industry: Publication Rotogravure Printing	
RR	Pressure Sensitive Tape and Label Surface Coating Operations	
SS	Industrial Surface Coating: Large Appliances	
TT	Metal Coil Surface Coating	
UU	Asphalt Processing and Asphalt Roofing Manufacture	
VV	Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry	X
WW	Beverage Can Surface Coating Industry	X
XX	Bulk Gasoline Terminals	X
AAA	New Residential Wool Heaters	
BBB	Rubber Tire Manufacturing Industry	
CCC	(Reserved)	
DDD	Volatile Organic Compounds (VOC) Emissions from the Polymer Manufacturing Industry	
EEE	(Reserved)	
FFF	Flexible Vinyl and Urethane Coating and Printing	
GGG	Equipment Leaks of VOC in Petroleum Refineries	X
HHH	Synthetic Fiber Production Facilities	
III	Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes.	
JJJ	Petroleum Dry Cleaners	X
KKK	Equipment Leaks of VOC From Onshore Natural Gas Processing Plants	
LLL	Onshore Natural Gas Processing: SO2 Emissions	
MMM	(Reserved)	
NNN	Volatile Organic Compound (VOC) Emissions From Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations.	X
OOO	Nonmetallic Mineral Processing Plants	X
PPP	Wool Fiberglass Insulation Manufacturing Plants	
QQQ	VOC Emissions From Petroleum Refinery Wastewater	X
RRR	Volatile Organic Compound Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes.	
SSS	Magnetic Tape Facilities	
TTT	Industrial Surface Coating: Surface Coating of Plastic Parts for Business Machines	
UUU	Calciners and Dryers in Mineral Industries	X
VVV	Polymeric Coating of Supporting Substrates Facilities	X
WWW	Municipal Solid Waste Landfills	
AAAA	Small MunIcipal Waste Combudtion Units for Which Construction is Commenced After August 30, 1999 or for Which Modification or Reconstruction is Commenced After June 6, 2001.	X
CCCC	Commercial and Industrial Solid Waste Incineration Units for Which Construction Is Commenced After November 30, 199 or for Which Modification or Reconstruction Is Commenced on or After June 1, 2001.	X

(4) Nevada. The following table identifies delegations as of October 21, 2004:

DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR NEVADA

	Subpart	Air Pollution Control Agency		
		Nevada DEP	Clark County	Washoe County
A	General Provisions	X	X	X
D	Fossil-Fuel Fired Steam Generators Constructed After August 17, 1971	X	X	X
Da	Electric Utility Steam Generating Units Constructed After September 18, 1978	X		
Db	Industrial-Commercial-Institutional Steam Generating Units			
Dc	Small Industrial Steam Generating Units			
E	Incinerators	X	X	X
Ea	Municipal Waste Combustors Constructed After December 20, 1989 and On or Before September 20, 1994.			
Eb	Municipal Waste Combustors Constructed After September 20, 1994			
Ec	Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996.			
F	Portland Cement Plants	X	X	X
G	Nitric Acid Plants	X		X
H	Sulfuric Acid Plants	X		X
I	Hot Mix Asphalt Facilities	X	X	X
J	Petroleum Refineries	X		X
K	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After June 11, 1973, and Prior to May 19, 1978.	X	X	X
Ka	Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction, or Modification Commenced After May 18, 1978, and Prior to July 23, 1984.	X	X	X
Kb	Volatile Organic Liquid Storage Vessels (Including X Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984.	X		
L	Secondary Lead Smelters	X	X	X
M	0Secondary Brass and Bronze Production Plants	X		X
N	Primary Emissions from Basic Oxygen Process Furnaces for Which Construction is Commenced After June 11, 1973.	X		X
Na	Secondary Emissions from Basic Oxygen Process Steelmaking Facilities for Which Construction is Commenced After January 20, 1983.	X		
O	Sewage Treatment Plants	X	X	X
P	Primary Copper Smelters	X	X	X
Q	Primary Zinc Smelters	X	X	X
R	Primary Lead Smelters	X	X	X
S	Primary Aluminum Reduction Plants	X		X
T	Phosphate Fertilizer Industry: Wet Process Phosphoric Acid Plants	X		X
U	Phosphate Fertilizer Industry: Superphosphoric Acid Plants	X		X
V	Phosphate Fertilizer Industry: Diammonium Phosphate Plants	X		X
W	Phosphate Fertilizer Industry: Triple Superphosphate Plants	X		X
X	Phosphate Fertilizer Industry: Granular Triple Superphosphate Storage Facilities	X		X
Y	Coal Preparation Plants	X	X	X
Z	Ferroalloy Production Facilities	X		X
AA	Steel Plants: Electric Arc Furnaces Constructed After October 21, 1974 and On or Before August 17, 1983.	X		X
AAa	Steel Plants: Electric Arc Furnaces and Argon-Oxygen Decarburization Vessels Constructed After August 7, 1983.	X		
BB	Kraft pulp Mills	X		X
CC	Glass Manufacturing Plants	X		X
DD	Grain Elevators	X	X	X
EE	Surface Coating of Metal Furniture	X	X	X
FF	(Reserved)			
GG	Stationary Gas Turbines	X	X	X
HH	Lime Manufacturing Plants	X	X	X
KK	Lead-Acid Battery Manufacturing Plants	X	X	X
LL	Metallic Mineral Processing Plants	X	X	X
MM	Automobile and Light Duty Trucks Surface Coating Operations	X	X	X
NN	Phosphate Rock Plants	X	X	X
PP	Ammonium Sulfate Manufacture	X		X
QQ	Graphic Arts Industry: Publication Rotogravure Printing	X	X	X
RR	Pressure Sensitive Tape and Label Surface Coating Operations	X		X
SS	Industrial Surface Coating: Large Appliances	X	X	X
TT	Metal Coil Surface Coating	X	X	X
UU	Asphalt Processing and Asphalt Roofing Manufacture	X	X	X
VV	Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry	X	X	X
WW	Beverage Can Surface Coating Industry	X		X
XX	Bulk Gasoline Terminals	X		X
AAA	New Residential Wool Heaters			
BBB	Rubber Tire Manufacturing Industry			
CCC	(Reserved)			
DDD	Volatile Organic Compounds (VOC) Emissions from the Polymer Manufacturing Industry			

DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR NEVADA—Continued

	Subpart	Air Pollution Control Agency		
		Nevada DEP	Clark County	Washoe County
EEE	(Reserved)			
FFF	Flexible Vinyl and Urethane Coating and Printing	X		X
GGG	Equipment Leaks of VOC in Petroleum Refineries	X		X
HHH	Synthetic Fiber Production Facilities	X		X
III	Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes.			
JJJ	Petroleum Dry Cleaners	X	X	X
KKK	Equipment Leaks of VOC From Onshore Natural Gas Processing Plants	X		
LLL	Onshore Natural Gas Processing: SO_2 Emissions			
MMM	(Reserved)			
NNN	Volatile Organic Compound (VOC) Emissions From Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations.			
OOO	Nonmetallic Mineral Processing Plants	X		X
PPP	Wool Fiberglass Insulation Manufacturing Plants	X		X
QQQ	VOC Emissions From Petroleum Refinery Wastewater Systems			
RRR	Volatile Organic Compound Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes.			
SSS	Magnetic Tape Coating Facilities			
TTT	Industrial Surface Coating: Surface Coating of Plastic Parts for Business Machines			
UUU	Calciners and Dryers in Mineral Industries			
VVV	Polymeric Coating of Supporting Substrates Facilities			
WWW	Municipal Solid Waste Landfills			

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PART 61—[AMENDED]

■ 1. The authority citation for part 61 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart—General Provisions

■ 2. Section 61.04 is amended by revising paragraphs (c)(9)(i), (c)(9)(ii)(G), (c)(9)(iii) and (c)(9)(iv) to read as follows:

§ 61.04 Address.

(c) * * *

(9) * * *

(i) Arizona. The following table identifies delegations as of October 21, 2004:

DELEGATION STATUS FOR NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR ARIZONA

	Subpart	Air Pollution Control Agency			
		Arizona DEQ	Maricopa County	Pima County	Pinal County
A	General Provisions	X	X	X	X
B	Radon Emissions From Underground Uranium				
C	Beryllium	X	X	X	X
D	Beryllium Rocket Motor Firing	X	X	X	X
E	Mercury	X	X	X	X
F	Vinyl Chloride	X	X	X	X
G	(Reserved)				
H	Emissions of Radionuclides Other Than Radon From Department of Energy Facilities.				
I	Radionuclide Emissions From Federal Facilities Other Than Nuclear Regulatory Commission Licensees and Not Covered by Subpart H.				
J	Equipment Leaks (Fugitive Emission Sources) of Benzene	X	X	X	X
K	Radionuclide Emissions From Elemental Phosphorus Plants				
L	Benzene Emissions for Coke By-Product Recovery Plants	X	X	X	X
M	Asbestos	X	X	X	X
N	Inorganic Arsenic Emissions From Glass Manufacturing Plants	X	X		X
O	Inorganic Arsenic Emissions From Primary Copper Smelters	X	X		X
P	Inorganic Arsenic Emissions From Arsenic Trioxide and Metallic Arsenic Production Facilities.	X	X		
Q	Radon Emissions From Department of Energy Facilities				
R	Radon Emissions From Phosphogypsum Stacks				
S	(Reserved)				
T	Radon Emissions From the Disposal of Uranium Mill Tailings				
U	(Reserved)				
V	Equipment Leaks (Fugitive Emission Sources)	X	X	X	X
W	Radon Emissions From Operating Mill Tailings				
X	(Reserved)				
Y	Benzene Emissions From Benzene Storage Vessels	X	X	X	X
Z–AA	(Reserved)				

DELEGATION STATUS FOR NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR ARIZONA—Continued

	Subpart	Air Pollution Control Agency			
		Arizona DEQ	Maricopa County	Pima County	Pinal County
BB	Benzene Emissions From Benzene Transfer Operations	X	X	X	X
CC–EE	(Reserved)				
FF	Benzene Waste Operations	X	X	X	X

(ii) * * *

(G) Delegations for San Diego County Air Pollution Control District, San Joaquin Valley Unified Air Pollution Control District, San Luis Obispo County Air Pollution Control District, and Santa Barbara County Air Pollution Control District are shown in the following table:

DELEGATION STATUS FOR NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SAN DIEGO COUNTY AIR POLLUTION CONTROL DISTRICT, SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT, SAN LUIS OBISPO COUNTY AIR POLLUTION CONTROL DISTRICT, AND SANTA BARBARA COUNTY AIR POLLUTION CONTROL DISTRICT

	Subpart	Air Pollution Control Agency			
		San Diego County APCD	San Joaquin Valley APCD	San Luis Obispo County APCD	Santa Barbara County APCD
A	General Provisions	X	X	X	X
B	Radon Emissions From Underground Uranium				
C	Beryllium	X	X	X	X
D	Beryllium Rocket Motor Firing	X	X	X	X
E	Mercury	X	X	X	X
F	Vinyl Chloride	X	X	X	X
G	(Reserved)				
H	Emissions of Radionuclides Other Than Radon From Department of Energy Facilities.				
I	Radionuclide Emissions From Federal Facilities Other Than Nuclear Regulatory Commission Licensees and Not Covered by Subpart H.				
J	Equipment Leaks (Fugitive Emission Sources) of Benzene		X	X	X
K	Radionuclide Emissions From Elemental Phosphorus Plants		X		
L	Benzene Emissions from Coke By-Product Recovery Plants		X	X	X
M	Asbestos	X	X	X	X
N	Inorganic Arsenic Emissions From Glass Manufacturing Plants		X	X	X
O	Inorganic Arsenic Emissions From Primary Copper Smelters		X	X	X
P	Inorganic Arsenic Emissions From Arsenic Trioxide and Metallic Arsenic Production Facilities.		X	X	X
Q	Radon Emissions From Department of Energy Facilities				
R	Radon Emissions From Phosphogypsum Stacks				
S	(Reserved)				
T	Radon Emissions From the Disposal of Uranium Mill Tailings				
U	(Reserved)				
V	Equipment Leaks (Fugitive Emission Sources)		X	X	X
W	Radon Emissions From Operating Mill Tailings				
X	(Reserved)				
Y	Benzene Emissions From Benzene Storage Vessels		X	X	X
Z–AA	(Reserved)				
BB	Benzene Emissions From Benzene Transfer Operations		X	X	X
CC–EE	(Reserved)				
FF	Benzene Waste Operations		X	X	X

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(iii) Hawaii. The following table identifies delegations as of October 21, 2004:

DELEGATION STATUS FOR NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR HAWAII

	Subpart	Hawaii
A	General Provisions	X
B	Radon Emissions From Underground Uranium	

DELEGATION STATUS FOR NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR HAWAII—Continued

	Subpart	Hawaii
C	Beryllium	X
D	Beryllium Rocket Motor Firing	X
E	Mercury	X
F	Vinyl Chloride	
G	(Reserved)	
H	Emissions of Radionuclides Other Than Radon From Department of Energy Facilities	
I	Radionuclide Emissions From Federal Facilities Other Than Nuclear Regulatory Commission Licensees and Not Covered by Subpart H.	
J	Equipment Leaks (Fugitive Emission Sources) of Benzene	X
K	Radionuclide Emissions From Elemental Phosphorus Plants	
L	Benzene Emissions from Coke By-Product Recovery Plants	
M	Asbestos	X
N	Inorganic Arsenic Emissions From Glass Manufacturing Plants	
O	Inorganic Arsenic Emissions From Primary Copper Smelters	
P	Inorganic Arsenic Emissions From Arsenic Trioxide and Metallic Arsenic Production Facilities	
Q	Radon Emissions From Department of Energy Facilities	
R	Radon Emissions From Phosphogypsum Stacks	
S	(Reserved)	
T	Radon Emissions From the Disposal of Uranium Mill Tailings	
U	(Reserved)	
V	Equipment Leaks (Fugitive Emission Sources)	X
W	Radon Emissions From Operating Mill Tailings	
X	(Reserved)	
Y	Benzene Emissions From Benzene Storage Vessels	X
Z–AA	(Reserved)	
BB	Benzene Emissions From Benzene Transfer Operations	X
CC–EE	(Reserved)	
FF	Benzene Waste Operations	X

(iv) Nevada. The following table identifies delegations as of October 21, 2004:

DELEGATION STATUS FOR NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR NEVADA

	Subpart	Air Pollution Control Agency		
		Nevada DEP	Clark County	Washoe County
A	General Provisions	X	X	
B	Radon Emissions From Underground Uranium			
C	Beryllium	X	X	X
D	Beryllium Rocket Motor Firing	X	X	
E	Mercury	X	X	X
F	Vinyl Chloride	X	X	
G	(Reserved)			
H	Emissions of Radionuclides Other Than Radon From Department of Energy Facilities			
I	Radionuclide Emissions From Federal Facilities Other Than Nuclear Regulatory Commission Licensees and Not Covered by Subpart H.			
J	Equipment Leaks (Fugitive Emission Sources) of Benzene	X		
K	Radionuclide Emissions From Elemental Phosphorus Plants			
L	Benzene Emissions from Coke By Product Recovery Plants			
M	Asbestos		X	X
N	Inorganic Arsenic Emissions From Glass Manufacturing Plants	X		
O	Inorganic Arsenic Emissions From Primary Copper Smelters	X		
P	Inorganic Arsenic Emissions From Arsenic Trioxide and Metallic Arsenic Production Facilities.	X		
V	Equipment Leaks (Fugitive Emission Sources)	X		
BB	Benzene Emissions From Benzene Transfer Operations	X		
FF	Benzene Waste Operations	X		

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Proposed Rules

Federal Register
Vol. 71, No. 10
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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 318, 381, and 439

[Docket No. 03–020P; FDMS Docket Number FSIS–2005–0023]

RIN: 0583–AD09

Accredited Laboratory Program

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to revise, edit, and consolidate provisions of the standards and procedures for the accreditation of non-Federal analytical chemistry laboratories. Laboratories in the Accredited Laboratory Program (ALP) are accredited to analyze official meat and poultry samples for specific chemical residues or classes of chemical residues, and moisture, protein, fat, and salt. In particular, FSIS is proposing to amend its current regulations regarding the accreditation of non-Federal analytical chemistry laboratories to accommodate the adoption of newer methods for analyzing chemical residues and to correct some data. In addition, FSIS is proposing to make editorial changes to its accredited laboratory regulations to reflect Agency reorganizations and program changes and to improve the clarity and consistency of application for all laboratories participating in the ALP. Finally, FSIS is proposing to consolidate the accredited laboratory regulations from 9 CFR Part 318.21 of the meat inspection regulations and 9 CFR Part 381.153 of the poultry products inspection regulations into a single new part, 9 CFR Part 439, that is applicable to both meat and poultry establishments. Along with the consolidation, redundancies within the regulations have been reduced, with the net result being a more succinct set of regulations.

DATES: Comments must be submitted by March 20, 2006.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by any of the following methods:

- Federal eRulemaking Portal: This website provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. FSIS prefers to receive comments through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and, in the ''Search for Open Regulations'' box, select ''Food Safety and Inspection Service'' from the agency drop-down menu, then click on ''Submit.'' In the Docket ID column, select FDMS Docket Number FSIS–2005–0023 to submit or view public comments and to view supporting and related materials available electronically. After the close of the comment period, the docket can be viewed using the ''Advanced Search'' function in Regulations.gov.
- Mail, including floppy disks or CD–ROM's, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.
- Electronic mail: *fsis.regulationscomments@fsis.usda.gov*.

All submissions received must include the Agency name and docket number 03–020P.

All comments submitted in response to this proposal, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/regulations_&_policies/2005_Proposed_Rules_Index/index.asp*.

FOR FURTHER INFORMATION CONTACT: Lynn Larsen, Ph.D., Senior Director for Program Services, Office of Public Health Science, FSIS, at (202) 690–6492 or fax (202) 690–6632.

SUPPLEMENTARY INFORMATION:

Background

In order to ensure compliance with the regulatory provisions of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), samples of meat and poultry products are periodically tested to determine moisture, protein, fat, and salt content. Analyses also are conducted to determine the presence of violative concentrations of drugs or other chemical residues.

When there is an indication of noncompliance with the FMIA and the PPIA, FSIS takes appropriate action against the processor of the noncompliant product. Depending on the type of product and the severity of the noncompliance, such actions may range from requiring that a product be reprocessed to the taking of an enforcement action. Because correct and accurate test results help prevent the distribution of adulterated and misbranded meat and poultry products, it is necessary that laboratories that conduct the tests in FSIS' accredited laboratory program maintain a high degree of integrity.

Before 1962, most official samples were analyzed by FSIS laboratories. However, in response to the meat and poultry industries' need for more rapid analytical results, and because of limitations in FSIS laboratory capacity, programs were established to certify non-Federal laboratories for certain tests of both meat and poultry products. In 1980 (45 FR 73947) and again in 1985 (50 FR 15435), the Agency proposed to consolidate these programs and establish an Accredited Laboratory Program (ALP) that contained standards and procedures for non-Federal laboratories eligible to analyze official samples. A final rule was issued in 1987 (52 FR 2176). A subsequent 1993 final rule (58 FR 65254) established user fees for the ALP and adjusted the standards and procedures established in the earlier rule for this program. User fees, which cover the costs of the ALP, are mandated by the Food, Agriculture, Conservation, and Trade Act of 1990 (the 1990 Farm Bill), as amended.

A processor whose sample is to be analyzed generally has the option of using an FSIS laboratory or a non-Federal FSIS-accredited laboratory. The cost of FSIS analysis is borne by the government; the cost of non-Federal analysis is borne by the processor. Because of the limited number (three) of FSIS laboratories and their heavy workload, processors may prefer to use

non-Federal accredited laboratories given the convenience of their location or the fact they can provide test results more quickly. Some non-Federal accredited laboratories are separate entities, while others are located in and owned by official establishments.

The Proposed Rule

This proposal updates the regulations governing the accredited laboratory program and clarifies and corrects some data. Issuance of these proposed regulations will give FSIS more flexibility in keeping up with current and future scientific changes without having to periodically reissue new regulations. For example, this proposal deletes from the regulations all references and footnotes to the Association of Official Analytical Chemists (AOAC) contained in the current food chemistry accreditation regulations and the definitions. The name and address of the organization have changed, and the cited edition of the methods manual is not the current edition. AOAC will no longer be specifically cited. Instead, the ALP will advise accredited laboratories, as provided in the proposed accreditation regulations, about suitable methods that are available from various compendia, such as FSIS guidebooks or current AOAC manuals, for determining the presence of the analytes covered by the ALP.

This proposed rule deletes all references to split samples because they are no longer part of the ALP program. In addition, this rule modifies Table 1 of the current regulations in §§ 318.21 and 381.153 by moving its footnote information into the main body of the table. The proposed rule modifies Table 2 and provisions for Quality Assurance (QA) and Quality Control (QC) recovery throughout the regulations by removing explicit figures for minimum proficiency levels (MPLs) and recoveries. Information on current recoveries established by FSIS for laboratory quality assurance and quality control will be available from the ALP Web site at *http://www.fsis.gov/Science/Accredited_Laboratories/index.asp.* A link to information on current MPLs is available on the ALP Web site, or you can access the information directly at *http://www.fsis.usda.gov/PDF/2003_Red_Book_Appendix3–4.PDF.*

Finally, the proposed rule eliminates duplicative provisions within the current regulations and consolidates §§ 318.21 and 381.153 into a single set of regulations in new Part 439. For example, new § 439.20 contains the criteria for maintaining either a food chemistry accreditation or a chemical residue accreditation for both meat and poultry products. A summary of the changes made is contained in the following table:

Meat	Poultry	New	Changes
318.21	381.153	Part 439	Editorial and conforming changes throughout the regulations are made, along with certain other revisions.
318.21(a)	381.153(a)	439.1	Updated to reflect change of address and to delete specific references to the Association of Official Analytical Chemists, amended to delete definition of split samples, to modify Tables 1 and 2 to revise performance standards, to add new definitions and to reuse certain current definitions.
318.21(b)(1), 318.21(c)(1)	381.153(b)(1), 381.153(c)(1)	439.5	Updated and consolidated application requirements.
318.21(b)(2), 318.21(c)(2)	381.153(b)(2), 381.153(c)(2)	439.10	Revised, consolidated, and clarified accreditation criteria.
318.21(b)(3), 318.21(c)(3)	381.153(b)(3), 381.153(c)(3)	439.20	Revised and consolidated criteria for maintaining accreditation.
318.21(d)	381.153(d)	439.50	Deletes current (d)(4) and replaces it with a cross reference to ''violations of law'' in new § 439.60 and makes certain other revisions.
318.21(e)	381.153(e)	439.51	Updated to cross reference sections of new § 439.20 and to make certain other revisions.
318.21(f)	381.153(f)	439.52	Deletes current (f) and instead cross references new § 439.60.
318.21(g)	381.153(g)	439.53	Updates and consolidates bases for revocation of accreditation. Deletes current (g)(4) and instead cross references new § 439.60, ''violations of law.''
318.21(e), 318.21(f)	381.153(e), 381.153(f)	439.60	New section that consolidates references to ''violations of law.''
318.21(h)	381.153(h)	439.70	Editorial changes.

Expansion of the Laboratory Program; Request for Comments

Although recent rulemakings and Agency policy decisions address a range of chemical contaminants, including most that present biosecurity concerns, FSIS does not intend to expand the ALP at this time. Expansion of the program to other analytes would require a statistical evaluation of historical data in order to develop the appropriate algorithms and correction factors needed to implement the same type of quality assurance procedures that are applied to the analytes currently included in the program. It would also require FSIS to make policy decisions regarding the acceptance of test results from non-Federal laboratories for these new analytes. The Agency does not intend to include the additional analytes (e.g., pesticide or drug residues) by laboratories in the ALP until such policy decisions have been made, and the necessary scientific foundation is established for them.

FSIS, however, would like to receive comments from the public on whether non-Federal laboratories should be accredited to analyze official samples for additional analytes and whether the laboratories should be used to supplement further the analytical capabilities of the three FSIS laboratories.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. The rule updates the quality standards and procedures that govern the accredited laboratory program.

States and local jurisdictions are preempted under the FMIA and the PPIA from imposing any requirements with respect to federally inspected

premises, facilities, and operations that are in addition to, or different than, those imposed under the FMIA or PPIA. However, State or local jurisdictions may 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 products, after their entry into the United States. State and local jurisdictions also may take other actions that are consistent with the FMIA and PPIA, with respect to any other matters regulated under the Acts.

Under FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements that are at least equal to those required under the Acts. However, these States may impose more stringent requirements on such State-inspected products and establishments.

Executive Order 12866

This proposed rule has been determined to be non-significant and has not been reviewed by the Office of Management and Budget under Executive Order 12866. The rule will not result in an annual effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, governments or geographic regions.

Effect on Small Entities

There are about 90 laboratories that have a total of about 110 accreditations in the FSIS Accredited Laboratory Program (ALP). About three-quarters of these are large entities, based on their volume of business, or are part of entities such as large business corporations, State universities, or State governments. The smaller laboratories participating in the ALP range from medium-sized laboratory facilities to one- or two-person operations. These laboratories provide analytical services of official samples to large and small establishments.

Participation in the Agency's ALP is voluntary. It is expected that a decision to participate would be based on a calculation of the benefits and costs to the firm, including a determination whether the resulting loss of business as a result of non-participation in ALP would be significant.

The Administrator has made an initial determination that this proposed rule would not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The effects of this proposed rule on the laboratories and on the establishments they serve will not be significant and will apply equally to large and small entities. The proposed rule does not involve a change in the accreditation fee, but rather adjustments and clarifications in the operational procedures and standards. The cost savings brought about by improved efficiencies in the requirements for participants in the ALP are likely to be small.

Paperwork Requirements

FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The Agency has determined that the paperwork requirements for the regulations that govern the accreditation of non-Federal analytical chemistry laboratories have already been accounted for in the Application for Inspection, Sanitation, and Accredited Laboratories information collection approved by the Office of Management and Budget (OMB). The OMB approval number for the Application for Inspection, Sanitation, and Accredited Laboratories information collection is 0583–0082.

Government Paperwork Elimination Act (GPEA)

FSIS is committed to compliance with the GPEA, which requires Government agencies, in general, to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. The Agency will ensure that to the extent possible, all forms used by the laboratories are made available electronically.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular that minorities, women, and persons with disabilities are aware of this proposal, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/2005_Proposed_Rules_Index/index.asp.*

The Regulations.gov Web site is the central online rulemaking portal of the United States Government. It is being offered as a public service to increase participation in the Federal Government's regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at *http://www.regulations.gov.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/* and allows FSIS customers to sign up for subscription options across eight categories. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

List of Subjects

9 CFR Part 318

Accredited laboratory program, Meat inspection, Recordkeeping and reporting requirements.

9 CFR Part 381

Accredited laboratory program, Poultry and poultry products inspection, Recordkeeping and reporting requirements.

9 CFR Part 439

Meat inspection, Poultry and poultry products inspection, Laboratory accreditation.

Accordingly, Title 9, Chapter III, Subchapter E of the Code of Federal Regulations is proposed to be amended as follows:

Subchapter E—Regulatory Requirements Under the Federal Meat Inspection Act and the Poultry Products Inspection Act

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority citation for part 318 would continue to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 318.21 [Removed and reserved]

2. Section 318.21 would be removed and reserved.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 would continue to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

§ 381.153 [Removed and reserved]

4. Section 381.153 would be removed and reserved.

5. A new part 439 would be added to Subchapter E of Chapter III to read as follows:

PART 439—ACCREDITATION OF CHEMISTRY LABORATORIES

Sec.

439.1 Definitions.
439.5 Applications for accreditation.
439.10 Criteria for obtaining accreditation.
439.20 Criteria for maintaining accreditation.
439.50 Refusal of accreditation.
439.51 Probation of accreditation.
439.52 Suspension of accreditation.
439.53 Revocation of accreditation.
439.60 Violations of law.
439.70 Notifications and hearings.

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

§ 439.1 Definitions.

(a) *Accreditation:* Determination by FSIS that a laboratory is qualified to analyze official samples of raw or processed meat and poultry products, because it has met the requirements for accreditation specified in this part, for the presence and amount of all four food chemistry analytes (protein, moisture, fat, and salt); or a determination by FSIS that a laboratory is qualified to analyze official samples of raw or processed meat and poultry products, because it has met the requirements for accreditation in this part, for the presence and amount of a specified chemical residue of any one of several classes of chemical residues. A laboratory may hold more than one accreditation.

(b) *Accredited laboratory:* A non-Federal analytical laboratory that has met the requirements for accreditation specified in this Part and, therefore, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of official samples is to be made by the establishment using the accredited laboratory.

(c) *Accredited Laboratory Program (ALP):* The FSIS program in which non-Federal laboratories are accredited as eligible to perform analyses on official regulatory samples of raw or processed meat and poultry products, and through which a check sample program for quality assurance is conducted. Program information and guidance can be obtained from the ALP Web site at *www.fsis.usda.gov/Science/Accredited_Laboratories/index.asp* or by writing to: Accredited Laboratory Program, Box 17 Aerospace Center, Room 377, 901 D Street SW, Washington, DC 20024; facsimile telephone number (202) 690–6632; voicemail telephone number (202) 690–6582.

(d) *Chemical residue misidentification:* see ''Correct chemical residue identification'' definition.

(e) *Coefficient of variation (CV):* The standard deviation of a distribution of analytical values multiplied by 100 and divided by the mean of those values.

(f) *Comparison mean:* The average result, for a sample, obtained from all submitted results that have a large deviation measure of zero. When only two laboratories perform the analysis and the large deviation measure is not zero, alternative procedures for establishing a comparison mean may be employed by FSIS. For purposes of computing the comparison mean, a laboratory's ''result'' for a food chemistry analyte is the obtained analytical value; a laboratory's ''result'' for a chemical residue is the logarithmic transformation of the obtained analytical value.

(g) *Correct chemical residue identification:* Reporting by a laboratory of the presence and analytical value of a chemical residue that was included in the ALP check sample above the minimum reporting level. Failure of a laboratory to report the presence of such a chemical residue is considered a misidentification. In addition, reporting the presence of and analytical value for a residue that was not included in the ALP check sample above the minimum reporting level is considered a misidentification.

(h) *CUSUM:* A class of statistical procedures for assessing whether or not a process is ''in control.'' Each CUSUM value is constructed by accumulating incremental values obtained from observed results of the process, and then determined to either exceed or fall within acceptable limits for that process. The initial CUSUM values for each laboratory whose application for accreditation is accepted are set at zero. The CUSUM values are reset to zero at the beginning of each year; that is, the CUSUM values associated with the first maintenance check sample each year are set equal to the CUSUM increment for that sample.

The four CUSUM procedures are:

(1) Positive systematic laboratory difference CUSUM (CUSUM–P)—monitors how consistently an accredited laboratory gets numerically greater results than the comparison mean;

(2) Negative systematic laboratory difference CUSUM (CUSUM–N)—monitors how consistently an accredited laboratory gets numerically smaller results than the comparison mean;

(3) Variability CUSUM (CUSUM–V)—monitors the average ''total deviation'' (i.e., the combination of the random fluctuations and systematic differences) between an accredited laboratory's results and the comparison mean; and

(4) Individual large deviation CUSUM (CUSUM–D)—monitors the magnitude and frequency of large differences between the results of an accredited laboratory and the comparison mean.

(i) *Food chemistry:* For the purposes of Part 439, ''food chemistry'' will refer to analysis of raw or processed meat or poultry products for the analytes moisture, protein, fat, and salt. All four analytes must be determined when a food chemistry analysis is conducted, unless otherwise advised by the ALP.

(j) *Individual large deviation:* An analytical result that differs from the sample comparison mean by more than would be expected assuming normal laboratory variability.

(k) *Initial accreditation check sample:* A sample provided by the ALP to a non-Federal laboratory to determine whether the laboratory's analytical capability meets the standards for granting accreditation.

(l) *Inter-laboratory accreditation maintenance check sample:* A sample provided by FSIS to an accredited laboratory to assist in determining whether the laboratory is maintaining acceptable levels of analytical capability.

(m) *Large deviation measure:* A measure that quantifies an unacceptably large difference between a laboratory's analytical result and the sample comparison mean.

(n) *Minimum proficiency level (MPL):* The minimum concentration of a residue at which an analytical result will be used to assess a laboratory's quantification capability. This concentration is an estimate of the smallest concentration for which the average coefficient of variation (CV) for reproducibility (i.e., combined within and between laboratory variability) does not exceed 20 percent. Information on the current MPLs may be obtained from the ALP staff at the address provided above in the definition of ''Accredited Laboratory Program,'' in § 439.1 or from the ALP Web site at *http://www.fsis@usda.gov/Science/Accredited_Laboratories/index.as.*

(o) *Minimum reporting level (MRL):* The number such that if any obtained analytical value for a residue in a check sample or official sample equals or exceeds this number, then the residue is reported together with the obtained analytical value. Information on the current MRLs may be obtained from the ALP staff at the address provided above, in the definition of ''Accredited Laboratory Program,'' in § 439.1. Official sample—A sample selected by an inspector or inspection service employee in accordance with FSIS procedures for regulatory use.

(p) *Probation:* The period commencing with official notification to an accredited laboratory that its check sample results no longer satisfy the performance requirements specified in this rule, and ending with official notification that accreditation either is fully restored, is suspended, or is revoked.

(q) *QA:* (See *Quality assurance recovery*)

(r) *QC:* (See *Quality control recovery*)

(s) *Quality assurance (QA) recovery:* The ratio of a laboratory's analytical value for a check sample residue to the established level of the analyte in the check sample, multiplied by 100. As dictated by the procedures for the analyte, the analytical value may be adjusted prior to the recovery computation.

(t) *Quality control (QC) recovery:* The ratio of a laboratory's analytical value of a quality control standard to the established level of the analyte in the standard, multiplied by 100. As dictated by the procedures for the analyte, the analytical value may be adjusted prior to the recovery computation.

(u) *Refusal of accreditation:* An action taken by FSIS when a laboratory that is applying for accreditation is denied the accreditation.

(v) *Responsibly connected:* Any individual who or entity which is a partner, officer, director, manager, or owner of 10 percent or more of the voting stock of the applicant or recipient of accreditation or an employee in a managerial or executive capacity or any employee who conducts or supervises the chemical analysis of FSIS official samples.

(w) *Revocation of accreditation:* An action taken by FSIS against a laboratory, removing the laboratory's right to analyze official samples.

(x) *Standardizing constant:* A number that results from a mathematical adjustment to the ''standardizing value'' and is used to compute the standardized difference for a check sample result. The number takes into consideration the expected variance of the difference between the accredited or applying laboratory's result(s) and the comparison mean for a sample, the standardizing value, the correlation and number of repeated results by a laboratory on a sample, and the number of laboratories that analyzed a sample. Information on the computation of the standardizing constant may be obtained from the ALP staff at the address provided above in the definition of ''Accredited Laboratory Program,'' in § 439.1.

(y) *Standardized difference:* The quotient of the difference between a laboratory's result on a sample and the comparison mean of the sample divided by the standardizing constant.

(z) *Standardizing value:* A number representing the performance standard deviation of an individual result. The number is given, or computed by, the information provided in Tables 1 and 2 and their footnotes.

(aa) *Suspension of accreditation:* Action taken by FSIS against a laboratory that temporarily removes the laboratory's right to analyze official samples. Suspension of accreditation ends when accreditation either is fully restored or is revoked.

(bb) *Systematic laboratory difference:* A comparison of one laboratory's results with the comparison mean for samples that show, on average, a consistent relationship. A laboratory that is reporting, on average, numerically greater results than the comparison mean has a positive systematic laboratory difference. Conversely, numerically smaller results indicate a negative systematic laboratory difference.

(cc) *Variability:* Random fluctuations in a laboratory's processes that cause its analytical results to deviate from a true value.

(dd) *Variance:* The expected average of the squared differences of sample results from an expected sample mean.

TABLE 1.—STANDARDIZING VALUES FOR FOOD CHEMISTRY

[By product class and analyte]

Product/class	Moisture	Protein [1]	Fat [1]		Salt [1]		
			<12.5%	>12.5%	<1%	1–4%	>4% [2]
Cured Pork/Canned Ham	0.50	0.060 ($X^{0.65}$)	0.26 ($X^{0.25}$)	0.30 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22
Ground Beef	0.71	0.060 ($X^{0.65}$)	N/A	0.35 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22
Other Meat Products	0.57	0.060 ($X^{0.65}$)	0.26 ($X^{0.25}$)	0.30 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22
Poultry Products	0.57	0.060 ($X^{0.65}$)	0.26 ($X^{0.25}$)	0.30 ($X^{0.25}$)	0.127	0.127 ($X^{0.25}$)	0.22

[1] The standardizing value is either the value given in the table or is computed by the formula set forth in the table, where X is the comparison mean of the sample. Standardizing values are provided for different percentages of fat and salt as indicated in the table.

[2] For dry salami and pepperoni products.

TABLE 2.—STANDARDIZING VALUES FOR CHEMICAL RESIDUES

Class of residues	Standardizing value [3]
Chlorinated Hydrocarbons: [1]	
Aldrin	0.20
Benzene Hexachloride	0.20
Chlordane	0.20
Dieldrin	0.20
DDT	0.20
DDE	0.20
TDE	0.20
Endrin	0.20
Heptachlor	0.20
Heptachlor Epoxide	0.20
Lindane	0.20
Methoxychlor	0.20
Toxaphene	0.20
Hexachlorobenzene	0.20
Mirex	0.20
Nonachlor	0.20
Polychlorinated Biphenyls:	0.20
Arsenic [2]	0.25
Sulfonamides [2]	0.25

[1] Laboratory statistics are computed over all results (excluding PCB results), and for specific chemical residues.
[2] Laboratory statistics are only computed for specific chemical residues.
[3] The standardizing value of all initial accreditation and probationary check samples computations is 0.15.

§ 439.5 Applications for accreditation.

(a) Application for accreditation shall be made on designated paper or electronic forms provided by FSIS, or otherwise in writing, by the owner or manager of a non-Federal analytical laboratory. The forms shall be sent to the ALP at the address provided above in the definition of ''Accredited laboratory'' § 439.1 of this part, or may be submitted electronically when so provided for by FSIS. The application shall specify the kinds of accreditation that are wanted by the owner or manager of the laboratory. A laboratory whose accreditation has been refused or revoked may reapply for accreditation after 60 days from the effective date of that action, and must provide written documentation specifying what corrections were made.

(b) At the time that an Application for Accreditation is filed with the ALP, the management of a laboratory shall, for each accreditation sought, submit a check, bank draft, or money order in the amount specified in 9 CFR 391.5 made payable to the U.S. Department of Agriculture, along with the completed application for the accreditation(s). When so provided for by FSIS, electronic transfer of funds may be accepted.

(c) Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid will be nonrefundable and will be credited to the account from which the expenses of the laboratory accreditation program are paid.

(d) Annually on the anniversary date of each accreditation, FSIS will issue a bill in the amount specified in 9 CFR 391.5 for each accreditation held. Bills are payable upon receipt by check, bank draft, or money order made payable to the U.S. Department of Agriculture and become delinquent 30 days from the date of the bill.

(e) Accreditation will be terminated without further procedure for having a delinquent account. The fee(s) paid will be nonrefundable and will be credited to the account from which the expenses of the ALP are paid.

§ 439.10 Criteria for obtaining accreditation.

(a) Analytical laboratories may be accredited for the analyses of food chemistry analytes, as defined in § 439.1, or a specific chemical residue or a class of chemical residues in raw or processed meat and poultry products.

(b) Accreditation will be given only if the applying laboratory successfully satisfies the requirements presented below. For food chemistry accreditation, the requirements must be satisfied for all four analytes.

(c) This accreditation authorizes official FSIS acceptance of the analytical test results provided by these laboratories on official samples.

(d) To obtain FSIS accreditation, an analytical laboratory must:

(1) Be supervised by a person holding, as a minimum, a bachelor's degree in chemistry, food science, food technology, or a related field.

(i) For food chemistry accreditation, the supervisor must also have 1 year's experience in food chemistry analysis, or equivalent qualifications, as determined by the Administrator.

(ii) For chemical residue accreditation, either the supervisor or the analyst assigned to analyze the sample must also have 3 years' experience determining analytes at or below part per million levels, or equivalent qualifications, as determined by the Administrator.

(2) Demonstrate an ability to achieve quality assurance levels that are within acceptable limits for systemic laboratory difference, variability, and individual large deviations, in the analyte category for which accreditation is sought, using analytical procedures designated by the FSIS ALP as being acceptable. An applying laboratory will successfully demonstrate these capabilities for:

(i) Food chemistry if its results from a 36 check sample accreditation study each satisfy the criteria presented in paragraph (e) of this section.

(ii) Chemical residues if its analytical results for each specific chemical residue provided in a check sample accreditation study containing a minimum of 14 check samples satisfy the criteria presented in paragraph (e) of this section, including criteria for QA and QC recovery and for residue identification. In addition, if the laboratory is requesting accreditation for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria. [Conformance to criteria in paragraph (e) of this section will only be determined when six or more analytical results with associated comparison means at or above the logarithm of the minimum proficiency level are available.]

(3) Round all check sample statistical computations to the nearest tenth, except where otherwise noted.

(4) Complete a second set of the requisite number of check samples if the results of the first set of check samples do not meet the criteria for obtaining accreditation.

(i) The second set of check samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. The second set of food chemistry check samples will be analyzed for only the analyte(s) for which unacceptable initial results had been obtained by the laboratory.

(ii) If the results of the second set of check samples do not meet the accreditation criteria, the laboratory may reapply after a 60-day waiting period, commencing from the date of refusal of accreditation by FSIS. At that time, a new application, all fees, and all documentation of corrective action required for accreditation must be submitted.

(5) Allow inspection of the laboratory by FSIS officials prior to the determination of granting accredited status.

(6) Pay the accreditation fee by the date required.

(e) *Quality assurance levels.* (1) *Systematic laboratory difference:* The absolute value of the average standardized difference must not exceed the following:

(i) For food chemistry, 0.73 minus the product of 0.17 and the standard deviation of the standardized differences; and

(ii) For chemical residues, 1.67 (2.00 if there are less than 12 analytical results) minus the product of 0.29 and

the standard deviation of the standardized differences.

(2) *Variability:* The estimated standard deviation of the standardized difference must not exceed the following:

(i) For food chemistry, 1.15; and

(ii) For chemical residues, a computed limit that is a function of the number of analytical results used in the computation of the standard deviation, and of the amount of variability.

(3) *Individual large deviations:* One hundred times the average of the large deviation measures of the individual samples must be less than 5.0. A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5 and otherwise a measure equal to 1 − (2.5/d).

(4) For residue analyses, the following additional quality assurance requirements must be met.

(i) *QA recovery:* The average of the QA recoveries of the individual check sample analytical results must lie within ranges established by FSIS. Information on recovery ranges may be obtained from the ALP at the address provided in § 439.1 of this chapter.

(ii) *QC recovery:* All QC recoveries must lie within ranges established by FSIS. Information on recovery ranges may be obtained from the ALP at the address provided in § 439.1 of this chapter. Supporting documentation must be made available to FSIS upon request.

(iii) *Correct identification:* There must be correct identification of all chemical residues in all samples.

§ 439.20 Criteria for maintaining accreditation.

(a) To maintain accreditation, an analytical laboratory must fulfill the requirements of paragraphs (b) through (i) of this section.

(b) *Official samples.* (1) An accredited laboratory must expeditiously report analytical results, in the analyte category for which accreditation was granted, of official samples on designated forms to the Data Center Staff, USDA/FSIS Eastern Laboratory, Russell Research Center, P.O. Box 6085, Athens, GA 30604 (for U.S. Postal Service delivery), or Data Center Staff, USDA/FSIS Eastern Laboratory, Russell Research Center, 950 College Station Road, Athens, GA 30605 (for commercial carrier delivery). When so provided for by FSIS, analytical results may be reported to the Data Center Staff by facsimile at 706–546–3589, or electronically. The Federal inspector at any establishment may assign the analysis of official samples to an FSIS laboratory if, in the inspector's judgment, there are delays in receiving test results on official samples from an accredited laboratory.

(2) Every QC recovery associated with reporting of official samples must lie within ranges established by FSIS. Information on recovery ranges may be obtained from the ALP at the address provided in § 439.1 of this chapter. Supporting documentation must be made available to FSIS upon request.

(c) *Records.* An accredited laboratory must:

(1) Maintain laboratory quality control records for the most recent 3 years that samples have been analyzed under this Program.

(2) Maintain complete records of the receipt, analysis, and disposition of official samples for the most recent 3 years that samples have been analyzed under this Program.

(3) Maintain in a secure electronic format or in a standards book, which is preferably a permanently bound book with sequentially numbered pages, all records, readings, and calculations for standard solutions. All entries are to be dated and signed by the analyst immediately upon completion of the entry, and by the supervisor, or in the absence of the supervisor by the supervisor's designee, before use of the standard solution but no later than within 1 week. The standards book is to be retained for 3 years after the last recorded entry.

(4) Maintain records and supervisor approvals of recoveries, and of instrument maintenance and calibration. The records are to be retained for 3 years after the last recorded entry.

(5) As provided in paragraph (f) of this section, records should be available for review by any duly authorized representative of the Secretary of Agriculture, including ALP personnel or their designees.

(d) *Check samples.* (1) An accredited laboratory must analyze interlaboratory accreditation maintenance check samples and return the results to FSIS within 3 weeks of sample receipt. This must be done whenever requested by FSIS and at no cost to FSIS.

(2) Results must be those of the accredited laboratory. Analyses of maintenance check samples shall not be contracted out by the accredited laboratory.

(3) As provided by the requirements in paragraph (h) of this section, a check sample report will be considered complete only if laboratories report all analytes present in the check sample for the analyte category in which accreditation was granted.

(e) *Corporate changes.* The ALP must be informed at the address provided in § 439.1 in the definition of ''Accredited laboratory'' of this part, by certified or registered mail, within 30 days of any change of address or in the laboratory's ownership, officers, directors, supervisory personnel, or other responsibly connected individual or entity.

(f) *On-site review.* An accredited laboratory must permit any duly authorized representative of the Secretary to perform both announced and unannounced on-site laboratory reviews of facilities and records, both hard copy and electronic, during normal business hours, and to copy any records pertaining to the laboratory's participation in the ALP.

(g) *Analytical procedures.* An accredited laboratory must use analytical procedures designated by the FSIS ALP as being acceptable.

(h) *Quality assurance levels.* (1) An accredited laboratory must demonstrate an ability to maintain quality assurance levels that are within acceptable limits for systematic laboratory difference, variability, and individual large deviations in the analysis of interlaboratory check samples for the analyte category for which accreditation was granted. An accredited laboratory will successfully demonstrate the maintenance of these capabilities if its analytical results from interlaboratory accreditation maintenance check samples satisfy the criteria presented in this paragraph, § 439.20(h). All statistical computations are to be rounded to the nearest tenth, except where otherwise noted.

(2) In addition, a laboratory accredited for a specific chemical residue or a chemical residue class:

(i) Must satisfy criteria presented in this paragraph, § 439.20(h), for chemical residue recoveries and proper identification;

(ii) Will demonstrate the maintenance of its capabilities by reporting its analytical results for each specific chemical residue found above the minimum proficiency level; and

(iii) Must, if accredited for the analysis of chlorinated hydrocarbons, obtain analytical results that collectively satisfy the criteria.

(3) *Systematic laboratory difference:* The standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine two CUSUM values, designated as CUSUM–P and CUSUM–N.

(i) When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: The average of the standardized differences of the analytical results within the sample, divided by a constant, is used in place of a single standardized difference to determine the CUSUM–P (or CUSUM–N) value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

(ii) Positive systematic laboratory difference: This value is computed and evaluated as follows:

(A) Determine the CUSUM–P increment for the sample.

(*1*) The CUSUM–P increment for food chemistry, as defined in § 439.1 of this Chapter, is set equal to:

2.0, if the standardized difference is greater than 2.4,

−2.0, if the standardized difference is less than −1.6, or

the standardized difference minus 0.4, if the standardized difference lies between −1.6 and 2.4, inclusive.

(*2*) The CUSUM–P increment for chemical residues is set equal to:

2.0, if the standardized difference is greater than 2.5,

−2.0, if the standardized difference is less than −1.5, or

the standardized difference minus 0.5, if the standardized difference lies between −1.5 and 2.5, inclusive.

(B) Compute the new CUSUM–P value. The new CUSUM–P value is obtained by adding, algebraically, the CUSUM–P increment to the last previously computed CUSUM–P value. If this computation yields a value smaller than 0, the new CUSUM–P value is set equal to 0.

(C) Evaluate the new CUSUM–P value. The new CUSUM–P value must not exceed:

(*1*) 5.2 for food chemistry.

(*2*) 4.8 for chemical residues.

(iii) Negative systematic laboratory difference: This value is computed and evaluated as follows:

(A) Determine the CUSUM–N increment for the sample.

(*1*) The CUSUM–N increment for food chemistry is set equal to:

2.0, if the standardized difference is greater than 1.6,

−2.0, if the standardized difference is less than −2.4, or

the standardized difference plus 0.4, if the standardized difference lies between − 2.4 and 1.6, inclusive.

(*2*) The CUSUM–N increment for chemical residues is set equal to:

2.0, if the standardized difference is greater than 1.5,

−2.0, if the standardized difference is less than −2.5, or

the standardized difference plus 0.5, if the standardized difference lies between −2.5 and 1.5, inclusive.

(B) Compute the new CUSUM–N value. The new CUSUM–N value is obtained by subtracting, algebraically, the CUSUM–N increment from the last previously computed CUSUM–N value. If this computation yields a value smaller than 0, the new CUSUM–N value is set equal to 0.

(C) Evaluate the new CUSUM–N value. The new CUSUM–N value must not exceed:

(*1*) 5.2 for food chemistry.

(*2*) 4.8 for chemical residues.

(4) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–V.

(i) When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: The square root of the sum of the within sample variance and the average standardized difference of the sample, divided by a constant, is used in place of the absolute value of the standardized difference to determine the CUSUM–V value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

(ii) The variability value is computed and designated as follows:

(A) Determine the CUSUM–V increment for the sample. The CUSUM increment is set equal to the larger of −0.4 or the absolute value of the standardized difference minus 0.9. If this computation yields a value larger than 1.6, the increment is set equal to 1.6.

(B) Compute the new CUSUM–V value. The new CUSUM–V value is obtained by adding, algebraically, the CUSUM–V increment to the last previously computed CUSUM–V value. If this computation yields a value less than 0, the new CUSUM–V value is set equal to 0.

(C) Evaluate the new CUSUM–V value. The new CUSUM–V value must not exceed 4.3.

(5) *Large deviations:* The large deviation measure of the accredited laboratory's result for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–D.

(i) A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5, and otherwise a measure equal to 1 − (2.5/d).

(ii) The large deviation value is computed and evaluated as follows:

(A) Determine the CUSUM–D increment for the sample. The CUSUM increment is set equal to the value of the large deviation measure minus 0.025.

(B) Compute the new CUSUM–D value. The new CUSUM–D value is obtained by adding, algebraically, the CUSUM–D increment to the last previously computed CUSUM–D value. If this computation yields a value less than 0, the new CUSUM–D value is set equal to 0.

(C) Evaluate the new CUSUM–D value. The new CUSUM–D value must not exceed 1.0.

(6) For chemical residues:

(i) Each QC recovery must lie within ranges established by FSIS. Information on recovery ranges may be obtained from the ALP at the address provided in § 439.1 of this Chapter. Supporting documentation must be made available to FSIS upon request.

(ii) Not more than 1 residue misidentification may be made in any 2 consecutive check samples.

(iii) Not more than 2 residue misidentifications may be made in any 8 consecutive check samples.

(i) *Fees.* An accredited laboratory must pay the required accreditation fee when it is due.

(j) *Probation.* An accredited laboratory must meet the following requirements if placed on probation pursuant to § 439.51 of this chapter:

(1) Send all official samples that have not been analyzed as of the date of written notification of probation to a specified FSIS laboratory by certified mail or private carrier or, as an alternative and as directed by FSIS, to a laboratory accredited by FSIS for the designated analyte(s). Mailing expenses will be paid by FSIS.

(2) Analyze a set of check samples similar to those used for initial accreditation, and submit the analytical results to FSIS within 3 weeks of receipt of the samples.

(3) Satisfy criteria for accreditation check samples specified in § 439.10 of this chapter.

§ 439.50 Refusal of accreditation.

Upon a determination by the Administrator, a laboratory will be refused accreditation for the following reasons:

(a) A laboratory will be refused accreditation for failure to meet the requirements of § 439.5 or § 439.10 of this chapter.

(b) A laboratory will be refused subsequent accreditation for failure to return to an FSIS laboratory, by certified mail or private carrier, or, as an alternative and as directed by FSIS, to a laboratory accredited by FSIS for the designated analytes, all official samples that have not been analyzed as of the notification of a loss of accreditation.

(c) A laboratory will be refused accreditation for the reasons described in § 439.60 of this chapter.

§ 439.51 Probation of accreditation.

Upon a determination by the Administrator, a laboratory will be placed on probation for the following reasons:

(a) If the laboratory fails to complete more than one interlaboratory accreditation maintenance check sample analysis as required by § 439.20(d) of this part within 12 consecutive months, unless written permission is granted by the Administrator.

(b) If the laboratory fails to meet any of the criteria set forth in §§ 439.20(d) and 439.20(h) of this chapter.

§ 439.52 Suspension of accreditation.

The accreditation of a laboratory will be suspended for the reasons described in § 439.60 of this chapter.

§ 439.53 Revocation of accreditation.

The accreditation of a laboratory will be revoked for the following reasons:

(a) An accredited laboratory that is accredited to perform analysis under §§ 439.5, 439.10 and 439.20 of this chapter will have its accreditation revoked for failure to meet any of the requirements of § 439.20 of this chapter, except for the following circumstances. If the accredited laboratory fails to meet any of the criteria set forth in §§ 439.20(d) and 439.20(h) of this chapter and it has not failed during the 12 months preceding its failure to meet the criteria, it shall be placed on probation, but if it has failed at any time during those 12 months, its accreditation will be revoked.

(b) An accredited laboratory will have its accreditation revoked if the Administrator determines that the laboratory or any responsibly connected individual or any agent or employee has:

(1) Altered any official sample or analytical finding; or

(2) Substituted any analytical result from any other laboratory and represented the result as its own.

(c) An accredited laboratory will have its accreditation revoked for violations of law as described in § 439.60 of this chapter.

§ 439.60 Violations of law.

An applicant or an accredited laboratory will have its accreditation refused, suspended, or revoked, as appropriate, if the laboratory or any individual or entity responsibly connected with the laboratory is convicted of, or is under indictment for, or has had charges on an information brought against them in a Federal or State court concerning any of the following violations of law:

(a) Any felony.

(b) Any misdemeanor based upon acquiring, handling, or distributing of unwholesome, misbranded, or deceptively packaged food or upon fraud in connection with transactions in food.

(c) Any misdemeanor based upon a false statement to any governmental agency.

(d) Any misdemeanor based upon the offering, giving or receiving of a bribe or unlawful gratuity.

§ 439.70 Notification and hearings.

Accreditation of any laboratory will be refused, suspended, or revoked under the conditions previously described in this Part 439. The owner or operator of the laboratory will be sent written notice of the refusal, suspension, or revocation of accreditation by the Administrator. In such cases, the laboratory owner or operator will be provided an opportunity to present, within 30 days of the date of the notification, a statement challenging the merits or validity of such action and to request an oral hearing with respect to the denial, suspension, or revocation decision. An oral hearing will be granted if there is any dispute of material fact joined in such responsive statement. The proceeding will be conducted thereafter in accordance with the applicable rules of practice which will be adopted for the proceeding. Any such refusal, suspension, or revocation will be effective upon the receipt by the laboratory of the notification and will continue in effect until final determination of the matter by the Administrator.

Done in Washington, DC, on January 9, 2006.

Barbara J. Masters,

Administrator.

[FR Doc. 06–284 Filed 1–13–06; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NE–21–AD]

RIN 2120–AA64

Airworthiness Directives; International Aero Engines AG (IAE) V2522–A5, V2524–A5, V2527–A5, V2527E–A5, V2527M–A5, V2530–A5, and V2533–A5 Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: This notice revises an earlier proposed airworthiness directive (AD) that applies to certain IAE V2522–A5, V2524–A5, V2527–A5, V2527E–A5, V2527M–A5, V2530–A5, and V2533–A5 turbofan engines. That proposal would have required initial and repetitive inspections of the master magnetic chip detector (MCD) or the No. 1, 2, 3 bearing chamber MCD. That proposal would also have required replacing certain No. 3 bearings and replacing or recoating certain high pressure compressor (HPC) stubshaft assemblies as mandatory terminating actions to the repetitive MCD inspections. That proposal resulted from IAE developing a terminating action to the repetitive inspections of the chip detectors. This action revises the proposed rule by expanding its applicability to include additional serial-numbered engines with certain No. 3 bearings installed. We are proposing this AD to prevent failure of the No. 3 bearing, which could result in an in-flight shutdown (IFSD) and smoke in the cockpit and cabin.

DATES: We must receive comments by March 20, 2006.

ADDRESSES: Use one of the following addresses to comment on this proposed AD:

- By mail: Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–NE–21–AD, 12 New England Executive Park, Burlington, MA 01803–5299.
- By fax: (781) 238–7055.
- By e-mail: *9-ane-adcomment@faa.gov.*

You can get the service information identified in this proposed AD from International Aero Engines AG, 400 Main Street, East Hartford, CT 06108; telephone: (860) 565–5515; fax: (860) 565–5510.

You may examine the AD docket, by appointment, at the FAA, New England

Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: James Rosa, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7152; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send 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–21–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 verbally, 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.

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

On September 11, 2003, we issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD) to apply to International Aero Engines AG IAE V2522–A5, V2524–A5, V2527–A5, V2527E–A5, V2527M–A5, V2530–A5, and V2533–A5 turbofan engines. The Office of the **Federal Register** published that proposal as a notice of proposed rulemaking (NPRM) supersedure in the **Federal Register** on September 17, 2003 (68 FR 54400). That NPRM would have required initial and repetitive inspections of the master magnetic chip detector (MCD) or the No. 1, 2, 3 bearing chamber MCD. Additionally, it would have required replacing certain No. 3 bearings and replacing or recoating certain HPC stubshaft assemblies as mandatory terminating actions to the repetitive MCD inspections. That NPRM resulted from IAE developing a terminating action to the repetitive chip detector inspections. That condition, if not corrected, could result in failure of the No. 3 bearing, which could result in an IFSD and smoke in the cockpit and cabin.

Since we issued that NPRM, we have received reports that more engines experienced No. 3 bearing failures attributed to ball spalling and race fracture. A total of 55 failures of the No. 3 bearing have occurred. Of the 55 failures, 12 resulted in IFSDs and 43 resulted in unscheduled engine removals (UER). Of the 12 IFSDs, three were associated with smoke in the cabin and cockpit. The smoke is a result of the ball spalling and race fracture of failed No. 3 bearings, P/N 2A1165, and occurs when there is hard particle contamination in the oil system. The release of coating particles on HPC stubshafts with low-energy plasma coating causes the contamination. The problem exists on certain No. 3 bearings, P/N 2A1165, that are less tolerant to damage from this contamination. As a result of these failures, we have added additional serial-numbered engines to this Supplemental NPRM. Since this change expands the scope of the originally proposed rule, we determined that it is necessary to reopen the comment period to provide additional opportunity for public comment. Also, since we issued that NPRM, IAE discovered that some of the original population of engines are not at risk for No. 3 ball bearing failure, so even though we are adding at least 100 engine SNs to this proposed AD, the number of engines listed in the Costs of Compliance is smaller.

Manufacturer's Service Information

We have reviewed and approved the technical contents of IAE SB V–2500–ENG–72–0452, Revision 3, dated March 4, 2005, that describes procedures for MCD inspections for engines in the range V10600 to V11365 with No. 3 bearing, P/N 2A1165, installed. We have also reviewed and approved the technical contents of IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005, that describes procedures for in shop action for engines in the range V10600 to V11365 with No. 3 bearing, P/N 2A1165, installed.

FAA's Determination of an Unsafe Condition and Proposed Actions

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design. Therefore, we are proposing this AD, which would require:

- Initial inspection of the master MCD or the No. 1, 2, 3 bearing chamber MCD within 125 hours time-in-service (TIS) after the effective date of the proposed AD; and
- Repetitive inspections of the master MCD or the No. 1, 2, 3 bearing chamber MCD within 125 hours time-since-last inspection; and
- Replacement of the No. 3 bearing, P/N 2A1165, at the next shop visit for any reason; and
- Replacement of HPC stubshafts that have a low-energy plasma coating with HPC stubshafts that have a high-energy plasma coating.

Costs of Compliance

We estimate that this proposed AD would affect 123 engines installed on airplanes of U.S. registry. We also estimate it would take 150 work hours per engine to perform the proposed actions, and that the average labor rate is $65 per work hour. Required parts would cost about $33,788 per engine. Based on these figures, we estimate the total cost of the proposed AD to U.S. operators to be $5,355,174.

Authority for This Rulemaking

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

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

Regulatory Analysis

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 at the address listed under **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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. Section 39.13 is amended by removing Amendment 39–13183 (68 FR 33621, June 5, 2003) and by adding the following new airworthiness directive:

International Aero Engines AG (IAE): Docket No. 2003–NE–21–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this airworthiness directive (AD) action by March 20, 2006.

Affected ADs

(b) This AD supersedes AD 2003–11–23, Amendment 39–13183.

Applicability

(c) This AD applies to International Aero Engines AG (IAE) V2522–A5, V2524–A5, V2527–A5, V2527E–A5, V2527M–A5, V2530–A5, and V2533–A5 turbofan engines with engine serial numbers V10600 through V11365 and bearings P/N 2A1165 installed. These engines are installed on, but not limited to, Airbus Industrie A319, A320, and A321 series airplanes.

Unsafe Condition

(d) This AD results from reports of No. 3 bearing failures that caused in-flight shutdown (IFSD) and smoke in the cockpit and cabin. We are issuing this AD to prevent failure of the No. 3 bearing, which could result in an IFSD and smoke in the cockpit and cabin.

Compliance

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

Inspection of the Master Magnetic Chip Detector (MCD) or the No. 1, 2, 3 Bearing Chamber MCD

(f) For engines listed in Appendix 1, Tables 1 and 2 of IAE service bulletin (SB) V–2500–ENG–72–0452, Revision 3, dated March 4, 2005, and that have a No. 3 bearing, part number (P/N) 2A1165, installed at new production build, do the following:

(1) Within 125 hours time-in-service (TIS) after the effective date of this AD, inspect the master MCD or the No. 1, 2, 3 bearing chamber MCD.

(2) Thereafter, within 125 hours time-since-last inspection, inspect the master MCD or the No. 1, 2, 3 bearing chamber MCD.

(3) If you find bearing material on the master MCD or No. 1, 2, 3 bearing chamber MCD, replace the engine before further flight.

Replacement of No. 3 Bearing

(g) For engines listed in Appendix 1, Tables 1 and 2 of IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005, that have a serial number (SN) from V10600 through V11365 inclusive, and that have a No. 3 bearing, part number (P/N) 2A1165, installed at new production, replace the No. 3 bearing at the next shop visit for any reason.

(h) After the effective date of this AD, do not install any No. 3 bearing, P/N 2A1165, removed in paragraph (g) of this AD, into any engine.

Replacement or Rework of High Pressure Compressor (HPC) Stubshaft

(i) For engines listed in Appendix 1, Tables 1 and 2 of IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005, that have a SN from V10600 through V11365 inclusive, at the next shop visit for any reason, replace the HPC stubshaft that has a low-energy plasma coating with an HPC stubshaft that has a high-energy plasma coating.

Terminating Action

(j) Performing the requirements specified in paragraphs (g) and (i) of this AD is terminating action to the repetitive MCD inspections specified in paragraph (f)(1) through (f)(3) of this AD.

Alternative Methods of Compliance (AMOCs)

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

Material Incorporated by Reference

(l) For lists identifying engines within the engine SN range of V10600 to V11365 inclusive, known to have had P/N 2A1165 installed, you must use Appendix 1, Tables 1 and 2 of IAE SB V–2500–ENG–72–0452, Revision 3, dated March 4, 2005, and IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005.

Related Information

(m) The following service bulletins contain additional information and procedures:

(1) You can find information on inspecting the master MCD and the No. 1, 2, 3 bearing chamber MCD in section 79–00–00–601 of the Aircraft Maintenance Manual.

(2) Additional information on inspection procedures is included in IAE SB V–2500–ENG–72–0452, Revision 3, dated March 4, 2005.

(3) You can find information on replacing the No. 3 bearing, and replacing or recoating the HPC stubshaft in IAE SB V–2500–ENG–72–0459, Revision 2, dated March 4, 2005.

Issued in Burlington, Massachusetts, on January 9, 2006.

Peter A. White,

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

[FR Doc. E6–379 Filed 1–13–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 56

[Docket No. 2001N–0322 (formerly 01N–0322)]

Institutional Review Boards: Requiring Sponsors and Investigators to Inform Institutional Review Boards of Any Prior Institutional Review Board Reviews; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of an advance notice of proposed rulemaking (ANPRM) entitled ''Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews'' that published in the **Federal Register** of March 6, 2002 (67 FR 10115).

DATES: The ANPRM is withdrawn February 16, 2006.

FOR FURTHER INFORMATION CONTACT: Patricia M. Beers Block, Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, rm. 9C24, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION: In 1998, the Department of Health and Human Services, Office of the Inspector General (OIG) issued several reports on institutional review boards (IRBs). The OIG sought to identify the challenges facing IRBs and to make recommendations on improving Federal

oversight of IRBs. One recommendation was that sponsors and clinical investigators be required to notify IRBs of any prior review (see OIG, Department of Health and Human Services, ''Institutional Review Boards: A Time for Reform,'' p. 14, June 1998; *http://oig.hhs.gov/oei/reports/oei–01–97–00193.pdf*). The OIG report stated that the OIG had:

> * * * heard of a few situations where sponsors and/or research investigators who were unhappy with one IRB's reviews switched to another without the new IRB being aware of the other's prior involvement. This kind of IRB shopping deprives the new IRB of information that it should have and that can be important in protecting human subjects. The ground rules should be changed so that sponsors and investigators have the clear obligation to inform an IRB of any prior reviews (footnote omitted). The obligation should be applied to all those conducting research funded by HHS or carried out on FDA-regulated products. It will have particular importance for those sponsors and investigators working with independent IRBs.

Id.

After reviewing the OIG's recommendation, FDA published an ANPRM on March 6, 2002 (67 FR 10115) (see *http://www.fda.gov/OHRMS/DOCKETS/98fr/030602a.pdf*) announcing it was considering whether to amend its IRB regulations to require sponsors and investigators to inform IRBs about any prior IRB review decisions. We invited public comments on: (1) The frequency of IRB shopping and under what circumstances IRB shopping has occurred; (2) what information about prior IRB review should be disclosed, where should it be disclosed, and who should disclose it; and (3) what methods, other than disclosure of prior IRB reviews, might prove to be valuable for dealing with IRB shopping.

In response to this ANPRM, FDA received 55 comments. The majority of the comments reported they had little or no first hand knowledge of instances of IRB shopping, and did not believe IRB shopping presented a significant problem. Many comments expressed concern about the logistics of maintaining a system that would enable the exchange of information among IRBs, especially when studies involved multiple study sites. There was concern that maintaining such a system would substantially increase the IRBs' workload and not provide any additional human subject protection. There was also concern that waiting for information from other IRBs prior to the review of research proposals within a particular institution might contribute to delays in the review of these proposals.

The Office for Human Research Protections (OHRP) also informed FDA that it considered the OIG's recommendation to require sponsors and investigators to notify IRBs of any prior IRB review of a research plan. OHRP concluded that it had no reason to believe that IRB shopping was occurring with any regularity in the review of HHS conducted or supported human subjects research.

Based on these reasons, FDA concluded that IRB shopping either does not occur or does not present a problem to an extent that would warrant rulemaking at this time.

In a letter dated February 26, 2005, FDA advised the OIG of these findings and conclusions. FDA is now withdrawing this ANPRM. A withdrawal does not prevent the agency from taking action in the future. Should FDA decide to undertake rulemaking sometime in the future, the agency will provide new opportunities for comment.

Dated: January 4, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–357 Filed 1–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 210

[Docket No. 2005N–0285]

Current Good Manufacturing Practice Regulation and Investigational New Drugs; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this companion proposed rule to the direct final rule, published elsewhere in this issue of the **Federal Register**, which is intended to amend our current good manufacturing practice (CGMP) regulations for human drugs, including biological products, to exempt most investigational ''Phase 1'' drugs from complying with the regulatory requirements. We will instead exercise oversight of production of these drugs under the agency's general statutory CGMP authority and investigational new drug application (IND) authority. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled ''INDs—Approaches to Complying With CGMP During Phase 1'' to provide further guidance on the subject.

DATES: Submit written or electronic comments by April 3, 2006.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/comments*.

FOR FURTHER INFORMATION CONTACT: Monica Caphart, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9047; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

SUPPLEMENTARY INFORMATION:

I. Background

As described more fully in the related direct final rule, a Phase 1 clinical trial includes the initial introduction of an investigational new drug into humans. Such studies are aimed at establishing basic safety and are designed to determine the metabolism and pharmacologic actions of the drug in humans. The total number of subjects in a Phase 1 study is limited—generally no more than 80 subjects. This is in contrast to Phase 2 and Phase 3 trials, which may involve substantially greater numbers of subjects, exposing more subjects to the drug product, and which aim to test the effectiveness of the drug product.

For several reasons, we believe that production of human drug products, including biological drug products, intended for use in Phase 1 clinical trials should be exempted from complying with the specific regulatory requirements set forth in parts 210 and 211 (21 CFR parts 210 and 211). First, even if exempted from the requirements of our CGMP regulations in parts 210 and 211, investigational drugs remain subject to the statutory provisions that deem a drug adulterated for failure to comply with CGMPs (21 U.S.C. 351(a)(2)(B)).

Second, we oversee drugs for use in Phase 1 trials through our existing IND authority. Every IND must contain, among other things, a section on chemistry, manufacturing, and control information that describes the composition, manufacture, and control of the investigational drug product (21 CFR 312.23(a)(7)). This information should suffice to enable us to

adequately protect subjects in early Phase 1 trials.

II. Additional Information

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. The proposed rule and the direct final rule are identical. This companion proposed rule provides the procedural framework to proceed with standard notice-and-comment rulemaking if the direct final rule receives significant adverse comment and is withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received on this companion proposed rule will also be treated as comments on the direct final rule and vice versa.

For additional information, see the corresponding direct final rule published in the final rules section of this issue of the **Federal Register**. All persons who may wish to comment should review the rationale for these amendments set out in the preamble discussion of the direct final rule. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this companion proposed rule. Instead, we will publish a confirmation notice within 30 days after the comment period ends, and we intend the direct final rule to become effective 30 days after publication of the confirmation notice. If we receive significant adverse comments, we will withdraw the direct final rule. We will proceed to respond to all of the comments received regarding the direct final rule, treating those comments as comments to this proposed rule. The agency will address the comments in a subsequent final rule. We will not provide additional opportunity for comment.

III. Legal Authority

Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 201 *et seq.*) a drug is deemed adulterated if the methods used in, or the facilities, or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated in conformity with CGMPs to ensure that such drug meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. The rulemaking authority conferred on FDA by Congress under the act permits the agency to amend its regulations as contemplated by this direct final rule. Section 701(a) of the act (21 U.S.C. 371) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the act. We refer readers to the legal authority section of the preamble of the 1978 CGMP regulations for a fuller discussion (43 FR 45014 at 45020–45026, September 29, 1978).

IV. Environmental Impact

The agency has determined that under 21 CFR 25.30(h) 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.

V. Analysis of Impacts

FDA examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. The agency has considered the effect that this rule would have on small entities. Because exempting production of drugs for use in Phase 1 studies from compliance with specific regulatory requirements does not add any burden, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

For a further discussion of the impacts of this rulemaking, see the Analysis of Impacts section in the corresponding direct final rule published in the final rules section of this issue of the **Federal Register**.

VI. Paperwork Reduction Act of 1995

This proposed rule contains no new information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Under the proposed rule, the production of human drug products, including biological drug products, intended for use in Phase 1 clinical trials would be exempted from complying with the specific regulatory requirements set forth in parts 210 and 211. Parts 210 and 211 contain information collection requirements that have been approved by OMB under control number 0910–0139. As explained in the following paragraph, the information collection requirements in parts 210 and 211 would be reduced under this proposed rule.

The OMB-approved hourly burden to comply with the information collection requirements in parts 210 and 211 (control number 0910–0139) is 848,625 hours. FDA estimates that, under the proposed rule, approximately 7,315 drugs would be exempted from complying with the specific regulatory requirements set forth in parts 210 and 211. Based on this number and the total number of drugs that are subject to parts 210 and 211, FDA estimates that the burden hours approved under control number 0910–0139 would be reduced by approximately 50,493 hours. Thus, as a result of the proposed rule, the amended burden hours in control number 0910–0139 would be approximately 798,132 hours.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA

has determined that the rule does not contain policies 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required. We invite comments on the federalism implications of this proposed rule.

VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. This comment period runs concurrently with the comment period for the direct final rule; any comments received will be considered as comments regarding the direct final rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 210

Drugs, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs it is proposed that 21 CFR part 210 be amended as follows:

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

1. The authority citation for 21 CFR part 210 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 210.2 is revised by adding paragraph (c) to read as follows:

§ 210.2 Applicability of current good manufacturing practice regulations.

* * * * *

(c) An investigational drug for use in a Phase 1 study, as defined in § 312.21(a) of this chapter, is subject to the statutory requirements set forth at 21 U.S.C. 351(a)(2)(B). The production of such drug is exempt from compliance with the regulations in part 211 of this chapter. However, this exemption does not apply to an investigational drug for use in a Phase 1 study once the investigational drug has been made available for use by or for the sponsor in a Phase 2 or Phase 3 study, as defined in § 312.21(b) and (c) of this chapter, or the drug has been lawfully marketed. If the investigational drug has been made available in a Phase 2 or 3 study or the drug has been lawfully marketed, the drug for use in the Phase 1 study must comply with part 211 of this chapter.

Dated: January 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–350 Filed 1–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–158080–04]

RIN–1545–BE79

Application of Section 409A to Nonqualified Deferred Compensation Plans; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document corrects a notice of proposed rulemaking that was published in the **Federal Register** on Tuesday, October 4, 2005 (70 FR 57930), regarding the application of section 409A to nonqualified deferred compensation plans. The regulations affect service providers receiving amounts of deferred compensation, and the service recipients for whom the service providers provide services.

FOR FURTHER INFORMATION CONTACT: Stephen Tackney, (202) 927–9639 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking (REG–158080–04) that is the subject of this correction is under section 409A of the Internal Revenue Code.

Need for Correction

As published, REG–158080–04 contains an error that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking (REG–158080–04) that was the subject of FR Doc. 05–19379, is corrected as follows:

On page 57930, column 1, in the preamble, under the paragraph heading **FOR FURTHER INFORMATION CONTACT:** lines 4 thru 8, the language ''concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Richard A. Hurst at (202) 622–7116 (not toll-free numbers).'' is corrected to read ''concerning submission of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Richard A. Hurst at (202) 622–7180 (not toll-free numbers).''.

Guy R. Traynor,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 06–395 Filed 1–12–06; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–106418–05]

RIN 1545–BE34

Guidance Under Subpart F Relating to Partnerships

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rule and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations that provide rules for determining whether a controlled foreign corporation's (CFC's) distributive share of partnership income is excluded from foreign personal holding company income under the exception contained in section 954(i). The regulations will affect CFCs that are qualified insurance companies, as defined in section 953(e)(3), that have an interest in a partnership and U.S. shareholders of such CFCs. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by April 17, 2006.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–106418–05), room 5203, Internal Revenue Service, PO 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:LPD:PR (REG–106418–05), 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* or via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS–REG–106418–05).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Kate Y. Hwa, (202) 622–3840; concerning submissions of comments, Treena Garrett, (202) 622–3401 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Temporary regulations in Rules and Regulations section of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR part 1) relating to the rules under section 954(i) of the Internal Revenue Code (Code) for determining whether a controlled foreign corporation's (CFC's) distributive share of partnership income is excluded from foreign personal holding company income under the exception contained in section 954(i). 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 that this proposed regulation is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedures Act (5 U.S.C. chapter 5) does not apply to these regulations and, because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted 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 these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and the 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. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

The IRS and the Treasury Department have become aware of possible uncertainty regarding the application of section 956 in certain transactions involving foreign partnerships. The IRS and the Treasury Department therefore also request comments regarding the proper application of section 956 in the case of a loan by a CFC to a foreign partnership in which one or more partners are domestic corporations that are U.S. shareholders of the CFC. Specifically, comments are requested regarding the circumstances, if any, under which the loan to the foreign partnership should be considered to be the obligation of such partners and, thus, U.S. property for purposes of section 956. The IRS and the Treasury Department are particularly interested in the relevance of (1) the consistent application of section 956 to CFC loans to foreign partnerships, domestic partnerships, foreign branches, and disregarded entities of U.S. shareholders; (2) the foreign partnership's status as a foreign person; (3) the partners' liability for the partnership's debt under local foreign law; (4) the use of the loan proceeds in business activities located inside or outside of the United States; and (5) the fact that the CFC earnings loaned to the partnership would not have been deferred had they been earned by the partnership.

Drafting Information

The principal author of these regulations is Kate Y. Hwa of the Office of the Associate Chief Counsel (International), IRS. However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for 26 CFR part 1 continues to read, in part, as follows:

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

Par. 2. Section 1.954–2 is amended by revising paragraphs (a)(5)(ii)(C) and (a)(5)(iii) *Example 2* to read as follows:

§ 1.954–2 Foreign personal holding company income.

(a) * * *

(5) * * *

(ii) * * *

(C) [The text of the proposed amendment to § 1.954–2(a)(5)(ii)(C) is the same as the text for § 1.954–2T(a)(5)(ii)(C) published elsewhere in this issue of the **Federal Register**.]

(iii) * * *

Example 2. [The text of proposed § 1.954–2(a)(5)(iii) *Example 2* is the same as the text of § 1.954–2T(a)(5)(iii) *Example 2* published elsewhere in this issue of the **Federal Register**.]

* * * * *

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

[FR Doc. E6–356 Filed 1–13–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–131739–03]

RIN 1545–BC45

Substitute for Return; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of public hearing on proposed rulemaking.

SUMMARY: This document provides notice of public hearing on proposed regulations relating to the IRS preparing or executing returns for persons who fail to make required returns.

DATES: The public hearing is being held on Wednesday, March 8, 2006, at 10 a.m. The IRS must receive outlines of the topics to be discussed at the hearing by Wednesday, February 15, 2006.

ADDRESSES: The public hearing is being held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building.

Mail outlines to: CC:PA:LPD:PR (REG–131739–03), room 5203, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–131739–03), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit outlines electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS and *notice.comment@irscounnsel.treas.gov* (REG–131739–03).

FOR FURTHER INFORMATION CONTACT: Concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing Treena Garrett, (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed rulemaking (REG–131739–03) that was published in the **Federal Register** on Monday, July 18, 2005 (70 FR 41165).

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who have submitted written or electronic comments and wish to present oral comments at the hearing must submit an outline of the topics to be discussed and the amount of time to be devoted to each topic (signed original and eight (8) copies) by February 15, 2006.

A period of 10 minutes is allotted to each person for presenting oral comments. After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available, free of charge, at the hearing. Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

Guy R. Traynor,

Federal Register Liaison, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, Procedures and Administration.

[FR Doc. E6–352 Filed 1–13–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–150088–02]

RIN 1545–BB96

Miscellaneous Changes to Collection Due Process Procedures Relating to Notice and Opportunity for Hearing Upon Filing of Notice of Federal Tax Lien; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations relating to a taxpayer's right to a hearing under section 6320 of the Internal Revenue Code of 1986 after the filing of a notice of Federal tax lien (NFTL).

DATES: The public hearing originally scheduled for January 19, 2006, at 10 a.m., is cancelled.

FOR FURTHER INFORMATION CONTACT: Robin R. Jones of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration), at (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on September 16, 2006 (70 FR 54681), announced that a public hearing was scheduled for January 19, 2005, at 10 a.m., in the IRS Auditorium, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. The subject of the public hearing is under section 6320 of the Internal Revenue Code. The public comment period for these regulations expired on December 29, 2005.

The notice of proposed rulemaking and notice of public hearing, instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. As of Monday, January, 9, 2006, no one has requested to speak. Therefore, the public hearing scheduled for January 19, 2006, is cancelled.

LaNita VanDyke,

Federal Register Liaison Officer, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, Procedure and Administration.

[FR Doc. E6–365 Filed 1–13–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 2

[Docket No. 2003–T–009]

RIN 0651–AB56

Miscellaneous Changes to Trademark Trial and Appeal Board Rules

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (Office) proposes to amend its rules to require plaintiffs in Trademark Trial and Appeal Board (Board) inter partes proceedings to serve on defendants their complaints or claims; to utilize in Board inter partes proceedings a modified form of the disclosure practices included in the Federal Rules of Civil Procedure; and to delete the option of making submissions to the Board in CD–ROM form. In addition, certain amendments clarify rules, conform the rules to current practice, and correct typographical errors or deviations from standard terminology.

DATES: Comments must be received by March 20, 2006 to ensure consideration.

ADDRESSES: Submit comments by electronic mail (e-mail) to *AB56Comments@uspto.gov.* Written comments may be submitted by mail to: Trademark Trial and Appeal Board, P.O. Box 1451, Alexandria, VA 22313–1451, attention Gerard F. Rogers; or by hand delivery to Trademark Assistance Center, Concourse Level, James Madison Building-East Wing, 600 Dulany Street, Alexandria, Virginia, attention Gerard F. Rogers.

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See the Federal eRulemaking Portal Web site (*http://www.regulations.gov*) for additional instructions on providing comments via the Federal eRulemaking Portal.

FOR FURTHER INFORMATION CONTACT: Gerard F. Rogers, Trademark Trial and Appeal Board, by telephone at (571) 272–4299, by e-mail to *gerard.rogers@uspto.gov,* or by facsimile at 571–273–0059.

SUPPLEMENTARY INFORMATION: The Office proposes to increase the efficiency of the processes for commencing inter partes cases, in light of the Board's deployment in recent years of electronic filing options and the increased availability and use of facsimile and e-

mail as methods of communication between parties involved in inter partes cases. Also, the Office proposes to increase the efficiency by which discovery and pre-trial information is exchanged between parties to inter partes cases, by adopting a modified form of the disclosure practice that is uniformly followed in the federal district courts. These practices have been found in the courts to enhance settlement prospects and to lead to earlier settlement of cases; and for cases that do not settle, disclosure has been found to promote greater exchange of information, leading to increased procedural fairness and a greater likelihood that cases eventually determined on their merits are determined on a fairly created record. Finally, in addition to the foregoing non-substantive changes to the rules, the Office proposes minor modifications necessary to make corrections or updates to certain rules and conform those rules to current practice.

Background

I. Commencement of Proceedings

The current process by which a plaintiff in a Board proceeding files notice of its complaint (or claim of right to a concurrent use registration) requires the plaintiff to prepare as many copies of its complaint (or claim of right) as there will be defendants in the action. The plaintiff is then required to file the requisite copies with the original, for subsequent forwarding to the defendants. Occasionally, before the Board can forward the copies to the defendants, the plaintiff will have to engage in additional correspondence with the Board, to provide the Board with updated correspondence address information the plaintiff has uncovered in its investigation of the defendant's application, registration or mark, particularly in cancellation and concurrent use proceedings.

Under the practice envisioned by the proposed rules, the initiation of a Board proceeding would become more efficient, because a plaintiff would be able to serve its copies directly on defendants. Use of a direct service approach recognizes that plaintiffs and defendants often are in contact prior to a plaintiff's filing of its complaint or claim, and also recognizes that continuation of such direct communication is vital both for promoting possible settlement of claims and for ensuring cooperation and procedural efficiency in the early stages of a proceeding.

(Plaintiffs in Board proceedings include an opposer that files a notice of opposition against an application, a petitioner that files a petition for cancellation of a registration, and a concurrent use applicant whose concurrent use application sets forth details about the concurrent use applicant's claim of entitlement to a concurrent use registration.)

In recent years, the Board has deployed its ESTTA system, the Electronic System for Trademark Trials and Appeals, so that virtually all filings a party may need to submit to the Board can be submitted electronically. In addition, more and more parties to Board proceedings are choosing to utilize fax or e-mail options for communicating with each other during an inter partes proceeding, either in lieu of using the mail or in combination with use of the mail.

Under the proposed rules changes, an opposer or petitioner would file its complaint with the Board and be required to concurrently serve a copy of its complaint (notice of opposition or petition for cancellation), including any exhibits, on the owner of record, or when applicable the attorney or domestic representative therefor, of the defending application or registration. A concurrent use applicant, however, would not have to serve copies of its application on any defending applicant, registrant or common law mark owner until notification of commencement of the concurrent use proceeding was issued by the Board, as discussed below.

A plaintiff would be expected to serve the owner of record according to Office records, or the domestic representative of the owner of record, as well as any party the plaintiff believed had an ownership interest (*e.g.*, an assignee or survivor of merger that had not recorded the document of transfer in the Office but was known to the plaintiff) at the correspondence address known to the plaintiff. The plaintiff would have to inform the Board of any service copies returned as undeliverable. As for a concurrent use applicant, current practice requires such party to provide, for forwarding by the Board, as many copies of its application as are necessary to forward one to each person or entity listed in the concurrent use application as an exception to the concurrent use applicant's rights. By these proposed changes to the trademark rules, the concurrent use applicant would directly serve the copies of its application on the excepted parties after notification by the Board that the concurrent use application was free of any opposition and the concurrent use proceeding therefore had been instituted. The concurrent use applicant would bear the same service obligations as an opposer or petitioner.

The Board would, after an opposition or petition was filed, or a concurrent use application was published for opposition and free of any opposition, send notice to all parties to the proceeding, noting the filing of the complaint, or publication of the concurrent use application, and setting via such notice the due date for an answer, and the discovery and trial schedule. Notification from the Board may be sent by e-mail when a party has provided an e-mail address. This would include a plaintiff providing an e-mail address when filing by ESTTA or with its complaint, an applicant that authorized the Office to communicate with it by e-mail when it filed its application, and any registrant whose registration file record includes such authorization.

A plaintiff may not serve its complaint or concurrent use application on a defendant by e-mail unless the defendant has agreed with the plaintiff to accept such service, notwithstanding that the defendant may have authorized the Office to communicate with it by e-mail.

Whenever a plaintiff has a service copy of a complaint or claim returned as undeliverable, it would have to inform the Board within 10 days of the return and, if known, any new address information for the defendant whose service copy was returned to the plaintiff. Any undelivered notice from the Board of the commencement of a proceeding may result in notice by publication in the Official Gazette, available via the Office's Web site (*http://www.uspto.gov*), for any proceeding.

II. Adoption of Disclosure

In 1993, significant amendments to the Federal Rules of Civil Procedure (federal rules) implemented a system requiring parties litigating in the federal courts to disclose certain information and/or documents and things without waiting for discovery requests. Individual district courts were permitted to opt out of the mandatory disclosure regime.

In 2000, the federal rules were further amended, with elimination of the option for individual courts to opt out of mandatory disclosure among the most significant changes.

By notice issued January 15, 1994 (and published in the Official Gazette at 1159 TMOG 14), the Board announced its decision not to follow many of the 1993 changes to the federal rules, including the disclosure regime established by Federal Rule 26. The Board subsequently amended the Trademark Rules of Practice (trademark

rules) in 1998. The original notice issued September 29, 1998 (and was published at 1214 TMOG 145) and a correction notice issued October 20, 1998 (and was published at 1215 TMOG 64). While it did not adopt a disclosure practice as an element of these amendments, the Board noted that it would monitor recurring procedural issues in Board cases and might propose and adopt additional changes to practice in the future.

Empirical study has shown that disclosure has been successful in the courts:

> In general, initial disclosure appears to be having its intended effects. Among those attorneys who believed there was an impact, the effects were most often of the type intended by the drafters of the 1993 amendments. Far more attorneys reported that initial disclosure decreased litigation expense, time from filing to disposition, the amount of discovery, and the number of discovery disputes than said it increased them. At the same time, many more attorneys said initial disclosure increased overall procedural fairness, the fairness of the case outcome, and the prospects of settlement than said it decreased them.

Thomas E. Willging, Donna Stienstra, John Shapard & Dean Miletich, *An Empirical Study of Discovery and Disclosure Practice Under the 1993 Federal Rule Amendments,* 39 B.C.L. Rev. 525, 534–35 (May 1998).

The Office has conducted a thorough review of the empirical study and available articles and reports on the subject of disclosure. The Office has concluded from such review that use of disclosure in Board proceedings, in a modified form of that used in the courts, would enhance the possibility of parties settling a Board proceeding and doing so sooner. In addition, disclosure will, if parties do not settle the case, promote more efficient discovery and trial, reduce incidents of unfair surprise, and increase the likelihood of fair disposition of the parties' claims and defenses. In large part, disclosure would serve as a substitute for a certain amount of traditional discovery and a more efficient means for exchange of information that otherwise would require the parties to serve traditional discovery requests and responses thereto.

The Board's standard protective order would be applicable to all cases and the Board notice of the commencement of a proceeding would so indicate (and would note the availability of the standard protective order on the Office's Web site or in hard copy form, by request made to the Board). The applicability of this standard protective order would not make all submissions confidential, as parties would still have to utilize its provisions as necessary. As under current practice, parties would be free to agree to modify the standard protective order. Absent approval of a stipulation to vary the terms of the standard protective order, approved by the Board, the parties would have to abide by it.

The parties may agree to use e-mail to communicate with each other and for forwarding of service copies.

1. The Schedule for Cases Under Disclosure

The Board's notice of the commencement of the proceeding (commonly referred to as the institution order) will set forth disclosure-related deadlines, as illustrated below.

The institution order will set forth specific dates for the various phases in a case. Since each deadline or phase is measured from the date of the institution order, the parentheticals explain the total number of days, as measured from that date, until each deadline:

Due date for an answer—40 days from the mailing date of institution order. (Institution date plus 40 days.)

Deadline for a discovery conference—30 days from the date the answer is due. (Institution date plus 70 days.)

Discovery opens—30 days after the date the answer is due. (Institution date plus 70 days.)

Deadline for making initial disclosures—30 days from the opening of the discovery period. (Institution date plus 100 days.)

Expert disclosure—90 days prior to close of discovery (the mid-point of the 180-day discovery period). (Institution date plus 160 days.)

Discovery closes—180 days from the opening date of the discovery period. (Institution date plus 250 days.)

Pre-Trial disclosures—30 days after the close of the discovery period. (Institution date plus 280 days.)

Plaintiff's 30-day testimony period—closes 90 days after the close of discovery. (Institution date plus 340 days.)

Defendant's 30-day testimony period—closes 60 days after the close of plaintiff's testimony period. (Institution date plus 400 days.)

Plaintiff's 15-day rebuttal testimony period—closes 45 days from close of defendant's testimony period. (Institution date plus 445 days.)

Under this schedule, discovery generally opens after the discovery conference, unless the parties defer their discovery conference to the deadline date, in which case discovery would open concurrently with the conference.

The deadline for making initial disclosures is similar to that of Federal Rule 26(a)(1), except that disclosure under the federal rule is measured from the actual date of, not the deadline for, the discovery conference. Plus, the Board approach provides a longer period for making disclosures than is provided under the federal rules. This will accommodate the possibility of motions to suspend for settlement talks, which are quite common in Board proceedings.

The length of the discovery period is the same as under current Board practice, i.e., 180 days. Disclosures would be made no later than 30 days into that period and the parties would have another 150 days for any necessary additional discovery. The trial schedule, with its 60-day break between discovery and trial and 30-day breaks between the respective testimony periods, is also the same as under current Board practice.

Because disclosure is tied to claims and defenses, in general, a defendant's default or the filing of various pleading motions under Federal Rule 12 would effectively stay the parties' obligation to conference and make initial disclosures. An answer must be filed and issues related to the pleadings resolved before the parties can know the extent of claims and defenses and, therefore, the extent of their initial disclosure obligations.

The Board anticipates it will be liberal in granting extensions or suspensions of time to answer, when requested to accommodate settlement talks, or submission of the dispute to an arbitrator or mediator. However, if a motion to extend or suspend for settlement talks, arbitration or mediation is not filed prior to answer, then the parties will have to proceed, after the filing of the answer, to their discovery conference, one point of which is to discuss settlement. It is unlikely the Board will find good cause for a motion to extend or suspend for settlement when the motion is filed after answer but prior to the discovery conference, precisely because the discovery conference itself provides an opportunity to discuss settlement.

The parties' discovery conference may be in person or by other means. A Board professional, i.e., an Interlocutory Attorney or an Administrative Trademark Judge, will participate in the conference upon the request of any party; but if the parties propose to meet in person, participation by a Board professional would be by telephone, by arrangement of the parties. A request for the participation of a Board professional may only be made after answer is filed but in no event later than 10 days prior

to the deadline for conducting the discovery conference. If neither party requests participation of a Board professional in the discovery conference, the Board will assume that the parties have met on their own, in person or by other means, no later than the prescribed deadline. The parties would not have to file a disclosure/discovery plan with the Board, following their discovery conference, unless they were seeking leave to alter standard deadlines/obligations; or unless they were so directed by a participating Board professional.

There is no Federal Rule 16(b) scheduling conference/order. The Board's institution order will already have set a schedule for the case.

Disclosure deadlines and obligations may be modified upon stipulation of the parties approved by the Board, or upon motion granted by the Board, or by order of the Board. If a stipulation or motion is denied, dates may remain as set. The Board is likely to employ rather strict time frames for filing such stipulations or motions and may routinely employ phone conferences when any request to alter disclosure obligations or deadlines is made by unilateral rather than consented motion.

2. The Interplay of Disclosure and Discovery

A party may not seek discovery through traditional devices until after it has made its disclosures. A party may not move for summary judgment except on claim or issue preclusion grounds until after it has made its disclosures.

The number of interrogatories will be limited to reflect the fact that core information (as discussed below) will be disclosed and interrogatories will not be needed to obtain this information.

Initial disclosure should be much more limited in Board cases than it is in civil actions. For a variety of reasons related to the unique nature of Board proceedings, the extent of initial disclosure can be more limited than in the courts while still promoting the goals of increased fairness and efficiency.

One reason is that the Board's jurisdiction is limited to determining the right of a party to obtain, or retain, a registration, and the extent of available claims and defenses that may be advanced is not nearly as broad as in the district courts. In addition, the Board recognizes the existence of other issues relatively unique to Board proceedings, for example, that a high percentage of applications involved in oppositions are not based on use of the applied-for mark in commerce, but rather, on intent to use, on a foreign registration or on an international registration. Further, certain precepts that govern analysis of issues raised by claims or defenses in typical Board cases effectively limit the Board's focus. For example, in a case under Section 2(d) of the Trademark Act, 15 U.S.C. 1052(d), the Board focuses only on goods or services recited in identifications, and on a mark as registered or applied-for, irrespective of many actual marketplace issues.

Federal Rule 26(a)(1) requires initial disclosure as a means of obviating the need to use traditional discovery to obtain ''core information'' about a party's claims or defenses. The federal rule is written very generally to account for the wide variety of types of cases tried in the federal district courts; even under the federal rule, however, a party is not obligated under initial disclosure to disclose every fact, document or thing that is considered discoverable about its claim or defense, but merely the ''information that the disclosing party may use to support its claims or defenses.'' Further, disclosure focuses on exchange of ''core information'' and does not substitute for comprehensive discovery.

In inter partes proceedings before the Board, parties will generally be found to have met their initial disclosure obligations if they provide information about the following, as applicable in any particular case:

Origin of any mark on which the party relies, including adoption or creation of the mark and original plans for use of the mark;

Dates of use of any marks, registered or not, on which the party's claims or defenses rely;

The extent of past or current use, if any, or plans for future use of any marks on which claims or defenses rely, including use by the party or by licensees;

Evidence of actual confusion possessed by a party in regard to the involved marks;

The party's awareness of third-party use or registration of marks that are the same or very similar for goods or services the same as or closely related to the involved marks and goods or services;

The extent of use by the party, if any, in a non-trademark manner of words or designs asserted by that party to be non-distinctive;

A party's awareness of use of involved words or designs by third parties when the party is asserting that such words or designs are non-distinctive;

Classes of customers for the party's involved goods or services, including information on the technical expertise or knowledge employed by customers in making purchasing decisions;

Channels of trade for the party's involved goods or services;

Methods of marketing and promoting the party's involved goods or services;

Surveys or market research conducted by the party in regard to any involved mark on which it will rely;

Information regarding other Board proceedings, litigation, or controversies in which the party has been involved, which were related to the involved marks or, if applicable, assertedly non-distinctive matter;

The names of individual officials or employees of a party, and contact information therefor, who are known to have the most extensive knowledge of subjects on which disclosure is made; and

General descriptions of and the probable locations of non-privileged documents and things maintained by the party or its attorneys related to the subjects on which disclosure is made.

The Board recognizes that the language used herein to describe subjects for which there must be initial disclosure, unless inapplicable in a particular case, may be subject to dispute. Parties are expected, however, to read the descriptions in light of the intended goals for disclosure and in a reasonable manner, and without engaging in artificial attempts to limit disclosure through arcane interpretation.

The Board also recognizes that the specificity of information released by a party to comply with its disclosure obligations may be subject to dispute. This is, however, one of the issues that must be anticipated and discussed by the parties during their discovery conference. In addition, the parties are free to discuss additional subjects for which disclosure should be made, or subjects which they do not believe should require disclosure because they are insignificant or not in genuine dispute.

Finally, the Board recognizes that a disclosure obligation may be met, in regard to some subjects, by providing summary information, round numbers, or representative samples. To emphasize, initial disclosure is not intended to substitute for all discovery, but rather, to prompt routine disclosure of core information that a party may use to support a claim or defense. Any adverse party is free to take discovery on subjects that will undermine a claim or defense.

Written disclosures may be used in support of or in opposition to a motion for summary judgment and may, at trial, be introduced by notice of reliance. Disclosed documents also may be used to support or contest a motion for summary judgment but, at trial, they may be introduced by notice of reliance only if otherwise appropriate for such filing. In essence, initial disclosures will be treated like responses to written discovery.

3. Expert Disclosure and Pre-trial Disclosure

A party's plan to use experts must be disclosed no later than 90 days prior to the close of discovery, so that any adverse party will have an opportunity to take necessary discovery. However, if the expert is retained early and an adverse party has inquired about experts through discovery, the party may not delay revealing the expert until the deadline for disclosure of experts. Also, the Board recognizes that there may be cases in which a party retains an expert after the deadline for expert disclosure. In such cases, disclosure must be made promptly when the expert is retained.

Pretrial disclosure will require disclosure of the identity of witnesses that a party expects to present, or may present if the need arises. For each witness, general summaries or descriptions of the subjects on which the witness will testify and the documents or things to be introduced during the deposition must be disclosed. These disclosures must be made 30 days prior to the opening of trial. A party may object to improper or inadequate pre-trial disclosures and may move to strike the testimony of a witness for lack of proper pre-trial disclosure.

Pretrial disclosure of plans to file notices of reliance is not required. The notice of reliance is a device for introduction of evidence that is unique to Board proceedings. There are established practices covering what can be introduced, how it must be introduced, and for objecting to, or moving to strike, notices or material attached thereto. There is less opportunity for surprise or trial by ambush with notices of reliance, because they are most often used to introduce discovery responses obtained from an adversary, or printed publications in general circulation, or government documents generally available to all parties.

III. Removal of Option To Make Submissions on CD–ROM

The Office proposes to remove from Trademark Rule 2.126, 37 CFR 2.126, the option to file submissions in CD–ROM form. CD–ROMs present technical problems for the ESTTA/TTABIS systems and have rarely been utilized by parties.

IV. Change to Rule on Briefing of Motions

The Office proposes to amend Trademark Rule 2.127, 37 CFR 2.127, to clarify that a table of contents, index of cases, description of record, statement of the issues, recitation of facts, argument and summary, whichever a party may choose to employ, all count against the limit of 25 pages for a brief in support of a motion or in response to a motion and the limit of 10 pages for a reply brief.

Discussion of Specific Rules

The Office proposes to make the following amendments:

[2.99(b) to (d)]

The Office proposes to revise § 2.99(b), (c) and (d)(1) by shifting applicant's time to furnish copies of applicant's application, specimens and drawing until after the Board's notification of the proceeding; and to indicate that the Office may transmit the notification of proceedings via e-mail to any party that has provided an e-mail address.

[2.101(a), (b) and (d)]

The Office proposes to revise § 2.101(a) to specify that proof of service on applicant at the correspondence address of record must be included with the filing of the notice of opposition.

The Office proposes to revise § 2.101(b) to define the phrase ''correspondence address of record''; and to specify the steps opposer should take if opposer believes that the correspondence address of record is not accurate, or if the service copy of the notice of opposition is returned as undeliverable to opposer.

The Office proposes to revise § 2.101(d)(4) to add to the requirements for receiving a filing date for the notice of opposition the inclusion of proof of service on applicant at the correspondence address of record.

[2.105(a) and 2.105(c)]

The Office proposes to revise § 2.105(a) to cross-reference rules concerning proper form and proper service; and to indicate that the Office may transmit the notification of proceedings via e-mail to any party that has provided an e-mail address.

The Office proposes to revise § 2.105(c) introductory text to shift to plaintiffs the responsibility for service of the complaint directly on defendants, rather than through the Board.

[2.111(a) to (c)]

The Office proposes to revise § 2.111(a) to specify that proof of service on the owner of record for the registration, or the owner's domestic representative of record, at the correspondence address of record must be included with the filing of the petition to cancel, along with the required fee.

The Office proposes to revise § 2.111(b) to define the phrase ''correspondence address of record'; and to specify the steps petitioner should take if petitioner believes that the correspondence address of record is not accurate, or if the service copy of the petition to cancel is returned as undeliverable to petitioner.

The Office proposes to revise § 2.111(c)(4) to add to the requirements for receiving a filing date for the petition to cancel the inclusion of proof of service on the owner of record or on the owner's domestic representative of record, at the correspondence address of record.

[2.113(a) and (c)]

The Office proposes to revise § 2.113(a) to clarify that the answer must be filed by the respondent; and to indicate that the Office may transmit the notification of proceedings via e-mail to any party that has provided an e-mail address.

The Office proposes to revise § 2.113(c) to shift to plaintiffs the responsibility for service of the complaint directly on defendants, rather than through the Board.

[2.113(e)] [remove]

The Office proposes to remove § 2.113(e) to conform the rule to the existing practice whereby the Office no longer advises petitioners of defective petitions to allow for correction of defects.

[2.116(g)] [add]

The Office proposes to add new paragraph (g) to § 2.116. Proposed § 2.116(g) provides that the Board's standard protective order, available via the Office's Web site or upon request made to the Board, is applicable to all inter partes proceedings, unless the parties agree to, and the Board approves, an alternative protective order, or unless a motion by a party to enter a specific protective order is granted by the Board.

[2.118]

The Office proposes to revise § 2.118 to extend its coverage to applicants as well as registrants, so as to allow for service of additional notice of a proceeding, by publication in the Official Gazette, when a notice mailed to an applicant is returned as undeliverable.

[2.119(a) and (b)]

The Office proposes to revise § 2.119(a) by changing ''Patent and Trademark Office'' to ''United States

Patent and Trademark Office;'' by making the singular ''notice of appeal'' the plural ''notices of appeal;'' and by striking out the list of filings that are exceptions to the general requirement that a party to a Board proceeding serve its filings on its adversary. The last of these changes will accommodate the Board's shift to service by plaintiffs on defendants, rather than through the Board, at the commencement of a proceeding.

The Office proposes to revise § 2.119(b) by adding subsection (6), which will allow parties to meet their service obligations by utilizing fax or e-mail, upon agreement of the parties.

[2.120(a), (d) through (j)]

The Office proposes to revise § 2.120(a)(1) to include detailed provisions regarding the requirements for a discovery conference and for initial and expert disclosures in lieu of discovery.

The Office proposes to revise § 2.120(d)(1) to limit the number of interrogatories a party may serve to 25; and to clarify that a motion or stipulation of the parties to allow interrogatories in excess of the limit requires approval of the Board.

The Office proposes to revise § 2.120(e) so that provisions regarding a motion for an order to compel will apply to discovery and disclosures in lieu of discovery.

The Office proposes to revise § 2.120(f) so that provisions regarding a motion for a protective order will apply to discovery and disclosures in lieu of discovery.

The Office proposes to revise § 2.120(g) so that provisions regarding a motion for sanctions may apply to a party's non-participation in the discovery conference, to a party's failure to comply with its disclosure obligations, and to its failure to comply with its discovery obligations; and to specify a deadline for filing a motion for sanctions for failure of a party to participate in the discovery conference.

The Office proposes to revise § 2.120(h)(2) to specify that the filing of a motion to test the sufficiency of responses to requests for admissions shall not toll the time for a party to comply with disclosure obligations, to respond to outstanding discovery requests, or to appear for a noticed deposition.

The Office proposes to revise § 2.120(i) to clarify the language in paragraph (i)(1), to conform titles used in paragraph (i)(2) to existing titles, and to specify that the existing provision through which the Board may require parties to attend a conference at the Board's offices can involve discovery or disclosure issues.

The Office proposes to revise § 2.120(j)(3) and (5) through (8) to provide that disclosures and disclosed documents shall be treated in essentially the same manner as information and documents obtained through discovery requests; and to remove a reference to a past practice of the Board whereby it would return to parties filings related to discovery that should not have been filed with the Board.

[2.121(a) and (d)]

The Office proposes to revise § 2.121(a) to provide for a deadline for pre-trial disclosures and for testimony periods.

The Office proposes to revise § 2.121(d) to account for the resetting of the pre-trial disclosure deadline and testimony periods.

[2.121(e)] [add]

The Office proposes to add § 2.121(e) to explain what is required of a party making pre-trial disclosures.

[2.122(d)]

The Office proposes to revise § 2.122(d)(1) to conform to existing practice by removing the requirement for an opposer or petitioner to file two copies when making a pleaded registration of record with a notice of opposition or petition for cancellation.

[2.123(e)]

The Office proposes to revise § 2.123(e)(3) to provide that a party may object to improper or inadequate pre-trial disclosures and may move to strike the testimony of a witness for lack of proper pre-trial disclosure.

[2.126(a)]

The Office proposes to revise § 2.126(a)(6) to reflect the proposed removal of § 2.126(b).

[2.126(b)] [remove]

The Office proposes to remove § 2.126(b), which allows a party to make submissions on CD-ROM.

[2.127(a), (c) and (e)]

The Office proposes to revise § 2.127(a) to clarify the provisions relating to briefing of motions and to conform them to existing practice.

The Office proposes to revise § 2.127(c) to update titles and to correct a typographical error.

The Office proposes to revise § 2.127(e) to provide that a party may not file a motion for summary judgment before it has made its initial disclosures; and to provide that a party may submit disclosures and disclosed documents when briefing a motion for summary judgment.

[2.129(a)]

The Office proposes to revise § 2.129(a) to update titles.

[2.133(a) and (b)]

The Office proposes to revise §§ 2.133(a) and (b) to conform to current practices related to amendment of an application or registration involved in an inter partes proceeding.

[2.142(e)]

The Office proposes to revise § 2.142(e)(1) to update titles.

[2.173(a)]

The Office proposes to revise § 2.173(a) to conform to current practices related to amendment of a registration involved in an inter partes proceeding.

[2.176]

The Office proposes to revise § 2.176 to conform to current practices related to amendment of a registration involved in an inter partes proceeding.

Rulemaking Requirements

I. Executive Order 13132

This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

II. Executive Order 12866

This rulemaking has been determined not to be significant for purposes of Executive Order 12866 (Sept. 30. 1993).

III. Regulatory Flexibility Act

The United States Patent and Trademark Office (Office) is amending its rules in 37 CFR Part 2 governing initiation of inter partes proceedings at the Trademark Trial and Appeal Board (Board) and the prosecution and defense of such proceedings, and making corrections or modifications that conform rules to current practice. There are no new fees or fee changes associated with any of the proposed rules.

The changes in this proposed rule involve interpretive rules, or rules of agency practice and procedure, and prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553(b)(A) (or any other law). Because prior notice and an opportunity for public comment are not required for the changes in this proposed rule, a Regulatory Flexibility

Act analysis is also not required for the changes proposed in this rule. *See* 5 U.S.C. 603. Nevertheless, the Office is publishing this notice of proposed rulemaking in the **Federal Register** and in the Official Gazette of the United States Patent and Trademark Office, in order to solicit public participation with regard to this rule package.

The primary changes in this rule are: (1) plaintiffs will serve certain papers (complaints or claims of right to a concurrent use registration) directly on defendants, and (2) parties will exchange core information supporting their claims or defenses and identify expert witnesses to be used during Board proceedings, as part of the discovery phase, and will disclose the identity of witnesses the party expects to call during a pre-trial phase.

These proposed rules will not have a significant economic impact on large or small entities. With regard to the first change, very little (if any) additional cost is associated with the rules because plaintiffs must currently serve these papers on the Office, which, in turn, serves the papers on the defendants. Changing the recipient of the papers will not have a significant economic impact on any party to a Board proceeding. With regard to the second change, very little (if any) additional cost is associated with these rules because under current Board procedures, parties are obligated to provide almost all of this information, when requested through discovery. This rule simply affects when the information is exchanged and eliminates the need for a party to incur expenses associated with preparing requests for the information.

The proposed rules also contemplate many instances in which parties may avoid disclosure obligations otherwise provided for by the rules. For example, if a case is suspended to allow the parties to discuss settlement, as occurs in the vast majority of Board cases, no disclosure would be required during settlement talks. In addition, parties can stipulate, subject to approval of the Board, that disclosure is not necessary in a particular case and can specify their own plans for exchanging information.

IV. Paperwork Reduction Act

The proposed amendments to the Trademark Trial and Appeal Board Rules do not impose any collection of information requirements within the meaning of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) (PRA). Accordingly, the PRA does not apply to these proposed amendments.

List of Subjects in 37 CFR Part 2

Administrative practice and procedure, Trademarks.

For the reasons given in the preamble and under the authority contained in 35 U.S.C. 2 and 15 U.S.C. 1123, as amended, the Office proposes to amend part 2 of title 37 as follows:

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

1. The authority citation for 37 CFR part 2 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

2. Revise § 2.99(b), (c) and (d)(1) to read as follows:

§ 2.99 Application to register as concurrent user.

* * * * *

(b) If it appears that the applicant is entitled to have the mark registered, subject to a concurrent use proceeding, the mark will be published in the Official Gazette as provided by § 2.80.

(c) If no opposition is filed, or if all oppositions that are filed are dismissed or withdrawn, the Trademark Trial and Appeal Board will send a notification to the applicant for concurrent use registration (plaintiff) and to each applicant, registrant or user specified as a concurrent user in the application (defendant). The notification for each defendant shall state the name and address of the plaintiff and of the plaintiff's attorney or other authorized representative, if any, together with the serial number and filing date of the application. If a party has provided the Office with an e-mail address, the notification may be transmitted via e-mail.

(d)(1) The applicant for concurrent use registration will be required to serve copies of its application, specimens and drawing on each applicant, registrant or user specified as a concurrent user in the application for registration, within ten days from the date of the Board's notification.

* * * * *

3. Revise § 2.101(a), (b) and (d)(4) to read as follows:

§ 2.101 Filing an opposition.

(a) An opposition proceeding is commenced by filing in the Office a timely opposition, with proof of service on the applicant at the correspondence address of record, and the required fee.

(b) Any person who believes that he, she or it would be damaged by the registration of a mark on the Principal Register may file an opposition addressed to the Trademark Trial and Appeal Board and must serve a copy of the opposition, including any exhibits, on the attorney for the applicant of record or, if there is no attorney, on the applicant or on the applicant's domestic representative, if one has been appointed, utilizing the correspondence address of record. The opposer must include with the opposition proof of service pursuant to § 2.119 at the correspondence address of record. If the opposer believes that the applicant of record or correspondence address of record is not accurate or current, the opposer should serve an additional copy of the opposition and exhibits on any party, or the party's attorney or domestic representative, that the opposer has reason to believe may be the correct applicant, or its successor-in-interest, and must also include with its opposition proof of such service. If any service copy of the opposition is returned to the opposer as undeliverable, the opposer should notify the Board within ten days. The opposition need not be verified, but must be signed by the opposer or the opposer's attorney, as specified in § 10.1(c) of this chapter, or other authorized representative, as specified in § 10.14(b) of this chapter. Electronic signatures pursuant to § 2.192(c)(1(iii) are required for oppositions filed under paragraphs (b) (1) or (2) of this section.

* * * * *

(d) * * *

(4) The filing date of an opposition is the date of receipt in the Office of the opposition, with proof of service on the applicant of record, at the correspondence address of record, and the required fee, unless filed in accordance with § 2.198.

4. Revise § 2.105(a) and the introductory text of paragraph (c) to read as follows:

§ 2.105 Notification to parties of opposition proceeding(s).

(a) When an opposition in proper form (see §§ 2.101 and 2.104), with proof of service in accordance with § 2.101(b), has been filed and the correct fee has been submitted, the Trademark Trial and Appeal Board shall prepare a notification, which shall identify the title and number of the proceeding and the application involved and shall designate a time, not less than thirty days from the mailing date of the notification, within which an answer must be filed. If a party has provided the Office with an e-mail address, the notification may be transmitted via e-mail.

* * * * *

(c) The Board shall forward a copy of the notification to applicant, as follows:

* * * * *

5. Revise § 2.111(a), (b) and (c)(4) to read as follows:

§ 2.111 Filing petition for cancellation.

(a) A cancellation proceeding is commenced by filing in the Office a timely petition for cancellation with the required fee. The petition must include proof of service on the owner of record for the registration, or the owner's domestic representative of record, at the correspondence address of record.

(b) Any person who believes that he, she or it is or will be damaged by a registration may file a petition, addressed to the Trademark Trial and Appeal Board, for cancellation of the registration in whole or in part. Petitioner must serve a copy of the petition, including any exhibits, on the owner of record for the registration, or on the owner's domestic representative of record, at the correspondence address of record. The petitioner must include with the petition for cancellation proof of service, pursuant to § 2.119, on the owner of record, or on the owner's domestic representative of record, at the correspondence address of record. If the petitioner believes that the owner of record, the domestic representative of record, or the correspondence address of record is not accurate or current, the petitioner should serve an additional copy of the petition and exhibits on any party, or the representative therefor, that the petitioner has reason to believe may be the correct owner or successor-in-interest and must also include with its petition proof of such service. If any service copy of the petition for cancellation is returned to the petitioner as undeliverable, the petitioner should notify the Board within ten days.

(c) * * *

(4) The filing date of a petition for cancellation is the date of receipt in the Office of the petition for cancellation, with proof of service on the owner of record, or on the owner's domestic representative of record, at the correspondence address of record, and with the required fee, unless filed in accordance with § 2.198.

6. Remove § 2.113(e) and revise § 2.113 (a) and (c) to read as follows:

§ 2.113 Notification of cancellation proceeding.

(a) When a petition for cancellation has been filed in proper form (see §§ 2.111 and 2.112), the Trademark Trial and Appeal Board shall prepare a notification which shall identify the title and number of the proceeding and the registration(s) involved and shall designate a time, not less than thirty days from the mailing date of the notification, within which an answer must be filed by the respondent. If a party has provided the Office with an e-mail address, the notification may be transmitted via e-mail.

* * * * *

(c) The Board shall forward a copy of the notification to the respondent (see § 2.118). The respondent shall be the party shown by the records of the Office to be the current owner of the registration(s) sought to be cancelled, except that the Board, in its discretion, may join or substitute as respondent a party who makes a showing of a current ownership interest in such registration(s).

* * * * *

7. Add § 2.116(g) to read as follows:

§ 2.116 Federal Rules of Civil Procedure.

* * * * *

(g) The Trademark Trial and Appeal Board's standard protective order is applicable during disclosure, discovery and at trial in all opposition, cancellation, interference and concurrent use registration proceedings, unless the parties, by stipulation approved by the Board, agree to an alternative order. The standard protective order is available at the Office's Web site, or upon request, a copy will be provided. No material disclosed or produced by a party, presented at trial, or filed with the Board, including motions or briefs which discuss such material, shall be treated as confidential or shielded from public view unless designated as protected under the Board's standard protective order, or under an alternative order stipulated to by the parties and approved by the Board, or under an order submitted by motion of a party granted by the Board.

8. Revise § 2.118 to read as follows:

§ 2.118 Undelivered Office notices.

When a notice sent by the Office to any registrant or applicant is returned to the Office undelivered, additional notice may be given by publication in the Official Gazette for the period of time prescribed by the Director.

9. Revise § 2.119(a) and add paragraph (b)(6) to read as follows:

§ 2.119 Service and signing of papers.

(a) Every paper filed in the United States Patent and Trademark Office in inter partes cases, including notices of appeal, must be served upon the other parties. Proof of such service must be made before the paper will be considered by the Office. A statement signed by the attorney or other authorized representative, attached to or appearing on the original paper when filed, clearly stating the date and manner in which service was made will be accepted as prima facie proof of service.

(b) * * *

(6) Electronic transmission when mutually agreed upon by the parties.

* * * * *

10. Revise paragraphs (a)(d)(1), (e), (f), (g), (h)(2), (i), (j)(3) and (j)(5) through (8) to read as follows:

§ 2.120 Discovery.

(a) *In general.* (1) Wherever appropriate, the provisions of the Federal Rules of Civil Procedure relating to disclosure and discovery shall apply in opposition, cancellation, interference and concurrent use registration proceedings except as otherwise provided in this section. The provisions of the Federal Rules of Civil Procedure relating to automatic disclosure, scheduling conferences, conferences to discuss settlement and to develop a discovery plan, and transmission to the court of a written report outlining the discovery plan, are applicable to Board proceedings in modified form, as noted in these rules and further explained in documents posted on the Web site of the Office. The Trademark Trial and Appeal Board will specify the deadline for a discovery conference, the opening and closing dates for the taking of discovery, and the deadlines within the discovery period for making initial disclosures and expert disclosure. The trial order setting these deadlines and dates will be included with the notice of institution of the proceeding.

(2) The discovery conference shall occur no later than the opening of the discovery period. A Board Interlocutory Attorney or Administrative Trademark Judge will participate in the conference upon request of any party made after answer but no later than 10 days prior to the deadline for the conference. The discovery period will be set for a period of 180 days. Initial disclosures shall be made no later than 30 days after the opening of the discovery period. Expert disclosure shall occur no later than 90 days prior to the close of the discovery period or, if the expert is retained after the deadline for disclosure of experts, promptly upon retention of the expert. The parties may stipulate to a shortening of the discovery period. The discovery period may be extended upon stipulation of the parties approved by the Board, or upon motion granted by the Board, or by order of the Board. If a motion for an extension is denied, the discovery period may remain as originally set or as reset. Disclosure

deadlines and obligations may be modified upon written stipulation of the parties approved by the Board, or upon motion granted by the Board, or by order of the Board. If a stipulation or motion for modification is denied, disclosure deadlines may remain as originally set or reset and obligations may remain unaltered.

(3) A party must make its initial disclosures prior to seeking discovery, absent modification of this requirement by a stipulation of the parties approved by the Board, or upon a motion granted by the Board, or by order of the Board. Discovery depositions must be taken, and interrogatories, requests for production of documents and things, and requests for admission must be served, on or before the closing date of the discovery period as originally set or as reset. Responses to interrogatories, requests for production of documents and things, and requests for admission must be served within 30 days from the date of service of such discovery requests. The time to respond may be extended upon stipulation of the parties, or upon motion granted by the Board, or by order of the Board. The resetting of a party's time to respond to an outstanding request for discovery will not result in the automatic rescheduling of the discovery and/or testimony periods; such dates will be rescheduled only upon stipulation of the parties approved by the Board, or upon motion granted by the Board, or by order of the Board.

(d) Interrogatories; request for production. (1) The total number of written interrogatories which a party may serve upon another party pursuant to Rule 33 of the Federal Rules of Civil Procedure, in a proceeding, shall not exceed twenty-five, counting subparts, except that the Trademark Trial and Appeal Board, in its discretion, may allow additional interrogatories upon motion therefor showing good cause, or upon stipulation of the parties, approved by the Board. A motion for leave to serve additional interrogatories must be filed and granted prior to the service of the proposed additional interrogatories and must be accompanied by a copy of the interrogatories, if any, which have already been served by the moving party, and by a copy of the interrogatories proposed to be served. If a party upon which interrogatories have been served believes that the number of interrogatories served exceeds the limitation specified in this paragraph, and is not willing to waive this basis for objection, the party shall, within the time for (and instead of) serving answers and specific objections to the interrogatories, serve a general objection on the ground of their excessive number. If the inquiring party, in turn, files a motion to compel discovery, the motion must be accompanied by a copy of the set(s) of the interrogatories which together are said to exceed the limitation, and must otherwise comply with the requirements of paragraph (e) of this section.

* * * * *

(e) Motion for an order to compel disclosure or discovery. (1) If a party fails to make required initial disclosures or expert disclosure, or fails to designate a person pursuant to Rule 30(b)(6) or Rule 31(a) of the Federal Rules of Civil Procedure, or if a party, or such designated person, or an officer, director or managing agent of a party fails to attend a deposition or fails to answer any question propounded in a discovery deposition, or any interrogatory, or fails to produce and permit the inspection and copying of any document or thing, the party entitled to disclosure or seeking discovery may file a motion before the Trademark Trial and Appeal Board for an order to compel disclosure, a designation, or attendance at a deposition, or an answer, or production and an opportunity to inspect and copy. A motion to compel disclosure must be filed prior to the close of the discovery period. A motion to compel discovery must be filed prior to the commencement of the first testimony period as originally set or as reset. A motion to compel discovery shall include a copy of the request for designation or of the relevant portion of the discovery deposition; or a copy of the interrogatory with any answer or objection that was made; or a copy of the request for production, any proffer of production or objection to production in response to the request, and a list and brief description of the documents or things that were not produced for inspection and copying. A motion to compel disclosure or discovery must be supported by a written statement from the moving party that such party or the attorney therefor has made a good faith effort, by conference or correspondence, to resolve with the other party or the attorney therefor the issues presented in the motion but the parties were unable to resolve their differences. If issues raised in the motion are subsequently resolved by agreement of the parties, the moving party should inform the Board in writing of the issues in the motion which no longer require adjudication.

(2) When a party files a motion for an order to compel disclosure or discovery, the case will be suspended by the Trademark Trial and Appeal Board with respect to all matters not germane to the motion, and no party should file any paper which is not germane to the motion, except as otherwise specified in the Board's suspension order. The filing of a motion to compel disclosure or discovery shall not toll the time for a party to comply with any disclosure requirement or to respond to any outstanding discovery requests or to appear for any noticed discovery deposition.

(f) Motion for a protective order. Upon motion by a party obligated to make disclosures or from whom discovery is sought, and for good cause, the Trademark Trial and Appeal Board may make any order which justice requires to protect a party from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the types of orders provided by clauses (1) through (8), inclusive, of Rule 26(c) of the Federal Rules of Civil Procedure. If the motion for a protective order is denied in whole or in part, the Board may, on such conditions (other than an award of expenses to the party prevailing on the motion) as are just, order that any party comply with disclosure obligations or provide or permit discovery.

(g) Sanctions. (1) If a party fails to participate in the required discovery conference, or if a party fails to comply with an order of the Trademark Trial and Appeal Board relating to disclosure or discovery, including a protective order, the Board may make any appropriate order, including any of the orders provided in Rule 37(b)(2) of the Federal Rules of Civil Procedure, except that the Board will not hold any person in contempt or award any expenses to any party. The Board may impose against a party any of the sanctions provided by this subsection in the event that said party or any attorney, agent, or designated witness of that party fails to comply with a protective order made pursuant to Rule 26(c) of the Federal Rules of Civil Procedure. A motion for sanctions to be imposed against a party for its failure to participate in the required discovery conference must be filed prior to the deadline for any party to make initial disclosures.

(2) If a party fails to make required disclosures, and such party or the party's attorney or other authorized representative informs the party or parties entitled to receive disclosures that required disclosures will not be made, the Board may make any appropriate order, as specified in paragraph (g)(1) of this section. If a party, or an officer, director, or managing agent of a party, or a person designated under Rule 30(b)(6) or 31(a)

of the Federal Rules of Civil Procedure to testify on behalf of a party, fails to attend the party's or person's discovery deposition, after being served with proper notice, or fails to provide any response to a set of interrogatories or to a set of requests for production of documents and things, and such party or the party's attorney or other authorized representative informs the party seeking discovery that no response will be made thereto, the Board may make any appropriate order, as specified in paragraph (g)(1) of this section.

(h) * * *

(2) When a party files a motion to determine the sufficiency of an answer or objection to a request made by that party for an admission, the case will be suspended by the Trademark Trial and Appeal Board with respect to all matters not germane to the motion, and no party should file any paper which is not germane to the motion, except as otherwise specified in the Board's suspension order. The filing of a motion to determine the sufficiency of an answer or objection to a request for admission shall not toll the time for a party to comply with any disclosure requirement or to respond to any outstanding discovery requests or to appear for any noticed discovery deposition.

(i) Telephone and pre-trial conferences. (1) Whenever it appears to the Trademark Trial and Appeal Board that a stipulation or motion filed in an inter partes proceeding is of such nature that its approval or resolution by correspondence is not practical, the Board may, upon its own initiative or upon request made by one or both of the parties, address the stipulation or resolve the motion by telephone conference.

(2) Whenever it appears to the Trademark Trial and Appeal Board that questions or issues arising during the interlocutory phase of an inter partes proceeding have become so complex that their resolution by correspondence or telephone conference is not practical and that resolution would likely be facilitated by a conference in person of the parties or their attorneys with an Administrative Trademark Judge or an Interlocutory Attorney of the Board, the Board may, upon its own initiative or upon motion made by one or both of the parties, request that the parties or their attorneys, under circumstances which will not result in undue hardship for any party, meet with the Board at its offices for a disclosure, discovery or pre-trial conference.

(j) * * *

(3)(i) Disclosures but not disclosed documents, a discovery deposition, an answer to an interrogatory, or an admission to a request for admission, which may be offered in evidence under the provisions of paragraph (j) of this section may be made of record in the case by filing the deposition or any part thereof with any exhibit to the part that is filed, or a copy of the written disclosure, or a copy of the interrogatory and answer thereto with any exhibit made part of the answer, or a copy of the request for admission and any exhibit thereto and the admission (or a statement that the party from which an admission was requested failed to respond thereto), together with a notice of reliance. The notice of reliance and the material submitted thereunder should be filed during the testimony period of the party which files the notice of reliance. An objection made at a discovery deposition by a party answering a question subject to the objection will be considered at final hearing.

(ii) A party which has obtained documents from another party through disclosure or under Rule 34 of the Federal Rules of Civil Procedure may not make the documents of record by notice of reliance alone, except to the extent that they are admissible by notice of reliance under the provisions of § 2.122(e).

* * * * *

(5) Disclosures, an answer to an interrogatory, or an admission to a request for admission, may be submitted and made part of the record by only the receiving or inquiring party except that, if fewer than all of the disclosures, answers to interrogatories, or fewer than all of the admissions, are offered in evidence by the receiving or inquiring party, the disclosing or responding party may introduce under a notice of reliance any other disclosures, answers to interrogatories, or any other admissions, which should in fairness be considered so as to make not misleading what was offered by the receiving or inquiring party. The notice of reliance filed by the disclosing or responding party must be supported by a written statement explaining why the disclosing or responding party needs to rely upon each of the additional disclosures or discovery responses listed in the disclosing or responding party's notice, failing which the Board, in its discretion, may refuse to consider the additional disclosures or responses.

(6) Paragraph (j) of this section will not be interpreted to preclude the reading or the use of disclosures or documents, a discovery deposition, or answer to an interrogatory, or admission as part of the examination or cross-examination of any witness during the testimony period of any party.

(7) When a disclosure, a discovery deposition, or a part thereof, or an answer to an interrogatory, or an admission, has been made of record by one party in accordance with the provisions of paragraph (j)(3) of this section, it may be referred to by any party for any purpose permitted by the Federal Rules of Evidence.

(8) Disclosures or disclosed documents, requests for discovery, responses thereto, and materials or depositions obtained through the disclosure or discovery process should not be filed with the Board, except when submitted with a motion relating to disclosure or discovery, or in support of or in response to a motion for summary judgment, or under a notice of reliance, when permitted, during a party's testimony period.

11. Revise paragraphs (a) and (d), and add paragraph (e), to read as follows:

§ 2.121 Assignment of times for taking testimony.

(a) The Trademark Trial and Appeal Board will issue a trial order setting a deadline for required pre-trial disclosures and assigning to each party the time for taking testimony. No testimony shall be taken except during the times assigned, unless by stipulation of the parties approved by the Board, or, upon motion, by order of the Board. The deadline for pre-trial disclosures and the testimony periods may be rescheduled by stipulation of the parties approved by the Board, or upon motion granted by the Board, or by order of the Board. If a motion to reschedule the pre-trial disclosure deadline and testimony periods is denied, the deadline and testimony periods may remain as set. The resetting of the closing date for discovery will result in the rescheduling of the pre-trial disclosure deadline and testimony periods without action by any party.

* * * * *

(d) When parties stipulate to the rescheduling of the deadline for pre-trial disclosures and testimony periods or to the rescheduling of the closing date for discovery and the rescheduling of the deadline for pre-trial disclosures and testimony periods, a stipulation presented in the form used in a trial order, signed by the parties, or a motion in said form signed by one party and including a statement that every other party has agreed thereto, shall be submitted to the Board.

(e) A party need not disclose, prior to its testimony period, any notices of reliance it intends to file during its testimony period. Each party must

disclose the name and address of each witness from whom it intends to take testimony, or may take testimony if the need arises, general information about the witness, a summary of subjects on which the witness is expected to testify, and a general summary of the types of documents and things which may be introduced as exhibits during the testimony of the witness. Pre-trial disclosure of a witness under this subsection does not substitute for issuance of a proper notice of examination under § 2.123(c) or § 2.124(b). If a party does not plan to take testimony from any witnesses, it must so state in its pre-trial disclosure. When a party fails to make required pre-trial disclosures, any adverse party or parties may have remedy by way of a motion to the Trademark Trial and Appeal Board to delay or reset testimony periods.

12. Revise § 2.122(d)(1) to read as follows:

§ 2.122 Matters in evidence.

* * * * *

(d) Registrations. (1) A registration of the opposer or petitioner pleaded in an opposition or petition to cancel will be received in evidence and made part of the record if the opposition or petition is accompanied by an original or photocopy of the registration prepared and issued by the Patent and Trademark Office showing both the current status of and current title to the registration. For the cost of a copy of a registration showing status and title, see § 2.6(b)(4).

* * * * *

13. Revise § 2.123(e)(3) to read as follows:

§ 2.123 Trial testimony in inter partes cases.

* * * * *

(e) * * *

(3) Every adverse party shall have full opportunity to cross-examine each witness. If pre-trial disclosures or the notice of examination of witnesses which is served pursuant to paragraph (c) of this section are improper or inadequate with respect to any witness, an adverse party may cross-examine that witness under protest while reserving the right to object to the receipt of the testimony in evidence. Promptly after the testimony is completed, the adverse party, if he wishes to preserve the objection, shall move to strike the testimony from the record, which motion will be decided on the basis of all the relevant circumstances. A motion to strike the testimony of a witness for lack of proper pre-trial disclosure or proper or adequate notice of examination must request the exclusion of the entire testimony of that witness and not only a part of that testimony.

* * * * *

14. Remove § 2.126(b) and redesignate paragraphs (c) and (d) as paragraphs (b) and (c), respectively, and revise paragraph (a)(6) to read as follows:

§ 2.126 Form of submissions to the Trademark Trial and Appeal Board.

(a) * * *

(6) Exhibits pertaining to a paper submission must be filed on paper and comply with the requirements for a paper submission.

* * * * *

15. Revise § 2.127(a), (c), and (e) to read as follows:

§ 2.127 Motions.

(a) Every motion must be submitted in written form and must meet the requirements prescribed in § 2.126. It shall contain a full statement of the grounds, and shall embody or be accompanied by a brief. Except as provided in paragraph (e)(1) of this section, a brief in response to a motion shall be filed within fifteen days from the date of service of the motion unless another time is specified by the Trademark Trial and Appeal Board, or the time is extended by stipulation of the parties approved by the Board, or upon motion granted by the Board, or upon order of the Board. If a motion for an extension is denied, the time for responding to the motion remains as specified under this section, unless otherwise ordered. Except as provided in paragraph (e)(1) of this section, a reply brief, if filed, shall be filed within fifteen days from the date of service of the brief in response to the motion. The time for filing a reply brief will not be extended. No further papers in support of or in opposition to a motion will be considered by the Board. Neither the brief in support of a motion nor the brief in response to a motion shall exceed twenty-five pages in length in its entirety, including table of contents, index of cases, description of the record, statement of the issues, recitation of the facts, argument, and summary. A reply brief shall not exceed ten pages in length in its entirety. Exhibits submitted in support of or in opposition to a motion are not considered part of the brief for purposes of determining the length of the brief. When a party fails to file a brief in response to a motion, the Board may treat the motion as conceded. An oral hearing will not be held on a motion except on order by the Board.

* * * * *

(c) Interlocutory motions, requests, and other matters not actually or potentially dispositive of a proceeding may be acted upon by a single Administrative Trademark Judge of the Trademark Trial and Appeal Board or by an Interlocutory Attorney of the Board to whom authority so to act has been delegated.

* * * * *

(e)(1) A party may not file a motion for summary judgment until the party has made its initial disclosures. A motion for summary judgment, if filed, should be filed prior to the commencement of the first testimony period, as originally set or as reset, and the Board, in its discretion, may deny as untimely any motion for summary judgment filed thereafter. A motion under Rule 56(f) of the Federal Rules of Civil Procedure, if filed in response to a motion for summary judgment, shall be filed within 30 days from the date of service of the summary judgment motion. The time for filing a motion under Rule 56(f) will not be extended. If no motion under Rule 56(f) is filed, a brief in response to the motion for summary judgment shall be filed within 30 days from the date of service of the motion unless the time is extended by stipulation of the parties approved by the Board, or upon motion granted by the Board, or upon order of the Board. If a motion for an extension is denied, the time for responding to the motion for summary judgment may remain as specified under this section. A reply brief, if filed, shall be filed within 15 days from the date of service of the brief in response to the motion. The time for filing a reply brief will not be extended. No further papers in support of or in opposition to a motion for summary judgment will be considered by the Board.

(2) For purposes of summary judgment only, disclosures or disclosed documents, a discovery deposition, or an answer to an interrogatory, or a document or thing produced in response to a request for production, or an admission to a request for admission, will be considered by the Trademark Trial and Appeal Board if any party files, with the party's brief on the summary judgment motion, the written disclosures or disclosed documents, deposition or any part thereof with any exhibit to the part that is filed, or a copy of the interrogatory and answer thereto with any exhibit made part of the answer, or a copy of the request for production and the documents or things produced in response thereto, or a copy of the request for admission and any exhibit thereto and the admission (or a statement that the party from which an

admission was requested failed to respond thereto).

* * * * *

16. Revise § 2.129(a) to read as follows:

§ 2.129 Oral argument; reconsideration.

(a) If a party desires to have an oral argument at final hearing, the party shall request such argument by a separate notice filed not later than ten days after the due date for the filing of the last reply brief in the proceeding. Oral arguments will be heard by at least three Administrative Trademark Judges of the Trademark Trial and Appeal Board at the time specified in the notice of hearing. If any party appears at the specified time, that party will be heard. If the Board is prevented from hearing the case at the specified time, a new hearing date will be set. Unless otherwise permitted, oral arguments in an inter partes case will be limited to thirty minutes for each party. A party in the position of plaintiff may reserve part of the time allowed for oral argument to present a rebuttal argument.

* * * * *

17. Revise § 2.133 (a) and (b) to read as follows:

§ 2.133 Amendment of application or registration during proceedings.

(a) An application subject to an opposition may not be amended in substance nor may a registration subject to a cancellation be amended or disclaimed in part, except with the consent of the other party or parties and the approval of the Trademark Trial and Appeal Board, or upon motion approved by the Board.

(b) If, in an inter partes proceeding, the Trademark Trial and Appeal Board finds that a party whose application or registration is the subject of the proceeding is not entitled to registration in the absence of a specified restriction to the application or registration, the Trademark Trial and Appeal Board will allow the party time in which to file a motion that the application or registration be amended to conform to the findings of the Trademark Trial and Appeal Board, failing which judgment will be entered against the party.

* * * * *

18. Revise § 2.142(e)(1) to read as follows:

§ 2.142 Time and manner of ex parte appeals.

* * * * *

(e)(1) If the appellant desires an oral hearing, a request therefor should be made by a separate notice filed not later than ten days after the due date for a reply brief. Oral argument will be heard by at least three Administrative Trademark Judges of the Trademark Trial and Appeal Board at the time specified in the notice of hearing, which may be reset if the Board is prevented from hearing the argument at the specified time or, so far as is convenient and proper, to meet the wish of the appellant or the appellant's attorney or other authorized representative.

* * * * *

19. Revise § 2.173(a) to read as follows:

§ 2.173 Amendment of registration

(a) A registrant may apply to amend a registration or to disclaim part of the mark in the registration. The registrant must submit a written request specifying the amendment or disclaimer and, if the registration is involved in an inter partes proceeding before the Trademark Trial and Appeal Board, the request must be filed by appropriate motion. This request must be signed by the registrant and verified or supported by a declaration under § 2.20, and accompanied by the required fee. If the amendment involves a change in the mark, the registrant must submit a new specimen showing the mark as used on or in connection with the goods or services, and a new drawing of the amended mark. The registration as amended must still contain registrable matter, and the mark as amended must be registrable as a whole. An amendment or disclaimer must not materially alter the character of the mark.

* * * * *

20. Revise § 2.176 to read as follows:

§ 2.176 Consideration of above matters.

The matters in §§ 2.171 to 2.175 will be considered in the first instance by the Post Registration Examiners, except for requests to amend registrations involved in inter partes proceedings before the Trademark Trial and Appeal Board, as specified in § 2.173(a), which shall be considered by the Board. If an action of the Post Registration Examiner is adverse, registrant may petition the Director to review the action under § 2.146. If the registrant does not respond to an adverse action of the Examiner within six months of the mailing date, the matter will be considered abandoned.

Dated: January 4, 2006.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 06–197 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–16–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 61

[FRL–8013–3]

Delegation of New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants for the States of Arizona, California, Hawaii, and Nevada

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve updates for delegation of certain federal standards to state and local agencies in Region IX for delegation of New Source Performance Standards (NSPS), and National Emission Standards for Hazardous Air Pollutants (NESHAPs). This document is addressing general authorities mentioned in the regulations for NSPS and NESHAPs, proposing to update the delegations tables and clarifying those authorities that are retained by EPA.

DATES: Any comments on this proposal must arrive by February 16, 2006.

ADDRESSES: Send comments to Andy Steckel, Rulemaking Office Chief (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901, or e-mail to *steckel.andrew@epa.gov*, or submit comments at *http://www.regulation.gov*.

Please contact Cynthia G. Allen at (415) 947–4120 to arrange a time if inspection of the supporting information is desired.

FOR FURTHER INFORMATION CONTACT: Cynthia G. Allen at (415) 947–4120, U.S. Environmental Protection Agency, Region IX, Rulemaking Office (Air-4), 75 Hawthorne Street, San Francisco, CA 94105.

SUPPLEMENTARY INFORMATION: This proposal updates the delegation tables in 40 CFR parts 60 and 61, to allow easier access by the public to the status of local jurisdictions. In the Rules and Regulations section of this **Federal Register**, we are updating these delegations tables in a direct final action without prior proposal because we believe these delegations are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this

time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: November 21, 2005.

Kerry Drake,

Acting Director, Air Division Region IX.

[FR Doc. 06–381 Filed 1–13–06; 8:45 am]

BILLING CODE 6560–50–U

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No 060109004–6004–01; I.D. 010406E]

RIN: 0648–AT76

Fisheries Off West Coast States and in the Western Pacific; Coastal Pelagic Species Fisheries; Annual Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule.

SUMMARY: NMFS proposes a regulation to implement the annual harvest guideline for Pacific sardine in the U.S. exclusive economic zone off the Pacific coast for the fishing season of January 1, 2006, through December 31, 2006. This harvest guideline has been calculated according to the regulations implementing the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP) and establishes allowable harvest levels for Pacific sardine off the Pacific coast.

DATES: Comments must be received by February 1, 2006.

ADDRESSES: You may submit comments on this proposed rule, identified by I.D. 010406E by any of the following methods:

• E-mail: *0648–AT76.SWR@noaa.gov*. Include the I.D. number 010406E in the subject line of the message.

• Federal e-Rulemaking portal: *http://www.regulations.gov*. Following the instructions for submitting comments.

• Mail: Rodney R. McInnis, Regional Administrator, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213.

• Fax: (562) 980–4047.

Copies of the report *Assessment of Pacific Sardine Stock for U.S. Management in 2006* and the Environmental Assessment/Regulatory Impact Review may be obtained from the Southwest Regional Office (see **ADDRESSES**).

FOR FURTHER INFORMATION CONTACT: Joshua B. Lindsay, Southwest Region, NMFS, (562) 980–4034.

SUPPLEMENTARY INFORMATION: The CPS FMP, which was implemented by publication of the final rule in the **Federal Register** on December 15, 1999 (64 FR 69888), divides management unit species into two categories: actively managed and monitored. Harvest guidelines for actively managed species (Pacific sardine and Pacific mackerel) are based on formulas applied to current biomass estimates. Biomass estimates are not calculated for species that are only monitored (jack mackerel, northern anchovy, and market squid).

At a public meeting each year, the biomass for each actively managed species is reviewed by the Pacific Fishery Management Council's (Council) CPS Management Team (Team). The biomass, harvest guideline, and status of the fisheries are then reviewed at a public meeting of the Council's CPS Advisory Subpanel (Subpanel). This information is also reviewed by the Council's Scientific and Statistical Committee (SSC). The Council reviews the reports from the Team, Subpanel, and SSC, provides time for public comment, and then makes its recommendation to NMFS. The annual harvest guideline and season structure are published by NMFS in the **Federal Register** as soon as practicable before the beginning of the appropriate fishing season. The Pacific sardine season begins on January 1 and ends on December 31 of each year.

Public meetings of the Team and Subpanel were held at NMFS Southwest Fisheries Science Center in La Jolla, CA on October 5 and 6, 2005 (70 FR 55335, September 21, 2005). The Council reviewed the report at its November meeting in San Diego, CA, and listened to comments from its advisory bodies and the public. The Council then adopted the 2006 harvest guideline for Pacific sardine. Based on a biomass estimate of 1,061,391 metric tons (mt), the harvest guideline for Pacific sardine for January 1, 2006, through December 31, 2006, is 118,937 mt.

The size of the sardine population was estimated using an integrated stock assessment model called Age-structured Assessment Program (ASAP). ASAP is a flexible forward-simulation that allows for the efficient and reliable estimation of a large number of parameters. ASAP uses fishery dependent and fishery independent data to obtain annual estimates of sardine abundance, year-class strength, and age-specific fishing mortality. The ASAP model allows one to account for the expansion of the Pacific sardine stock northward to include waters off the northwest Pacific coast and for the incorporation of data from the Mexican sardine fishery. Information on the fishery and the stock assessment are found in the report *Assessment of Pacific Sardine Stock for U.S. Management in 2006* (see **ADDRESSES**).

The formula in the FMP uses the following factors to determine the harvest guideline:

1. *The biomass of sardines age one and above.* For 2006, this estimate is 1,061,391 mt.

2. *The cutoff.* This is the biomass level below which no commercial fishery is allowed. The FMP established this level at 150,000 mt.

3. *The portion of the sardine biomass that is in U.S. waters.* For 2006, this estimate is 87 percent. It is based on the average larval distribution obtained from scientific cruises and the distribution of the resource obtained from logbooks of aerial fish-spotters.

4. *The harvest fraction.* This is the percentage of the biomass above 150,000 mt that may be harvested. The fraction varies from 5 to 15 percent, depending on current ocean temperatures. The higher fraction is used for warmer ocean temperatures, which favor production of Pacific sardine, and the lower fraction is used for cooler temperatures. Based on the last three seasons of sea surface temperatures at Scripps Pier, California, a fraction of 15 percent was used for 2006.

Based on the estimated biomass of 1,061,391 mt and the formula in the FMP, a harvest guideline of 118,937 mt was determined for the fishery beginning January 1, 2006.

Amendment 11 to the CPS FMP, which is now undergoing Secretarial review, would change the framework for the annual apportionment of the Pacific sardine harvest guideline along the U.S. Pacific coast and set up a new long-term allocation scheme. A proposed rule to implement Amendment 11 was published in the **Federal Register** on November 16, 2005 (70 FR 69502). Based on this new long-term allocation scheme, 35 percent of the harvest guideline would be released coastwide on January 1; 40 percent of the harvest guideline, plus any portion not harvested from the initial 35 percent would be released coastwide on July 1; and on September 15 the remaining 25 percent, plus any portion not harvested from the earlier releases would then be available for harvest.

If the total harvest guideline or these apportionment levels for Pacific sardine

are reached at any time, the Pacific sardine fishery shall be closed until either it re-opens per the allocation scheme or the beginning of the next fishing season. The Regional Administrator shall announce in the **Federal Register** the date of the closure of the directed fishery for Pacific sardine.

Normally, an incidental landing allowance of sardine in landings of other CPS is set at the beginning of the fishing season. The incidental allowance would become effective if the harvest guideline is reached and the fishery closed. A landing allowance of sardine up to 45 percent by weight of any landing of CPS is authorized by the FMP. An incidental allowance prevents fishermen from being cited for a violation when sardine occur in schools of other CPS, and it minimizes bycatch of sardine if sardine are inadvertently caught while fishing for other CPS. Sardine landed with other species also requires sorting at the processing plant, which adds to processing costs. Mixed species in the same load may damage smaller fish.

Classification

These proposed specifications are issued under the authority of, and NMFS has preliminarily determined that it is in accordance with, the Magnuson-Stevens Fishery Conservation and Management Act, the FMP, and the regulations implementing the FMP.

This proposed rule is exempt from review under Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities as follows:

The purpose of the proposed rule is to establish the 2006 harvest guideline for Pacific sardine off the Pacific coast. The CPS FMP and its implementing regulations require NMFS to set an annual harvest guideline for Pacific sardine based on the formula in the FMP. The harvest guideline is derived by a formula applied to the current biomass estimate. The formula leaves little latitude for discretion except when errors are found in the calculations or in the data, at which time adjustments may be made. There is no alternative to the harvest guideline as specified; there is no discretion to use an adjusted formula. Further, there is only one stock assessment method available to establish the adult biomass used to derive the harvest guideline.

The proposed harvest guideline for the 2006 fishing season is 118,937 mt. Although this is 13 percent lower than the 2005 harvest guideline, it is still 22,049 mt higher than the largest recent harvest by the United States. If the fleet were to take the full harvest guideline, and assuming no change in average exvessel price from the current level, the total revenue to the fleet would be just over $15 million. Whether this occurs depends on market forces and the ability of the fishing fleet to find pure schools of Pacific sardine. However, even if there is no change in market conditions, it is not likely that the full harvest guideline will be taken in the 2006 fishing year (because of the availability of the fleet to find pure schools of Pacific sardine), in which case total revenue would likely be lower. The Pacific sardine season begins on January 1, 2006, and ends on December 31, 2006, or when the harvest guideline is caught and the fishery is closed.

Approximately 104 vessels were permitted to operate in the Pacific sardine fisheries off the U.S. West Coast in 2004; 63 vessels were permitted in the Federal CPS limited entry fishery off California (south of 39° N. lat.), while 41 vessels were permitted in Oregon and Washington's state Pacific sardine fisheries. All of these vessels would be considered small businesses under the Small Business Administration standards since the vessels do not have annual receipts in excess of $3.5 million. Therefore, NMFS does not anticipate any disproportionate economic impacts resulting between small and large vessels under the proposed action. Additionally, this proposed action is not likely to significantly affect (both positive and negative effects) these small entities.

As a result, a regulatory flexibility analysis is not required and none has been prepared.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 11, 2006.

James W. Balsiger,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. E6–419 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register

Vol. 71, No. 10

Tuesday, January 17, 2006

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

National Agricultural Library; Notice of Intent To Seek Approval To Collect Information

AGENCY: USDA, Agricultural Research Service, National Agricultural Library.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13) and Office of Management and Budget (OMB) regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995), this notice announces the National Agricultural Library's intent to request approval for a new electronic mailing list subscription form from those working with water quality and water resources.

DATES: Comments on this notice must be received by March 23, 2006 to be assured of consideration.

ADDRESSES: Address all comments concerning this notice to Joseph Makuch, Coordinator, Water Quality Information Center, National Agricultural Library, 10301 Baltimore Avenue, Beltsville, MD 20705–2351. Comments may be sent by facsimile to (301) 504–6409. Submit electronic comments to: *wqic@nal.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Joseph Makuch (301) 504–6077.

SUPPLEMENTARY INFORMATION:

Title: Electronic Mailing List Subscription Form.

OMB Number: Not yet assigned.

Expiration Date: Not yet assigned.

Type of Request: Approval for data collection from individuals working in the areas of water quality and water resources.

Abstract: The form would include the following items:

This form contains five items and is used to collect information about participants who are interested in joining an electronic discussion group. The form collects data to see if a person is eligible to join the discussion group. Because these electronic discussion groups are only available to people who work in the areas of water quality and water resources, it is necessary to gather this information. The questionnaire asks for the person's name, e-mail address, job title, work affiliation, and topics of interest.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 1 minute per response.

Respondents: Individuals who are interested in joining an electronic discussion group.

Estimated Number of Respondents: 750 per year.

Estimated Total Annual Burden on Respondents: 750 minutes or 12.5 hours.

Comments are invited on (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who respond, including the use of appropriate automated, electronic, mechanical, or other technology. Comments should be sent to the address in the preamble. All responses to the notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

Dated: December 14, 2005.

Antoinette A. Betschart,

Associate Administrator, ARS.

[FR Doc. E6–367 Filed 1–13–06; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

January 11, 2006.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Monitoring Trends in the Public Health Nutrition Workforce.

OMB Control Number: 0584–NEW.

Summary of Collection: The Food and Nutrition Service Programs (FNS) wishes to conduct a study to monitor trends in the education and training, work experience, areas of practice, and training needs of the public health nutrition workforce at the state and local government levels. FNS will conduct a survey to obtain information to assess the agency's efforts to recruit and retain public health and community nutritionists to staff the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). There are two levels of respondents: (1) the 55 designated state and territorial

public health nutrition directors and (2) persons employed in public health nutrition programs within states, including persons employed by Indian Tribal Organizations. State public health nutrition directors through their professional association—the Association of State and Territorial Public Health Nutrition Directors (ASTPHND)—will carry out this data collection under a grant agreement with the U.S. Department of Agriculture, Food and Nutrition Service.

Need and Use of the Information: ASTPHND will collect information through a Web-based survey. A paper version of the survey will be used only for those respondents who do not have Internet access. A profile describing the workforce will assist FNS to determine the extent to which the current and future workforces have the necessary requirements to carry out the WIC program, for which FNS is responsible. Workforce profile data are essential to evaluate the impact of the agency's effort to recruit and retain public health and community nutritionists. Recruitment and retention of qualified staff is essential to maintaining quality nutrition services by providing an environment where staff are appropriately selected, trained, and supported.

Description of Respondents: State, local, or tribal government.

Number of Respondents: 10,055.

Frequency of Responses: Reporting: Other (one-time).

Total Burden Hours: 4,645.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. E6–402 Filed 1–13–06; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Newspapers Used for Publication of Legal Notice of Appealable Decisions for the Northern Region; Northern Idaho, Montana, North Dakota, and portions of South Dakota and Eastern Washington

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: This notice lists the newspapers that will be used by all Ranger Districts, Forests, Grasslands, and the Regional Office of the Northern Region to publish legal notices for public comment and decisions subject to appeal and predecisional administrative review under 36 CFR 215, 217, and 218. The intended effect of this action is to inform interested members of the public which newspapers will be used to publish legal notices for public comment or decisions; thereby allowing them to receive constructive notice of a decision, to provide clear evidence of timely notice, and to achieve consistency in administering the appeals process.

DATES: Publication of legal notices in the listed newspapers will begin with decisions subject to appeal that are made on or after January 9, 2006. The list of newspapers will remain in effect until another notice is published in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Appeals and Litigation Group Leader; Northern Region; P.O. Box 7669; Missoula, Montana 59807. Phone: (406) 320–3696.

The newspapers to be used are as follows:

Northern Regional Office

Regional Forester decisions in Montana:

The Missoulian, Great Falls Tribune, and The Billings Gazette.

Regional Forester decisions in Northern Idaho and Eastern Washington:

The Spokesman Review and Lewiston Tribune.

Regional Forester decisions in North Dakota: Bismarck Tribune.

Regional Forester decisions in South Dakota: Rapid City Journal.

Beaverhead/Deerlodge NF—Montana Standard
Bitterroot NF—Ravalli Republic
Clearwater NF—Lewiston Tribune
Custer NF—Billings Gazette (Montana), Rapid City Journal (South Dakota)
Dakota Prairie Grasslands—Bismarck Tribune (North and South Dakota)
Flathead NF—Daily Inter Lake
Gallatin NF—Bozeman Chronicle
Helena NF—Independent Record
Idaho Panhandle NFs—Spokesman Review
Kootenai NF—Daily Inter Lake
Lewis & Clark NF—Great Falls Tribune
Lolo NF—Missoulian
Nez Perce NF—Lewiston Tribune

Supplemental notices may be placed in any newspaper, but time frames/deadlines will be calculated based upon notices in newspapers of record listed above.

Dated: January 4, 2006.

Kathleen A. McAllister,

Deputy Regional Forester.

[FR Doc. 06–372 Filed 1–13–06; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

National Urban & Community Forestry Advisory Council Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The National Urban and Community Forestry Advisory Council will meet in Washington, DC, February 7–9, 2006. The purpose of the meeting is to discuss emerging issues in urban and community forestry.

DATES: The meeting will be held February 7–9, 2006.

ADDRESSES: The meeting will be held at the Washington Terrace Hotel, 1515 Rhode Island Avenue, NW., Washington, DC 20005. Individuals who wish to speak at the meeting or to propose agenda items must send their names and proposals to Suzanne M. del Villar, Executive Assistant, National Urban and Community Forestry Advisory Council, P.O. Box 1003, Sugarloaf, CA 92386–1003. Individuals may fax their names and proposed agenda items to (909) 585–9527.

FOR FURTHER INFORMATION CONTACT: Suzanne M. del Villar, Urban and Community Forestry Staff, (909) 585–9268, or via e-mail at *sdelvillar@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Council discussion is limited to Forest Service staff and Council members; however, persons who wish to bring urban and community forestry matters to the attention of the Council may file written statements with the Council staff before or after the meeting. Public input sessions will be provided.

Dated: January 10, 2006.

Robin L. Thompson,

Associate Deputy Chief, State and Private Forestry.

[FR Doc. E6–368 Filed 1–13–06; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: International Dolphin Conservation Program.

Form Number(s): None.

OMB Approval Number: 0648–0387.

Type of Request: Regular submission.

Burden Hours: 146.

Number of Respondents: 62.

Average Hours per Response: Vessel permit application: 30 minutes; operator permit application: 10 minutes; waiver request: 30 minutes; vessel departure notification: 10 minutes; change in permit operator notification: 10 minutes; modified net notification: 10 minutes; experimental fishing permit application: 10 hours; dolphin mortality limit request: 15 minutes; arrival notification: 10 minutes; tuna tracking form submission: 1 hour; monthly tuna storage removal report: 10 minutes; monthly tuna receiving report: 1 hour; produce report: 30 minutes.

Needs and Uses: The National Oceanic and Atmospheric Administration (NOAA) collects information to implement the International Dolphin Conservation Program Act (Act). The Act allows entry of yellowfin tuna into the United States, under specific conditions, from nations in the Program that would otherwise be under embargo. The Act also allows U.S. fishing vessels to participate in the yellowfin tuna fishery in the eastern tropical Pacific Ocean on terms equivalent with the vessels of other nations. NOAA collects information to allow tracking and verification of ''dolphin safe'' and ''non-dolphin safe'' tuna products from catch through the U.S. market.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Annually, monthly and on occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, FAX number (202) 395–7285, or *David_Rostker@omb.eop.gov*.

Dated: January 10, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–346 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Deep Seabed Mining Regulations for Exploration Licenses.

Form Number(s): None.

OMB Approval Number: 0648–0471.

Type of Request: Regular submission.

Burden Hours: 169.

Number of Respondents: 45.

Average Hours per Response: 2 hours for a scientific research plan; 40 minutes for an application for an Exempted Fishing Permit (EFP), display permit, Scientific Research Permit, chartering permit, or Letter of Acknowledgment for Highly Migratory Species; 1 hour for an interim report; 30 minutes for an annual fishing report; 15 minutes for an application for an amendment to an EFP; 5 minutes for notification of departure phone calls to NMFS Enforcement; 2 minutes for ''no-catch'' reports; and 2 minutes for tag applications.

Needs and Uses: Information is requested that will be used in support of the National Marine Fisheries Service (NMFS) issuing Scientific Research Permits, Exempted Fishing Permits, and Letters of Acknowledgment regarding highly migratory species (HMS), and that will also enhance and facilitate NMFS compliance and enforcement capabilities regarding HMS scientific research and exempted fishing activities. In addition, the information will assist with future stock assessments.

Affected Public: Business or other for-profit.

Frequency: Annually, monthly and within five days of fishing.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, FAX number (202) 395–7285, or *David_Rostker@omb.eop.gov*.

Dated: January 10, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–347 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

International Trade Administration

Participation Agreement and Trade Mission Application

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burdens, invites the general public and other Federal agencies to take this opportunity to comment on the continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506 (2)(A)).

DATES: Written comments must be submitted on or before March 20, 2006.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th & Constitution Avenue, NW., Washington, DC 20230. Phone number: (202) 482–0266. E-mail: *dHynek@doc.gov*.

FOR FURTHER INFORMATION CONTACT: Request for additional information or copies of the information collection instrument and instructions should be directed to: Joseph J. English, U.S. & Foreign Commercial Service, Export Promotion Services, Room 2110, 14th & Constitution Avenue, NW., Washington, DC 20230; Phone number: (202) 482–3334, and fax number: (202) 482–0115.

SUPPLEMENTARY INFORMATION:

I. Abstract

The ITA–4008P, ''Participation Agreement'', is the vehicle by which individual firms agree to participate in any of ITA's trade promotion programs

and record their required participation fee to the U.S. Department of Commerce (DOC). Together with the relevant ITA–4008P–A, ''Conditions of Participation'', it forms a contract between the individual firm and the DOC. The ITA–4008P–1, ''Trade Mission Application'', is used to solicit information from firms seeking to participate in DOC overseas trade missions covered by the Statement of Policy Governing Overseas Trade Missions of the Department of Commerce issued by Secretary Daley on March 3, 1997. Trade Mission participants are required to complete the Forms ITA–4008P, ITA–4008P–1, and ITA–4008P–A. Other DOC trade event (not trade mission) participants complete Forms ITA–4008P and ITA–4008P–A, but do not complete Form ITA–4008P–1.

II. Method of Collection

The forms are sent by request to potential U.S. firms.

III. Data

OMB Number: 0625–0147.

Form Number: ITA–4008P, ITA–4008P–1 and ITA–4008P–A.

Type of Review: Regular Submission.

Affected Public: Business or other for profit.

Estimated Number of Respondents: 7,500.

Estimated Time Per Response: 20–70 minutes.

Estimated Total Annual Burden Hours: 2,792 hours.

Estimated Total Annual Costs: The estimated annual cost for this collection is $150,315.00 ($100,495.00 for respondents and $56,720.00 for federal government).

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 costs) 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 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: January 10, 2006.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–348 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Application Form for Membership on a National Marine Sanctuary Advisory Council.

Form Number(s): None.

OMB Approval Number: 0648–0397.

Type of Request: Regular submission.

Burden Hours: 500.

Number of Respondents: 500.

Average Hours Per Response: 1 hour.

Needs and Uses: Section 315 of the National Marine Sanctuaries Act (16 U.S.C. 1445a) allows the Secretary of Commerce to establish one or more advisory councils to provide advice to the Secretary regarding the designation and management of national marine sanctuaries.

The councils are individually chartered for each sanctuary to meet the needs of that sanctuary. Once a council has been chartered, the Sanctuary Manager starts a process to recruit members for that Council by providing notice to the public and asking interested parties to apply for the available seats. An application form and guidelines for a narrative submission must be submitted to the Sanctuary Manager.

Affected Public: Individuals or households; business or other for-profit organizations; not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, fax number (202) 395–7285, or *David_Rostker@omb.eop.gov*.

Dated: January 10, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–360 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Protocol for Access to Tissue Specimen Samples from the National Marine Mammal Tissue Bank.

Form Number(s): None.

OMB Approval Number: 0648–0468.

Type of Request: Regular submission.

Burden Hours: 80.

Number of Respondents: 20.

Average Hours per Response: 2 hours.

Needs and Uses: The National Marine Fisheries Service proposes to make available tissue specimen samples to the scientific community for research that is consistent with the goal of the National Marine Mammal Tissue Bank (NMMTB) and the Marine Mammal Health and Stranding Response Program (MMHSRP). There is a very limited amount of samples available and the NMMTB emphasizes that the intended use of these tissue specimens be for retrospective analysis. Priority will be given to requests that fulfill the goals of the NMMTB, MMHSRP, and to research that would otherwise not be accomplished because of limited availability of samples.

Affected Public: Not-for-profit institutions; business or other for-profit organizations; individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefit.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and

Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, FAX number (202) 395–7285, or *David_Rostker@omb.eop.gov.*

Dated: January 10, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–372 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Sensors and Instrumentation Technical Advisory Committee; Notice of Partially Closed Meeting

The Sensors and Instrumentation Technical Advisory Committee (SITAC) will meet on January 31, 2006, 9:30 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Constitution and Pennsylvania Avenues, NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration on technical questions that affect the level of export controls applicable to sensors and instrumentation equipment and technology.

Agenda

Public Session

1. Welcome and Introductions.
2. Remarks from the Bureau of Industry and Security Management.
3. Industry Presentations.
4. New Business.

Closed Session

5. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to the Committee members, the Committee suggests that the materials be forwarded before the meeting to Ms. Yvette Springer at *Yspringer@bis.doc.gov.*

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on January 6, 2006, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d)), that the portion of this meeting dealing with pre-decisional changes to the Commerce Control List and U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information contact Yvette Springer on (202) 482–4814.

Dated: January 10, 2006.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 06–394 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–JT–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–824]

Silicomanganese From Brazil: Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce..

SUMMARY: On September 9, 2005, the Department of Commerce published the preliminary results of the administrative review of the antidumping duty order on silicomanganese from Brazil. The review covers exports of this merchandise to the United States by the collapsed parties, Rio Doce Manganês S.A. (RDM), Companhia Paulista de Ferro–Ligas (CPFL), and Urucum Mineração S.A. (Urucum) (collectively RDM/CPFL), for the period December 1, 2003, through November 30, 2004. We gave interested parties an opportunity to comment on the preliminary results. Based on our analysis of the comments received, we have made a change in the margin calculation for the final results of this review. The final weighted–average margin is listed below in the ''Final Results of Review'' section of this notice.

EFFECTIVE DATE: January 17, 2006.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun at (202) 482–5760 or Dmitry Vladimirov at (202) 482–0665, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On September 9, 2005, the Department of Commerce (the Department) published the preliminary results of this review and invited parties to comment. *See Silicomanganese From Brazil: Preliminary Results of Antidumping Duty Administrative Review*, 70 FR 53628 *(Preliminary Results)*. On October 10, 2005, RDM/CPFL, the respondent, filed a case brief. Eramet Marietta, the petitioner, did not file case or rebuttal briefs.

Scope of the Order

The merchandise covered by this order is silicomanganese. Silicomanganese, which is sometimes called ferrosilicon manganese, is a ferroalloy composed principally of manganese, silicon and iron, and normally contains much smaller proportions of minor elements, such as carbon, phosphorus, and sulfur. Silicomanganese generally contains by weight not less than 4 percent iron, more than 30 percent manganese, more than 8 percent silicon, and not more than 3 percent phosphorous. All compositions, forms, and sizes of silicomanganese are included within the scope of the order, including silicomanganese slag, fines, and briquettes. Silicomanganese is used primarily in steel production as a source of both silicon and manganese.

Silicomanganese is currently classifiable under subheading 7202.30.0000 of the *Harmonized Tariff Schedule of the United States* (HTSUS). Some silicomanganese may also currently be classifiable under HTSUS subheading 7202.99.5040. This order covers all silicomanganese, regardless of its tariff classification. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the order remains dispositive.

Analysis of Comments Received

All issues raised in RDM/CPFL's case brief in the context of this administrative review are addressed in the January 9, 2006, Issues and Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Silicomanganese from Brazil December 1, 2003, through November 30, 2004 (the Decision Memorandum), which is hereby adopted by this notice. Attached to this notice as an appendix is a list of the issues that RDM/CPFL has raised and to which we have responded in the Decision Memorandum. Parties can find a complete discussion of all issues raised in this review and the

corresponding recommendations in this public memorandum, which is on file in the Central Records Unit, Room B–099 of the main Department building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Internet at http://ia.ita.doc.gov/frn. The paper copy and electronic version of the Decision Memorandum are identical in content.

Sales Below Cost in the Home Market

The Department conducted an investigation to determine whether RDM/CPFL made home–market sales at prices below the cost of production. See *Preliminary Results*, 70 FR at 53630. As a result of its investigation, the Department disregarded certain below–cost home–market sales for these final results.

Changes Since the Preliminary Results

Based on our analysis of the comments received, we have made a change in the margin calculation for the final results of this review and described the change in the accompanying Issues and Decision Memorandum dated January 9, 2006. See also Analysis Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Silicomanganese from Brazil: Rio Doce Manganês S.A. (RDM), Companhia Paulista de Ferro–Ligas (CPFL), and Urucum Mineração S.A. (Urucum) (collectively, RDM/CPFL), dated January 9, 2006.

Final Results of Review

As a result of our review, we determine that a margin of 0.00 percent exists for RDM/CPFL for the period December 1, 2003, through November 30, 2004.

Duty Assessment and Cash–Deposit Requirements

The Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212(b)(1), we have calculated an importer–specific per–unit dollar amount for the subject merchandise. The Department will issue appropriate assessment instructions directly to CBP within 15 days of publication of these final results of review.

The following deposit requirements will be effective upon publication of this notice of final results of administrative review for all shipments of silicomanganese entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results, as provided by section 751(a)(2)(C) of the Act: (1) the cash–deposit rate for RDM/CPFL will be 0.00 percent; (2) for previously reviewed or investigated companies not mentioned above, the cash–deposit rate will continue to be the company–specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less–than-fair–value (LTFV) investigation but the manufacturer is, then the cash–deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the producer is a firm covered in this review, a prior review, or the LTFV investigation, the cash–deposit rate shall be 17.60 percent, the all–others rate established in the LTFV investigation. See *Notice of Final Determination of Sales at Less Than Fair Value: Silicomanganese from Brazil*, 59 FR 55432 (November 7, 1994). These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

Notification to Importers

This notice serves as a primary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding APOs

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO as explained in the APO itself. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

We are publishing these final results of administrative review and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 9, 2006.

David M. Spooner,

Assistant Secretary for Import Administration.

APPENDIX—Issues in the Decision Memorandum

Comment 1: Affiliation with Certain Home–Market Customers

Comment 2: U.S. Gross Unit Price

[FR Doc. E6–410 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–601]

Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Final Results of 2003–2004 Administrative Review and Partial Rescission of Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') published its preliminary results of administrative review of the antidumping duty order on tapered roller bearings and parts thereof, finished and unfinished (''TRBs''), from the People's Republic of China (''PRC'') on July 11, 2005. The period of review (''POR'') is June 1, 2003, through May 31, 2004. We invited interested parties to comment on our preliminary results. Based on our analysis of the comments received, we have made changes to our margin calculations. Therefore, the final results differ from the preliminary results. The final dumping margins for this review are listed in the ''Final Results of Review'' section below.

EFFECTIVE DATE: January 17, 2006.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita, Eugene Degnan or Hua Lu, Office 8, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–4243, (202) 482–0414 or (202) 482–6478, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 11, 2005, the Department published its preliminary results. *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Preliminary Results of 2003–2004*

Antidumping Administrative Review, and Notice of Intent to Rescind in Part, 70 FR 39744 (July 11, 2005) (''*Preliminary Results*''). On July 27, 2005, Yantai Timken Company Limited (''Yantai Timken'') submitted additional surrogate value information. On July 29, 2005, The Timken Company (''Petitioner'') submitted comments on surrogate values. On August 2, 2005, Yantai Timken requested an extension of the briefing schedule. On August 4 and August 8, 2005, Yantai Timken requested to submit additional factual information. On August 10, 2005, Yantai Timken requested a hearing. On September 21, 2005, the Department determined that it was unable to grant Yantai Timken's requests to supplement the record with new factual information. On October 5, 2005, we received case briefs from China National Machinery Import & Export Corporation (''CMC''), Luoyang Bearing Corporation (Group) (''LYC'') and Yantai Timken. On October 13, 2005, the Department rejected Yantai Timken's case brief because it contained new factual information. On November 8, 2005, the Department published a notice extending the time limit for the final results of review until January 7, 2006. *See Notice of Extension of Final Results of the 2003–2004 Administrative Review of Tapered Roller Bearings and Parts Thereof, Finished or Unfinished from the People's Republic of China*, 70 FR 67668 (November 8, 2005). On November 30, 2005, Yantai Timken resubmitted its case brief. On December 5, 2005, Peer Bearing Company (''Peer'') and Petitioner submitted rebuttal briefs. On December 9, 2005, the Department held a public hearing.

We have conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (''the Act''), and 19 CFR 351.213.

Scope of Order

Merchandise covered by this order is TRBs from the PRC; flange, take up cartridge, and hanger units incorporating tapered roller bearings; and tapered roller housings (except pillow blocks) incorporating tapered rollers, with or without spindles, whether or not for automotive use. This merchandise is currently classifiable under the *Harmonized Tariff Schedule of the United States* (''HTSUS'') item numbers 8482.20.00, 8482.91.00.50, 8482.99.30, 8483.20.40, 8483.20.80, 8483.30.80, 8483.90.20, 8483.90.30, 8483.90.80, 8708.99.80.15, and 8708.99.80.80. Although the HTSUS item numbers are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Rescission of Review

In our preliminary results, we stated we are rescinding the review with respect to Chin Jun Industrial Ltd. (''Chin Jun''), Weihai Machinery Holding (Group) Company, Ltd. (''Weihai Machinery''), and Zhejiang Machinery Import & Export Corp (''ZMC'') because we had no evidence that Chin Jun, Weihai Machinery or ZMC had any shipments to the United State. of subject merchandise during the POR. *See Preliminary Results*, 70 FR at 39746. Consequently, in accordance with 19 CFR 351.213(d)(1) and consistent with the Department's practice, we preliminarily rescinded our review with respect to Chin Jun, Weihai Machinery and ZMC. Since we have received no new information since the preliminary results that contradicts the decision made in the preliminary results of review, we are rescinding the administrative review with respect to Chin Jun, Weihai Machinery and ZMC.

Analysis of Comments Received

All issues raised in the post–preliminary comments by parties in this review are addressed in the memorandum from Stephen J. Claeys, Deputy Assistant Secretary for Import Administration, to David M. Spooner Assistant Secretary, for Import Administration, ''Issues and Decision Memorandum for the Final Results of the 17th Administrative Review of the Antidumping Duty Order on Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China,'' dated January 9, 2006 (''*Issues and Decision Memorandum*''), which is hereby adopted by this notice. A list of the issues which parties raised and to which we responded in the *Issues and Decision Memorandum* is attached to this notice as an appendix. The *Issues and Decision Memorandum* is a public document which is on file in the Central Records Unit (''CRU'') in room B–099 in the main Department building, and is accessible on the Web at *http://ia.ita.doc.gov/*. The paper copy and electronic version of the memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of comments received, we have made changes in the margin calculations for CMC and LYC. See Issues and Decision Memorandum at Comments 1–6.

CMC

- In the preliminary results, we inadvertently cited the variable name for skilled packing labor incorrectly in the margin calculation program. We have corrected the error for the final results. *See Issues and Decisions Memo* at Comment 1 for a thorough discussion of this issue and ''Analysis Memorandum for the Final Determination of Administrative Review on Tapered Roller Bearings and Parts Thereof from the People's Republic of China of China: National Machinery Import & Export Corp'' from Hua Lu, Case Analyst, through Robert Bolling, Program Manager, to the File, dated January 9, 2006 (''*CMC Final Analysis Memorandum*.'')
- In the preliminary results we inadvertently used ''0.0001'' as the conversion factor from metric tons to kilograms for the freight surrogate values for steel consumption of cups, rollers and cages. No interested party commented on this error. We have corrected the conversion factor to ''0.001'' for these final results of review. *See CMC Final Analysis Memorandum*.
- For the preliminary results, when calculating ratios for factory overhead, selling, general, and administrative expenses, interest, depreciation, and profit from the surrogate companies' financial statements, we inadvertently included excise duties in the sum of the cost of materials for one of the surrogate companies. For the final results, we have excluded excise duties from the cost of manufacturing when calculating the surrogate financial ratios. Further, we have applied the revised surrogate financial ratios to all respondents in this review for whom we are calculating a margin. *See Issues and Decisions Memorandum* at Comment 5 and Memorandum to the final regarding ''Final Results of Review of Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Surrogate Value Memorandum for the Final Results of Review'' (''*Final Results Surrogate Value Memorandum*''), dated January 9, 2005.

LYC

- In the preliminary results, the Department applied partial adverse facts available (''AFA'') to LYC's U.S. inventory carrying costs (''ICCs'') for certain constructed export price (''CEP'') sales. For

these final results, we have used LYCs ICCs as reported. *See Issues and Decisions Memorandum* at Comment 3 and ''Final Results of Review of the Order on Tapered Roller Bearings and Parts Thereof from the People's Republic of China, Program Analysis for the Final Results of Review: Luoyang Bearing Corporation (Group)'' (''*LYC Final Analysis Memorandum*''), dated January 9, 2006.

- In the preliminary results we failed to convert the surrogate value for ''cage'' from Indian rupees to U.S. dollars in the margin calculation program. For the final results, we have made this conversion. *See Issues and Decisions Memorandum* at Comment 6.
- For the preliminary results, when calculating ratios for factory overhead, selling, general, and administrative expenses, interest, depreciation, and profit from the surrogate companies' financial statements, we inadvertently included excise duties in the sum of the cost of materials for one of the surrogate companies. For a complete discussion on this issue, see CMC above and Comment 5 in the *Issues and Decisions Memorandum*.

Calculation of a Margin for Yantai Timken

In addition, based on further analysis of record evidence in this review, the Department is reversing its decision to apply total AFA to Yantai Timken's margin for the final results. After examining the record of this review, including the verification reports and the documentation provided at verification, we have determined that Yantai Timken was able to substantiate one of its reported expenses, marine insurance. However, we continue to conclude that Yantai Timken was unable to substantiate two reported factors of production and several other expenses reported as adjustments to U.S. price. Thus, we have determined that the use of partial AFA is warranted. *See Issues and Decision Memorandum* at Comments 7–16. As a result, we have calculated a margin for Yantai Timken in this review. An explanation of our calculations follows.

Separate Rates

In proceedings involving non–market-economy (''NME'') countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of merchandise subject to administrative review 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.

In the *Preliminary Results*, we found that Yantai Timken did not demonstrate its eligibility for a separate rate as a consequence of our determination to base its margin on total AFA. Accordingly, we preliminarily determined that Yantai Timken was a part of the PRC–wide entity. For the final results of review, we have reconsidered our determination to apply total AFA to Yantai Timken's margin and its eligibility for a separate rate.

The Department's separate–rate test to determine whether the exporters are independent from government control does not consider, in general, macroeconomic/border–type controls, *e.g.*, export licenses, quotas, and minimum export prices, particularly if these controls are imposed to prevent dumping. The test focuses, rather, on controls over the investment, pricing, and output decision–making process at the individual firm level. *See 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 *Notice of Final Determination of Sales at less Than Fair Value: Certain Frozen and Canned Warmwater Shrimp From the People's Republic of China*, 69 FR 71005 (December 8, 2004), and accompanying Issues and Decision Memoramdum, at Comment II.

To establish whether a firm is sufficiently independent from government control to be entitled to a separate rate, the Department analyzes each exporting entity 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, 20589 (May 6, 1991) (''Sparklers''), as modified by *Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China*, 59 FR 22585, 22586 (May 2, 1994) (''*Silicon Carbide*''). Under the separate rates criteria, the Department assigns separate rates in NME cases only if the respondent can demonstrate the absence of both *de jure* and *de facto* government control over its export activities. *See Silicon Carbide*, 59 FR at 22586, and *Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol from the People's Republic of China*, 60 FR 22544 (May 8, 1995) (''Furfuryl Alcohol'').

Yantai Timken provided company–specific separate–rates information and stated that it met the standards for the assignment of separate rates.

A. 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; or (3) any other formal measures by the government decentralizing control of companies. *See* Sparklers.

Yantai Timken placed on the record statements and documents to demonstrate absence of *de jure* control. In its questionnaire responses, Yantai Timken reported that it is a wholly foreign–owned enterprise, established in accordance with the ''Law of the PRC on Foreign Capital Enterprise'' *See* Yantai Timken's August 26, 2004, Section A response (''AQR'') at A–2. Yantai Timken reported that it is 100–percent owned by The Timken Company. *See* AQR at A–2. Yantai Timken reported that it does not have any relationship with the central, provincial, or local governments with respect to ownership, internal management, and daily business operations. *See* AQR at A–3. Yantai Timken submitted a copy of its business license and stated it is renewed annually as long as the company submits its annual financial statements and profit/loss statement to the appropriate State Administration of Industry and Commerce office and no activities prohibited by Article 30 of the Administrative Regulations have occurred. *See* AQR at A–5 and at exhibit A–5. Yantai Timken reported that the subject merchandise did not appear on any government list regarding export provisions or export licensing, and the subject merchandise is not subject to export quotas or export control licenses imposed by the PRC government. *See* AQR at A–6. Yantai Timken reported that it may engage in business activities within the scope of its business license. *See* AQR at A–4. Furthermore, Yantai Timken stated that the China Chamber of Commerce is not involved in Yantai Timken's export activities. *See* AQR at A–8. Yantai Timken submitted a copy of the ''Regulations of the PRC for Controlling the Registration of Enterprises as Legal Persons'' and the ''Company Law of the PRC'' to demonstrate that there is no centralized

control over its export activities. *See* AQR at exhibits A–3 and A–4. Through the questionnaire responses, we examined each of the related laws and Yantai Timken's business license and have determined that they demonstrate the absence of *de jure* control over the export activities and evidence in favor of the absence of government control associated with Yantai Timken's business license.

B. Absence of De Facto Control

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 Final Determination of Sales at Less Than Fair Value: Certain Preserved Mushrooms from the People's Republic of China*, 63 FR 72255, 72257 (December 31, 1998). Therefore, the Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of government control which would preclude the Department from assigning separate rates. The Department typically considers four factors in evaluating whether each respondent is subject to *de facto* government control of its export functions: (1) whether the exporter sets its own export prices independent of the government and without the approval of a government authority; (2) whether the respondent has authority to negotiate and sign contracts, and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of its management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses. *See* Furfuryl Alcohol.

In support of an absence of *de facto* control, Yantai Timken reported the following. During the POR, Yantai Timken explained that it sold the subject merchandise in the United States only to its affiliated party in the United States, The Timken Company. *See* AQR at A–7 and A–8. Therefore, Yantai Timken reported that the question of whether its prices are subject to governmen control is not applicable, since The Timken Company in the United States sets and negotiates the prices with its customers in the United States. *See* AQR at A–7. Yantai Timken explained that its Board of Directors appoints the general manager and all other senior management members are nominated by the general manager and approved by the board of directors. *See* AQR at A–9. Yantai Timken explained that it is required to notify the Yantai Administration for Industry & Commerce of any senior management changes for informational purposes. *See* AQR at A–9. Yantai Timken explained that there are no restrictions on the use of its export revenues. *See* AQR at A10. Additionally, Yantai Timken stated that it is not required to sell any of its foreign currency earnings to the government and it is allowed to freely convert all foreign currency earnings on sales of the merchandise under review to the United States into renminbi for domestic use in China at the prevailing market rates of any bank. *See* AQR at A–11 and A–12. Yantai Timken explained that it can and does use foreign currency for operating expenses and capital equipment purchases. *See* AQR at A–11.

The evidence placed on the record of this administrative review by Yantai Timken, and verified by the Department, demonstrates an absence of government control, both in law and in fact, with respect to Yantai Timken's exports of the merchandise under review. *See* Memorandum to the File, from Laurel LaCivita, Senior Case Analyst and Eugene Degnan, Analyst, through Robert Bolling, Program Manager, and Wendy Frankel, Director, NME/China Unit, Office 8, ''Verification of Sales and Factors of Production Reported by the Yantai Timken Company in the 2003/2004 Antidumping Duty Administrative Review of Tapered Roller Bearings and Parts, Thereof from the People's Republic of China,'' dated June 30, 2005 (''*FOP Verification Report*''). As a result, for these final results, the Department is granting a separate, company–specific rate to Yantai Timken, the exporter which shipped the subject merchandise to the United States during the POR.

Partial Adverse Facts Available

We have determined that the use of partial facts available with adverse inferences is warranted for Yantai Timken's consumption rate for electricity and natural gas in the determination of normal value. In addition, we have determined that the use of a partial facts available with adverse inferences is warranted with respect to Yantai Timken's adjustments to U.S. prices for indirect selling expenses (''ISEs''), warehousing, ocean freight, rebates, and commissions incurred in the United States.

During Yantai Timken's factors–of-production (''FOP'') verification, we determined that Yantai Timken failed to account for its total consumption of electricity and to substantiate its allocation of natural gas to the production of the subject merchandise. *See FOP Verification Report* at 2 and the *Preliminary Results*, 70 FR at 39749. Because Yantai Timken provided factor values for electricity and natural gas that could not be verified, pursuant to section 776(a)(1)(D) of the Act, we have resorted to the facts otherwise available to determine the consumption rates for these inputs. The Department also finds that Yantai Timken did not act to the best of its ability through its failure to accurately report its factor consumption rates for electricity and natural gas pursuant to section 776(b) of the Act. Thus, adverse inferences are warranted for electricity and natural gas. We used the total quantity of Yantai Timken's electricity consumption during the POR, as determined at verification, as AFA for electricity. See the memorandum to the file from Laurel LaCivita, Senior Case Analyst, through Robert Bolling, Program Manager, ''Analysis for the Final Results of the 2003–2004 Administrative Review of Tapered Roller Bearings and Parts Thereof, Finished or Unfinished, from the People's Republic of China: Yantai Timken Company, Ltd. and the Timken Company,'' dated January 9, 2006 (''*Yantai Timken Final Analysis Memorandum*''), at 8. In addition, Yantai Timken could not substantiate its allocation of natural gas between production- and non–production-related activities. *See Yantai Timken Final Analysis Memorandum* at 9. Therefore, as AFA, we have attributed 50 percent of Yantai Timken's total factory–wide consumption of natural gas (as determined at verification) to the production of the subject merchandise.

During Yantai Timken's constructed export sales (''CEP'') verification, we determined that the Timken Company, Yantai Timken's parent, could not demonstrate that the expenses it reported in its Section C response for warehousing, ISEs, international freight, commissions, and rebates represent the total value of these expenses applicable to the subject merchandise during the POR. *See* the memorandum to the file from Laurel LaCivita, Senior Case Analyst and Hua Lu, Case Analyst, through Robert Bolling, Program Manager, and Wendy J. Frankel, Director, NME/China Unit, Office 8, ''Verification of the Constructed Export Price Sales Reported by The Timken Company (''Timken'') in the Antidumping Duty Administrative Review of Tapered Roller Bearings and Parts, Thereof from the People's Republic of China,'' dated June 30, 2005 (''*Timken CEP Verification Report*''), at

2, 14, 25, 20, and 22, and the *Preliminary Results*, 70 FR at 39749. In addition, we found at verification that Timken based its distributor warehousing expenses, U.S. inland freight, commissions, and rebates reported in the Section C response on either preliminary or hypothetical data. *See Timken CEP Verification Report* at 2, 3, 20, and 21, and the *Preliminary Results*, 70 FR at 39749. Because Timken reported values for warehousing, ISE, international freight, commissions and rebates that could not be verified, pursuant to section 776(a)(1)(D) of the Act, we must resort to the facts otherwise available to determine the values for these adjustments. Further, pursuant to section 776(b) of the Act, the Department also finds that Timken did not act to the best of its ability through its failure to accurately report its adjustment data for these items. Thus, adverse inferences are warranted for warehousing, ISE, international freight, commissions and rebates. We used the total verified value of Timken's warehousing expense, ISE expense, and international freight as the basis of AFA for these items. *See Yantai Timken Final Analysis Memorandum* at pages 3 and 4, and Attachments III, IV, and V. We could not tie Timken's reported commissions and rebates into its audited financial statements, and thus could not determine the completeness of its reporting methodology. Moreover, Timken could not demonstrate the full universe of commissions and rebates paid on sales of sujbect merchandise during the POR. Therefore, we applied, as total AFA, the highest contractual amount of commissions and rebates that its sales agents or customers could earn to all sales of subject merchandise in the United States during the POR. *See Yantai Timken Final Analysis Memorandum* at 4.

In our *Preliminary Results*, we stated that because we could not verify the total value of Timken's marine insurance expense, pursuant to section 776(a)(1)(D) of the Act, we must resort to the facts otherwise available. *See Preliminary Results*, 70 FR at 39749. However, further examination of the information on the record reveals that Yantai Timken appropriately reported and substantiated its marine insurance expense. Therefore, for the final results, we will not apply AFA or make adverse inferences with respect to Timken's marine insurance expense, but will use the amount as reported in its Section C questionnaire response. *See Yantai Timken Final Analysis Memorandum* at 4.

Date of Sale

Section 351.401(i) of the Department's regulation states that ''in identifying the date of sale of the subject merchandise or foreign like product, the Secretary normally will use the date of invoice, as recorded in the exporter or producer's records kept in the normal course of business. However, the Secretary may use a date other than the date of invoice if the Secretary is satisfied that a different date better reflects the date on which the exporter or producer establishes the material terms of sale.'' 19 CFR 351.401(i); *See also Allied Tube and Conduit Corp. v. United States*, 132 F. Supp. 2d 1087, 1090–1093 (CIT 2001).

After examining the sales documentation placed on the record by Yantai Timken, we determine that invoice date is the most appropriate date of sale for Yantai Timken's CEP sales. We made this determination based on statements on page C–9 of the October 4, 2004, Section C response that Yantai Timken's invoice date, which is generally the same as the shipment date from the U.S. warehouse, establishes the material terms of sale to the extent required by our regulations. *See Notice of Final Determination of Sales at Less Than Fair Value: Structural Steel Beams From Germany*, 67 FR 35497 (May 20, 2002), and accompanying Issues and Decision Memorandum at *Comment 2*.

Normal Value Comparisons

To determine whether sales of TRBs to the United States by Yantai Timken were made at less than normal value (''NV''), we compared CEP to NV, as described in the ''*Constructed Export Price*'' and ''*Normal Value*'' sections of this notice.

Constructed Export Price

In accordance with section 772(b) of the Act, CEP is the price at which the subject merchandise is first sold (or agreed to be sold) in the United States before or after the date of importation by or for the account of the producer or exporter of such merchandise or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter, as adjusted under sections 772 (c) and (d). In accordance with section 772(b) of the Act, we used CEP for all of Yantai Timken's sales because it sold all of its subject merchandise to Timken, its affiliated party in the United States, which in turn sold subject merchandise to unaffiliated U.S. customers.

We compared NV to individual CEP transactions, in accordance with section 777A(d)(2) of the Act. For Timken's CEP sales, we based the CEP on delivered prices to unaffiliated purchasers in the United States. In accordance with section 772(d)(1) of the Act, we made deductions from the starting price for billing adjustments, movement expenses, discounts, commissions, rebates and re–packing expenses. Movement expenses included expenses for foreign inland freight from the plant to the port of exportation, domestic brokerage and handling, international freight, marine insurance, U.S. brokerage and handling, U.S. duty, U.S. inland freight, U.S. warehousing expenses, distributor warehousing expenses, and inland freight from the warehouse to the unaffiliated U.S. customer. We made adjustments to Timken's reported ISEs, commissions, rebates, international movement expenses (ocean freight and U.S. brokerage) and U.S. warehouse expense to account for failures at verification. See the ''Partial AFA'' section of this notice. In addition, we adjusted Timken's reported distributor warehouse and inland freight from the warehouse to the unaffiliated U.S. customer to account for minor corrections presented at verification. *See CEP Verification Report* at 1 to 3 and *Yantai Timken Final Analysis Memorandum* at 4 and 5. In accordance with section 772(d)(1) of the Act, we additionally deducted credit expenses, iICCs and ISEs from the U.S. price, all of which relate to commercial activity in the United States. In accordance with section 772(d)(1) of the Act, we calculated Yantai Timken's credit expenses and ICCs based on the Federal Reserve short–term rate. Finally, we deducted CEP profit in accordance with sections 772(d)(3) and 772(f) of the Act. *See Yantai Timken Prelim Analysis Memorandum* at 2–5.

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine the NV using an FOP methodology if: (A) the merchandise is exported from an NME country; and (B) 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. The Department will base NV on FOPs because the presence of government controls on various aspects of these economies renders price comparisons and the calculation of production costs invalid under our normal methodologies.

FOPs 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 based our determination of NV on Yantai Timken's reported FOPs for materials, energy (with the exceptions discussed above), labor, by–products, and packing.

In accordance with 19 CFR 351.408(c)(1), the Department will normally use publicly available information to value FOPs, but when a producer sources an input from a market economy and pays for it in market–economy currency, the Department will normally value the factor using the actual price paid for the input. *See* 19 CFR 351.408(c)(1); *See also Lasko Metal Products v. United States*, 43 F. 3d 1442, 1445–1446 (Fed. Cir. 1994). Yantai Timken reported that a significant portion of at least one of its raw material inputs was sourced from a market–economy country and paid for in a market–economy currency. *See* Yantai Timken's October 4, 2004, Section D response at page D–16. Pursuant to 19 CFR 351.408(c)(1), we used Yantai Timken's verified actual price for inputs purchased from a market–economy supplier and paid for in a market–economy currency, except when prices may have been distorted by subsidies.

With regard to both the Indian import–based surrogate values and the market–economy input values, we have disregarded prices that we have reason to believe or suspect may be subsidized. We have reason to believe or suspect that prices of inputs from India, Indonesia, South Korea, and Thailand may have been subsidized. We have found in other proceedings that these countries maintain broadly available, non–industry-specific export subsidies and, therefore, it is reasonable to infer that all exports to all markets from these countries may be subsidized. *See Certain Helical Spring Lock Washers from the People's Republic of China; Final Results of Administrative Review*, 61 FR 66255 (December 17, 1996) and accompanying Issues and Decision Memorandum, at Comment 1; *Automotive Replacement Glass Windshields From the People's Republic of China: Final Results of Administrative Review*, 69 FR 61790 (October 21, 2004) and accompanying Issues and Decision Memorandum, at Comment 5; and, *China National Machinery Import & Export Corporation v. United States*, 293 F. Supp. 2d 1334 (CIT 2003), *aff'd*, 104 Fed. Appx. 183 (Fed. Cir. 2004). We are also guided by the legislative history not to conduct a formal investigation to ensure that such prices are not subsidized. *See* H.R. Rep. 100–576 at 590 (1988). Rather, the Department was instructed by Congress to base its decision on information that is available to it at the time it is making its determination. Therefore, we have not used prices from these countries either in calculating the Indian import–based surrogate values or in calculating market–economy input values. In instances where a market–economy input was obtained solely from suppliers located in these countries, we used Indian import–based surrogate values to value the input.

Factor Valuations

In accordance with section 773(c) of the Act, we calculated NV based on Yantai Timken's FOPs for the POR. To calculate NV, the 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 contemporaneity of the data.

We valued packing material inputs using the weighted–average unit import values derived from the World Trade Atlas® online (''Indian Import Statistics''), which were published by the Directorate General of Commercial Intelligence and Statistics (''DGCI&S''), Ministry of Commerce of India, were reported in rupees and are contemporaneous with the POR. *See* memoranda to the file from Eugene Degnan, Case Analyst, through Wendy Frankel and Robert Bolling, ''Preliminary Results of Review of Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Factors of Production Valuation Memorandum for the Preliminary Results of Review,'' dated June 30, 2005 (''*Factor Valuation Memorandum*'') and *Yantai Timken Final Analysis Memorandum*. Where we could not obtain publicly available information contemporaneous with the POR with which to value factors, we adjusted the surrogate values using the Indian Wholesale Price Index (''WPI'') as published in the *International Financial Statistics* of the International Monetary Fund. We adjusted Yantai Timken's reported factors for wooden pallets and packing labels to account for minor corrections to the response: *See FOP Verification Report* at 23–24 and Yantai Timken Final Analysis Memorandum at 7. We also revised the factor consumption rate of boxes, packing boards and packing buttons to account for findings at verification. See FOP Verification Report at 23–24 and *Yantai Timken Final Analysis Memorandum* at 8.

We adjusted the Indian surrogate values for packing materials to account for freight delivery charges. Specifically, we calculated the surrogate freight charges based on the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory. *See* Yantai Timken's November 30, 2005, case brief at 12. We made no freight adjustments to raw material prices for those materials which Yantai Timken purchased from market–economy suppliers on a delivered basis. *See* Yantai Timken's October 4, 2004, Section D response (''DQR'') at D–10 to D–12 and exhibits D–5 and D–6. For raw materials purchased from a market–economy supplier on an FOB basis, we calculated a surrogate freight value using the distance from the port of import to the factory. *See* DQR at D–12 and exhibit D–7. This adjustment is in accordance with the decision of the Federal Circuit in *Sigma Corp. v. United States*, 117 F. 3d 1401 (Fed. Cir. 1997).

To value electricity, we used values from the International Energy Agency (''IEA'') to calculate a surrogate value in India for 2000, adjusted for inflation. The Petitioner was the only interested party to submit information or comments regarding surrogate values for electricity on the record. However, the submitted value was less contemporaneous than the 2000 value reported by the IEA, which has been used in previous cases. *See Notice of Final Determination of Sales at Less Than Fair Value: Chlorinated Isocyanurates From the People's Republic of China*, 70 FR 24502 (May 10, 2005) and accompanying Issues and Decision Memorandum, at Comment 5; and, *Amended Final Determination of Sales at Less Than Fair Value: Magnesium Metal from the People's Republic of China*, 70 FR 15838 (March 29, 2005). Further, the Department was unable to find a more contemporaneous surrogate value than the 2000 value reported by the IEA. Therefore, we used the International Energy Agency 2000 Indian price for electricity to the POR, as adjusted for inflation. We adjusted Yantai Timken's factor consumption rate for electricity to account for findings at verification. *See FOP Verification Report* at 16–19 and attachment IV. *See* also *Yantai Timken Final Analysis Memorandum* at 9.

To value natural gas, we used values obtained from *http://www.indiainfoline.com* in June 2000, used in the *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, 67202 (December 28, 2001), as unchanged in the *Notice of Final Determination of Sales at Less Than Fair Value: Structural Steel Beams From*

Germany, 67 FR 35497 (May 20, 2002), and reported in Yantai Timken's November 17, 2004, surrogate value submission. *See* letter from Yantai Timken, ''Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China: Administrative Review (6/1/03–5/31/04): Submission of Yantai Timken's Surrogate Country selection and Potential Surrogate Values,'' at page 3 and exhibit 3. Yantai Timken was the only interested party to submit information or comments regarding surrogate values for natural gas on the record. In addition, we were unable to find a more contemporaneous surrogate value. Therefore, we adjusted this value for inflation. We adjusted Yantai Timken's factor consumption rate for natural gas to account for minor corrections to the response and for other findings at verification. *See FOP Verification Report* at 3, 20–21 and verification exhibit 1B. *See* also *Yantai Timken Final Analysis Memorandum* at 9–10, and *Issues and Decisions Memorandum* at Comment 8.

For direct labor, indirect labor, SG&A labor and packing labor, consistent with 19 CFR 351.408(c)(3), we used the PRC regression–based wage rate as reported on Import Administration's home page, Import Library, Expected Wages of Selected NME Countries, revised in November 2004, *http://ia.ita.doc.gov/wages/02wages/02wages.html*. The source of these wage rate data on the Import Administration's web site is the Yearbook of Labour Statistics 2002, ILO, (Geneva: 2002), Chapter 5B: Wages in Manufacturing. The years of the reported wage rates range from 1996 to 2002. Because this regression–based wage rate does not separate the labor rates into different skill levels or types of labor, we have applied the same wage rate to all skill levels and types of labor reported by each respondent.

To value factory overhead, depreciation, selling, general and administrative expense, interest expenses and profit, we used the 2003 audited financial statements for two Indian producers of tapered roller bearings, SKF Bearings India Ltd., and Timken India Limited. *See Final Results Surrogate Value Memorandum* for a full discussion of the calculation of these ratios from the Indian companies' financial statements.

In order to demonstrate that prices paid to market–economy sellers for some portion of a given input are representative of prices paid overall for that input, the amounts purchased from the market–economy supplier must be meaningful. *See Antidumping Duties; Countervailing Duties; Final Rule*, 62 FR 27296, 27366 (May 19, 1997). Where the quantity of the input purchased from market–economy suppliers is insignificant, the Department will not rely on the price paid by an NME producer to a market–economy supplier because it cannot have confidence that a company could fulfill all its needs at that price. Yantai Timken's reported information demonstrates that the quantity of steel purchased from a market economy source used to produce cups and cones is significant. *See* Yantai Timken's October 4, 2004 Section D response at page D–10. Therefore, we used the actual price Yantai Timken paid for this steel in our calculations.

Yantai Timken reported that it also recovered scrap steel from the production of cups, cones and rollers resale. We offset Yantai Timken's cost of production by the amount of scrap that Yantai Timken reported that it sold. *See Factor Valuation Memorandum* at 3–4 and attachment 3.

Finally, we used Indian Import Statistics for the POR to value material inputs for packing which, for Yantai Timken, are wooden pallets, plastic covers, cardboard boxes, packing labels, plastic strips and packing cardboard. We used Indian Import Statistics for the POR for wooden pallets, plastic covers, cardboard boxes and plastic strips, and packing cardboard. *See Factor Valuation Memorandum* at page 4 and attachment 3 for wooden pallets, plastic covers, cardboard boxes and plastic strips. *See Yantai Timken Final Analysis Memorandum* at Attachment VIII for packing labels and packing cardboard. We were unable to find contemporaneous information for packing labels. Therefore, we used the Indian Import Statistics for packing labels from a previous period adjusted for inflation in our calculations.

Final Results of Review

We determine that the following dumping margins exist for the period June 1, 2003, through May 31, 2004:

Exporter/manufacturer	Weighted–average margin percentage
China National Machinery Import & Export Corporation **	0.00
Luoyang Bearing Corporation (Group) **	0.18
Yantai Timken Company Limited	41.58

** These rates are *de minimis*.

Assessment Rates

The Department will issue appraisement instructions directly to U.S. Customs and Border Protection (''CBP'') within 15 days of publication of these final results of administrative review. In accordance with 19 CFR 351.212(b)(1), we have calculated importer–specific assessment rates for merchandise subject to this review. For LYC and CMC, we divided the total dumping margins of its reviewed sales by the total entered value of its reviewed sales for each applicable importer to calculate *ad–valorem* assessment rates. For Yantai Timken, we divided the total dumping margins of its reviewed sales by the total quantity of its reviewed sales for each applicable importer to calculate *per–unit* assessment rates. We will direct CBP to assess the resulting assessment rates against the entered customs values for the subject merchandise on each importer's entries under the relevant order during the POR.

To determine whether the duty assessment rates were *de minimis*, in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer–specific *ad valorem* rates. For CMC and LYC, we aggregated the dumping margins calculated for all U.S. sales to each importer and divided this amount by the entered value of the sales to each importer. For further details *see CMC Final Analysis Memo* and *LYC Final Analysis Memo*. Where an importer–specific *ad valorem* rate is *de minimis*, we will order CBP to liquidate appropriate entries without regard to antidumping duties.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of this notice of final results of administrative review for all shipments of TRBs from the PRC entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by Section 751(a)(1) of the Act: (1) The cash deposit rates for the reviewed companies will be the rates shown above, except that the Department shall require no deposit of estimated antidumping duties for firms whose weighted–average margins are less than 0.5 percent and therefore *de minimis*; (2) for previously reviewed or investigated companies not listed above that have a separate rate, the cash deposit rate will continue to be the company–specific rate published for the most recent period; (3) the cash deposit rate for all other PRC exporters will be 60.95 percent, the current PRC–wide rate; and (4) the cash deposit rate for all non–PRC exporters will be the rate applicable to the PRC exporter that supplied that exporter. These deposit requirements, when imposed, shall remain in effect until publication of the

final results of the next administrative review.

Notification of Interested Parties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties. This notice also serves as a reminder to parties subject to administrative protective orders (''APOs'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 9, 2006.

David M. Spooner,

Assistant Secretary for Import Administration.

APPENDIX

List of Comments and Issues in the Decision Memorandum

CMC

Comment 1: Skilled Packing Labor Citing Error for CMC

LYC

Comment 2: Application of Adverse Facts Available to Value Certain Merchandise of LYC
Comment 3: Application of Adverse Facts Available to Value Inventory Carrying Costs (''ICC'') for Certain Constructed Export Price (''CEP'') Sales
Comment 4: Federal Reserve Board Prime Rate Used to Value ICC
Comment 5: Excise Duties on Closing Stock
Comment 6: Calculation of the Surrogate Value for the Raw Material Input ''Cage''

YANTAI TIMKEN

Comment 7: The Department Should Find That Yantai Timken Was Cooperative and Use Yantai Timken's Data as Modified by the Results of Verification.
Comment 8: Yantai Timken's Verification Results and Level of Cooperation: Natural Gas
Comment 9: Yantai Timken's Verification Results and Level of Cooperation: Electricity
Comment 10: Yantai Timken's Verification Results and Level of Cooperation: Supplier's Distances for Packing Materials
Comment 11: Yantai Timken's Verification Results and Level of Cooperation: Indirect Selling Expenses in the U.S. Market
Comment 12: Yantai Timken's Verification Results and Level of Cooperation: Warehouse Expense
Comment 13: Yantai Timken's Verification Results and Level of Cooperation: Marine Insurance
Comment 14: Yantai Timken's Verification Results and Level of Cooperation: International Freight
Comment 15: Yantai Timken's Verification Results and Level of Cooperation: Rebates and Commissions
Comment 16: Yantai Timken's Request to Supplement the Record
Comment 17: The Department Should Determine a Margin That Is Not Punitive
Comment 18: Continued Application of the Order to Yantai Timken Is Necessary to Offset Dumping
Comment 19: Separate Rate Status for Yantai Timken

[FR Doc. E6–411 Filed 1–16–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Voluntary Laboratory Accreditation Program Workshop for Laboratories Interested in Testing Radiation Detection Instruments for Homeland Security Applications

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The National Voluntary Laboratory Accreditation Program (NVLAP) will hold a public workshop on Thursday, January 26, 2006, at the Doubletree Paradise Valley Resort in Scottsdale, Arizona. The purpose of the workshop is to exchange information among NVLAP, laboratories interested in testing radiation detection instruments for Department of Homeland Security applications, and other interested parties. The results of the workshop will be used in the development of the Radiation Detection Instruments Laboratory Accreditation Program. There is no charge for the workshop.

DATES: The workshop is scheduled for Thursday, January 26, 2006.

ADDRESSES: National Voluntary Laboratory Accreditation Program, 100 Bureau Drive/MS 2140, Gaithersburg, MD 20899–2140.

FOR FURTHER INFORMATION CONTACT: Betty Ann Torres, Senior Program Manager, NVLAP, 100 Bureau Drive/MS2140, Gaithersburg, MD 20899–2140, Phone: (301) 975–8446 or e-mail: *betty.torres@nist.gov;* Charlie Brannon, Physics Laboratory, Phone: (301) 975–3855 or e-mail: *charlie.brannon@nist.gov.*

Information regarding NVLAP and the accreditation process can be viewed at *http://www.nist.gov/nvlap.*

SUPPLEMENTARY INFORMATION:

Background

The United States Department of Homeland Security (DHS) has requested that a laboratory accreditation program be established for laboratories that test radiation detection instruments used in homeland security applications. The National Voluntary Laboratory Accreditation Program (NVLAP) is establishing an accreditation program to meet DHS requirements.

NVLAP accreditation criteria are established in accordance with the Code of Federal Regulations (CFR, title 15, Part 285), NVLAP Procedures and General Requirements. Laboratories conducting this testing will be required to meet ISO/IEC International Standard 17025, General Requirements for the Competence of Testing and Calibration Laboratories; the requirements of the ANSI/IEEE N42 series of standards and their corresponding Test and Evaluation Protocols; and any other criteria deemed necessary by the U.S. Department of Homeland Security.

For each new laboratory accreditation program (LAP), NVLAP works with the affected testing community to develop program-specific technical requirements. These requirements tailor the general accreditation criteria referenced in Sections 4 and 5 of NIST Handbook 150 to the tests and services in the new LAP. Program-specific requirements include the details of the Scope of Accreditation, test and measurement equipment, personnel requirements, validation of test methods, and reporting test results.

Dated: January 11, 2006.

Hratch G. Semerjian,

Deputy Director.

[FR Doc. E6–414 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket 051229349–5349–01]

Establishment of a Laboratory Accreditation Program for Radiation Detection Instruments Under National Voluntary Laboratory Accreditation Program

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) publishes this notice to announce that it is establishing an accreditation program for laboratories that perform testing of radiation detection instruments. This program will provide for the accreditation of laboratories that test radiation detection instruments using standards developed by the American National Standards Institute (ANSI) and the Homeland Security Instrumentation (HSI) and Radiation Protection Instrumentation (RPI) groups.

DATES: Laboratories interested in seeking accreditation that will allow them to be considered for Department of Homeland Security recognition should contact NVLAP immediately.

ADDRESSES: National Voluntary Laboratory Accreditation Program, 100 Bureau Drive/MS 2140, Gaithersburg, MD 20899–2140.

FOR FURTHER INFORMATION CONTACT: Betty Ann Torres, Senior Program Manager, NVLAP, 100 Bureau Drive/MS2140, Gaithersburg, MD 20899–2140, Phone: (301) 975–8446 or e-mail: *betty.torres@nist.gov*. Information regarding NVLAP and the accreditation process can be viewed at *http://www.nist.gov/nvlap.*

SUPPLEMENTARY INFORMATION:

Background

The United States Department of Homeland Security (DHS) has requested that NIST establish a laboratory accreditation program for laboratories that test radiation detection instruments used in homeland security applications. In response to the request by DHS, National Voluntary Laboratory Accreditation Program (NVLAP) is establishing an accreditation program for laboratories that test radiation detection instruments.

This notice is issued in accordance with the NVLAP procedures and general requirements, found in title 15, Part 285 of the Code of Federal Regulations.

Technical Requirements for the Accreditation Process

NVLAP accreditation criteria are established in accordance with the Code of Federal Regulations (CFR, title 15, Part 285), NVLAP Procedures and General Requirements. NVLAP is in full conformance with the standards of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), including ISO/IEC 17025.

Accreditation is granted to a laboratory following successful completion of a process, which includes submission of an application and payment of fees by the laboratory, an on-site assessment by technical experts, resolution of any deficiencies identified during the on-site assessment, and participation in proficiency testing. The accreditation is formalized through issuance of a Certificate of Accreditation and Scope of Accreditation.

NVLAP provides an unbiased, third-party evaluation and recognition of competence. NVLAP accreditation signifies that a laboratory has demonstrated that it operates in accordance with NVLAP management and technical requirements pertaining to quality systems; personnel; accommodation and environment; test and calibration methods; equipment; measurement traceability; sampling; handling of test and calibration items; and test and calibration reports.

NVLAP accreditation does not imply any guarantee (certification) of laboratory performance or test/calibration data. NVLAP accreditation is a finding of laboratory competence.

PRA Clearance

This action contains a collection of information requirements subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995. Collection activities for National Voluntary Laboratory Accreditation Program are currently approved by the OMB under control number 0693–0003. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information unless it displays a currently valid OMB Control Number.

Executive Order 12866

This action has been determined to be not significant under Executive Order 12866.

Dated: January 10, 2006.

Hratch G. Semerjian,

Deputy Director.

[FR Doc. E6–413 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; StormReady and TsunamiReady/StormReady Application Forms

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

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.

DATES: Written comments must be submitted on or before March 20, 2006.

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 and instructions should be directed to Donna Franklin at *Donna.Franklin@noaa.gov* or 301–713–0090 ext 141.

SUPPLEMENTARY INFORMATION:

I. Abstract

StormReady and TsunamiReady are voluntary programs offered to provide guidance and incentive to officials who wish to improve their hazardous weather operations. Applicants will use the StormReady Application form and TsunamiReady/StormReady Application form to apply for initial StormReady or TsunamiReady/StormReady recognition and renewal of that recognition every three years. A typical StormReady community would use this form 3 times every 10 years. The government will use the information collected by application to determine whether a community has

met all of the guidelines to receive StormReady and/or TsunamiReady selection.

II. Method of Collection

Applications will be submitted on paper (faxed or mailed) or electronically.

III. Data

OMB Number: 0648–0419.
Form Number: None.
Type of Review: Regular submission.
Affected Public: State, local or tribal government (emergency managers).
Estimated Number of Respondents: 75.
Estimated Time Per Response: 1 hour.
Estimated Total Annual Burden Hours: 75.
Estimated Total Annual Cost to Public: $27.75.

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: January 10, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–371 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–KE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Availability of Record of Decision and Final Findings on Approvability for the Office of Ocean and Coastal Resource Management's Review of Amendments to the Alaska Coastal Management Program Final Environmental Impact Statement (EIS)

AGENCY: Department of Commerce, National Oceanic and Atmospheric Administration (NOAA), Office of Ocean and Coastal Resource Management.

ACTION: Notice of availability of Record of Decision and Final Findings of Approvability for Amendment to the Alaska Coastal Management Program.

SUMMARY: NOAA's Office of Ocean and Coastal Resource Management (OCRM) announces availability of the Record of Decision (ROD) and Final Findings of Approvability (Findings) for OCRM's Review of Amendments to the Alaska Coastal Management Program (ACMP) final Environmental Impact Statement (EIS). On June 2, 2005, OCRM received the State of Alaska's request to incorporate Executive Order 106, House Bills 191, 69, 86, Senate Bill 102, revisions to statute AS 46, and new implementing regulations at 11 AAC 110, 11 AAC 112, and 11 AAC 114 as an amendment to the ACMP. The new implementing regulations replace the existing consistence review procedure regulations previously found at 6 AAC 50, the statewide standards previously found at 6 AAC 80, and the district program guidelines previously found at 6 AAC 85 as the enforceable policies of the ACMP. The final EIS was released to the public for 30 days after the publication of a Notice of Availability in the **Federal Register** on November 25, 2005 (79 FR 71139). The ROD documents the selection of Alternative 1 (the NOAA preferred alternative) in the final EIS. The Findings make a final determination that the ACMP, as amended by the June 2, 2005, ACMP Amendment Document, still constitutes an approvable program and that procedural requirements of the CZMA and its implementing regulations have been met. The ROD and Findings were signed by the Deputy Assistant Administrator, National Ocean Service (NOS) on December 29, 2005. Federal consistency applies to the revised ACMP enforceable policies as of December 29, 2005.

ADDRESSES: A copy of the ROD and the Findings may be obtained from Helen Bass, Environmental Protection Specialist, National Oceanic and Atmospheric Administration, OCRM/CPD, N/ORM3, Station 11207, 1305 East-West Highway, Silver Spring, MD 20910, or at *Helen.Bass@noaa.gov*, (301) 713–3155, extension 175 (telephone) and 301–713–4367 (FAX). The documents are also available on OCRM's Web site at *http://coastalmanagement.noaa.gov/pcd/up.html*.

FOR FURTHER INFORMATION CONTACT: Bill Millhouser, Pacific Regional Team Leader, National Oceanic and Atmospheric Administration, OCRM/CPD, N/ORM3, Station 11204, 1305 East-West Highway, Silver Spring, MD 20910, or *Bill.Millhouser@noaa.gov*, (301) 713–3155, extension 189, (telephone), 301–713–4367 (FAX).

SUPPLEMENTARY INFORMATION: The following is a summary of the ROD and the Findings. On June 2, 2005, Alaska formally submitted to NOAA a request to amend the ACMP.

The amendment included the above-referenced laws and new implementing regulations, which replace the existing consistency review procedure regulations previously found at 6 AAC 50, the statewide standards previously found at 6 AAC 80, and the district program guidelines previously found at 6 AAC 85. The Rod selects final EIS Alternative 1, Approve Alaska's Request for Amendment of the ACMP. OCRM arrived at this decision while taking environmental, economic, and agency statutory mission considerations into account, as discussed in greater detail in the ROD and Section 10 of the final EIS. The Findings provide an analysis of how the ACMP, as amended, meets the requirements of the CZMA at 15 CFR part 923, including uses subject to management, special management areas, boundaries, authorities and organization, and coordination, public involvement, and national interest.

The following factors weighed most heavily in OCRM's decision: (1) Continued ACMP approvability as amended by the proposed program change; and (2) impacts to coastal resources and communities associated with the continued existence of the ACMP. OCRM approved the ACMP amendment because OCRM believes Alternative 1 meets the program change requirements of the CZMA, and will be the best opportunity for continued comprehensive protection of Alaska's coastal resources. OCRM did not select either Alternative 2 (Failure to Approve Alaska's Request for Amendment of the ACMP) or Alternative 3 (Deny Alaska's Request for Amendment of the ACMP) because both ultimately would have resulted in the repeal and termination of the ACMP. Termination of the ACMP would potentially lead to adverse physical and socio-economic impacts to coastal resources and communities associated with (1) lack of Federal consistency requirements available only through participation in the national coastal management program; (2) loss of funding for implementation of the ACMP; and (3) loss of Alaska's comprehensive coastal management program which allows for district

participation in State coastal resource management decisions. In addition, the ROD identifies mitigation and monitoring measures OCRM will implement as part of its continued oversight of Alaska's implementation of the ACMP.

(Federal Domestic Assistance Catalog 11.419 Coastal Zone Management Program Administration)

Dated: January 6, 2006.

Eldon Hout,

Director, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 06–356 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 010506A]

Marine Mammals; File No. 984–1814

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that the following individual has applied in due form for a permit to conduct research on marine mammals: Dr. Terrie Williams, Department of Ecology and Evolutionary Biology, Center for Ocean Health - Long Marine Laboratory, University of California, 100 Shaffer Road, Santa Cruz, CA, 95060.

DATES: Written, telefaxed, or e-mail comments must be received on or before February 16, 2006.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562)980–4001; fax (562)980–4018.

Written comments or requests for a public hearing on this application should be mailed to the Chief, Permits, Conservation and Education Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on the request would be appropriate.

Comments may also be submitted by facsimile to (301)427–2521, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period.

Comments may also be submitted by e-mail to *NMFS.Pr1Comments@noaa.gov*. Include the appropriate document identifier in the subject line of the e-mail comment: File No. 984–1814.

FOR FURTHER INFORMATION CONTACT: Kate Swails or Tammy Adams, (301)713–2289.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216).

The applicant requests a five-year permit to investigate the behavioral and energetic adaptations that enable Weddell seals (*Leptonychotes weddellii*) to forage in the Antarctic fast-ice environment, particularly in the dark. The applicant proposes to capture up to 20 adults and disturb up to 40 adults annually. The animals would have a data logger/video system attached, muscle biopsies and blood samples collected, and blubber thickness measured. Study results are expected to increase understanding of the foraging behavior of this marine mammal. The animals would be recaptured up to three times to remove or tend to the instruments. The applicant also requests authorization for the research-related mortality of up to two seals per year.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of these applications to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: January 11, 2006.

Stephen L. Leathery,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E6–422 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 011106B]

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of meetings of the North Pacific Fishery Management Council Observer Advisory Committee.

SUMMARY: The North Pacific Fishery Management Council (Council) Observer Advisory Committee will meet at the Alaska Fisheries Science Center.

DATES: The meeting will be held on January 30–31, 2006, from 8:30 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Alaska Fishery Science Center, 7600 Sand Point Way NE., Bldg 4, Room 1055, Seattle, WA 98115.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Nicole Kimball, Council staff, telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to review the draft environmental analysis/regulatory impact review/initial regulatory flexibility analysis to restructure the North Pacific Groundfish Observer Program.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen at 907–271–2809 at least 7 working days prior to the meeting date.

Dated: January 11, 2006.

Emily Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E6–417 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Customer Input: United States Patent and Trademark Office Customer Surveys

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the continuing information collection, 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 March 20, 2006.

ADDRESSES: You may submit comments by any of the following methods:

- E-mail: *Susan.Brown@uspto.gov*. Include ''0651–0038 comment'' in the subject line of the message.
- Fax: 571–273–0112, marked to the attention of Susan Brown.
- Mail: Susan K. Brown, Records Officer, Office of the Chief Information Officer, Office of Data Architecture and Services, Data Administration Division, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.
- Federal e-Rulemaking Portal: *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Martin Rater, Management Analyst, Office of the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–5966; or by e-mail at *martin.rater@uspto.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a generic clearance for an undefined number of voluntary surveys that the United States Patent and Trademark Office (USPTO) may conduct over the next 3 years. The USPTO uses telephone surveys, questionnaires, and customer surveys to collect feedback from their customers.

With the exception of the telephone surveys, the surveys are mailed to the USPTO's customers. The USPTO provides the option for customers to respond to the questionnaires and surveys electronically. Although the USPTO is moving to an electronic environment and would prefer to administer the questionnaires and customer surveys wholly via the web to coincide with other e-government initiatives, the USPTO's customers have requested that the surveys be made available in paper format as well since many of them only find the time to complete the surveys during their commutes, on planes, etc., where they do not have Internet access. Consequently, the surveys are primarily answered in the paper format.

Customers either access the survey in question through the USPTO's Web site or through the Web sites of the USPTO's survey contractors. Instructions for using the online surveys are provided in the cover letter that accompanies the survey. The cover letter also contains the username and password required to enter the survey site and the access code to activate the survey. The electronic version of the survey mirrors the paper version.

The USPTO also conducts customer surveys of the entire agency. These surveys were previously covered under this generic clearance. However, since the 21st Century Strategic Plan changed the timing of these surveys from annually to biannually, these surveys will now be covered under a separate and distinct information collection. The face-to-face interviews, comment cards, and focus groups used previously have also been deleted from the collection.

The surveys in this collection are designed to obtain customer feedback regarding products, services, and related service standards of the USPTO. At this time, the USPTO is unable to state precisely which survey vehicles will be used during the renewal period. As the USPTO's survey needs are determined, the USPTO will submit the specific survey instrument for approval.

II. Method of Collection

These surveys will either be conducted by telephone, mailed to the USPTO in a pre-addressed, self-stamped envelope, or completed electronically. A random sample is used to collect the data. Statistical methods will be followed.

III. Data

OMB Number: 0651–0038.

Form Number(s): The USPTO will have surveys and questionnaires in both paper and electronic formats.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; business or other for-profit; not-for-profit institutions; farms; the Federal Government; and State, local, or tribal governments.

Estimated Number of Respondents: 1,900 responses per year.

Estimated Time Per Response: The USPTO estimates that it will take the public approximately 15 minutes to complete the telephone surveys and 5 minutes to complete the questionnaires and customer surveys, whether they are mailed to the USPTO or submitted electronically. This includes the time to gather the necessary information, complete the surveys, and submit them to the USPTO.

Estimated Total Annual Respondent Burden Hours: 220 hours per year.

Estimated Total Annual Respondent Cost Burden: $51,700. The USPTO believes that both professionals and para-professionals will complete these surveys, at a rate of 75% of the current professional rate of $286 per hour and 25% of the para-professional rate of $81 per hour. Using a combination of these rates, the USPTO is using an hourly rate of $235 to calculate the respondent costs. The USPTO estimates that the respondent cost burden for this collection will be $51,700 per year.

Item	Estimated time for response	Estimated annual responses	Estimated annual burden hours
Telephone Surveys	5 minutes	400	100
Questionnaires and Customer Surveys	5 minutes	750	60
Electronic Questionnaires and Customer Surveys	5 minutes	750	60
Total		1,900	220

Note: The burden figures shown in the table above are estimates based on the surveys that the USPTO may conduct during the next three years. At this time, the USPTO cannot predict which or how many surveys will be conducted. Depending on the number of surveys that the USPTO actually conducts, it is possible that the burden hours could decrease or even increase from the totals shown in the table.

Estimated Total Annual Non-hour Respondent Cost Burden: $0. (There are no capital start-up or maintenance costs associated with this information collection.) Although the USPTO conducts mail surveys, self-addressed and stamped envelopes are provided with them. Respondents incur no postage costs resulting from these surveys.

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, *e.g.*, the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 10, 2006.

Susan K. Brown,

Records Officer, USPTO, Office of the Chief Information Officer, Office of Data Architecture and Services, Data Administration Division.

[FR Doc. E6–380 Filed 1–13–06; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 11 a.m., Friday, February 3, 2006.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 06–418 Filed 1–12–06; 11:56 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 11 a.m., Friday, February 10, 2006.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 06–419 Filed 1–12–06; 11:56 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 11 a.m., Friday, February 17, 2006.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 06–420 Filed 1–12–06; 11:56 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING

Sunshine Act Meetings

TIME AND DATE: 11 a.m., Friday, February 24, 2006.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 06–421 Filed 1–12–06; 11:56 am]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[OMB Control Number 0704–0250]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Contract Administration

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. DoD invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection for use through February 28, 2006. DoD proposes that OMB extend its approval for use for 3 additional years.

DATES: DoD will consider all comments received by March 20, 2006.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0250, using any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *dfars@osd.mil.* Include OMB Control Number 0704–0250 in the subject line of the message.
- Fax: (703) 602–0350.

• Mail: Defense Acquisition Regulations System, Attn: Ms. Deborah Tronic, OUSD(AT&L)DPAP(DARS), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062.

• Hand Delivery/Courier: Defense Acquisition Regulations System, Crystal Square 4, Suite 200A, 241 18th Street, Arlington, VA 22202–3402.

Comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Deborah Tronic, at (703) 602–0289. The information collection requirements addressed in this notice are available via the Internet at: *http://www.acq.osd.mil/dpap/dars/dfars/index.htm.* Paper copies are available from Ms. Deborah Tronic, OUSD(AT&L)DPAP(DARS), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–2062.

SUPPLEMENTARY INFORMATION:

Title, Associated Form, and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 242, Contract Administration, and related clauses in DFARS Part 252; DD Form 1659, Application for U.S. Government Shipping Documentation/Instructions; OMB Control Number 0704–0250.

Needs and Uses: DoD needs this information to perform contract administration functions. DoD uses the information as follows:

a. Contract administration offices use the information required by DFARS Subpart 242.11 to determine contractor progress and to identify any factors that may delay contract performance.

b. Administrative contracting officers use the information required by DFARS Subpart 242.73 to determine the allowability of insurance/pension costs under Government contracts.

c. Contract administration offices and transportation officers use the information required by DFARS 252.242–7003, and submitted on DD Form 1659, in providing Government bills of lading to contractors.

d. Contracting officers use the information required by DFARS 252.242–7004 to determine if contractor material management and accounting systems conform to established DoD standards.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Annual Burden Hours: 276,773.

Number of Respondents: 15,049.

Responses Per Respondent: Approximately 7.

Annual Responses: 105,748.

Average Burden Per Response: Approximately 3 hours.

Frequency: On occasion.

Summary of Information Collection

This information collection includes requirements relating to DFARS Part 242, Contract Administration.

a. DFARS Subpart 242.11 requires DoD contract administration personnel to conduct production reviews to determine contractor progress and to identify any factors that may delay contract performance. Contractors must provide information needed to support the reviews and must submit production progress reports.

b. DFARS Subpart 242.73 contains requirements for Government conduct of contractor insurance/pension reviews. Contractors must provide documentation needed to support the reviews.

c. DFARS 252.242–7003 requires contractors to request Government bills of lading by submitting DD Form 1659 to the transportation officer or the contract administration office.

d. DFARS 252.242–7004 requires contractors to establish, maintain, disclose, and demonstrate material management and accounting systems.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

[FR Doc. E6–389 Filed 1–13–06; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Publication of Housing Price Inflation Adjustment Under 50 U.S.C. App. § 531

AGENCY: DoD, Office of the Under Secretary (Personnel and Readiness).

ACTION: Notice.

SUMMARY: The Servicemembers Civil Relief Act, as codified at 50 U.S.C. App. § 531, prohibits a landlord from evicting a Service member (or the Service member's family) from a residence during a period of military service except by court order. The law as originally passed by Congress applied to monthly rents of $2,400 or less. The law requires the Department of Defense to adjust this amount annually to reflect inflation, and to publish the new amount in the **Federal Register**. We have applied the inflation index required by the statute. The maximum monthly rental amount for U.S.C. App. § 531(a)(1)(A)(ii) as of January 1, 2006, will be $2,615.16.

EFFECTIVE DATE: January 1, 2006.

FOR FURTHER INFORMATION CONTACT: Colonel C. Garcia, Office of the Under Secretary of Defense for Personnel and Readiness, (703) 697–3387.

Dated: January 10, 2006

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 06–348 Filed 1–13–06; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Government-Owned Invention; Available for Licensing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of the availability of exclusive or partially exclusive license to practice worldwide under the following pending patent. Any license granted shall comply with 35 U.S.C. 209 and 37 CFR Part 404. Applications will be evaluated utilizing the following criteria: (1) Ability to manufacture and market the technology; (2) manufacturing and marketing ability; (3) time required to bring technology to market and production rate; (4) royalties; (5) technical capabilities; and (6) small business status.

Patent application Serial Numbers 11/090,916 and PCT/US05/010061 entitled ''ANTI–MUCOLYTIC AND ANTI–ELASTASE COMPOUNDS AND METHODS OF USE THEREOF'' filed on March 24, 2005. The present inventions relate to the use of a compound containing a dithiol active site, preferably in reduced state, to induce, enhance and/or increase the liquefaction of mucus or sputum through mucolysis, and/or to inhibit elastase.

DATES: Applications for an exclusive or partially exclusive license may be submitted at any time from the date of this notice.

ADDRESSES: Submit application to the Office of Technology Transfer, Naval Medical Research Center, 503 Robert Grant Ave., Silver Spring, MD 20910–7500.

FOR FURTHER INFORMATION CONTACT: Dr. Charles Schlagel, Director, Office of Technology Transfer, Naval Medical Research Center, 503 Robert Grant Ave., Silver Spring, MD 20910–7500, telephone 301–319–7428 or e-mail at: *schlagelc@nmrc.navy.mil.*

Dated: January 6, 2006.

Eric McDonald,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E6–375 Filed 1–13–06; 8:45 am]

BILLING CODE 3810–FF–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8021–9]

Access to Confidential Business Information by Enrollees Under the Senior Environmental Employment Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has authorized grantee organizations under the Senior Environmental Employment (SEE) Program, and their enrollees; access to information which has been submitted to EPA under the environmental statutes administered by the Agency. Some of this information may be claimed or determined to be confidential business information (CBI).

DATES: Comments concerning CBI access will be accepted on or before January 23, 2006.

ADDRESSES: Comments should be submitted to: Susan Street, National Program Director, Senior Environmental Employment Program (MC 3650A), U.S. Environmental Protection Agency; Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Susan Street at (202) 564–0410.

SUPPLEMENTARY INFORMATION: The Senior Environmental Employment (SEE) program is authorized by the Environmental Programs Assistance Act of 1984 (Pub. L. 98–313), which provides that the Administrator may ''make grants or enter into cooperative agreements'' for the purpose of ''providing technical assistance to: Federal, State, and local environmental agencies for projects of pollution prevention, abatement, and control.'' Cooperative agreements under the SEE program provide support for many functions in the Agency, including clerical support, staffing hot lines, providing support to Agency enforcement activities, providing library services, compiling data, and support in scientific, engineering, financial, and other areas.

In performing these tasks, grantees and cooperators under the SEE program and their enrollees may have access to potentially all documents submitted under the Resource Conservation and Recovery Act, Clean Air Act, Clean Water Act, Safe Drinking Water Act, Federal Insecticide, Fungicide and Rodenticide Act, and Comprehensive Environmental Response, Compensation, and Liability Act, to the extent that these statutes allow disclosure of confidential information to authorized representatives of the United States (or to ''contractors'' under the Federal Insecticide, Fungicide, and Rodenticide Act). Some of these documents may contain information claimed as confidential.

EPA provides confidential information to enrollees working under the following cooperative agreements:

Cooperative Agreement No.	Organization
National Association for Hispanic Elderly	
CQ–832815	NAHE
CQ–832816	NAHE
CQ–832820	NAHE
National Asian Pacific Center on Aging	
National Caucus and Center on Black Aged, Inc.	
CQ–832550	NCBA
CQ–832790	NCBA
CQ–832791	NCBA
CQ–832792	NCBA
CQ–832793	NCBA
CQ–832794	NCBA
CQ–832795	NCBA
National Council on the Aging, Inc.	
CQ–832227	NCOA
CQ–832396	NCOA
CQ–832718	NCOA
National Older Workers Career Center	
CQ–830918	NOWCC
CQ–830969	NOWCC
CQ–831021	NOWCC
CQ–831022	NOWCC
CQ–831023	NOWCC
CQ–832729	NOWCC
Senior Service America, Inc.	
CQ–832396	SSAI
CQ–832427	SSAI
CQ–832625	SSAI
CQ–832626	SSAI

Among the procedures established by EPA confidentiality regulations for granting access is notification to the submitters of confidential data that SEE grantee organizations and their enrollees will have access. 40 CFR 2.201(h)(2)(iii). This document is intended to fulfill that requirement.

The grantee organizations are required by the cooperative agreements to protect confidential information. SEE enrollees are required to sign confidentiality agreements and to adhere to the same security procedures as Federal employees.

Dated: December 22, 2005.

Susan Street,

SEE Program Manager, Customer Services Support Center (3661A).

[FR Doc. E6–403 Filed 1–13–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8021–6]

Guidelines for Awarding Clean Water Act Section 319 Base Grants to Indian Tribes in FY 2006; Request for Proposals From Indian Tribes for Competitive Grants Under Clean Water Act Section 319 in FY 2006 (CFDA 66.460—Nonpoint Source Implementation Grants; Funding Opportunity Number EPA–OW–OWOW–06–2)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of guidelines for Section 319 Base Grants and Request for Proposals for Section 319 Competitive Grants.

SUMMARY: This notice publishes EPA's national guidelines for the award of base grants and EPA's Request for Proposals (RFP) for the award of supplemental funding in the form of competitive grants under the Clean Water Act (CWA) section 319(h) nonpoint source (NPS) grants program to Indian Tribes in FY 2006. Section 319 of the CWA authorizes EPA to award grants to eligible Tribes for the purpose of assisting them in implementing approved NPS management programs developed pursuant to section 319(b). The primary goal of the NPS management program is to control NPS pollution through implementation of management measures and practices to reduce pollutant loadings resulting from each category or subcategory of NPSs identified in the Tribe's NPS assessment report developed pursuant to section 319(a). EPA intends to award a total of $7,000,000 to eligible Tribes which have approved NPS assessments and management programs and ''treatment-as-a-state'' (TAS) status as of October 14, 2005. EPA expects the allocation of funds will be similar to the amount distributed in FY 2005, which included approximately $2.8 million in base grants awarded to 84 Tribes and $4.2 million awarded to 31 Tribes through a competitive process. Section A includes

EPA's national guidelines which govern the process for awarding base grants to all eligible Tribes, and section B is the national RFP for awarding the remaining funds on a competitive basis.

DATES: This notice is effective January 17, 2006.

FOR FURTHER INFORMATION CONTACT: Stacie Craddock, Office of Wetlands, Oceans, and Watersheds, Assessment and Watershed Protection Division, telephone: (202) 566–1204; fax: (202) 566–1331, e-mail: *craddock.stacie@epa.gov*. Also contact the appropriate EPA Regional Tribal NPS Coordinator identified in section B.VII.

SUPPLEMENTARY INFORMATION:

Background

For the seventh year in a row, Congress has authorized EPA to award NPS control grants to Indian Tribes in FY 2006 in an amount that exceeds the statutory cap (in section 518(f) of the CWA) of ⅓ of 1 percent of the total section 319 appropriation. There is continuing recognition that Indian Tribes need increased financial support to implement NPS programs that address critical water quality concerns on Tribal lands. EPA will continue to work closely with the Tribes to assist them in developing and implementing effective Tribal NPS pollution programs.

EPA was pleased by the quality of the Tribes' work plans that formed the basis of the grants awarded to Tribes in FY 2005, which included approximately $2.8 million in base grants awarded to 84 Tribes and $4.2 million awarded to 31 Tribes for specific watershed projects through a competitive process. We believe that the FY 2005 grants were directed towards high-priority activities that will produce on-the-ground results that provide improved water quality. We look forward to working with Tribes again in FY 2006 to implement successful projects addressing the extensive NPS control needs throughout Indian country.

Guidelines for Awarding CWA Section 319 Base Grants to Indian Tribes in FY 2006 (See Section A Below)

Section 319 of the CWA authorizes EPA to award grants to eligible Tribes for the purpose of assisting them in implementing approved NPS management programs developed pursuant to section 319(b). The primary goal of the NPS management program is to control NPS pollution through implementation of management measures and practices to reduce pollutant loadings resulting from each category or subcategory of NPSs identified in the Tribe's NPS assessment report developed pursuant to section 319(a). EPA will award section 319 base grants to eligible Tribes in the amount of $30,000 or $50,000 (depending on land area). Section 319 base funds may be used for a range of activities that implement the Tribe's approved NPS management program, including: Hiring a program coordinator; conducting NPS education programs; providing training and authorized travel to attend training; updating the NPS management program; developing watershed-based plans; and implementing, alone or in conjunction with other agencies or other funding sources, watershed-based plans and on-the-ground watershed projects.

Request for Proposals From Indian Tribes for Competitive Grants Under Clean Water Act Section 319 in FY 2006 (See Section B Below)

Overview Information:

This RFP is issued pursuant to section 319(h) of the CWA. Section 319 of the CWA authorizes EPA to award grants to eligible Tribes for the purpose of assisting them in implementing approved NPS management programs developed pursuant to section 319(b). The primary goal of the NPS management program is to control NPS pollution through implementation of management measures and practices to reduce pollutant loadings resulting from each category or subcategory of NPSs identified in the Tribe's NPS assessment report developed pursuant to section 319(a). EPA has set aside a portion of section 319 funds appropriated by Congress for competitive grant awards to Tribes for the purpose of funding: (1) The development of watershed-based plans; and/or (2) the implementation of watershed projects that implement a watershed-based plan; and/or (3) the implementation of other watershed projects not implementing a watershed-based plan. Tribes are strongly encouraged to submit proposals that develop and/or implement watershed-based plans designed to protect unimpaired waters and restore NPS-impaired waters. EPA believes that watershed-based plans provide the best means for preventing and resolving NPS problems and threats. Watershed-based plans provide a coordinating framework for solving water quality problems by providing a specific geographic focus, integrating strong partnerships, integrating strong science and data, and coordinating priority setting and integrated solutions. EPA anticipates awarding approximately 30 competitive grants, subject to availability of funds and the quality of applications submitted. Eligible Tribes may apply for competitive funding by submitting a proposal for up to a maximum budget of $150,000 of federal section 319 funding (plus the additional required match of the total project cost).

Federal Agency Name: EPA.

Funding Opportunity Title: Tribal Nonpoint Source Implementation Grants.

Announcement Type: Request for Proposals.

Funding Opportunity Number: EPA–OW–OWOW–06–2.

Catalog of Federal Domestic Assistance (CFDA) Number: 66.460.

Dates:

Date EPA uses to determine eligibility to receive competitive 319 grants. October 14, 2005.

Deadline for Tribes to submit proposals to Region or electronically through grants.gov. March 1, 2006.

Headquarters notifies Regions/Tribes of selections for competitive 319 grants. May 5, 2006.

Tribes submit final grant application to Region for competitive 319 grants. June 5, 2006.

Other than the date EPA will use to determine eligibility to receive 319 grants, the dates above are the anticipated dates for those actions.

Dated: January 9, 2006.

Benjamin H. Grumbles,

Assistant Administrator for Water.

Section A. Guidelines for Awarding Clean Water Act Section 319 Base Grants to Indian Tribes in FY 2006

I. General

Each eligible Tribe will receive base funding in accordance with the following land area scale:

Square miles (acres)	Base amount
Less than 1,000 sq. mi. (less than 640,000 acres)	$30,000
Over 1,000 sq. mi. (over 640,000 acres)	50,000

The land area scale is the same as used in previous years. EPA continues to rely upon land area as the deciding factor for allocation of funds because NPS pollution is strongly related to land use; thus land area is a reasonable factor that generally is highly relevant to identifying Tribes with the greatest needs (recognizing that many Tribes have needs that significantly exceed available resources).

Section 319 base funds may be used for a range of activities that implement the Tribe's approved NPS management program, including: Hiring a program coordinator; conducting NPS education programs; providing training and

authorized travel to attend training; updating the NPS management program; developing watershed-based plans; and implementing, alone or in conjunction with other agencies or other funding sources, watershed-based plans and on-the-ground watershed projects. In general, base funding should not be used for general assessment activities (*e.g.,* monitoring the general status of reservation waters, which may be supported with CWA section 106 funding). EPA encourages Tribes to use section 319 funding, and explore the use of other funding such as CWA section 106 funding, to support project-specific water quality monitoring, data management, data analysis, assessment activities, and the development of watershed-based plans.

II. Eligibility and Match Requirements

To be eligible for NPS base grants, a Tribe must: (1) Be federally recognized; (2) have an approved NPS assessment report in accordance with CWA section 319(a); (3) have an approved NPS management program in accordance with CWA section 319(b); and (4) have ''treatment-as-a-state'' (TAS) status in accordance with CWA section 518(e). To be eligible for NPS grants in FY 2006, Tribes must meet these eligibility requirements as of October 14, 2005 (as announced in the FY 2005 guidelines on December 22, 2004 at 69 FR 76733). Tribes should contact their EPA Regional Tribal NPS Coordinator for further information about the eligibility process (*see* section B.VII for Agency contact information).

Section 319(h)(3) of the CWA requires that the match for NPS grants is 40 percent of the total project cost. In general, as required in 40 CFR 31.24, the match requirement can be satisfied by any of the following: Allowable costs incurred by the grantee, subgrantee, or a cost-type contractor, including those allowable costs borne by non-federal grants; by cash donations from non-federal third parties; or by the value of third party in-kind contributions.

EPA's regulations also provide that EPA may decrease the match requirement to as low as ten percent if the Tribe can demonstrate in writing to the Regional Administrator that fiscal circumstances within the Tribe or within each Tribe that is a member of the intertribal consortium are constrained to such an extent that fulfilling the match requirement would impose undue hardship (*see* 40 CFR 35.635). In making grant awards to Tribes that provide for a reduced match requirement, Regions must include a brief finding in the final award package that the Tribe has demonstrated that it does not have adequate funds to meet the required match.

III. Application Requirements for Base Allocation Grants

1. Address To Request Application Package for Base Allocation Grants

Applicants may download individual grant application forms, or electronically request a paper application package and an accompanying computer CD of information related to applicants/grant recipients roles and responsibilities from EPA's Grants Web site by visiting: *http://www.epa.gov/ogd/grants/how_to_apply.htm*. Please note that only the narrative work plan needs to be included in the initial application. If your application is approved, a complete application package will need to be submitted by June 5, 2006.

2. Content and Form of Application Submission for Base Allocation Grants

Section 319 base funds may be used for a range of activities that implement the Tribe's approved NPS management program, including: Hiring a program coordinator; conducting NPS education programs; providing training and authorized travel to attend training; updating the NPS management program; developing watershed-based plans; and implementing, alone or in conjunction with other agencies or other funding sources, watershed-based plans and on-the-ground watershed projects.

The specific content and form of the application for the award of section 319 base grants is as follows:

a. Narrative Work Plan

Tribes must submit a work plan to receive base funding for FY 2006. All work plans must be consistent with the Tribe's approved NPS management program and conform to legal requirements that are applicable to all environmental program grants awarded to Tribes (*see* 40 CFR 35.505 and 35.507) as well as the grant requirements which specifically apply to NPS management grants (*see* 40 CFR 35.638). As provided in 40 CFR 35.507, 40 CFR 35.515, and 40 CFR 35.638, all work plans must include:

i. Description of each significant category of NPS activity to be addressed;

ii. Work plan components;

iii. Work plan commitments for each work plan component;

iv. Estimated funding amounts for each work plan component;

v. Estimated work years for each work plan component;

vi. Roles and responsibilities of the recipient and EPA in carrying out the work plan commitments; and

vii. Reporting schedule and a description of the performance evaluation process that will be used that accounts for: (a) A discussion of accomplishments as measured against work plan commitments; (b) a discussion of the cumulative effectiveness of the work performed under all work plan components; (c) a discussion of existing and potential problem areas; and (d) suggestions for improvement, including, where feasible, schedules for making improvements.

b. Work Plan To Develop a Watershed-Based Plan

If a Tribe submits a work plan to develop a watershed-based plan, it must include a commitment to incorporate the nine components of a watershed-based plan identified in section A.V.1 below.

c. Work Plan To Implement a Watershed-Based Plan

If a Tribe submits a work plan to implement a watershed-based plan, it must be accompanied by a statement that the Region finds that the watershed-based plan to be implemented includes the nine components of a watershed-based plan identified in section A.V.1 below.

IV. Submission Dates and Times for Initial Applications for Base Funding

Eligible Tribes must submit to the appropriate EPA Regional Tribal NPS Coordinator applications for base funding by 5 p.m. local time on March 1, 2006 (see section B.VII for Agency contact information). Each EPA Region will review the proposed work plan for base funding and, where appropriate, recommend improvements to the plan by March 15, 2006. The Tribe must submit a final work plan by April 14, 2006. If a Tribe has not submitted an approvable work plan for base funding by April 14, its allocated amount will be added to the competitive pool which will be used to fund Tribal NPS competitive grants (*see* section B).

V. Watershed-Based Plans

EPA strongly encourages Tribes to use section 319 funding for the development and/or implementation of watershed-based plans to protect unimpaired waters and restore NPS-impaired waters. EPA also encourages Tribes to explore the use of other funding such as CWA section 106 funding to support the development of watershed-based plans. EPA believes that watershed-based plans provide the best means for preventing and resolving NPS problems and threats. Watershed-based plans provide a coordinating framework for solving water quality problems by providing a specific geographic focus, integrating strong partnerships,

integrating strong science and data, and coordinating priority setting and integrated solutions. This section outlines the specific information that should be included in all watershed-based plans that are developed or implemented using section 319 funding. This information correlates with the elements of a watershed-based plan outlined in the NPS grants guidelines for States (*see FY 2004 Nonpoint Source Program and Grants Guidelines for States and Territories*, available at *http://www.epa.gov/owow/nps/cwact.html*). One significant difference from the State guidelines is that a watershed-based plan for Tribes provides for the integration of ''water quality-based goals'' (*see* element (c) below), whereas the State guidelines call for specific estimates of load reductions that are expected to be achieved by implementing the plan. EPA has incorporated this flexibility for Tribes in recognition that not all Tribes have yet developed water quality standards and many Tribes may need additional time and/or technical assistance in order to develop more sophisticated estimates of the NPS pollutants that need to be addressed. Where such information does exist, or is later developed, EPA expects that it will be incorporated as appropriate into the watershed-based plan.

To the extent that information already exists in other documents (*e.g.*, NPS assessment reports or NPS management programs), the information may be incorporated by reference into the watershed-based plan. Thus, the Tribe need not duplicate any existing process or document that already provides needed information.

1. Components of a Watershed-Based Plan

a. An identification of the causes and sources or groups of similar sources that will need to be controlled to achieve the goal identified in element (c) below. Sources that need to be controlled should be identified at the significant subcategory level with estimates of the extent to which they are present in the watershed (*e.g.*, X number of dairy cattle feedlots needing upgrading, including a rough estimate of the number of cattle per facility; Y acres of row crops needing improved nutrient management or sediment control; or Z linear miles of eroded streambank needing remediation).

b. A description of the NPS management measures that will need to be implemented to achieve a water quality-based goal described in element (c) below, as well as to achieve other watershed goals identified in the watershed-based plan, and an identification (using a map or a description) of the critical areas which those measures will be needed to implement the plan.

c. An estimate of the water quality-based goals expected to be achieved by implementing the measures described in element (b) above. To the extent possible, estimates should identify specific water quality-based goals, which may incorporate, for example: Load reductions; water quality standards for one or more pollutants/uses; NPS total maximum daily load allocations; measurable, in-stream reductions in a pollutant; or improvements in a parameter that indicates stream health (*e.g.*, increases in fish or macroinvertebrate counts). If information is not available to make specific estimates, water quality-based goals may include narrative descriptions and best professional judgment based on existing information.

d. An estimate of the amounts of technical and financial assistance needed, associated costs, and/or the sources and authorities that will be relied upon to implement the plan. As sources of funding, Tribes should consider other relevant Federal, State, local and private funds that may be available to assist in implementing the plan.

e. An information and education component that will be used to enhance public understanding and encourage early and continued participation in selecting, designing, and implementing the NPS management measures that will be implemented.

f. A schedule for implementing the NPS management measures identified in this plan that is reasonably expeditious.

g. A description of interim, measurable milestones for determining whether NPS management measures or other control actions are being implemented.

h. A set of criteria that can be used to determine whether the water quality-based goals are being achieved over time and substantial progress is being made towards attaining water quality-based goals and, if not, the criteria for determining whether the watershed-based plan needs to be revised.

i. A monitoring component to evaluate the effectiveness of the implementation efforts over time, measured against the criteria established under element (h) above.

EPA recognizes the difficulty of developing the information described above with precision and, as these guidelines reflect, believes that there must be a balanced approach to address this concern. On one hand, it is absolutely critical that Tribes make, at the subcategory level, a reasonable effort to identify the significant sources; identify the management measures that will most effectively address those sources; and broadly estimate the expected water quality-based goals that will be achieved. Without such information to provide focus and direction, it is much less likely that a project that implements the plan can efficiently and effectively address the NPSs of water quality impairments. On the other hand, EPA recognizes that even with reasonable steps to obtain and analyze relevant data, the available information at the planning stage (within reasonable time and cost constraints) may be limited; preliminary information and estimates may need to be modified over time, accompanied by mid-course corrections in the watershed plan; and it often will require a number of years of effective implementation to achieve the goals. EPA fully intends that the watershed planning process described above should be implemented in a dynamic and iterative manner to assure that projects implementing the plan may proceed even though some of the information in the watershed plan is imperfect and may need to be modified over time as information improves.

2. Scale and Scope of Watershed-Based Plans

The watershed-based plan should address a large enough geographic area so that its implementation addresses all of the significant sources and causes of impairments and threats to the waterbody in question. EPA recognizes that many Tribes may face jurisdictional limitations outside reservation boundaries. To the extent possible, EPA encourages Tribes to engage other partners and include mixed ownership watersheds when appropriate to solve the water quality problems (*e.g.,* Tribal, Federal, State, and private lands). While there is no rigorous definition or delineation for this concept, the general intent is to avoid single segments or other narrowly defined areas that do not provide an opportunity for addressing a watershed's stressors in a rational and economic manner. At the same time, the scale should not be so large as to minimize the probability of successful implementation.

Once a watershed-based plan that contains the information identified above has been established, it can be used as the foundation for preparing annual work plans. Like the NPS management program approved under section 319(b), a watershed-based plan may be a multi-year planning document. Whereas the NPS management program

provides overall program guidance to address NPS pollution on Tribal lands, a watershed-based plan focuses NPS planning on a particular watershed identified as a priority in the NPS management program. Due to the greater specificity of a watershed-based plan, it will generally have considerably more detail than a NPS management program, and identified portions may be implemented through highly specific annual work plans. While the watershed-based plan can be considered a subset of the NPS management program, the annual work plan can be considered a subset of the watershed-based plan.

A Tribe may choose to implement the watershed-based plan in prioritized portions (*e.g.,* based on particular segments, other geographic subdivisions, NPS categories in the watershed, or specific pollutants or impairments), consistent with the schedule established pursuant to item (f) above. In doing so, Tribes may submit annual work plans for section 319 grant funding that implement specific portions of the watershed-based plan. A watershed-based plan is a strategic plan for long-term success; annual work plans are the specific ''to-do lists'' to achieve that long-term success.

VI. Base Grant Requirements

1. Performance Partnership Grants

Performance Partnership Grants (PPG) enable Tribes to combine funds from more than one environmental program grant into a single grant with a single budget. If the Tribe includes the section 319 grant as a part of an approved PPG, the match requirement may be reduced to 5 percent of the allowable cost of the work plan budget for the first 2 years in which the Tribe receives a PPG; after 2 years, the match may be increased up to 10 percent of the work plan budget (as determined by the Regional Administrator). (*See* 40 CFR 35.536).

A section 319 base grant awarded under this notice should not be included in a PPG unless the work plan upon which a decision is made to award the grant is included in the PPG. If a proposed PPG work plan differs significantly from the section 319 work plan approved for funding, the Regional Administrator must consult with the National Program Manager. (*See* 40 CFR 35.535). The purpose of this requirement is to avoid any potential that the project will not ultimately be implemented once commingled with other grant programs in a PPG.

2. Intertribal Consortia

Some Tribes have formed intertribal consortia to promote cooperative work. An intertribal consortium is a partnership between two or more Tribes that is authorized by the governing bodies of those Tribes to apply for and receive assistance under this program. (*See* 40 CFR 35.502.) Individual Tribes who are a part of an intertribal consortia that is awarded a section 319 base grant may not also be awarded an individual section 319 base grant. (Note that individual Tribes may still be eligible to apply for competitive funds described below in Section B if they do not also submit a proposal for competitive funds as part of an intertribal consortium.) The intertribal consortium is eligible only if the consortium demonstrates that all its members meet the eligibility requirements for the section 319 program and authorize the consortium to apply for and receive assistance in accordance with 40 CFR 35.504. An intertribal consortium must submit to EPA adequate documentation of the existence of the partnership and the authorization of the consortium by its members to apply for and receive the grant. (*See* 40 CFR 35.504.)

3. Non-Tribal Lands

The following discussion explains the extent to which section 319 grants may be awarded to Tribes for use outside the reservation. We discuss two types of off-reservation activities: (1) Activities that are related to waters within a reservation, such as those relating to sources upstream of a waterway entering the reservation; and (2) activities that are unrelated to waters of a reservation. As discussed below, the first type of these activities may be eligible; the second is not.

a. Activities That Are Related to Waters Within a Reservation

Section 518(e) of the CWA provides that EPA may treat an Indian Tribe as a State for purposes of section 319 of the CWA if, among other things, ''the functions to be exercised by the Indian Tribe pertain to the management and protection of water resources which are * * * within the borders of an Indian reservation'' (*see* 33 U.S.C. 1377(e)(2)). EPA already awards grants to Tribes under section 106 of the CWA for activities performed outside of a reservation (on condition that the Tribe obtains any necessary access agreements and coordinates with the State, as appropriate) that pertain to reservation waters, such as evaluating impacts of upstream waters on water resources within a reservation. Similarly, EPA has awarded section 106 grants to States to conduct monitoring outside of State borders. EPA has concluded that grants awarded to an Indian Tribe pursuant to section 319 may similarly be used to perform eligible section 319 activities outside of a reservation if: (1) The activity pertains to the management and protection of waters within a reservation; and (2) just as for on-reservation activities, the Tribe meets all other applicable requirements.

b. Activities That Are Unrelated to Waters of a Reservation

As discussed above, EPA is authorized to award section 319 grants to Tribes to perform eligible section 319 activities if the activities pertain to the management and protection of waters within a reservation and the Tribe meets all other applicable requirements. In contrast, EPA is not authorized to award section 319 grants for activities that do not pertain to waters of a reservation. For off-reservation areas, including ''usual and accustomed'' hunting, fishing, and gathering places, EPA must determine whether the activities pertain to waters of a reservation prior to awarding a grant.

4. Administrative Costs

Pursuant to CWA section 319(h)(12), administrative costs in the form of salaries, overhead, or indirect costs for services provided and charged against activities and programs carried out with the grant shall not exceed 10 percent of the grant award. The costs of implementing enforcement and regulatory activities, education, training, technical assistance, demonstration projects, and technology transfer are not subject to this limitation.

5. Satisfactory Progress

For a Tribe (or intertribal consortium) that received section 319 funds in the preceding fiscal year, section 319(h)(8) of the CWA requires that the Region determine whether the Tribe made ''satisfactory progress'' during the previous fiscal year in meeting the schedule of activities specified in its approved NPS management program. The Region will base this determination on an examination of Tribal activities, reports, reviews, and other documents and discussions with the Tribe in the previous year. Regions must include in each section 319 base funding allocation (or in a separate document, such as the grant-issuance cover letter, that is signed by the same EPA official who signs the grant), a written determination that the Tribe has made satisfactory progress during the previous fiscal year in meeting the schedule of milestones

specified in its NPS management program. The Regions must include brief explanations that support their determinations.

VII. Technical Assistance to Tribes

In addition to providing NPS grant funding to Tribes, EPA remains committed to providing continued technical assistance to Tribes in their efforts to control NPS pollution. During the past nine years, EPA has presented many workshops to Tribes nationwide to assist them in developing: (1) NPS assessments to further their understanding of NPS pollution and its impact on water quality; (2) NPS management programs to apply solutions to address their NPS problems; and (3) specific projects to effect on-the-ground solutions. The workshops have provided information on related EPA and other programs that can help Tribes address NPSs, including the provision of technical and funding assistance. Other areas of technical assistance include watershed-based planning, water quality monitoring, section 305(b) reports on water quality, and section 303(d) lists of impaired waters. EPA intends to continue providing NPS workshops to interested Tribes in FY 2006 and to provide other appropriate technical assistance as needed. EPA also intends to include special emphasis in the workshops on the development and implementation of watershed-based plans that are designed to address on-the-ground water quality improvements.

VIII. Anticipated Deadlines and Milestones for FY 2006 Base Grants

Date for Tribes to be eligible for 319 grants. October 14, 2005.

Tribes submit base grant initial application to Region. March 1, 2006 (anticipated).

Region comments on Tribe's base grant work plan. March 15, 2006 (anticipated).

Tribes submit final base grant work plan to Region. April 14, 2006 (anticipated).

Tribes submit final grant application to Region. June 5, 2006 (anticipated).

Other than the date EPA will use to determine eligibility to receive 319 grants, the dates above are the anticipated dates for those actions.

IX. Anticipated Deadlines and Milestones for FY 2007 Base Grants

Beginning in FY 2007, the schedule for submitting work plans and awarding section 319 base grants will be modified to expedite the grant awards process. These modifications are intended to ensure that award decisions are made earlier in the fiscal year to provide adequate time for Tribes to implement projects within the applicable fiscal year.

Date for Tribes to be eligible for 319 grants. October 13, 2006.

Tribes submit base grant initial application to Region. December 1, 2006 (anticipated).

Region comments on Tribe's base grant work plan. December 15, 2006 (anticipated).

Tribes submit final base grant work plan to Region. January 16, 2007 (anticipated).

Tribes submit final grant application to Region. April 5, 2007 (anticipated).

Other than the date EPA will use to determine eligibility to receive 319 grants, the dates above are the anticipated dates for those actions.

Section B. Request for Proposals From Indian Tribes for Competitive Grants under Clean Water Act Section 319 in FY 2006 (Funding Opportunity Number EPA–OW–OWOW–06–2)

I. Funding Opportunity Description for Competitive Grants

This RFP is issued pursuant to section 319(h) of the Clean Water Act (CWA). Section 319 of the CWA authorizes EPA to award grants to eligible Tribes for the purpose of assisting them in implementing approved nonpoint source (NPS) management programs developed pursuant to section 319(b). The primary goal of the NPS management program is to control NPS pollution through implementation of management measures and practices to reduce pollutant loadings resulting from each category or subcategory of NPSs identified in the Tribe's NPS assessment report developed pursuant to section 319(a). EPA has set aside a portion of the section 319 funds appropriated by Congress for competitive grant awards to Tribes for the purpose of funding: (1) The development of watershed-based plans; and/or (2) the implementation of watershed projects that implement a watershed-based plan; and/or (3) the implementation of other watershed projects not implementing a watershed-based plan. Tribes are strongly encouraged to submit proposals that develop and/or implement watershed-based plans designed to protect unimpaired waters and restore NPS-impaired waters.

Grants awarded under this RFP will advance the protection and improvement of water quality in support of Goal 2 (Clean and Safe Water), Objective 2 (Protect Water Quality), Sub-objective 1 (Protect and Improve Water Quality on a Watershed Basis) of EPA's Strategic Plan (*see http://www.epa.gov/ocfo/plan/plan.htm*). In support of Sub-objective 2.2.1, and consistent with EPA Order 5700.7 on *Environmental Results under EPA Assistance Agreements* (*see http://www.epa.gov/ogd/grants/award/5700.7.pdf*), grants awarded under this RFP will be expected to accomplish various environmental outcomes and outputs as described below. Applicants must discuss anticipated environmental outcomes and outputs in proposed work plan objectives and performance measures.

Expected environmental outcomes mean the result, effect, or consequence that will occur from carrying out an environmental program or activity that is related to an environmental or programmatic goal or objective. Outcomes may be environmental, behavioral, health-related or programmatic in nature, must be quantitative, and may not necessarily be achieved within an assistance agreement funding period. Examples of outcomes from the grants to be awarded under this RFP may include but are not limited to: an increased number of NPS-impaired waterbodies that have been partially or fully restored to meet water quality standards or other water quality-based goals established by the Tribes; and/or an increased number of waterbodies that have been protected from NPS pollution.

Expected environmental outputs (or deliverables) refer to an environmental activity, effort, and/or associated work product related to an environmental goal or objective, that will be produced or provided over a period of time or by a specified date. Outputs may be quantitative or qualitative but must be measurable during an assistance agreement funding period. Examples of environmental outputs under the grants awarded under this RFP may include but are not limited to: a watershed-based plan, progress reports, or a particular number of on-the-ground management measures or practices installed or implemented during the project period. Including the environmental output of a watershed-based plan furthers progress towards achieving the specific indicator measure for Sub-objective 2.2.1 in EPA's Strategic Plan which measures the number of Tribes that have developed and begun to implement a watershed-based plan for Tribal waters (*see* Measure WQ–28, EPA's National Water Program Guidance for FY 2006 at *http://www.epa.gov/water/waterplan/#nwp06*).

II. Award Information

In FY 2005, EPA awarded approximately $4.2 million to 31 Tribes for specific watershed projects through a competitive process. EPA expects that the amount of competitive funding available in FY 2006 will be similar or slightly lower than the amount available in FY 2005, since the availability of competitive funding is dependent, in part, upon the amount of funding that remains after a portion is first distributed as base grants to all eligible Tribes (which may increase due to additional Tribes entering the NPS program).

EPA anticipates awarding approximately 30 competitive grants, subject to availability of funds and the quality of applications submitted under this RFP. Eligible Tribes may apply for competitive funding by submitting a proposal up to a maximum budget of $150,000 of federal section 319 funding (plus the additional required match of the total project cost). Proposals evaluated, but not selected for this funding, may be retained for consideration for possible future awards if additional funding materializes. Any additional selections for award under this RFP based on additional funding will be in accordance with the rankings developed by the review Committee (discussed below in section B.V.2) and must be made within six months of the original competitive funding decisions.

EPA reserves the right to make partial awards by funding discrete activities, portions, or phases of the proposal. If EPA decides to partially fund the proposal, it will do so in a manner that does not prejudice any applicants or affect the basis upon which the proposal/application, or portion thereof, was evaluated and selected for award, and that maintains the integrity of the competition and the evaluation/selection process.

III. Eligibility Information

1. Eligible Applicants

To be eligible for NPS grants, a Tribe or intertribal consortium must: (1) Be federally recognized; (2) have an approved NPS assessment report in accordance with CWA section 319(a); (3) have an approved NPS management program in accordance with CWA section 319(b); and (4) have ''treatment-as-a-state'' (TAS) status in accordance with CWA section 518(e). To be eligible for NPS grants in FY 2006, Tribes must meet these eligibility requirements as of October 14, 2005.

Some Tribes have formed intertribal consortia to promote cooperative work. An intertribal consortium is a partnership between two or more Tribes that is authorized by the governing bodies of those Tribes to apply for and receive assistance under this program. (*See* 40 CFR 35.502.) Individual Tribes who are a part of an intertribal consortia that is awarded a section 319 competitive grant may not also be awarded an individual section competitive 319 grant. (Note that individual Tribes may still be eligible to apply for base funds described above in Section A if they do not also submit a proposal for base funds as part of an intertribal consortium.)

The intertribal consortium is eligible only if the consortium demonstrates that all its members meet the eligibility requirements for the section 319 program and authorize the consortium to apply for and receive assistance in accordance with 40 CFR 35.504. An intertribal consortium must submit to EPA adequate documentation of the existence of the partnership and the authorization of the consortium by its members to apply for and receive the grant. (*See* 40 CFR 35.504.)

2. Cost Sharing or Matching

Section 319(h)(3) of the CWA requires that the match for NPS grants is 40 percent of the total project cost. In general, as required in 40 CFR 31.24, the match requirement can be satisfied by any of the following: Allowable costs incurred by the grantee, subgrantee, or a cost-type contractor, including those allowable costs borne by non-federal grants; by cash donations from non-federal third parties; or by the value of third party in-kind contributions.

EPA's regulations also provide that EPA may decrease the match requirement to as low as ten percent if the Tribe can demonstrate in writing to the Regional Administrator that fiscal circumstances within the Tribe or within each Tribe that is a member of the intertribal consortium are constrained to such an extent that fulfilling the match requirement would impose undue hardship. (*See* 40 CFR 35.635.) In making grant awards to Tribes that provide for a reduced match requirement, Regions must include a brief finding in the final award package that the Tribe has demonstrated that it does not have adequate funds to meet the required match.

Performance Partnership Grants (PPG) enable Tribes to combine funds from more than one environmental program grant into a single grant with a single budget. If the Tribe includes the section 319 competitive grant as a part of an approved PPG, the match requirement may be reduced to 5 percent of the allowable cost of the work plan budget for the first 2 years in which the Tribe receives a PPG; after 2 years, the match may be increased up to 10 percent of the work plan budget (as determined by the Regional Administrator). (*See* 40 CFR 35.536).

A section 319 grant awarded under this RFP should not be included in a PPG unless the work plan upon which a decision is made to award the competitive grant is included in the PPG. If a proposed PPG work plan differs significantly from the section 319 work plan approved for funding under this RFP, the Regional Administrator must consult with the National Program Manager. (*See* 40 CFR 35.535). The purpose of this requirement is to avoid any potential that the project will not ultimately be implemented once commingled with other grant programs in a PPG.

3. Threshold Evaluation Criteria

In addition to applicant eligibility and cost-share (discussed above in sections B.III.1 and B.III.2, respectively), all of the following additional threshold evaluation criteria must be met in order for a Tribe's application to be evaluated under section B.V and be considered for award.

a. An individual Tribe (or intertribal consortium) may not be awarded competitive funding for more than one competitive grant proposal in a given year.

b. An individual Tribe (or intertribal consortium) may apply for competitive funding by submitting a proposal up to a maximum budget of $150,000 of federal section 319 funding (plus the additional required match of the total project cost). If a Tribe submits a proposal that exceeds $150,000 (of federal section 319 funding), it will be rejected from further consideration.

c. All applications must propose to fund activities that are related to waters within a reservation or they will be rejected. Section 319 grants may be awarded to Tribes for use outside the reservation only if they fund activities that are related to waters within a reservation, such as those relating to sources upstream of a waterway entering the reservation.

i. Activities That Are Related to Waters Within a Reservation

Section 518(e) of the CWA provides that EPA may treat an Indian Tribe as a State for purposes of section 319 of the CWA if, among other things, ''the functions to be exercised by the Indian Tribe pertain to the management and protection of water resources which are * * * within the borders of an Indian reservation'' (*see* 33 U.S.C. 1377(e)(2)).

EPA already awards grants to Tribes under section 106 of the CWA for activities performed outside of a reservation (on condition that the Tribe obtains any necessary access agreements and coordinates with the State, as appropriate) that pertain to reservation waters, such as evaluating impacts of upstream waters on water resources within a reservation. Similarly, EPA has awarded section 106 grants to States to conduct monitoring outside of State borders. EPA has concluded that grants awarded to an Indian Tribe pursuant to section 319 may similarly be used to perform eligible section 319 activities outside of a reservation if: (1) The activity pertains to the management and protection of waters within a reservation; and (2) just as for on-reservation activities, the Tribe meets all other applicable requirements.

ii. Activities That Are Unrelated to Waters of a Reservation

As discussed above, EPA is authorized to award section 319 grants to Tribes to perform eligible section 319 activities if the activities pertain to the management and protection of waters within a reservation and the Tribe meets all other applicable requirements. In contrast, EPA is not authorized to award section 319 grants for activities that do not pertain to waters of a reservation. For off-reservation areas, including ''usual and accustomed'' hunting, fishing, and gathering places, EPA must determine whether the activities pertain to waters of a reservation prior to awarding a grant.

d. All work plans must be consistent with the Tribe's approved NPS management program and conform to legal requirements that are applicable to all environmental program grants awarded to Tribes (*see* 40 CFR 35.505 and 35.507) as well as the legal requirements that specifically apply to NPS management grants (*see* 40 CFR 35.638). As provided in those regulations, all proposed work plans must include:

i. Description of each significant category of NPS activity to be addressed;

ii. Work plan components;

iii. Work plan commitments for each work plan component, including anticipated environmental outcomes and outputs (as required by EPA Order 5700.7) and the applicant's plan for tracking and measuring its progress towards achieving the expected outcomes and outputs identified in Section B.I of this RFP;

iv. Estimated funding amounts for each work plan component;

v. Estimated work years for each work plan component;

vi. Roles and responsibilities of the recipient and EPA in carrying out the work plan commitments; and

vii. Reporting schedule and a description of the performance evaluation process that will be used that accounts for: (a) A discussion of accomplishments as measured against work plan commitments and anticipated environmental outcomes and outputs; (b) a discussion of the cumulative effectiveness of the work performed under all work plan components; (c) a discussion of existing and potential problem areas; and (d) suggestions for improvement, including, where feasible, schedules for making improvements.

IV. Application and Submission Information

EPA will respond to questions from individual applicants regarding threshold eligibility criteria, administrative issues related to the submission of the proposal/application, and requests for clarification about the announcement. Questions must be submitted before February 15, 2006 in writing to the appropriate EPA Regional Tribal NPS Coordinator and written responses will be posted on EPA's Web site at: *http://www.epa.gov/owow/nps/tribal.* In accordance with EPA's Competition Policy (EPA Order 5700.5A1), EPA staff will not meet with individual applicants to discuss draft proposals, provide informal comments on draft proposals, or provide advice to applicants on how to respond to ranking criteria. Applicants are responsible for the contents of their applications.

1. Address To Request Application Package

Applicants may download individual grant application forms, or electronically request a paper application package and an accompanying computer CD of information related to applicants/grant recipients roles and responsibilities from EPA's Grants Web site by visiting: *http://www.epa.gov/ogd/grants/how_to_apply.htm.* Applicants may also apply electronically through *http://www.grants.gov* as explained below.

2. Content and Form of Application Submission

Please note that only the one-page Standard Form 424 needs to be included in the initial application, along with the work plan narrative described in this RFP. If your application is selected, the entire grants package will need to be completed by June 5, 2006.

a. Signed Standard Form 424 (one page)

b. Narrative Work Plan

Tribes must submit a work plan following the required outline above in section B.III.3.d to be considered for competitive funding for FY 2006.

3. Submission Dates and Times for Proposals for Competitive Funding

You may submit either a paper proposal or an electronic proposal through *http://www.grants.gov* (but not both) for this announcement. If you submit a paper application, the appropriate EPA Regional Tribal NPS Coordinator must receive the SF 424 and proposed work plan described above for competitive funding by 5 p.m. local time on March 1, 2006 (*see* section B.VII for Agency contact information). If you submit your application electronically through *http://www.grants.gov,* you must meet the requirements for electronic submission outlined in section B.IV.6 below and your proposal must be received through *http://www.grants.gov* no later than 11:59 p.m. on March 1, 2006. Any application packages received after the due date will not be considered for funding.

4. Funding Restrictions

The use of competitive funding for the development of a watershed-based plan will be limited to 20 percent of the competitive award (*e.g.,* up to $30,000 of a $150,000 grant) to assure that these competitive funds are primarily focused on implementation activities. If a Tribe submits a work plan to develop a watershed-based plan, it must be submitted as a component of the overall work plan for implementing a watershed project (*i.e.,* a Tribe will not receive competitive funding only for the development of a watershed-based plan).

5. Confidential Business Information

In accordance with 40 CFR 2.203, applicants may claim all or a portion of their application/proposal as confidential business information. EPA will evaluate confidentiality claims in accordance with 40 CFR Part 2. Applicants must clearly mark applications/proposals or portions of applications/proposals they claim as confidential. If no claim of confidentiality is made, EPA is not required to make the inquiry to the applicant otherwise required by 40 CFR 2.204(c)(2) prior to disclosure.

6. Submission Instructions for Electronic Applications Using Grants.gov

In lieu of hard copy submission, you may submit the proposal described above electronically through *http://www.grants.gov* as explained below. The electronic submission of your proposal

must be made by an official representative of your institution who is registered with Grants.gov. For more information, go to *http://www.grants.gov* and click on ''Get Started,'' and then ''For AORs'' (Authorized Organizational Representative) on the left side of the page. *Note that the registration process may take a week or longer to complete.* If your organization is not currently registered with Grants.gov, please encourage your office to designate an AOR and ask that individual to begin the registration process as soon as possible.

To begin the application process for this grant program, go to *http://www.grants.gov* and click on ''Apply for Grants.'' Then click on ''Apply Step 1: Download a Grant Application Package and Application Instructions'' to download the PureEdge viewer and obtain the application package (*https://www.apply.grants.gov/forms_apps_idx.html*). You may retrieve the application package by entering either the CFDA number of 66.460 or Funding Opportunity Number EPA–OW–OWOW–06–2 in the space provided. You may also be able to access the application package by clicking on the button at the bottom right side of the synopsis on *http://www.grants.gov* that says ''Apply for Grants Electronically.''

Your organization's AOR must submit your complete proposal electronically to EPA through Grants.gov (*http://www.grants.gov*) no later than 11:59 p.m. on March 1, 2006. The application package must include the following materials:

a. Signed Standard Form 424

Complete the form. There are no attachments. Please be sure to include organization fax number and e-mail address in Block 5 of the Standard Form 424.

b. Narrative Work Plan

The work plan must include the minimum components set forth in section B.III.3.d of this RFP and will be evaluated based on the selection criteria set forth below in section B.V.1 of this announcement. Applicants who elect to use *http://www.grants.gov* to apply will need to refer to section B.III.3.d of this RFP when preparing the work plan.

Documents a and b listed above should appear in the ''Mandatory Documents'' box on the Grants.gov Grant Application page.

For Document a, click on the SF424 form and then click ''Open Form'' below the box. The fields that must be completed will be highlighted in yellow. Optional fields and completed fields will be displayed in white. If you enter an invalid response or incomplete information in a field, you will receive an error message. When you have finished filling out the form, click ''Save.'' When you return to the electronic Grant Application Package page, click on the form you just completed, and then click on the box that says, ''Move Form to Submission List.'' This action will move the document over to the box that says, ''Mandatory Completed Documents for Submission.''

For document b, you will need to attach electronic files containing the information required by section B.III.3.d of this RFP. Prepare your work plan and save it to your computer as an MS Word, PDF, or WordPerfect file. When you are ready to attach your work plan to the application package, click on ''Project Narrative Attachment Form,'' and open the form. Click ''Add Mandatory Project Narrative File,'' and then attach your work plan (previously saved to your computer) using the browse window that appears. You may then click ''View Mandatory Project Narrative File Filename;'' the file name should be no more than 40 characters long. If there are other attachments that you would like to submit to accompany your proposal, you may click ''Add Optional Project Narrative File'' and proceed as before. When you have finished attaching the necessary documents, click ''Close Form.'' When you return to the ''Grant Application Package'' page, select the ''Project Narrative Attachment Form'' and click ''Move Form to Submission List.'' The form should now appear in the box that says, ''Mandatory Completed Documents for Submission.''

Once you have finished filling out all of the forms/attachments and they appear in one of the ''Completed Documents for Submission'' boxes, click the ''Save'' button that appears at the top of the Web page. It is suggested that you save the document a second time, using a different name, since this will make it easier to submit an amended package later if necessary. Please use the following format when saving your file: ''Applicant Name—FY06 Tribal 319 Competitive Grants—1st Submission'' or ''Applicant Name—FY06 Tribal 319 Competitive Grants—Back-up Submission.'' If it becomes necessary to submit an amended package at a later date, then the name of the 2nd submission should be changed to ''Applicant Name—FY06 Tribal 319 Competitive Grants—2nd Submission.''

Once your application package has been completed and saved, send it to your AOR for submission to U.S. EPA through Grants.gov. Please advise your AOR to close all other software programs before attempting to submit the application package through Grants.gov.

In the ''Application Filing Name'' box, your AOR should enter your organization's name (abbreviate where possible), the fiscal year (*e.g.,* FY06), and the grant category (*e.g.*, Tribal 319 Grants). The filing name should not exceed 40 characters. From the ''Grant Application Package'' page, your AOR may submit the application package by clicking the ''Submit'' button that appears at the top of the page. The AOR will then be asked to verify the agency and funding opportunity number for which the application package is being submitted. If problems are encountered during the submission process, the AOR should reboot his/her computer before trying to submit the application package again. [It may be necessary to turn off the computer (not just restart it) before attempting to submit the package again.] If the AOR continues to experience submission problems, he/she may contact Grants.gov for assistance by phone at 1–800–518–4726 or e-mail at *support@grants.gov.*

If you have not received a confirmation of receipt from EPA (not from *support@grant.gov*) within 30 days of the application deadline, please contact the appropriate EPA Regional Tribal NPS Coordinator identified in section B.VII below. Failure to do so may result in your application not being reviewed.

V. Application Review Information

1. Selection Criteria for Competitive Grants

Tribes submitting proposals for competitive grants must comply with all of the threshold evaluation criteria described in section B.III.3 in order to be considered for further evaluation under this section. The EPA Regional Tribal NPS Coordinator will determine whether the proposals comply with the threshold evaluation criteria, and will forward proposals that do to EPA Headquarters NPS Control Branch for distribution to EPA's Watershed Project Review Committee. Proposals that do not comply with the threshold evaluation criteria will be rejected and not evaluated under this section.

EPA's Watershed Project Review Committee will evaluate proposals by assigning a value of 0 to 5 (with 5 being highest) for each factor described below based upon how well the following list of specific elements are represented in the work plan. Each factor has been assigned a specific weight which will be

multiplied (by a value of 0–5) to calculate a total point score for the particular factor. The scores for each factor are then combined to result in a total score for the overall work plan—the total maximum score available is 900.

EPA's Watershed Project Review Committee will evaluate proposals for competitive grants based upon the following evaluation factors (and corresponding weights):

a. The extent, and quality, to which the subcategories of NPS pollution are identified and described. (Weight = 20; 100 points maximum.)

The work plan will be evaluated based upon the extent, and quality, to which it identifies each significant subcategory of NPS pollution. Since identifying the categories of NPS pollution (*e.g.,* agriculture) is a threshold evaluation criteria, the proposed work plan will be evaluated based upon how well it identifies sources at the *subcategory* level with estimates of the extent to which these subcategories are present in the watershed (*e.g.,* X number of dairy cattle feedlots needing upgrading, including a rough estimate of the number of cattle per facility; Y acres of row crops needing improved nutrient management or sediment control; or Z linear miles of eroded streambank needing remediation).

b. The extent, and quality, to which the water quality problems or threats to be addressed are identified and described. (Weight = 20; 100 points maximum.)

The work plan will be evaluated based upon the extent, and quality, to which it identifies each water quality problem or threat to be addressed caused by the subcategories of NPS pollution identified in evaluation factor (a) above. EPA encourages Tribes to incorporate specific descriptions of water quality problems or threats, for example, in relation to impairments to water quality standards or other parameters that indicate stream health (*e.g.*, decreases in fish or macroinvertebrate counts).

c. The extent, and quality, to which the goals and objectives of the project specifically identify the project location and activities to be implemented. (Weight = 20; 100 points maximum.)

The work plan will be evaluated based upon how well it specifically identifies where the NPS project will take place and the waterbody affected by the NPS pollutants (provides map); and the level of detail provided in relation to the specific activities that will be implement (*e.g.,* identifies specific management measures and practices to be implemented).

d. The extent to which significant water quality benefits will be achieved as a result of the project. (Weight = 20; 100 points maximum.)

The work plan will be evaluated based upon the extent to which it describes how significant water quality benefits will be achieved as a result of the project, either through restoring NPS-impaired waters or addressing threats to unimpaired waters. EPA encourages Tribes to incorporate specific water quality-based goals that are linked to: Load reductions; water quality standards for one or more pollutants/uses; NPS total maximum daily load allocations; measurable, in-stream reductions in a pollutant; or improvements in a parameter that indicates stream health (*e.g.*, increases in fish or macroinvertebrate counts). If information is not available to make specific estimates, water quality-based goals may include narrative descriptions and best professional judgment based on existing information.

e. The specificity of the budget in relation to each work plan component. (Weight = 15; 75 points maximum.)

The work plan will be evaluated based upon the level of specificity of the budget in relation to each work plan component, and the extent to which it outlines the total operational and construction costs of the project (including match). Budget categories may include, but are not limited to, the following items: personnel; travel; equipment; supplies; contractual; and construction costs.

f. The level of detail in relation to the schedule for achieving the activities identified in the work plan. (Weight = 15; 75 points maximum.)

The work plan will be evaluated based upon the level of detail and clarity that it includes in relation to the schedule of activities for each work plan component. Such information includes, but is not limited to, the following: identifies a specific ''start'' and ''end'' date for each work plan component; an estimate of the specific work years for each work plan component; and interim milestone dates for achieving each work plan component. A proposal that includes a schedule that can be implemented with minimal delay upon the award of the grant (*i.e.,* indicates a ''readiness to proceed'') will score higher than proposals which may require significant further action before the project can be implemented.

g. The extent to which the roles and responsibilities of the recipient and project partners in carrying out the work plan activities are specifically identified. (Weight = 15; 75 points maximum.)

The work plan will be evaluated based upon how specifically and clearly it defines the roles and responsibilities of each responsible party in relation to each work plan component, which may include, but is not limited to, the following: defining the specific level of effort for the responsible parties for each work plan component; identifying parties who will take the lead in carrying out the work plan commitments; and identifying other programs, parties, and agencies that will provide additional technical and/or financial assistance.

h. The extent to which the performance evaluation process includes specific, measurable, and objective factors that are clearly linked to specific work plan activities throughout the project period and the anticipated environmental outcomes and outputs. (Weight = 15; 75 points maximum.)

The work plan will be evaluated based on the extent to which the performance evaluation process includes specific, measurable, and objective factors that are clearly linked to specific work plan activities throughout the project period and how clearly it tracks and measures progress towards achieving the expected outcomes and outputs identified in Section B.I.

i. The extent, and quality, to which the proposal addresses one of the following four factors (for factors 1, 2, and 3 the applicant must include the information described in Attachment A in its work plan). (Weight = 40; 200 points maximum.)

1: The proposed work plan develops a watershed-based plan and implements a watershed-based plan.

If a work plan includes a plan to develop a watershed-based plan, it will be evaluated based on the extent to which it: Includes a commitment to incorporate the nine components of a watershed-based plan described in Attachment A; clearly identifies the geographical coverage of the watershed; includes a specific schedule for developing the watershed-based plan; and clearly identifies the estimated funds that will be used to develop the watershed-based plan (not to exceed 20 percent of the overall competitive grant).

If a Tribe submits a work plan to implement a watershed-based plan, it will be evaluated based on the extent to which it: Is accompanied by a statement that the Region finds that the watershed-based plan to be implemented includes the nine components of a watershed-

based plan identified in Attachment A; identifies and briefly summarizes the watershed-based plan that will be implemented; and describes how the proposed work plan will make progress towards achieving the overall goals of the watershed-based plan and the specific water quality-based goals identified in the watershed-based plan.

2: The proposed work plan develops a watershed-based plan and implements a watershed project (that does not implement a watershed-based plan).

If a work plan includes a plan to develop a watershed-based plan, it will be evaluated based on the extent to which it: Includes a commitment to incorporate the nine components of a watershed-based plan described in Attachment A; clearly identifies the geographical coverage of the watershed; includes a specific schedule for developing the watershed-based plan; and clearly identifies the estimated funds that will be used to develop the watershed-based plan (not to exceed 20 percent of the overall competitive grant).

If a work plan is designed to implement a watershed project that is not implementing a watershed-based plan, it will be evaluated based on the extent to which it can be linked to or expanded upon to address NPS impairments or threats on a watershed-wide basis. For example, a work plan that sets a precedent for future implementation on a watershed-basis will be ranked higher than a work plan that implements an individual demonstration project designed to address an individual threat or problem.

3: The proposed work plan implements a watershed-based plan.

If a Tribe submits a work plan to implement a watershed-based plan, it will be evaluated based on the extent to which it: Is accompanied by a statement that the Region finds that the watershed-based plan to be implemented includes the nine components of a watershed-based plan identified in Attachment A; identifies and briefly summarizes the watershed-based plan that will be implemented; and describes how the proposed work plan will make progress towards achieving the overall goals of the watershed-based plan and the specific water quality-based goals identified in the watershed-based plan.

4: The proposed work plan implements a watershed project that is a significant step towards solving NPS impairments or threats on a watershed-wide basis.

If a work plan is designed to implement a watershed project that is not implementing a watershed-based plan, it will be evaluated based on the extent to which can be linked to or expanded upon to address NPS impairments or threats on a watershed-wide basis. For example, a work plan that sets a precedent for future implementation on a watershed-basis will be ranked higher than a work plan that implements an individual demonstration project designed to address an individual threat or problem.

2. Review and Selection Process for Competitive Funding

The EPA Regional Tribal NPS Coordinators will determine whether the proposals comply with the threshold evaluation criteria described in section B.III.3, and will forward those proposals that meet the threshold evaluation criteria to EPA Headquarters NPS Control Branch by approximately March 15, 2006.

EPA will establish a Watershed Project Review Committee (Committee) comprised of nine EPA staff, including three EPA Regional State NPS Coordinators, three EPA Regional Tribal NPS Coordinators, two staff members of the EPA Headquarters NPS Control Branch, and one staff member of EPA's American Indian Environmental Office.

EPA Headquarters NPS Control Branch will forward copies of the proposed work plans for competitive funding to the Committee and hold a conference call with the Committee on or around March 29, 2006, to ensure that all Committee members fully understand how to objectively and consistently apply the criteria discussed above. Scores for each proposal will be developed by each Committee member based on evaluating proposals against the factors identified above in accordance with the weighting system described in section B.V.1.

On or around April 26, 2006, the Committee will forward the scores for each proposal to EPA Headquarters NPS Control Branch. Based on these scores, EPA Headquarters NPS Control Branch will calculate the average score for each proposal and then rank the proposals based on the resulting average scores. On or around May 3, 2006, EPA Headquarters NPS Control Branch will send the resulting average scores and rankings to the Committee and hold a conference call to provide a final opportunity for members of the Committee to discuss the rankings based on the average scores. The Committee will then make funding recommendations to EPA Headquarters NPS Control Branch based on these rankings; however, in making the funding recommendations, in addition to considering the rankings, the Committee may also give priority consideration to high quality proposals that are designed to develop and/or implement a watershed-based plan. EPA Headquarters NPS Control Branch then will make the final funding decision based on the Committee's recommendations.

The Committee will use the following ''Competitive Work Plan Evaluation Review Sheet'' to rank proposed work plans in accordance with the evaluation criteria discussed above.

Competitive Work Plan Evaluation Review Sheet

Tribe Name_____ Reviewer_____(Weight × Value = Score) (Value: 0 is Lowest; 5 is Highest) (Maximum ''Max'' Score is 900)

Weight	Evaluation factors	Value	Score
20	(1) The extent, and quality, to which the subcategories of NPS pollution are identified and described. Comments (strengths, weaknesses):	5 Max ..	100 Max.
20	(2) The extent, and quality, to which the water quality problems or threats to be addressed are identified and described. Comments (strengths, weaknesses):	5 Max ..	100 Max.
20	(3) The extent, and quality, to which the goals and objectives of the project specifically identify the project location and activities to be implemented. Comments (strengths, weaknesses):	5 Max ..	100 Max.
20	(4) The extent to which significant water quality benefits will be achieved as a result of the project. Comments (strengths, weaknesses):	5 Max ..	100 Max.
15	(5) The specificity of the budget in relation to each work plan component. Comments (strengths, weaknesses):	5 Max ..	75 Max.
15	(6) The level of detail in relation to the schedule for achieving the activities identified in the work plan. Comments (strengths, weaknesses):	5 Max ..	75 Max.
15	(7) The extent to which the roles and responsibilities of the recipient and project partners in carrying out the work plan activities are specifically identified. Comments (strengths, weaknesses):	5 Max ..	75 Max.

Weight	Evaluation factors	Value	Score
15	(8) The extent to which the performance evaluation process includes specific, measurable, and objective factors that are clearly linked to specific work plan activities throughout the project period and the anticipated environmental outcomes and outputs. Comments (strengths, weaknesses):	5 Max ..	75 Max.
40	(9) The extent, and quality, to which the proposal addresses one of the following four factors: (a) The proposed work plan develops a watershed-based plan and implements a watershed-based plan. (b) The proposed work plan develops a watershed-based plan and implements a watershed project (that does not implement a watershed-based plan). (c) The proposed work plan implements a watershed-based plan. (d) The proposed work plan implements a watershed project that is a significant step towards solving NPS impairments or threats on a watershed-wide basis. Comments (strengths, weaknesses):	5 Max ..	200 Max.
	Total Maximum Score	900	

3. Anticipated Announcement and Award Dates

On or around May 5, 2006, EPA Headquarters NPS Control Branch will select the proposals for award and announce to the Regions which Tribes' work plans have been selected for competitive funding. These Tribes will be notified immediately by phone or e-mail, with a written letter to follow.

VI. Award Administration Information

1. Award Notices

Following final selections, all applicants will be notified regarding their application's status.

a. EPA anticipates notification to *successful* applicant(s) will be made by the appropriate EPA Regional Tribal NPS Coordinator via telephone, electronic, or postal mail on or around May 5, 2006. This notification, which advises that the applicant's proposal has been selected and is being recommended for award, is not an authorization to begin performance. The award notice signed by the EPA award official is the authorizing document and will be provided through postal mail. At a minimum, this process can take 90 days from the date of selection notification.

b. EPA anticipates notification to *unsuccessful* applicant(s) will be made by the appropriate EPA Regional Tribal NPS Coordinator via electronic or postal mail within 15 calendar days after final selection of successful applicants. In either event, the notification will be sent to the signer of the application.

c. The appropriate EPA Regional Tribal NPS Coordinator will notify applicants which do not meet the threshold eligibility criteria under section B.III.3 within 15 calendar days of EPA's decision on applicant eligibility.

2. Administrative and National Policy Requirements

a. A listing and description of general EPA regulations applicable to the award of assistance agreements may be viewed at: *http://www.epa.gov/ogd/AppKit/appplicable_epa_regulations_and_description.htm.*

b. All applicants are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for a Federal grant or cooperative agreement. Applicants can receive a DUNS number, at no cost, by calling the dedicated tollfree DUNS Number request line at 1–866–705–5711, or visiting the D&B Web site at: *http://www.dnb.com.*

c. Pursuant to CWA section 319(h)(12), administrative costs in the form of salaries, overhead, or indirect costs for services provided and charged against activities and programs carried out with the grant shall not exceed 10 percent of the grant award. The costs of implementing enforcement and regulatory activities, education, training, technical assistance, demonstration projects, and technology transfer are not subject to this limitation.

d. For a Tribe (or intertribal consortium) that received section 319 funds in the preceding fiscal year, section 319(h)(8) of the CWA requires that the Region determine whether the Tribe made ''satisfactory progress'' during the previous fiscal year in meeting the schedule of activities specified in its approved NPS management program in order to receive section 319 funding in the current fiscal year. The Region will base this determination on an examination of Tribal activities, reports, reviews, and other documents and discussions with the Tribe in the previous year. Regions must include in each section 319 grant (or in a separate document, such as the grant-issuance cover letter, that is signed by the same EPA official who signs the grant), a written determination that the Tribe has made satisfactory progress during the previous fiscal year in meeting the schedule of milestones specified in its NPS management program. The Regions must include brief explanations that support their determinations.

3. Reporting

As provided in 40 CFR 31.40, 31.41, 35.507, 35.515, and 35.638, all section 319 grants must include a set of reporting requirements and a process for evaluating performance. Some of these requirements have been explicitly incorporated into the required work plan components that all Tribes must include in order to receive section 319 grant funding.

The work plan components required for section 319 funding, specifically those relating to work plan commitments and timeframes for their accomplishment, facilitate the management and oversight of Tribal grants by providing specific activities and outputs by which progress can be monitored. The performance evaluation process and reporting schedule (both work plan components) also establish a formal process by which accomplishments can be measured. Additionally, the satisfactory progress determination (for Tribes that received section 319 funding in the preceding fiscal year) helps ensure that Tribes are making progress in achieving the goals in their NPS management programs.

Regions will ensure that the required evaluations are performed according to the negotiated schedule (at least annually) and that copies of evaluation reports are placed in the official files and provided to the recipient.

4. Dispute Resolution

Assistance agreement competition-related disputes will be resolved in accordance with the dispute resolution procedures published in 70 FR 3629, 3630 (January 26, 2005) which can be found at *http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/05-1371.htm.* Copies of these procedures may also be requested by contacting the EPA Regional Tribal NPS Coordinator listed in section B.VII below.

VII. Agency Contacts: EPA Headquarters and Regional Tribal NPS Coordinators

EPA Headquarters—Stacie Craddock, Office of Wetlands, Oceans, and Watersheds, Assessment and Watershed Protection Division, telephone: 202–566–1204; e-mail: *craddock.stacie@epa.gov.*

Region I—Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; Warren Howard; mailing address: U.S. EPA Region I, 1 Congress Street, Suite 1100, Boston, MA 02203; telephone: 617–918–1587; e-mail: *howard.warren@epa.gov.*

Region II—New Jersey, New York, Puerto Rico, U.S. Virgin Islands; Donna Somboonlakana; mailing address: U.S. EPA Region II, 290 Broadway—24th Floor (MC DEPP:WPB), New York, New York 10007; telephone: 212–637–3700; e-mail: *somboonlakana.donna@epa.gov.*

Region III—Delaware, Maryland, Pennsylvania, Virginia, West Virginia, Washington, DC; Fred Suffian; mailing address: U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103; telephone: 215–814–5753; e-mail: *suffian.fred@epa.gov.*

Region IV—Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee; Yolanda Brown; mailing address: U.S. EPA Region IV, Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, GA 30303; telephone: 404–562–9451; e-mail: *brown.yolanda@epa.gov.*

Region V—Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin; Daniel Cozza; mailing address: U.S. EPA Region V, 77 West Jackson Blvd. (MC: WS–15J), Chicago, IL 60604; telephone: 312–886–7252; e-mail: *cozza.daniel@epa.gov.*

Region VI—Arkansas, Louisiana, New Mexico, Oklahoma, Texas; George Craft; mailing address: U.S. EPA Region VI, 1445 Ross Avenue, Dallas, TX 75202; telephone: 214–665–6684; e-mail: *craft.george@epa.gov.*

Region VII—Iowa, Kansas, Missouri, Nebraska; Peter Davis; mailing address: U.S. EPA Region VII, 901 N. 5th Street, Kansas City, KS 66101; telephone: 913–551–7372; e-mail: *davis.peter@epa.gov.*

Region VIII—Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming; Mitra Jha; mailing address: U.S. EPA Region VIII, 999 18th Street, Suite 300 (MC: EPR–EP), Denver, CO 80202; telephone: 303–312–6895; e-mail: *jha.mitra@epa.gov.*

Region IX—Arizona, California, Hawaii, Nevada, American Samoa, Mariana Islands, Guam; Tiffany Eastman; mailing address: U.S. EPA Region IX, 75 Hawthorne Street (MC: WTR–10), San Francisco, CA 94105; telephone: 1–800–735–2922, relay #415–972–3404; e-mail: *eastman.tiffany@epa.gov.*

Region X—Alaska, Idaho, Oregon, Washington; Krista Mendelman; mailing address: U.S. EPA Region X, 1200 6th Avenue (MC: OWW–137), Seattle, WA 98101; telephone: 206–553–1571; e-mail: *mendelman.krista@epa.gov.*

VIII. Other Information

1. Anticipated Deadlines and Milestones for FY 2007 Competitive Grants

Beginning in FY 2007, the schedule for submitting work plans and awarding section 319 competitive grants will be modified to expedite the grant awards process. These modifications are intended to ensure that award decisions are made earlier in the fiscal year to provide adequate time for Tribes to implement work plans within the applicable fiscal year. The following estimated dates are provided in order to assist Tribes in planning for EPA's FY 2007 funding cycle for competitive grants:

Date for Tribes to be eligible for 319 grants. October 13, 2006.

Tribes submit competitive grant proposals. December 1, 2006 (anticipated).

Headquarters notifies Regions/Tribes of selections. March 5, 2007 (anticipated).

Tribes submit final grant application to Region. April 5, 2007 (anticipated).

Other than the date EPA will use to determine eligibility to receive 319 grants, the dates above are the anticipated dates for those actions.

2. Right to Reject All Proposals

EPA reserves the right to reject all proposals or applications and make no award as a result of this announcement. The EPA Grant Award Officer is the only official that can bind the Agency to the expenditure of funds for selected projects resulting from this announcement.

Attachment A—Components of a Watershed-Based Plan

1. An identification of the causes and sources or groups of similar sources that will need to be controlled to achieve the goal identified in element 3 below. Sources that need to be controlled should be identified at the significant subcategory level with estimates of the extent to which they are present in the watershed (*e.g.*, X number of dairy cattle feedlots needing upgrading, including a rough estimate of the number of cattle per facility; Y acres of row crops needing improved nutrient management or sediment control; or Z linear miles of eroded streambank needing remediation).

2. A description of the NPS management measures that will need to be implemented to achieve a water quality-based goal described in element 3 below, as well as to achieve other watershed goals identified in the watershed-based plan, and an identification (using a map or a description) of the critical areas which those measures will be needed to implement the plan.

3. An estimate of the water quality-based goals expected to be achieved by implementing the measures described in element 2 above. To the extent possible, estimates should identify specific water quality-based goals, which may incorporate, for example: load reductions; water quality standards for one or more pollutants/uses; NPS total maximum daily load allocations; measurable, in-stream reductions in a pollutant; or improvements in a parameter that indicates stream health (*e.g.*, increases in fish or macroinvertebrate counts). If information is not available to make specific estimates, water quality-based goals may include narrative descriptions and best professional judgment based on existing information.

4. An estimate of the amounts of technical and financial assistance needed, associated costs, and/or the sources and authorities that will be relied upon to implement the plan. As sources of funding, Tribes should consider other relevant Federal, State, local and private funds that may be available to assist in implementing the plan.

5. An information and education component that will be used to enhance public understanding and encourage early and continued participation in selecting, designing, and implementing the NPS management measures that will be implemented.

6. A schedule for implementing the NPS management measures identified in this plan that is reasonably expeditious.

7. A description of interim, measurable milestones for determining whether NPS management measures or other control actions are being implemented.

8. A set of criteria that can be used to determine whether the water quality-based goals are being achieved over time and substantial progress is being made towards attaining water quality-based goals and, if not, the criteria for determining whether the watershed-based plan needs to be revised.

9. A monitoring component to evaluate the effectiveness of the implementation efforts over time, measured against the criteria established under element 8 above.

[FR Doc. E6–408 Filed 1–13–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2004–0337; FRL–7757–3]

Ferbam Reregistration Eligibility Decision; Notice of Availability; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; correction.

SUMMARY: EPA issued a notice in the **Federal Register** of December 30, 2005, concerning the Availability of the Ferbam RED. This document is being issued to correct typographical omissions and errors, specifically to correct the docket number OPP–2004–0337 and to add the comment period closing date (March 20, 2006.)

FOR FURTHER INFORMATION CONTACT: Amaris Johnson, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–9542; e-mail address: *johnson.amaris@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

The Agency included in the notice a list of those who may be potentially affected by this action. If you have 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 EPA–HQ–OPP–2004–0337. 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, 1801 S. Bell St., 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/*.

EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions.

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. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. What Does this Correction Do?

FR Doc. E5–8034 published in the **Federal Register** of December 30, 2005 (70 FR 77387) (FRL–7742–8) is corrected as follows:

1. On page 77387, in the first column, the docket ID no. now reading ''[OPP–2005–0478; FRL–7742–8]'' should read ''[EPA–HQ–OPP–2004–0337–FRL–7742–8]''

2. On the same page, in the first column, the **DATES** section was omitted and should be inserted after the **SUMMARY** paragraph to read ''**DATES**: March 20, 2006.''

List of Subjects

Environmental protection, Pesticides and pests.

Dated: January 6, 2006.

Peter Caulkins,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. E6–407 Filed 1–13–06; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL HOUSING FINANCE BOARD

[No. 2006–N–01]

Submission for OMB Review; Comment Request

AGENCY: Federal Housing Finance Board.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995, the Federal Housing Finance Board (Finance Board) has submitted the information collection entitled ''Community Support Requirements'' to the Office of Management and Budget (OMB) for review and approval of a 3 year extension of the OMB control number, 3069–0003, which is due to expire on February 28, 2006.

DATES: Interested persons may submit comments on or before February 16, 2006.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs of the Office of Management and Budget, Attention: Desk Officer for the Federal Housing Finance Board, Washington, DC 20503.

FOR FURTHER INFORMATION OR COPIES OF THE INFORMATION COLLECTION CONTACT: Emma Fitzgerald, Program Analyst, Office of Supervision, by telephone at 202–408–2874, by electronic mail at *fitzgeralde@fhfb.gov*, or by regular mail at the Federal Housing Finance Board, 1625 Eye Street, NW., Washington, DC 20006.

SUPPLEMENTARY INFORMATION:

A. Need for and Use of the Information Collection

Section 10(g)(1) of the Federal Home Loan Bank Act (Bank Act) requires the Finance Board to promulgate regulations establishing standards of community investment or service that Federal Home Loan Bank (FHLBank) members must meet in order to maintain access to long-term advances. *See* 12 U.S.C. 1430(g)(1). In establishing these community support requirements for FHLBank members, the Finance Board must take into account factors such as the FHLBank member's performance under the Community Reinvestment Act of 1977 (CRA), 12 U.S.C. 2901, *et seq.*, and record of lending to first-time homebuyers. 12 U.S.C. 1430(g)(2).

Part 944 of the Finance Board regulations implements section 10(g) of the Bank Act. *See* 12 CFR part 944. The rule provides uniform community support standards all FHLBank members must meet and review criteria Finance Board staff must apply to determine compliance with section 10(g). More specifically, section 944.2 of the rule (12 CFR 944.2) implements the statutory community support requirement and requires each member selected for review to submit a completed Community Support Statement Form to the Finance Board. A copy of the Community Support Statement Form is attached to this Notice. Section 944.3 (12 CFR 944.3) establishes community support standards for the two statutory factors—CRA and first-time homebuyer performance—and provides guidance to a respondent on how it may satisfy the standards. Sections 944.4 and 944.5 (12 CFR 944.4–5) establish the procedures and criteria the Finance Board uses in determining whether FHLBank members satisfy the statutory and regulatory community support requirements.

The information collection contained in the Community Support Statement Form and sections 944.2 through 944.5 of the rule is necessary to enable and is used by the Finance Board to determine whether FHLBank members satisfy the statutory and regulatory community support requirements. Only FHLBank members that meet these requirements may maintain continued access to long-term FHLBank advances. *See* 12 U.S.C. 1430(g).

The OMB number for the information collection is 3069–0003. The OMB clearance for the information collection expires on February 28, 2006. The likely respondents are institutions that are members of an FHLBank.

B. Burden Estimate

The Finance Board estimates the total annual average number of respondents at 5170 FHLBank members, with one response per member. The estimate for the average hours per response is one hour. The estimate for the total annual hour burden is 5170 hours (5170 members × 1 response per member × 1 hour).

C. Comment Request

In accordance with 5 CFR 1320.8(d), the Finance Board published a request for public comments regarding this information collection in the **Federal Register** on October 14, 2005. *See* 70 FR 60079 (October 14, 2005). The 60-day comment period closed on December 13, 2005. The Finance Board received no public comments.

Written comments are requested on: (1) Whether the collection of information is necessary for the proper performance of Finance Board functions, including whether the information has practical utility; (2) the accuracy of the Finance Board estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on applicants and housing associates, including through the use of automated collection techniques or other forms of information technology. Comments may be submitted to OMB in writing at the address listed above.

Dated: January 10, 2006.

By the Federal Housing Finance Board.

John P. Kennedy,

General Counsel.

BILLING CODE 6725–01–P

FEDERAL HOUSING FINANCE BOARD
COMMUNITY SUPPORT STATEMENT

(Instructions on Reverse)

Name of Institution: _____

Address: _____

City: _____ **State:** _____ **Zip Code:** _____

Docket Number: _____

Contact Person: (Mr./Ms.) _____ **Title:** _____

Phone Number: (___) _____ **Fax Number:** (___) _____

I. CRA Factor

Most recent federal CRA Rating: _____ CRA Evaluation Date: _____

II. First-time Homebuyer Factor *(You may complete either Section A or B, or both sections. Members with "Outstanding" federal CRA ratings need not complete this section.)*

A. Complete the following four questions using data for the past year.

1. Number of mortgage loans made to first-time homebuyers _____
2. Dollar amount of loans made to first-time homebuyers $_____
3. Loans made to first-time homebuyers as a percentage of all mortgage loans _____%
4. Dollars loaned to first-time homebuyers as a percentage of all mortgage dollars loaned _____%

B. Check as many boxes as appropriate

1. In-house first-time homebuyer program *(e.g.* marketing plans and outreach programs) _____
2. Other in-house lending products that serve first-time homebuyers or low- and moderate-income homebuyers _____
3. Flexible underwriting standards for first-time homebuyers _____
4. Participate in nationwide first-time homebuyer programs (Fannie Mae, Freddie Mac, etc.) _____
5. Participate in federal government programs that serve first-time homebuyers (FHA, VA, etc.) _____
6. Participate in state or local government programs targeted to first-time homebuyers _____
7. Financial support or technical assistance to community groups or organizations that assist first-time homebuyers _____
8. Participate in loan consortia that make loans to first-time homebuyers _____
9. Participate in or support special counseling or homeownership education targeted to first-time homebuyers _____
10. Hold investments or make loans that support first-time homebuyer programs _____
11. Hold mortgage-backed securities that may include a pool of loans to low- and moderate-income homebuyers _____
12. Participate in service organizations that provide mortgages _____
13. Participate in FHLBank community lending programs _____
14. Other (see instructions for Part II) _____

III. Certify that information in this Community Support Statement and the attachments is correct to the best of your knowledge by filling out the information below.

Signed _____ Title _____

Print Name _____ Date _____

FHFB Form 96-01 OMB Number 3069-0003 Expires 2-28-2006

Community Support Statement Instructions

Purpose: To maintain continued access to long-term advances, section 10(g) of the Federal Home Loan Bank Act [12 U.S.C. §1430(g)] requires the Federal Housing Finance Board (Finance Board) to take into account a Federal Home Loan Bank member's performance under the Community Reinvestment Act of 1977 [12 U.S.C. §2901 et seq.] (CRA) and its record of lending to first-time homebuyers. For purposes of community support review, the term "long-term advances" means advances with a term to maturity greater than one year.

Part I (CRA Factor): Members subject to CRA may complete this section. Indicate your institution's most recent federal CRA evaluation rating and date. [If your institution is not subject to CRA, indicate this in the CRA evaluation field on this form.]

If a member's most recent federal CRA evaluation is rated "Needs to Improve," the Finance Board will place that member on probation until it receives the rating from its next CRA examination. During the probationary period, it will retain access to long-term advances. If the member does not receive an improved CRA rating at its next CRA evaluation, its access to long-term advances will be restricted.

If a member's most recent federal CRA rating is "Substantial Non-compliance," the Finance Board immediately will take action to restrict that member's access to long term advances. The restriction will remain in effect until the member's rating improves.

Part II (First-time Homebuyer Factor): All members, except those with "Outstanding" federal CRA ratings must complete this section. An institution may demonstrate assistance to first-time homebuyers in many ways, but the Finance Board is particularly interested in actual loans, products, and services to first-time homebuyers. Although completion of both Section A and Section B is requested, you may satisfy the first-time homebuyer factor by demonstrating adequate lending performance (Section A), by demonstrating participation in programs that assist first-time homebuyers (Section B), or by a combination of both factors. If the information requested in Part II is inadequate to reflect your institution's compliance with the first-time homebuyer factor, you may attach a one-page description of your efforts to assist first-time homebuyers and/or an explanation of factors affecting your institution's ability to assist first-time homebuyers. No other information beyond this one-page description will be considered.

If a member does not submit evidence of assistance to first-time homebuyers, the Finance Board immediately will take action to restrict that member's access to long term advances. The restriction will remain in effect until the member submits information satisfactory to the Finance Board.

Part III (Certification): All members must complete this section. An appropriate senior official must certify that the information in this Community Support Statement and the attachments is correct to the best of his/her knowledge.

Assistance: Your Federal Home Loan Bank has a Community Support Program that can assist you in preparing your Community Support Statement.

Once you have completed this form, please submit it, along with any attachments, to the Federal Housing Finance Board, Office of Supervision, Community Investment and Affordable Housing, 1625 Eye Street NW, Washington, DC 20006, or by electronic mail to fitzgeralde@fhfb.gov.

[FR Doc. 06–365 Filed 1–13–06; 8:45 am]
BILLING CODE 6725–01–C

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 January 31, 2006.

A. Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Renee A. Brouwer and William R. Brouwer, both of Oak Lawn, Illinois; to retain, as a group acting in concert, outstanding voting shares of TeamCo., Inc., and thereby indirectly retain control of Oak Lawn Bank, both of Oak Lawn, Illinois, and Renee A. Brouwer, to individually retain outstanding voting shares of TeamCo., Inc., and thereby retain control of Oak Lawn Bank, both of Oak Lawn, Illinois.

Board of Governors of the Federal Reserve System, January 11, 2006.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E6–399 Filed 1–13–06; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center Web site at *http://www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 10, 2006.

A. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. First National Bancorp, Inc., Green Forest, Arkansas (Bancorp); to acquire additional shares for a total of 9.9 percent of Legacy National Bank, Springdale, Arkansas.

B. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. Hulett Holding Company, Hulett, Wyoming; to become a bank holding company by acquiring 100 percent of the voting shares of Summit National Bank, Hulett, Wyoming.

Board of Governors of the Federal Reserve System, January 10, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E6–341 Filed 1–13–06; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *http://www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 10, 2006.

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30303:

1. GB&T Bancshares, Inc., Gainesville, Georgia; to merge with Mountain Bancshares, Inc., and thereby acquire Mountain State Bank, both of Dawsonville, Georgia.

B. Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Exchange Financial, Inc., Adair, Iowa; to become a bank holding company by acquiring 100 percent of the voting shares of Exchange State Bank, Adair, Iowa.

2. First Midwest Bancorp, Inc., Itasca, Illinois; to acquire 100 percent of the voting shares of Bank Calumet, Inc., and thereby indirectly acquire Bank Calumet, National Association, both of Hammond, Indiana.

Board of Governors of the Federal Reserve System, January 11, 2006.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E6–398 Filed 1–13–06; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center Web site at *http://www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 30, 2006.

A. Federal Reserve Bank of New York (Jay Bernstein, Bank Supervision Officer) 33 Liberty Street, New York, New York 10045-0001:

1. Rabobank International Holding B.V., Utrecht, The Netherlands, Utrecht-America Holdings, Inc., New York, New York, and VIB Corp El, Centro, California; to engage in making and acquiring loans and extensions of credit, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, January 10, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E6–342 Filed 1–13–06; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HHS Managing Partner Grants.gov E-Government Initiative; Governmentwide Notice of Opportunity to Register Early for Electronic Submission of Grant Applications for Federal Funding Opportunities; Early Registration With Grants.gov

AGENCY: Grants.gov Program Management Office; HHS Managing Agency; Office of Assistant Secretary for Budget, Technology and Finance for the Grants Executive Board, HHS.

ACTION: Notice.

SUMMARY: Federal grant applicants must complete a three-step registration process before applying for a federal grant opportunity through Grants.gov. Grants.gov is the federal government's free, single, and secure site for finding and submitting applications electronically for federal grant funding. It is part of the ongoing implementation of Electronic Government (E-Government) and a key component of the President's Management Agenda. Expanding electronic government makes it simpler for the public to receive high-quality services from the federal government in addition to improving the federal government's efficiency in the delivery of its services. To protect the applicant and the applicant's information, and to assure federal agencies that they are interacting with officials authorized to submit applications for funding on behalf of applicant entities, an applicant must register with Grants.gov.

In fiscal year 2005, 20 out of 26 federal grant making departments and agencies achieved their goals, set through OMB guidance, of making 25 percent of their discretionary funding opportunities available for the electronic submission of applications on Grants.gov and over 15,000 applications were received. Per OMB milestones, in fiscal year 2006 the percentage of discretionary funding opportunities available for electronic submission will increase to 75 percent and then to 100 percent in fiscal year 2007. This planned increase in utilization of the Grants.gov system is indicative of a governmentwide transition to electronic grant processes.

The twenty-six federal grant making departments and agencies participating in Grants.gov are: The Departments of Health and Human Services, Housing and Urban Development, Transportation, Education, Agriculture, Justice, Labor, Homeland Security, Defense, Commerce, Veterans Affairs, State, Treasury, Interior, and Energy, and the National Science Foundation, Environmental Protection Agency, National Aeronautics and Space Administration, National Endowment of the Arts, National Endowment of Humanities, Corporation for National & Community Service, U.S. Agency for International Development, National Archives and Records Administration, Small Business Administration, Institute of Museum and Library Services, and Social Security Administration.

Each of the federal grant-making departments and agencies listed above are posting funding opportunities and grant application materials on Grants.gov. To facilitate the federal grant application process, this notice encourages prospective applicants to register early. Registering in advance of agencies posting their grant opportunities will eliminate many of the issues that applicants have faced by not meeting registration requirements in time to meet application deadlines. Registering early will allow the Federal agencies and Grants.gov sufficient time to address questions applicants may have in completing the registration process.

I. The Need To Register With Grants.gov

Before applying for a grant opportunity on Grants.gov, an applicant must complete the registration process. Registration protects both the applicant and the federal agencies against fraudulent activities. Registration confirms that the applicant has designated a certain individual or entity to submit an application on behalf of the applicant and assures the federal agency that it is interacting with the designated representative of the applicant.

II. What Is Involved in Registration?

Before applying for a grant opportunity on Grants.gov, an applicant must complete the registration process. Registration protects both the applicant and the federal agencies against fraudulent activities. Registration confirms that the applicant has designated a certain individual or entity to submit an application on behalf of the applicant and assures the federal agency that it is interacting with the designated representative of the applicant.

Registration is a three-step process:

1. Register your organization.
2. Register yourself as an Authorized Organization Representative.
3. Become authorized by your organization to submit applications.

1. Register Your Organization. Before you can apply for a grant via Grants.gov

your organization must register with the Central Contractor Registry (CCR), which requires a Data Universal Number System (DUNS) number. A DUNS number is a unique number that identifies an organization and has been adopted by the Federal Government. The CCR is the central government repository for organizations working with the Federal government. The CCR collects, validates, stores and disseminates data in support of agency acquisitions. For grants, CCR stores an applicant's information, allowing Grants.gov to verify an organization's identity and identify key business contacts for the organization. An organization will be required to provide a DUNS number, an E-Business point-of-contact (POC) and a Marketing Partner ID Number (MPIN) when registering with CCR. Please note that CCR recently began validating the tax identification number with IRS/ Department of Treasury, which delays the activation of the registration by approximately 24–48 hours. Active CCR registrations and changes to registration information are passed to Grants.gov on a daily basis. A yearly validation of the CCR information is required to maintain an active registration.

- CCR Registration Assistance: 1–888–227–2423 (*http://www.ccr.gov*).

2. Register as an Authorized Organization Representative (AOR). An AOR is a person named by an organization to submit an application for funding consideration on behalf of the organization. In order to safeguard the security of your electronic information and to submit a Federal grant application via Grants.gov, an AOR must first obtain a Username and Password from Grants.gov. The organizational DUNS number will be needed to access the registration form, *http://grants.gov/Register1*. Completion of the registration form will provide a Grants.gov Username and Password. The AOR's must then register the Username and Password with Grants.gov, *http://grants.gov/Register2*.

3. Organization Authorizes Submitter (AOR). Grants.gov will send the organization's CCR E-Business point-of-contact (POC) an e-mail notifying them that someone from their organization has registered with Grants.gov and needs to be authorized as an AOR. The E-Business POC must log into Grants.gov, using their organization DUNS # and MPIN and authorize the AOR to submit an application via Grants.gov. The registration process is complete once the AOR has been authorized.

III. Time Allotted for Registration

Based on Grants.gov applicant feedback, it usually takes 3–5 days to complete registration with Grants.gov. Registrants should be aware that portions of the Grants.gov registration process leverage other governmentwide databases such as CCR. Some organizations have found it can take up to 2 weeks to complete the registration process when unexpected delays are encountered during the CCR registration process.

FOR FURTHER INFORMATION CONTACT: The Grants.gov Web site provides detailed registration checklists that guide users through the registration process. The checklists are available through the ''Get Started'' link on the Grants.gov Web site (*http://www.grants.gov*). Questions may also be referred to the Grants.gov Contact Center at 1–800–518–4726 or by e-mail at *support@Grants.gov*. A Webcast has been scheduled for the end of January 2006 specifically to cover the Grants.gov registration process. Interested organizations may sign-up for the Webcast at the Grants.gov Web site (*http://www.grants.gov*).

Dated: January 10, 2006.

Charles E. Johnson,

Assistant Secretary for Budget, Technology and Finance.

[FR Doc. E6–396 Filed 1–13–06; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) allow the proposed information collection project: ''Security Checkpoints and Patients with Radiopharmaceuticals.'' In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on November 2, 2005 and allowed 60 Days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 Days for public comment.

DATES: Comments on this notice must be received by February 16, 2006.

ADDRESSES: Written comments should be submitted to: John Kraemer, at the Office of Information and Regulatory Affairs, OMB at the following e-mail address: *John_Kraemer@omb.eop.gov* and the fax number is (202) 395–6974.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Cynthia D. McMichael, AHRQ, Reports Clearance Officer, (301) 427–1651.

SUPPLEMENTARY INFORMATION:

Proposed Project

''Security Checkpoints and Patients With Radiopharmaceuticals''

Patients receiving radioactive therapeutic or diagnostic compounds (called ''radiopharmaceuticals'') can emit radiation at the time when they are released from a hospital facility and present danger to their families and the public. In addition, these individuals might activate radiation detectors at airports, stadiums, and other public place, and will be stopped for questioning by law enforcement personnel. It is very important that hospitals provide patients with educational materials that explain the unique problems patients may face as a result of receiving this treatment, as well as provide guidance about how to respond to situations where law enforcement questions and other concerns may arise.

The goal of the study is to determine what procedures are followed by hospitals when releasing patients treated with radioactive compounds.

The study will involve interviewing 60 health care providers who are directly involved in the release of patients treated with radioactive compounds.

Specifically, the interview protocol will be centered on the following topics:

(1) How health care providers determine when patients receiving radiopharmaceuticals can be released from care?

(2) What type of information is provided to patients to ensure safety to their families and the public?

(3) How this information is communicated to patients?

(4) What information is (or can be) provided to patients who may activate radiation detectors at security checkpoints so that their processing is

facilitated should questions regarding their medical procedures arise?

Best practices identified through the analyses of interview data could lead to the development of standardized procedures to: (a) Reduce secondary exposure to radiation by members of the patient's family and by the public; and (b) ensure that patients who activate radiation detectors at security checkpoints understand why they emit radiation and carry the appropriate documentation to validate their statements. The study findings will be disseminated to the health care community through a scholarly publication journal article (title is to be determined).

Data Confidentiality Provisions

Data collected by the contractor and the contractor's draft analyses will be retained for one year after final acceptance of all contract deliverables, unless, longer retention is requested by the agency for audit purposes.

All agency documents pertaining to the contract will be archived after the contract is completed and retained in accordance with a Federal Records Act of 1950 retention schedule.

Methods of Collection

The data will be collected using a telephone survey. The contractor will contact each health provider through appropriate management offices explaining this survey and ask to be directed to the appropriate, knowledgeable staff in their facility. The interviews will be conducted by telephone. If requested, the contractor will provide a copy of the interview questions in advance so that the hospital staff has time to obtain pertinent information. The contractor will also request copies of educational materials provided to patients, any specific tools used to calculate radiation dose to members of the public as well as other pertinent material. The contractor will obtain and evaluate the referenced educational materials qualitatively, describing the content and detail of such materials and reviewing them for clarity. in addition, the contractor will analyze the responses to the interview questions quantitatively and qualitatively as appropriate.

To recruit the appropriate interviewees, we will first contact the Chief of medicine's office and ask the staff to refer us to the Head of the Department of Radiology/Radiation Oncology/Nuclear Medicine. (Based on our experience surveying health care providers, for smaller hospitals it is sometimes more effective to start with the Hospital Administrator's office.) We will introduce ourselves, explain the goals of the study, and volunteer to provide a cover letter describing the study and any letters of endorsement. We will then contact the Department Heads and request that they refer us to the appropriate, knowledgeable staff in their departments.

Estimated Annual Respondent Burden

Type of survey	Number of respondents	Estimated time per respondent in minutes	Estimated total burden hours	Estimated annual cost to the respondents
Telephone interviews	60	45	45	$4500
Total	60	45	45	4500

Request for Comments

In accordance with the above cited legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of AHRQ, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: January 6, 2006.

Carolyn M. Clancy,

Director.

[FR Doc. 06–349 Filed 1–13–06; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0122]

Guidance for Industry on Exploratory Investigational New Drug Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Exploratory IND Studies.'' This guidance describes the preclinical and clinical issues as well as chemistry, manufacturing, and controls information that should be considered when planning exploratory studies, including studies of closely related drugs or biologics, under an investigational new drug (IND) application.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5346.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Exploratory IND Studies.'' In its March

2004, Critical Path Report,[1] the agency explained that to reduce the time and resources expended during early drug development on candidates that are unlikely to succeed,[2] tools are needed to allow developers to distinguish earlier in the process those candidates that hold promise from those that do not. This guidance describes some exploratory approaches that will protect human subjects while providing early information about candidate performance in humans.

Exploratory IND studies have a number of different goals. In some cases, an exploratory study can help developers gain an understanding of the relationship between a specific mechanism of action and the treatment of a disease. In other cases, a study can provide important information on pharmacokinetics, including, for example, biodistribution of a candidate drug. Whatever the goal of the study, exploratory IND studies can help sponsors identify, early in the process, promising candidates for continued development.

Existing regulations allow a great deal of flexibility in terms of the amount of data that need to be submitted in an IND application, depending on the goals of an investigation, the specific human testing being proposed, and the expected risks. But sponsors have not always taken advantage of that flexibility, and limited, early phase 1 studies, such as those described in this guidance, are often supported by a more extensive preclinical database than is needed.

This guidance applies to exploratory studies (i.e., early phase 1 clinical studies), involving IND and biological products, that assess feasibility for further development of a drug or biological product.[3] For the purposes of this guidance the phrase ''exploratory study'' is intended to describe clinical trials that occur very early in phase 1, involve very limited human exposure, and often have no therapeutic or diagnostic intent.

Typically, these exploratory studies are conducted prior to the traditional dose evaluation, safety, and tolerance studies that ordinarily initiate a clinical drug development program. The amount and type of preclinical information necessary to support an exploratory study will depend on the planned nature and extent of human exposure relative to the toxicity (or lack thereof) at the planned dose. The studies discussed in this guidance ordinarily do not have therapeutic intent. They are designed to evaluate whether a particular candidate should be entered into a drug development program.

FDA published a notice in the **Federal Register** of April 14, 2005 (70 FR 19764), announcing the availability of a draft version of this guidance. The agency was interested in soliciting input on the draft guidance. The comment period closed on July 13, 2005. A number of comments were received on the draft, and the agency considered them very carefully during finalization of the guidance. A number of clarifying changes were made during finalization of the guidance, but substantive changes were not made.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on exploratory IND studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information has been approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–354 Filed 1–12–06; 8:45 am]

BILLING CODE 4160–01–S

[1]Food and Drug Administration, ''Innovation or Stagnation, Challenge and Opportunity on the critical Path to New Medical Products,'' March 2004.

[2]A new medical compound entering phase 1 testing, often representing the culmination of upwards of a decade of preclinical screening and evaluation, is estimated to have only an eight percent chance of reaching the market, ''Critical Path Report,'' March 2004.

[3]This guidance applies to drug and certain well-characterized therapeutic biological products (e.g., recombinant therapeutic proteins and monoclonal antibodies regulated by the Center for Drug Evaluation and Research). The guidance does not apply to human cell or tissue products, blood and blood proteins, vaccines, or to products regulated as devices.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0286]

Draft Guidance for Industry on Investigational New Drugs; Approaches to Complying with Current Good Manufacturing Practice During Phase 1; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''INDs—Approaches to Complying with CGMP During Phase 1.'' This draft guidance is intended to assist persons producing drug and biological products (investigational drugs) for use during phase 1 development in complying with relevant current good manufacturing practice (CGMP) as required by the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Controls for producing an investigational new drug (IND) for use in a phase 1 study are primarily aimed at ensuring subject safety. This guidance is being issued concurrently with a direct final rule and companion proposed rule published elsewhere in this issue of the **Federal Register**, which, if finalized, will specify that the particular requirements in the regulations need not be met for most investigational drugs manufactured for use during phase 1 development. Instead, the agency recommends the approaches outlined in this guidance for complying with the FD&C Act.

DATES: Submit written or electronic comments on the draft guidance by March 20, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800.

FOR FURTHER INFORMATION CONTACT: Monica Caphart, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9047, or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''INDs—Approaches to Complying with CGMP During Phase 1.'' The FD&C Act specifies that drugs must be manufactured, processed, packed, and held in accordance with CGMP, or they are deemed to be adulterated. In September 1978, FDA implemented revised CGMP regulations for drug and biological products (see parts 210 and 211 (21 CFR parts 210 and 211)). These regulations were written primarily with commercial manufacturing in mind. Although the agency stated at the time that the regulations applied to all types of pharmaceutical production,[1] we indicated in the preamble to the regulations that we were considering proposing additional regulations governing drugs used in investigational clinical studies. This guidance makes recommendations for complying with CGMPs for certain phase 1 products.

This guidance applies to investigational new human drug and biological products (including finished dosage forms used as placebos) intended for human use during phase 1 development. Examples of investigational biological products covered by this guidance include investigational recombinant and nonrecombinant therapeutic products, vaccine products, allergenic products, in vivo diagnostics, plasma derivative products, blood and blood components, gene therapy products, and somatic cellular therapy products (including xenotransplantation products) that are subject to the CGMP requirements of section 501(a)(2)(B) of the FD&C Act. The guidance applies to investigational products whether they are produced in small- or large-scale environments because such studies are typically designed to assess tolerability or feasibility for further development of a specific drug or biological product. However, if an investigational drug has already been manufactured by an IND sponsor for use during phase 2 or phase 3 studies or has been lawfully marketed, manufacture of such a drug must comply with the appropriate sections of part 211 for the drug to be used in any subsequent phase 1 investigational studies, irrespective of the trial size or duration of dosing.

This guidance does not apply to human cell or tissue products regulated solely under section 361 of the Public Health Service Act; clinical trials for products regulated as devices; or already approved products that are being used during phase 1 studies (e.g., for a new indication).

This guidance (once finalized) and the regulation it complements (once finalized) represent the agency's effort to proceed with its plans to formally lay out an approach to aid manufacturers in implementing manufacturing controls that are appropriate for the stage of development. The use of this approach recognizes that some controls and the extent of controls needed to achieve appropriate product quality differ not only between investigational and commercial manufacture, but also among the various phases of clinical studies. Consistent with the agency's CGMP for the 21st Century initiative,[2] where applicable, manufacturers are also expected to implement controls that reflect product and production considerations and evolving process and product knowledge and manufacturing experience.[3]

The draft guidance describes FDA's current thinking regarding controls for special production situations (e.g., a laboratory setting, exploratory studies, multiproduct and multibatch testing) and specific product types (e.g., biological/biotechnology products, aseptically processed products) of IND products manufactured for use during phase 1 clinical trials as described in the scope section of the guidance. As the new rule will specify if finalized, the particular requirements in part 211 need not be met for most exploratory products manufactured for use during phase 1 clinical trials.

When finalized, this guidance will replace the 1991 ''Guideline on the Preparation of Investigational New Drug Products (Human and Animal)'' for the production of IND products for phase 1 clinical trials described in the scope section of the guidance. Phase 2 and 3 production will continue to be subject to those portions of parts 210 and 211 that are applicable.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on how to comply with CGMP during certain phase 1 clinical studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to collections of information that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). OMB approved the collection of information under OMB control number 0910–0139.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic

[1] Preamble to the 1978 CGMP regulation (43 FR 45076, September 29, 1978), comment #49, ''The Commissioner finds that, as stated in §211.1, these CGMP regulations apply to the preparation of any drug product for administration to humans or animals, including those still in investigational stages. It is appropriate that the process by which a drug product is manufactured in the development phase be well documented and controlled in order to assure the reproducibility of the product for further testing and for ultimate commercial production. The Commissioner is considering proposing additional CGMP regulations specifically designed to cover drugs in research stages.''

[2] See *http://www.fda.gov/cder/gmp/*.

[3] We are considering issuing additional guidance and/or regulations to clarify the agency's expectations with regard to fulfilling the CGMP requirements when producing investigational drugs for phase 2 and phase 3 clinical studies.

comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: January 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–352 Filed 1–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Voluntary Partner Surveys in the Health Resources and Services Administration—(OMB No. 0915–0212—Extension

In response to Executive Order 12862, the Health Resources and Services Administration (HRSA) conducts voluntary customer surveys of its ''partners'' to assess strengths and weaknesses in program services. An extension of a generic approval is being requested from OMB to conduct these customer or partner satisfaction surveys. HRSA partners are typically State or local governments, health care facilities, health care consortia, health care providers, and researchers.

Partner surveys to be conducted by HRSA might include, for example, brief surveys of grantees to determine satisfaction with a technical assistance contractor, or in-class evaluation forms completed by providers who receive training from HRSA grantees, to measure satisfaction with the training experience. Results of these surveys will be used to plan and redirect resources and efforts as needed to improve service. Focus groups may also be used to potential method to obtain input on services and training. Focus groups, in-class evaluation forms, mail surveys, and telephone surveys are expected to be the preferred methodologies.

The estimated response burden is as follows:

Instrument	Number of respondents	Responses per respondent	Hours per response	Total hour burden
In-class evaluations	40,000	1	.05	2,000
Surveys	12,000	1	.25	3,000
Focus groups	50	1	1.5	75
Total	52,050	1	.10	5,075

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 9, 2006.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–351 Filed 1–13–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: December 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of December 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject name	Address	Effective date
Program-Related Convictions		
ALVAREZ, CANDELARIA	MIAMI, FL	1/20/2006
AMIGO, ORLANDO	MIAMI, FL	1/19/2006
ANDERSON, LINDA	ELK RIVER, MN	1/20/2006
ANDREWS, CINDY	ONTARIO, OR	1/20/2006
ARNOLD, MARY	SHUSHAN, NY	1/19/2006
ARTILES, HELDY	MIAMI BEACH, FL	1/20/2006
ARTILES, ORLANDO	MIAMI BEACH, FL	1/20/2006
BAUMLI, CHRISTOPHER	LAKEWAY, TX	1/20/2006
BENNETT, WILLIAM	NORTH BEND, OR	11/21/2005
BICKEL, STEPHEN	TERRE HAUTE, IN	1/19/2006
BONILLA, IRIS	HOUSTON, TX	1/20/2006
BOYD, WESLEY	HOUSTON, TX	1/20/2006
CAMPOS, MARGARITA	GREENVILLE, IL	1/20/2006
CARNARU, ALEJANDRA	COLEMAN, FL	1/20/2006
CHUNG, SAMUEL	JACKSON, TN	1/19/2006
DAVILA, NOELIA	ALDERSON, WV	1/20/2006
DEL CORAL, TOMAS	MIAMI, FL	1/20/2006
DUDLEY, JACKLIN	NEW IBERIA, LA	1/20/2006
GALVAN, ANTHONY	SAN RAMON, CA	1/20/2006
GELLER, JOEL	WAWICK, NY	1/19/2006
GONZALEZ, OLGA	COLEMAN, FL	1/20/2006
HOFFMANN, AMANDA	ABERDEEN, SD	1/19/2006
JACKSON, JONATHAN	HOUSTON, TX	1/20/2006
JARI, STEVE	TAFT, CA	1/20/2006
KENNEDY, BILL	LOS ANGELES, CA	1/20/2006
KUSHNIR, MICHAEL	SUNNY ISLAND BEACH, FL	1/20/2006
LYONS, JAMES	MIAMI, FL	1/20/2006
MARGULIS ENTERPRISES, INC	OPELIKA, AL	1/20/2006
MASTELLER, ROBERT	LYONS, CO	1/20/2006
MEILE, DAVID	LINCOLN, NE	1/20/2006
MONTEAGUDO, ELVA	COLEMAN, FL	1/20/2006
MUELLER, WENDI	MONROE, WI	1/19/2006
MULKEY, JESSICA	ELMONT, NY	1/19/2006
NGUYEN, JAMES	RANDALLSTOWN, MD	1/19/2006
NUNEZ, REBECA	COLEMAN, FL	1/19/2006
O'DANIEL, ROBERT	PENSACOLA, FL	1/20/2006
PICHARDO, CARMEN	FORT WORTH, TX	1/20/2006
SANCHEZ, FRANK	SPOKANE, WA	1/20/2006
SCHMIEDERER, PATRICK	PROSPECT HEIGHTS, IL	1/19/2006
SMITH, DONNY	FREDERICK, MD	1/19/2006
SNYDER, ANGELA	SILVERDALE, WA	1/20/2006
SUAREZ, DULCE	COLEMAN, FL	1/19/2006
TOWNSEND, BERNARD	TAFT, CA	1/20/2006
TSYNMAN, NAUM	BROOKLYN, NY	1/19/2006
VEGA, JOSE	MIAMI, FL	1/19/2006
WERNER, SCOTT	ST GEORGE, UT	1/6/2005
Felony Conviction for Health Care Fraud		
ACKERT, ROBERT	PHILADELPHIA, PA	1/19/2006
ALLEN, MORGANNA	COLUMBUS, OH	1/19/2006
BAKER, ANDREA	HAMILTON, OH	1/19/2006
BEEM, JEWELL	INDEPENDENCE, MO	1/20/2006
BLAKELY, JUDY	LEIPSIC, OH	1/20/2006
BOETTCHER, WILLIAM	CHARLOTTE, VT	1/20/2006
DAVIDSON, JESSICA	VALLEJO, CA	1/20/2006
GARY, CHENITA	PENSACOLA, FL	1/20/2006
GOODRICH, ROBYN	ST PETERS, MO	1/20/2006
HART, DONALD	PORT WASHINGTON, OH	1/19/2006
HULL, CURTIS	HILLIARD, OH	1/20/2006
KING, HEATHER	JEFFERSONVILLE, IN	1/19/2006
LITTLE, STEPHANIE	BATESVILLE, MS	1/20/2006
MOORE, JOHN	BELLBROOK, OH	1/20/2006
PELPHREY, ANGIE	MARYSVILLE, OH	1/20/2006
PERALTA, RAE	CARLSBAD, CA	1/20/2006
RAGIN, CORINE	BROOKLYN, NY	1/19/2006
SCHWARTZ, BRADLEY	MANSFIELD, OH	1/20/2006
SIM, CHRISTOPHER	CUPERTINO, CA	1/19/2006
SON, KISIK	DALY CITY, CA	1/19/2006
SPENCER, MARIA	SHIPROCK, NM	1/19/2006
SUHADOLNIK, MICHAEL	MORGANTOWN, WV	1/19/2006
SULLIVAN, KIM	SUMMIT, MS	1/20/2006

Subject name	Address	Effective date
UNNERSTALL, RENEE	WRIGHT CITY, MO	1/20/2006
YI, JOHN	BUFORD, GA	1/19/2006
Felony Control Substance Conviction		
BARNES, JACQUI	WAKEFIELD, MA	1/20/2006
BERG, SUSAN	BARTLESVILLE, OK	1/20/2006
COOK, CHARLES	BETTENDORF, IA	1/19/2006
DAVIS, DELORES	TYLER, TX	1/19/2006
HOUGH, RODNEY	CARLISLE, PA	1/19/2006
JOHNSON, JULIA	CLARKSVILLE, TN	1/19/2006
LOPEZ, KRISTINA	VICTORIA, TX	1/20/2006
MOSS, JOE	CHAPEL HILL, TN	1/19/2006
RICHARDSON, KIMBERLY	WINSTON SALEM, NC	1/19/2006
RINGEL, STEVEN	YANKTON, SD	1/20/2006
SHIPLETT, PAULA	NOBLE, OK	1/20/2006
SMITH, MELISSA	SAN ANGELO, TX	1/19/2006
WILLIAMS, TARA	SOUTH SALEM, OH	1/20/2006
Patient Abuse/Neglect Convictions		
ADAMS, CYNTHIA	BUFFALO, NY	1/19/2006
BARNES, KISSILA	DENHAM SPRINGS, LA	1/20/2006
BRYANT, WILLIAM	CROWN POINT, IN	1/20/2006
COSBY, JUAN	GONZALES, LA	1/19/2006
COULBOURNE, SHARON	BLOUNTVILLE, TN	1/19/2006
COX, ROY	SAN DIEGO, CA	1/20/2006
DULANEY, JESSE	MCCOMB, MS	1/19/2006
GARRETT, SHAWN	BUFFALO, NY	1/19/2006
HOLLISTER, PHILIP	HOPKINTON, RI	1/20/2006
JACKSON, RUBY	BALL, LA	1/20/2006
KILLEBREW, RUTH	MINCO, OK	1/19/2006
KIRKLAND, TERESA	ALDEN, NY	1/19/2006
LAMIS, EMERITA	FAIR OAKS, CA	1/19/2006
LAYSSARD, LATOYA	COLFAX, LA	1/20/2006
LEWIS, JANICE	BOGUE CHITTO, MS	1/20/2006
MAIORANO, DAWN	PORT JEFFERSON STATION, NY	1/19/2006
MONSEBAIS, VALERIE	CHICKASHA, OK	1/20/2006
NILSEN, ELSIE	STATEN ISLAND, NY	1/19/2006
NORTON, RABECKA	SHAWNEE, OK	1/20/2006
OAMIL, MERLINA	WAIALUA, HI	1/20/2006
SMITH, KIMITRIA	COFFEEVILLE, MS	1/20/2006
SWINDERMAN–LAUGHTER, MICHELLE	SEVILLE, OH	1/20/2006
THOM, DESIREE	S OZONE PARK, NY	1/19/2006
VANDI, SOLOMON	GREENBELT, MD	1/20/2006
WOOD, CHRISTINE	RICHFORD, NY	1/19/2006
WORWA, PATRICIA	CHEEK TOWAGA, NY	1/19/2006
Conviction for Health Care Fraud		
CURL, HELENE	CEDAR RAPIDS, IA	
YALDIZIAN, RICHARD	HOWARD BEACH, NY	1/19/2006
Controlled Substance Convictions		
ERVIN, SUZIE	MOUNT PLEASANT, MI	1/20/2006
License Revocation/Suspension/Surrendered		
ALEXANDER, VINCILIA	RIVERVIEW, FL	1/20/2006
ALLBRITTON, JAMES	VERO BEACH, FL	1/20/2006
ALLEN, CORIE	SEBASTOPOL, CA	1/20/2006
ANDERSON–MCKAY, TOBY	WALDOBORO, ME	1/19/2006
ASHMAN, LEONARD	SACRAMENTO, CA	1/20/2006
ATTENBOROUGH, CHRISTIE	CHICAGO, IL	1/20/2006
BALDERRAMA, MARIA	GARDEN GROVE, CA	1/20/2006
BALL, DAVID	TUCSON, AZ	1/20/2006
BARBER, LISA	SUN VALLEY, CA	1/20/2006
BARNETT, DEBRA	DEEP RUN, NC	1/20/2006
BARREIRO, MANUEL	PLANT CITY, FL	1/20/2006
BEYDLER, LISA	LARNED, KS	1/20/2006
BLAXTON, JENNIFER	HILLSBORO, AL	1/20/2006
BLEDSOE, MICHELLE	KNOXVILLE, TN	1/20/2006
BRISTOL, LECONTI	JASPER, FL	1/20/2006
BROWN, ALISON	AUGUSTA, GA	1/20/2006

Subject name	Address	Effective date
BROWN, DONNA	MERIDIAN, MS	1/19/2006
BROWN, MILFORD	RUSSELLVILLE, AR	1/20/2006
BROWNLEE, GWENDOLYN	FRESNO, CA	1/19/2006
BUCKMAN, ROBERTA	CHESAPEAKE, VA	1/19/2006
CALDWELL, JENNIE	KINGS MOUNTAIN, NC	1/20/2006
CALLINS, JAN	GUYS, TN	1/20/2006
CAMPBELL, KAREN	SAN ANGELO, TX	1/19/2006
CARBONE, MARY LOU	PHOENIX, AZ	1/20/2006
CARTER, CHARLOTTE	ELGIN, TX	1/20/2006
CASDEN, TERRI	ORMOND BEACH, FL	1/20/2006
CLAY, YUWANYA	ORLANDO, FL	1/20/2006
CLEGG, BARBARA	FLAGSTAFF, AZ	1/20/2006
COBB, JULIE	DALEVILLE, AL	1/20/2006
COLLETTE, ROBERT	HAYMARKET, VA	1/19/2006
COMBES, CHERIE	HORN LAKE, MS	1/19/2006
DANGER, OSNER	FT MYERS, FL	1/20/2006
DAVID, BARBARA	CANTONMENT, FL	1/20/2006
DONALDSON, WILLIAM	TULSA, OK	1/20/2006
DRISCOLL, KIMBERLY	MIAMI, FL	1/20/2006
EFIRD, JILL	MONROE, NC	1/20/2006
ELLIOTT, ROSS	CHARLOTTE, NC	1/20/2006
ENGLER, KEVIN	MEDFORD, OR	1/19/2006
ESTEP, LORA	MORRISTOWN, TN	1/20/2006
FANN, MARGARET	RICHLAND, WA	1/20/2006
FANNIN, RHONDA	HILLIARD, OH	1/20/2006
FAWCETT, DEAN	POLLOCK PINES, CA	1/20/2006
FAYARD, DANIELLE	LONG BEACH, MS	1/20/2006
FILKA, JACKIE	ST PETERSBURG, FL	1/19/2006
FINDLAY, THOMAS	WEST PALM BEACH, FL	1/20/2006
FOSHEE, DEBRA	PINSON, AL	1/20/2006
FOSTER, RITA	MORTON, MS	1/19/2006
FOUNTAIN, POMEROYAL	ITHACHA, NY	1/19/2006
GABRIEL, JULIO	CONCORD, CA	1/19/2006
GALLER, CHERIE	MASPETH, NY	1/19/2006
GIBSON, KATHY	ORANGE CITY, FL	1/19/2006
GIBSON, MELANIE	HORTON, KS	1/20/2006
GO, ESTRELLITA	PITTSBURG, CA	1/19/2006
GOEDDEL, JOYCE	SEBRING, FL	1/20/2006
GONZALES, CRESENDO	CLEAR LAKE, CA	1/20/2006
GOOCH, JOHN	GARDENDALE, AL	1/20/2006
GUFFEY, CHERYL	SHEPHERDSVILLE, KY	1/20/2006
HAMAD, JAMAL	OCALA, FL	1/20/2006
HAMMOND, ROBERT	SKOKIE, IL	1/20/2006
HARPER, MARGARET	SCHENECTADY, NJ	1/19/2006
HARRIS, RHONDA	NEW JOHNSONVILLE, TN	1/20/2006
HARRISON, CHARLENE	BONITA SPRINGS, FL	1/20/2006
HARVEY, KELLY	CLEVELAND, MS	1/19/2006
HATFIELD, ANGEL	SPRINGFIELD, IL	1/19/2006
HAWKINS, TERESA	COCOA, FL	1/20/2006
HECKMAN, SONYA	CLEARWATER, FL	1/20/2006
HENDERSON, AMEENAH	SCOTTSDALE, AZ	1/20/2006
HIGHSMITH, WILLIE	TAMPA, FL	1/20/2006
HUNTER, IAN	PENN VALLEY, CA	1/19/2006
JACKSON, SCOCIA	OAKLAND, CA	1/20/2006
JENKINS, TAIWANA	SAINT PETERSBURG, FL	1/20/2006
JENT, JOHN	GALLATIN, TN	1/20/2006
JOHNSON, CAROLYN	CHINO VALLEY, AZ	1/20/2006
JOHNSON, STEVEN	LANGSTON, AL	1/20/2006
JOHNSTON, JOHN	GRANADA HILLS, CA	1/20/2006
JONES, ETHEL	PHOENIX, AZ	1/20/2006
KAUR, RAJVINDER	PINOLE, CA	1/20/2006
KAVOOSSI, PARVIZ	UPLAND, CA	1/20/2006
KEEMON, CRYSTAL	OROVILLE, CA	1/19/2006
KIENZLE, RICHARD	COPPERHILL, TN	1/20/2006
LACKEY, EDITH	HICKORY, NC	1/20/2006
LAMB, AIMEE	MONROE, NC	1/20/2006
LEPPLA, GAIL	RALEIGH, NC	1/20/2006
LEWIS, MELISSA	MATTHEWS, NC	1/20/2006
LEWIS, YOLANDA	BROCKTON, MA	1/19/2006
LOCKE, BEVERLY	WINONA, MS	1/19/2006
LOFTON, SHERRY	HAMILTON, MS	1/20/2006
LOTT, MARK	LEESBURG, GA	1/20/2006
MATTICE, PERDITA	MESA, AZ	1/20/2006
MATUSIK, MARY	MERRILLVILLE, IN	1/19/2006

Subject name	Address	Effective date
MAUCH, BRETT	SARASOTA, FL	1/20/2006
MCCORA, THOMAS	SALISBURY, NC	1/20/2006
MCCRAW, APRIL	LOUIN, MS	1/20/2006
MCGUFFIE, DIANA	CANTON, MS	1/19/2006
MCLEROY, KEVIN	GOLD HILL, OR	1/20/2006
MCPHERSON, WARREN	RENTON, WA	1/19/2006
MEDICAP PHARMACY	GRAND BLANC, MI	1/19/2006
MELLS, ELLA	ST PETERSBURG, FL	1/19/2006
MELTON, TAMMY	WEWAHITCHKA, FL	1/20/2006
MILLAIRE, JENNIFER	OCOEE, FL	1/20/2006
MOMONGAN, DIOSDADO	NORTHBROOK, IL	1/20/2006
MOORE, HOLLY	HUTCHINSON, KS	1/20/2006
MULLINS, KIMBERLY	PLANT CITY, FL	1/20/2006
MUNOZ FLORES, J	SPOKANE, WA	1/19/2006
NEELY, JEANA	LOUISVILLE, MS	1/20/2006
NEWMAN, STEVEN	HENDERSON, NV	1/20/2006
NEWMAN, SUSAN	DUNLAP, TN	1/20/2006
NUNLEY, RONALD	NICEVILLE, FL	1/20/2006
ODOM, CAROL	GREEN VALLEY, AZ	1/20/2006
PARANTO, RONALD	WASHINGTON, IL	1/19/2006
PASLAY, CYNTHIA	FT. WORTH, TX	1/20/2006
PAULUS, KELLIE	VERO BEACH, FL	1/19/2006
PAYNE, GEORGE	CULLMAN, AL	1/19/2006
PHILLIPS, TERESA	SEMINARY, MS	1/19/2006
PINDER, SHARAYNE	MIAMI, FL	1/20/2006
PITMAN, CAMERON	PENSACOLA, FL	1/19/2006
POSTON, KATRINA	OPP, AL	1/19/2006
PRICHER, MICHELLE	PLANT CITY, FL	1/19/2006
RADA, GEORGE	BONIFAY, FL	1/19/2006
RAMSEY, SUSAN	PIKETON, OH	1/19/2006
RIVERA, ADA	HIALEAH, FL	1/20/2006
SCHAFER, ROSEMARIE	WEIRSDALE, FL	1/19/2006
SCHEFFEY, ERIC	HOUSTON, TX	1/20/2006
SCHULTZ, TERRI	EVANSVILLE, IN	1/20/2006
SHELTON, DAVID	TRENTON, FL	1/20/2006
SMETANA, DENNIS	NEW YORK, NY	1/19/2006
SMITH, ADAM	STUART, FL	1/19/2006
SMITH, COLEEN	NEODESHA, KS	1/20/2006
SMITH, JAMEY	WELLSVILLE, OH	1/19/2006
SMITH, LAURA	INDEPENDENCE, MO	1/20/2006
SMITH, LEACIA	ROCKY POINT, NC	1/20/2006
STARLING, DIANNA	PENSACOLA, FL	1/20/2006
STIERHEIM, LAURA	PHOENIXVILLE, PA	1/19/2006
SULKOWSKI, HOPE	LAKE GROVE, NY	1/19/2006
SULLIVAN, NORMA	KECHI, KS	1/20/2006
THOMAS, MARY	HORTON, KS	1/20/2006
TONN, KERRIE	HUTCHINSON, KS	1/20/2006
TRACEY, COREEN	DUNEDIN, FL	1/20/2006
TUCKER, DENISE	HAVENLOCK, NC	1/20/2006
VANDERGRIFF, CHARLES	SEATTLE, WA	1/19/2006
VILLAGRACIA, ROMANO	VALLEJO, CA	1/19/2006
WAIBLE, SANDRA	CRAWFORDSVILLE, IN	1/20/2006
WARREN, DOROTHY	HIMA, KY	1/20/2006
WHITE BROWN, ADELINE	CENTRALIA, IL	1/20/2006
WHITE, JANICE	MAPLE VALLEY, CA	1/19/2006
WHITEHEAD, GEORGE	LYNNWOOD, WA	1/19/2006
WHITLEY, TRACI	WILSON, NC	1/20/2006
WILSON, TRACEY	HOPKINSVILLE, KY	1/19/2006
WOOD, MARY	NAPA, CA	1/19/2006
ZAMZOW, JAMES	GLENVIEW, IL	1/20/2006
ZIMMERMAN, JEANEASE	BAKERSFIELD, CA	1/19/2006
Fraud/Kickbacks/Prohibited Acts/Settlement Agreements		
BEST DME CORPORATION	EGLIN AFB, FL	7/15/2002
CONTINUOUS MGMT CONSULTING & FINANCIAL SVCS LIMITED	EGLIN AFB, FL	7/15/2002
DME SERVICES, CORP	EGLIN AFB, FL	7/15/2002
INTERCORPORATE FINANCIAL SVCS & MGMT GROUP, INC	EGLIN AFB, FL	7/15/2002
PM CONSULTING GROUP, INC	TAMPA, FL	7/15/2002
QUALITY BILLING SERVICES, INC	TAMPA, FL	7/15/2002
T–TECH MEDICAL SERVICES, INC	SAFETY HARBOR, FL	7/15/2002
Default on Heal Loan		
CAZARES–MARTINEZ, MARK	CATHEDRAL CITY, CA	1/20/2006

Subject name	Address	Effective date
JAIMES, LAURA	PICO RIVERA, CA	1/20/2006
JAKUBOWICZ, LEEOR	WALNUT CREEK, CA	1/20/2006
LENNARTZ, THOMAS	CULVER CITY, CA	1/20/2006
LIPSCHUTZ, ROBERT	PHILADELPHIA, PA	1/20/2006
MARTINEZ-DELEON, ANDRES	GOLDENROD, FL	1/20/2006
MITCHELL, JIMMY	CONCORD, CA	1/20/2006
MORALES, MARIELY	KISSIMMEE, FL	1/20/2006

Dated: January 9, 2006.

Kathleen Pettit,

Acting Director, Exclusions Staff, Office of Inspector General.

[FR Doc. 06–371 Filed 1–13–06; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–22541]

Merchant Mariner Credentials: Temporary Procedures

AGENCY: Coast Guard, DHS.

ACTION: Notice of extension of validity for merchant mariner credentials.

SUMMARY: On August 29, 2005, Hurricane Katrina devastated the coastlines of Alabama, Mississippi, and Louisiana. The Regional Examination Center at New Orleans, which provided credentialing services to approximately 29,000 mariners in those three states and 14 percent of mariners nationwide, was completely flooded, destroying vital records and equipment and rendering the facility temporarily inoperable. Mariners in the area may have lost their credentials in the storm and subsequent flooding, or may be in possession of credentials that either have expired or will soon be expiring. The Coast Guard has previously implemented temporary measures to relieve the hardship on mariners in the Gulf Coast area who need replacement documents. With new temporary authority granted by Congress, the Coast Guard is implementing the additional measure of extending the expiration dates for the credentials of eligible mariners until February 28, 2006.

DATES: This Notice is effective January 17, 2006.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call Mr. Donald J. Kerlin, Deputy Director, Coast Guard National Maritime Center (NMC), (202) 493–1006.

SUPPLEMENTARY INFORMATION: Pursuant to section 3 of the Coast Guard Hurricane Relief Act of 2005, Public Law 109–141, the Coast Guard is initiating temporary credentialing measures for merchant mariner's documents (MMD), merchant marine licenses, certificates of registry (COR), and Standards of Training, Certification and Watchkeeping endorsements (STCW endorsement) for individuals who meet the following conditions:

(1) if the individual is a resident of Alabama, Mississippi, or Louisiana as confirmed by the Coast Guard's Merchant Mariner Licensing and Documentation system (MMLD), or

(2) if the individual is a resident of any other State, and the records of the individual—

(A) were located at the Coast Guard facility in New Orleans that was damaged by Hurricane Katrina; or

(B) were damaged or lost as a result of Hurricane Katrina.

A credential that shows that it was issued in New Orleans, LA, will be sufficient proof that the mariner's records were located at the Coast Guard facility in New Orleans for category (2)(A) above.

The following measures are applicable to all eligible mariners whose credentials have been lost, or have expired, or may expire, during the period indicated within this Notice.

Until February 28, 2006, mariners from Alabama, Mississippi, and Louisiana who lost their credentials may apply at any REC to receive a duplicate credential that will bear the same expiration date and qualifications as the original document that was lost. The evaluation and issuance fees, usually charged for the issuance of duplicate credentials, will be waived. Please see the Notices published in the **Federal Register** in Volume 70, pages 57885 (October 4, 2005) and 59078 (October 11, 2005) for more details on the waiver program.

Due to the time it takes to process renewal applications, mariners who visit an REC to obtain a duplicate credential that is within one year of expiration should apply for a renewal or upgraded credential at the same time that they receive their duplicate credential.

If a credential in a mariner's possession, including a duplicate issued under the provisions described above, has expired or will expire between March 1, 2005, and February 28, 2006, and the credential indicates that either the mariner's home of record is in Alabama, Mississippi, or Louisiana, or that the credential was issued at New Orleans, LA, then that credential together with a copy of this Notice will serve as a valid credential until February 28, 2006.

A mariner who is a resident of any other State, and whose credential was issued at a location other than New Orleans and has expired or will expire between March 1, 2005, and February 28, 2006, and whose records were damaged or lost as a result of Hurricane Katrina, should contact any REC for the procedures to obtain official correspondence affirming that the mariner's credential remains valid until February 28, 2006.

Due to the hurricane, Regional Examination Center (REC) New Orleans was forced to close for approximately six months or more and additional resources were allocated to RECs Memphis, Houston, Miami, and Charleston. Mariners may seek assistance at these or any of the other 12 RECs around the country, a list of which appears at 46 CFR 10.105 and 12.01–7.

Authority: Coast Guard Hurricane Relief Act of 2005, PL 109–141, 2005 HR 4508, 46 U.S.C. 2103, 2110, 7101, 7302, 7501, and 7502, and Department of Homeland Security Delegation No. 0170.1.

Dated: January 11, 2006.

C.E. Bone,

Acting Assistant Commandant for Prevention, RDML, U.S.C.G.

[FR Doc. E6–406 Filed 1–13–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: Application for Citizenship and Issuance of

Certificate under Section 322; Form N–600K, 1615–0087.

The Department of Homeland Security, U.S. Citizenship and Immigration Services will submit the following information collection request for review and clearance in accordance with the Paperwork Reduction Act 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until March 20, 2006.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Director, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHA via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov.* When submitting comments by e-mail please make sure to add OMB Control Number 1615–0087 in the subject box. Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection.

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of Form/Collection:* Application for Citizenship and Issuance of Certificate under section 322.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Application for Citizenship and Issuance of Certificate under section 332; Form N–600K.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form provides an organized framework for establishing the authenticity of an applicant's eligibility and is essential for providing prompt, consistent and correct processing of such applications for citizenship under section 322 of the Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,500 responses at 1 hour and 35 minutes (1.583 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 2,374 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please visit the USCIS Web site at: *http://uscis.gov/graphics/formsfee/forms/pra/index.htm.*

If additional information is required contact: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, 3rd Floor, Washington, DC 20529, (202) 272–8377.

Dated: January 10, 2006.

Richard A. Sloan

Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 06–364 Filed 1–13–06; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Mackay Island National Wildlife Refuge

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of the Draft Comprehensive Conservation Plan and Environmental Assessment for the Mackay Island National Wildlife Refuge in Currituck County, NC, and Virginia Beach, VA.

SUMMARY: This notice announces that a Draft Comprehensive Conservation Plan and Environmental Assessment for Mackay Island National Wildlife Refuge are available for review and comment. The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, requires the Service to develop comprehensive conservation plan for each national wildlife refuge. The purpose in developing a comprehensive conservation plan is to provide refuge managers with a 15-year strategy for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and Service policies. In addition to outlining broad management direction on conserving wildlife and their habitats, the plan identifies wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation.

DATES: Meetings will be held in early 2006 in Knotts Island, Currituck, and Corolla, North Carolina, and Virginia Beach, Virginia, to present the plan to the public. Mailings, newspaper articles, and postings on the refuge's Web site will be the avenues to inform the public of the dates and times of the meetings. Individuals wishing to comment on the Draft Comprehensive Conservation Plan and Environmental Assessment for Mackay Island National Wildlife Refuge should do so no later than February 16, 2006. Public comments were requested, considered, and incorporated throughout the planning process in numerous ways. Public outreach has included scoping meetings, a review of the biological program, an ecosystem planning newsletter, and a **Federal Register** notice.

ADDRESSES: Requests for copies of the Draft Comprehensive Conservation Plan and Environmental Assessment should be addressed to Tim Cooper, P.O. Box 39, Knotts Island, North Carolina 27950, or you may send your comments via electronic mail to: *tim_cooper@fws.gov* with a subject line, ''Draft CCP Comments: Mackay Island NWR.'' Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home addresses from the record, which we will honor to the extent allowed by law.

SUPPLEMENTARY INFORMATION: The Service analyzed three alternatives for future management of the refuge and chose Alternative 2 as the preferred alternative.

Proposed goals for the refuge include:

- Conserve and maintain healthy and viable populations of migratory birds, wildlife, fish, and plants, including Federal and State endangered species and trust species.

• Restore, enhance, and maintain the health and biodiversity of brackish marsh, forests, and other habitats to ensure optimum ecological productivity and to protect the water quality of Currituck Sound and Back Bay.

• Provide the public with safe, quality wildlife-dependent recreational and educational opportunities that focus on the wildlife and habitats of the refuge and the National Wildlife Refuge System.

• Protect refuge resources by limiting the adverse impacts of human activities and development.

• Acquire and manage adequate funding, human resources, facilities, equipment, and infrastructure to accomplish the other refuge goals.

Also available for review are draft compatibility determinations for recreational hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation.

Alternatives

Alternative 1 proposes to maintain the status quo. The refuge would manage very intensively the water levels of the impoundments and the vegetation to create optimum habitat for migrating waterfowl. It would also manage marshes with prescribed fire. The staff would survey waterfowl on a routine basis. The refuge would allow the six priority public use activities: hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation. The staff would conduct environmental education and interpretation on a request basis only. There would be seven staff members stationed at Mackay Island Refuge. They would spend 4.15 full-time equivalent staff years at Mackay Island Refuge and 2.85 full-time equivalent staff years at Currituck National Wildlife Refuge.

Alternative 2, the preferred alternative, proposes moderate program increases. The refuge would develop a habitat management plan and manage all habitats on the refuge. It would survey a wide range of wildlife on the refuge. The refuge would continue to allow the six priority public use activities, but would have the capacity to increase the number of opportunities. The staff would conduct regularly scheduled environmental education and interpretation programs. The Service would build an environmental education center. There would be fifteen staff members, eleven of whom would be stationed at Mackay Island Refuge and four of whom would be stationed at Currituck Refuge. They would spend 7.8 full-time equivalent staff years at Mackay Island Refuge and 7.2 full-time equivalent staff years at Currituck Refuge. The staff would include a biologist and public use specialist.

Alternative 3 proposes substantial program increases. The refuge would develop a habitat management plan and manage all habitats on the refuge. The staff would survey all wildlife on the refuge. The refuge would increase further the number of public use opportunities. The Service would build an environmental education center. There would be twenty-four staff members, seventeen of whom would be stationed at Mackay Island Refuge and seven of whom would be stationed at Currituck Refuge. They would spend 11.25 full-time equivalent staff years at Mackay Island Refuge and 12.75 full-time equivalent staff years at Currituck Refuge. The staff would include separate law enforcement officers and public use specialists for Mackay Island and Currituck Refuges.

Actions Common to All Alternatives

All three alternatives share the following concepts and techniques for achieving the goals of the refuge:

• Cooperating with local, State, and Federal agencies, as well as non-governmental organizations, to administer refuge programs;

• Utilizing volunteers to execute the public use, biological, and maintenance programs on the refuge;

• Monitoring populations of waterfowl, shorebirds, and wading birds, and vegetation in the refuge impoundments;

• Maintaining vegetation in the marsh with prescribed fire; and

• Encouraging scientific research on the refuge.

Mackay Island National Wildlife Refuge, in northeastern North Carolina, consists of 8,219 acres, of which 4,251 acres are brackish marsh, 1,515 acres are coastal fringe evergreen forest, 995 acres are managed wetlands (impoundments), and 298 acres are cropland. These habitats support a variety of wildlife species, including waterfowl, shorebirds, wading birds, marsh birds, neotropical migratory songbirds, and deer.

The refuge hosts more than seventy five thousand visitors annually, who participate in hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation.

Authority: This notice is published under the authority of the National Wildlife Refuge System Improvement act of 1997, Public Law 105–57.

Dated: April 29, 2005.

Cynthia K. Dohner,

Acting Regional Director.

Editorial Note: This document was received at the Office of the Federal Register January 11, 2006.

[FR Doc. 06–370 Filed 1–13–06; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Supplement to the Draft Comprehensive Conservation Plan and Environmental Impact Statement for the Upper Mississippi River National Wildlife and Fish Refuge, Illinois, Iowa, Minnesota, and Wisconsin; Extension of Comment Period

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of extension of comment period.

SUMMARY: The Supplement to the Draft Comprehensive Conservation Plan (CCP) and Environmental Impact Statement (EIS) was released to the public on December 5, 2005, (70 FR 72462, December 5, 2005) for a 60-day review and comment period ending February 3, 2006. Due to public and elected official requests, the comment period for the Supplement is being extended 30 days.

DATES: Comments on the Supplement to the Draft CCP/EIS received by March 6, 2006, will be considered in the preparation of the Final CCP/EIS.

ADDRESSES: All comments should be addressed to Upper Mississippi National Wildlife and Fish Refuge, Attention: CCP Supplement Comment, 51 East 4th Street, Room 101, Winona, Minnesota 55987, or direct e-mail to *r3planning@fws.gov*. Comments may also be submitted through the Service's regional Web site at: *http://www.fws.gov/midwest/planning/uppermiss/index.html*.

FOR FURTHER INFORMATION CONTACT: Don Hultman, at (507) 452–4232.

SUPPLEMENTARY INFORMATION: The Upper Mississippi River National Wildlife and Fish Refuge encompasses 240,000 acres along 261 miles of Mississippi River floodplain in Minnesota, Wisconsin, Iowa, and Illinois. The Refuge was established by Congress in 1924 to provide a refuge and breeding ground for migratory birds, fish, other wildlife, and plants.

The U.S. Fish and Wildlife Service released the Supplement to the Draft CCP/EIS for the refuge on December 5,

2005, for a 60-day comment period. The Supplement to the Draft CCP/EIS was prepared pursuant to the National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, and the National Environmental Policy Act of 1969. Goals and objectives in the CCP describe how the agency intends to manage the refuge over the next 15 years.

Upon release of the Supplement, citizen groups and elected officials requested an extension of the comment period. They cited the importance of the plan to the citizens affected, the commitments of the holidays, and the need for the public to be able to incorporate in their comments what they hear and learn at nine public meetings scheduled for January 2006. Given the above, an extension of 30 days will help ensure full public review and comment.

Dated: January 4, 2006.

Charles M. Wooley,

Acting Regional Director, U.S. Fish and Wildlife Service, Fort Snelling, Minnesota.

[FR Doc. E6–378 Filed 1–13–06; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with endangered species and/or marine mammals.

DATES: Written data, comments or requests must be received by February 16, 2006.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax (703) 358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone (703) 358–2104.

SUPPLEMENTARY INFORMATION:

Endangered Species

The public is invited to comment on the following applications for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address above).

Applicant: James R. Brann, Houston, TX, PRT–112828.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Robert E. Mann, Kingwood, TX, PRT–114026.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Paul Page, Midland, TX, PRT–115656.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Hawthorn Corporation, Grayslake, IL, PRT–087703, 016881, 088950, 088955, 088956, 088957, 088958, 088959, and 088960.

The applicant requests renewal of permits to export captive born tigers (*Panthera tigris*) to worldwide locations for the purpose of enhancement of the species through conservation education. The permit numbers and animals are: 087703, Massey; 016881, Terra; 088950, China; 088955, Diego; 088956, Frieda; 088957, Shaman; 088958, Shiua; 088959, Natari; and 088960, Darsha. This notification covers activities to be conducted by the applicant over a three-year period and the import of any potential progeny born while overseas.

Applicant: Jacksonville Zoological Society, Jacksonville, FL, PRT–080458.

The applicant requests a permit to import three harpy eagles (*Harpia harpyja*) from the government of Guyana, for the purpose of enhancement of the species through captive propagation and conservation education.

Dated: December 16, 2005.

Michael L. Carpenter,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E6–359 Filed 1–13–06; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with endangered species.

DATES: Written data, comments or requests must be received by February 16, 2006.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION:

Endangered Species

The public is invited to comment on the following applications for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address above).

Applicant: William G. Hatcher, Augusta, GA, PRT–113778.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Shawn R. Merriman, Aurora, CO, PRT–112712.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Dated: December 23, 2005.

Monica Farris,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E6–364 Filed 1–13–06; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of an Application for an Incidental Take Permit for the Florida Scrub-Jay Resulting From Construction of a Multi-Home Subdivision in Volusia County, FL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Ocean Shore Estates, LLC (Applicant) requests an incidental take permit (ITP) for a duration of five years, pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973 (Act), as amended (U.S.C. 1531 *et seq.*). The Applicant anticipates destroying about 1.8 acres of occupied Florida scrub-jay (*Aphelocoma coerulescens* (scrub-jay) habitat in Section 21, Township 13 South, Range 32 East, Volusia County, Florida. Habitat destruction would be expected due to vegetation clearing and the subsequent construction of infrastructure and single-family homes. One scrub-jay family could be taken as a result of the Applicant's proposed actions.

The Applicant's Habitat Conservation Plan (HCP) describes the alternatives considered, as well as mitigation and minimization measures proposed to address the effects of the project on the scrub-jay. These measures are also outlined in the **SUPPLEMENTARY INFORMATION** section below. We announce the availability of the ITP application, HCP, and an environmental assessment. Copies of the application, HCP, and environmental assessment may be obtained by making a request to the Southeast Regional Office (see **ADDRESSES**). Requests must be in writing to be processed. This notice is provided pursuant to section 10 of the Act and National Environmental Policy Act (NEPA) regulations (40 CFR 1506.6).

DATES: Written comments on the ITP application, HCP, and environmental assessment should be sent to the Service's Southeast Regional Office (see **ADDRESSES**) and should be received on or before March 20, 2006.

ADDRESSES: Persons wishing to review the application, HCP, and environmental assessment may obtain a copy by writing the Service's Southeast Regional Office at the address below. Please reference permit number TE105727–0 in such requests. Documents will also be available for public inspection by appointment during normal business hours either at the Southeast Regional Office, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: Endangered Species Permits), or at the Jacksonville Field Office, U.S. Fish and Wildlife Service, 6620 Southpoint Drive South, Suite 310, Jacksonville, Florida 32216–0912 (Attn: Field Supervisor).

FOR FURTHER INFORMATION CONTACT: Mr. David Dell, Regional HCP Coordinator, Southeast Regional Office (see **ADDRESSES** above), telephone: (404) 679–7313, facsimile: (404) 679–7081; or Mr. Mike Jennings, Fish and Wildlife Biologist, Jacksonville Field Office (see **ADDRESSES** above), telephone: (904) 232–2580.

SUPPLEMENTARY INFORMATION: If you wish to comment, you may submit comments by any one of several methods. Please reference permit number TE105727–0 in such comments. You may mail comments to the Service's Southeast Regional Office (see **ADDRESSES**). You may also comment via the internet to *david_dell@fws.gov.* Please submit comments over the internet as an ASCII file, avoiding the use of special characters and any form of encryption. Please also include your name and return address in your e-mail message. If you do not receive a confirmation from us that we have received your e-mail message, contact us directly at either telephone number listed above (see **FOR FURTHER INFORMATION CONTACT**). Finally, you may hand-deliver comments to either Service office listed above (see **ADDRESSES**).

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home addresses from the administrative record. We will honor such requests to the extent allowable by law. There may also be other circumstances in which we would withhold from the administrative record a respondent's identity, as allowable by law. If you wish us to withhold your name and address, you must state this prominently at the beginning of your comments. We will not, however, consider 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 Florida scrub-jay (scrub-jay) is geographically isolated from other species of scrub-jays found in Mexico and the western United States. The scrub-jay is found exclusively in peninsular Florida and is restricted to xeric uplands (well-drained, sandy soil habitats supporting a growth of oak-dominated scrub). Increasing urban and agricultural development has resulted in habitat loss and fragmentation, which has adversely affected the distribution and numbers of scrub-jays. The total estimated population is between 7,000 and 11,000 individuals.

The decline in the number and distribution of scrub-jays in east-central Florida has been exacerbated by agricultural land conversions and urban growth in the past 100 years. Much of the historic commercial and residential development has occurred on the dry soils that previously supported scrub-jay habitat. Based on existing soils data, much of the historic and current scrub-jay habitat of coastal east-central Florida occurs proximal to the current shoreline and larger river basins. Much of this area of Florida was settled early because few wetlands restricted urban and agricultural development. Due to the effects of urban and agricultural development over the past 100 years, much of the remaining scrub-jay habitat is now relatively small and isolated. What remains is largely degraded, due to interruption of the natural fire regime that is needed to maintain xeric uplands in conditions suitable for scrub-jays.

From 2003 through 2005, one family of scrub-jays was found using 1.8 acres within the project site. Scrub-jays using the project site are part of a small complex of scrub-jays located in a matrix of urban and natural settings in areas of the barrier islands of Flagler and northern Volusia Counties. Persistent urban growth in the vicinity of the project is expected to result in further reductions in the amount of suitable habitat for scrub-jays. Increasing urban pressures are also likely to result in the continued degradation of scrub-jay habitat as fire exclusion slowly results in vegetative overgrowth. Thus, over the long-term, scrub-jays are unlikely to persist in the vicinity of the project, and conservation

efforts for this species should target acquisition and management of large parcels of land outside the direct influence of urbanization.

Construction of the project's home sites, facilities and infrastructure would result in harm to scrub-jays, incidental to the carrying out of these otherwise lawful activities. The proposed residential construction and associated infrastructure would eliminate the availability of foraging, sheltering, and possible nesting habitat for one family of scrub-jays.

The Applicant proposes to mitigate the loss of 1.8 acres of scrub-jay habitat by providing $78,214.00 to the National Fish and Wildlife Foundation, Florida Scrub Jay Mitigation Fund, or to another entity identified by the Service. Mitigation funding would be used for scrub-jay conservation and may include the acquisition, management, and/or restoration of scrub-jay habitat. This contribution has been determined by the Service to be sufficient to purchase and permanently manage 3.6 acres of scrub-jay habitat in Volusia County. In addition, the Applicant would minimize the loss by surveying for any possible scrub-jay nesting activity during the breeding season. If active nesting were observed in the project area, construction would be halted until any young fledged.

The Service has made a preliminary determination that the issuance of the ITP is not a major Federal action significantly affecting the quality of the human environment within the meaning of section 102(2)(C) of NEPA. This preliminary information may be revised due to public comment received in response to this notice and is based on information contained in the environmental assessment and HCP.

The Service will evaluate the HCP and comments submitted thereon to determine whether the application meets the requirements of section 10(a)(1)(B) of the Act. If it is determined that those requirements are met, the ITP will be issued for incidental take of the Florida scrub-jay. The Service will also evaluate whether issuance of the section 10(a)(1)(B) ITP complies with section 7 of the Act by conducting an intra-Service section 7 consultation. The results of this consultation, in combination with the above findings, will be used in the final analysis to determine whether or not to issue the ITP.

Dated: December 19, 2005.

Cynthia K. Dohner,

Acting Regional Director, Southeast Region.

[FR Doc. E6–376 Filed 1–13–06; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits for marine mammals.

SUMMARY: The following permits were issued.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION:

Notice is hereby given that on the dates below, as authorized by the provisions of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service issued the requested permits subject to certain conditions set forth therein.

Marine Mammals

Permit No.	Applicant	Receipt of application Federal Register notice	Permit issuance date
106766	Scott L. Koelzer	70 FR 58234; October 5, 2005	December 7, 2005.
108268	William M. McCarty	70 FR 58234; October 5, 2005	December 7, 2005.

Dated: December 16, 2005.

Michael L. Carpenter,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E6–363 Filed 1–13–06; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM–910–06–0777–XX]

Notice of Public Meeting, New Mexico Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management, New Mexico Resource Advisory Council (RAC), will meet as indicated below.

DATES: The Meeting dates are February 28–March 2, 2006, at The Bishop's Lodge, 1297 Bishop's Lodge Road, Santa Fe, New Mexico. An optional field trip is planned for February 28, 2006. The public comment period is scheduled for February 28, 2006, from 6–7 p.m. at The Bishop's Lodge. The public may present written comments to the RAC. Depending on the number of individuals wishing to comment and time available, oral comments may be limited. The three established RAC working groups may have a late afternoon or an evening meeting on Wednesday, March 1, 2006.

SUPPLEMENTARY INFORMATION: The 15-member RAC advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in New Mexico. All Meetings are open to the public. At this Meeting, topics include issues on renewable and nonrenewable resources.

FOR FURTHER INFORMATION CONTACT: Theresa Herrera, New Mexico State Office, Office of External Affairs, Bureau of Land Management, P.O. Box 27115, Santa Fe, New Mexico 87502–0115, (505) 438–7517.

Dated: January 6, 2006.

Linda S.C. Rundell,

State Director.

[FR Doc. E6–377 Filed 1–13–06; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–957–1420–BJ]

Idaho: Filing of Plats of Survey

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of surveys.

SUMMARY: The Bureau of Land Management (BLM) has officially filed the plats of survey of the lands described below in the BLM Idaho State Office, Boise, Idaho, effective 9 a.m., on the dates specified.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho 83709–1657.

SUPPLEMENTARY INFORMATION: These surveys were executed at the request of the Bureau of Land Management to meet their administrative needs. The lands surveyed are:

The plat representing the corrective dependent resurvey and dependent resurvey of portions of the west boundary (east boundary of T. 5 S., R. 6 E.), and the dependent resurvey of portions of the south boundary, the subdivisional lines, and the 1910 meanders of the left bank of the Snake River in section 31, and the subdivision of section 31, the survey of the 2002 meanders of the right bank of the Snake River in section 31, and the metes-and-bounds survey of Parcels A and B, section 31, in T. 5 S., R. 7 E., Boise Meridian, Idaho, was accepted June 9, 2004.

The plat, in 2 sheets, constituting the entire survey record, of the dependent resurvey of portions of the east boundary of T. 6 S., R. 6 E., north boundary, and subdivisional lines, the subdivision of section 6, and the survey of an access easement in section 6, in T. 6 S., R. 7 E., Boise Meridian, Idaho, was accepted June 9, 2004.

The plat representing the dependent resurvey of a portion of the east boundary, a portion of the north boundary, and a portion of the subdivisional lines, and the subdivision of sections 1, 12, and 13, in T. 10 N., R. 41 E., Boise Meridian, Idaho, was accepted December 14, 2005.

The plat representing the dependent resurvey of a portion of the west boundary, and a portion of the subdivisional lines, and the subdivision of section 6, in T. 3 N., R. 46 E., was accepted December 16, 2005.

The plat representing the dependent resurvey of a portion of the south boundary, a portion of the west boundary, and a portion of the subdivisional lines, and the subdivision of sections 30 and 31, in T. 4 N., R. 46 E., Boise Meridian, Idaho, was accepted December 16, 2005.

The plat representing dependent resurvey of a portion of the First Standard Parallel South (south boundary), a portion of the west boundary, and a portion of the subdivisional lines, and the subdivision of sections 31 and 32, in T. 6 S., R. 36 E., Boise Meridian, Idaho, was accepted December 28, 2005.

These surveys were executed at the request of the Bureau of Indian Affairs to meet certain administrative and management purposes. The lands surveyed are:

The plat representing the dependent resurvey of portions of the west boundary, the subdivisional lines, and the subdivision of sections 3, 10, and 19, and the additional subdivision of sections 3, 10, and 19, in T. 33 N., R. 2 E., Boise Meridian, Idaho, was accepted November 10, 2005.

The plat representing the dependent resurvey of a portion of the subdivisional lines and the subdivision of sections 21, 22, and 26, in T. 48 N., R. 5 W., Boise Meridian, Idaho, was accepted December 14, 2005.

This survey was executed at the request of the Bureau of Reclamation to meet certain administrative and management purposes. The lands surveyed are:

The plat representing the dependent resurvey of portions of the west boundary and subdivisional lines, and the subdivision of sections 17, 18, and 20, and certain metes-and-bound surveys in sections 17, 18, and 20, in T. 9 S., R. 21 E., Boise Meridian, Idaho, was accepted November 7, 2005.

Dated: January 10, 2006.

Stanley G. French,

Chief Cadastral Surveyor for Idaho.

[FR Doc. E6–382 Filed 1–13–06; 8:45 am]

BILLING CODE 4310–GG–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–559]

In the Matter of Certain Digital Processors and Digital Processing Systems, Components Thereof, and Products Containing Same Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 9, 2005, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of BIAX Corporation of Boulder, Colorado. An amended complaint was filed on December 29, 2005. The amended complaint alleges violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital processors and digital processing systems, components thereof, and products containing same by reason of infringement of claims 3, 4, 6, 8–12, and 36 of U.S. Patent No. 5,021,945, claims 18–20, 23, and 25–27 of U.S. Patent No. 5,517,628, and claims 3–11, 13, 14, 19, and 21–25 of U.S. Patent No. 6,253,313. The amended complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337. The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and permanent cease and desist orders.

ADDRESSES: The amended complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: Benjamin D.M. Wood, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202–205–2582.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2005).

Scope of Investigation: Having considered the amended complaint, the U.S. International Trade Commission, on January 9, 2006, ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain digital processors or digital processing systems, components thereof, or products containing same by reason of

infringement of one or more of claims 3, 4, 6, 8–12, and 36 of U.S. Patent No. 5,021,945, claims 18–20, 23, and 25–27 of U.S. Patent No. 5,517,628, and claims 3–11, 13, 14, 19, and 21–25 of U.S. Patent No. 6,253,313, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—

BIAX Corporation, 1942 Broadway, Suite 404, Boulder, Colorado 80302.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Philips Semiconductors B.V., Bldg. BE P, PO Box 218, 5600 Eindhoven, Netherlands.

Philips Consumer Electronics Services B.V., Boschdjik 525, Postbus 90050, 5600 PB Eindhoven, Netherlands.

Philips Consumer Electronics North America Corp., 64 Perimeter Center East, Atlanta, GA 30346.

2Wire, Inc., 1704 Automation Parkway, San Jose, CA 95131.

(c) Benjamin D.M. Wood, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Suite 401, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, the Honorable Sidney Harris is designated as the presiding administrative law judge.

Responses to the amended complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the amended complaint and the notice of investigation. Extensions of time for submitting responses to the amended complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the amended complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondents, to find the facts to be as alleged in the complaint and this notice and to enter a final determination containing such findings, and may result in the issuance of a limited exclusion order or cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: January 9, 2006.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E6–370 Filed 1–13–06; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–06–006]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: January 18, 2006 at 11 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436. Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meetings: None.
2. Minutes.
3. Ratification List.
4. Inv. Nos. 731–TA–457–A–D (Second Review) (Heavy Forged Hand Tools from China)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before January 31, 2006.)
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: January 11, 2006.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 06–445 Filed 1–12–06; 1:36 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–58,037]

Cabot Corporation, Supermetals Division, Boyertown, PA; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Cabot Corporation, Supermetals Division, Boyertown, Pennsylvania. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–58,037; Cabot Corporation Supermetals Division Boyertown, Pennsylvania (January 5, 2006)

Signed at Washington, DC this 6th day of January 2006.

Erica R. Cantor,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E6–384 Filed 1–13–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–57,867]

Capital City Press, Inc., Publication Services Division, Barre, VT; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Capital City Press, Inc., Publication Services Division, Barre, Vermont. The application did not contain new information supporting a conclusion that the determination was erroneous, and also did not provide a justification for reconsideration of the determination that was based on either mistaken facts or a misinterpretation of facts or of the law. Therefore, dismissal of the application was issued.

TA–W–57,867; Capital City Press, Publication Services Division, Barre, Vermont (January 10, 2006)

Signed at Washington, DC this 10h day of January 2006.

Erica R. Cantor,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E6–386 Filed 1–13–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than January 27, 2006.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than January 27, 2006.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 10th day of January 2006.

Erica R. Cantor,

Director, Division of Trade Adjustment Assistance.

APPENDIX

[TAA petitions instituted between 12/26/05 and 12/30/05]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
58547	Nicholson Manufacturing Company (Wkrs)	Seattle, WA	12/27/05	12/23/05
58548	Keeler Brass Company (Comp)	Grand Rapids, MI	12/27/05	12/27/05
58549	Vision Knit Technology, Inc. (Comp)	Gastonia, NC	12/28/05	12/16/05
58550	Baxter—Financial Center of Excellence (Comp)	Deerfield, IL	12/28/05	12/28/05
58551	Werner Company (Comp)	Carrollton, KY	12/28/05	12/22/05
58552	Parker Hannifin Corp. (IAM)	Lebanon, TN	12/29/05	12/29/05
58553	P and C Quality Turned Components (Wkrs)	Esmond, RI	12/29/05	12/28/05
58554	Logistics Services, Inc. (Comp)	Oklahoma City, OK	12/30/05	12/09/05
58555	Penske Logistics (UAW)	Oklahoma City, OK	12/30/05	12/09/05
58556	Carolina Mirror (Wkrs)	N. Wilkesboro, NC	12/30/05	12/29/05
58557	Dannex Printing Corporation (Wkrs)	Wood-Ridge, NJ	12/30/05	12/14/05
58558	Thomas C. Wilson, Inc. (State)	Long Island City, NY	12/30/05	12/19/05
58559	T and H Sewing Co. (Wkrs)	San Francisco, CA	12/30/05	12/16/05
58560	Bennett Forest Industries (Comp)	Grangeville, ID	12/30/05	12/16/05
58561	Lustrik, Inc. (Wkrs)	Philadelphia, PA	12/30/05	12/19/05
58562	Scholle Packaging (Comp)	Rancho Dominguez, CA	12/30/05	12/30/05
58563	Authentic Specialty Foods, Inc. (State)	Rosemead, CA	12/30/05	12/30/05
58564	Lizette Creations, Inc. (State)	Long Beach, CA	12/30/05	12/30/05

[FR Doc. E6–387 Filed 1–13–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended, (19 U.S.C. 2273), the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the periods of December 2005.

In order for an affirmative determination to be made and a certification of eligibility to apply for directly-impacted (primary) worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of

articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;
2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or
3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance as an adversely affected secondary group to be issued, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) either—

(A) the workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) a loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of (a)(2)(A) (increased imports) of Section 222 have been met.

TA–W–58,375; Spartacraft, Inc., Connelly Springs, NC, November 15, 2004.

TA–W–58,386; Shepherd Hardware Products, LLC, Three Oaks, MI, November 16, 2004.

TA–W–58,469; Rockford Corporation, Adecco Services, Walker, MI, November 29, 2004.

TA–W–58,484; Big River Zinc Corporation, Sauget, IL, December 7, 2004.

TA–W–58,346; Weavetex, Inc., Jonesville, SC, November 14, 2004.

TA–W–58,359; Strongwater Group, LLC (The), Moonachie, NJ, November 16, 2004.

TA–W–58,359A; Strongwater Group, LLC (The), Englewood, NJ, November 16, 2004.

TA–W–58,359B; Strongwater Group, LLC (The), Tetate, CA, November 16, 2004.

TA–W–58,385; Car Component Technologies, A Subsidiary of American Remanufacturers, Inc., Bedford, NH, November 18, 2004.

TA–W–58,385A; Car Component Technologies, A Subsidiary of American Remanufacturers, Distribution Center, Merrimack, NH, November 18, 2004.

TA–W–58,425; Carolina Mills, Inc., Corporate Headquarters, Maiden, NC, November 30, 2004.

The following certifications have been issued. The requirements of (a)(2)(B) (shift in production) of Section 222 have been met.

TA–W–58,371; Carhartt, Inc., Sebree, KY, November 17, 2004.

TA–W–58,371A; Carhartt, Inc., Morehead, KY, November 17, 2004.

TA–W–58,371B; Carhartt, Inc., Glasgow, KY, November 17, 2004.

TA–W–58,447; May and Scofield, LLC, Madison, SD, December 1, 2004.

TA–W–58,512; Tri-State Hospital Supply Corp., Salisbury, NC, December 16, 2004.

TA–W–58,345; Formica Corporation, Odenton, MD, November 14, 2004.

TA–W–58,363; Thomasville Furniture Ind., Inc., Corporate Office, Thomasville, NC, March 11, 2005.

TA–W–58,367; Springfield Wire, Inc., Leased Wkrs of Summit Careers, Spherion Staffing, Valley Employment, Springfield, MA, November 10, 2004.

The following certification has been issued. The requirement of supplier to a trade certified firm has been met.

TA–W–58,419; Dean Company (The), Princeton, WV, November 29, 2004.

The following certification has been issued. The requirement of downstream producer to a trade certified firm has been met.

None

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

The investigation revealed that criterion (a)(2)(A)(I.A) and (a)(2)(B)(II.A) (no employment decline) has not been met.

TA–W–58,390; JK Tool, A Subsidiary of Siegel—Robert, Inc., Portageville, MO.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B) (No shift in production to a foreign country) have not been met.

TA–W–58,435; Paxar Americas, Inc., Systems Div., Adecco, Sayre, PA.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B) (No shift in production to a foreign country) have not been met.

TA–W–58,202; Key Plastics, Hamilton, IN.

TA–W–58,485; Rawlings Sporting Goods, A Subsidiary of K2, Inc., Licking, MO.

TA–W–58,158; Falcon Plastics, Washington, PA.

TA–W–58,372; Tin, Inc., dba Temple Inland, Inc., Corrugated Packaging Division, Newark, DE.

The investigation revealed that criteria (a)(2)(A)(I.C.) (Increased imports and (a)(2)(B)(II.C) (has shifted production to a foreign country) have not been met.

None

The workers firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–58,287; Agilent Technologies, Global Infrastructure Services, Customer & Quality, Loveland, CO.

TA–W–58,406; Adobe Air, Phoenix, AZ.

TA–W–58,428; Apple Computer, Inc., Continuation Engineering Department, Cupertino, CA.

The investigation revealed that criteria (2) has not been met. The workers firm (or subdivision) is not a supplier or downstream producer to trade-affected companies.

None

Affirmative Determinations for Alternative Trade Adjustment Assistance

In order for the Division of Trade Adjustment Assistance to issue a

certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determinations.

In the following cases, it has been determined that the requirements of Section 246(a)(3)(ii) have been met.

I. Whether a significant number of workers in the workers' firm are 50 years of age or older.

II. Whether the workers in the workers' firm possess skills that are not easily transferable.

III. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

TA–W–58,375; Spartacraft, Inc., Connelly Springs, NC, November 15, 2004.

TA–W–58,386; Shepherd Hardware Products, LLC, Three Oaks, MI, November 16, 2004.

TA–W–58,469; Rockford Corporation, Adecco Services, Walker, MI, November 29, 2004.

TA–W–58,484; Big River Zinc Corporation, Sauget, IL, December 7, 2004.

TA–W–58,346; Weavetex, Inc., Jonesville, SC, November 14, 2004.

TA–W–58,359; Strongwater Group, LLC (The), Moonachie, NJ, November 16, 2004.

TA–W–58,359A; Strongwater Group, LLC (The), Englewood, NJ, November 16, 2004.

TA–W–58,359B; Strongwater Group, LLC (The), Tetate, CA, November 16, 2004.

TA–W–58,385; Car Component Technologies, A Subsidiary of American Remanufacturers, Inc., Bedford, NH, November 18, 2004.

TA–W–58,385A; Car Component Technologies, A Subsidiary of American Remanufacturers, Distribution Center, Merrimack, NH, November 18, 2004.

TA–W–58,425; Carolina Mills, Inc., Corporate Headquarters, Maiden, NC, November 30, 2004.

TA–W–58,371; Carhartt, Inc., Sebree, KY, November 17, 2004.

TA–W–58,371A; Carhartt, Inc., Morehead, KY, November 17, 2004.

TA–W–58,371B; Carhartt, Inc., Glasgow, KY, November 17, 2004.

TA–W–58,447; May and Scofield, LLC, Madison, SD, December 1, 2004.

TA–W–58,512; Tri-State Hospital Supply Corp., Salisbury, NC, December 16, 2004.

TA–W–58,363; Thomasville Furniture Ind., Inc., Corporate Office, Thomasville, NC, March 11, 2005.

TA–W–58,367; Springfield Wire, Inc., Leased Wkrs of Summit Careers, Spherion Staffing, Valley Employment, Springfield, MA, November 10, 2004.

TA–W–58,419; Dean Company (The), Princeton, WV, November 29, 2004.

Negative Determinations for Alternative Trade Adjustment Assistance

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

In the following cases, it has been determined that the requirements of Section 246(a)(3)(ii) have not been met for the reasons specified.

Since the workers are denied eligibility to apply for TAA, the workers cannot be certified eligible for ATAA.

TA–W–58,390; JK Tool, A Subsidiary of Siegel—Robert, Inc., Portageville, MO.

TA–W–58,435; Paxar Americas, Inc., Systems Div., Adecco, Sayre, PA.

TA–W–58,158; Falcon Plastics, Washington, PA.

TA–W–58,372; Tin, Inc., dba Temple Inland, Inc., Corrugated Packaging Division, Newark, DE.

TA–W–58,202; Key Plastics, Hamilton, IN.

TA–W–58,485; Rawlings Sporting Goods, A Subsidiary of K2, Inc., Licking, MO.

TA–W–58,287; Agilent Technologies, Global Infrastructure Services, Customer & Quality, Loveland, CO.

TA–W–58,406; Adobe Air, Phoenix, AZ.

TA–W–58,428; Apple Computer, Inc., Continuation Engineering Department, Cupertino, CA.

The Department as determined that criterion (1) of Section 246 has not been met. Workers at the firm are 50 years of age or older.

None

The Department as determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

TA–W–58,345; Formica Corporation, Odenton, MD, November 14, 2004.

The Department as determined that criterion (3) of Section 246 has not been met. Competition conditions within the workers' industry are not adverse.

None

I hereby certify that the aforementioned determinations were issued during the month of December 2005. Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: January 10, 2006.

Erica R. Cantor,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E6–390 Filed 1–13–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–58,519]

Tri-Mountain Machining, Idledale, CO; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on December 20, 2005 in response to a petition filed by a state workforce representative on behalf of workers at TRI-Mountain Machining, Idledale, Colorado.

The state workforce representative has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC this 5th day of January, 2006

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–388 Filed 1–13–06; 8:45 am]

BILLING CODE 4510–30–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[06–001]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, 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 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

DATES: All comments should be submitted within 30 calendar days from the date of this publication.

ADDRESSES: All comments should be addressed to Desk Officer for NASA, Office of Information and Regulatory Affairs, Room 10236, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Mr. Walter Kit, NASA Reports Officer, JA000, NASA Headquarters, 300 E Street, SW., Washington, DC 20546, 202–358–1350, *Walter.Kit-1@nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Aeronautics and Space Administration (NASA) is requesting renewal of an existing collection that is used to help NASA ensure proper accounting of Federal funds provided under grants and cooperative agreements with institutions of higher education and other non-profit organizations. Reporting and recordkeeping are prescribed in 14 CFR § 1260.10, § 1260.20, § 1260.21, § 1260.22, § 1260.24, § 1260.26, § 1260.32, § 1260.33, § 1260.35, § 1260.73, § 1260.75, and § 1260.77. Furthermore, collection constitutes NASA's implementation of those parts of OMB Circular A–110 deemed applicable to Agency awards; i.e., submission of SF 272's, recordkeeping, and prudent stewardship of Government-provided funds.

II. Method of Collection

NASA uses electronic methods to collect information from collection respondents.

III. Data

Title: Financial Monitoring and Control—Grants and Cooperative Agreements.

OMB Number: 2700–0049.

Type of review: Renewal of a currently approved collection.

Affected Public: Not-for-profit institutions.

Estimated Number of Respondents: 1,172.

Estimated Time Per Response: varies.

Estimated Number of Responses Per Respondent: varies.

Number of Annual Responses: 47,710.

Estimated Total Annual Burden Hours: 291,326.

Estimated Total Annual Cost: $0.

Frequency of Report: As needed.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of information on respondents, including automated collection techniques or the use of other forms of information technology.

Patricia L. Dunnington,

Chief Information Officer.

[FR Doc. E6–424 Filed 1–13–06; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[06–002]

Notice of Information Collection Under OMB Review

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection under OMB review.

SUMMARY: The National Aeronautics and Space Administration, 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 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

DATES: All comments should be submitted within 30 calendar days from the date of this publication.

ADDRESSES: All comments should be addressed to Desk Officer for NASA; Office of Information and Regulatory Affairs; Room 10236; New Executive Office Building; Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Walter Kit, NASA Reports Officer, NASA Headquarters, 300 E Street, SW., JA000, Washington, DC 20546, (202) 358–1350, *Walter.Kit-1@hq.nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Aeronautics and Space Administration (NASA) is requesting renewal of an existing collection that is used to help NASA to assess the services provided by its procurement offices. The NASA Procurement Customer Survey is used to determine whether NASA's Procurement Offices are providing an acceptable level of service to the business/educational community, and if not, which areas need improvement. Respondents will be business concerns and educational institutions that have been awarded a NASA procurement, or are interested in receiving such an award.

II. Method of Collection

NASA uses electronic methods to collect information from collection respondents.

III. Data

Title: NASA Procurement Customer Survey.

OMB Number: 2700–0101.

Type of review: Extension of a currently approved collection.

Affected Public: Business or other for-profit; Not-for-profit institutions.

Estimated Number of Respondents: 1,000.

Estimated Annual Responses: 500.

Estimated Time Per Response: 15 minutes.

Estimated Total Annual Burden Hours: 125.

Estimated Total Annual Cost: $0.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Patricia L. Dunnington,

Chief Information Officer.

[FR Doc. E6–425 Filed 1–13–06; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act; Notice of Meeting

TIME AND DATE: 10 a.m., Thursday, January 19, 2006.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Proposed Rule: Interpretive Ruling and Policy Statement (IRPS) 06–1, Section 701.1 of NCUA's Rules and Regulations, Amendments to NCUA's Chartering and Field of Membership Policies.
2. Final Rule: Section 741.6(a) of NCUA's Rules and Regulations, Financial and Statistical and Other Reports.
3. Final Rule: Section 701.34 of NCUA's Rules and Regulations, Uninsured Secondary Capital Accounts.
4. Final Rule: Part 742 of NCUA's Rules and Regulations, Regulatory Flexibility Program.

RECESS: 11:15 a.m.

TIME AND DATE: 11:30 a.m., Thursday, January 19, 2006.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Administrative Action under Section 206(h)(1)(A) of the Federal Credit Union Act. Closed pursuant to Exemptions (8), (9)(A)(ii), and (9)(B).
2. One (1) Insurance Appeal. Closed pursuant to Exemption (6).

FOR FURTHER INFORMATION CONTACT: Mary Rupp, Secretary of the Board, Telephone: 703–518–6304.

Mary Rupp,

Secretary of the Board.

[FR Doc. 06–460 Filed 1–12–06; 3:50 pm]

BILLING CODE 7535–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Federal Advisory Committee on International Exhibitions

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Federal Advisory Committee on International Exhibitions (FACIE) to the National Council on the Arts will be held on January 25, 2006 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506. This meeting, which will be held by teleconference from 1 p.m. to 1:30 p.m., will be closed.

Closed meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of April 8, 2005, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of Title 5, United States Code.

Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5691.

Dated: January 11, 2006.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 06–398 Filed 1–13–06; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for International Science and Engineering; Notice of Meeting

In accordance with Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Advisory Committee for International Science and Engineering (#25104).

Date/Time:
February 9, 2006 8:30 a.m. to 5 p.m.
February 10, 2006 8:30 a.m. to noon.

Place: National Science Foundation, 4201 Wilson Boulevard, Room 920, Arlington, VA.

Type of Meeting: Open.

Contact Person: Eduardo Feller, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, (703) 292–8710.

If you are attending the meeting and need access to the NSF, please contact the individual listed above so your name may be added to the building access list.

Purpose of Meeting: To provide advice concerning issues related to the current NSF international programs and initiatives.

Agenda

February 9, 2006

Introductions and Updates—Current initiatives, budget and programs. Activities of the NSF overseas Offices. Update on the Partnerships for International Research and Education.

February 10, 2006

Committee discussion of current international initiatives and programs. Initiatives for the coming fiscal year. Planning for the next meeting, feedback and other business.

Dated: January 11, 2006.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 06–375 Filed 1–13–06; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[IA–05–052]

David Geisen; Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)

I

Mr. David Geisen was previously employed, at times relevant to this Order, as the Manager of Design Engineering at the Davis-Besse Nuclear Power Station (Davis-Besse) operated by FirstEnergy Nuclear Operating Company (FENOC or licensee). The licensee holds License No. NPF–3 which was issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR part 50 on April 22, 1977. The license authorizes the operation of Davis-Besse in accordance with the conditions specified therein. The facility is located on the licensee's site near Oak Harbor, Ohio.

II

On August 3, 2001, the NRC issued Bulletin 2001–001, ''Circumferential Cracking of Reactor Pressure Vessel Head Penetration Nozzles,'' (Bulletin). In the Bulletin, the NRC requested that all holders of operating licenses for pressurized water nuclear power reactors (PWR), including FENOC for the Davis-Besse facility, provide information to the NRC relating to the structural integrity of the reactor pressure vessel (RPV) head penetration nozzles at their respective facilities. The information requested from the licensees included the extent of RPV head penetration nozzle leakage and cracking that had been found to date, a description of the inspections and repairs undertaken to satisfy applicable regulatory requirements, and the basis for concluding that a licensee's plans for future inspections would ensure compliance with applicable regulatory requirements. The NRC also required that all Bulletin addressees, including FENOC, submit a written response to the NRC in accordance with the provisions of 10 CFR 50.54(f). That

regulation provides, in part, that upon request of the NRC, an NRC-licensee must submit written statements, signed under oath or affirmation, to enable the NRC to determine whether the license should be modified, suspended, or revoked.

On September 4, October 17, and October 30, 2001, the licensee provided written responses to the Bulletin. Additionally, the licensee met with the NRC staff on numerous occasions during October and November of 2001 to provide clarifying information. Based, in part, on the information provided by FENOC in its written responses to the Bulletin and during meetings with the NRC staff, the NRC staff allowed the licensee to continue operation of the Davis-Besse facility until February 2002, rather than requiring FENOC to shut the unit down to perform inspections by December 31, 2001, as provided in the Bulletin.

On February 16, 2002, FENOC shut down Davis-Besse for refueling and inspection of control rod drive mechanism (CRDM) RPV head penetration nozzles. Using ultrasonic testing, the licensee found cracks in three CRDM RPV head penetration nozzles and on March 6, 2002, the licensee discovered a cavity in the RPV head in the vicinity of CRDM Penetration Nozzle No. 3. The cavity measured approximately 5 to 7 inches long, 4 to 5 inches wide, and penetrated through the 6.63 inch-thick low-alloy steel portion of the RPV head, leaving the stainless steel cladding material (measuring 0.202 to 0.314 inches-thick) as the sole reactor coolant system (RCS) pressure boundary. A smaller cavity was also found near CRDM Penetration Nozzle No. 2.

The licensee conducted a root cause evaluation and determined that, contrary to the earlier information provided to the NRC, the cavities were caused by boric acid from the RCS released through cracks in the CRDM RPV head penetration nozzles. The root cause evaluation found that the licensee conducted limited cleaning and inspections of the RPV head during the Twelfth Refueling Outage (12RFO) that ended on May 18, 2000. However, neither the limited RPV head cleaning nor the resultant inspections during 12RFO were sufficient to ensure that the significant boric acid deposits on the RPV head were only a result of CRDM flange leakage, as supposed, and were not a result of RCS pressure boundary leakage.

On March 6 and March 10, 2002, the licensee provided information to the NRC concerning the identification of a large cavity in the RPV head adjacent to CRDM Penetration Nozzle No. 3. The NRC conducted an Augmented Inspection Team (AIT) inspection at Davis-Besse from March 12 to April 5, 2002, to determine the facts and circumstances related to the significant degradation of the RPV head. The results of the AIT inspection were documented in NRC Inspection Report No. 50–346/2002–03, issued on May 3, 2002. A follow-up Special Inspection was conducted from May 15 to August 9, 2002, and on October 2, 2002, the NRC issued the AIT Follow-up Special Inspection Report No. 50–346/2002–08 documenting ten apparent violations associated with the RPV head degradation.

On April 22, 2002, the NRC Office of Investigations (OI) initiated an investigation at Davis-Besse to determine, among other matters, whether FENOC and individual employees at the Davis-Besse facility failed to provide complete and accurate information to the NRC in its September 4, October 17, and October 30, 2001, responses to the Bulletin and during numerous conference calls and meetings in violation of 10 CFR 50.9 and 10 CFR 50.5(a)(2). The OI report (No. 3–2002–006) was issued on August 22, 2003. A copy of the OI report was provided to the U.S. Department of Justice (DOJ), Office of the United States Attorney, Northern District of Ohio for review. The matter remains under continued Federal investigation. Mr. Geisen, through the performance of his engineering duties, and through oral and written communications with other FENOC employees, was aware of the results of previous RPV head inspections. For example:

- On April 27, 2000, Mr. Geisen signed and closed out Condition Report (CR) 2000–1037 which included the following problem statement associated with the identification of five leaking control rod drives:

> ''Identified at locations: F10, D10, C11, F8, and G9 * * * There are no boron deposits on the vertical faces of the flange of G9 drive. The bottom of the flange of G9 drive is inaccessible for inspection due to the boron buildup on the reactor head insulation, not allowing full camera insertion. Since the boron is evident only under the flange and not on the vertical surfaces, there is a high probability that G9 is a leaking CRD.''

- On June 27, 2001, Mr. Giesen approved and signed an intra-company memorandum that indicated that ''large boron leakage from a control rod drive mechanism (CRDM) flange was observed during 12RFO inspection'' and ''This leakage did not permit the detailed inspection of CRDM nozzles.''
- On August 11, 2001, Mr. Geisen received an E-mail that stated, in part: ''it was pointed out that we cannot clean our head thru the mouse holes and a system engineer is requesting that three large holes be cut in the Service Structure for viewing [inspection] and cleaning.''
- Mr. Geisen reviewed a Piedmont Management and Technical Services, Inc., report, dated September 14, 2001, that indicated, in part, that at the completion of 12RFO the RPV head had boric acid deposits of considerable depth left at the center top area of the head.
- A Senior Staff Nuclear Advisor (former inservice inspector), FENOC, at the request of a system engineer from Davis-Besse plant engineering, reviewed a CD ROM video that the system engineer had made from videos of the reactor vessel head. The purpose of the review was to assist in locating or determining the location of some nozzles. Shortly after completing the review, Mr. Geisen asked the Senior Staff Nuclear Advisor what he thought, from a visual standpoint, of the data he had seen on the video. The Senior Staff Nuclear Advisor replied, in part, that, based on an Electric Power Research Institute (EPRI) head examination document being developed, boron on the Davis-Besse head would preclude an examination of that nature [EPRI] from being performed.
- In March 2002, a consultant from Martin Sigmund Consulting Services, Inc., conducted an assessment of reactor head management issues at Davis-Besse. The consultant provided his assessment to the Davis-Besse Site Vice President via a memorandum dated March 28, 2002. The assessment, in part, consisted of interviews with many of the personnel involved with the reactor head corrosion issues. Mr. Geisen was interviewed for this assessment on March 27, 2002, and stated, in part, that some boric acid was left on the head in 2000 and that the condition report was not very thoroughly evaluated. Mr. Geisen also stated that he became aware that the reactor vessel head had not been cleaned completely when reviewing the videos of the inspections in preparation for interacting with the NRC in August, 2001.
- On June 18, 2002, the licensee interviewed Mr. Geisen regarding the Davis-Besse responses to Bulletin 2001–001. When asked whether the reactor vessel head was inspected in accordance with plant procedure, Mr. Geisen stated, in part, that we did the inspection but clearly not with [in accordance with] the procedure. Mr. Geisen further stated that Davis-Besse

was taking credit for a general inspection which clearly did not meet the requirements in Bulletin 2001–001.

The above information demonstrates that Mr. Geisen had sufficient knowledge of the results of previous inspections of the RPV head and that he knew that the licensee's written and oral responses to NRC Bulletin 2001–001 were incomplete and inaccurate.

Several FENOC employees, including Mr. David Geisen, were responsible for the information provided to the NRC by FENOC in response to the Bulletin.

III

David Geisen was employed by FENOC as the Manager of Design Engineering at Davis-Besse at the time the licensee developed and transmitted to the NRC its written responses to the Bulletin and at the time the licensee met with the NRC to provide clarifying information regarding its written responses.

On August 28, October 17, and October 30, 2001, respectively, Mr. Geisen concurred in the issuance of the licensee's September 4, October 17, and October 30, 2001, responses to the Bulletin. On the concurrence sheets, Mr. Geisen was listed as the FENOC manager responsible for ensuring the completeness and accuracy of the responses. Mr. Geisen participated in the development and presentation of information to the NRC during information briefings held on October 3, October 11, and November 9, 2001.

Item 1.d of the Bulletin requested each pressurized water reactor (PWR) licensee, including FENOC for Davis-Besse, to provide a description of the RPV head penetration nozzles and RPV head inspection (including type, scope, qualification requirements, and acceptance criteria) that were performed at PWRs in the 4 years preceding the date of the Bulletin, and the findings resulting from the inspections. The licensees were requested to include a description of any limitations (insulation or other impediments) to accessibility of the bare metal of the RPV head for visual examinations.

On September 4, 2001, FENOC submitted its written response to the Bulletin for Davis-Besse. Item 1.d of the licensee's September 4, 2001, response to the Bulletin stated, in part, that:

''The DBNPS [Davis-Besse] has performed two inspections within the past four years, during the 11th Refueling Outage (RFO) in April 1998 and during the 12th RFO in April 2000. The scope of the visual inspection was to inspect the bare metal RPV head area that was accessible through the weep holes to identify any boric acid leaks/deposits. The DBNPS also inspected 100% of Control Rod Drive Mechanism (CRDM) flanges for leaks in response to Generic Letter 88–05, 'Boric Acid Corrosion of Carbon Steel Reactor pressure Boundary Components in PWR Plants.' The results of these two recent inspections are described below.

Inspections of the RPV head are performed with the RPV head insulation installed in accordance with DBNPS procedure NG–EN–0324, 'Boric Acid Corrosion Control Program,' which was developed in response to Generic Letter 88–05. As stated previously, a gap exists between the RPV head and the insulation, the minimum gap being at the dome center of the RPV head where it is approximately 2 inches, and does not impede visual inspection. The service structure envelopes the DBNPS RPV head and has 18 openings (weep holes) at the bottom through which inspections are performed. There are 69 CRDM nozzles that penetrate the RPV head. The metal reflective insulation is located above the head and does not interfere with the visual inspection. The visual inspection is performed by the use of a small camera. This camera is inserted through the weep holes.''

Item 1.d of the licensee's September 4, 2001, response, under the section entitled, ''April 2000 Inspection Results (12RFO),'' stated:

''The boric acid deposits were located beneath the leaking flanges with clear evidence of downward flow. No visible evidence of nozzle leakage was detected.''

Item 1.d of the licensee's September 4, 2001, response, under the section entitled, ''Subsequent Review of 1998 and 2000 Inspection Videotapes Results,'' stated:

''Since May 2001, a review of the 1998 and 2000 inspection videotapes of the RPV head has been performed. This review was conducted to re-confirm the indications of boron leakage experienced at the DBNPS were not similar to the indications seen at ONS and ANO–1; i.e., was not indicative of RPV nozzle leakage. This review determined that indications such as those that would result from RPV head penetration leakage were not evident.''

The licensee's September 4, 2001, response was materially incomplete and inaccurate in that the response: (1) Mischaracterized the accumulation of boric acid on the RVP head as a result of the 12RFO RPV head inspection; (2) failed to include information that during the Eleventh Refueling Outage (11RFO) and 12RFO, the licensee's access to the RPV head bare metal was impeded by the presence of significant accumulations of boric acid deposits; (3) failed to indicate that the presence of boric acid deposits was not limited to the area beneath control rod drive mechanism flanges; and (4) failed to indicate that the build-up of boric acid deposits was so significant that the licensee could not inspect all of the RPV head penetration nozzles. Mr. Geisen was aware that the licensee's September 4, 2001, response to the Bulletin was materially incomplete and inaccurate, but nevertheless concurred on the response, thereby allowing it to be submitted to the NRC.

The NRC staff determined that the September 4, 2001 response did not include sufficient information to justify the NRC permitting FENOC to operate Davis-Besse beyond December 31, 2001. As a result, FENOC met with the NRC staff, Commissioners' Technical Assistants, the Advisory Committee on Reactor Safeguards, and Congressional staff members, and developed supplemental responses in an effort to better communicate its justification for continued operations beyond December 31, 2001.

On October 3, 2001, Mr. Geisen participated in a conference call with the NRC staff. Mr. Geisen was also involved in preparatory meetings for the October 3rd conference call. The agenda for the conference call stated ''Video Inspection Review from RFO10, RFO11, and RFO12: Further Confirmation of no indication of leakage attributable to CRDM nozzle leakage; clearly CRDM flange leakage.'' During the conference call, Mr. Geisen informed the NRC that 100% of the reactor pressure vessel head had been inspected during the last outage (RFO12) but some areas were precluded from inspection and that videotapes of the 10RFO, 11RFO, and 12RFO reactor pressure vessel head inspections had been reviewed. The information communicated by the Mr. Geisen during the conference call was materially incomplete and inaccurate in that the licensee did not conduct a 100% inspection of the RPV head during 12RFO due to the presence of significant amount of boric acid on the reactor pressure vessel head which obscured a significant number of RPV head nozzles.

On October 10, 2001, Mr. Geisen attended a meeting with other FENOC management officials for the purposes of finalizing presentation slides for an October 11, 2001, meeting with the NRC Commissioner's Technical Assistants. Draft Presentation Slide 20 stated: ''Reviewed video inspections of Reactor Vessel head taken during 11RFO (April 1998) and 12RFO (April 2000) and confirmed that Davis-Besse has not experienced boron leakage as seen at Oconee or Arkansas Nuclear.'' Presentation Draft Slide 21 stated: ''Reviewed past 3 outages of Reactor Vessel Head inspection video tapes which were taken to satisfy Generic Letter 97–01: No telltale ''popcorn'' type boron deposits; During 12RFO (Spring 2000), Davis-Besse identified sources of

boron that precluded the visual inspection of some CRDM penetrations, as five leaking flanges above the mirror insulation; Viewed past 3 outages of inspection video tapes of area masked by boron in 12 RFO did not have previous leakage.''

On October 11, 2001, Mr. Geisen and other licensee staff briefed the NRC Commissioners' Technical Assistants as to FENOC's basis for determining that Davis-Besse was safe to operate until the next refueling outage (March 2002). During the briefing, FENOC and Mr. Geisen, as a presenter, discussed the presentation slides that were finalized the previous day. Presentation Slide 6, as presented by FENOC stated, in part: ''Conducted and recorded video inspections of the head during 11RFO (April 1998) and 12RFO (April 2000)—No head penetration leakage was identified.'' Presentation Slide 7, as presented by Mr. Geisen stated, in part: ''All CRDM [control rod drive mechanism] penetrations were verified to be free from ''popcorn'' type boron deposits using video recordings from 11RFO or 12RFO.''

The licensee's October 11, 2001, presentation to the NRC Commissioners' Technical Assistants was materially incomplete and inaccurate in that the presentation slides did not state that the build-up of boric acid on the RPV head was so significant that the licensee could not inspect all of the RPV head penetration nozzles. Due to the significant amount of boric acid present on the RPV head, of which he was aware, Mr. Geisen did not have a basis for stating that no visible evidence of RPV penetration nozzle leakage was detected.

On October 17, 2001, the licensee provided a supplemental response to the Bulletin. The second paragraph under the section entitled, ''Previous Inspection Results,'' on Page 2 of Attachment 1 of the licensee's October 17, 2001, supplemental response stated, in part:

> ''The inspections performed during the 10th, 11th, and 12th Refueling Outage (10RFO, conducted April 8 to June 2, 1996; 11RFO, conducted April 10 to May 23, 1998; and, 12RFO, conducted April 1 to May 18, 2000) consisted of a whole head visual inspection of the RPV head in accordance with the DBNPS Boric Acid Control Program pursuant to Generic Letter 88–05 'Boric Acid Corrosion of Carbon Steel Reactor Pressure Boundary Components in PWR Plants.' The visual inspections were conducted by remote camera and included below insulation inspections of the RPV bare head such that the Control Rod Drive Mechanism (CRDM) nozzle penetrations were viewed. During 10RFO, 65 of 69 nozzles were viewed, during 11RFO, 50 of 69 nozzles were viewed, and during 12RFO, 45 of 69 nozzles were viewed. It should be noted that 19 of the obscured nozzles in 12RFO were also those obscured in 11RFO.''

Information included under Column 6 of Attachment 2 of the licensee's October 17, 2001, supplemental response stated, in part, that 24 nozzles have a ''flange leak evident.'' Note 1 on the same table stated, in part:

> ''In 1996 during 10 RFO, the entire RPV head was inspected. Since the video was void of head orientation narration, each specific nozzle view could not be correlated.''

The licensee's October 17, 2001, supplemental response was materially incomplete and inaccurate, in that the licensee did not view the stated number of RPV head penetration nozzles during the referenced outages, and the licensee believed that only five RPV head control rod drive mechanism flanges were leaking instead of the 24 RPV head control rod drive mechanism flanges noted in the response. Mr. Geisen was aware that the licensee's October 17, 2001, supplemental response was materially incomplete and inaccurate but, nevertheless, concurred on the response, thereby allowing it to be submitted to the NRC.

On October 30, 2001, the licensee provided a supplemental response to the Bulletin. In an enclosure to the supplemental response, the licensee provided a summary table and photographic images of areas of accumulated boric acid crystal deposits on the RPV head. The photographic images were labeled to indicate the time the images were captured, the specific RPV nozzle locations associated with the images, except for those associated with 10 RFO (1996), and narrative comments. The labels also represented that the images were generally indicative of the condition of the RPV head for 10RFO and 11RFO.

The licensee's October 30, 2001, supplemental response was materially incomplete and inaccurate, in that the photographic images of the RPV head nozzles and the accompanying labels were not consistent with the actual RPV head conditions and with the actual RPV head nozzle pictured. Specifically, the RPV head images omitted images of the significant boric acid accumulations present on the RPV head, and many of the RPV head nozzle images were mislabeled to indicate that the images were of different RPV head nozzles than actually presented in the image. In addition, several of the images were mere copies of other images with the labels changed. Mr. Geisen labeled the images based on his understanding of the head inspections and his discussions with a former Davis-Besse system engineer. Mr. Geisen was aware that the information contained in the licensee's October 30, 2001, supplemental response was materially incomplete and inaccurate but, nevertheless, concurred on the response, thereby allowing it to be submitted to the NRC.

On November 9, 2001, in a transcribed presentation to the Advisory Committee on Reactor Safeguards (ACRS), Mr. Geisen stated that the 11RFO (1998) and 12RFO (2000) inspections were focused on inspecting the RPV for indications of the impact of boric acid leakage from leaking flanges. Mr. Geisen stated that the 1998 and 2000 inspections (video tapes) did not give a good view of the control rod drives because the camera angle was looking upwards at the structural material of the service structure on top of the head. Mr. Geisen stated that the video tape of the 10RFO (1996) inspection was a better video because the camera was following around a vacuum and probe that were specifically looking for head wastage as a result of boron deposits on the head. The information provided by the licensee and Mr. Geisen to the ACRS was materially incomplete and inaccurate in that each of the video tapes was helpful in understanding the significant boron accumulations present at the start of each outage, the clear impediments to 100% inspection of the RPV head nozzles, and difficulty the licensee encountered in its attempts to fully clean the RPV head of boron or to complete a comprehensive inspection of the RPV head nozzles.

Following the 1996 RPV head inspection, the licensee generated Potential Condition Adverse to Quality Report 96–0551, which stated, in part, on Continuation Sheet Page 9, Part C, Item 1:

> ''The extent of the inspection was limited to approximately 50 to 60% of the head area because of the restrictions imposed by the location and size of mouseholes. The inspection showed varying sizes of boric acid mounds scattered in various areas of the head. It is extremely difficult to develop an estimate of the amount of boric acid deposit because of the deposit scatter and limited inspection.''

Based on the above information, the NRC concludes that Mr. Geisen had knowledge of the RPV head conditions and the limitations experienced during RPV head inspections, and that, notwithstanding that knowledge, he deliberately provided materially incomplete and inaccurate information when he: (1) Concurred, on August 28,

October 17, and October 30, 2001, respectively, in the licensee's September 4, October 17, and October 30, 2001, responses to the Bulletin; and (2) assisted in the preparation and presentation of incomplete or inaccurate information during internal meetings on October 2 and 10, 2001, and during meetings or teleconferences held with the NRC on October 3, 11, and November 9, 2001.

The information provided by the licensee under oath in the Bulletin responses based, in part on the concurrence of Mr. Geisen, was material to the NRC because the NRC used the information, in part, to allow FENOC to operate Davis-Besse until February 2002 rather than requiring the plant to shut down by December 31, 2001, to conduct inspections of the head as discussed in Item 3.v.1. of the Bulletin. The information provided to the NRC during teleconferences and meetings was material to the NRC because the information gave the impression to the NRC staff that the Davis-Besse RPV head had been completely inspected and that the licensee had not identified any indications of RPV head penetration nozzle cracks when this was not the case at the time the response was submitted.

Based on the above information, Mr. David Geisen, while employed by the licensee, engaged in deliberate misconduct by deliberately providing FENOC and the NRC information that he knew was not complete or accurate in all material respects to the NRC, a violation of 10 CFR 50.5(a)(2). Mr. Geisen's actions also placed FENOC in violation of 10 CFR 50.9. The NRC determined that these violations were of very high safety and regulatory significance because they demonstrated a pattern of deliberate inaccurate or incomplete documentation of information that was required to be submitted to the NRC. Had the NRC been aware of this incomplete and inaccurate information, the NRC would likely have taken immediate regulatory action to shut down the plant and require the licensee to implement appropriate corrective actions.

The NRC must be able to rely on the licensee and its employees to comply with NRC requirements, including the requirement to provide information that is complete and accurate in all material respects. Mr. Geisen's action violated 10 CFR 50.5(a)(2) and caused the licensee to violate 10 CFR 50.9, and raise serious doubt as to whether he can be relied upon to comply with NRC requirements and to provide complete and accurate information to the NRC.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected if Mr. Geisen is permitted to be involved in NRC-licensed activities. Therefore, the public health, safety and interest require that Mr. Geisen be prohibited from any involvement in NRC-licensed activities for a period of five years from the effective date of this Order. Additionally, Mr. Geisen is required to notify the NRC of his first employment in NRC-licensed activities for a period of five years following the prohibition period.

V

Accordingly, pursuant to sections 103, 104, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR 50.5, and 10 CFR 150.20, *It is hereby ordered* that effective immediately:

1. Mr. David Geisen is prohibited for five years from the date of this Order from engaging in NRC-licensed activities. The NRC considers NRC-licensed activities to be those activities that are conducted pursuant to a specific or general license issued by the NRC, including those activities of Agreement State licensees conducted pursuant to the authority granted by 10 CFR 150.20.

2. If Mr. Geisen is currently involved with another licensee in NRC-licensed activities, he must immediately cease those activities, and inform the NRC of the name, address and telephone number of the employer, and provide a copy of this Order to the employer.

3. For a period of five years after the five-year period of prohibition has expired, Mr. Geisen shall, within 20 days of acceptance of his first employment offer involving NRC-licensed activities or his becoming involved in NRC-licensed activities, as defined in Paragraph IV.1 above, provide notice to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, of the name, address, and telephone number of the employer or the entity where he is, or will be, involved in NRC-licensed activities. In the notification, Mr. Geisen shall include a statement of his commitment to compliance with regulatory requirements and the basis why the Commission should have confidence that he will now comply with applicable NRC requirements.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Geisen of good cause.

VI

In accordance with 10 CFR 2.202, David Geisen must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order within 20 days of the date of this Order. However, since this enforcement action is being proposed prior to the U.S. Department of Justice completing its review of the OI investigation results, consideration may be given to extending the response time for submitting an answer as well as the time for requesting a hearing, for good cause shown. 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. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Mr. Geisen or other person adversely affected relies and the reasons as to why the Order should not have been issued. Pursuant to 10 CFR 2.202(c)(2)(i), Mr. Giesen, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement at the same address, to the Regional Administrator, NRC Region III, 2443 Warrenville Road, Lisle, IL 60532–4352, and to Mr. Geisen if the answer or hearing request is by a person other than Mr. Geisen. 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 a person other than Mr. Geisen requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309.

If a hearing is requested by Mr. Geisen or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Mr. Goyal, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be effective immediately and 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 V shall be final when the extension expires if a hearing request has not been received.

Dated this 4th day of January 2006.

For the Nuclear Regulatory Commission.

Martin J. Virgilio,

Deputy Executive Director for Materials, Research, State and Compliance Programs, Office of the Executive Director for Operations.

[FR Doc. E6–437 Filed 1–13–06; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[IA–05–055]

Prasoon Goyal; Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)

I

Mr. Prasoon Goyal was previously employed, at times relevant to this Order, as a Senior Engineer at the Davis-Besse Nuclear Power Station (Davis-Besse) operated by FirstEnergy Nuclear Operating Company (FENOC or licensee). The licensee holds License No. NPF–3 which was issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR part 50 on April 22, 1977. The license authorizes the operation of Davis-Besse in accordance with the conditions specified therein. The facility is located on the licensee's site near Oak Harbor, Ohio.

II

On August 3, 2001, the NRC issued Bulletin 2001–001, ''Circumferential Cracking of Reactor Pressure Vessel Head Penetration Nozzles,'' (Bulletin). In the Bulletin, the NRC requested that all holders of operating licenses for pressurized water nuclear power reactors (PWR), including FENOC for the Davis-Besse facility, provide information to the NRC relating to the structural integrity of the reactor pressure vessel (RPV) head penetration nozzles at their respective facilities. The information requested from the licensees included the extent of RPV head penetration nozzle leakage and cracking that had been found to date, a description of the inspections and repairs undertaken to satisfy applicable regulatory requirements, and the basis for concluding that a licensee's plans for future inspections would ensure compliance with applicable regulatory requirements. The NRC also required that all Bulletin addressees, including FENOC, submit a written response to the NRC in accordance with the provisions of 10 CFR 50.54(f). That regulation provides, in part, that upon request of the NRC, an NRC-licensee must submit written statements, signed under oath or affirmation, to enable the NRC to determine whether the license should be modified, suspended, or revoked.

On September 4, October 17, and October 30, 2001, the licensee provided written responses to the Bulletin. Additionally, the licensee met with the NRC staff on numerous occasions during October and November of 2001 to provide clarifying information. Based, in part, on the information provided by FENOC in its written responses to the Bulletin and during meetings with the NRC staff, the NRC staff allowed the licensee to continue operation of the Davis-Besse facility until February 2002, rather than requiring FENOC to shut the unit down to perform inspections by December 31, 2001, as provided in the Bulletin.

On February 16, 2002, FENOC shut down Davis-Besse for refueling and inspection of control rod drive mechanism (CRDM) RPV head penetration nozzles. Using ultrasonic testing, the licensee found cracks in three CRDM RPV head penetration nozzles and on March 6, 2002, the licensee discovered a cavity in the RPV head in the vicinity of CRDM Penetration Nozzle No. 3. The cavity measured approximately 5 to 7 inches long, 4 to 5 inches wide, and penetrated through the 6.63 inch-thick low-alloy steel portion of the RPV head, leaving the stainless steel cladding material (measuring 0.202 to 0.314 inches-thick) as the sole reactor coolant system (RCS) pressure boundary. A smaller cavity was also found near CRDM Penetration Nozzle No. 2.

The licensee conducted a root cause evaluation and determined, contrary to the earlier information provided to the NRC, that the cavities were caused by boric acid from the RCS released through cracks in the CRDM RPV head penetration nozzles. The root cause evaluation found that the licensee conducted limited cleaning and inspections of the RPV head during the Twelfth Refueling Outage (12RFO) that ended on May 18, 2000. However, neither the limited RPV head cleaning nor the resultant inspections during 12RFO were sufficient to ensure that the significant boric acid deposits on the RPV head were only a result of CRDM flange leakage, as supposed, and were not a result of RCS pressure boundary leakage.

On March 6 and March 10, 2002, the licensee provided information to the NRC concerning the identification of a large cavity in the RPV head adjacent to CRDM Penetration Nozzle No. 3. The NRC conducted an Augmented Inspection Team (AIT) inspection at Davis-Besse from March 12 to April 5, 2002, to determine the facts and circumstances related to the significant degradation of the RPV head. The results of the AIT inspection were documented in NRC Inspection Report No. 50–346/2002–03, issued on May 3, 2002. A follow-up Special Inspection was conducted from May 15 to August 9, 2002, and on October 2, 2002, the NRC issued the AIT Follow-up Special Inspection Report No. 50–346/2002–08 documenting ten apparent violations associated with the RPV head degradation.

On April 22, 2002, the NRC Office of Investigations (OI) initiated an investigation at Davis-Besse to determine, among other matters, whether FENOC and individual employees at the Davis-Besse facility failed to provide complete and accurate information to the NRC in its September 4, October 17, and October 30, 2001, responses to the Bulletin and during numerous conference calls and meetings in violation of 10 CFR 50.9 and 10 CFR 50.5(a)(2). The OI report (No. 3–2002–

006) was issued on August 22, 2003. A copy of the OI report was provided to the U. S. Department of Justice (DOJ), Office of the United States Attorney, Northern District of Ohio for review. The matter remains under continued Federal investigation.

Mr. Goyal, through the performance of his engineering duties, through his direct involvement in the licensee's 1996 RPV head inspection and cleaning activities, and through oral and written communications with other FENOC employees was aware of the results of previous RPV head inspections.

• Mr. Goyal was the engineer responsible for performing the 1996 reactor head inspection during the Tenth Refueling Outage (10RFO). During a sworn, transcribed interview with OI, Mr. Goyal stated that he could not see the top of the RPV head during 10RFO due to the limited access through the mouseholes and the accumulation of boric acid on the RPV head.

• Mr. Goyal wrote Potential Condition Adverse to Quality Report (PCAQR) 96–0551 documenting that the accumulation of boric acid on the head and the size of the mouseholes limited the extent of the inspection. Mr. Goyal documented in PCAQR 96–0551, in part:

''Since the boric acid deposits are not cleaned it is difficult to distinguish whether the deposits occurred because of the leaking flanges or the leaking CRDM.''

''This PCAQR is the quality document which recorded the boric acid deposit on the RV head. The deposits were discovered during the visual inspection of the RV head performed through the mouseholes utilizing a video camera. The extent of the inspection was limited to approximately 50 to 60% of the head areas because of the restrictions imposed by the location and sized of mouseholes. The inspection showed varying sizes of boric acid mounds scattered in various areas of head. It is extremely difficult to develop an estimate of the amount of boric acid deposit because of the deposit scatter and limited inspection.''

• Mr. Goyal authored a ''White'' paper, distributed to other Davis-Besse staff on May 8, 1996, that discussed control rod drive nozzle cracking within the nuclear power industry. Mr. Goyal documented in the ''White'' paper, in part:

''All plants, except Davis-Besse and Arkansas Nuclear 1, have large access holes in the skirt area of the service structure to view/clean the entire head. Davis-Besse's access is limited to about 50 percent of the head area.''

Several FENOC employees, including Mr. Prasoon Goyal, were responsible for the information provided to the NRC by FENOC in response to the Bulletin.

III

Prasoon Goyal was employed by FENOC as a senior engineer in the Design Basis Engineering organization at Davis-Besse at the time the responses to the Bulletin were developed and transmitted to the NRC. Mr. Goyal was a design engineer and the individual who reviewed the licensee's 1996 inspection of the CRDM flanges, and conducted the licensee's inspection of the RPV head and CRDM nozzles during 10RFO.

Mr. Goyal reviewed the October 17, 2001 supplemental response to the bulletin. On October 17, 2001, Mr. Goyal concurred as ''Design Basis Engrg—Mech'' [Design Basis Engineering—Mechanical] in the issuance of the licensee's October 17, 2001 supplemental response to the Bulletin.

Item 1.d of the Bulletin requested each pressurized water reactor (PWR) licensee, including FENOC for Davis-Besse, to provide a description of the RPV head penetration nozzles and RPV head inspection (including type, scope, qualification requirements, and acceptance criteria) that were performed at PWRs in the 4 years preceding the date of the Bulletin, and the findings resulting from the inspections. The licensees were requested to include a description of any limitations (insulation or other impediments) to accessibility of the bare metal of the RPV head for visual examinations.

On September 4, 2001, FENOC submitted its written response to the Bulletin for Davis-Besse. On October 17, 2001, FENOC submitted a supplemental response to the Bulletin for Davis-Besse and included information not provided in the September 4, 2001, response with regard to RPV inspections and cleaning conducted during 10RFO. Attachment 1 to the licensee's October 17, 2001, supplemental response to the Bulletin stated under the section entitled, ''Summary,'' in part:

''In May 1996, during a refueling outage, the RPV head was inspected. No leakage was identified, and these results have been recently verified by a re-review of the video tapes obtained from that inspection.''

The October 17, 2001, supplemental response to the Bulletin also stated under the section entitled, ''Previous Inspection Results,'' in part:

''The inspections performed during the 10th, 11th, and 12th Refueling Outage (10RFO, conducted April 8 to June 2, 1996; 11RFO, conducted April 10, to May 23, 1998; and, 12RFO, conducted April 1 to May 28, 2000) consisted of a whole head visual inspection of the RPV head in accordance with the DBNPS Boric Acid Control Program pursuant to Generic Letter 88–05, 'Boric Acid Corrosion of Carbon Steel Reactor Pressure Boundary Components in PWR Plants.' The visual inspections were conducted by remote camera and included below insulation inspections of the RPV bare head such that the Control Rod Drive Mechanism (CRDM) nozzle penetrations were viewed. During 10RFO, 65 of 69 nozzles were viewed, during 11RFO, 50 of 69 nozzles were viewed, and during 12 RFO, 45 of 69 nozzles were viewed.''

Information included under Column 6 of Attachment 2 of the licensee's October 17, 2001, supplemental response stated, in part, that 24 nozzles have a ''flange leak evident.'' Note 1 on the same table stated, in part:

''In 1996 during 10 RFO, the entire RPV head was inspected. Since the video was void of head orientation narration, each specific nozzle view could not be correlated.''

The licensee's October 17, 2001, supplemental response was materially incomplete and inaccurate in that the licensee did not view the stated number of RPV head penetration nozzles during the referenced outages, and the licensee believed that only five RPV head control rod drive mechanism flanges were leaking instead of the 24 RPV head control rod drive mechanism flanges noted in the response. Mr. Goyal was aware that the licensee's October 17, 2001, supplemental response was materially incomplete and inaccurate and concurred on the response, thereby allowing it to be submitted to the NRC.

Based on the above information, the NRC concludes that Mr. Goyal had sufficient knowledge of the condition of the RPV head and the limitations experienced during the RPV head inspections conducted during 10RFO, and notwithstanding that knowledge, he deliberately provided materially incomplete and inaccurate information, when on October 17, 2001, he concurred on the licensee's October 17, 2001, supplemental response to the NRC.

The information provided by the licensee under oath in the Bulletin supplemental response was material to the NRC because the NRC used the information, in part, to allow FENOC to operate Davis-Besse until February 2002 rather than requiring the plant to shut down by December 31, 2001, to conduct inspections of the head as discussed in Item 3.v.1. of the Bulletin.

Based on the above information, Mr. Prasoon Goyal, while employed by the licensee, engaged in deliberate misconduct by deliberately providing incomplete or inaccurate information that he knew was not complete and accurate in all material respects to the NRC, a violation of 10 CFR 50.5(a)(2).

Mr. Goyal's actions also placed FENOC in violation of 10 CFR 50.9. The NRC determined that these violations were of very high safety and regulatory significance because they involved a pattern of deliberate documentation of inaccurate or incomplete information that was required to be submitted to the NRC. Had the NRC been aware of this incomplete and inaccurate information, the NRC would likely have taken immediate regulatory action to shut down the plant and require the licensee to implement appropriate corrective actions.

IV

The NRC must be able to rely on the licensee and its employees to comply with NRC requirements, including the requirement to provide information and maintain records that are complete and accurate in all material respects. Mr. Goyal's deliberate actions raise serious doubt as to whether he can be relied upon to comply with NRC requirements and to provide complete and accurate information to the NRC.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected if Mr. Goyal is permitted to be involved in NRC-licensed activities. Therefore, the public health, safety and interest require that Mr. Goyal be prohibited from any involvement in NRC-licensed activities for a period of one year effective immediately. Additionally, Mr. Goyal is required to notify the NRC of his first employment in NRC-licensed activities for a period of one year following the prohibition period.

V

Accordingly, pursuant to sections 103, 104, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR 50.5, and 10 CFR 150.20, *It is hereby ordered* that effective immediately:

1. Mr. Prasoon Goyal is prohibited for one year from the date of this Order from engaging in NRC-licensed activities. The NRC considers NRC-licensed activities to be those activities that are conducted pursuant to a specific or general license issued by the NRC, including those activities of Agreement State licensees conducted pursuant to the authority granted by 10 CFR 150.20.

2. If Mr. Goyal is currently involved with another licensee in NRC-licensed activities, he must immediately cease those activities, and inform the NRC of the name, address and telephone number of the employer, and provide a copy of this Order to the employer.

3. For a period of one year after the one-year period of prohibition has expired, Mr. Goyal shall, within 20 days of acceptance of his first employment offer involving NRC-licensed activities or his becoming involved in NRC-licensed activities, as defined in Paragraph IV.1 above, provide notice to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, of the name, address, and telephone number of the employer or the entity where he is, or will be, involved in NRC-licensed activities. In the notification, Mr. Goyal shall include a statement of his commitment to compliance with regulatory requirements and the basis why the Commission should have confidence that he will now comply with applicable NRC requirements.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Goyal of good cause.

VI

In accordance with 10 CFR 2.202, Prasoon Goyal must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order within 20 days of the date of this Order, consideration may be given to extending the response time for submitting an answer as well as the time for requesting a hearing, for good cause shown. 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. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Mr. Goyal or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement at the same address, to the Regional Administrator, NRC Region III, 2443 Warrenville Road, Lisle, IL 60532–4352, and to Mr. Goyal if the answer or hearing request is by a person other than Mr. Goyal. 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 a person other than the Mr. Goyal requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309.

If a hearing is requested by Mr. Goyal or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Mr. Goyal, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be effective immediately and 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 V shall be final when the extension expires if a hearing request has not been received.

Dated this 4th day of January 2006.

For the Nuclear Regulatory Commission.

Martin J. Virgilio,

Deputy Executive Director for Materials, Research, State, and Compliance Programs, Office of the Executive Director for Operations.

[FR Doc. E6–418 Filed 1–13–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[IA–05–053]

Dale Miller; Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)

I

Mr. Dale Miller was previously employed, at times relevant to this Order, as a Compliance Supervisor at the Davis-Besse Nuclear Power Station (Davis-Besse) operated by FirstEnergy Nuclear Operating Company (FENOC or licensee). The licensee holds License No. NPF–3 which was issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 50 on April 22, 1977. The license authorizes the operation of Davis-Besse in accordance with the conditions specified therein. The facility is located on the licensee's site near Oak Harbor, Ohio.

II

On August 3, 2001, the NRC issued Bulletin 2001–001, ''Circumferential Cracking of Reactor Pressure Vessel Head Penetration Nozzles,'' (Bulletin). In the Bulletin, the NRC requested that all holders of operating licenses for pressurized water nuclear power reactors (PWR), including FENOC for the Davis-Besse facility, provide information to the NRC relating to the structural integrity of the reactor pressure vessel (RPV) head penetration nozzles at their respective facilities. The information requested from the licensees included the extent of RPV head penetration nozzle leakage and cracking that had been found to date, a description of the inspections and repairs undertaken to satisfy applicable regulatory requirements, and the basis for concluding that a licensee's plans for future inspections would ensure compliance with applicable regulatory requirements. The NRC also required that all the Bulletin addressees, including FENOC, submit a written response to the NRC in accordance with the provisions of 10 CFR 50.54(f). That regulation provides, in part, that upon request of the NRC, an NRC-licensee must submit written statements, signed under oath or affirmation, to enable the NRC to determine whether the license should be modified, suspended, or revoked.

On September 4, October 17, and October 30, 2001, the licensee provided written responses to the Bulletin. Additionally, the licensee met with the NRC staff on numerous occasions during October and November of 2001 to provide clarifying information. Based, in part, on the information provided by FENOC in the written responses to the Bulletin and during meetings with the NRC staff, the NRC staff allowed the licensee to continue operation of the Davis-Besse facility until February 2002, rather than requiring FENOC to shut the unit down to perform inspections by December 31, 2001, as provided in the Bulletin.

On February 16, 2002, FENOC shut down Davis-Besse for refueling and inspection of control rod drive mechanism (CRDM) RPV head penetration nozzles. Using ultrasonic testing, the licensee found cracks in three CRDM RPV head penetration nozzles and on March 6, 2002, the licensee discovered a cavity in the RPV head in the vicinity of CRDM Penetration Nozzle No. 3. The cavity measured approximately 5 to 7 inches long, 4 to 5 inches wide, and penetrated through the 6.63 inch-thick low-alloy steel portion of the RPV head, leaving the stainless steel cladding material (measuring 0.202 to 0.314 inches-thick) as the sole reactor coolant system (RCS) pressure boundary. A smaller cavity was also found near CRDM Penetration Nozzle No. 2.

The licensee conducted a root cause evaluation and determined that, contrary to the earlier information provided to the NRC, the cavities were caused by boric acid from the RCS released through cracks in the CRDM RPV head penetration nozzles. The root cause evaluation found that the licensee conducted limited cleaning and inspections of the RPV head during the Twelfth Refueling Outage (12RFO) that ended on May 18, 2000. However, neither the limited RPV head cleaning nor the resultant inspections during 12RFO were sufficient to ensure that the significant boric acid deposits on the RPV head were only a result of CRDM flange leakage, as supposed, and were not a result of RCS pressure boundary leakage.

On March 6 and March 10, 2002, the licensee provided information to the NRC concerning the identification of a large cavity in the RPV head adjacent to CRDM Penetration Nozzle No. 3. The NRC conducted an Augmented Inspection Team (AIT) inspection at Davis-Besse from March 12 to April 5, 2002, to determine the facts and circumstances related to the significant degradation of the RPV head. The results of the AIT inspection were documented in NRC Inspection Report No. 50–346/2002–03, issued on May 3, 2002. A follow-up Special Inspection was conducted from May 15 to August 9, 2002, and on October 2, 2002, the NRC issued the AIT Follow-up Special Inspection Report No. 50–346/2002–08 documenting ten apparent violations associated with the RPV head degradation.

On April 22, 2002, the NRC Office of Investigations (OI) initiated an investigation at Davis-Besse to determine, among other matters, whether FENOC and individual employees at the Davis-Besse facility failed to provide complete and accurate information to the NRC in its September 4, October 17, and October 30, 2001, responses to the Bulletin and during numerous conference calls and meetings in violation of 10 CFR 50.9 and 10 CFR 50.5(a)(2). The OI report (No. 3–2002–006) was issued on August 22, 2003. A copy of the OI report was provided to the U.S. Department of Justice (DOJ), Office of the United States Attorney, Northern District of Ohio for review. The matter remains under continued Federal investigation. Mr. Miller, through the performance of his duties as a supervisor in the licensee's regulatory affairs organization, and through oral and written communications with other FENOC employees was aware of the results of previous RPV head inspections. For example:

- Mr. Miller received several E-mails during August 2001, while FENOC was preparing the September 4, 2001, response to the NRC. These E-mails, in part, made Mr. Miller aware that the boric acid deposits on the RPV head and the RPV head service structure weepholes were an impediment to viewing all RPV head nozzle penetrations.
- Mr. Miller received a copy of an E-mail, dated August 28, 2001, that questioned whether a discussion in the licensee's draft response to the Bulletin relative to a subsequent review of 1998 and 2000 inspection videotaped results should be reworded. The August 28, 2001, E-mail received by Mr. Miller stated, in part:

> ''the discussion gives an impression to the reader that we were able to look at all the CRDMs. It is very difficult to look at the CRDMs when there is boric acid around it.''

- Mr. Miller also received a copy of an E-mail, dated August 30, 2001, in which the author stated, in part:

> ''I have not seen any EWR [engineering work request] to cut openings in the service structure in the 13th RFO. If we need these it should be funded and P.O. [Purchase Order] issued to Framatone immediately. We do not say anywhere in our response to the Bulletin that inspection thru the mouse holes creates an impediment for 100% visual inspection examination. (Management need[s] to know this).''

• During a sworn, transcribed interview with OI, Mr. Miller stated that if the author of the E-mail was concerned about addressing the impediments [discussed in the E-mails listed above] before the licensee issued its response to the Bulletin the individual should have brought it to the attention of his supervisor and his management chain in the Engineering Department.

• Mr. Miller also told OI that he looked-up the word ''impediment'' in the dictionary upon being informed of the size of the RPV head service structure weepholes, the two inch gap between the RPV head and the insulation at the top of the RPV head, the RPV head curvature, and the inspection limitations resulting from the presence of boron deposits. Specifically, Mr. Miller stated:

> ''I even went to the point of looking up the word ''impede'' in the dictionary, you know. It says obstruct or hinder. Obstruct. Does the mouse hole obstruct? No. Does the curvature of the head obstruct? No. Does the two inch gap obstruct? No. Does it hinder? It may hinder it, but again, I think the collective thought was that it could be done.''

Mr. Miller concluded that impediment meant something that obstructed or hindered. Using the dictionary definition, Mr. Miller concluded that none of these issues obstructed an inspection, though these issues may hinder it.

• Mr. Miller also stated in his interview with OI that at the time the September 4, 2001, response was being issued to the NRC:

> ''From what I knew, at that time they were able to look at them to a degree, but because there was boron, you know, on the head in some areas, it couldn't be credited as a qualified visual inspection. It's very difficult to look at CRDMs when there is boric acid around it.
>
> And in a sense, we were looking—we were—and my understanding at that time was that we were looking, you know, can we inspect to see that there's, you know, popcorn boron, or whatever, and it's very difficult to look at the CRDMs when there's boric acid around it.
>
> In other words, to me, it doesn't really say, it doesn't talk about, you know, and I'm speaking now, you know, somewhat what I know now, too. And this is where it's very difficult.
>
> You look back at this stuff and you could say, oh, for sure, you know, oh, it was obvious to the casual observer. Well, not to me it wasn't, because, you know, I'm this licensing guy taking input from engineering. It is very difficult to look at CRDMs when there's boric acid around it.''

The above information demonstrates that Mr. Miller had sufficient knowledge of the results of previous inspections of the RPV head and that he knew that the licensee's written response to NRC Bulletin 2001–001 was incomplete and inaccurate.

Several FENOC employees, including Mr. Dale Miller, were responsible for the information provided to the NRC by FENOC in response to the Bulletin.

III

Dale Miller was employed by FENOC as a Compliance Supervisor in the Regulatory Affairs organization at Davis-Besse at the time the responses to the Bulletin were developed and transmitted to the NRC. Additionally, Mr. Miller was the supervisor of the individual assigned the responsibility to prepare the September 4, 2001, response to the Bulletin. On August 30, 2001, Mr. Miller concurred as the ''Supervisor, DB Compliance'' in the issuance of the licensee's September 4, 2001, response to the Bulletin.

Item 1.d of the Bulletin requested each PWR licensee, including FENOC for Davis-Besse, provide a description of the RPV head penetration nozzles and RPV head inspection (including type, scope, qualification requirements, and acceptance criteria) that were performed at PWRs in the 4 years preceding the date of the Bulletin, and the findings resulting from the inspections. The licensee's were requested to include a description of any limitations (insulation or other impediments) to accessibility of the bare metal of the RPV head for visual examinations.

On September 4, 2001, FENOC submitted its written response to the Bulletin for Davis-Besse. Item 1.d of the licensee's September 4, 2001, response to the Bulletin stated, in part,

> ''a gap exits between the RPV head and the insulation, the minimum gap being at the dome center of the RPV head where it is approximately 2 inches, and does not impede visual inspection.''

The licensee included a description of the Eleventh Refueling Outage (11RFO) (April 1998) inspection of RPV head penetration nozzles and RPV head at Davis-Besse in its September 4, 2001, letter to the NRC, and stated, in part,

> ''The head was cleaned by use of a manual scrubber and vacuum through the weepholes.''

The licensee's September 4, 2001, response also described the results of the inspections conducted during 12RFO (April 2000) and included a statement that:

> ''Inspection of the RPV head/nozzles area indicated some accumulation of boric acid deposits. The boric acid deposits were located beneath the leaking flanges with clear evidence of downward flow. No visible evidence of nozzle leakage was detected.''

The licensee's September 4, 2001, response was materially incomplete and inaccurate in that the response did not describe impediments to accessing the RPV head bare metal during the 11RFO (1998) and 12RFO (2000). Access to the RPV head bare metal was limited due to significant accumulations of boric acid deposits and the size of the service structure access holes.

Based on the above information, the NRC concludes that Mr. Miller had sufficient knowledge of the condition of the RPV head and the limitations experienced during RPV head inspections, and he deliberately provided materially incomplete and inaccurate information when, on August 30, 2001, Mr. Miller concurred on the licensee's September 4, 2001, response to the NRC.

The information provided by the licensee under oath in the Bulletin response, based, in part, on the concurrence of Mr. Miller, was material to the NRC because the NRC used the information, in part, to allow FENOC to operate Davis-Besse until February 2002 rather than requiring the plant to shut down by December 31, 2001, to conduct inspections of the head as discussed in Item 3.v.1. of the Bulletin.

Based on the above information, Mr. Dale Miller, while employed by the licensee, engaged in deliberate misconduct by deliberately providing FENOC and the NRC information that he knew was not complete or accurate in all material respects to the NRC, a violation of 10 CFR 50.5(a)(2). Mr. Miller's actions also placed FENOC in violation of 10 CFR 50.9. The NRC determined that these violations were of very high safety and regulatory significance because they demonstrated a pattern of deliberate inaccurate or incomplete documentation of information that was required to be submitted to the NRC pursuant to 10 CFR 50.54(f). Had the NRC been aware of this incomplete and inaccurate information, the NRC would likely have taken immediate regulatory action to shut down the plant and require the licensee to implement appropriate corrective actions.

IV

The NRC must be able to rely on the licensee and its employees to comply with NRC requirements, including the requirement to provide information and maintain records that are complete and accurate in all material respects. Mr. Miller's deliberate actions raised serious doubt as to whether he can be relied upon to comply with NRC requirements

and to provide complete and accurate information to the NRC.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected if Mr. Miller is permitted to be involved in NRC-licensed activities. Therefore, the public health, safety and interest require that Mr. Miller be prohibited from any involvement in NRC-licensed activities for a period of five years effective immediately. Additionally, Mr. Miller is required to notify the NRC of his first employment in NRC-licensed activities for a period of five years following the prohibition period.

V

Accordingly, pursuant to sections 103, 104, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR 50.5, and 10 CFR 150.20, *It is hereby ordered* that effective immediately:

1. Mr. Dale Miller is prohibited for five years from the date of this Order from engaging in NRC-licensed activities. The NRC considers NRC-licensed activities to be those activities that are conducted pursuant to a specific or general license issued by the NRC, including those activities of Agreement State licensees conducted pursuant to the authority granted by 10 CFR 150.20.

2. If Mr. Miller is currently involved with another licensee in NRC-licensed activities, he must immediately cease those activities, and inform the NRC of the name, address and telephone number of the employer, and provide a copy of this Order to the employer.

3. For a period of five years after the five-year period of prohibition has expired, Mr. Miller shall, within 20 days of acceptance of his first employment offer involving NRC-licensed activities or his becoming involved in NRC-licensed activities, as defined in Paragraph IV.1 above, provide notice to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, of the name, address, and telephone number of the employer or the entity where he is, or will be, involved in NRC-licensed activities. In the notification, Mr. Miller shall include a statement of his commitment to compliance with regulatory requirements and the basis why the Commission should have confidence that he will now comply with applicable NRC requirements.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Miller of good cause.

VI

In accordance with 10 CFR 2.202, Dale Miller must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order within 20 days of the date of this Order, consideration may be given to extending the response time for submitting an answer as well as the time for requesting a hearing, for good cause shown. 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. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Mr. Miller or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement at the same address, to the Regional Administrator, NRC Region III, 2443 Warrenville Road, Lisle, IL 60532–4352, and to Mr. Miller if the answer or hearing request is by a person other than Mr. Miller. 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 a person other than the Mr. Miller requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309.

If a hearing is requested by Mr. Miller or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(I), Mr. Miller, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be effective immediately and 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 V shall be final when the extension expires if a hearing request has not been received.

Dated this 4th day of January 2006.

For the Nuclear Regulatory Commission.

Martin J. Virgilio,

Deputy Executive Director for Materials, Research, State, and Compliance Programs, Office of the Executive Director for Operations.

[FR Doc. E6–438 Filed 1–13–06; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[IA–05–054]

Steven Moffitt; Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)

I

Mr. Steven Moffitt was previously employed, at times relevant to this Order, as the Technical Services Director at the Davis-Besse Nuclear Power Station (Davis-Besse) operated by FirstEnergy Nuclear Operating Company (FENOC or licensee). The licensee holds License No. NPF–3 which was issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 50 on April 22, 1977. The license authorizes the operation of Davis-Besse in accordance with the conditions specified therein. The facility is located on the Licensee's site near Oak Harbor, Ohio.

II

On August 3, 2001, the NRC issued Bulletin 2001–001, ''Circumferential Cracking of Reactor Pressure Vessel Head Penetration Nozzles,'' (Bulletin).

In the Bulletin, the NRC requested that all holders of operating licenses for pressurized water nuclear power reactors (PWR), including FENOC for the Davis-Besse facility, provide information to the NRC relating to the structural integrity of the reactor pressure vessel (RPV) head penetration nozzles at their respective facilities. The information requested from the licensees included the extent of RPV head penetration nozzle leakage and cracking that had been found to date, a description of the inspections and repairs undertaken to satisfy applicable regulatory requirements, and the basis for concluding that a licensee's plans for future inspections would ensure compliance with applicable regulatory requirements. The NRC also required that all the Bulletin addressees, including FENOC, submit a written response to the NRC in accordance with the provisions of 10 CFR 50.54(f). That regulation provides, in part, that upon request of the NRC, an NRC-licensee must submit written statements, signed under oath or affirmation, to enable the NRC to determine whether the license should be modified, suspended, or revoked.

On September 4, October 17, and October 30, 2001, the licensee provided written responses to the Bulletin. Additionally, the licensee met with the NRC staff on numerous occasions during October and November of 2001 to provide clarifying information. Based, in part, on the information provided by FENOC in its written responses to the Bulletin and during meetings with the NRC staff, the NRC staff allowed the licensee to continue operation of the Davis-Besse facility until February 2002, rather than requiring FENOC to shut the unit down to perform inspections by December 31, 2001, as provided in the Bulletin.

On February 16, 2002, FENOC shut down Davis-Besse for refueling and inspection of control rod drive mechanism (CRDM) RPV head penetration nozzles. Using ultrasonic testing, the licensee found cracks in three CRDM RPV head penetration nozzles and on March 6, 2002, the licensee discovered a cavity in the RPV head in the vicinity of CRDM Penetration Nozzle No. 3. The cavity measured approximately 5 to 7 inches long, 4 to 5 inches wide, and penetrated through the 6.63 inch-thick low-alloy steel portion of the RPV head, leaving the stainless steel cladding material (measuring 0.202 to 0.314 inches-thick) as the sole reactor coolant system (RCS) pressure boundary. A smaller cavity was also found near CRDM Penetration Nozzle No. 2.

The licensee conducted a root cause evaluation and determined that, contrary to the earlier information provided to the NRC, the cavities were caused by boric acid from the RCS released through cracks in the CRDM RPV head penetration nozzles. The root cause evaluation found that the licensee had previously conducted limited cleaning and inspections of the RPV head during the Twelfth Refueling Outage (12RFO) that ended on May 18, 2000. However, neither the limited RPV head cleaning nor the resultant inspections during 12RFO were sufficient to ensure that the significant boric acid deposits on the RPV head were only a result of CRDM flange leakage and were not a result of RCS pressure boundary leakage.

On March 6 and March 10, 2002, the licensee provided information to the NRC concerning the identification of a large cavity in the RPV head adjacent to CRDM Penetration Nozzle No. 3. The NRC conducted an Augmented Inspection Team (AIT) inspection at Davis-Besse from March 12 to April 5, 2002, to determine the facts and circumstances related to the significant degradation of the RPV head. The results of the AIT inspection were documented in NRC Inspection Report No. 50–346/2002–03, issued on May 3, 2002. A follow-up Special Inspection was conducted from May 15 to August 9, 2002, and on October 2, 2002, the NRC issued the AIT Follow-up Special Inspection Report No. 50–346/2002–08 documenting ten apparent violations associated with the RPV head degradation.

On April 22, 2002, the NRC Office of Investigations (OI) initiated an investigation at Davis-Besse to determine, among other matters, whether FENOC and individual employees at the Davis-Besse facility failed to provide complete and accurate information to the NRC in its September 4, October 17, and October 30, 2001, responses to the Bulletin and during numerous conference calls and meetings in violation of 10 CFR 50.9 and 10 CFR 50.5(a)(2). The OI report (No. 3–2002–006) was issued on August 22, 2003. A copy of the OI report was provided to the U. S. Department of Justice (DOJ), Office of the United States Attorney, Northern District of Ohio for review. The matter remains under continued Federal investigation.

Mr. Moffitt was aware of the scope of the previous reactor vessel head inspections and the condition of the reactor vessel head due to his official duties and written and oral communications he received from other FENOC employees. For example;

- During a sworn, transcribed interview with OI, Mr. Moffitt stated that it was common knowledge that the reactor head was not totally cleaned during 12RFO.
- On June 27, 2001, Mr. Moffitt was sent a memorandum that provided an engineering evaluation of the question, ''Should Davis-Besse Perform a Visual Head Inspection if The Plant Shut Down to Mode 5 Conditions?'' Page 2 of the memorandum stated:

> ''During 12th RFO at Davis-Besse (DB) the Reactor Vessel head inspection was performed in accordance with boron inspection walkdown as required by GL–88–05 and GL 97–01. Large boron leakage from a CRDM flange was observed. This leakage did not permit the detailed inspection of CRDM nozzles.''

- On August 11, 2001, FENOC held a meeting to discuss its pending response to the Bulletin. Mr. Moffitt was listed as an attendee at the meeting, as documented in an E-mail from a design engineer that same day. As stated in the E-mail, ''it was pointed out that we can not clean our head thru the mouse holes and a system engineer is requesting that three large holes be cut in the Service Structure for viewing [inspection] and cleaning.''
- During a sworn, transcribed interview with OI, Mr. Moffitt stated that around the August 11, 2001, time frame he remembered talking to the engineer who had cleaned the RPV head regarding how much of the head was cleaned. Mr. Moffitt further stated that the engineer told him about 80 percent of the head was cleaned.
- During September 2001, Mr. Moffitt hired a contractor employed by Piedmont Management and Technical Services, Inc. to review Davis-Besse's preparation for 13RFO with implementing the requirements of Bulletin 2001–001. On September 14, 2001, the contractor provided Mr. Moffitt a copy of the letter [report] containing his recommendations and approximately one week later verbally briefed Mr. Moffitt on the contents of the report. The report stated, in part: ''It is noted that on completion of 12RFO, the Reactor Vessel head did have boric acid crystal deposits of considerable depth left in the center top area of the head, since cleaning of this area at that time was not successful in removing all the deposits (partly due to limited access).''
- During a licensee interview of Mr. Moffitt on July 1, 2002, Mr. Moffitt indicated that he knew in the July to August 2001 time-frame that boric acid was left on the head in 12RFO and that the boric acid impeded a complete inspection of the head.

The above information demonstrates that Mr. Moffitt had sufficient knowledge of the results of previous inspections of the RPV head and that he knew the licensee's written and oral responses to NRC Bulletin 2001–001 were incomplete and inaccurate.

Several FENOC employees, including Mr. Steven Moffitt, were responsible for the information provided to the NRC by FENOC in response to the Bulletin.

III

Steven Moffitt was employed by FENOC as the Technical Services Director at Davis-Besse at the time the responses to the Bulletin were developed and transmitted to the NRC. Mr. Moffitt participated in an October 3, 2001, teleconference with the NRC staff and a presentation on October 11, 2001, to the NRC Commissioners' Technical Assistants. On October 17, 2001, Mr. Moffitt concurred in the issuance of the supplemental licensee response, dated October 17, 2001.

On October 3, 2001, Mr. Moffitt was a senior Davis-Besse management official on a conference call with the NRC staff. Mr. Moffitt was also involved in preparatory meetings for the October 3rd conference call. The agenda for the conference call stated: ''Video Inspection Review from RFO10, RFO11, and RFO12: Further Confirmation of no indication of leakage attributable to CRDM Nozzle leakage; clearly CRDM flange leakage.'' During the conference call, Mr. Moffitt's direct subordinate informed the NRC that 100% of the RPV head had been inspected during the last outage (12RFO) but that some areas were precluded from inspection and that videotapes of the inspections conducted during 10RFO, 11RFO, and 12RFO had been reviewed. Mr. Moffitt was aware at the time of the October 3, 2001, meeting that the licensee did not conduct a 100% inspection of the RPV head during 12RFO due to the presence of boric acid on the head which obscured a significant number of the RPV head nozzles yet approved the misleading statements thereby causing the incomplete and inaccurate information to be submitted to the NRC.

On October 10, 2001, Mr. Moffitt participated in a meeting with other FENOC officials for the purpose of finalizing presentation slides to be used during an October 11, 2001, meeting with the NRC Commissioner's Technical Assistants. Draft Presentation Slide 20 stated: ''Reviewed video inspections of Reactor Vessel head taken during 11RFO (April 1998) and 12RFO (April 2000) and confirmed that Davis-Besse has not experienced boron leakage as seen at Oconee or Arkansas Nuclear.'' Presentation Draft Slide 21 for the briefing stated: ''Reviewed past 3 outages of Reactor Vessel Head inspection video tapes which were taken to satisfy Generic Letter 97–01: No telltale ''popcorn'' type boron deposits; During 12RFO (Spring 2000), Davis-Besse identified sources of boron that precluded the visual inspection of some CRDM penetrations, as five leaking flanges above the mirror insulation; Viewed past 3 outages of inspection video tapes of area masked by boron in 12 RFO did not have previous leakage.''

On October 11, 2001, Mr. Moffitt and other licensee staff briefed the NRC Commissioners' Technical Assistants on FENOC's basis for concluding that Davis-Besse was safe to operate until the next refueling outage (March 2002). During the briefing, FENOC utilized the presentation slides that were finalized the previous day. Presentation Slide 6 stated, in part: ''Conducted and recorded video inspections of the head during 11RFO (April 1998) and 12RFO (April 2000)—No head penetration leakage was identified.'' Presentation Slide 7 stated, in part: ''All CRDM [control rod drive mechanism] penetrations were verified to be free from ''popcorn'' type boron deposits using video recordings from 11RFO or 12RFO.''

The licensee's October 11, 2001, presentation to the NRC Commissioners' Technical Assistants was materially incomplete and inaccurate in that the presentation slides did not state that the build-up of boric acid on the RPV head was so significant that the licensee could not inspect all of the RPV head penetration nozzles. Due to the significant amount of boric acid present on the RPV head, of which Mr. Moffitt was aware, the licensee also did not have a basis for stating that no visible evidence of RPV penetration nozzle leakage was detected. Mr. Moffitt knew the information was incomplete and inaccurate and allowed it to be submitted to the NRC.

On October 17, 2001, the licensee provided a supplemental response to the Bulletin. The second paragraph under the section entitled, ''Previous Inspection Results,'' on Page 2 of Attachment 1 of the licensee's October 17, 2001, supplemental response stated, in part:

> ''The inspections performed during the 10th, 11th, and 12th Refueling Outage (10RFO, conducted April 8 to June 2, 1996; 11RFO, conducted April 10 to May 23, 1998; and, 12RFO, conducted April 1 to May 18, 2000) consisted of a whole head visual inspection of the RPV head in accordance with the DBNPS Boric Acid Control Program pursuant to Generic Letter 88–05 ''Boric Acid Corrosion of Carbon Steel Reactor Pressure Boundary Components in PWR Plants.'' The visual inspections were conducted by remote camera and included below insulation inspections of the RPV bare head such that the Control Rod Drive Mechanism (CRDM) nozzle penetrations were viewed. During 10RFO, 65 of 69 nozzles were viewed, during 11RFO, 50 of 69 nozzles were viewed, and during 12RFO, 45 of 69 nozzles were viewed. It should be noted that 19 of the obscured nozzles in 12RFO were also those obscured in 11RFO.''

Information included under Column 6 of Attachment 2 of the licensee's October 17, 2001, response stated, in part, that 24 nozzles have a ''flange leak evident.'' Note 1 on the same table stated, in part:

> ''In 1996 during 10 RFO, the entire RPV head was inspected. Since the video was void of head orientation narration, each specific nozzle view could not be correlated.''

The licensee's October 17, 2001, supplemental response was materially incomplete and inaccurate, in that the licensee did not view the stated number of RPV head penetration nozzles during the referenced outages, and the licensee believed that only five RPV head control rod drive mechanism flanges were leaking instead of the 24 RPV head control rod drive mechanism flanges noted in the response. Specifically, during 12RFO the licensee did not clean all of the RPV head; therefore, the licensee could not have viewed each of the RPV head penetration nozzles and determined that the observed boric acid accumulation was not a result of RPV nozzle leakage. Mr. Moffitt knew the information was incomplete and inaccurate but nonetheless, concurred on the response, thereby allowing the information to be submitted to the NRC.

Based on the above information, the NRC concludes that Mr. Moffitt had knowledge of the condition of the RPV head and the limitations experienced during RPV head inspections, and he deliberately failed to ensure that information that was developed for and presented during an October 3, 2001, teleconference with the NRC; was developed during an October 10, 2001, meeting and presented during an October 11, 2001, meeting with the NRC; and was included in the licensee's October 17, 2001, supplemental response to the NRC Bulletin 2001–001 was materially complete and accurate.

The information presented to the NRC and provided in the licensee's October 17, 2001, supplemental response was material to the NRC because the information gave the impression to the NRC staff that the Davis-Besse RPV head had been completely inspected for

evidence of nozzle cracks, when this was not the case at the time the information was provided or the supplemental response was submitted. In addition, information provided during the October 3 and October 11, 2001, meetings and in the licensee's October 17, 2001, supplemental response to the NRC was material to the NRC because the NRC used the information, in part, to allow FENOC to operate Davis-Besse until February 2002 rather than requiring the plant to shut down by December 31, 2001, to conduct inspections of the RPV head as discussed in Item 3.v.1 of the Bulletin.

Based on the above, Mr. Steven Moffitt, while employed by the licensee, engaged in deliberate misconduct by providing FENOC and the NRC information that he knew was not complete and accurate in all material respects to the NRC, a violation of 10 CFR 50.5(a)(2). Mr. Moffitt's actions also placed FENOC in violation of 10 CFR 50.9. The NRC determined that these violations were of very high safety and regulatory significance because they demonstrated a pattern of deliberate inaccurate or incomplete documentation of information that was required to be submitted to the NRC. Had the NRC been aware of this incomplete and inaccurate information, the NRC would likely have taken immediate regulatory action to shut down the plant and require the licensee to implement appropriate corrective actions.

IV

The NRC must be able to rely on the licensee and its employees to comply with NRC requirements, including the requirement to provide information and maintain records that are complete and accurate in all material respects. Mr. Moffitt's deliberate actions raise serious doubt as to whether he can be relied upon to comply with NRC requirements and to provide complete and accurate information to the NRC.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected if Mr. Moffitt is permitted to be involved in NRC-licensed activities. Therefore, the public health, safety and interest require that Mr. Moffitt be prohibited from any involvement in NRC-licensed activities for a period of five years from the date of this Order.

Additionally, Mr. Moffitt is required to notify the NRC of his first employment in NRC-licensed activities for a period of five years following the prohibition period.

V

Accordingly, pursuant to sections 103, 104, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR 50.5, and 10 CFR 150.20, *It is hereby ordered* that effective immediately:

1. Mr. Steven Moffitt is prohibited for five years from the date of this Order from engaging in NRC-licensed activities. The NRC considers NRC-licensed activities to be those activities that are conducted pursuant to a specific or general license issued by the NRC, including those activities of Agreement State licensees conducted pursuant to the authority granted by 10 CFR 150.20.

2. If Mr. Moffitt is currently involved with another licensee in NRC-licensed activities, he must immediately cease those activities, and inform the NRC of the name, address and telephone number of the employer, and provide a copy of this Order to the employer.

3. For a period of five years after the five-year period of prohibition has expired, Mr. Moffitt shall, within 20 days of acceptance of his first employment offer involving NRC-licensed activities or his becoming involved in NRC-licensed activities, as defined in Paragraph IV.1 above, provide notice to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, of the name, address, and telephone number of the employer or the entity where he is, or will be, involved in NRC-licensed activities. In the notification, Mr. Moffitt shall include a statement of his commitment to compliance with regulatory requirements and the basis why the Commission should have confidence that he will now comply with applicable NRC requirements.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Moffitt of good cause.

VI

In accordance with 10 CFR 2.202, Steven Moffitt must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order within 20 days of the date of this Order. However, since this enforcement action is being proposed prior to the U.S. Department of Justice completing its review of the OI investigation results, consideration may be given to extending the response time for submitting an answer as well as the time for requesting a hearing, for good cause shown. 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. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Mr. Moffitt or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement at the same address, to the Regional Administrator, NRC Region III, 2443 Warrenville Road, Lisle, IL 60532–4352, and to Mr. Moffitt if the answer or hearing request is by a person other than Mr. Moffitt. 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 a person other than Mr. Moffitt requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309.

If a hearing is requested by Mr. Moffitt or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(I), Mr. Moffitt, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be effective immediately and 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 V shall be final when the extension expires if a hearing request has not been received.

Dated this 4th day of January 2006.

For the Nuclear Regulatory Commission.

Martin J. Virgilio,

Deputy Executive Director for Materials, Research, State, and Compliance Programs, Office of the Executive Director for Operations.

[FR Doc. E6–416 Filed 1–13–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–321 and 50–366]

Southern Nuclear Operating Company, Inc., Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2 Exemption

1.0 Background

The Southern Nuclear Operating Company, Inc. (SNC, or the licensee), is the holder of Facility Operating License Nos. DPR–57 and NPF–5 which authorizes operation of the Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2 (Hatch 1 and 2), respectively. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the Nuclear Regulatory Commission (NRC, Commission) now or hereafter in effect.

The facility consists of two boiling water reactors located in Appling County, Georgia.

2.0 Request/Action

Title 10 of the Code of Federal Regulations (10 CFR), Section 50.55a(b)(2)(ix), states the requirements for the examination of metal containments and liners of concrete containments. In particular, Section 50.55a(b)(2)(ix)(G) requires, in part, that a VT–3 examination method be used to conduct examinations of Item E.20 of Table IWE–2500–1 of Section IX of the American Society of Mechanical Engineers, Boiler and Pressure Vessel Code (ASME Code).

By letter dated March 30, 2005, as supplemented by letters dated August 2 and 24, 2005, the licensee submitted a request for an exemption from the requirements of Section 50.55a(b)(2)(ix)(G). The exemption request would allow the licensee to perform an alternative examination of the accessible surface areas of the containment vessel pressure retaining boundary vent system, in lieu of the VT–3 examination required by the rule. The licensee stated that the alternate examination method is currently in use at Hatch 1 and 2 and has proven to be sufficient to maintain the structural integrity and leak-tightness of the containment surfaces, and, therefore, serves the underlying purpose of the rule.

The licensee is currently in its 3rd 10-year inservice inspection (ISI) interval. The licensee's code of record for the 3rd 10-year ISI interval is the 1992 edition through the 1992 addenda of the ASME Code. The code of record contains the requirement to perform a VT–3 examination of the accessible surface areas of the vent system. In Relief Request RR-MC–9 submitted by letter dated July 19, 2000, the licensee requested relief from the requirement to perform a VT–3 examination on nonsubmerged, accessible pressure boundary surfaces, including the vent system, at the end of the 3rd 10-year ISI interval. The licensee explained that the proposed alternative to perform a general visual examination was sufficient to detect the types of corrosion expected in the components covered by the relief. On October 4, 2000, this request was approved by the NRC staff.

The licensee's 4th 10-year ISI interval is scheduled to begin in 2006. The licensee's code of record for this interval will be the 2001 edition through the 2003 addenda of the ASME Code. Modifications to the ASME Code and 10 CFR 50.55a since the beginning of the 3rd 10-year ISI interval have relocated the requirement to perform the subject VT–3 examination from the ASME Code to 10 CFR 50.55a(b)(2)(ix). As a result, licensees wanting relief from the requirement to perform a VT–3 examination for the subject structures must now request an exemption from the requirements of 10 CFR 50.55a(b)(2)(ix)(G).

The licensee stated in its August 24, 2005, letter that the examination provisions previously authorized through Relief Request RR-MC–9 have proven to be sufficient to maintain the structural integrity and leak-tightness of the containment surfaces, and, therefore, serve the underlying purpose of the rule. As an alternative to the VT–3 examination, SNC is proposing the examination on all nonsubmerged, accessible pressure boundary surfaces of the vent system. This general visual-type examination will be performed in accordance with the Hatch 1 and 2 Qualified (N) Coatings Program. The licensee indicated that the details of this program were provided in the October 19, 1998, response to NRC Generic Letter 98–04, ''Potential for Degradation of the Emergency Core Cooling System and the Containment Spray System after a Loss-of-Coolant Accident Because of Construction and Protective Coating Deficiencies and Foreign Material in Containment.'' The procedures and personnel qualifications applicable for the coatings program implementation are in compliance with Regulatory Guide 1.54 (1973), and the implementation is based on the following documents: (1) ANSI N 101.2–1972, ''Protective Coatings (Plants) for Light Water Nuclear Reactor Containment Facilities;'' (2) ANSI N101.4–1972, ''Quality Assurance for Protective Coatings Applied to Nuclear Facilities;'' and (3) EPRI Report TR–109937, ''Guideline on Nuclear Safety-Related Coatings.'' This program was approved by the NRC staff in a letter dated November 19, 1999.

The licensee further noted that the Qualified (N) Coatings program examination frequency is equivalent to the requirements of Section XI to the ASME Code, and the program requires that when evidence of degradation is detected, a detailed examination and evaluation be performed. The detailed visual examination would be performed in accordance with the provisions of ASME Code, Section XI, paragraph IWE–2310(c). The exterior surfaces of the vent system that connects the drywell to the suppression pool are located in the reactor building. The reactor building environment does not pose adverse conditions that would promote rapid degradation of the outside pressure boundary surfaces of the vent system. The interior surfaces of the vent system that connect the drywell to the suppression pool and the portions of the vent system located inside the suppression pool are maintained in a nitrogen inerted environment during normal power operation in accordance with technical specification requirements. Operational experience and previous examinations have indicated that this environment does not promote rapid degradation of the surfaces.

The licensee stated that the requirements specified for a VT–3 examination were developed for detecting flaws in metal components and are more stringent than those required for detecting corrosion-related degradation. Since corrosion of base metal is the primary issue of concern for

containment pressure boundary surface areas, a general visual-type examination, in accordance with the Hatch 1 and 2 Qualified (N) Coatings Program, is sufficient to inspect the subject surface areas of the containment and will provide an acceptable level of quality and safety.

In summary, the licensee is proposing an exemption from the requirements of Section 50.55a(b)(2)(ix)(G) to use an alternate examination method to examine Item E.20 of Table IWE–2500–1 of ASME Code, Section XI, pursuant to 10 CFR 50.12(a)(1) and 10 CFR 50.12(a)(2)(ii). The licensee stated in its application that compliance with the visual examination requirements of Section 50.55a(b)(2)(ix)(G) is not necessary for accessible surface areas of the containment vessel pressure retaining boundary Vent System to achieve the underlying purpose of the rule.

3.0 Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50 when: (1) The exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. Special circumstances are present whenever, in accordance with 10 CFR Part 50.12(a)(2)(ii), ''Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule * * *.'' Therefore, in determining the acceptability of the licensee's exemption request, the NRC staff has performed the following evaluation to satisfy the requirements of 10 CFR 50.12 for granting the exemption.

The underlying purpose of 10 CFR 50.55a(b)(2)(ix)(G), as it applies to Item E1.20 of Table IWE–2500–1, is to ensure that an examination of the metal containment or the metal liner of a concrete containment is performed to identify corrosion or other degradation that could affect the structural or leak-tight integrity of the structure.

The NRC staff examined the licensee's rationale to support the exemption request and concluded that maintaining the integrity of the coating system applied to the Hatch 1 and 2 containment vent system components is a preventive measure that would protect against corrosion of the coated components. As the licensee emphasizes the effectiveness of its coating program, the NRC staff believes that the general visual examination performed as part of maintaining the integrity of the coating system is a proactive action and will ensure the integrity of the coated vent system components. The proposed alternative will provide the quality and safety level similar to the one intended by the use of VT–3 examination of the vent system components, and would meet the underlying purpose of 10 CFR Section 50.55a(b)(2)(ix)(G).

Based on a consideration of proposed alternatives contained in the licensee's letters dated March 20, and August 2 and 24, 2005, the NRC staff concludes that degradation of the containment structure would be detected using the proposed alternative, thus meeting the underlying purpose of the rule. Therefore, the NRC staff concludes that the proposed exemption from 10 CFR Section 50.55a(b)(2)(ix)(G) is acceptable.

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants SNC an exemption from the requirement of 10 CFR Section 50.55a(b)(2)(ix)(G) to perform a VT–3 examination for Item E1.2 of Table IWE–2500–1, for Hatch 1 and 2, for the 4th 10-year ISI interval.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment (70 FR 76082).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 6th day of January 2006.

For the Nuclear Regulatory Commission.

Catherine Haney,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E6–415 Filed 1–13–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Biweekly Notice; Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from December 22, 2005 to January 5, 2006. The last biweekly notice was published on January 3, 2006 (71 FR 145).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this

proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner/requestor intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner/requestor intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner/requestor to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff; (3) E-mail addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, *HearingDocket@nrc.gov*; or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemakings and Adjudications Staff at (301) 415–1101, verification number is (301) 415–1966. A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and it is requested that copies be transmitted either by means of facsimile transmission to (301) 415–3725 or by e-

mail to *OGCMailCenter@nrc.gov.* A copy of the request for hearing and petition for leave to intervene should also be sent to the attorney for the licensee.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer of the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(a)(1)(i)–(viii).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov.*

AmerGen Energy Company, LLC, et al., Docket No. 50–219, Oyster Creek Nuclear Generating Station (OCNGS), Ocean County, New Jersey

Date of amendment request: December 2, 2005.

Description of amendment request: The amendment would revise the Technical Specifications to increase the allowable as-found main steam safety valve code safety function lift setpoint tolerance from ±1% to ±3%.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Will operation of the facility in accordance with the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed TS changes allow for an increase in the as-found Main Steam Safety Valve (MSSV) setpoint tolerance from ±1% to ±3%. The proposed changes do not alter the MSSV nominal lift setpoints or MSSV lift setpoint test frequency.

The proposed TS changes have been evaluated on both a generic and plant specific basis. The NRC has approved the general approach of this change; however, implementation is contingent on several plant specific evaluations. The required plant specific analyses and evaluations included transient analysis of the anticipated operational transients (AOTs); analysis of the design basis overpressurization event; evaluation of the performance of high pressure systems, and evaluation of the containment response during Loss-of-Coolant Accident (LOCA) and hydrodynamic loads on the MSSV discharge lines and containment. These analyses and evaluations demonstrate that there is adequate margin to the design core thermal limits and reactor vessel pressure limits using the ±3% MSSV as-found setpoint tolerance. The analyses and evaluations also demonstrate that the operation of high-pressure safety systems will not be adversely affected and that the containment response during a LOCA will be acceptable.

Evaluations of the impact of the proposed change on the equipment important to safety have been performed and no adverse conditions were identified. The reactor pressure vessel and attached systems and piping have been evaluated for the impact of this proposed TS change. A plant specific analysis has been performed which indicates that the ASME Code upset limits for the reactor pressure vessel will not be exceeded for the limiting event, i.e., Main Steam Isolation Valve (MSIV) closure with flux Scram. The reactor pressure vessel and attached piping design values will not be exceeded. Therefore, the probability of a malfunction of the reactor pressure vessel and attached systems and piping is not increased and the consequences of such an accident remain acceptable.

The nuclear fuel has been evaluated for the impact of the proposed change.

Plant specific analyses were performed which indicate that for all abnormal operational transients adequate margin to the fuel thermal limit parameters, i.e., Minimum Critical Power Ratio (MCPR) and thermal-mechanical limits, is maintained. Emergency Core Cooling System (ECCS)/LOCA performance is maintained adequate to meet the requirements of 10 CFR 50.46. Therefore, the consequences of these accidents remain acceptable and the probability of the malfunction of the nuclear fuel is not increased.

The Containment response during a LOCA has been evaluated for the impact of the proposed change. The major factor in the Containment pressure response to a LOCA is the rate of reactor vessel water inventory loss due to a DBA LOCA. The rate of reactor vessel water inventory loss is mainly dependent on the initial reactor pressure, which is not affected by the proposed setpoint tolerance change. The major factor in the Containment temperature response to a LOCA is the integrated steam inventory loss due to Main Steamline Break. The rate of reactor vessel steam inventory loss is mainly dependent on the reactor decay heat, which is not affected by the proposed setpoint tolerance change. Therefore, the consequences of these accidents remain acceptable and the probability of the malfunction of Containment is not increased.

The Control Rod Drive (CRD) system has been evaluated for the impact of the proposed change. The CRD system capability of controlling reactor power during normal plant operation and rapidly inserting control rod blades (Scram) during abnormal plant conditions is not impacted by the proposed change. Therefore, the probability of a malfunction of the CRD system is not increased.

The Reactor Vessel Instrumentation System has been evaluated for the impact of the proposed change. The Reactor Vessel Instrumentation System will continue to be operated within the current design pressure/temperature requirements; therefore, the probability of a malfunction of the Reactor Vessel Instrumentation System is not increased.

An administrative change is also being proposed to correct the reference to ''IWV–3510 of Section XI of the ASME Boiler and Pressure Vessel Code'' in TS 4.3.E because the stated ASME section no longer exists. The TS is being changed to reference specification 4.3.C for MSSV testing. This is an administrative change and does not affect previously evaluated accidents.

Therefore, the proposed TS changes do not significantly increase the probability or consequences of an accident previously evaluated.

2. Will operation of the facility in accordance of the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed TS changes allow for an increase in the as-found MSSV setpoint tolerance from ±1% to ±3%. Generic and plant specific analyses and evaluations indicate that the plant response to any previously evaluated event will remain acceptable. All plant systems, structures, and components will continue to be capable of performing their required safety function as required by event analysis guidance.

The proposed TS changes do not alter the MSSV nominal lift setpoints or MSSV lift setpoint test frequency. The operation and response of the affected equipment important to safety is unchanged. All systems, structures, and components will continue to be operated within acceptable operating and/or design parameters. No system, structure, or component will be subjected to a condition that has not been evaluated and determined to be acceptable using the guidance required for specific event analysis.

The change to correct the reference to ''IWV–3510 of Section XI of the ASME Boiler and Pressure Vessel Code'' in TS 4.3.E is an administrative change and does not affect the possibility of a new or different kind of accident.

Therefore, the proposed TS changes do not create the possibility of a new or different kind of accident from any previously identified.

3. Will operation of the facility in accordance with the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed TS changes allow for an increase in the as-found MSSV setpoint tolerance from ±1% to ±3%. The proposed TS changes do not alter the MSSV nominal lift setpoints or MSSV lift setpoint test

frequency. The operation and response of the affected equipment important to safety is unchanged. All systems, structures, and components will continue to be operated within acceptable operating and/or design parameters. While the calculated peak reactor vessel pressure for the ASME overpressure event is higher than that calculated without the increase in setpoint tolerance, it is still within the respective licensing acceptance limits associated with this event. These licensing acceptance limits have been determined by the NRC to provide a sufficient margin of safety.

The increase in MSSV steam flow and reactor vessel pressure does not reduce the margin of safety associated with the MSSVs and associated components and structures since the increased MSSV steam flow rate and reactor vessel pressure are bounded by the current design analysis.

The margin of safety for fuel thermal limits and 10 CFR 50.46 limits are unaffected by the proposed change.

The margin of safety for the Containment is unaffected by the proposed change.

The capability of the SLC system and the CRD system to perform their safety functions during all required events, using the required guidance for event analysis, is maintained. Therefore, the proposed changes do not reduce the margin of safety provided by the SLC and CRD systems.

The change to correct the reference to ''IWV–3510 of Section XI of the ASME Boiler and Pressure Vessel Code'' in TS 4.3.E is an administrative change and does not affect the margin of safety.

Therefore, these proposed TS changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Thomas S. O'Neill, Associate General Counsel, Exelon Generation Company, LCC, 4300 Winfield Road, Warrenville, IL 60555.

NRC Branch Chief: Darrell J. Roberts.

Calvert Cliffs Nuclear Power Plant, Inc., Docket Nos. 50–317 and 50–318, Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland

Date of amendments request: November 3, 2005.

Description of amendments request: The proposed amendments would revise the accident source term in the design-basis radiological consequences analyses and the associated Technical Specifications (TSs), pursuant to section 50.67 of part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR 50.67). The proposed amendments would provide for the full implementation of the alternate source term (AST) in accordance with the guidance in Regulatory Guide 1.183, ''Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors.'' The proposed amendments would also increase the flow rate for the control room emergency ventilation system (CREVS) from 2000 to 10000 cubic feet per minute in TS 5.5.11, ''Ventilation Filter Testing Program,'' by means of a modification to the CREVS. In addition, automatic isolation dampers and radiation monitors will also be installed at access control heating, ventilating, and air conditioning (HVAC) unit no. RTU–1 and access control air conditioning unit no. 13.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The results of the applicable radiological design basis accidents (DBAs) re-evaluation demonstrated that, with the requested changes, the dose consequences of these limiting events are within the regulatory limits and guidance provided by the Nuclear Regulatory Commission in 10 CFR 50.67 and Regulatory Guide 1.183 for AST methodology. The AST is an input to calculations used to evaluate the consequences of an accident and does not by itself affect the plant response or the actual pathway of the activity released from the fuel. It does, however, better represent the physical characteristics of the release such that appropriate mitigation techniques may be applied.

The change from the original source term to the new proposed AST is a change in the analysis method and assumptions and has no effect on accident initiators or causal factors that contribute to the probability of occurrence of previously analyzed accidents. Use of an AST to analyze the dose effect of DBAs shows that regulatory acceptance criteria for the new methodology continues to be met. Changing the analysis methodology does not change the sequence or progression of the accident scenario.

The proposed Technical Specification changes reflect the plant configuration that will either support implementation of the AST analyses or eliminate requirements that are no longer needed as a result of the revised DBA analyses. The equipment affected by the proposed changes is mitigative in nature and relied upon after an accident has been initiated. The operation of various filtration systems have been considered in the evaluations for these proposed changes. While the operation of some systems does change with the implementation of an AST, the affected systems are not accident initiators; and application of the AST methodology, itself, is not an initiator of a DBA.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Operation of the facility in accordance with the proposed amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated.

As described in Item 1 above, the changes proposed in this license amendment request involve the use of a new analysis methodology and related regulatory acceptance criteria. The proposed Technical Specification changes reflect the plant configuration that will either support implementation of the new methodology or eliminate requirements that are no longer needed as a result of the new methodology. No new or different accidents result from utilizing the proposed changes. Although the proposed changes require modification to the Control Room emergency ventilation system and installation of automatic isolation dampers and radiation monitors at Access Control HVAC Unit RTU–1 and Access Control Air Conditioning Unit 13 on the Auxiliary Building roof, none of these changes can initiate a new or different kind of accident since they are only related to system capabilities that provide protection from accidents that have already occurred. As a result, no new failure modes are being introduced that could lead to different accidents. These changes do not alter the nature of events postulated in the Updated Final Safety Analysis Report nor do they introduce any unique precursor mechanisms.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Operation of the facility in accordance with the proposed amendment would not involve a significant reduction in a margin of safety.

As described in Item 1 above, the changes proposed in this license amendment request involve the use of a new analysis methodology and related regulatory acceptance criteria. The proposed Technical Specification changes reflect the plant configuration that will either support implementation of the new methodology or eliminate requirements that are no longer needed as a result of the new methodology. Safety margins and analytical conservatisms have been evaluated and have been found acceptable. The analyzed events have been carefully selected and, with plant modification, margin has been retained to ensure that the analyses adequately bound postulated event scenarios. The analyses have been performed using conservative methodologies, as specified in Regulatory Guide 1.183. The dose consequences of these DBAs remain within the acceptance criteria presented in 10 CFR 50.67, ''Accident Source Term,'' and Regulatory Guide 1.183. The proposed changes continue to ensure that the doses at the exclusion area boundary and low population zone boundary, as well as the Control Room, are within corresponding regulatory limits.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendments request involves no significant hazards consideration.

Attorney for licensee: Carey Fleming, Sr. Counsel—Nuclear Generation, Constellation Generation Group, LLC, 750 East Pratt Street, 17th floor, Baltimore, MD 21202.

NRC Branch Chief: Richard J. Laufer.

Exelon Generation Company, LLC, Docket No. 50–352, Limerick Generating Station, Unit 1, Montgomery County, Pennsylvania

Date of amendment request: December 14, 2005.

Description of amendment request: The proposed amendment modifies the Technical Specifications (TSs) to incorporate a revised Single Loop Operation Safety Limit Minimum Critical Power Ratio (SLO SLMCPR) due to the cycle-specific analysis.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The derivation of the cycle specific Single Loop Operation Safety Limit Minimum Critical Power Ratio (SLO SLMCPR) for incorporation into the Technical Specifications (TS), and its use to determine cycle-specific thermal limits, has been performed using the methodology discussed in ''General Electric Standard Application for Reactor Fuel,'' NEDE–24011–P–A–15 (GESTAR–II), and U.S. Supplement, NEDE–24011–P–A–15–US, September, 2005, which includes Amendment 25. Amendment 25 was approved by the NRC in a March 11, 1999 safety evaluation report.

The basis of the SLO SLMCPR calculation is to ensure that greater than 99.9% of all fuel rods in the core avoid transition boiling if the limit is not violated. The new SLO SLMCPR preserves the existing margin to transition boiling. The GE–14 fuel is in compliance with Amendment 22 to ''General Electric Standard Application for Reactor Fuel,'' NEDE–24011–P–A–15 (GESTAR–II), and U.S. Supplement, NEDE–24011–P–A–15–US, September 2005, which provides the fuel licensing acceptance criteria. The probability of fuel damage will not be increased as a result of this change. Therefore, the proposed TS change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The SLO SLMCPR is a TS numerical value, calculated to ensure that transition boiling does not occur in 99.9% of all fuel rods in the core if the limit is not violated. The new SLO SLMCPR is calculated using NRC approved methodology discussed in ''General Electric Standard Application for Reactor Fuel,'' NEDE–24011–P–A–15 (GESTAR–II), and U.S. Supplement, NEDE–24011–P–A–15–US, September 2005, which includes Amendment 25. Additionally, the GE–14 fuel is in compliance with Amendment 22 to ''General Electric Standard Application for Reactor Fuel,'' NEDE–24011–P–A–15 (GESTAR–II), and U.S. Supplement, NEDE–24011–P–A–15–US, September, 2005, which provides the fuel licensing acceptance criteria. The SLO SLMCPR is not an accident initiator, and its revision will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

There is no significant reduction in the margin of safety previously approved by the NRC as a result of the proposed change to the SLO SLMCPR, which includes the use of GE–14 fuel. The new SLO SLMCPR is calculated using methodology discussed in ''General Electric Standard Application for Reactor Fuel,'' NEDE–24011–P–A–15 (GESTAR–II), and U.S. Supplement, NEDE–24011–P–A–15–US, September, 2005, which includes Amendment 25. The SLO SLMCPR ensures that greater than 99.9% of all fuel rods in the core will avoid transition boiling if the limit is not violated when all uncertainties are considered, thereby preserving the fuel cladding integrity.

Therefore, the proposed TS change will not involve a significant reduction in [a] margin of safety previously approved by the NRC.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. Brad Fewell, Assistant General Counsel, Exelon Generation Company, LLC, 200 Exelon Way, Kennett Square, PA 19348.

NRC Branch Chief: Darrell J. Roberts.

Exelon Generation Company, LLC, Docket Nos. 50–352 and 50–353, Limerick Generating Station, Units 1 and 2, Montgomery County, Pennsylvania

Date of amendment request: December 21, 2005.

Description of amendment request: The proposed amendment revises the Technical Specifications by relocating the Pressure Isolation Valve (PIV) tables to the Technical Requirements Manual (TRM).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed relocation of Technical Specification Table 3.4.3.2–1 does not alter the requirements for pressure isolation valve operability or surveillance currently in the Technical Specifications. The proposed change to remove the pressure isolation valve table from TS and relocate the information to an administratively controlled document, and to revise the wording in TS to reflect this change, will have no impact on any safety related structures, systems or components. The probability of occurrence of a previously evaluated accident is not increased because this change does not introduce any new potential accident initiating conditions. The consequences of accidents previously evaluated in the UFSAR [Updated Final Safety Analysis Report] are not affected because the ability of the PIVs to limit leakage through these valves in amounts that do not compromise safety is not affected. Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes are administrative in nature and do not result in physical alterations or changes in the method by which any safety related system performs its intended function(s). The proposed changes do not impact any safety analysis assumptions. The proposed changes do not create any new accident initiators or involve an activity that could be an initiator of an accident of a different type.

All PIVs and alarm instrumentation will continue to be tested to the same rigorous requirements as defined in the Technical Specification Surveillance Requirements. The proposed revision does not make changes in any method of testing or how any safety related system performs its safety functions. Therefore, the possibility of an accident of a different type than any previously evaluated in the UFSAR is not created.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The administrative change to relocate Technical Specification Table 3.4.3.2–1 to the Technical Requirements Manual does not alter the basic regulatory requirement for Reactor Coolant System pressure isolation and will not affect the isolation capability for credible accident scenarios. Future revisions to the Technical Requirements Manual Table will be subject to evaluation pursuant to 10 CFR 50.59.

Additionally, the proposed relocation does not alter the requirements for pressure isolation valve and alarm instrumentation operability currently in the Technical Specifications. The LCO [limiting condition for operation] and Surveillance Requirements will be retained in the revised Technical Specifications. The proposed change will not affect the meaning, application, and function of the current Technical Specification requirements for the valves in Table 3.4.3.2–1. Therefore, the proposed changes do not result in a significant reduction in [a] margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. Brad Fewell, Assistant General Counsel, Exelon Generation Company, LLC, 200 Exelon Way, Kennett Square, PA 19348.

NRC Branch Chief: Darrell J. Roberts.

Exelon Generation Company, LLC (EGC, licensee), Docket No. 50–265, Quad Cities Nuclear Power Station (QCNPS), Unit 2, Rock Island County, Illinois

Date of amendment request: December 15, 2005.

Description of amendment request: The proposed change revises the values of the safety limit minimum critical power ratio (SLMCPR) in Technical Specification (TS) section 2.1.1, ''Reactor Core SLs.'' Specifically, the proposed change would require that for Unit 2, the minimum critical power ratio (MCPR) for Global Nuclear Fuel (GNF) fuel shall be ≥1.09 for two recirculation loop operation, or ≥1.10 for single recirculation loop operation. Additionally, the proposed change would require that MCPR for Westinghouse fuel shall be ≥1.11 for two recirculation loop operation, or ≥1.13 for single recirculation loop operation.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

According to 10 CFR 50.92, ''Issuance of amendment,'' paragraph (c), a proposed amendment to an operating license involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

EGC has evaluated the proposed change to the TS for QCNPS, Unit 2, using the criteria in 10 CFR 50.92, and has determined that the proposed change does not involve a significant hazards consideration. The following information is provided to support a finding of no significant hazards consideration.

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The probability of an evaluated accident is derived from the probabilities of the individual precursors to that accident. The consequences of an evaluated accident are determined by the operability of plant systems designed to mitigate those consequences. Limits have been established consistent with NRC-approved methods to ensure that fuel performance during normal, transient, and accident conditions is acceptable. The proposed change conservatively establishes the SLMCPR for QCNPS, Unit 2, Cycle 19 such that the fuel is protected during normal operation and during plant transients or anticipated operational occurrences (AOOs).

Changing the SLMCPR does not increase the probability of an evaluated accident. The change does not require any physical plant modifications, physically affect any plant components, or entail changes in plant operation. Therefore, no individual precursors of an accident are affected.

The proposed change revises the SLMCPR to protect the fuel during normal operation as well as during plant transients or AOOs. Operational limits will be established based on the proposed SLMCPR to ensure that the SLMCPR is not violated. This will ensure that the fuel design safety criterion (i.e., that at least 99.9% of the fuel rods do not experience transition boiling during normal operation and AOOs) is met. Since the proposed change does not affect operability of plant systems designed to mitigate any consequences of accidents, the consequences of an accident previously evaluated are not expected to increase.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Creation of the possibility of a new or different kind of accident would require creating one or more new accident precursors. New accident precursors may be created by modifications of plant configuration, including changes in allowable modes of operation.

The proposed change does not involve any plant configuration modifications or changes to allowable modes of operation. The proposed change to the SLMCPR assures that safety criteria are maintained for QCNPS, Unit 2, Cycle 19.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The SLMCPR provides a margin of safety by ensuring that at least 99.9% of the fuel rods do not experience transition boiling during normal operation and AOOs if the MCPR limit is not violated. The proposed change will ensure the appropriate level of fuel protection by continuing to ensure that at least 99.9% of the fuel rods do not experience transition boiling during normal operation and AOOs if the MCPR limit is not violated. Additionally, operational limits will be established based on the proposed SLMCPR to ensure that the SLMCPR is not violated. This will ensure that the fuel design safety criteria (i.e., that no more than 0.1% of the rods are expected to be in boiling transition if the MCPR limit is not violated) are met.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based upon the above, EGC concludes that the proposed amendment presents no significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and, accordingly, a finding of no significant hazards consideration is justified.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendments involve no significant hazards consideration.

Attorney for licensee: Mr. Brad Fewell, Assistant General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.

NRC Acting Branch Chief: Mindy S. Landau.

First Energy Nuclear Operating Company, Docket No. 50–440, Perry Nuclear Power Plant, Unit 1 (PNPP), Lake County, Ohio

Date of amendment request: November 21, 2005.

Description of amendment request: The proposed amendment would revise the acceptance criteria of Technical Specification (TS) Surveillance Requirements (SRs) associated with TS 3.8.1, ''AC Sources—Operating,'' to modify the Emergency Diesel Generator (EDG) start tests to provide minimum voltage and frequency limits and clarify other limits as steady state parameters. Specifically, the amendment would revise SRs 3.8.1.2, 3.8.1.7, 3.8.1.12, 3.8.1.15 and 3.8.1.20. This change is consistent with the approved Technical Specification Task Force Traveler (TSTF) 163, Revision 2.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change is a LAR (license amendment request) that modifies the acceptance criteria for the PNPP TS SRs pertaining to the EDGs. The EDGs mitigate the consequences of previously evaluated

accidents involving a loss of offsite power. The EDGs are used to support mitigation of the consequences of an accident, but they are not considered as the initiator of any previously analyzed accident.

The proposed LAR does not change the manner in which the EDGs are operated and when implemented will continue to ensure the EDGs perform their function when called upon. The proposed revision to the TS SRs will continue to ensure that minimum frequency and voltage are attained within the required time. The SRs will continue to ensure that proper steady state voltage and frequency are attained consistent with proper EDG governor and voltage regulator performance.

The proposed LAR does not affect the design of the EDGs, the operational characteristics of the EDGs, the interfaces between the EDGs and other plant systems, the function, or reliability of the EDGs. Thus, the EDGs will be capable of performing their accident mitigation function and there is no impact to the radiological consequences of any accident analysis.

As such, the proposed change continues to provide adequate assurance of operable EDGs and does not involve any increase to the probability or consequences of an accident previously evaluated.

2. The proposed change would not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed LAR introduces no new mode of plant operation and it does not involve physical modification to the plant. New equipment is not installed with the proposed LAR, nor does the proposed LAR cause existing equipment to be operated in a new or different manner.

Since the proposed changes do not involve a change to the plant design or operation, no new system interactions are created by this change. The proposed LAR does not produce any parameters or conditions that could contribute to the initiation of accidents different from those already evaluated in the Updated Safety Analysis Report.

The changes to the affected TS SRs do not affect the assumed accident performance of the EDGs, nor any plant structure, system or component previously evaluated.

Therefore, the proposed LAR does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed change will not involve a significant reduction in the margin of safety.

The proposed change is a LAR that does not impact EDG performance, including the capability for each EDG to attain and maintain required voltage and frequency for accepting and supporting plant safety loads within the required time, as assumed in the plant safety analysis.

The proposed LAR does not involve a significant reduction in a margin of safety since the operability of the EDGs continues to be determined as required to support the capability of the EDGs to provide emergency power to plant equipment that mitigate the consequences of an accident.

The proposed LAR does not introduce changes to setpoints or limits established or assumed by the accident analysis. Therefore, implementation of the proposed LAR does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David W. Jenkins, Attorney, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

NRC Branch Chief: Mindy Landau, Acting.

FPL Energy Seabrook, LLC, Docket No. 50–443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire

Date of amendment request: December 6, 2005.

Description of amendment request: The proposed amendment would revise the Seabrook Station, Unit No. 1 Technical Specification 3.8.3.1, ''Onsite Power Distribution,'' to extend the allowed outage time for balance-of-plant vital inverters 1–EDE–I–1E and 1–EDE–I–1F from 24 hours to 7 days.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change extends the allowed outage time (AOT) for the balance-of-plant (BOP) instrument bus inverters from 24 hours to 7 days. The BOP instrument bus inverters do not solely support any risk-significant functions. The failure of an inverter is not an initiator of any analyzed event and does not increase the frequency of an initiating event. Consequently, extending the AOT will not have an impact on the frequency of occurrence of any event previously analyzed. The proposed change does not alter the design, configuration, operation, or function of any plant system, structure, or component. As a result, the outcomes of previously evaluated accidents are unaffected. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

No new accident scenarios, failure mechanisms, or limiting single failures are introduced as a result of the proposed change. The proposed change does not challenge the performance or integrity of any safety-related system. The proposed change neither installs nor removes any plant equipment, not alters the design, physical configuration, or mode of operation of any plant structure, system, or component. Installed equipment will not be operated in a new or different manner. No physical changes are being made to the plant, so no new accident causal mechanisms are being introduced. Procedures that ensure the unit operates within analyzed limits and procedures that respond to off-normal and emergency conditions are not altered with this proposed change. Therefore, the proposed change does not create the possibility of a new or different accident from any previously evaluated.

3. The proposed changes do not involve a significant reduction in [a] margin of safety.

The margin of safety associated with the acceptance criteria of any accident is unchanged. The proposed change does not alter the design, configuration, operation, or function of any plant system, structure, or component. The ability of any operable structure, system, or component to perform its designated safety function is unaffected by this change. Operation with one instrument bus inverter inoperable and the associated instrument bus aligned to its maintenance supply does not result in a significant reduction in [a] margin of safety. Surveillance testing of the emergency diesel generators (EDGs) and the electrical distribution system provides confidence that the EDGs will energize the emergency AC buses following a loss of power. Therefore, the proposed change does not involve a significant reduction in [a] margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: M. S. Ross, Florida Power & Light Company, P.O. Box 14000, Juno Beach, FL 33408–0420.

NRC Branch Chief: Darrell J. Roberts.

Nuclear Management Company, LLC, Docket Nos. 50–266 and 50–301, Point Beach Nuclear Plant, Units 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin

Date of amendment request: November 12, 2004.

Description of amendment request: The proposed amendment would revise Technical Specification (TS) 5.5.7, ''Inservice Testing Program,'' and TS 5.5.8, ''Steam Generator (SG) Tube Surveillance Program,'' to update references to the American Society of Mechanical Engineers (ASME) *Boiler and Pressure Vessel Code* (Code) and certain associated periodicities for inservice testing activities consistent with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) section 50.55a, ''Codes and standards.''

The proposed amendment would also correct a typographical error contained in TS 5.5.8.b.2.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

1. Operation of the Point Beach Nuclear Plant in accordance with the proposed amendments does not result in a significant increase in the probability or consequences of any accident previously evaluated.

The proposed change revises Technical Specifications for consistency with the requirements of 10 CFR 50.55a(f)(4) and 10 CFR 50.55a(g)(4).

The proposed change incorporates revisions to the ASME Code that result in a net improvement in the measures for testing pumps and valves.

The proposed change does not involve any hardware changes, nor does it affect the probability of any event initiators. There will be no change to normal plant operating parameters, engineered safety feature actuation setpoints, accident mitigation capabilities, or accident analysis assumptions or inputs.

Therefore, the probability or consequences of any accident previously evaluated will not be significantly increased as a result of the proposed change.

2. Operation of the Point Beach Nuclear Plant in accordance with the proposed amendments does not result in a new or different kind of accident from any accident previously evaluated.

The proposed change incorporates revisions to the ASME Code that result in a net improvement in the measures for testing. The proposed change does not involve a modification to the physical configuration of the plant (i.e., no new equipment will be installed) or change in the methods governing normal plant operation. The proposed change will not impose any new or different requirements or introduce a new accident initiator, accident precursor, or malfunction mechanism. Additionally, there is no change in the types or increases in the amounts of any effluent that may be released off-site and there is no increase in individual or cumulative occupational exposure.

Equipment important to safety will continue to operate as designed. The changes do not result in any event previously deemed incredible been made credible. The changes do not result in adverse conditions or result in any increase in the challenges to safety systems. Therefore, operation of the Point Beach Nuclear Plant in accordance with the proposed amendment will not create the possibility of a new or different type of accident from any accident previously evaluated.

3. Operation of the Point Beach Nuclear Plant in accordance with the proposed amendments does not result in a significant reduction in a margin of safety.

The proposed change incorporates revisions to the ASME Code that result in a net improvement in the measures for testing. The safety function of the affected components will be maintained.

There are no new or significant changes to the initial conditions contributing to accident severity or consequences. The proposed amendment will not otherwise affect the plant protective boundaries, will not cause a release of fission products to the public, nor will it degrade the performance of any other structures, systems or components (SSCs) important to safety. Therefore, the requested change will not result in a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jonathan Rogoff, Esquire, Vice President, Counsel & Secretary, Nuclear Management Company, LLC, 700 First Street, Hudson, WI 54016.

NRC Branch Chief: L. Raghavan.

PSEG Nuclear LLC, Docket No. 50–354, Hope Creek Generating Station, Salem County, New Jersey

Date of amendment request: October 11, 2005.

Description of amendment request: The proposed amendment would revise certain 18-month Technical Specification (TS) Surveillance Requirements (SRs) to eliminate the condition that testing be conducted during shutdown.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes permit PSEG to evaluate the conditions required to safely perform a TS SR. These surveillance tests verify that equipment will perform its intended safety function of mitigating an accident. No analyzed accident scenario is being revised. The initiating conditions and assumptions for accidents described in the Hope Creek Generating Station Updated Final Safety Analysis Report (UFSAR) remain as previously analyzed.

The proposed changes do not reduce the ability of the mitigating equipment to perform its safety function. The TS will continue to require the surveillance tests to be performed on an eighteen-month periodicity to verify operability. As a result, the ability of the mitigating equipment to perform its safety function is unaffected by the proposed change.

The capitalization change is proposed to improve readability and does not alter any requirement.

Based upon the above, the proposed changes will not involve a significant increase in the probability or consequences of an accident previously analyzed.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated in the UFSAR. No new accident scenarios, failure mechanisms, or limiting single failures are introduced as a result of the proposed changes. Specifically, no new hardware is being added to the plant as part of the proposed change, no existing equipment is being modified, and no significant changes in operations are being introduced.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes will not alter any assumptions, initial conditions, or results of any accident analyses. The proposed changes to remove the requirement to perform certain testing during shutdown conditions allows PSEG to evaluate the conditions needed to safely perform the required testing. There is no change to the frequency of testing or in the testing that is required. There is no change in the responsibility of PSEG to perform tests in a safe and responsible manner. Any changes to procedures will have to be individually evaluated to ensure that they do not reduce the margin of safety. The changes do not affect the ability of systems, structures or components to perform their safety related functions. In addition, the proposed changes do not affect the ability of the safety systems to ensure that the facility can be maintained in a shutdown or refueling condition for extended periods of time.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jeffrie J. Keenan, Esquire, Nuclear Business Unit—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Branch Chief: Darrell J. Roberts.

PSEG Nuclear LLC, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of amendment request: August 31, 2005; as supplemented December 8, 2005.

Description of amendment request: The proposed amendment would relocate the containment high range accident monitors from the radiation monitoring instrumentation technical specification (TS) to the accident monitoring TS and correct a typographical error contained in a previous amendment.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change presents no change in the probability of a previously evaluated accident.

The proposed change presents no change in the consequence of an accident, since the containment high range accident monitors are used post-accident to determine the amount of core damage and status of the fission product barriers.

The containment high range accident monitors are used post accident to assess the conditions inside containment. They have an automatic function to switch the subcooling margin monitor (SCMM) to ''adverse'' mode (i.e., it displays a more conservative indication of the amount of subcooling in the RCS) [reactor coolant system]. Additionally, the containment high range accident monitors provide an indication that is used post accident in determining the status of the fission product barriers. There will be no change in the operation or use of the containment high range accident monitors.

The remaining change is editorial in nature and does not impact the accident analysis in any manner.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated.

Response: No.

The proposed change is a minor change that is administrative in nature. No new accident scenarios, failure mechanisms, or limiting single failures are introduced as a result of the proposed changes. No new hardware is added, existing hardware is not modified and no significant changes in operations are implemented. Post accident monitoring instrumentation is not associated with the initiation of an accident.

3. Does the proposed change involve a significant reduction in [a] margin of safety?

Response: No.

The proposed change does not alter the manner in which safety limits, limiting safety systems settings or limiting conditions for operation are determined. The proposed change will not alter any assumptions, initial conditions or results specified in any accident analysis.

There is no change in the containment high range accident monitor high level alarm setpoint. The ECS [electronic check source] is functionally equivalent to the TS definition of SOURCE CHECK.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jeffrie J. Keenan, Esquire, Nuclear Business Unit—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Branch Chief: Darrell J. Roberts.

PSEG Nuclear LLC, Docket No. 50–311, Salem Nuclear Generating Station, Unit No. 2, Salem County, New Jersey

Date of amendment request: September 21, 2005.

Description of amendment request: The amendment would change the scope of steam generator (SG) tube inspections required in the SG tubesheet region.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

Of the various accidents previously evaluated, the proposed changes only affect the steam generator tube rupture (SGTR) event evaluation and the postulated steam line break (SLB) accident evaluation. Loss-of-coolant accident (LOCA) conditions cause a compressive axial load to act on the tube. Therefore, since the LOCA tends to force the tube into the tubesheet rather than pull it out, it is not a factor in this amendment request. Another faulted load consideration is a safe shutdown earthquake (SSE); however, the seismic analysis of Westinghouse 51 Series SGs has shown that axial loading of the tubes is negligible during an SSE.

PSEG's amendment request takes credit for how the tubesheet enhances the tube integrity in the Westinghouse Electric Company explosive tube expansion (WEXTEX) region by precluding tube deformation beyond its initial expanded outside diameter. For the SGTR and SLB events, the required structural margins of the SG tubes will be maintained due to the presence of the tubesheet. Tube rupture is precluded for axial cracks in the WEXTEX region due to the constraint provided by the tubesheet. Therefore, the normal operating 3ΔP margin and the postulated accident 1.43ΔP margin against burst are maintained.

The W* length supplies the necessary resistive force to preclude pullout loads under both normal operating and accident conditions. The contact pressure results from the WEXTEX expansion process, thermal expansion mismatch between the tube and tubesheet, and from the differential pressure between the primary and secondary side. Therefore, the proposed change results in no significant increase in the probability or the occurrence of an SGTR or SLB accident.

The proposed changes do not affect other systems, structures, components or operational features. Therefore, based on the above evaluation, the proposed changes do not involve a significant increase in the probability of an accident previously evaluated.

The consequences of an SGTR event are primarily affected by the primary-to-secondary flow rate and the time duration of the primary-to-secondary flow during the event. Primary-to-secondary flow rate through a postulated ruptured tube (i.e., complete severance of a single SG tube) is not affected by the proposed change since the flow rate is based on the inside diameter of a[n] SG tube and the pressure differential. PSEG's amendment request does not change either of these. The duration of primary-to-secondary leakage is based on the time required for an operator to determine that a[n] SGTR has occurred, the time to identify and isolate the faulted SG, and ensure termination of radioactive release to the atmosphere from the faulted SG. PSEG's amendment request does not affect the duration of the primary-to-secondary leakage because it does not change the control room indicators with which an operator would determine that an SGTR has occurred. The consequences of an SGTR are secondarily affected by primary-to-secondary leakage, which could occur due to axial cracks remaining in service in the WEXTEX region in a non-faulted SG. During a[n] SGTR, the primary-to-secondary differential pressure is less than or equal to the normal operating differential pressure; therefore, the primary-to-secondary leakage due to axial cracks in the WEXTEX region of a non-faulted SG during a[n] SGTR would be less than or equal to the primary-to-secondary leakage experienced during normal operation. Primary-to-secondary leakage is considered in the calculation determining the consequences of a[n] SGTR and the value is bounding.

The postulated SLB has the greatest primary-to-secondary pressure differential, and therefore could experience the greatest primary-to-secondary leakage. PSEG's amendment request requires the aggregate leakage, (i.e., the combined leakage for the tubes with service induced degradation inside the tubesheet) to remain below the maximum allowable SLB primary-to-secondary leakage rate limit such that the doses are maintained to less than the 10 CFR [Part] 100 limits and also less than the GDC-[General Design Criterion]19 limits.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

PSEG's amendment request does not introduce any physical changes to the Salem Unit 2 SGs. PSEG's amendment request takes credit for how the tubesheet enhances the SG tube integrity in the WEXTEX region. Because degradation detected within the W* distance are required to be plugged, it is highly unlikely that a tube would fail as a result of a circumferential defect. Therefore a tube severance, which would strike neighboring tubes and create a multiple tube rupture, is not credible. The proposed change does not introduce any new equipment or any change to existing equipment. No new effects on existing equipment are created. Based on the above evaluation, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The amendment request maintains the structural margins of the SG tubes for both normal and accident conditions that are required by Regulatory Guide 1.121. For cracking located within the tubesheet, tube burst is precluded due to the presence of the tubesheet. WCAP–14797, Revision 2 defines a length W* of degradation free expanded tubing, that provides the necessary resistance to tube pullout due to the pressure induced forces (with applicable safety factor applied). Application of the W* methodology will preclude unacceptable primary-to-secondary leakage during all plant conditions. The methodology for determining leakage provides for large margins between calculated and actual leakage values in the W* criteria.

Based on the above, it is concluded that the proposed changes do not result in a significant reduction of margin with respect to plant safety as defined in the Updated Final Analysis Report or Technical Specifications. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jeffrie J. Keenan, Esquire, Nuclear Business Unit—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Branch Chief: Darrell J. Roberts.

PPL Susquehanna, LLC, Docket No. 50–387, Susquehanna Steam Electric Station, Unit 1 (SSES 1), Luzerne County, Pennsylvania

Date of amendment request: December 1, 2005.

Description of amendment request: The proposed amendment would change the SSES–1 Technical Specifications (TSs) by revising the Unit 1 Cycle 15 (U1C15) minimum critical power ratio (MCPR) safety limit for single loop operation in section 2.1.1.2 and references listed in TS 5.6.5.b.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability of occurrence or consequences of an accident previously evaluated?

Response: No.

The proposed change to the single-loop MCPR Safety Limit does not directly or indirectly affect any plant system, equipment, component, or change the processes used to operate the plant. Further, the proposed U1C15 MCPR Safety Limit was generated using NRC approved methodology and meets the applicable acceptance criteria. Thus, this proposed amendment does not involve a significant increase in the probability of occurrence or consequences of an accident previously evaluated.

Prior to the startup of U1C15, licensing analyses are performed (using NRC approved methodology referenced in Technical Specification Section 5.6.5.b) to determine changes in the critical power ratio as a result of anticipated operational occurrences. These results are added to the MCPR Safety Limit values to generate the MCPR operating limits in the U1C15 COLR [core operating limits report]. These limits could be different from those specified for the current Unit 1 COLR. The COLR operating limits thus assure that the MCPR Safety Limit will not be exceeded during normal operation or anticipated operational occurrences. Postulated accidents are also analyzed prior to the startup of U1C15 and the results shown to be within the NRC approved criteria.

The changes to the references in Section 5.6.5.b were made to properly reflect the NRC approved methodology used to generate the U1C15 core operating limits. The use of this approved methodology does not increase the probability of occurrence or consequences of an accident previously evaluated.

Therefore, the proposed amendment does not involve a significant increase in the probability of occurrence or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The change to the single-loop MCPR Safety Limit does not directly or indirectly affect any plant system, equipment, or component and therefore does not affect the failure modes of any of these items. Thus, the proposed change does not create the possibility of a previously unevaluated operator error or a new single failure. The changes to the references in Section 5.6.5.b were made to properly reflect the NRC approved methodology used to generate the U1C15 core operating limits. The use of this approved methodology does not create the possibility of a new or different kind of accident.

Therefore, this proposed amendment does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Since the proposed changes do not alter any plant system, equipment, component, or the processes used to operate the plant, the proposed change will not jeopardize or degrade the function or operation of any plant system or component governed by Technical Specifications. The proposed single-loop MCPR Safety Limit does not involve a significant reduction in the margin of safety as currently defined in the Bases of the applicable Technical Specification sections, because the MCPR Safety Limits calculated for U1C15 preserve the required margin of safety.

The changes to the references in section 5.6.5.b were made to properly reflect the NRC approved methodology used to generate the U1C15 core operating limits. This approved methodology is used to demonstrate that all applicable criteria are met, thus, demonstrating that there is no reduction in the margin of safety.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Bryan A. Snapp, Esquire, Assoc. General Counsel, PPL Services Corporation, 2 North Ninth St., GENTW3, Allentown, PA 18101–1179.

NRC Branch Chief: Richard J. Laufer.

PPL Susquehanna, LLC, Docket Nos. 50–387 and 50–388, Susquehanna Steam Electric Station, Units 1 and 2 (SSES 1 and 2), Luzerne County, Pennsylvania

Date of amendment request: October 5, 2005.

Description of amendment request: The proposed amendment would revise the SSES 1 and 2 Technical Specifications (TSs) 3.4.10, ''RCS [reactor coolant system] Pressure and Temperature (P/T) Limits,'' to remove valid P/T curve limit date and replacing

it with the effective full-power years (EFPY) of radiation exposure on each of the P/T limit curves for SSES 1 and 2. The new P/T limit would be 35.7 EFPY for SSES 1 and 30.2 EFPY for SSES 2.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed changes request that the P/T limits curves in TS 3.4.10, ''RCS Pressure and Temperature (P/T) Limits'' be revised by removing the valid date and replacing it with the Effective Full Power Years of radiation exposure limit on each of the P/T curves for SSES Units 1 and 2.

The P/T limits are prescribed during all operational conditions to avoid encountering pressure, temperature, and temperature rate of change conditions that might cause undetected flaws to propagate, resulting in nonductile failure of the reactor coolant pressure boundary, an unanalyzed condition. Therefore, the proposed changes do not have any effect on the probability of an accident previously evaluated.

The P/T curves are used as operational limits during heatup or cooldown maneuvering, when pressure and temperature indications are monitored and compared to the applicable curve to determine that operation is within the allowable region. The P/T curves provide assurance that station operation is consistent with previously evaluated accidents. Thus, the radiological consequences of an accident previously evaluated are not increased.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed changes do not change the response of any plant equipment to transient conditions. The proposed changes do not introduce any new equipment, modes of system operation, or failure mechanisms.

Therefore, there are no new types of failures or new or different kinds of accidents or transients that could be created by these changes. The proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

No. The consequences of a previously evaluated accident are not increased by these proposed changes, since the Loss of Coolant Accident analyzed in the FSAR [Final Safety Analysis Report] assumes a complete break of the reactor coolant pressure boundary. The changes to the P/T limits curves do not change this assumption.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Bryan A. Snapp, Esquire, Assoc. General Counsel, PPL Services Corporation, 2 North Ninth St., GENTW3, Allentown, PA 18101–1179.

NRC Branch Chief: Richard J. Laufer.

PPL Susquehanna, LLC, Docket Nos. 50–387 and 50–388, Susquehanna Steam Electric Station, Units 1 and 2 (SSES 1 and 2), Luzerne County, Pennsylvania

Date of amendment request: November 9, 2004, as supplemented December 15, 2005. This notice supersedes the original notice published on April 26, 2005 (70 FR 21463), which was based upon the licensee's application dated November 9, 2004.

Description of amendment request: The proposed amendments would change the SSES 1 and 2 Technical Specifications (TSs) 3.8.4, ''DC Sources— Operating,'' 3.8.5, ''DC Sources—Shutdown,'' 3.8.6, ''Battery Cell Parameters,'' and add a new TS section, 5.5.13, ''Battery Monitoring and Maintenance Program.'' These changes are consistent with Technical Specification Change Traveler (TSTF) 360, Revision 1.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed changes restructure the Technical Specifications (TSs) for the DC Electrical Power Systems. The proposed changes consist of the relocation of several surveillance requirements that perform preventive maintenance on the safety related batteries, to a new license controlled program. The DC electrical power systems, including associated battery chargers, are not initiators to any accident sequence analyzed in the Final Safety Analysis Report (FSAR). Operation in accordance with the proposed TS ensures that the DC electrical power systems are capable of performing functions as described in the FSAR. Therefore, the mitigative functions supported by the DC Power Systems will continue to provide the protection assumed by the analysis.

The relocation of preventive maintenance surveillance, and certain operating limits and actions to a newly created, licensee-controlled TS 5.5.13, ''Battery Monitoring and Maintenance Program,'' will not challenge the ability of the DC electrical power systems to perform their design functions. The maintenance and monitoring required by current TS, which are based on industry standards, will continue to be performed. In addition, the DC Power Systems are within the scope of 10 CFR 50.65, ''Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants,'' which will ensure the control of maintenance activities associated with the DC electrical power systems. The integrity of fission product barriers, plant configuration, and operating procedures as described in the FSAR will not be affected by the proposed changes.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed changes involve restructuring the TS for the DC electrical power systems. These changes will rely on a new license controlled program to monitor battery parameters for operability. The DC electrical power systems, which include the associated battery chargers, are not initiators to any accident sequence analyzed in the FSAR. Rather, the DC electrical power systems are used to supply equipment used to mitigate an accident. These mitigative functions, supported by the DC electrical power systems are not affected by these changes and they will continue to provide the protection assumed by the safety analysis described in the FSAR. There are no new types of failures or new or different kinds of accidents or transients that could be created by these changes.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

No. The margin of safety is established through equipment design, operating parameters, and the setpoints at which automatic actions are initiated. The proposed changes will not adversely affect operation of plant equipment. These changes will not result in a change to the setpoints at which protective actions are initiated. Sufficient DC electrical system capacity is ensured to support operation of mitigation equipment. The changes associated with the new Battery Maintenance and Monitoring Program will ensure that the station batteries are maintained in a highly reliable state. The equipment fed by the DC electrical sources will continue to provide adequate power to safety related loads in accordance with analysis assumptions.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Bryan A. Snapp, Esquire, Assoc. General Counsel, PPL Services Corporation, 2 North Ninth St., GENTW3, Allentown, PA 18101–1179.

Union Electric Company, Docket No. 50–483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application request: October 26, 2005.

Description of amendment request: The amendment would revise Technical Specification (TS) 3.6.6, ''Containment Spray and Cooling Systems,'' to change Required Action D.1 that currently allows 72 hours of operation with both containment cooling trains out of service as long as both containment spray trains are operable. The required action would be revised to impose the more stringent requirement of requiring plant shutdown if both containment cooling trains are out of service instead of allowing the 72 hours to restore an inoperable train. There are also changes to other required actions in TS 3.6.6 to reflect the revision to Required Action D.1. In addition, the required action for two inoperable containment spray trains is being revised.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No

The proposed change in the required action when two containment cooling trains are inoperable to require plant shutdown is more restrictive than the current required action that allows 72 hours of operation [to restore one containment cooling train to operable status]. Also the proposed change to the required action [F.1 for] when two containment cooling trains are inoperable to be in MODE 3 within 6 hours and MODE 5 within 36 hours [are the same as in the current Required Actions E.1 and E.2 for when the two containment cooling trains are inoperable. The proposed change to the required action for two containment spray trains being inoperable] is more restrictive than the current required action to enter LCO [Limiting Condition for Operation] 3.0.3 immediately [because] LCO 3.0.3 requires the plant to be in MODE 3 within 7 hours. The more stringent requirements are imposed to ensure process variables, structures, systems and components are maintained consistently with the safety analysis and licensing basis [for Callaway].

All of these proposed changes have been reviewed to ensure no previously evaluated accident has been adversely affected. [The proposed changes are not accident initiators.] Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed) or changes in controlling [plant] parameters. The proposed change does impose different requirements. However, these changes are consistent with [the] assumptions made in the safety analysis and licensing basis [for Callaway]. Thus, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Does the proposed change involve a significant reduction in a margin of safety?

Response: No

The imposition of more stringent requirements has no impact on or will increase the margin of safety. The change in the required action when two containment cooling trains are out of service will increase the margin of safety by decreasing the allowed restoration time [to restore an inoperable containment cooling train to operable status].

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: John O'Neill, Esq., Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Branch Chief: David Terao.

Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov.*

AmerGen Energy Company, LLC, et al., Docket No. 50–219, Oyster Creek Nuclear Generating Station (OCNGS), Ocean County, New Jersey

Date of application for amendment: December 17, 2004.

Brief description of amendment: The amendment revised Appendix B, Environmental Technical Specifications, of the OCNGS Facility Operating License, principally by deleting redundant reporting requirements, aligning various requirements with regulations and accepted guidance documents, and correcting administrative errors.

Date of Issuance: January 4, 2006.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment No.: 257.

Facility Operating License No. DPR–16: The amendment revised the Environmental Technical Specifications.

Date of initial notice in ***Federal Register:*** April 12, 2005 (70 FR 19113).

The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated January 4, 2006.

No significant hazards consideration comments received: No.

Dominion Nuclear Connecticut, Inc., Docket No. 50–336, Millstone Power Station, Unit No. 2, New London County, Connecticut

Date of application for amendment: February 25, 2005, as supplemented by letter dated August 4, 2005.

Brief description of amendment: The amendment revised the Millstone Power Station, Unit No. 2, Technical Specifications Surveillance Requirement for trisodium phosphate to remove the granularity term and chemical detail. In addition, the proposed change will increase the allowed outage time from 48 to 72 hours.

Date of issuance: January 3, 2006.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment No.: 290.

Facility Operating License No. DPR–65: The amendment revised the Technical Specifications.

Date of initial notice in ***Federal Register:*** July 19, 2005 (70 FR 41444). The additional information provided in the supplemental letter dated August 4, 2005, did not expand the scope of the application as noticed and did not change the NRC staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated January 3, 2006.

No significant hazards consideration comments received: No.

Dominion Nuclear Connecticut, Inc., et al., Docket No. 50–423, Millstone Power Station, Unit No. 3, New London County, Connecticut

Date of application for amendment: December 16, 2004, as supplemented on October 5, 2005.

Brief description of amendment: The amendment revised the current fuel rod average licensing basis burnup limit for one lead test assembly containing advanced zirconium based alloys to a limit not exceeding 71,000 megawatt-days per metric ton of uranium.

Date of issuance: December 30, 2005.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment No.: 228

Facility Operating License No. NPF–49: The amendment revised the design basis.

Date of initial notice in ***Federal Register:*** February 1, 2005 (70 FR 5238). The October 5, 2005, supplement provided clarifying information and did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 30, 2005.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., Docket No. 50–382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: July 20, 2005, as supplemented by letter dated September 14, 2005.

Brief description of amendment: The amendment approves the transfer of Facility Operating License and Materials License No. NPF–38, held by Entergy Louisiana, Inc. (ELI) and Entergy Operatings, Inc. (EOI), for the Waterford Steam Electric Station, Unit 3 (Waterford 3). The transfer is associated with the restructuring of ELI from a Louisiana corporation to a Texas limited liability company, Entergy Louisiana, LLC (ELL). EOI will continue to operate Waterford 3, and the restructuring will not affect the technical or financial qualifications of ELL or EOI.

Date of issuance: December 31, 2005.

Effective date: At the time the transfer is completed.

Amendment No.: 203.

Facility Operating License No. NPF–38: The amendment revised the Facility Operating License and Materials License.

Date of initial notice in ***Federal Register:*** October 17, 2005 (70 FR 60374).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 2, 2005.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, and PSEG Nuclear LLC, Docket Nos. 50–277 and 50–278, Peach Bottom Atomic Power Station, Units 2 and 3, York and Lancaster Counties, Pennsylvania

Date of application for amendments: December 17, 2004.

Brief description of amendments: The amendments revised the Appendix B, Environmental Technical Specifications.

Date of issuance: January 3, 2006.

Effective date: As of the date of issuance, to be implemented within 60 days.

Amendments Nos.: 257 and 260.

Renewed Facility Operating License Nos. DPR–44 and DPR–56: The amendments revised the Environmental Technical Specifications.

Date of initial notice in ***Federal Register:*** April 12, 2005 (70 FR 19112).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 3, 2006.

No significant hazards consideration comments received: No.

FPL Energy Seabrook, LLC, Docket No. 50–443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire

Date of amendment request: March 28, 2005, as supplemented September 23, 2005.

Description of amendment request: The amendment extended the expiration of Facility Operating License (FOL) NPF–86 for Seabrook Station, Unit No. 1, by approximately 3.4 years. The extension sets the date of expiration of the FOL to occur 40 years from the date of issuance of the full-power operating license. Specifically, the FOL, with a previous expiration date of October 17, 2026, now expires March 15, 2030. This change allows the recapture of zero-power and low-power testing time in accordance with SECY–98–296, ''Agency Policy Regarding Licensee Recapture of Low-Power Testing or Shutdown Time for Nuclear Power Plants,'' dated December 21, 1998.

Date of issuance: December 28, 2005.

Effective date: As of its date of issuance, and shall be implemented within 30 days.

Amendment No.: 105.

Facility Operating License No. NPF–86: The amendment revised the License.

Date of initial notice in ***Federal Register:*** May 24, 2005 (70 FR 29797). The licensee's September 23, 2005 supplement provided clarifying information that did not change the scope of the proposed amendment as described in the original notice of proposed action published in the **Federal Register**, and did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 28, 2005.

No significant hazards consideration comments received: No.

Florida Power and Light Company, et al., Docket No. 50–389, St. Lucie Plant, Unit No. 2, St. Lucie County, Florida

Date of application for amendment: March 31, 2005, as supplemented November 9, 2005.

Brief description of amendment: This amendment extended the date for the next Appendix J, Type A test at St. Lucie Unit 2 until the end of the SL2–17 refueling outage.

Date of Issuance: December 23, 2005.

Effective Date: As of the date of issuance and shall be implemented within 60 days.

Amendment No.: 140.

Renewed Facility Operating License No. NPF–16: Amendment revised the Technical Specifications.

*Date of initial notice in **Federal Register:*** June 7, 2005 (70 FR 33215). The November 9, 2005, supplement did not affect the original proposed no significant hazards determination, or expand the scope of the request as noticed in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 23, 2005.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: October 29, 2004, as supplemented by letters dated May 6 and October 31, 2005.

Brief description of amendments: The amendments revised the Technical Specification (TS) requirements for the handling of irradiated fuel in the containment and fuel building, and certain specifications related to performing core alterations. These changes are based on analysis of the postulated fuel handling and core alteration accidents and transients for Diablo Canyon Nuclear Power Plant, Units 1 and 2. The amendments are consistent with the NRC-approved Industry/Technical Specification Task Force (TSTF) Standard Technical Specifications Change Traveler, TSTF–51, Revision 2, ''Revise containment requirements during handling irradiated fuel and core alterations.'' In addition, the amendments made editorial corrections to TS 3.1.7, ''Rod Position Indication,'' TS 3.3.1, ''Reactor Trip System (RTS) Instrumentation,'' TS 3.4.16, ''RCS Specific Activity,'' TS 3.7.3, ''Main Feedwater Isolation Valve (MFIVs), Main Feedwater Regulating Valves (MFRVs), MFRV Bypass Valves, and Main Feedwater Pump (MFWP) Turbine Stop Valves,'' and TS 3.7.13, ''Fuel Handling Building Ventilation System (FHBVS).''

Date of issuance: January 3, 2006.

Effective date: January 3, 2006, and shall be implemented within 90 days of issuance.

Amendment Nos.: Unit 1—184; Unit 2—86.

Facility Operating License Nos. DPR–80 and DPR–82: The amendments revised the Technical Specifications.

*Date of initial notice in **Federal Register:*** January 4, 2005 (70 FR 403)

The supplements dated May 6 and October 31, 2005, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 3, 2006.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of application for amendments: November 12, 2004, as supplemented by letters dated September 2 and September 16, 2005.

Brief description of amendments: The amendments revised the Technical Specifications (TS) 3.1.7, ''Standby Liquid Control (SLC) System,'' for Hatch, Units 1 and 2. The amendments update Figure 3.1.7–1 and 3.1.7–2 of the Units 1 and 2 TS to reflect the increased concentration of Boron-10 in the solution. Conforming revisions to Bases B3.1.7, are also included.

Date of issuance: January 5, 2006.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment Nos.: 247/191.

Renewed Facility Operating License Nos. DPR–57 and NPF–5: Amendments revised the Technical Specifications.

*Date of initial notice in **Federal Register:*** February 1, 2005 (70 FR 5249).

The supplemental letter dated September 2, 2005, contained clarifying information only and did not change the initial proposed no significant hazards consideration determination or expand the scope of the original **Federal Register** notice. The supplemental letter dated September 16, 2005, contained information that expanded the scope of the original **Federal Register** notice. The proposed amendment was re-noticed on October 25, 2005 (70 FR 61662).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 5, 2006.

No significant hazards consideration comments received: No.

Tennessee Valley Authority, Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of application for amendments: April 27, 2005, as supplemented by letter dated November 17, 2005.

Brief description of amendments: The amendments relocate several Technical Specification (TS) requirements to the Sequoyah Technical Requirements Manual (TRM). Specifically, the amendments relocate the provisions for TS 3.3.2 (Movable Incore Detectors), TS 3.3.3.4 (Meteorological Instrumentation), TS 3.4.7 (Reactor Coolant System Chemistry), TS 3.4.11 (Reactor Coolant System Head Vents), TS 3.7.2 (Steam Generator Pressure and Temperature Limitations), TS 3.7.10 (Sealed Source Contamination), TS 3.9.5 (Refueling Operations Communications), and TS 3.9.6 (Manipulator Crane) to the TRM. These changes are consistent with the latest version of NUREG–1431, Revision 3, ''Standard Technical Specifications for Westinghouse Plants,'' and do not diminish the level of safety found in the current TSs.

Date of issuance: December 28, 2005.

Effective date: As of the date of issuance and shall be implemented within 45 days.

Amendment Nos.: 305, 295.

Facility Operating License Nos. DPR–77 and DPR–79: Amendments revised the technical specifications.

*Date of initial notice in **Federal Register:*** July 5, 2005 (70 FR 38723). The supplemental letter of November 17, 2005, provided clarifying information that did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated December 28, 2005.

No significant hazards consideration comments received: No.

Virginia Electric and Power Company, et al., Docket Nos. 50–280 and 50–281, Surry Power Station, Unit Nos. 1 and 2, Surry County, Virginia

Date of application for amendments: December 17, 2004.

Brief Description of amendments: These amendments revised the reactor coolant pressure and temperature limits, low-temperature overpressure protection system (LTOPS) setpoint values, and LTOPS enable temperatures that are valid for up to 47.6 effective full-power years (EFPY) and 48.1 EFPY of operation at Surry Power Station, Unit Nos. 1 and 2, respectively.

Date of issuance: January 3, 2006.

Effective date: As of the date of issuance and shall be implemented within 180 days from the date of issuance.

Amendment Nos.: 245/244.

Renewed Facility Operating License Nos. DPR–32 and DPR–37: Amendments change the Technical Specifications.

Date of initial notice in ***Federal Register:*** March 1, 2005 (70 FR 9999).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 3, 2006.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 9th day of January 2006.

For the Nuclear Regulatory Commission.

Edwin M. Hackett,

Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 06–320 Filed 1–13–06; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

Proposed Risk Assessment Bulletin

AGENCY: Office of Management and Budget.

ACTION: Notice of proposed Bulletin and request for comments.

SUMMARY: As part of an ongoing effort to improve the quality, objectivity, utility, and integrity of information disseminated by the Federal Government to the public, the Office of Management and Budget (OMB), in consultation with the Office of Science and Technology Policy (OSTP), has referred to the National Academy of Sciences (NAS), for their expert review, new guidance to enhance the quality and objectivity of risk assessments produced by the Federal Government. OMB will also be accepting public comment on this document until June 15, 2006.

DATES: Written comments regarding OMB's Proposed Risk Assessment Bulletin are due by June 15, 2006. This date has been selected in order to permit the public to participate in a related workshop to be organized by the NAS, prior to submitting their written comments.

ADDRESSES: Because of potential delays in OMB's receipt and processing of mail, respondents are strongly encouraged to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Electronic comments may be submitted to: *OMB_RAbulletin@omb.eop.gov.* Please put 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. Please be aware that all comments are available for public inspection. Accordingly, please do not submit comments containing trade secrets, confidential or proprietary commercial or financial information, or other information that you do not want to be made available to the public. Comments also may be submitted via facsimile to (202) 395–7245.

FOR FURTHER INFORMATION CONTACT: Dr. Nancy Beck, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., New Executive Office Building, Room 10201, Washington, DC 20503. Telephone (202) 395–3093.

SUPPLEMENTARY INFORMATION: OMB is seeking comments on its Proposed Risk Assessment Bulletin by June 15, 2006. The proposed Risk Assessment Bulletin is posted on OMB's Web site, *http://www.whitehouse.gov/omb/inforeg/infopoltech.html#iq.*

John D. Graham,

Administrator, Office of Information and Regulatory Affairs.

[FR Doc. E6–345 Filed 1–13–06; 8:45 am]

BILLING CODE 3110–01–P

PENSION BENEFIT GUARANTY CORPORATION

Exemption From the Bond/Escrow Requirement Relating to the Sale of Assets by an Employer Who Contributes to a Multiemployer Plan; LA Team Co. LLC

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of exemption.

SUMMARY: The Pension Benefit Guaranty Corporation has granted a request from the LA Team Co. LLC for an exemption from the bond/escrow requirement of section 4204(a)(1)(B) of the Employee Retirement Income Security Act of 1974, as amended, with respect to the Major League Baseball Players Pension Plan. A notice of the request for exemption from the requirement was published on July 7, 2005 (70 FR 39349). The effect of this notice is to advise the public of the decision on the exemption request.

ADDRESSES: The non-confidential portions of the request for an exemption and the PBGC response to the request may be obtained by writing PBGC's Communications and Public Affairs Department (''CPAD'') at Suite 1200, 1200 K Street, NW., Washington, DC 20005–4026, or by visiting or calling CPAD (202–326–4040) during normal business hours.

FOR FURTHER INFORMATION CONTACT: Gennice D. Brickhouse, Office of the Chief Counsel, Suite 340, 1200 K Street, NW., Washington, DC 20005–4026; telephone 202–326–4020. (For TTY/TDD users, call the Federal Relay Service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4020).

SUPPLEMENTARY INFORMATION:

Background

Section 4204 of the Employee Retirement Income Security Act of 1974, as amended by the Multiemployer Pension Plan Amendments Act of 1980 (''ERISA'' or ''the Act''), provides that a bona fide arm's-length sale of assets of a contributing employer to an unrelated party will not be considered a withdrawal if three conditions are met. These conditions, enumerated in section 4204(a)(1)(A)–(C), are that:

(A) The purchaser has an obligation to contribute to the plan with respect to the operations for substantially the same number of contribution base units for which the seller was obligated to contribute;

(B) The purchaser obtains a bond or places an amount in escrow, for a period of five plan years after the sale, in an amount equal to the greater of the seller's average required annual contribution to the plan for the three plan years preceding the year in which the sale occurred or the seller's required annual contribution for the plan year preceding the year in which the sale occurred (the amount of the bond or escrow is doubled if the plan is in reorganization in the year in which the sale occurred); and

(C) The contract of sale provides that if the purchaser withdraws from the plan within the first five plan years

beginning after the sale and fails to pay any of its liability to the plan, the seller shall be secondarily liable for the liability it (the seller) would have had but for section 4204.

The bond or escrow described above would be paid to the plan if the purchaser withdraws from the plan or fails to make any required contributions to the plan within the first five plan years beginning after the sale. Additionally, section 4204(b)(1) provides that if a sale of assets is covered by section 4204, the purchaser assumes by operation of law the contribution record of the seller for the plan year in which the sale occurred and the preceding four plan years.

Section 4204(c) of ERISA authorizes the Pension Benefit Guaranty Corporation (''PBGC'') to grant individual or class variances or exemptions from the purchaser's bond/escrow requirement of section 4204(a)(1)(B) when warranted. The legislative history of section 4204 indicates a Congressional intent that the sales rules be administered in a manner that assures protection of the plan with the least practicable intrusion into normal business transactions. Senate Committee on Labor and Human Resources, 96th Cong., 2nd Sess., S. 1076, The Multiemployer Pension Plan Amendments Act of 1980: Summary and Analysis of Considerations 16 (Comm. Print, April 1980); 128 Cong. Rec. S10117 (July 29, 1980). The granting of an exemption or variance from the bond/escrow requirement does not constitute a finding by the PBGC that a particular transaction satisfies the other requirements of section 4204(a)(1).

Under the PBGC's regulation on variances for sales of assets (29 CFR part 4204), a request for a variance or waiver of the bond/escrow requirement under any of the tests established in the regulation (sections 4204.12 & 4204.13) is to be made to the plan in question. The PBGC will consider waiver requests only when the request is not based on satisfaction of one of the three regulatory tests or when the parties assert that the financial information necessary to show satisfaction of one of the regulatory tests is privileged or confidential financial information within the meaning of 5 U.S.C. 552(b)(4) of the Freedom of Information Act.

Under section 4204.22 of the regulation, the PBGC shall approve a request for a variance or exemption if it determines that approval of the request is warranted, in that it:

(1) Would more effectively or equitably carry out the purposes of Title IV of the Act; and

(2) Would not significantly increase the risk of financial loss to the plan.

Section 4204(c) of ERISA and section 4204.22(b) of the regulation require the PBGC to publish a notice of the pendency of a request for a variance or exemption in the **Federal Register**, and to provide interested parties with an opportunity to comment on the proposed variance or exemption. The PBGC received no comments on the request for exemption.

Decision

On July 7, 2005, the PBGC published a notice of the pendency of a request by the LA Team Co. LLC (the ''Buyer'') for an exemption from the bond/escrow requirement of section 4204(a)(1)(B) with respect to its purchase of the Los Angeles Baseball Team from the Los Angeles Dodgers, Inc. (the ''Seller'') (70 FR 39349). According to the request, the Major League Baseball Players Pension Plan (the ''Fund'') was established and is maintained pursuant to a collective bargaining agreement between the professional major league baseball teams (the ''Clubs'') and the Major League Baseball Players Association (the ''Players Association'').

According to the Buyer's representations, the Seller was obligated to contribute to the Fund for certain employees of the sold operations. Effective February 13, 2004, the Buyer and Seller entered into an agreement under which the Buyer agreed to purchase substantially all of the assets and assume substantially all of the liabilities of the Seller relating to the business of employing employees under the Fund. The Buyer agreed to contribute to the Fund for substantially the same number of contribution base units as the Seller. The Seller agreed to be secondarily liable for any withdrawal liability it would have had with respect to the sold operations (if not for section 4204) should the Buyer withdraw from the Fund within the five plan years following the sale and fail to pay its withdrawal liability. The amount of the bond/escrow required under section 4204(a)(1)(B) of ERISA is $2,466,666.67. The estimated amount of the unfunded vested benefits allocable to the Seller with respect to the operations subject to the sale could be as high as $32,300,000. The transaction had to be approved by Major League Baseball, which required that the debt-equity ratio of the Buyer be no more than 60 percent. While the separate major league clubs are the nominal contributing employers to the Fund, the Major League Central Fund, under the Officer of the Commissioner, receives the revenues and makes the payments for certain common expenses including each club's contribution to the Fund. In support of the waiver request, the requester asserts that ''[t]he Fund is * * * funded directly from revenues which are paid from the Central Fund directly to the Fund without passing through the hands of any of the Clubs. The revenues of the Central Fund are * * * not exclusively or even largely dependent on the financial viability of any one Club. [A] change in ownership of a Club does not affect the obligation of the Central Fund to fund the Fund out of the Revenue. Accordingly, the Fund enjoys a substantial degree of security with respect to contributions on behalf of the Clubs, and as such, approval of this exemption request would not significantly increase the risk of financial loss to the Fund.''

Based on the facts of this case and the representations and statements made in connection with the request for an exemption, the PBGC has determined that an exemption from the bond/escrow requirement is warranted, in that it would more effectively carry out the purposes of Title IV of ERISA and would not significantly increase the risk of financial loss to the Fund. Therefore, the PBGC hereby grants the request for an exemption for the bond/escrow requirement. The granting of an exemption or variance from the bond/escrow requirement of section 4204(a)(1)(B) does not constitute a finding by the PBGC that the transaction satisfies the other requirements of section 4204(a)(1). The determination of whether the transaction satisfies such other requirements is a determination to be made by the Fund sponsor.

Issued at Washington, DC, on this 9th day of January 2006.

Bradley D. Belt,

Executive Director.

[FR Doc. E6–383 Filed 1–13–06; 8:45 am]

BILLING CODE 7708–01–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

SUMMARY: In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including

whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and purpose of information collection: Application for Survivor Death Benefits: OMB 3220–0031.

Under Section 6 of the Railroad Retirement Act (RRA), lump-sum death benefits are payable to surviving widow and widowers, children and certain other dependents. Lump-sum death benefits are payable after the death of a railroad employee only if there are no qualified survivors of the employee immediately eligible for annuities. With the exception of the residual death benefit, eligibility for survivor benefits depend on whether the employee was ''insured'' under the RRA at the time of death. If a deceased employee was not so insured, jurisdiction of any survivor benefits payable is transferred to the Social Security Administration and survivor benefits are paid by that agency instead of the RRB. The collection obtains the information required by the RRB to determine entitlement to and amount of the survivor death benefits applied for.

The RRB currently utilizes Form(s) AA–11a (*Designation for Change of Beneficiary for Residual Lump-Sum*), AA–21cert, (*Application Summary and Certification*), AA–21 (*Application for Lump-Sum Death Payment and Annuities Unpaid at Death*), G–131 (*Authorization of Payment and Release of All Claims to a Death Benefit or Accrued Annuity Payment*), and G–273a (*Funeral Director's Statement of Burial Charges*), to obtain the necessary information. One response is requested of each respondent. Completion is required to obtain benefits.

The RRB proposes non-burden impacting, editorial and formatting changes to Form G–273a and Form G–131. No other changes are proposed.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

[The estimated annual respondent burden is as follows:]

Form Nos.	Annual responses	Time (min.)	Burden (hrs.)
AA–11a	400	10	67
AA–21cert (with assistance)	9,700	20	3,233
AA–21 manual (without assistance)	300	40	200
G–131	600	5	50
G–273a	9,600	10	1,600
Total	20,600		5,150

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, please call the RRB Clearance Officer at (312) 751–3363 or send an e-mail request to *Charles.Mierzwa@RRB.GOV*. Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or send an e-mail to *Ronald.Hodapp@RRB.GOV*. Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Clearance Officer.

[FR Doc. E6–385 Filed 1–13–06; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application of Aquacell Technologies, Inc. To Withdraw Its Common Stock, $.001 Par Value, From Listing and Registration on the American Stock Exchange LLC File No. 1–16165

January 9, 2006.

On December 23, 2005, Aquacell Technologies, Inc., a Delaware corporation (''Issuer''), filed an application with the Securities and Exchange Commission (''Commission''), pursuant to section 12(d) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 12d2–2(d) thereunder,[2] to withdraw its common stock, $.001 par value (''Security''), from listing and registration on the American Stock Exchange LLC (''Amex'').

On December 14, 2005, the Board of Directors (''Board'') of the Issuer unanimously approved a resolution to withdraw the Security from listing and registration on Amex and list the Security on the OTC Bulletin Board. The Issuer stated that the Board is taking such action following discussions regarding a letter received from Amex regarding the Issuer's listing status and the benefits of maintaining the listing and the costs associated with listing on Amex.

The Issuer stated in its application that it has met the requirements of Amex Rule 18 by complying with all applicable laws in effect in the State of Delaware, in which it is incorporated, and providing written notice of withdrawal to Amex.

The Issuer's application relates solely to withdrawal of the Security from listing on Amex and from registration under section 12(b) of the Act,[3] and shall not affect its obligation to be registered under section 12(g) of the Act.[4]

Any interested person may, on or before February 2, 2006, comment on the facts bearing upon whether the application has been made in accordance with the rules of Amex, and what terms, if any, should be imposed by the Commission for the protection of investors. All comment letters may be submitted by either of the following methods:

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(b).

[4] 15 U.S.C. 78*l*(g).

Electronic Comments

• Use the Commission's Internet comment form (*http://www.sec.gov/rules/delist.shtml*); or

• Send an e-mail to *rule-comments@sec.gov.* Please include the File Number 1–16165 or;

Paper Comments

• Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number 1–16165. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/delist.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Nancy M. Morris,

Secretary.

[FR Doc. E6–392 Filed 1–13–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application of Sony Corporation To Withdraw its American Depositary Shares, Each Presenting One Share of Common Stock, No Par Value, From Listing and Registration on the Chicago Stock Exchange, Inc. File No. 1–06439

January 9, 2006.

On December 21, 2005, Sony Corporation, a company incorporated in Japan (''Issuer''), filed an application with the Securities and Exchange Commission (''Commission''), pursuant to section 12(d) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 12d2–2(d) thereunder,[2] to withdraw its American Depositary Shares, each representing one share of common stock, no par value (''Security''), from listing and registration on the Chicago Stock Exchange, Inc. (''CHX'').

The Board of Directors (''Board'') of the Issuer approved a resolution on October 26, 2005 to withdraw the Security from CHX. The Issuer stated that the primary factor considered by the Board was that most of the trading volume in the Security occurs on the New York Stock Exchange (''NYSE''), with very little trading volume occurring on CHX. The Issuer stated that the Security will continue to trade on NYSE. The Issuer believes that delisting the Security from CHX will cause no substantial inconvenience to the Issuer's shareholders and investors.

The Issuer stated in its application that it has complied with the rules of CHX by complying with all applicable laws in effect in Japan, the jurisdiction in which the Issuer is incorporated and by providing CHX with the required documents governing the withdrawal of securities from listing and registration on CHX.

The Issuer's application relates solely to the withdrawal of the Security from listing on CHX and shall not affect its continued listing on NYSE or its obligation to be registered under section 12(b) of the Act.[3]

Any interested person may, on or before February 2, 2006, comment on the facts bearing upon whether the application has been made in accordance with the rules of CHX, and what terms, if any, should be imposed by the Commission for the protection of investors. All comment letters may be submitted by either of the following methods:

Electronic Comments

• Send an e-mail to *rule-comments@sec.gov.* Please include the File Number 1–06439 or;

Paper Comments

• Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE.,Washington, DC 20549–9303.

All submissions should refer to File Number 1–06439. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/delist.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Nancy M. Morris,

Secretary.

[FR Doc. E6–391 Filed 1–13–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53060; File No. 10–137]

Acknowledgement of Receipt of Notice of Registration as a National Securities Exchange Pursuant to Section 6(g) of the Securities Exchange Act of 1934 by the Board of Trade of the City of Chicago, Inc.

January 5, 2006.

Section 6(g) of the Securities Exchange Act of 1934 (''Act'')[1] provides that an exchange may register as a national securities exchange for the sole purpose of trading security futures products by filing a written notice with the Securities and Exchange Commission (''Commission'') if such exchange is a board of trade, as that term is defined by the Commodity Exchange Act,[2] that is designated as a contract market by the Commodity Futures Trading Commission or registered as a derivative transaction execution facility under Section 5a of the Commodity Exchange Act.[3] Rule 6a–4 under the Act[4] requires that such an exchange submit written notice of registration to the Commission on Form 1–N.[5] An exchange's registration

[5] 17 CFR 200.30–3(a)(1).

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(b).

[4] 17 CFR 200.30–3(a)(1).

[1] 15 U.S.C. 78f(g).

[2] 7 U.S.C. 1a(2).

[3] 7 U.S.C. 7a.

[4] 17 CFR 240.6a–4.

[5] Upon receipt of a Form 1–N, the Division of Market Regulation examines the notice to determine whether all necessary information has been supplied and whether all other required documents have been furnished in proper form. Rule

Continued

as a national securities exchange becomes effective contemporaneously with the submission of the written notice on Form 1–N.[6]

On December 19, 2005, the Board of Trade of the City of Chicago, Inc. (''CBOT'') filed a Form 1–N with the Commission. Pursuant to Section 6(g)(3) of the Act,[7] the Commission hereby acknowledges receipt of the Form 1–N submitted by CBOT. Copies of the Form 1–N, including all exhibits, are available in the Commission's Public Reference Room, File No. 10–137.

For questions regarding this Release, please contact Nathan Saunders, Special Counsel, at (202) 551–5515 or Molly M. Kim, Attorney, at (202) 551–5644; Division of Market Regulation, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–6628.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Nancy M. Morris,

Secretary.

[FR Doc. E6–366 Filed 1–13–06; 8:45 am]

BILLING CODE 8010–01–P

202.3(b)(3) of the Commission's Procedural Rules, 17 CFR 202.3(b)(3).

[6] Section 6(g)(2)(B) of the Act, 15 U.S.C. 78f(g)(2)(B).

[7] 15 U.S.C. 78f(g)(3).

[8] 17 CFR 200.30–3(a)(75).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53085; File No. SR–Amex–2005–064]

Self-Regulatory Organizations; American Stock Exchange LLC; Order Approving Proposed Rule Change and Amendment Nos. 1 and 2 Thereto Relating to Telemarketing

January 9, 2006.

On June 14, 2005, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed amendment to Amex Rule 429. On September 23, 2005, the Amex filed Amendment No. 1 to the proposed rule change.[3] On November 15, 2005, the Amex filed Amendment No. 2 to the proposed rule change.[4] The proposed rule change, as amended, was published for comment in the **Federal Register** on December 5, 2005.[5] The Commission received no comments on the proposal. This order approves the proposed rule change, as amended.

Amex Rule 429 currently prohibits members, member organizations and associated persons from making outbound calls to the residence of any person for the purposes of soliciting the purchase of securities or related services other than between the hours of 8 a.m. and 9 p.m., without the prior consent of the person. It also requires disclosure to the called person of the caller's identity, firm telephone number and address, and the purpose of the call. Rule 429 currently includes exceptions from its time of day and disclosure requirements for telephone calls to certain categories of existing customers.

The proposed amendment to Amex Rule 429 would require Amex members and member organizations to participate in the national do-not-call registry maintained by the Federal Trade Commission (''FTC'') and to follow applicable regulations of the Federal Communications Commission (''FCC''). The amendment would delete current Rule 429 and replace it with new language that incorporates the requirements of FCC regulations applicable to broker-dealers engaged in telemarketing. The amended rule would generally prohibit Amex members, member organizations, and persons associated with a member or member organization from making telemarketing calls to people who have registered with the national do-not-call registry. It also would set forth firm-specific do-not-call restrictions,[6] and would retain time-of-day restrictions and disclosure requirements similar to those contained in current Rule 429.

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.[7] In particular, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Exchange Act,[8] which requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and national market system, and in general, to protect investors and the public interest. The Commission believes that the proposed rule change, as amended, is designed to accomplish these ends by requiring Amex members, member organizations and associated persons to observe time-of-day restrictions on telephone solicitations, maintain firm-specific do-not-call lists, and refrain from initiating telephone solicitations to investors and other members of the public who have registered their telephone numbers on the national do-not-call registry. The Commission also believes that the proposed rule change, as amended, establishes adequate procedures to prevent Amex members, member organizations and associated persons from making telephone solicitations to do-not-call registrants, which should have the effect of protecting investors by enabling persons who do not want to receive telephone solicitations from members or member organizations to receive the protections of the national do-not-call registry, while providing appropriate exceptions to the rule's restrictions, which should promote just and equitable principles of trade.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[9] that the proposed rule change (SR–Amex–2005–064), as amended, be and is hereby approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Nancy M. Morris,

Secretary.

[FR Doc. E6–394 Filed 1–13–06; 8:45 am]

BILLING CODE 8010–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Amex partially amended the text of proposed amended Amex Rule 429 and made conforming and technical changes to the original filing.

[4] In Amendment No. 2, the Amex made additional changes to the text of proposed amended Amex Rule 429 and to the original filing.

[5] *See* Securities Exchange Act Release No. 52844 (November 28, 2005), 70 FR 72477 (December 5, 2005).

[6] Amex Rule 428, which is not being amended, requires members and member organizations who engage in telephone solicitation to market their products and services to maintain a centralized do-not-call list of persons who do not wish to receive telephone solicitations from such members or their associated persons.

[7] In approving this proposed rule change, the Commission has considered whether the proposed rule change will promote efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(2).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53088; File No. SR–CBOE–2005–92]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Approving Proposed Rule Change To Prohibit the Practice of Unbundling Orders To Maximize Rebates of Fees

January 10, 2006.

I. Introduction

On November 7, 2005, the Chicago Board Options Exchange, Incorporated (''CBOE'' 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 prohibit the practice of unbundling orders to maximize rebates of fees. The proposed rule change was published for notice and comment in the **Federal Register** on December 8, 2005.[3] The Commission received no comments on the proposal. This order approves the proposed rule change.

II. Description of the Proposal

CBOE proposed to adopt a new rule to expressly prohibit its members from dividing single orders into multiple orders for the sole purpose of maximizing market data rebates.

III. Discussion and Commission Findings

The Commission has reviewed carefully the proposed rule change and finds that it is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange,[4] particularly section 6(b)(5) of the Act which, among other things, requires that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating securities transactions, to remove impediments to perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.[5] The Commission believes that the proposed rule change should help eliminate the distortive practice of trade shredding, and, therefore, promote just and equitable principles of trade.

IV. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[6] that the proposed rule change (File No. SR–CBOE–2005–92), be and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

Nancy M. Morris,

Secretary.

[FR Doc. E6–397 Filed 1–13–06; 8:45 am]

BILLING CODE 8010–01–P

[1] 15 U.S.C. 78s(b)(l).

[2] 17 CFR 240. 19b–4.

[3] *See* Securities Exchange Act Release No. 52872 (December 1, 2005), 70 FR 73043.

[4] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53072; File No. SR–CBOE–2006–02]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend CBOE Rule 8.4 Relating to Remote Market-Maker Appointments

January 6, 2006.

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 January 5, 2006, the Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal pursuant to section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to amend CBOE Rule 8.4 relating to Remote Market-Maker appointments. Below is the text of the proposed rule change. Proposed new language is italicized; proposed deletions are in [brackets].

* * * * *

Rule 8.4—Remote Market-Makers

Rule 8.4. (a) No Change.

(b) No change.

(c) No change.

(d) Appointment of RMMs: An RMM will have a Virtual Trading Crowd (''VTC'') Appointment, which confers the right to quote electronically (and not in open outcry) an appropriate number of products selected from ''tiers'' that have been structured according to trading volume statistics. Of the products included in the Hybrid 2.0 Platform, Tier A will consist of the 20% most actively-traded products over the preceding three calendar months, excluding ''A+'' tier products, Tier B will consist of the next 20% most actively-traded products, etc., through Tier E, which will consist of the 20% least actively-traded products. Tier ''A+'' will consist of options on Standard & Poor's Depositary Receipts, options on the Nasdaq-100 Index Tracking Stock, options on Diamonds, [and] reduced value options on the Standard & Poor's 500 Stock Index*, and options based on The Dow Jones Industrial Average.*

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this rule change is to amend CBOE Rule 8.4 relating to Remote Market-Maker (''RMM'') appointments. CBOE Rule 8.4 provides that RMMs will have a Virtual Trading Crowd (''VTC'') Appointment, which confers the right to quote electronically in a certain number of products selected from various ''tiers''. There are five tiers that are structured according to trading volume statistics and an ''A+'' Tier

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

which consists of four option classes—options on Standard & Poor's Depositary Receipts, options on the Nasdaq-100 Index Tracking Stock, options on Diamonds, and reduced value options on the Standard & Poor's 500 Stock Index.

CBOE proposes to amend CBOE Rule 8.4(d) relating to the ''A+'' Tier to include an additional option class in the ''A+'' Tier, namely options based on The Dow Jones Industrial Average (''DJX''). CBOE believes it is appropriate to include this option class in this tier based on its trading volume.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5),[6] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange neither solicited nor received comments on the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange asserts that the foregoing proposed rule change has become effective upon filing pursuant to section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6) thereunder[8] because it does not:

(i) significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest; provided that the Exchange has given the Commission written notice of its intent to file the proposed rule change at least five business days prior to the filing date of the proposal or such shorter time as designated by the Commission.[9]

A proposed rule change filed under Rule 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[10] However, Rule 19b–4(f)(6)(iii)[11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the five days prefiling requirement and waive the 30-day pre-operative period, which would make the rule change operative immediately. The Commission believes that waiving the five day prefiling requirement and waiving the 30-day operative delay is consistent with the protection of investors and the public interest.[12] The proposed change to the ''A+'' Tier that is described in this proposed rule change does not raise any new, unique, or substantive issues from those raised in previous filings with the Commission.[13] Accordingly, the Commission designates that the proposal become operative immediately.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2006–02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–CBOE–2006–02. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the CBOE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2006–02 and should be submitted on or before February 7, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Nancy M. Morris,

Secretary.

[FR Doc. E6–400 Filed 1–13–06; 8:45 am]

BILLING CODE 8010–01–P

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6).

[9] As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposal.

[10] 17 CFR 240.19b–4(f)(6)(iii).

[11] *Id.*

[12] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] *See* Securities Exchange Act Release Nos. 51543 (April 14, 2005), 70 FR 20952 (April 22, 2005) (File No. SR–CBOE–2005–23) (establishing the ''A+'' Tier); 52398 (September 8, 2005), 70 FR 54597 (September 15, 2005) (File No. SR–CBOE–2005–74) (adding options on Diamonds to the ''A+'' Tier); and 52624 (October 18, 2005), 70 FR 61480 (October 24, 2005) (File No. SR–CBOE–2005–79) (adding reduced value options on the Standard & Poor's 500 Stock Index to the ''A+'' Tier).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53082; File No. SR–NASD–2005–155]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change and Amendment No. 1 Thereto To Modify the Pricing for Non-Members Using Nasdaq's Brut Facility

January 9, 2006

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 28, 2005, 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 and II below, which Items have been prepared by Nasdaq. On December 30, 2005, Nasdaq submitted Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons, and at the same time is granting accelerated approval of the proposed rule change, as amended.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to modify the pricing for non-members using Nasdaq's Brut Facility (''Brut''). Nasdaq requests approval to implement the proposed rule change, as amended, retroactively as of January 1, 2006, for a pilot period running through February 28, 2006. The text of the proposed rule change, as amended, is below. Proposed new language is in *italics.* Proposed deletions are in [brackets].

* * * * *

7010. System Services

(a)–(h) No change.

(i) Nasdaq Market Center and Brut Facility Order Execution

(1)–(5) No change.

(6) The fees applicable to non-members using Nasdaq's Brut Facility shall be the fees established for members under Rule 7010(i), as amended by SR–NASD–2005–019, SR–NASD–2005–035, SR–NASD–2005–048, and SR–NASD–2005–071, SR–NASD–2005–125, [and] SR–NASD–2005–137*, and SR–NASD–2005–154*, and as applied to non-members by SR–NASD–2005–020, SR–NASD–2005–038, SR–NASD–2005–049, SR–NASD–2005–072, SR–NASD–2005–126, [and] SR–NASD–2005–138*, and SR–NASD–2005–155*.

(j)–(v) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change, as amended, and discussed any comments it received on the proposed rule change, as amended. The text of these statements may be examined at the places specified in Item III 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

In SR–NASD–2005–137 and SR–NASD–2005–138,[4] Nasdaq created a pilot program under which liquidity providers (*i.e.*, market participants that post quotes or orders that are accessed by incoming orders) [5] may receive a credit of $0.0005 per share executed with respect to forty stocks listed on the New York Stock Exchange.[6]

As stated in the prior filings, Nasdaq notes that it planned to run the pilot for a period of at least three months; however, Nasdaq states that, because the authority for this proposal provided by the Nasdaq Board of Directors ran only through December 31, 2005, Nasdaq needed to obtain Board approval for a longer pilot. Having obtained such approval, Nasdaq filed to extend the pilot for NASD members through February 28, 2005.[7] In this filing, Nasdaq is proposing to apply the same extension to non-NASD members that use Nasdaq's Brut Facility.

2. Statutory Basis

Nasdaq believes that the proposed rule change, as amended, is consistent with the provisions of section 15A of the Act,[8] in general, and with section 15A(b)(5) of the Act,[9] in particular, in that the proposed rule change, as amended, provides 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 NASD operates or controls. The proposed rule change, as amended, applies to non-members that use Nasdaq's Brut Facility a fee change that is being implemented for NASD members that use the Nasdaq Market Center and/or Nasdaq's Brut Facility. Accordingly, Nasdaq believes that the proposed rule change, as amended, promotes an equitable allocation of fees between members and non-members using Nasdaq's order execution facilities. Nasdaq states that the proposed change, as amended, will continue a pilot to make a liquidity provider credit available to all market participants that opt to provide liquidity through Nasdaq or Brut to support executions in any of forty stocks included in the pilot program.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change, as amended, will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Nasdaq states that written comments were neither solicited nor received.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Partial Amendment No. 1 clarified that the proposed rule change is a pilot program.

[4] Securities Exchange Act Release Nos. 52939 (December 9, 2005), 70 FR 75229 (December 19, 2005) (SR–NASD–2005–137) and 52938 (December 9, 2005), 70 FR 75231 (December 19, 2005) (SR–NASD–2005–138).

[5] Telephone conversation between John Yetter, Associate General Counsel, Exchange, and Michou Nguyen, Attorney, Division of Market Regulation, Commission, on January 4, 2006.

[6] Advanced Micro Devices Inc. (AMD); Apache Corp. (APA); AT&T Corp. (T); Avaya, Inc. (AV); Baker Hughes, Inc. (BHI); BJ Services Co. (BJS); Bristol-Myers Squibb Co. (BMY); Burlington Resources, Inc. (BR); Calpine Corp. (CPN); Charles Schwab Corp. (SCH); Citigroup Inc. (C); ConocoPhillips (COP); Corning Inc. (GLW); Devon Energy Corp. (DVN); EMC Corp. (EMC); Exxon Mobil Corp. (XOM); Ford Motor Co. (F); Gateway, Inc. (GTW); General Electric Co. (GE); Halliburton Co. (HAL); Hewlett-Packard Co. (HPQ); Johnson & Johnson (JNJ); JPMorgan Chase & Co. (JPM); Kohl's Corp. (KSS); LSI Logic Corp. (LSI); Micron Technology, Inc. (MU); Motorola, Inc. (MOT); Noble Corp. (NE); Occidental Petroleum Corp. (OXY); Office Depot Inc. (ODP); Pfizer Inc. (PFE); Phelps Dodge Corp. (PD); Pulte Homes, Inc. (PHM); Qwest Communications International Inc. (Q); Schlumberger Ltd. (SLB); Solectron Corp. (SLR); Sovereign Bancorp, Inc. (SOV); Time Warner, Inc. (TWX); Valero Energy Corp. (VLO); and Verizon Communications, Inc. (VZ).

[7] *See* SR–NASD–2005–154.

[8] 15 U.S.C. 78*o*–3.

[9] 15 U.S.C. 78*o*–3(b)(5).

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASD–2005–155 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–NASD–2005–155. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the NASD. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASD–2005–155 and should be submitted on or before February 7, 2006.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a self-regulatory organization.[10] Specifically, the Commission believes that the proposed rule change, as amended, is consistent with section 15A(b)(5) of the Act,[11] which requires that the rules of the self-regulatory organization provide for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facilities or system which it operates or controls.

The Commission notes that this proposal would retroactively modify pricing for non-NASD members using the Nasdaq's Brut Facility to extend a pilot running through February 28, 2005. This proposal would permit the schedule for non-NASD members to mirror the schedule applicable to NASD members that became effective January 1, 2006, pursuant to SR–NASD–2005–154 and that Nasdaq stated it would implement on a pilot basis from January 1, 2006 to February 28, 2006.

The Commission finds good cause for approving the proposed rule change, as amended, prior to the 30th day of the date of publication of the notice thereof in the **Federal Register**. The Commission notes that the proposed fees for non-NASD members are identical to those in SR–NASD–2005–154, which implemented those fees for NASD members and which became effective as of January 1, 2006. The Commission notes that this change will promote consistency in Nasdaq's fee schedule by applying the same pricing schedule with the same date of effectiveness for both NASD members and non-NASD members. Therefore, the Commission finds that there is good cause, consistent with section 19(b)(2) of the Act,[12] to approve the proposed rule change, as amended, on an accelerated basis.

V. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[13] that the proposed rule change, as amended, (File No. SR–NASD–2005–155), is approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Nancy M. Morris,

Secretary.

[FR Doc. E6–395 Filed 1–13–06; 8:45 am]

BILLING CODE 8010–01–P

[10] The Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[11] 15 U.S.C. 78*o*–3(b)(5).

[12] 15 U.S.C. 78s(b)(2).

[13] 15 U.S.C. 78s(b)(2).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53081; File No. SR–NASD–2005–154]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto To Modify Pricing for NASD Members Using the Nasdaq Market Center and Nasdaq's Brut Facility

January 9, 2006.

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 28, 2005, 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. On December 30, 2005, Nasdaq submitted Amendment No. 1 to the proposed rule change.[3] Nasdaq has designated this proposal as one establishing or changing a due, fee, or other charge imposed by the self-regulatory organization under Section 19(b)(3)(A)(ii)[4] of the Act and Rule 19b–4(f)(2) thereunder,[5] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

Nasdaq proposes to modify the pricing for NASD members using the Nasdaq Market Center and Nasdaq's Brut Facility (''Brut''). Nasdaq states that it will implement the proposed rule change on January 1, 2006 for a pilot period running through February 28, 2006.

The text of the proposed rule change, as amended, is below. Proposed new language is in *italics*; proposed deletions are in [brackets].

* * * * *

7010. System Services

(a)–(h) No change.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Partial Amendment No. 1 (''Amendment No. 1'') clarified that the proposed rule change is a pilot program.

[4] 15 U.S.C. 78s(b)(3)(A)(ii).

[5] 17 CFR 240.19b–4(f)(2).

(i) Nasdaq Market Center and Brut Facility Order Execution

(1)–(4) No change.

(5) There shall be no charges or credits for order entry, execution, routing, or cancellation by members accessing the Nasdaq Market Center or Nasdaq's Brut Facility to buy or sell exchange-listed securities subject to the Consolidated Quotations Service and Consolidated Tape Association plans, other than:

(A)–(D) No change.

(E) for a pilot period beginning December 1, 2005 and ending [December 31, 2005]

February 28, 2006, a credit of $0.0005 per share executed to a member providing liquidity for a transaction in the following stocks: Advanced Micro Devices Inc. (AMD); Apache Corp. (APA); AT&T Corp. (T); Avaya, Inc. (AV); Baker Hughes, Inc. (BHI); BJ Services Co. (BJS); Bristol-Myers Squibb Co. (BMY); Burlington Resources, Inc. (BR); Calpine Corp. (CPN); Charles Schwab Corp. (SCH); Citigroup Inc. (C); ConocoPhillips (COP); Corning Inc. (GLW); Devon Energy Corp. (DVN); EMC Corp. (EMC); Exxon Mobil Corp. (XOM); Ford Motor Co. (F); Gateway, Inc. (GTW); General Electric Co. (GE); Halliburton Co. (HAL); Hewlett-Packard Co. (HPQ); Johnson & Johnson (JNJ); JPMorgan Chase & Co. (JPM); Kohl's Corp. (KSS); LSI Logic Corp. (LSI); Micron Technology, Inc. (MU); Motorola, Inc. (MOT); Noble Corp. (NE); Occidental Petroleum Corp. (OXY); Office Depot Inc. (ODP); Pfizer Inc. (PFE); Phelps Dodge Corp. (PD); Pulte Homes, Inc. (PHM); Qwest Communications International Inc. (Q); Schlumberger Ltd. (SLB); Solectron Corp. (SLR); Sovereign Bancorp, Inc. (SOV); Time Warner, Inc. (TWX); Valero Energy Corp. (VLO); and Verizon Communications, Inc. (VZ).

(6) No change.

(j)–(v) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change, as amended, and discussed any comments it received on the proposed rule change, as amended. 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

In SR–NASD–2005–137 and SR–NASD–2005–138,[6] Nasdaq created a pilot program under which liquidity providers (*i.e.*, market participants that post quotes or orders that are accessed by incoming orders) [7] may receive a credit of $0.0005 per share executed with respect to forty stocks listed on the New York Stock Exchange.[8]

As stated in the prior filings, Nasdaq notes that it planned to run the pilot for a period of at least three months; however, Nasdaq states that, because the authority for this proposal provided by the Nasdaq Board of Directors ran only through December 31, 2005, Nasdaq needed to obtain Board approval for a longer pilot. Having obtained such approval, Nasdaq is now filing to extend the pilot through February 28, 2006.[9]

2. Statutory Basis

Nasdaq believes that the proposed rule change, as amended, is consistent with the provisions of Section 15A of the Act,[10] in general, and with Section 15A(b)(5) of the Act,[11] in particular, in that the proposed rule change, as amended, provides 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 NASD operates or controls. Nasdaq states that the proposed rule change, as amended, will continue a pilot to make a liquidity provider credit available to all market participants that opt to provide liquidity through Nasdaq or Brut to support execution in any of forty stocks included in the pilot program.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change, as amended, will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Nasdaq states that written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change, as amended, is subject to Section 19(b)(3)(A)(ii) of the Act [12] and subparagraph (f)(2) of Rule 19b–4 [13] thereunder because it establishes or changes a due, fee, or other charge imposed by the self-regulatory organization. Accordingly, the proposal is effective upon Commission receipt of the filing. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[14]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

[6] Securities Exchange Act Release Nos. 52939 (December 9, 2005), 70 FR 75229 (December 19, 2005) (SR–NASD–2005–137) and 52938 (December 9, 2005), 70 FR 75231 (December 19, 2005) (SR–NASD–2005–138).

[7] Telephone conversation between John Yetter, Associate General Counsel, Exchange, and Michou Nguyen, Attorney, Division of Market Regulation, Commission, on January 4, 2006.

[8] Advanced Micro Devices Inc. (AMD); Apache Corp. (APA); AT&T Corp. (T); Avaya, Inc. (AV); Baker Hughes, Inc. (BHI); BJ Services Co. (BJS); Bristol-Myers Squibb Co. (BMY); Burlington Resources, Inc. (BR); Calpine Corp. (CPN); Charles Schwab Corp. (SCH); Citigroup Inc. (C); ConocoPhillips (COP); Corning Inc. (GLW); Devon Energy Corp. (DVN); EMC Corp. (EMC); Exxon Mobil Corp. (XOM); Ford Motor Co. (F); Gateway, Inc. (GTW); General Electric Co. (GE); Halliburton Co. (HAL); Hewlett-Packard Co. (HPQ); Johnson & Johnson (JNJ); JPMorgan Chase & Co. (JPM); Kohl's Corp. (KSS); LSI Logic Corp. (LSI); Micron Technology, Inc. (MU); Motorola, Inc. (MOT); Noble Corp. (NE); Occidental Petroleum Corp. (OXY); Office Depot Inc. (ODP); Pfizer Inc. (PFE); Phelps Dodge Corp. (PD); Pulte Homes, Inc. (PHM); Qwest Communications International Inc. (Q); Schlumberger Ltd. (SLB); Solectron Corp. (SLR); Sovereign Bancorp, Inc. (SOV); Time Warner, Inc. (TWX); Valero Energy Corp. (VLO); and Verizon Communications, Inc. (VZ).

[9] The change proposed by this filing applies to NASD members that use the Nasdaq Market Center and Brut; in SR–NASD–2005–155, Nasdaq proposes to make the same change applicable to non-members that use Brut.

[10] 15 U.S.C. 78*o*–3.

[11] 15 U.S.C. 78*o*–3(b)(5).

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

[13] 17 CFR 240.19b–4(f)(2).

[14] The effective date of the original proposed rule change is December 28, 2005, and the effective date of Amendment No. 1 is December 30, 2005. For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change, as amended, the Commission considers the period to commence on December 30, 2005, the date on which the Exchange submitted Amendment No. 1. *See* 15 U.S.C. 78s(b)(3)(C).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NASD–2005–154 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–NASD–2005–154. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the NASD. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASD–2005–154 and should be submitted on or before February 7, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Nancy M. Morris,

Secretary.

[FR Doc. E6–401 Filed 1–13–06; 8:45 am]

BILLING CODE 8010–01–P

[15] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

The Ticket To Work and Work Incentives Advisory Panel Meeting

AGENCY: Social Security Administration (SSA).

ACTION: Notice of Quarterly Meeting.

DATES: February 1, 2006—9 a.m. to 5 p.m., February 2, 2006—9 a.m. to 5 p.m., February 3, 2006—8 a.m. to 12:15 p.m.

ADDRESSES: Embassy Suites San Juan, 8000 Tartak Street, Isla Verde Carolina, San Juan, PR 00979. *Phone:* 787–791–0505.

SUPPLEMENTARY INFORMATION:

Type of meeting: On February 1–3, 2006, the Ticket to Work and Work Incentives Advisory Panel (the ''Panel'') will hold a quarterly meeting open to the public.

Purpose: In accordance with section 10(a)(2) of the Federal Advisory Committee Act, the Social Security Administration (SSA) announces a meeting of the Ticket to Work and Work Incentives Advisory Panel. Section 101(f) of Public Law 106–170 establishes the Panel to advise the President, the Congress, and the Commissioner of SSA on issues related to work incentive programs, planning, and assistance for individuals with disabilities as provided under section 101(f)(2)(A) of the TWWIA. The Panel is also to advise the Commissioner on matters specified in section 101(f)(2)(B) of that Act, including certain issues related to the Ticket to Work and Self-Sufficiency Program established under section 101(a) of that Act.

Interested parties are invited to attend the meeting. The Panel will use the meeting time to receive briefings and presentations on matters of interest, conduct full Panel deliberations on the implementation of the Act and receive public testimony.

The Panel will meet in person commencing on Wednesday, February 1, 2006, from 9 a.m. until 5 p.m. The quarterly meeting will continue on Thursday, February 2, 2006, from 9 a.m. until 5 p.m. The meeting will continue on Friday, February 3, 2006, from 8 a.m. until 12:15 p.m.

Agenda: Members of the public must schedule a time slot in order to comment. In the event public comments do not take the entire scheduled time period, the Panel may use that time to deliberate or conduct other Panel business. Public testimony will be heard on Thursday, February 2, 2006, from 9 a.m. until 10 a.m. Individuals interested in providing testimony in person should contact the Panel staff as outlined below to schedule a time slot. Each presenter will be acknowledged by the Chair in the order in which they are scheduled to testify and is limited to a maximum five-minute, verbal presentation.

Full written testimony on the Implementation of the Ticket to Work and Work Incentives Program, no longer than five (5) pages, may be submitted in person or by mail, fax or e-mail on an ongoing basis to the Panel for consideration.

Since seating may be limited, persons interested in providing testimony at the meeting should contact the Panel staff by e-mailing Ms. Tinya White-Taylor, at *Tinya.White-Taylor@ssa.gov* or by calling (202) 358–6430. Social Security beneficiary testimony will be heard on Friday, February 3, 2006, from 10:45 a.m. until 12:15 p.m. The Panel is seeking beneficiary testimony on how changes in the following would affect beneficiaries' return to work experiences: (1) Ending the requirement that an individual's medical benefits must be tied to their eligibility for Social Security Disability Insurance (SSDI) cash benefits; (2) gradually reducing beneficiaries' monthly SSDI checks once they earn a certain amount for a certain period of time instead of ending them all at once; (3) allowing beneficiaries to earn more and still remain eligible for a monthly Social Security check; (4) providing beneficiaries accurate, understandable information about how Social Security work rules would affect them; (5) extending beneficiaries' eligibility for other federally funded support services, such as financial help with housing and food for a transition period of up to 3 years after reaching full-time employment; and (6) any other issues not listed above that would affect beneficiaries' ability to return to work. Beneficiaries who would like to speak to the Panel should contact Tinya White-Taylor by January 25, 2006, and state which of the above issues they'll be addressing. (See contact information above.) Beneficiary testimony will be presented by topic area. Written comments from those who do not attend are also welcomed and must be submitted in person or by mail, fax, or e-mail by January 25, 2006.

The full agenda for the meeting will be posted on the Internet at *http://www.ssa.gov/work/panel* at least one week before the starting date or can be received, in advance, electronically or by fax upon request.

Contact Information: Records are kept of all proceedings and will be available for public inspection by appointment at the Panel office. Anyone requiring

information regarding the Panel should contact the staff by:

- Mail addressed to the Social Security Administration, Ticket to Work and Work Incentives Advisory Panel Staff, 400 Virginia Avenue, SW., Suite 700, Washington, DC 20024.
- Telephone contact with Tinya White-Taylor at (202) 358–6420.
- Fax at (202) 358–6440.
- E-mail to *TWWIIAPanel@ssa.gov*.

Dated: January 9, 2006

Chris Silanskis,

Designated Federal Officer.

[FR Doc. E6–381 Filed 1–13–06; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 5223]

Overseas Buildings Operations; Industry Advisory Panel: Meeting Notice

The Industry Advisory Panel of the Overseas Buildings Operations will meet on Thursday, February 16th, 2006 from 9:45 a.m. until 3:30 p.m. Eastern Standard Time. The meeting will be held at the Department of State, 2201 C Street, NW. (entrance on 23rd Street), Room 1107, Washington, DC. The majority of the meeting is devoted to an exchange of ideas between the Department's Bureau of Overseas Buildings Operations' senior management and the panel members, on design, operations and building maintenance. Members of the public are asked to kindly refrain from joining the discussion until Director Williams opens the discussion to the public.

Due to limited seating space for members of the public, we ask that you kindly e-mail your information. To participate in this meeting, simply register by e-mail at *IAPR@STATE.GOV* before February 9th, 2006. Your e-mail should include the following information; Date of birth, social security number, company name and title. This information is required to issue a temporary pass to enter the building.

For questions, please contact *PinzinoLE3@state.gov,* tel: 703/875–6872 for Ms. Gina Pinzino; or *SpragueMA@state.gov,* tel: 703/875–7173 for Michael Sprague.

Dated: 3 January 2006.

Charles E. Williams,

Director & Chief Operating Officer, Overseas Buildings Operations, Department of State.

[FR Doc. E6–404 Filed 1–13–06; 8:45 am]

BILLING CODE 4710–27–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment

AGENCY: Office of the United States Trade Representative.

ACTION: Request for written submissions from the public.

SUMMARY: Section 182 of the Trade Act of 1974 (Trade Act) (19 U.S.C. 2242), requires the United States Trade Representative (USTR) to identify countries that deny adequate and effective protection of intellectual property rights or deny fair and equitable market access to U.S. persons who rely on intellectual property protection. (Section 182 is commonly referred to as the ''Special 301'' provisions of the Trade Act.) In addition, USTR is required to determine which of these countries should be identified as Priority Foreign Countries. Acts, policies, or practices that are the basis of a country's identification as a priority foreign country are normally the subject of an investigation under the Section 301 provisions of the Trade Act. Section 182 of the Trade Act contains a special rule for the identification of actions by Canada affecting United States cultural industries.

USTR requests written submissions from the public concerning foreign countries' acts, policies, and practices that are relevant to the decision whether particular trading partners should be identified under Section 182 of the Trade Act.

DATES: Submissions must be received on or before 10 a.m. on Monday, February 13, 2006.

ADDRESSES: All comments should be addressed to Sybia Harrison, Special Assistant to the Section 301 Committee, and sent (i) electronically, to the following e-mail address: *FR0606@ustr.eop.gov,* with ''Special 301 Review'' in the subject line, or (ii) by fax, to (202) 395–9458, with a confirmation copy sent electronically to the e-mail address above.

FOR FURTHER INFORMATION CONTACT: Jennifer Choe Groves, Director for Intellectual Property and Chair of the Special 301 Committee (202) 395–4510, Office of the United States Trade Representative.

SUPPLEMENTARY INFORMATION: Pursuant to Section 182 of the Trade Act, USTR must identify those countries that deny adequate and effective protection for intellectual property rights or deny fair and equitable market access to U.S. persons who rely on intellectual property protection. Those countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies or practices have the greatest adverse impact (actual or potential) on relevant U.S. products are to be identified as Priority Foreign Countries. Acts, policies or practices that are the basis of a country's designation as a Priority Foreign Country are normally the subject of an investigation under the Section 301 provisions of the Trade Act.

USTR may not identify a country as a Priority Foreign Country if it is entering into good faith negotiations, or making significant progress in bilateral or multilateral negotiations, to provide adequate and effective protection of intellectual property rights.

USTR requests that, where relevant, submissions mention particular regions, provinces, states, or other subdivisions of a country in which an act, policy, or practice deserves special attention in this year's report. Such mention may be positive or negative, so long as it deviates from the general norm in that country.

Section 182 contains a special rule regarding actions of Canada affecting United States cultural industries. The USTR must identify any act, policy, or practice of Canada that affects cultural industries, is adopted or expanded after December 17, 1992, and is actionable under Article 2106 of the North American Free Trade Agreement (NAFTA). Any act, policy, or practice so identified shall be treated the same as an act, policy, or practice that was the basis for a country's identification as a Priority Foreign Country under Section 182(a)(2) of the Trade Act, unless the United States has already taken action pursuant to Article 2106 of the NAFTA.

USTR must make the above-referenced identifications within 30 days after publication of the National Trade Estimate (NTE) report, i.e., no later than April 30, 2006.

Requirements for comments: Comments should include a description of the problems experienced and the effect of the acts, policies, and practices on U.S. industry. Comments should be as detailed as possible and should provide all necessary information for assessing the effect of the acts, policies, and practices. Any comments that include quantitative loss claims should be accompanied by the methodology used in calculating such estimated losses.

Comments must be in English. No submissions will be accepted via postal service mail. Documents should be submitted as either WordPerfect, MS

Word, or text (.TXT) files. Supporting documentation submitted as spreadsheets is acceptable as Quattro Pro or Excel files. A submitter requesting that information contained in a comment be treated as confidential business information must certify that such information is business confidential and would not customarily be released to the public by the submitter. A non-confidential version of the comment must also be provided. For any document containing business confidential information, the file name of the business confidential version should begin with the characters ''BC-'', and the file name of the public version should begin with the character ''P-''. The ''P-'' or ''BC-'' should be followed by the name of the submitter. Submissions should not include separate cover letters; information that might appear in a cover letter should be included in the submission itself. To the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files.

All comments should be addressed to Sybia Harrison, Special Assistant to the Section 301 Committee, and sent (i) electronically, to the following e-mail address: *FR0606@ustr.eop.gov,* with ''Special 301 Review'' in the subject line, or (ii) by fax, to (202) 395–9458, with a confirmation copy sent electronically to the e-mail address above.

Public inspection of submissions: Within one business day of receipt, non-confidential submissions will be placed in a public file, open for inspection at the USTR reading room, Office of the United States Trade Representative, Annex Building, 1724 F Street, NW., Room 1, Washington, DC. An appointment to review the file must be scheduled at least 48 hours in advance and may be made by calling Jacqueline Caldwell at (202) 395–6186. The USTR reading room is open to the public from 10 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday.

Victoria Espinel,

Acting Assistant USTR for Intellectual Property.

[FR Doc. E6–426 Filed 1–13–06; 8:45 am]

BILLING CODE 3190–D2–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Pennsylvania

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 USC 139(1)(1). The actions relate to a proposed highway project, Mon/Fayette Expressway, PA Route 51 in Large PA to I–376 in Monroeville and Pittsburgh in Allegheny County, Pennsylvania and those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 USC 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before July 21, 2006. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Karyn Vandervoort, Environmental Program Manager, Federal Highway Administration, 228 Walnut Street, Room 508, Harrisburg, PA 17101–1720, between 8 a.m. and 4 p.m., (717) 221–2276, *karyn.vandervoort@fhwa.dot.gov* or David Willis, Environmental Manager, Pennsylvania Turnpike Commission, P.O. Box 67676, Harrisburg, PA 17106–7676 between 9 a.m. and 3 p.m., (717) 939–9551, *dwillis@paturnpike.com*

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA have taken final agency actions by issuing licenses, permits and approvals for the following highway project in the Commonwealth of Pennsylvania: a four-lane, limited access, tolled highway extending approximately 24 miles from PA 51 in Large, Pennsylvania north to the Parkway East (I–376) in the Municipality of Monroeville and west along the north shore of the Monongahela River to a connection with the Parkway East at Bates Street and Second Avenue (PA Route 885) in the City of Pittsburgh. The highway will improve access to neighborhoods, emergency providers and economic redevelopment areas; relieve existing and future congestion; improve major highway linkages, and improve vehicular and pedestrian safety. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS) for the project, approved on January 8, 2004, in the FHWA Record of Decision (ROD) issued on December 7, 2004, and in other documents in the FHWA administrative record. The FEIS, ROD, and other documents in the FHWA administrative record file are available by contacting the FHWA or the Pennsylvania Turnpike Commission at the addresses provided above. The FHWA ROD can be viewed and downloaded from the project Web site at *http://www.paturnpike.com*.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351].
2. Federal-Aid Highway Act [23 U.S.C. 109].
3. Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303].
4. Clean Air Act, 42 U.S.C. 7401–7671(q).
5. Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*].

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 USC § 139(l)(1).

Issued on: January 10, 2006.

James A. Cheatham,

Division Administrator, Harrisburg.

[FR Doc. 06–367 Filed 1–13–06; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket Number 2006 23377]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel TRIPLE TROUBLE.

SUMMARY: As authorized by Public Law 105–383 and Public Law 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief

description of the proposed service, is listed below. The complete application is given in DOT docket 2005–23377 at *http://dms.dot.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Public Law 105–383 and MARAD's regulations at 46 CFR Part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

DATES: Submit comments on or before February 16, 2006.

ADDRESSES: Comments should refer to docket number MARAD–2006 23377. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. DOT Dockets, Room PL–401, Department of Transportation, 400 7th St., SW., Washington, DC 20590–0001. You may also send comments electronically via the Internet at *http://dmses.dot.gov/submit/.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., e.t., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, MAR–830 Room 7201, 400 Seventh Street, SW., Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel TRIPLE TROUBLE is:

Intended Use: '' '6-pack' fishing license.''

Geographic Region: Gulf of Mexico, Florida Coast.

Dated: January 9, 2006.

By order of the Maritime Administrator.

Joel C. Richard,

Secretary, Maritime Administration.

[FR Doc. E6–412 Filed 1–13–06; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Pipeline Safety: Notice to Operators of Natural Gas and Hazardous Liquid Pipelines To Integrate Operator Qualification Regulations into Excavation Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice; issuance of Advisory Bulletin.

SUMMARY: PHMSA is issuing this advisory bulletin to pipeline operators to reinforce the need for safe excavation practices and recommend that pipeline operators integrate the Operator Qualification regulations into their marking, trenching, and backfilling operations to prevent excavation damage mishaps.

ADDRESSES: This document can be viewed on the PHMSA home page at: *http://www.phmsa.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Joy Kadnar, (202) 366–0568, or by e-mail at *Joy.Kadnar@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the past few years PHMSA has seen recurring similarities in pipeline incidents involving excavation. In November 2005, a pipeline company contractor struck a 2-inch tap off an 18-inch natural gas transmission pipeline that was operating at more than 800 pounds per square inch gauge (psig). In October 2005, near an elementary school in Chantilly, Virginia, pipeline operator personnel struck the pipeline while excavating it in a Class 3 populated area. This incident resulted in the evacuation of more than 850 school children and area residents. In June 2005, a pipeline company contractor knocked a 2-inch pipe nipple off a 30-inch natural gas transmission pipeline while uncovering it. The pipeline was operating at more than 800 psig. In January 2005, contractor personnel being supervised by a pipeline operator struck a six-inch valve on a hazardous liquid pipeline while modifying it in preparation for an inline inspection. This accident resulted in a release of about 700 barrels of crude oil. In November 2004, a serious hazardous liquid pipeline accident in Walnut Creek, California, resulted in five deaths and several injuries. This accident was caused by a contractor installing a water main in the vicinity of a hazardous liquid pipeline. PHMSA is also aware of several incidents that occurred in the last three years on pipeline facilities owned by local distribution companies where pipelines have been struck near schools and locations where people congregate.

Investigations by PHMSA and its State partners revealed that the pipeline operators involved in these incidents did not comply with Federal pipeline safety regulations or their own operator qualifications programs. Investigations found similar problems, such as:

- Pipeline operators did not follow their own construction, ditching, and backfilling specifications for existing pipelines, such as machine excavation, which is prohibited within two feet of existing pipelines;
- Construction inspectors working for pipeline operators failed to assist their own employees, their own contractors, and third-party construction contractors in verifying the staked locations of the existing pipeline facilities; and,
- Pipeline ''as-built'' drawings were not verified and made available to the excavators at construction sites before or during excavation activity.

From these investigations PHMSA also determined that, in many cases, pipeline operators did not correctly mark all pipelines in the vicinity of the construction and did not confirm whether all individuals performing the covered tasks were qualified. In one instance, the spotter assigned to the task at the excavation site did not have the necessary qualifications for observing excavation and backfilling tasks. In another instance, the pipeline operator did not follow its own maintenance manual that requires the company representative to review the location of the pipeline prior to excavation. The pipeline company representative did not verify that the location of the pipeline was correctly marked.

II. Advisory Bulletin (ADB–06–01)

To: Owners and Operators of Natural Gas and Hazardous Liquid Pipeline Systems

Subject: Notification on Safe Excavation Practices and the use of Qualified Personnel to oversee all Excavations and Backfilling Operations

Advisory: Excavation damage continues to be one of the three leading causes of pipeline damage. PHMSA has seen an increase in pipeline operators damaging their own pipeline facilities. To protect excavators and private citizens from injury and to guard the integrity of buried pipelines and other underground facilities, PHMSA reminds operators to ensure all procedures and processes to perform excavation and backfilling are followed. Only qualified

personnel must oversee all marking, trenching, and backfilling operations.

Furthermore, PHMSA reminds pipeline operators that although excavation is not explicitly addressed in 49 CFR parts 192 and 195, excavation is considered a covered task under the pipeline operator qualifications regulations (49 CFR 192.801–809 and 195.501–509). These regulations require that pipeline operators and contractors be qualified to perform pipeline excavation activities. A qualified individual is one who has been evaluated and can perform assigned covered tasks and can recognize and react appropriately to abnormal conditions.

In particular, PHMSA recommends pipeline operators review the adequacy of covered tasks involving line locating, one-call notifications, and inspection of excavation activities. Operators should also review the adequacy of required training, evaluation and qualification methods for each of these covered tasks to ensure that each employee and contractor is qualified to perform that task.

Authority: 49 U.S.C. Chapter 601; 49 CFR 1.53.

Issued in Washington, DC, on January 10, 2005.

Theodore L. Willke,

Deputy Associate Administrator for Pipeline Safety.

[FR Doc. 06–387 Filed 1–13–06; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Office of the Secretary

Notice of Call for Redemption: 13⅞ Percent Treasury Bonds of 2006–11, Washington, DC

1. As of January 13, 2006, public notice is hereby given that all outstanding 13⅞ percent Treasury Bonds of 2006–11 (CUSIP No. 912810 CV 8) dated May 15, 1981, due May 15, 2011, are hereby called for redemption at par on May 15, 2006, on which date interest on such bonds will cease.

2. Full information regarding the presentation and surrender of such bonds held in coupon and registered form for redemption under this call will be found in Department of the Treasury Circular No. 300 dated March 4, 1973, as amended (31 CFR part 306), and from the Definitives Section of the Bureau of the Public Debt (telephone (304) 480–7936), and on the Bureau of the Public Debt's Web site, *http://www.publicdebt.treas.gov*.

3. Redemption payments for such bonds held in book-entry form, whether on the books of the Federal Reserve Banks or in Treasury Direct accounts, will be made automatically on May 15, 2006.

Donald V. Hammond,

Fiscal Assistant Secretary.

[FR Doc. 06–360 Filed 1–13–06; 8:45 am]

BILLING CODE 4810–40–M

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 a continuing information collection, as required by the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The OCC is soliciting comment concerning its information collection titled, ''Community and Economic Development Entities, Community Development Projects—12 CFR part 24.'' The OCC also gives notice that it has sent the information collection to OMB for review and approval.

DATES: You should submit comments by February 16, 2006.

ADDRESSES: Communications Division, Office of the Comptroller of the Currency, Public Information Room, Mailstop 1–5, Attention: 1557–0194, 250 E Street, SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874–4448, or by electronic mail to *regs.comments@occ.treas.gov*. You can inspect and photocopy the comments at the OCC's Public Information Room, 250 E Street, SW., Washington, DC 20219. You can make an appointment to inspect the comments by calling (202) 874–5043.

Additionally, you should send a copy of your comments to OCC Desk Officer, 1557–0194, by mail to U.S. Office of Management and Budget, 725 17th Street, NW., #10235, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: You can request additional information or a copy of the collection from Mary Gottlieb, OCC Clearance Officer, or Camille Dixon, (202) 874–5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: On November 7, 2005, the OCC published in the **Federal Register** (70 FR 67536) a notice concerning the revision of this information collection. The OCC received no public comments and is now submitting its request to OMB for approval.

Title: Community and Economic Development Entities, Community Development Projects—12 CFR 24.

OMB Number: 1557–0194.

Description: This submission covers an existing regulation and involves no change to the regulation or to the information collection requirements. The OCC requests only that OMB approve its revised estimates and extend its approval of the information collection.

Section 24.5(a) provides that an eligible bank may make an investment without prior notification to, or approval by, the OCC if the bank submits an after-the-fact notification of an investment within 10 days after it makes the investment.

Section 24.5(a)(4) provides that a national bank that is not an eligible bank but that is at least adequately capitalized may submit a letter to the OCC requesting authority to self-certify investments.

Section 24.5(b) provides that if a national bank does not meet the requirements for after-the-fact notification, the bank must submit an investment proposal to the OCC.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals; Businesses or other for-profit.

Estimated Number of Respondents: 250.

Estimated Total Annual Responses: 250.

Frequency of Response: On occasion.

Estimated Total Annual Burden: 371 hours.

Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

(b) The accuracy of the agency's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: January 9, 2006.

Stuart Feldstein,

Assistant Director, Legislative and Regulatory Activities Division.

[FR Doc. E6–405 Filed 1–13–06; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF VETERANS AFFAIRS

VA Directive and Handbook 5021, Employee/Management Relations

AGENCY: Department of Veterans Affairs.

ACTION: Notice with request for comments.

SUMMARY: Section 302 of the Veterans Health Care, Capital Asset and Business Improvement Act of 2003 (Pub. L. 108–170), dated December 6, 2003, authorizes the Secretary of Veterans Affairs to appoint chiropractors as permanent full-time title 38 employees under 38 U.S.C. 7401(1). Also appointed under this authority are physicians, dentists, podiatrists, optometrists, nurses, nurse anesthetists, physician assistants and expanded-function dental auxiliaries. Upon successful completion of probationary status as required by 38 U.S.C. 7403(b), these title 38 employees may file an appeal to a Disciplinary Appeals Board if they are subjected to major adverse action that is based in whole or in part on a question of professional conduct and competence.

As part of its implementation of Public Law 108–170, the Department of Veterans Affairs proposes to revise its Directive and Handbook 5021, Employee/Management Relations, to clarify that chiropractors now have the same right to appeal major adverse actions to Disciplinary Appeal Boards and grieve certain actions as other title 38 employees. The revisions that are the subject of this notice will amend portions of the following regulations: VA Directive 5021, Appendix A, sections A.3, B.1.b.(1), B.2.b, B.2.c., B.4.a–d., and B.4.f. The revisions also would amend the following portions of VA Handbook 5021: Part 1, Chapter 3, section 3.a.; Part III, Chapter 1, section 1, third note to section 2., and sections 3.a., and 3.h.(5); and Part IV, Chapter 3 (title), sections 1.b.(1), 2.b. and 2.c. In some of these sections, the word ''chiropractors'' has been added to a listing of occupations appointed under 38 U.S.C. 7401(1). In the other sections, Public Law 108–170 has been added to an existing list of statutory references. In all cases, the words or phrases that are proposed to be added to the regulations are shown in brackets. Only those sections of the existing regulations that contain proposed changes are included in this notice.

DATES: Comments must be received on or before February 16, 2006. The proposed effective date of these amendments is 30 days after publication of this notice.

ADDRESSES: Send written comments to: Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420.

FOR FURTHER INFORMATION CONTACT: Larry Ables, Director, Employee Relations and Performance Management Service, Department of Veterans Affairs, Office of Human Resources Management and Labor Relations (051), 810 Vermont Avenue, NW., Washington, DC 20420. Mr. Ables may be reached at (202) 273–9827.

SUPPLEMENTARY INFORMATION: Title 38 U.S.C. 7461(e) requires that ''[w]henever the Secretary proposes to prescribe regulations [relating to Disciplinary and Grievance Procedures] under this subchapter, the Secretary shall publish the proposed regulations in the **Federal Register** for notice and comment not less than 30 days before the day on which they take effect.''

Proposed Revisions to VA Directive 5021, Employee/Management Relations

Appendix A. Disciplinary and Grievance Procedures

Section A. Disciplinary and Major Adverse Actions

3. Definitions. Unless otherwise noted, the following definitions apply to this appendix only.

a. [*Admonishment.* An official letter of censure to an employee for minor act(s) of misconduct or deficiency in competence. This letter normally remains in the employee's personnel folder for two years].

b. [*Discharge.* The involuntary separation of an employee from employment based on conduct or performance].

c. [*Disciplinary Actions.* These are adverse actions, other than major adverse actions, which include admonishment and reprimand based on conduct or performance].

d. [*Disciplinary Appeals Board.* The three member board designated to hear an employee's appeal of a major adverse action which is based in whole or in part on a question of professional conduct or competence].

e. [*Grade.* The established grades for the positions covered by this chapter will be as defined by 38 U.S.C. 7404, and the qualification standards issued pursuant to 38 U.S.C. 7402. (See part II of VA Handbook 5005, Staffing.)]

f. [*Major Adverse Actions.* These are suspension, transfer, reduction in grade, reduction in basic pay, and discharge based on conduct or performance].

g. [*Mixed Case.* This is a case that includes both (1) a major adverse action arising out of (or including) a question of professional conduct or competence, and (2) a major adverse action which does not arise out of a question of professional conduct or competence, or a disciplinary action].

h. [*Professional Conduct or Competence.* A question of professional conduct or competence involves direct patient care and/or clinical competence. The term clinical competence includes issues of professional judgment].

i. [*Reduction in Basic Pay.* The involuntary reduction, based on conduct or performance, of the annual rate of basic pay to which an employee is entitled under 38 U.S.C. 7404, including above minimum entrance rates and special salary rates authorized under 38 U.S.C. 7455. This does not apply to reductions in pay other than basic pay, such as the loss of physician or dentist special pay or head nurse differential, other differentials, allowances or premium pay such as standby, on-call, shift, overtime, Sunday, holiday, night work, hazardous duty, and interim geographic adjustment].

j. [*Reduction in Grade.* The involuntary assignment to a lower grade on the same pay schedule based on conduct or performance].

k. [*Reprimand.* An official letter of censure to an employee for an act of misconduct or deficiency in competence. A reprimand is a more severe disciplinary action than an admonishment. This letter normally remains in the employee's personnel folder for three years].

l. [*Suspension.* The involuntary placement of an employee, for disciplinary reasons, in a non-duty, non-pay status for a temporary period of time].

m. [*Transfer.* The involuntary movement of an employee from one VA facility to another (under separate

managerial authority) based on conduct or performance and without a break in service].

Authority: 38 U.S.C. 501(a), 7421.

Section B. Grievances

1. Scope and Authority.

* * * * *

b. Employee Coverage

(1) This section applies to all physicians, dentists, podiatrists, optometrists, [chiropractors,] nurses, nurse anesthetists, physician assistants, and expanded-function dental auxiliaries who are not on time-limited appointments.

* * * * *

2. References.

* * * * *

b. [Section 302 of the Veterans Healthcare, Capital Asset and Business Improvement Act of 2003 (Pub. L. 108–170].

[c.] 38 U.S.C. 501(a), 7421, [ ] 7461–7464.

* * * * *

4. *Definitions.*

a. [*Bargaining Unit Employee.* An employee included in an appropriate unit, pursuant to 5 U.S.C. 7112 and 7135, for which a labor organization has been accorded exclusive recognition].

b. [*Decision Official.* An official designated to (1) receive and attempt to adjust formal grievances; (2) refer formal grievances for further review and inquiry; and (3) decide formal grievances based on the results of impartial reviews and recommendations].

c. [*Employee.* Any physician, dentist, podiatrist, chiropractor, optometrist, nurse, nurse anesthetist, physician assistant, or expanded-function dental auxiliary covered in the scope of this section. Former employees of the VA are also included, but only in connection with a grievance over discharges or actions resulting in loss of pay or benefits (for example, a former employee charged with 8 hours absence without leave (AWOL) who has requested that the 8 hours of pay be restored). Former employees must have filed a timely grievance in accordance with the provisions of this appendix in order to receive consideration].

d. [*Grievance.* A request by an employee, or group of employees, for personal relief in a matter of concern or dissatisfaction relating to employment which is subject to the control of agency management. Matters not covered by the grievance procedure may be found in paragraph 14 of this section].

* * * * *

f. [*Personal Relief.* A specific remedy directly benefiting the grievant, but may not include a request for disciplinary or other action affecting another employee].

Authority: 38 U.S.C. 501(a), 7421, [ ] 7461–7464.

Proposed Revisions to VA Handbook 5021, Employee/Management Relations

Part I. Disciplinary and Adverse Actions Under Title 5

Chapter 3. Adverse Actions

3. Employees Excluded

a. Physicians, dentists, nurses, nurse anesthetists, expanded-function dental auxiliaries, physician assistants, podiatrists, [chiropractors,] optometrists, and other health care professionals appointed under 38 U.S.C. 74 (see part II of this handbook).

Part III. Probationary Period Actions

Chapter 1. Title 38 Probationary Employees

1. *Scope.* This chapter contains the policy and procedures needed for taking actions against title 38 employees serving on a probationary period under 38 United States Code (U.S.C.) 7403(b) in the Department of Veterans Affairs (VA). This includes employees appointed under 38 U.S.C. 7401(1), i.e., physicians, dentists, podiatrists, [chiropractors,] optometrists, nurses, nurse anesthetists, physician assistants, and expanded-function dental auxiliaries. The Under Secretary for Health's designee refers to a designee in the VA Central Office. This chapter does not apply to employees appointed under 38 U.S.C., chapter 3, 38 U.S.C. 7306, 38 U.S.C. 7401(3), 38 U.S.C. 7405 or 38 U.S.C. 7406.

2. *Responsibilities.*

* * * * *

* * *

* * *

For podiatrists, [ ] optometrists, [and chiropractors,] the appropriate service chief is the authorizing official; however, the review will be conducted by the VA Central Office Professional Standards Board.

* * * * *

3. Summary Board Reviews.

a. *Purpose.* Summary reviews are limited to situations where summary separation from Federal service may be justified. Officials identified in paragraph 2a–2e [ ] are responsible for deciding whether to conduct a summary review of an employee's services. Supervisors may initiate requests for summary reviews at any time during the probationary period.

* * * * *

h. Action on Board Recommendations.

* * * * *

(5) *Separations Requiring VHA Approval/Review.* All field facility recommendations for separation during probation requiring VHA summary review or approval (*e.g.*, actions related to facility directors and requests for summary reviews for podiatrists, [ ] optometrists, [chiropractors]) are to be sent through the appropriate Network (10N/051). The material forwarded will include the Director's recommendation (where appropriate) and any other applicable comments; VA Form 10–2543, Board Action, (in duplicate); one copy of all related documents, including one copy of all Proficiency Reports prepared during the probationary period; and the employee's personnel folder.

* * * * *

Part IV. Probationary Period Actions

Chapter 3. Title 38 Grievances

1. *Scope and Authority.*

* * * * *

b. *Employee Coverage.*

(1) This chapter applies to all permanent and probationary physicians, dentists, podiatrists, [chiropractors,] optometrists, nurses, nurse anesthetists, physician assistants, and expanded-function dental auxiliaries.

* * * * *

2. References.

* * * * *

b. [Section 302 of the Veterans Healthcare, Capital Asset and Business Improvement Act of 2003 (Pub. L. 108–170)].

[c.] 38 U.S.C. 501(a), 512(a), 7421, [ ] 7461–7464.

Dated: January 10, 2006.

R. James Nicholson,

Secretary of Veterans Affairs.

[FR Doc. E6–393 Filed 1–13–06; 8:45 am]

BILLING CODE 8320–01–P

Corrections

Federal Register

Vol. 71, No. 10

Tuesday, January 17, 2006

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 419

[CMS–1501–CN2]

RIN 0938–AN46

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Correction

Corrections

In rule document 05–24447 beginning on page 76176 in the issue of Friday, December 23, 2005, make the following corrections:

§419.43 [Corrected]

1. On page 76178, in the second column, in §419.43, under the heading *B. Corrections to Addendum A*, in instruction 4b.,in the last paragraph, in the last line, ''1m1'' should read ''1 ml''.

2. On page 76186, in the table **Addendum L.—Out-Migration Wage Adjusted CY 2006**, in the first column, in the third line, ''010047'' should read ''040047''.

3. On the same page, in the same table, in the same column, in the fourth line, ''010069'' should read ''040069''.

4. On the same page, in the same table, in the same column, in the fifth line, ''010071'' should read ''040071''.

5. On page 76190, in the table **Addendum L.—Out-Migration Wage Adjustment CY 2006**, in the third column, in the 28th line, ''0.0240'' should read ''0.0249''.

[FR Doc. C5–24447 Filed 1–13–06; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Tuesday,
January 17, 2006

Part II

Environmental Protection Agency

40 CFR Part 50

National Ambient Air Quality Standards for Particulate Matter; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[OAR–2001–0017; FRL–8015–8]

RIN 2060–AI44

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for particulate matter (PM), EPA proposes to make revisions to the primary and secondary NAAQS for PM to provide requisite protection of public health and welfare, respectively, and to make corresponding revisions in monitoring reference methods and data handling conventions for PM.

With regard to primary standards for fine particles (particles generally less than or equal to 2.5 micrometers (μm) in diameter, $PM_{2.5}$), EPA proposes to revise the level of the 24-hour $PM_{2.5}$ standard to 35 micrograms per cubic meter (μg/m^3), providing increased protection against health effects associated with short-term exposure (including premature mortality and increased hospital admissions and emergency room visits) and to retain the level of the annual $PM_{2.5}$ standard at 15 μg/m^3, continuing protection against health effects associated with long-term exposure (including premature mortality and development of chronic respiratory disease). The EPA solicits comment on alternative levels of the 24-hour $PM_{2.5}$ standard (down to 25 μg/m^3 and up to 65 μg/m^3) and the annual $PM_{2.5}$ standard (down to 12 μg/m^3), and on alternative approaches for selecting the standard levels.

With regard to primary standards for particles generally less than or equal to 10 μm in diameter (PM_{10}), EPA proposes to revise the 24-hour PM_{10} standard in part by establishing a new indicator for thoracic coarse particles (particles generally between 2.5 and 10 μm in diameter, $PM_{10-2.5}$), qualified so as to include any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. The EPA proposes to set the new $PM_{10-2.5}$ standard at a level of 70 μg/m^3, continuing to provide a generally equivalent level of protection against health effects associated with short-term exposure (including hospital admissions for cardiopulmonary diseases, increased respiratory symptoms and possibly premature mortality). Also, EPA proposes to revoke, upon finalization of a primary 24-hour standard for $PM_{10-2.5}$, the current 24-hour PM_{10} standard in all areas of the country except in areas where there is at least one monitor located in an urbanized area (as defined by the U.S. Bureau of the Census) with a minimum population of 100,000 that violates the current 24-hour PM_{10} standard based on the most recent three years of data. In addition, EPA proposes to revoke the current annual PM_{10} standard upon promulgation of this rule. The EPA solicits comment on alternative approaches for selecting the level of a 24-hour $PM_{10-2.5}$ standard, on alternative approaches based on retaining the current 24-hour PM_{10} standard, and on revoking and not replacing the 24-hour PM_{10} standard.

With regard to secondary PM standards, EPA proposes to revise the current standards by making them identical to the suite of proposed primary standards for fine and coarse particles, providing protection against PM-related public welfare effects including visibility impairment, effects on vegetation and ecosystems, and materials damage and soiling. Also, EPA solicits comment on adding a new sub-daily $PM_{2.5}$ standard to address visibility impairment.

DATES: Written comments on this proposed decision must be received by April 17, 2006.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2001–0017 by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- E-mail: *a-and-r-Docket@epa.gov.*
- Fax: 202–566–1749.
- Mail: Docket ID No. EPA–HQ–OAR–2001–0017, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies.
- Hand Delivery: Environmental Protection Agency, EPA West Building, Room B102, 1301 Constitution Avenue, NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2001–0017. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The 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 Public Reading Room is 202–566–1744 and the telephone number for the Air and Radiation Docket and Information Center is 202–566–1742.

Public Hearings: The EPA intends to hold public hearings around the end of

February in Philadelphia, Chicago, and San Francisco, and will announce in a separate **Federal Register** notice the date, time, and address of the public hearings on this proposed decision.

FOR FURTHER INFORMATION CONTACT: Dr. Erika Sasser, mail code C539–01, Air Quality Strategies and Standards Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone: (919) 541–3889, e-mail: *sasser.erika@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

A. What Should I Consider As I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *http://www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

Availability of Related Information

A number of documents are available on EPA Web sites. The Air Quality Criteria for Particulate Matter (Criteria Document) (two volumes, EPA/600/P–99/002aF and EPA/600/P–99/002bF, October 2004) is available on EPA's National Center for Environmental Assessment Web site. To obtain this document, go to *http://www.epa.gov/ncea,* and click on ''Particulate Matter''. The Staff Paper, human health risk assessment, and several other related technical documents are available on EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Web site. The Staff Paper is available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html,* and the risk assessment and technical documents are available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_td.html.* These and other related documents are also available for inspection and copying in the EPA docket identified above.

Table of Contents

The following topics are discussed in today's preamble:

I. Background
A. Legislative Requirements
B. Review of Air Quality Criteria and Standards for PM
C. Related Control Programs to Implement PM Standards
D. Overview of Current PM NAAQS Review
II. Rationale for Proposed Decisions on Primary $PM_{2.5}$ Standards
A. Health Effects Related to Exposure to Fine Particles
1. Mechanisms
2. Nature of Effects
3. Integration and Interpretation of the Health Evidence
4. Sensitive Subgroups for $PM_{2.5}$-Related Effects
5. $PM_{2.5}$-Related Impacts on Public Health
B. Quantitative Risk Assessment
1. Overview
2. Scope and Key Components
3. Risk Estimates and Key Observations
C. Need for Revision of the Current Primary $PM_{2.5}$ Standards
D. Indicator of Fine Particles
E. Averaging Time of Primary $PM_{2.5}$ Standards
F. Form of Primary $PM_{2.5}$ Standards
1. 24-Hour $PM_{2.5}$ Standard
2. Annual $PM_{2.5}$ Standard
G. Level of Primary $PM_{2.5}$ Standards
1. 24-Hour $PM_{2.5}$ Standard
2. Annual $PM_{2.5}$ Standard
H. Proposed Decisions on Primary $PM_{2.5}$ Standards
III. Rationale for Proposed Decisions on the Primary PM_{10} Standards
A. Health Effects Related to Exposure to Thoracic Coarse Particles
1. Mechanisms
2. Nature of Effects
3. Integration and Interpretation of the Health Evidence
4. Sensitive Subgroups for Effects of Thoracic Coarse Particle Exposure
5. Impacts on Public Health from Thoracic Coarse Particle Exposure
B. Quantitative Risk Assessment
C. Need for Revision of the Current Primary PM_{10} Standards
D. Indicator of Thoracic Coarse Particles
E. Averaging Time of Primary $PM_{10\text{-}2.5}$ Standard
F. Form of Primary $PM_{10\text{-}2.5}$ Standard
G. Level of Primary $PM_{10\text{-}2.5}$ Standard
H. Proposed Decisions on Primary $PM_{10\text{-}2.5}$ Standard
IV. Rationale for Proposed Decisions on Secondary PM Standards
A. Visibility Impairment
1. Visibility Impairment Related to Ambient PM
2. Need for Revision of the Current Secondary PM Standards for Visibility Protection
3. Indicator of PM for Secondary Standard to Address Visibility Impairment
4. Averaging Time of a Secondary $PM_{2.5}$ Standard for Visibility Protection
5. Elements of a Secondary $PM_{2.5}$ Standard for Visibility Protection
B. Other PM-related Welfare Effects
1. Nature of Effects
2. Need for Revision of Current Secondary PM Standards to Address Other PM-related Welfare Effects
C. Proposed Decision on Secondary PM Standards
V. Interpretation of the NAAQS for PM
A. Proposed Amendments to Appendix N—Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$
1. General
2. $PM_{2.5}$ Monitoring and Data Reporting Considerations
3. $PM_{2.5}$ Computations and Data Handling Conventions
4. Secondary Standard
5. Conforming Revisions
B. Proposed Appendix P—Interpretation of the National Ambient Air Quality Standards for $PM_{10\text{-}2.5}$
1. General
2. $PM_{2.5}$ Data Reporting Considerations
3. $PM_{10\text{-}2.5}$ Computations and Data Handling Conventions
4. Exceptional Events
VI. Reference Methods for the Determination of Particulate Matter as $PM_{2.5}$ and $PM_{10\text{-}2.5}$
A. Proposed Appendix O: Reference Method for the Determination of Coarse Particulate Matter (as $PM_{10\text{-}2.5}$) in the Atmosphere
1. Purpose of the New Reference Method
2. Rationale for Selection of the New Reference Method
3. Consideration of Other Methods for the Federal Reference Method
4. Consideration of Automated Method
5. Relationship of Proposed FRM to Transportation Equity Act Requirements
6. Use of the Proposed Federal Reference Method

7. Basic Requirements of the Proposed Federal Reference Method Sampler
8. Other Important Aspects of the Proposed Federal Reference Method Sampler
B. Proposed Amendments to Appendix L—Reference Method for the Determination of Fine Particulate Matter (as $PM_{2.5}$) in the Atmosphere
VIII. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks
H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use
I. National Technology Transfer Advancement Act
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
References

I. Background

A. Legislative Requirements

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list ''air pollutants'' that ''in his judgment, may reasonably be anticipated to endanger public health and welfare'' and whose ''presence * * * in the ambient air results from numerous or diverse mobile or stationary sources'' and to issue air quality criteria for those that are listed. Air quality criteria are intended to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air * * *.''

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants listed under section 108. Section 109(b)(1) defines a primary standard as one ''the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' [1] A secondary standard, as defined in section 109(b)(2), must ''specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' [2]

In setting standards that are ''requisite'' to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In establishing ''requisite'' primary and secondary standards, EPA may not consider the costs of implementing the standards. See generally *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 465–472, 475–76 (2001).

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association* v. *EPA,* 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied,* 449 U.S. 1042 (1980); *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied,* 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels (see *Lead Industries Association* v. *EPA, supra,* 647 F.2d at 1156 n. 51), but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association* v. *EPA, supra,* 647 F.2d at 1161–62.

Section 109(d)(1) of the CAA requires that ''not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards * * * and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate * * *.'' Section 109(d)(2) requires that an independent scientific review committee ''shall complete a review of the criteria * * * and the national primary and secondary ambient air quality standards * * * and shall recommend to the Administrator any new * * * standards and revisions of existing criteria and standards as may be appropriate * * *.'' This independent review function is performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

B. Review of Air Quality Criteria and Standards for PM

Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. Particles originate from a variety of anthropogenic stationary and mobile sources as well as from natural sources. Particles may be emitted directly or formed in the atmosphere by transformations of gaseous emissions such as sulfur oxides (SO_X), nitrogen oxides (NO_X), and volatile organic compounds (VOC). The chemical and physical properties of PM vary greatly with time, region, meteorology, and source category, thus complicating the assessment of health and welfare effects.

The last review of PM air quality criteria and standards was completed in July 1997 with notice of a final decision to revise the existing standards (62 FR 38652, July 18, 1997). In that decision, EPA revised the PM NAAQS in several respects. While EPA determined that the PM NAAQS should continue to focus on particles less than or equal to 10 μm in

[1] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group'' [S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970)].

[2] Welfare effects as defined in section 302(h) [42 U.S.C. 7602(h)] include, but are not limited to, ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

diameter (PM_{10}), EPA also determined that the fine and coarse fractions of PM_{10} should be considered separately. The EPA added new standards, using $PM_{2.5}$ as the indicator for fine particles (with $PM_{2.5}$ referring to particles with a nominal mean aerodynamic diameter less than or equal to 2.5 μm), and retained PM_{10} standards for the purpose of regulating the coarse fraction of PM_{10} (referred to as thoracic coarse particles or coarse-fraction particles; generally including particles with a nominal mean aerodynamic diameter greater than 2.5 μm and less than or equal to 10 μm, or $PM_{10-2.5}$). The EPA established two new $PM_{2.5}$ standards: an annual standard of 15 μg/m^3, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors; and a 24-hour standard of 65 μg/m^3, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area. Also, EPA established a new reference method for the measurement of $PM_{2.5}$ in the ambient air and adopted rules for determining attainment of the new standards. To continue to address thoracic coarse particles, EPA retained the annual PM_{10} standard, while revising the form, but not the level, of the 24-hour PM_{10} standard to be based on the 99th percentile of 24-hour PM_{10} concentrations at each monitor in an area. The EPA revised the secondary standards by making them identical in all respects to the primary standards.

Following promulgation of the revised PM NAAQS, petitions for review were filed by a large number of parties, addressing a broad range of issues. In May 1999, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit issued an initial decision that upheld EPA's decision to establish fine particle standards, holding that ''the growing empirical evidence demonstrating a relationship between fine particle pollution and adverse health effects amply justifies establishment of new fine particle standards.'' *American Trucking Associations* v. *EPA,* 175 F.3d 1027, 1055–56 (D.C. Cir. 1999) (rehearing granted in part and denied in part, 195 F.3d 4 (D.C. Cir. 1999), affirmed in part and reversed in part, *Whitman* v. *American Trucking Associations,* 531 U.S. 457 (2001). The Panel also found ''ample support'' for EPA's decision to regulate coarse particle pollution, but vacated the 1997 PM_{10} standards, concluding in part that PM_{10} is a ''poorly matched indicator for coarse particulate pollution'' because it includes fine particles. *Id.* at 1053–55. Pursuant to the court's decision, EPA removed the vacated 1997 PM_{10} standards from the Code of Federal Regulations (CFR) (69 FR 45592, July 30, 2004) and deleted the regulatory provision (at 40 CFR 50.6(d)) that controlled the transition from the pre-existing 1987 PM_{10} standards to the 1997 PM_{10} standards (65 FR 80776, December 22, 2000). The pre-existing 1987 PM_{10} standards remained in place. *Id.* at 80777.

More generally, the three-judge panel held (with one dissenting opinion) that EPA's approach to establishing the level of the standards in 1997, both for PM and for ozone NAAQS promulgated on the same day, effected ''an unconstitutional delegation of legislative authority.'' *Id.* at 1034–40. Although the panel stated that ''the factors EPA uses in determining the degree of public health concern associated with different levels of ozone and PM are reasonable,'' it remanded the rule to EPA, stating that when EPA considers these factors for potential non-threshold pollutants ''what EPA lacks is any determinate criterion for drawing lines'' to determine where the standards should be set. Consistent with EPA's long-standing interpretation, the panel also reaffirmed prior rulings holding that in setting NAAQS EPA is ''not permitted to consider the cost of implementing those standards.'' *Id.* at 1040–41.

Both sides filed cross appeals on these issues to the United States Supreme Court, and the Court granted *certiorari.* In February 2001, the Supreme Court issued a unanimous decision upholding EPA's position on both the constitutional and cost issues. *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 464, 475–76. On the constitutional issue, the Court held that the statutory requirement that NAAQS be ''requisite'' to protect public health with an adequate margin of safety sufficiently guided EPA's discretion, affirming EPA's approach of setting standards that are neither more nor less stringent than necessary. The Supreme Court remanded the case to the Court of Appeals for resolution of any remaining issues that had not been addressed in that court's earlier rulings. *Id.* at 475–76. In March 2002, the Court of Appeals rejected all remaining challenges to the standards, holding under the traditional standard of judicial review that EPA's $PM_{2.5}$ standards were reasonably supported by the administrative record and were not ''arbitrary and capricious.'' *American Trucking Associations* v. *EPA,* 283 F.3d 355, 369–72 (D.C. Cir. 2002).

In October 1997, EPA published its plans for the current periodic review of the PM criteria and NAAQS (62 FR 55201, October 23, 1997), including the 1997 $PM_{2.5}$ standards and the 1987 PM_{10} standards. As part of the process of preparing an updated Air Quality Criteria Document for Particulate Matter (henceforth, the ''Criteria Document''), EPA's National Center for Environmental Assessment (NCEA) hosted a peer review workshop in April 1999 on drafts of key Criteria Document chapters. The first external review draft Criteria Document was reviewed by CASAC and the public at a meeting held in December 1999. Based on CASAC and public comment, NCEA revised the draft Criteria Document and released a second draft in March 2001 for review by CASAC and the public at a meeting held in July 2001. A preliminary draft of a staff paper, Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information (henceforth, the ''Staff Paper'') prepared by EPA's Office of Air Quality Planning and Standards (OAQPS) was released in June 2001 for public comment and for consultation with CASAC at the same public meeting. Taking into account CASAC and public comments, a third draft Criteria Document was released in May 2002 for review at a meeting held in July 2002.

Shortly after the release of the third draft Criteria Document, the Health Effects Institute (HEI) [3] announced that researchers at Johns Hopkins University had discovered problems with applications of statistical software used in a number of important epidemiological studies that had been discussed in that draft Criteria Document. In response to this significant issue, EPA took steps in consultation with CASAC to encourage researchers to reanalyze affected studies and to submit them expeditiously for peer review by a special expert panel convened at EPA's request by HEI. The results of this reanalysis and peer-review process were subsequently incorporated into a fourth draft Criteria Document, which was released in June 2003 and reviewed by CASAC and the public at a meeting held in August 2003.

The first draft Staff Paper, based on the fourth draft Criteria Document, was released at the end of August 2003, and was reviewed by CASAC and the public at a meeting held in November 2003.

[3] The HEI is an independent research institute, jointly sponsored by EPA and a group of U.S. manufacturers and marketers of motor vehicles and engines, that conducts health effects research on major air pollutants related to motor vehicle emissions.

During that meeting, EPA also consulted with CASAC on a new framework for the final chapter (integrative synthesis) of the Criteria Document and on ongoing revisions to other Criteria Document chapters to address previous CASAC comments. The EPA held additional consultations with CASAC at public meetings held in February, July, and September 2004, leading to publication of the final Criteria Document in October 2004. The second draft Staff Paper, based on the final Criteria Document, was released at the end of January 2005, and was reviewed by CASAC and the public at a meeting held in April 2005. The CASAC's advice and recommendations to the Administrator, based on its review of the second draft Staff Paper, were further discussed during a public teleconference held in May 2005 and are provided in a June 6, 2005 letter to the Administrator (Henderson, 2005a). The final Staff Paper, issued in June, 2005, takes into account the advice and recommendations of CASAC and public comments received on the earlier drafts of this document. The Administrator subsequently received additional advice and recommendations from the CASAC, specifically on potential standards for thoracic coarse particles in a teleconference on August 11, 2005, and in a letter to the Administrator dated September 15, 2005 (Henderson, 2005b).[4]

The schedule for completion of this review is governed by a consent decree resolving a lawsuit filed in March 2003 by a group of plaintiffs representing national environmental organizations. The lawsuit alleged that EPA had failed to perform its mandatory duty, under section 109(d)(1), of completing the current review within the period provided by statute. *American Lung Association* v. *Whitman* (No. 1:03CV00778, D.D.C. 2003). An initial consent decree was entered by the court in July 2003 after an opportunity for public comment. The consent decree, as modified by the court, provides that EPA will sign for publication notices of proposed and final rulemaking concerning its review of the PM NAAQS no later than December 20, 2005 and September 27, 2006, respectively.

C. Related Control Programs to Implement PM Standards

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the CAA (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration (PSD) program (42 U.S.C. 7470–7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal Mobile Source Control Program under title II of the CAA (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, nonroad or off-highway, and aircraft emissions; the new source performance standards under section 111 (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 (42 U.S.C. 7412).

As described in a recent EPA report, The Particle Pollution Report: Current Understanding of Air Quality and Emissions through 2003 (EPA, 2004b), State and Federal programs have made substantial progress in reducing ambient concentrations of PM_{10} and $PM_{2.5}$. For example, PM_{10} concentrations have decreased 31 percent nationally since 1988. Regionally, PM_{10} concentrations decreased most in areas with historically higher concentrations—the Northwest (39 percent decline), the Southwest (33 percent decline), and southern California (35 percent decline). Direct emissions of PM_{10} have decreased approximately 25 percent nationally since 1988.

Programs aimed at reducing direct emissions of particles have played an important role in reducing PM_{10} concentrations, particularly in western areas. Some examples of PM_{10} controls include paving unpaved roads and using best management practices for agricultural sources of resuspended soil. Additionally, EPA's Acid Rain Program has substantially reduced sulfur dioxide (SO_2) emissions from power plants since 1995 in the eastern United States, contributing to lower PM concentrations. Of the 87 areas that were designated nonattainment for PM_{10} in the early 1990s, 64 now meet those standards. In cities that have not attained the PM_{10} standards, the number of days above the standards is down significantly.

Nationally, $PM_{2.5}$ concentrations have declined by 10 percent from 1999 to 2003. Generally, $PM_{2.5}$ concentrations have also declined the most in regions with the highest concentrations—the Southeast (20 percent decline), southern California (16 percent decline), and the Industrial Midwest (9 percent decline). With the exception of the Northeast, the remaining regions posted modest declines in $PM_{2.5}$ concentrations from 1999 to 2003. Direct emissions of $PM_{2.5}$ have decreased by 5 percent nationally over the past 5 years.

National programs that affect regional emissions have contributed to lower sulfate concentrations and, consequently, to lower $PM_{2.5}$ concentrations, particularly in the Industrial Midwest and Southeast. National ozone-reduction programs designed to reduce emissions of volatile organic compounds (VOCs) and nitrogen oxides (NO_X) also have helped reduce carbon and nitrates, both of which are components of $PM_{2.5}$. Nationally, SO_2 emissions have declined 9 percent, NO_X emissions have declined 9 percent, and VOC emissions have declined by 12 percent from 1999 to 2003. In eastern States affected by the Acid Rain Program, sulfates decreased 7 percent over the same period.

Over the next 10 to 20 years, national and regional regulations will make major reductions in ambient $PM_{2.5}$ levels. The Clean Air Interstate Rule (CAIR) and the NO_X SIP Call will reduce SO_2 and NO_X emissions from electric generating units and industrial boilers across the eastern half of the U.S., regulations to implement the current ambient air quality standards for $PM_{2.5}$ will require direct $PM_{2.5}$ and $PM_{2.5}$ precursor controls in nonattainment areas, and new national mobile source regulations affecting heavy-duty diesel engines, highway vehicles, and other mobile sources will reduce emissions of NO_X, direct $PM_{2.5}$, SO_2, and VOCs. The EPA estimates that these regulations for stationary and mobile sources will cut SO_2 emissions by 6 million tons annually in 2015 from 2001 levels. Emissions of NO_X will be cut by 9 million tons annually in 2015 from 2001 levels. Emissions of VOCs will drop by 3 million tons, and direct $PM_{2.5}$ emissions will be cut by 200,000 tons in 2015, compared to 2001 levels.

Modeling done by EPA indicates that by 2010, 18 of the 39 areas currently not attaining the $PM_{2.5}$ standards will come into attainment just based on regulatory programs already in place, including CAIR, the Clean Diesel Rules, and other Federal measures. Four more $PM_{2.5}$ areas are projected to attain the standards by 2015 based on the implementation of these programs. All areas in the eastern U.S. will have lower $PM_{2.5}$ concentrations in 2015 relative to present-day conditions. In most cases,

[4] The EPA has posted on its Web site (*http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html*) a second edition of the Staff Paper which was prepared for the purpose of including as an attachment this September 2005 letter from CASAC.

the predicted improvement in $PM_{2.5}$ ranges from 10 percent to 20 percent.

D. Overview of Current PM NAAQS Review

This action presents the Administrator's proposed decisions on the review of the current primary and secondary $PM_{2.5}$ and PM_{10} standards. Primary standards for fine particles and for thoracic coarse particles are addressed separately below in sections II and III, respectively, consistent with the decision made by EPA in the last review and with the conclusions in the Criteria Document and Staff Paper that fine and thoracic coarse particles should continue to be considered as separate subclasses of PM pollution. Thus, the principal focus of this current review of the air quality criteria and primary standards for PM is on evidence of health effects and risks related to exposures to fine particles and to thoracic coarse particles. Secondary standards for fine and coarse-fraction particles are addressed below in section IV.

Past and current decisions to address fine particles and thoracic coarse particles separately are based in part on long-established information on differences in sources, properties, and atmospheric behavior between fine and coarse particles (EPA, 2005a, section 2.2). Fine particles are produced chiefly by combustion processes and by atmospheric reactions of various gaseous pollutants, whereas thoracic coarse particles are generally emitted directly as particles as a result of mechanical processes that crush or grind larger particles or the resuspension of dusts. Sources of fine particles include, for example, motor vehicles, power generation, combustion sources at industrial facilities, and residential fuel burning. Sources of thoracic coarse particles include, for example, resuspension of traffic-related emissions such as tire and brake lining materials, direct emissions from industrial operations, construction and demolition activities, and agricultural and mining operations. Fine particles can remain suspended in the atmosphere for days to weeks and can be transported thousands of kilometers, whereas thoracic coarse particles generally deposit rapidly on the ground or other surfaces and are not readily transported across urban or broader areas. The approach in this review to continue to address fine and thoracic coarse particles separately is reinforced by new information that advances our understanding of differences in human exposure relationships and dosimetric patterns characteristic of these two subclasses of PM pollution, as well as the apparent independence of health effects that have been associated with them in epidemiologic studies (EPA, 2004, section 3.2.3). See also *American Trucking Associations* v. *EPA*, 175 F. 3d at 1053–54, 1055–56 (EPA justified in establishing separate standards for fine and thoracic coarse particles).

Today's proposed decisions separately addressing fine and coarse particles are based on a thorough review in the Criteria Document of the latest scientific information on known and potential human health and welfare effects associated with exposure to these subclasses of PM at levels typically found in the ambient air. These proposed decisions also take into account: (1) Staff assessments in the Staff Paper of the most policy-relevant information in the Criteria Document and as well as a quantitative risk assessment; (2) CASAC advice and recommendations, as reflected in the CASAC's letters to the Administrator, discussions of drafts of the Criteria Document and Staff Paper at public meetings, and separate written comments prepared by individual members of the CASAC PM Review Panel [5] (henceforth, ''CASAC Panel''), and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately.

The EPA is aware that a number of new scientific studies on the health effects of PM have been published since the 2002 cutoff date for inclusion in the Criteria Document. As in the last PM NAAQS review, EPA intends to conduct a review and assessment of any significant new studies published since the close of the Criteria Document, including studies submitted during the public comment period in order to ensure that, before making a final decision, the Administrator is fully aware of the new science that has developed since 2002. In this assessment, EPA will examine these new studies in light of the literature evaluated in the Criteria Document. This assessment and a summary of the key conclusions will be placed in the rulemaking docket. A preliminary list of potentially significant new studies identified to date has been compiled and placed in the rulemaking docket for this proposal, and EPA solicits comment on other relevant studies that may be added to this list. This list includes a wide array of different types of studies that are potentially relevant to various issues discussed in the following sections, including issues related to the elements of the standards under review.

Throughout this preamble a number of conclusions, findings, and determinations by the Administrator are noted. It should be understood that these are all provisional and proposed in nature. While they identify the reasoning that supports this proposal, they are not intended to be final or conclusive in nature. The EPA invites comments on all issues involved with this proposal, including all such proposed judgments, conclusions, findings, and determinations.

II. Rationale for Proposed Decisions on Primary $PM_{2.5}$ Standards

As discussed more fully below, the rationale for the proposed revisions of the primary $PM_{2.5}$ NAAQS includes consideration of: (1) Evidence of health effects related to short- and long-term exposures to fine particles; (2) insights gained from a quantitative risk assessment; and (3) specific conclusions regarding the need for revisions to the current standards and the elements of $PM_{2.5}$ standards (i.e., indicator, averaging time, form, and level) that, taken together, would be requisite to protect public health with an adequate margin of safety.

In developing this rationale, EPA has drawn upon an integrative synthesis of the entire body of evidence of associations between exposure to ambient fine particles and a broad range of health endpoints (EPA, 2004, Chapter 9), focusing on those health endpoints for which the Criteria Document concludes that the associations are likely to be causal. This body of evidence includes hundreds of studies conducted in many countries around the world, using various indicators of fine particles. In its assessment of the evidence judged to be most relevant to making decisions on elements of the primary $PM_{2.5}$ standards, EPA has placed greater weight on U.S. and Canadian studies using $PM_{2.5}$ measurements, since studies conducted in other countries may well reflect different demographic and air pollution characteristics.

As with virtually any policy-relevant scientific research, there is uncertainty in the characterization of health effects attributable to exposure to ambient fine particles. As discussed below, however, an unprecedented amount of new research has been conducted since the last review, with important new information coming from epidemiologic, toxicologic, controlled human exposure,

[5] The CASAC PM Review Panel is comprised of the seven members of the chartered CASAC, supplemented by fifteen subject-matter experts appointed by the Administrator to provide the types of scientific expertise relevant to this review of the PM NAAQS.

and dosimetric studies. Moreover, the newly available research studies evaluated in the Criteria Document have undergone intensive scrutiny through multiple layers of peer review and extended opportunities for public review and comment. While important uncertainties remain, the review of the health effects information has been extensive and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence has provided an adequate basis for regulatory decision making at this time. This review also provides important input to EPA's research plan for improving our future understanding of the relationships between exposures to ambient fine particles and health effects.

A. Heath Effects Related to Exposure to Fine Particles

This section outlines key information contained in the Criteria Document (Chapters 6–9 and the Staff Paper (Chapter 3) on known or potential effects associated with exposure to fine particles and their major constituents. The information highlighted here summarizes: (1) New information available on potential mechanisms for health effects associated with exposure to fine particles and constituents; (2) the nature of the effects that have been associated with ambient fine particles or fine particle constituents; (3) an integrative assessment of the evidence on fine particle-related health effects; (4) subpopulations that appear to be sensitive to effects of exposure to fine particles; and (5) the public health impact of exposure to ambient fine particles.

As was true in the last review, evidence from epidemiologic studies plays a key role in the Criteria Document's evaluation of the scientific evidence. Some highlights of the new epidemiologic evidence include:

(1) New multi-city studies that use uniform methodologies to investigate the effects of various indicators of PM on health with data from multiple locations with varying climate and air pollution mixes, contributing to increased understanding of the role of various potential confounders, including gaseous co-pollutants, on observed associations with fine particles. These studies provide more precise estimates of the magnitude of an effect of exposure to PM, including fine particles, than most smaller-scale individual city studies.

(2) More studies of various health endpoints evaluating associations between effects and fine particles and thoracic coarse particles (discussed below in section III), as well as ultrafine particles or specific components (e.g., sulfates, nitrates, metals, organic compounds, and elemental carbon) of fine particles.

(3) Numerous new studies of cardiovascular endpoints, with particular emphasis on assessment of cardiovascular risk factors or physiological changes.

(4) Studies relating population exposure to fine particles and other pollutants measured at centrally located monitors to estimates of exposure to ambient pollutants at the individual level. Such studies have led to a better understanding of the relationship between ambient fine particles levels and personal exposures to fine particles of ambient origin.

(5) New analyses and approaches to addressing issues related to potential confounding by gaseous co-pollutants, possible thresholds for effects, and measurement error and exposure misclassification.[6]

(6) Preliminary attempts to evaluate the effects of fine particles from different sources (e.g., motor vehicles, coal combustion, vegetative burning, crustal[7]), using factor analysis or source apportionment methods with fine particle speciation data.

(7) Several new ''intervention studies'' providing evidence for improvements in respiratory or cardiovascular health with reductions in ambient concentrations of particles and gaseous co-pollutants.

In addition, the body of evidence on PM-related effects has greatly expanded with findings from studies on potential mechanisms or pathways by which particles may result in the effects identified in the epidemiologic studies. These studies include important new dosimetry, toxicologic and controlled human exposure studies, as highlighted below:

(8) Animal and controlled human exposure studies using concentrated ambient particles (CAPs), new indicators of response (e.g., C-reactive protein and cytokine levels, heart rate variability), and animal models simulating sensitive human subpopulations. The results of these studies are relevant to evaluation of plausibility of the epidemiologic evidence and provide insights into potential mechanisms for PM-related effects.

(9) Dosimetry studies using new modeling methods that provide increased understanding of the dosimetry of different particle size classes and in members of potentially sensitive subpopulations, such as people with chronic respiratory disease.

1. Mechanisms

In the last review, EPA considered the lack of demonstrated biologic mechanisms for the varying effects observed in epidemiologic studies to be an important caution in its integrated assessment of the health evidence. Much new evidence is now available on potential mechanisms or pathways for PM-related effects, ranging from effects on the respiratory system to indicators of cardiovascular response; these new findings are discussed in depth in Chapter 7 of the Criteria Document. While questions remain, the new findings have advanced our understanding of the complex and different patterns of particle deposition and clearance in the respiratory tract and provide insights into potential mechanisms for PM-related effects and support the plausibility of the findings of epidemiologic studies.

Although there are differences among the size fractions of particles, fine particles, including accumulation mode and ultrafine particles, and thoracic coarse particles can all penetrate into and be deposited in the tracheobronchial and alveolar regions of the respiratory tract (i.e., the ''thoracic'' regions).[8] Penetration into the tracheobronchial and alveolar regions is greater for accumulation mode particles than for coarse or ultrafine particles, since coarse and ultrafine particles are more efficiently removed from the air in the extrathoracic region than are accumulation-mode fine particles; the evidence from dosimetric studies is

[6] ''Confounding'' occurs when a health effect that is caused by one risk factor is attributed to another variable that is correlated with the causal risk factor; epidemiologic analyses attempt to adjust or control for potential confounders (EPA, 2004, section 8.1.3.2; EPA, 2005a, section 3.6.4). A ''threshold'' is a concentration below which it is expected that effects are not observed (EPA, 2004, section 8.4.7; EPA, 2005a, section 3.6.6). ''Gaseous co-pollutants'' generally refer to other commonly-occuring air pollutants, specifically O_3, CO, SO_2 and NO_2. ''Measurement error'' refers to uncertainty in the air quality measurements, while ''exposure misclassification'' includes uncertainty in the use of ambient pollutant measurements in characterizing population exposures to PM (EPA, 2004, section 8.4.5; EPA, 2005a, section 3.6.2)

[7] ''Crustal'' is used here to describe particles of geologic origin, which can be found in both fine- and coarse-fraction PM.

[8] Particles are often classified in modes based on their distribution by characteristics such as mass, surface area, and particle number. ''Coarse mode'' particles are those with diameters mostly greater than the minimum in the particle mass distribution, which generally occurs between about 1 and 3 μm. ''Accumulation mode'' particles are those with diameters from about 0.1 μm to between about 1 and 3 μm. Ultrafine particles are generally those with diameters below about 0.1 μm (EPA, 2004, pages 2–14).

reviewed in detail in Chapter 6 of the Criteria Document.

Fine particles have varying physical or chemical characteristics that may influence health responses. Physical characteristics that may be of importance are solubility or physical state of the particles (e.g., solid, liquid). Fine particle components include metals, acids, organic compounds, biogenic constituents, sulfate and nitrate salts, elemental carbon, and reactive components such as peroxides; size and surface area of the particles can also influence health responses. By way of illustration, Mauderly et al. (1998) discussed particle components or characteristics hypothesized to contribute to health, producing an illustrative list of 11 components or characteristics of interest for which some evidence existed. The list included: (1) Particle mass concentration, (2) particle size/surface area, (3) ultrafine particles, (4) metals, (5) acids, (6) organic compounds, (7) biogenic particles, (8) sulfate and nitrate salts, (9) peroxides, (10) soot, and (11) co-factors, including effects modification or confounding by co-occurring gases and meteorology. The authors stressed that this list is neither definitive nor exhaustive, and note that ''it is generally accepted as most likely that multiple toxic species act by several mechanistic pathways to cause the range of health effects that have been observed'' (Mauderly et al., 1998). The range of health outcomes linked with fine particle exposures is also broad, including effects on the cardiovascular and respiratory systems, and potential links with developmental effects in children (e.g., low birth weight) and death from lung cancer. It appears unlikely that the complex mixes of particles that are present in ambient air would act alone through any single pathway of response. Accordingly, it is plausible that several physiological responses might occur in concert to produce reported health endpoints.

As discussed in section 7.10 of the Criteria Document, the potential pathways for direct effects on the respiratory system include lung injury and inflammation, increased airway reactivity and asthma exacerbation, and increased susceptibility to respiratory infections. New toxicologic or controlled human exposure studies have reported some evidence of inflammatory responses in animals, as well as increased susceptibility to infections. Toxicologic studies also report evidence of lung injury, inflammation, or altered host defenses with exposure to ambient particles or particle constituents. Some toxicologic evidence, particularly from results of studies using diesel exhaust particle exposures, also indicates that PM can aggravate asthmatic symptoms or increase airway reactivity.

Potential pathways for fine particle-related effects also include systemic effects that are secondary to effects in the respiratory system. These include impairment of lung function leading to cardiac effects, pulmonary inflammation and cytokine production leading to systemic hemodynamic effects, lung inflammation leading to increased blood coagulability, and lung inflammation leading to hematopoiesis effects. While more limited than for direct pulmonary effects, some new toxicologic studies suggest that injury or inflammation in the respiratory system can lead to changes in heart rhythm, reduced oxygenation of the blood, changes in blood cell counts, and changes in the blood that can increase the risk of blood clot formation, a risk factor for heart attacks and strokes. In addition, health studies have suggested potential pathways for effects on the heart that include effects related to uptake of particles or particle constituents in the blood, and effects on the autonomic control of the heart and circulatory system. In the last review, little or no evidence was available from toxicologic studies on potential cardiovascular effects. More recent studies have provided some initial evidence that particles can have direct cardiovascular effects. Particle deposition in the respiratory system also could lead to cardiovascular effects, such as fine particle-induced pulmonary reflexes resulting in changes in the autonomic nervous system that then could affect heart rhythm. Also, inhaled fine particles could affect the heart or other organs if particles or particle constituents are released into the circulatory system from the lungs; some new evidence indicates that the smaller ultrafine particles or their soluble constituents can move directly from the lungs into systemic circulation.

The potential mechanisms and/or general pathways for effects discussed above are primarily effects related to short-term rather than long-term exposure to fine particles; for the most part, air pollution toxicologic studies are not designed to assess long-term exposure effects. While repeated occurrences of some short-term insults, such as inflammation, might contribute to long-term effects, it is likely that wholly different mechanisms are involved in the development of chronic health responses. Some mechanistic evidence is available, however, for potential carcinogenic or genotoxic effects of ambient fine particles and combustion products of coal, wood, diesel, and gasoline (discussed in section 7.8 of the Criteria Document).

Overall, the findings indicate that different health responses are linked with different particle characteristics and that both individual components and complex particle mixtures appear to be responsible for many biologic responses relevant to fine particle exposures. In evaluating the new body of evidence, the Criteria Document states: ''Thus, there appear to be multiple biologic mechanisms that may be responsible for observed morbidity/mortality due to exposure to ambient PM. It also appears that many biologic responses are produced by PM whether it is composed of a single component or a complex mixture'' (EPA, 2004, p. 7–206).

2. Nature of Effects

In the last review, evidence from health studies indicated that exposure to PM (using various indicators) was associated with premature mortality and indices of morbidity including respiratory hospital admissions and emergency room visits, school absences, work loss days, restricted activity days, effects on lung function and symptoms, morphological changes, and altered host defense mechanisms.[9] As reviewed in Chapter 8 of the Criteria Document, recent epidemiologic studies have continued to report associations between short-term exposure to fine particles or fine particle indicators, and effects such as premature mortality, hospital admissions or emergency department visits for respiratory disease, and effects on lung function and symptoms. In addition, recent epidemiologic studies have provided some new evidence linking short-term fine particle exposures to effects on the cardivascular system, including cardiovascular hospital admissions and more subtle indicators of cardiovascular health. Long-term exposure to $PM_{2.5}$ and sulfates has also been associated with mortality from cardiopulmonary diseases and lung cancer, and effects on the respiratory system such as decreased lung function or the development of chronic respiratory disease. The

[9] Historical reports of dramatic pollution episodes, considered in the 1987 review of the PM NAAQS, provided clear evidence of mortality associated with high levels of PM and other pollutants, such as the air pollution episode that occurred in London in 1952 (EPA, 1996a, pp. 12–28 to 12–31).

evidence for such effects is summarized below.

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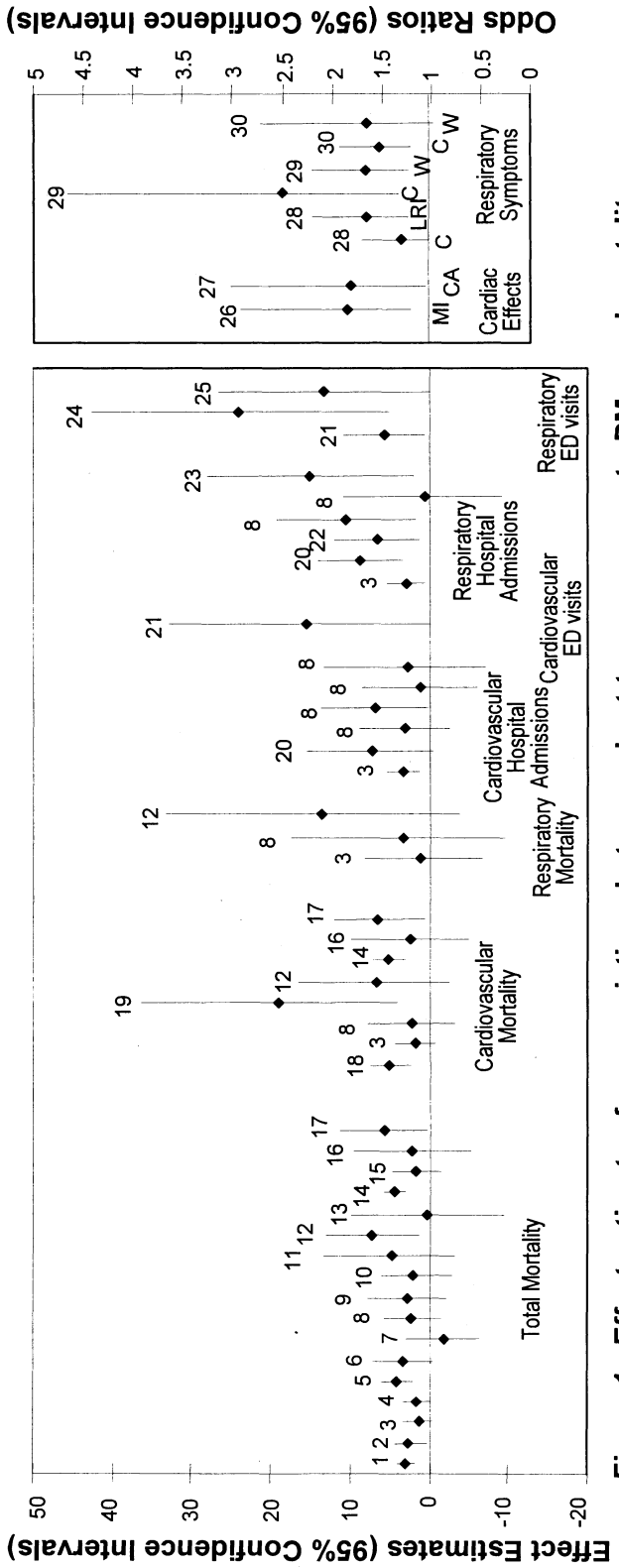

Figure 1. Effect estimates for associations between short-term exposure to $PM_{2.5}$ and mortality or morbidity health outcomes in U.S. and Canadian Studies; multi-city studies noted by bold text below.

(ED=Emergency Department; MI=myocardial infarction; CA=cardiac arrhythmia; C=cough; LRI=lower respiratory infection; W=wheeze)

1. **Klemm and Mason (2003), 6 U.S. cities**
2. **Burnett and Goldberg (2003), 8 Canadian cities**
3. Moolgavkar (2003), Los Angeles
4. Klemm and Mason (2003), St. Louis
5. Klemm and Mason (2003), Boston
6. Klemm and Mason (2003), Kingston-Harriman
7. Klemm and Mason (2003), Portage
8. Ito (2003), Detroit
9. Chock et al. (2000), Pittsburgh (< 75 y.o.)
10. Chock et al. (2000), Pittsburgh (75+ y.o.)
11. Klemm and Mason (2000), Atlanta
12. Fairley (2003), Santa Clara County
13. Klemm and Mason (2003), Topeka
14. Tsai et al. (2000), Newark
15. Klemm and Mason (2003), Steubenville
16. Tsai et al. (2000), Elizabeth
17. Tsai et al (2000), Camden
18. Lipfert et al. (2000), Philadelphia
19. Mar et al. (2003), Phoenix
20. Burnett et al. (1997), Toronto
21. Stieb et al. (2000), St. John
22. Sheppard et al., (2003), Seattle
23. Thurston et al. (1994), Toronto
24. Delfino et al. (1997), Montreal
25. Delfino et al. (1998), Montreal
26. Peters et al. (2001), Boston
27. Peters et al. (2000), Boston
28. **Schwartz and Neas (2000), 6 U.S. cities**
29. Neas et al. (1995), Uniontown
30. Neas et al. (1996), State College

Results presented are from time-series studies that did not use generalized additive models or were reanalyzed using general linear models. For consistency across studies, effect estimates are from single-pollutant, general linear models, based on an increment of 25 $\mu g/m^3$ $PM_{2.5}$, and have been plotted in order of decreasing study power, using as an indicator the natural log of the product of the number of study days and number of health events per day. Results for studies of respiratory symptoms are presented as odds ratios; an odds ratio of 1.0 is equivalent to no effect, and thus is presented as equivalent to the zero effect estimate line.

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a. Effects Associated With Short-Term Exposure to Fine Particles

Numerous epidemiologic studies have demonstrated statistical associations between short-term exposure to fine particles and health outcomes ranging from total mortality to respiratory symptoms, as discussed below. Figure 1 summarizes results from both multi-city and single-city epidemiologic studies using short-term exposures to $PM_{2.5}$, including all U.S. and Canadian studies that used direct measurements of $PM_{2.5}$ and for which effect estimates and confidence intervals were reported.[10] The central effect estimate is indicated by a diamond for each study result, with the vertical bar representing the 95 percent confidence interval around the estimate. In the discussions that follow, an individual study result is considered to be statistically significant if the 95 percent confidence interval does not include zero. Positive effect estimates indicate increases in the health outcome with $PM_{2.5}$ exposure. In considering these results as a whole, it is important to consider not only whether statistical significance at the 95 percent confidence level is reported in individual studies, but also the general pattern of results, focusing in particular on studies with greater statistical power that report relatively more precise results.

i. Mortality

Since the last review, a large number of new time-series studies of the relationship between short-term exposure to PM, including $PM_{2.5}$, and mortality have been published, including several multi-city studies that are responsive to the recommendations from the last review. As discussed in section 8.2 of the Criteria Document, these include studies that have been conducted in single cities or locations in the U.S. or Canada, as well as Mexico City and locations in Europe, South America, Asia, and Australia.

Several recent multi-city studies have been published since the last review that are of particular relevance for this review. The results of multi-city studies on associations between PM_{10} and mortality across 90 U.S. cities (Dominici, 2003) and across ten U.S. cities (Schwartz, 2003b), while not specifically on fine particles, have provided important new information to help address uncertainties regarding a number of issues, including model specification, potential confounding by co-pollutants and the form of concentration-response functions (EPA, 2004, section 8.2.2.3). Two multi-city studies have included measurements of $PM_{2.5}$; one was conducted in six U.S. cities (Schwartz et al., 2003a; Klemm and Mason, 2003) and the other in eight Canadian cities (Burnett and Goldberg, 2003). In the last review, results from one multi-city study (the Six Cities study) were available, in which the authors reported significant associations for total mortality with $PM_{2.5}$ and PM_{10}, but not with $PM_{10\text{-}2.5}$. Reanalyses of Six Cities data have reported results consistent with the findings of the original study, with statistically significant increases for total mortality with short-term exposure to $PM_{2.5}$ (Schwartz, 2003a; Klemm and Mason, 2003). In a study using data from the eight largest Canadian cities, positive associations were reported for $PM_{2.5}$, PM_{10}, and $PM_{10\text{-}2.5}$ with mortality, and the association with $PM_{2.5}$ was statistically significant (Burnett and Goldberg, 2003).

Single-city studies of mortality associations with short-term exposures to fine particles have also been conducted in areas across U.S. and Canada as well as in Europe, Australia and Mexico (some using fine particle indicators such as British Smoke). In general, it can be seen in Figure 1 that the effect estimates for associations between mortality and short-term exposure to $PM_{2.5}$ are positive and a number are statistically significant, particularly when focusing on the results of studies with greater precision. For total nonaccidental mortality, the effect estimates from the multi-city and single-city studies with greater precision generally fall in a range of 2 to 6 percent increases per 25 $\mu g/m^3$ $PM_{2.5}$.[11] Somewhat larger effect estimates have been reported for associations with cardiovascular or respiratory mortality than with total nonaccidental mortality although the confidence intervals may also be larger, especially for respiratory mortality since respiratory deaths comprise only a small proportion of total deaths (EPA, 2005a, p. 3–15). Some studies evaluated seasonal variation in effects, and there is no consistent pattern in results. The Criteria Document concludes that the results of recent epidemiologic studies are generally consistent with findings available in the previous review (EPA, 2004, p. 8–305).

In addition, associations have been reported between mortality and short-term exposure to a number of fine particle components, including sulfates, nitrates, metals, organic compounds and elemental carbon (EPA, 2004, Section 8.2.2.5.2), as well as gaseous precursors such as SO_2 and NO_2 and other gaseous pollutants such as CO. Further, three recent studies have used $PM_{2.5}$ speciation data to evaluate the effects of air pollutant combinations or mixtures using factor analysis or source apportionment methods to evaluate potential associations between mortality and $PM_{2.5}$ from different source categories. These studies reported that short-term exposures to fine particles from combustion sources, including motor vehicle emissions, coal combustion, oil burning and vegetative burning, were associated with increased mortality (EPA, 2004, Section 8.2.2.5.3). However, different patterns of associations between various components or source categories of fine particles and total or cardiovascular mortality are seen in different studies (EPA, 2004, p. 8–70, Tables 8–3, 8–4).

ii. Respiratory Morbidity

As discussed in Section 8.4.6.4 of the Criteria Document, recent epidemiologic studies have provided further evidence for fine particle effects on morbidity, including effects such as hospital admissions or emergency department for respiratory diseases, respiratory symptoms and lung function changes.

(a) Hospital Admissions or Emergency Department Visits for Respiratory Diseases

In the last review, results were available from one study that reported associations between $PM_{2.5}$ and hospitalization for respiratory diseases; these findings were also supported by a number of studies using other fine particle indicators. Numerous studies had also reported statistically significant associations between hospital admissions or emergency department visits for respiratory diseases short-term exposures with various indicators ambient PM, especially PM_{10}, in areas where fine particles are the predominant fraction of PM_{10}, such as locations in the Eastern U.S. and in Ontario, Canada (EPA, 1996a, p. 13–39).

The body of evidence has been expanded with numerous new studies in the U.S. and other countries that have reported associations between $PM_{2.5}$ and hospitalization or emergency department visits (discussed more fully in Section 8.3.2 of the Criteria Document). As shown in Figure 1, all U.S. and Canadian studies report

[10] In the following discussion of specific studies, results from single-pollutant models are referred to, as shown in Figure 1, unless otherwise noted.

[11] In general, the results of studies conducted over shorter time periods and/or smaller areas have a broader range or effect estimates with larger standard errors, as shown in Figure 1.

associations between $PM_{2.5}$ and hospitalization for all respiratory causes that are positive and statistically significant. A number of studies have also reported findings for hospital admissions for individual disease categories (COPD, pneumonia, and asthma) that are positive, but not always statistically significant, perhaps due to smaller sample sizes for the specific respiratory diseases. The effect estimates for respiratory hospital admissions tend to fall in the range of 5 to 15 percent per 25 μg/m³ $PM_{2.5}$.[12] In addition, several studies have reported positive, statistically significant associations between exposure to $PM_{2.5}$ and emergency department visits for respiratory diseases. The effect estimates for these associations range up to about 25 percent per 25 μg/m³ $PM_{2.5}$ (EPA, 2005a, pp. 3–20, 3–21).

(b) Respiratory Symptoms and Lung Function Changes

Associations between short-term exposure to $PM_{2.5}$ and symptoms in U.S. and Canadian studies are presented in Figure 1. As discussed in Section 8.3.3 of the Criteria Document, a number of new studies have reported significant associations between short-term exposure to PM and increased respiratory symptoms (e.g., cough, wheeze, shortness of breath) and decreased lung function in people with asthma. In studies of nonasthmatic subjects, there were generally positive associations between short-term $PM_{2.5}$ exposures and respiratory symptoms that often were not statistically significant and the results for changes in lung function were somewhat inconsistent. The Criteria Document concludes that the findings of these studies suggest associations with fine PM in reduced lung function and increased respiratory symptoms. For example, significant associations were reported between ambient $PM_{2.5}$ and lower respiratory symptoms in children in a number of U.S. cities (Schwartz and Neas, 2000), and significant associations were found with reduced lung function in Philadelphia (Neas et al., 1999). These findings are supported by results from numerous studies conducted in Europe and Central and South America. The Criteria Document finds that the recent epidemiologic findings are consistent with those of the previous review in showing associations with both respiratory symptom incidence and decreased lung function (EPA, 2004, Section 8.4.6.4).

iii. Cardiovascular Morbidity

In the last review, none of the available studies had evaluated associations between exposure to PM and cardiovascular morbidity, though some studies had reported associations with cardiopulmonary morbidity. In this area, the evidence on PM-related effects has been greatly expanded. Numerous recent studies, including multi-city analyses, have reported significant associations between short-term exposures to PM and health endpoints related to cardiovascular morbidity, including hospitalization or emergency department visits for cardiovascular diseases, incidence of myocardial infarction, cardiac arrhythmia, changes in heart rate or heart rate variability and changes in cardiac health indicators such as fibrinogen or C-reactive protein (EPA, 2004, section 9.2.3.2.1).

(a) Hospital Admissions and Emergency Department Visits for Cardiovascular Diseases

Several recent studies, including multi-city analyses, have reported significant associations between short-term exposures to various PM indicators and hospital admissions or emergency department visits for cardiovascular diseases. Among the studies using $PM_{2.5}$ measurements are a number of single-city analyses of hospitalization or emergency department visits for cardiovascular diseases. As shown in Figure 1, studies conducted in Los Angeles, Toronto and Detroit have reported associations with hospital admissions or emergency department visits for all cardiovascular diseases that are positive and statistically significant or nearly so (Burnett et al., 1997; Ito, 2003; Moolgavkar, 2003). As was true for respiratory diseases, the results for specific diseases (ischemic heart disease, dysrhythmia, congestive heart disease or heart failure, and stroke) are positive but often not statistically significant. The effect estimates reported for associations with hospitalization for cardiovascular diseases range from about 1 to 10 percent per 25 μg/m³ $PM_{2.5}$ (EPA, 2004, p. 8–310); effect estimates reported for associations with emergency department visits are generally somewhat larger.

(b) Cardiovascular Health Indicators

In addition to the greatly expanded body of evidence on hospitalization or emergency department visits for cardiovascular diseases, new epidemiologic studies have also reported associations with more subtle physiological changes in the cardiovascular system with short-term exposures to PM, particularly PM_{10} and $PM_{2.5}$ (EPA, 2004, p. 9–67). Associations between short-term exposures to ambient PM (often using PM_{10}) have been reported with measures of changes in cardiac function such as arrhythmia, alterations in electrocardiogram (ECG) patterns, heart rate or heart rate variability changes, although the Criteria Document urges caution in drawing conclusions regarding the effects of PM on heart rhythm, recognizing the need for further research to more firmly establish and understand links between particles and these more subtle endpoints. Recent studies have also reported increases in blood components or biomarkers such as increased levels of C-reactive protein and fibrinogen. Several of these studies report significant associations between various cardiovascular endpoints and short-term $PM_{2.5}$ exposures, including one in which statistically significant associations were reported between onset of myocardial infarction and short-term $PM_{2.5}$ exposures averaged over 2 and 24 hours (EPA, 2004, p. 8–165; Peters et al., 2001). In this study, the effect estimates for the two averaging periods are quite similar in magnitude suggesting that for certain health outcomes very short-term fine particle concentration fluctuations are important (EPA, 2004, p. 9–42; Peters et al., 2001). These new epidemiologic findings provide important insight into potential biologic mechanisms that could underlie associations between short-term PM exposure and cardiovascular mortality and hospitalization that have been reported previously.

b. Effects Associated With Long-Term Exposure to Fine Particles

In the last review, results were available from several cohort studies that suggested associations between long-term exposure to PM (using various indicators) and both mortality and respiratory morbidity. Two studies of adult populations (the Six Cities and ACS studies) reported associations between increases in mortality and long-term exposure to $PM_{2.5}$, and results of a 24-city study indicated that long-term exposure to fine particles was associated with increased respiratory illness in children.

As discussed below, the new evidence available in the current review includes an extensive reanalysis of data from the Six Cities and ACS studies, new analyses using updated data from the ACS and California Seventh Day

[12] Some studies have evaluated seasonal variation in effects, and no consistent pattern is apparent in the results. For example, stronger associations were reported between $PM_{2.5}$ and asthma hospitalization in the warmer season in Seattle (Sheppard et al., 2003) but in the cooler season in Los Angeles (Nauenberg and Basu, 1999).

Adventist (AHSMOG) studies, and a new analysis using data from a cohort of veterans. In addition, new studies have been published on the association between long-term exposure to fine particles and respiratory morbidity using data from a cohort of schoolchildren in Southern California. In general, the newly available evidence has supported earlier findings, and the results of reanalyses have increased confidence in the associations reported in previous prospective cohort studies.

i. Mortality

In the 1996 Criteria Document, statistically significant associations between long-term exposure to both $PM_{2.5}$ and sulfates and mortality were reported in studies from the Six Cities and ACS cohorts (Dockery et al., 1993; Pope et al., 1995). These studies reported effect estimates of 6.6 percent (95 percent CI: 3.5, 9.8) increases in total mortality per 10 μg/m^3 $PM_{2.5}$ in the ACS study and 13 percent (95 percent CI: 4.2, 23) increases in total mortality per 10 μg/m^3 $PM_{2.5}$ in the Six Cities study, with somewhat larger effect estimates reported for cardiopulmonary mortality (EPA, 2004, p. 8–117). A number of reviewers raised questions about the adequacy of adjustments for potential confounders and other issues (61 FR 65642, December 13, 1996). Subsequently, as discussed in more detail in Section 8.2.3 of the Criteria Document, the Health Effects Institute conducted a major reanalysis of the data from the Six Cities and ACS studies by a group of independent investigators to address questions and uncertainties raised about these prospective cohort studies. The reanalysis included two major components, a replication and validation study and a sensitivity analysis. In the first part of the reanalysis, the investigators validated the data used by the original investigators in both studies, and they were able to replicate the original results. The results confirmed the original investigators' findings of associations with both total and cardiorespiratory mortality, and the authors reported that the results were not dependent on the computer programs used in the original analyses (EPA, 2004, p. 8–91; Krewski et al., 2000, p. 91).

The second component of the reanalysis project evaluated an array of different models and variables to determine whether the original results would remain robust to different analytic assumptions. This included controlling for other individual level variables, such as cigarette smoking, alcohol consumption, obesity and occupational exposures to dusts or other pollutants, and evaluation of the sensitivity of results to the addition of a range of additional city-level variables such as population change, income, education levels, and access to health care. The sensitivity analysis included assessment of effects in different subgroups of the population. The investigators also evaluated the sensitivity of the results to the inclusion of gaseous co-pollutants, and tested the effects of different statistical modeling approaches, including methods to adjust for spatial patterns, such as the correlation in pollutant levels between cities.

The authors found that adjustment for individual-level variables did not alter the results for the association between long-term $PM_{2.5}$ or sulfate exposure and mortality (Krewski et al., 2000, p. 218). In addition, in most (but not all) cases the associations between mortality and long-term exposure to $PM_{2.5}$ and sulfates were unchanged when additional city-level variables were added to the models (Krewski et al., 2000, p. 233). Analyses to assess the potential modification of effects in different subgroups of the population found, for the most part, little difference in effects for different subgroups. However, education level was found to modify the estimated effect of fine particles, in that associations were statistically significant for those subgroups with lower education levels, whereas the effect estimates from associations for the subgroup with better than high school education were appreciably smaller and were statistically insignificant. The authors suggest that educational attainment may be a marker for lower socioeconomic status and thus greater vulnerability to fine particle-related effects (EPA, 2004, p. 8–94; Krewski et al., 2000, p. 232).[13]

In single-pollutant models, none of the gaseous co-pollutants was significantly associated with mortality except SO_2. Further reanalysis included multi-pollutant models with the gaseous pollutants, and the associations between mortality and both fine particles and sulfates were unchanged in these models, except when SO_2 was included, which decreased the size of the effect estimates for $PM_{2.5}$ to one-sixth of its original value and for sulfates to less than one-third of its original value (EPA, 2004, p. 8–136; Krewski et al., 2000, pp. 183–184).[14] However, the regional association of SO_2 and $PM_{2.5}$ was relatively high, such that the effects of the separate pollutants could not be distinguished. The authors conclude that these findings support the notion that increased mortality may be attributable to more than one component of ambient air pollution, and that throughout the reanalyses, fine particles, sulfates, and SO_2 demonstrated positive associations with mortality (Krewski et al., 2000, p. 233–234). As discussed more generally in the Criteria Document, this result may be reflecting the relatively high correlation between $PM_{2.5}$ levels and SO_2 levels that would be expected in cities across the industrial Midwest and northeastern states, the role that SO_2 has as a precursor to sulfate components in the mix of $PM_{2.5}$, and/or the likelihood that SO_2 is part of the causal pathway linking exposure to $PM_{2.5}$ to adverse health outcomes (EPA, 2004, section 8.1.3.2).

Finally, Krewski and colleagues used several methods to address spatial patterns in the data; for example, concentrations of air pollutants may be correlated between cities within a region. These analyses were primarily based on sulfate concentrations, since more cities had data for sulfates than for fine particles. Addressing spatial patterns in the data generally reduced the size of the association between sulfates and mortality, but the models all continued to show associations between mortality risk and long-term sulfate exposures, although not all were statistically significant (Krewski et al., 2000, p. 228). Overall, considering the results of the extensive set of replication and sensitivity analyses, the authors report that the reanalysis confirmed the association between mortality and fine particle and sulfate exposures (EPA, 2004, p. 8–95; Krewski et al., 2000).

In addition, extended analyses were conducted for the ACS cohort study that included follow-up health data and air quality data from the new fine particle

[13] In multivariate models, the association found between mortality and long-term $PM_{2.5}$ exposure was little changed with addition of education level to the model (Krewski et al., 2000, p. 184). This indicates that education level was not a confounder in the relationship between fine particles and mortality, but the relationship between fine particles and mortality is larger in the population subsets with lower education in this study and not statistically significant in the population subset with the highest education (EPA, 2004, p. 8–100).

[14] For a 24.5 μg/m^3 change in $PM_{2.5}$, the relative risk for the association between mortality and $PM_{2.5}$ alone was 1.20 (95 percent CI: 1.11–1.29), and after adjustment for SO_2 it was 1.03 (95 percent CI: 0.95–1.13). The relative risk for SO_2 alone was 1.49 (95 percent CI: 1.36–1.64) and after adjustment for $PM_{2.5}$ was 1.46 (95 percent CI: 1.32–1.63) (Krewski et al., 2000, p. 184). The relative risk for sulfates alone was 1.28 (95 percent CI: 1.18–1.40) and after adjustment for SO_2 it was 1.14 (95 percent CI: 1.04–1.25) (Krewski et al., 2000, p. 184). These relative risks for $PM_{2.5}$ are equivalent to effect estimates of 7.5 percent and 1.2 percent increases in mortality per 10 μg/m^3, in single-pollutant and two-pollutant models, respectively.

monitoring network for 1999–2000. In this study of the expanded ACS cohort, significant associations were reported between long-term exposure to fine particles (using various averaging periods for air quality concentrations) and premature mortality from all causes, cardiopulmonary diseases, and lung cancer (Pope et al., 2002; EPA, 2004, 8–102). This extended analysis included the use of more recent data on fine particle concentrations, as well as data on gaseous co-pollutant concentrations, though no multi-pollutant model results are presented. Further evaluation of the influence of other covariates (e.g., dietary intake data, occupational exposure) used methods similar to those in the reanalysis described above, and new statistical approaches were used for modeling the PM-mortality relationship as well as adjusting for spatial correlation (EPA, 2004, section 8.2.3.2.2). The investigators reported that the associations found with fine particle and sulfate concentrations were not markedly affected by adjustment for numerous socioeconomic variables, demographic factors, environmental variables, indicators of access to health services or personal health variables (e.g., dietary factors, alcohol consumption, body mass index). Similar to the results of Krewski et al. (2000), education level was found to be a modifier in the relationship between fine particles and mortality, in that associations were statistically significant for those subgroups with lower education levels, whereas effect estimates from associations for those with better than a high school education were close to zero and were statistically insignificant.

There are also new analyses using updated data from the AHSMOG cohort. These include estimated $PM_{2.5}$ concentrations from visibility data, along with new health information from continued follow-up of the Seventh Day Adventist cohort. Positive associations were reported for mortality with $PM_{2.5}$ in males, but the estimates were generally not statistically significant (Abbey et al., 1999; McDonnell et al., 2000; EPA, 2004, pp. 8–110 and 8–117). In addition, one new set of analyses was done using subsets of PM exposure and mortality time periods and data from a Veterans Administration (VA) cohort of hypertensive men. The investigators report inconsistent and largely nonsignificant associations between PM exposure (including, depending on availability, TSP, PM_{10}, $PM_{2.5}$, PM_{15} and $PM_{15\text{-}2.5}$) and mortality (EPA, 2004, pp. 8–110 to 8–111; Lipfert et al., 2000b).

The Criteria Document and Staff Paper place greatest weight on the findings of the Six Cities and ACS studies (including reanalyses and extended analyses) that include measured fine particle data (in contrast with AHSMOG effect estimates based on TSP or visibility measurements), have study populations more similar to the general population than the VA study cohort, and have been replicated and examined through exhaustive reanalysis (EPA, 2005a, at 5–22; see also EPA, 2004, at 8.2.3.2.5.). In these studies, effect estimates for deaths from all causes fall in a range of 6 to 13 percent increased risk per 10 $\mu g/m^3$ $PM_{2.5}$, while effect estimates for deaths from cardiopulmonary causes fall in a range of 6 to 19 percent per 10 $\mu g/m^3$ $PM_{2.5}$. For lung cancer mortality, the effect estimate was a 13 percent increase per 10 $\mu g/m^3$ $PM_{2.5}$ in the results of the extended analysis from the ACS cohort (Pope et al., 2002; CD, Table 8–12).

The prospective cohort studies have used air quality measurements averaged over long periods of time, such as several years, to characterize the long-term ambient levels in the community. The exposure comparisons are basically cross-sectional in nature, and do not provide evidence concerning any temporal relationship between exposure and effect (EPA, 2004, p. 9–42). As discussed in the Criteria Document, it is not easy to differentiate the role of historic exposures from more recent exposures, leading to potential exposure measurement error that is increased if average PM concentrations change over time differentially between areas (EPA, 2004, p. 5–118). Several new studies have used different air quality periods for estimating long-term exposure and tested associations with mortality for the different exposure periods. As discussed in section 3.6.5.4 of the Staff Paper, these analyses indicate that averaging PM concentrations over a longer time period results in stronger associations, and that the longer series of data is likely a better indicator of cumulative exposure. Thus, in evaluating these findings, EPA has focused on the results of analyses using fine particle or sulfate measurements for the longer exposure periods in the studies.

ii. Respiratory Morbidity

In the last review, several studies had reported that long-term PM exposure was linked with increased respiratory disease and decreased lung function. One study, using data from 24 U.S. and Canadian cities (''24 Cities'' study), reported associations with these effects and long-term exposure to fine particles or acidic particles, but not with PM_{10} exposure (Dockery et al., 1996; Raizenne et al., 1996). More specifically, statistically significant associations were reported between long-term exposure to fine particles and decreases in several measures of lung function evaluated at a single point in time (Raizenne et al., 1996). In addition, positive but not statistically significant associations were reported between long-term exposure to fine particles and prevalence of a range of respiratory conditions (e.g., asthma, bronchitis, chronic cough) (Dockery et al., 1996).

In the current review, new studies conducted in the U.S. have been based on data from cohorts of schoolchildren in 12 Southern California Communities and an adult cohort of Seventh Day Adventists (AHSMOG) (EPA, 2004, section 8.3.3.2). Information specifically on associations with long-term $PM_{2.5}$ exposures are available from the Southern California children's cohort study. Early findings from cross-sectional analyses done at the beginning of the study suggested associations between long-term $PM_{2.5}$ exposures and respiratory morbidity, but the findings were generally not statistically significant.[15] Later publications from this cohort have reported associations with lung function growth in children over four-year follow-up periods. In a study of a cohort of children followed from 4th to 7th grade, some measures of decreases in lung function growth were statistically significantly associated with increasing exposure to $PM_{2.5}$, whereas in a second cohort of 4th graders, the associations generally did not reach statistical significance (Gauderman et al., 2002). Decreases in measures of lung function growth were also reported for cohorts of older children, but the associations did not reach statistical significance (Gauderman et al., 2000). The Criteria Document finds that these studies ''provide the best evidence'' on effects of long-term fine particle exposure (EPA, 2004, p. 8–314). However, this is the only cohort study to have evaluated associations with decreases in lung function growth in children over time. Considered together, the Criteria Document finds that the evidence from these studies indicates that long-term $PM_{2.5}$ exposures may

[15] In an initial report on the prevalence of respiratory illnesses reported at the beginning of the study, positive associations, though not statistically significant, were reported between long-term $PM_{2.5}$ exposure and risk of bronchitis and cough only in the subset of children with asthma (McConnell et al., 1999), and no significant associations with long-term $PM_{2.5}$ exposure were reported for the full cohort (Peters et al., 1999a). In addition, long-term $PM_{2.5}$ exposure was associated with decreases in some lung function measurements made at that time, but the associations were only statistically significant for females (Peters et al., 1999b).

result in chronic respiratory effects (EPA, 2004, p. 8–314).

3. Integration and Interpretation of the Health Evidence

In evaluating the evidence from epidemiologic studies, the Criteria Document and Staff Paper focused on well-recognized criteria, including the strength of associations; robustness of reported associations to the use of alternative model specifications, potential confounding by co-pollutants, and exposure misclassification related to measurement error; consistency of findings in multiple studies of adequate power, and in different persons, places, circumstances and times; the nature of concentration-response relationships; and information from so-called natural experiments or intervention studies. These evaluations addressed key methodological issues that are relevant to interpretation of evidence from epidemiologic studies. Further, findings from epidemiologic studies were integrated with experimental (e.g., dosimetric and toxicologic) studies, in considering the extent of coherence and biological plausibility of effects observed in epidemiologic studies. This integrative assessment provided the basis for the judgments made in the Criteria Document and Staff Paper about the extent to which causal inferences can be made about observed associations between health endpoints and $PM_{2.5}$ (as well as other indicators or constituents of ambient PM), acting alone and/or in combination with other pollutants. Key elements of these evaluations are briefly summarized below.

(1) For short-term exposures to fine particles, in considering the magnitude and statistical strength of the associations, there is a pattern of positive and often statistically significant associations for cardiovascular and respiratory health outcomes with short-term exposure to PM_{10} and $PM_{2.5}$. Of particular note are several multi-city studies that have yielded relative risk estimates for associations between short-term exposure to various indices of PM and mortality or morbidity. Although small in size, the effect estimates from multi-city studies have great precision due to the statistical power of the studies. New analyses of pre-existing cohorts with studies of long-term exposure to fine particles are available that confirm and strengthen conclusions from the previous review, although the effect estimates are sensitive to education level, co-pollutant effects of SO_2, and spatial correlation, as discussed above.

(2) The Criteria Document and Staff Paper have evaluated the robustness of epidemiologic associations in part by considering the effect of differences in statistical model specification, potential confounding by co-pollutants and exposure error on PM-health associations (EPA, 2004, section 9.2.2.2; EPA, 2005a, sections 3.4.2 and 3.6).

As discussed in section 8.4.2 of the Criteria Document and section 3.6.3 of the Staff Paper, the influence of alternative modeling strategies on epidemiologic study results was assessed, with a particular focus on the recent set of analyses to address statistical modeling questions in epidemiologic studies for short-term PM exposures. Numerous recent studies used a certain type of statistical method (i.e., generalized additive methods (GAM)) in widely used statistical software (Splus), and it was discovered that the default program settings could potentially result in biased effect estimates for associations between pollutants and health outcomes. Results from a number of epidemiologic studies were reanalyzed to address this problem. These reanalyses also more broadly included the use of alternative statistical models and alternative methods of control for time-varying effects, such as weather or season (HEI, 2003). In general, the results of the reanalyses to address the use of default program settings in the Splus software showed little change in effect estimates for some studies; in others the effect estimates were reduced in size, though it was observed that the reductions were often not substantial (EPA, 2004, p. 9–35). For example, in comparing results for numerous studies of mortality associations with PM_{10}, the Criteria Document found that the extent of reduction in effect estimates resulting from reanalysis was smaller than the variation in effect estimate size across studies (EPA, 2004, p. 8–229 and Figure 8–15). A review panel commentary on the set of reanalysis studies (using various PM indicators) notes that most studies were considered to show ''little or no change'' in results with initial reanalyses to address questions about the use of modeling specifications in the statistical software package (HEI, 2003, pp. 258–259).

In addition, the reanalyses also refocused attention in general on the control for relationships between health effects and weather variables in time-series epidemiologic studies; such issues had been also discussed at length in the 1996 Criteria Document (EPA, 2004, section 8.4.3.5). The reanalysis results showed greater sensitivity to the modeling approach used to account for temporal effects and weather variables than to correcting the initial problem with default settings in the use of GAM in Splus software (EPA, 2004, p. 8–236). For example, in the review panel commentary, sixteen of the reanalyzed studies were considered to have ''little or no change'' in results of initial reanalyses, while only two studies showed ''substantial'' changes (Goldberg and Burnett, 2003; some results in Ito, 2003; HEI, 2003, pp. 258–259). In contrast, four of the eight studies that were reanalyzed with additional methods to adjust for time-related variables were considered to show ''substantial'' changes in effect estimate size (HEI, 2003, p. 262).

The recent time-series epidemiologic studies evaluated in the Criteria Document have included some degree of control for variations in weather and seasonal variables. As summarized in the HEI review panel commentary, selecting a level of control to adjust for time-varying factors, such as temperature, in time-series epidemiologic studies involves a trade-off. For example, if the model does not sufficiently adjust for the relationship between the health outcome and temperature, some effects of temperature could be falsely ascribed to the pollution variable. Conversely, if an overly aggressive approach is used to control for temperature, the result would possibly underestimate the pollution-related effect and compromise the ability to detect a small but true pollution effect (EPA, 2004, p. 8–236; HEI, 2003, p. 266). The selection of approaches to address such variables depends in part on prior knowledge and judgments made by the investigators, for example, about weather patterns in the study area and expected relationships between weather and other time-varying factors and health outcomes considered in the study. While recognizing the need for further exploration of alternative modeling approaches for time-series analyses, the Criteria Document found that the studies included in this part of the reanalysis in general continued to demonstrate associations between PM and mortality and morbidity beyond those attributable to weather variables alone (EPA, 2004, pp. 8–340, 8–341). Further, considering the full set of reanalyses, the Criteria Document concludes that associations between short-term exposure to PM and various health outcomes are generally robust to the use of alternative modeling strategies, again recognizing that further evaluation of alternative modeling strategies was warranted (EPA, 2004, p. 9–48).

For long-term exposure to fine particles, the reanalysis and extended analyses of data from prospective cohort studies, discussed above in section II.A.2, have shown that reported associations between mortality and long-term exposure to fine particles are robust to alternative modeling strategies (Krewski et al., 2000). As stated in the reanalysis report, ''The risk estimates reported by the Original Investigators were remarkably robust to alternative specifications of the underlying risk models, thereby strengthening confidence in the original findings'' (Krewski et al., 2000, p. 232). In extended analysis, Krewski et al. (2000) identified model sensitivities related to education level and spatial correlation, as well as to co-pollutant effects of SO_2, as discussed below.

The Criteria Document also included extensive evaluation of the sensitivity of PM-health responses to confounding by gaseous co-pollutants (EPA, 2004, section 8.4.3, Figures 8–16 to 8–19). Results of new multi-city short-term exposure studies, that combine data from locations with different mixes of pollutants, provide important new results. Using PM_{10}, the NMMAPS results indicated that associations with mortality were not confounded by co-pollutant concentrations across 90 U.S. cities (Dominici, 2003),[16] and a similar lack of confounding was observed in a mortality study across 10 U.S. cities (Schwartz, 2003b) (EPA, 2004, Figure 8–16). That is, in these studies, the size of the effect estimates are little changed and the associations remain statistically significant in multi-pollutant models including one or more of the gaseous co-pollutants. Similar results are seen in some single-city studies using $PM_{2.5}$ for some health outcomes in which the single-pollutant model association was statistically significant (EPA, 2004, Figures 8–16 to 8–18), including the association with mortality in Santa Clara County, CA (Fairley, 2003); associations with hospital admissions in Detroit (for heart failure and pneumonia in Ito, 2003) and Seattle (for asthma in Sheppard et al., 2003); and associations with cardiovascular-related biomarkers in Boston (Gold et al., 2000). The size of the effect estimates were little changed in other studies as well in which the single-pollutant model associations were not statistically significant (e.g., for some health outcomes in Ito, 2003; for mortality in Chock et al., 2000). In yet other studies, however, for some combinations of pollutants in some areas, substantial reductions in the size of the effect estimates for $PM_{2.5}$ were observed; notably, Moolgavkar (2003) reports substantial reductions in effect estimates when CO is included in models for mortality and hospitalization in Los Angeles, and Thurston et al. (1994) and Delfino et al. (1998) report substantial reductions when O_3 is included in models for hospital admissions in Toronto and emergency department visits in Montreal, respectively.[17] It is recognized that collinearity between co-pollutants can make interpretation of such multi-pollutant model results difficult (EPA, 2004, p. 8–253). Further, associations between long-term exposure to $PM_{2.5}$ and mortality were not generally sensitive to inclusion of co-pollutants, with the notable exception of the inclusion of SO_2 in multipollutant models used in the reanalysis of the ACS study, as discussed above in section II.A.2 (EPA, 2004, p. 8–136). Overall, the Criteria Document concluded that these studies indicate that effect estimates for associations between mortality and morbidity and various PM indices are generally robust to confounding by co-pollutants, while recognizing that disentangling the effects attributable to various pollutants within an air pollution mixture is challenging (EPA, 2004, p. 9–37).

Finally, as discussed in section 3.6.2, a number of recent studies have evaluated the influence of exposure error on PM-health associations. This includes both consideration of error in measurements of PM and other co-pollutants, and the degree to which measurements from an individual monitor reflect exposures to the surrounding community. As further discussed in section 3.6.2, several studies have shown that fairly extreme conditions (e.g., very high correlation between pollutants and no measurement error in the ''false'' pollutant) are needed for complete ''transfer of causality'' of effects from one pollutant to another (EPA, 2004, p. 9–38). In comparing fine and thoracic coarse particles, the Criteria Document observes that exposure error is likely to be more important for associations with $PM_{10-2.5}$ than with $PM_{2.5}$, since there is generally greater error in $PM_{10-2.5}$ measurements, $PM_{10-2.5}$ concentrations are less evenly distributed across a community, and less likely to penetrate into buildings (EPA, 2004, p. 9–38). Therefore, while the Criteria Document concludes that associations reported with PM_{10}, $PM_{2.5}$ and $PM_{10-2.5}$ are generally robust, it recognizes that factors related to exposure error may result in reduced precision for epidemiologic associations with $PM_{10-2.5}$ (EPA, 2004, p. 9–46).

(3) Consistency refers to the persistent finding of an association between exposure and outcome in multiple studies of adequate power in different persons, places, circumstances and times (CDC, 2004). The 1996 Criteria Document reported associations between short-term PM exposure and mortality or morbidity from studies conducted in locations across the U.S. as well as in other countries, and concluded that the epidemiologic data base had ''general internal consistency'' (EPA, 1996a, p. 13–30). New multi-city studies have allowed evaluation of consistency in effect estimates across geographic locations, using uniform statistical modeling approaches; the results suggest that effect estimates differ from one location to another, but the extent of variation is not clear. For example, the Canadian 8-city study reported no evidence of heterogeneity in city-specific results in the initial study findings; however, in the reanalysis to address model specification issues, the findings suggested more evidence of heterogeneity in associations between mortality and short-term $PM_{2.5}$ exposure (Burnett and Goldberg, 2003; EPA, 2004, p. 9–39). The Criteria Document discussed a number of factors that would be likely to cause variation in PM-health outcomes in different populations and geographic areas in section 9.2.2.3, including indicators of exposure to traffic-related pollution, population characteristics that affect susceptibility or exposure differences, distribution of PM sources, or geographic features that would affect the spatial distribution of PM (EPA, 2004, p. 9–41). In addition, the use of data collected on a 1-in-6 or 1-in-3 day schedule results in reduced statistical power, resulting in less precision for estimated effect estimates for the individual cities and increased potential variability in results (EPA, 2004, p. 9–40). Overall, the Criteria document concluded that ''[f]ocusing on the studies with the most precision, it can be concluded that there is much consistency in epidemiologic evidence regarding associations between short-term and long-term exposures to fine

[16] In the HEI Review Panel commentary on the results of the NMMAPS multi-city analyses, the Panel stated that the results did not show a confounding effect of other pollutants, observing that the PM_{10} effects on mortality were not changed by addition of either O_3, SO_2, NO_2 or CO to the models (HEI, 2000, p. 77).

[17] The correlation coefficients between concentrations of $PM_{2.5}$ and the noted co-pollutants in these studies were high; the coefficient with CO in Los Angeles was 0.58, and the coefficients with O_3 were 0.58 and 0.72 in Montreal and Toronto, respectively.

particles and cardiopulmonary mortality and morbidity.'' (EPA, 2004, p. 9–47).

(4) The form of concentration-response relationships (e.g., linear, sigmoid) and the potential existence of thresholds was one of the important research questions remaining in the previous review. The Criteria Document recognized that it is reasonable to expect that there likely are biologic thresholds for different health effects in individuals or groups of individuals with similar innate characteristics and health status (EPA, 2004, Section 9.2.2.5). Individual thresholds would presumably vary substantially from person to person due to individual differences in genetic-level susceptibility and pre-existing disease conditions (and could even vary from one time to another for a given person). Thus, it would be difficult to detect a distinct threshold at the population level, below which no individual would experience a given effect, especially if some members of a population are unusually sensitive even down to very low concentrations. The person-to-person difference in the relationship between personal exposure to PM of ambient origin and the concentration observed at a monitor may also add to the variability in observed concentration-response relationships, further obscuring potential population thresholds within the range of observed concentrations (CD, p. 9–43, 9–44).

Several new epidemiologic studies have used different modeling methods to address this question, and most have been unable to detect threshold levels in the relationship between short-term PM exposure (generally using PM_{10}) and mortality; in fact, one single-city analysis suggests that statistical methods would allow detection of a threshold in the epidemiologic data if a clear threshold existed. However, a few analyses in individual cities have provided suggestions of some potential threshold levels, generally at fairly low ambient concentrations. One single-city study used $PM_{2.5}$ and $PM_{10\text{-}2.5}$ measurements in Phoenix and reported that there was suggestive evidence of a threshold for the association between mortality and short-term exposure to $PM_{2.5}$ in the range of 20–25 $\mu g/m^3$ (Smith et al., 2000; EPA, 2004, p. 8–322).

The shape of the concentration-response function for long-term exposure to $PM_{2.5}$ with mortality was evaluated using data from the ACS cohort. In the ACS reanalysis, the authors report that the concentration-response functions for $PM_{2.5}$ and all-cause and cardiopulmonary mortality demonstrate near-linear increasing trends through the range of particle levels observed in the fine particle cohort (Krewski, p. 160). However, the HEI Review Committee concluded that these results show no clear evidence either for or against overall linearity (Krewski, p. 265). In the extended ACS study, the authors reported that the associations for all-cause, cardiovascular and lung cancer mortality ''were not significantly different from linear associations'' (Pope, et al., 2002).

Thus, evaluation of the health effects data summarized in the Criteria Document provides no evidence to support selecting any particular population threshold for $PM_{2.5}$. The Staff Paper also recognized, however, that it is reasonable to expect that, for individuals, there may be thresholds for specific health responses and that it is possible that such thresholds exist toward the lower end of these ranges (or below these ranges) but cannot be detected due to variability in susceptibility across a population. Even in those few studies with suggestive evidence of such thresholds, the potential thresholds are at fairly low concentrations (EPA, 2004, sections 8.4.7 and 9.2.2.5).

(5) Few studies are available that assess the extent to which reductions in ambient PM actually lead to reductions in health effects attributable to PM. As discussed in sections 8.2.3.4 and 9.2.2.6 of the Criteria Document, several epidemiologic studies were done in the Utah Valley area over a time period when a major source of PM was closed, resulting in markedly decreased PM_{10} concentrations. An epidemiologic study reported that respiratory hospital admissions decreased during the plant closure time period (EPA, 2004, p. 8–131; Pope et al., 1989). Newly available controlled human exposure and animal toxicology studies, using particles extracted from stored PM_{10} sampling filters from the Utah Valley, have shown inflammatory responses that are greater with extracts of particles collected during the time period of source operation than when the source was closed, suggesting that the PM from the steel mill was more harmful than other ambient PM on an equal mass basis (EPA, 2004, p. 9–73). Epidemiologic studies in Dublin, Ireland and Hong Kong also provides evidence for reduced relative risks for mortality when PM (measured as BS or PM_{10}) and SO_2 were reduced as the result of interventions aimed at reducing air pollution. The Criteria Document concluded that this small group of studies add further support to the results of the hundreds of other epidemiologic studies linking ambient PM exposure to an array of health effects, and provide strong evidence that reducing emissions of PM and gaseous pollutants has beneficial public health impacts (EPA, 2004, p. 9–45 to 9–46).

(6) Several issues related to fine particle exposure time periods were assessed in the Criteria Document, as summarized in section 3.6.5 of the Staff Paper. As discussed above in this section, these include the exposure time periods used in long-term exposure studies as well as health outcome associations with very short time periods (e.g., 2-hour average). An additional issue is the time period (''lag'') between fine particle exposure and health outcome that is reported in short-term exposure study results. In these epidemiologic studies, associations are often tested for a range of lag periods, for example, with PM concentrations from the same day as the effect, and one or more days preceding the effect. In evaluating these results, it is important to consider the pattern of results that is seen across the series of lag periods. If there is an apparent pattern of results across the different lags, with positive associations reported for a series of consecutive lag periods, then selecting the single-day lag with the largest effect from a series of positive associations is likely to underestimate the overall effect size, since single-day lag effect estimates do not fully capture the risk that may be distributed over adjacent or other days (EPA, 2004, sections 8.4.4 and 9.2.2.4). For many epidemiologic studies, the authors have reported just such a pattern of associations across several consecutive lag periods (EPA, 2004, p. 8–279). However, if there is no apparent pattern or reported effects vary across lag days, any result for a single day may well be biased (CD, p. 9–42).

Some new studies have used a ''distributed lag'' model approach, that captures an effect of PM over a series of days following exposure.[18] Where effects are found for a series of lag periods, a distributed lag model will more accurately characterize the effect estimate size. A number of recent studies that have investigated associations with distributed lags provide effect estimates for health responses that persist over a period of time (days to weeks) after the exposure period. Effect estimates from distributed lag models are thus often, but not always, larger in size that those for single-day lag periods (EPA, 2004, p. 8–281).

[18] The available studies have generally used PM_{10}, but not $PM_{2.5}$ or $PM_{10\text{-}2.5}$.

The Criteria Document concludes that it is likely that the most appropriate lag period for a study will vary depending on the health outcome and the specific pollutant under study. For example, for a health outcome such as a delayed asthma response, the lag period of a day or several days might be expected between exposure and outcome; however, some cardiovascular responses might be expected to occur within a very short time period (e.g., an hour) after exposure (EPA, 2004, p. 8–279). As shown in Figures 8–24 to 8–28, the Criteria Document notes a pattern of stronger associations between PM_{10} and mortality or cardiovascular hospitalization with shorter lag periods (e.g., same-day or 1-day lagged PM_{10}). For other effects, however, such as respiratory symptoms, asthma emergency department visits or hospitalization, stronger effects were reported with PM concentrations averaged over several days (EPA, 2004, pp. 8–273 to 8–279). Thus, the Criteria Document concludes that one would expect to see different best-fitting lags for different health effects, based on potentially different biological mechanisms as well as individual variability in responses (EPA, 2004, p. 8–342). For some health outcomes, it is reasonable to expect associations to be observed with PM exposures on the same day or with very short lag periods, but not longer lag periods. In other cases, multi-day average exposure periods or distributed lag models would more appropriately estimate potential PM-related health risks.

(7) Looking more broadly to integrate epidemiologic evidence with that from exposure-related, dosimetric and toxicologic studies, EPA has considered the coherence of the evidence and the extent to which the new evidence provides insights into mechanisms by which PM, especially fine particles, may be affecting human health. Progress made in gaining insights into potential mechanisms lends support to the biologic plausibility of results observed in epidemiologic studies. For cardiovascular effects, the convergence of important new epidemiologic and toxicologic evidence (especially from studies using concentrated ambient particles) builds support for the plausibility of causal associations, especially between fine particles and physiological endpoints indicative of increased risk of cardiovascular disease and changes in cardiac rhythm. This finding is supported by new cardiovascular effects research focused on fine particles that has notably advanced our understanding of potential mechanisms by which $PM_{2.5}$ exposure, especially in susceptible individuals, could result in changes in cardiac function or blood parameters that are risk factors for cardiovascular disease. For respiratory effects, toxicologic studies have provided evidence that supports plausible biologic pathways for fine particles, including inflammatory responses, increased airway responsiveness, or altered responses to infectious agents. Further, coherence across a broad range of cardiovascular and respiratory health outcomes is supported by evidence from epidemiologic and toxicologic studies done in the same location, for example, in the series of studies conducted in or evaluating ambient PM from Boston and the Utah Valley (EPA, 2004, 7–42 to 43, 7–46 to 47, and 9–45). Toxicologic studies have suggested that some combustion-related particles, including particles from wood burning and diesel engine exhaust, but not others such as coal fly ash, may have carcinogenic effects (EPA, 2004, Section 7.8.4). This evidence supports the plausibility of the observed relationship between fine particles and lung cancer mortality. Evidence for PM-related infant mortality and developmental effects poses an emerging concern, but the current information is still very limited in support of the plausibility of potential ambient PM relationships. More generally, toxicologic animal studies often test effects of exposures to individual chemical components, and thus the physical and chemical characteristics may differ from those of particles in ambient air to which humans are exposed. These and other differences in toxicologic and epidemiologic study designs complicate the assessment of coherence in results from across disciplines (EPA, 2004, section 9.2.3.1; Schlesinger and Cassee, 2003).

Overall, the Criteria Document finds that much more evidence is now available related to the coherence and plausibility of effects than in the last review. For short-term exposures, integration of evidence from epidemiologic and toxicologic studies indicates both coherence and plausibility of effects on the cardiovascular and respiratory systems, especially for fine particles (EPA, 2004, p. 9–79). There is evidence supporting coherence and plausibility for the observed associations between long-term exposures to fine particles and lung cancer mortality (EPA, 2004, p. 9–78).

(8) In summary, as discussed in the Staff Paper (section 3.5) and the Criteria Document (section 9.2.2), the extensive body of epidemiologic evidence now available continues to support likely causal associations between $PM_{2.5}$ and a broad range of mortality and morbidity health outcomes based on an assessment of the strength of the evidence, including the strength and robustness of reported associations and the consistency of the results. While the limitations and uncertainties in the available evidence suggest caution in interpreting the epidemiologic studies at the lower levels of air quality observed in the studies, the evidence now available provides strong support that both short-term and long-term exposures to fine particles are plausibly associated with a broad range of effects on the respiratory and cardiovascular systems. The Criteria Document concludes: ''the epidemiological evidence continues to support likely causal associations between $PM_{2.5}$ and PM_{10} and both mortality and morbidity from cardiovascular and respiratory diseases, based on an assessment of strength, robustness, and consistency in results.'' (EPA, 2004, p. 9–48). In its integrative assessment, the Criteria Document finds that health evidence from various disciplines provides a strong and coherent basis for concluding that both short-term and long-term exposure to fine particles is associated with health effects ranging from subtle changes in lung function to premature mortality.

4. Sensitive Subgroups for $PM_{2.5}$-Related Effects

As described in the PM Criteria Document, the term susceptibility refers to innate (e.g., genetic or developmental) or acquired (e.g., personal risk factors, age) factors that make individuals more likely to experience effects with exposure to pollutants. A number of population subgroups have been identified as potentially susceptible to health effects as a result of PM exposure, including people with existing heart and lung diseases, including diabetes, and older adults and children. In addition, new attention has been paid to the concept of some population groups having increased vulnerability to pollution-related effects due to factors such as socioeconomic status or factors that result in particularly elevated exposure levels, such as residence near sources such as roadways (EPA, 2004, p. 9–81).

A good deal of evidence indicates that people with existing heart or lung diseases are more susceptible to PM-related effects. In addition, new studies have suggested that people with diabetes, who are at risk for cardiovascular disease, may have

increased susceptibility to PM exposures. As discussed in Section 9.2.4.1 of the Criteria Document, this body of evidence includes findings from epidemiologic studies that associations with mortality or morbidity are greater in those with preexisting conditions, as well as evidence from toxicologic studies using animal models of cardiopulmonary disease. In addition, dosimetric evidence indicates that deposition of particles is increased, and can be focused in ''hot spots'' in the respiratory tract, in people with chronic respiratory diseases.

Two age groups, older adults and the very young, are also potentially at greater risk for PM-related effects. Epidemiologic studies have generally not shown striking differences between adult age groups. However, some epidemiologic studies have suggested that serious health effects, such as premature mortality, are greater among older populations (EPA, 2005a, p. 8–328). In addition, preexisting respiratory or cardiovascular conditions are more prevalent in older adults than younger age groups; thus there is some overlap between potentially susceptible groups of older adults and people with heart or lung diseases.

Epidemiologic evidence has reported associations with emergency hospital admissions for respiratory illness and asthma-related symptoms in children. Several factors may make children susceptible to PM-related effects, including the greater ventilation rate per kilogram body weight in children, greater prevalence of chronic asthma, and the fact that children are more likely to be active outdoors and thus have greater exposures. In addition, there is a more limited body of new evidence from epidemiologic studies for potential PM-related health effects in infants, using various PM indicators. Results from this body of evidence, though mixed, are suggestive of possible effects; more research is needed to further elucidate the potential risks of PM exposure for these health outcomes (EPA, 2004, p. 8–222).

In summary, there are several population groups that may be especially susceptible or vulnerable to PM-related effects. These groups include those with preexisting heart and lung diseases, older adults and children. Emerging evidence indicates that people from lower socioeconomic strata or who have particularly elevated exposures may be more vulnerable to PM-related effects.

5. $PM_{2.5}$-Related Impacts on Public Health

As just discussed, there are several population groups that may be especially susceptible or vulnerable to effects from exposure to PM. These population subgroups, such as young children or older adults, and people with pre-existing heart or lung diseases, constitute a large portion of the U.S. population. For example, approximately 22 million people, or 11 percent of the U.S. population, have received a diagnosis of heart disease, about 20 percent of the population has hypertension and about 9 percent of adults and 11 percent of children in the U.S. have been diagnosed with asthma. In addition, about 26 percent of the U.S. population is under 18 years of age,[19] and about 12 percent is 65 years of age or older (EPA, 2004, Table 9–4). EPA recognizes that combining fairly small risk estimates and small changes in PM concentrations with large groups of the U.S. population would result in large public health impacts.

One issue that is important for interpreting the public health implications of the associations reported between mortality and short-term exposure to PM is whether mortality is occurring only in very frail individuals (sometimes referred to as ''harvesting''), resulting in loss of just a few days of life expectancy. A number of new analyses assess the likelihood of such ''harvesting'' occurring in the short-term exposure studies. Overall, the Criteria Document concludes from the time-series studies that there appears to be no strong evidence to suggest that short-term exposure to PM is only shortening life by a few days (EPA, 2004, Section 8.4.10). In addition to the evidence from short-term exposure studies discussed above, one new report used the mortality risk estimates from the ACS prospective cohort study to estimate potential loss of life expectancy from PM-related mortality in a population. The authors estimated that the loss of population life expectancy associated with long-term exposure to $PM_{2.5}$ was on the order of a year or so (EPA, 2004, p. 8–334). The Criteria Document recognizes that these calculations were based on studies in adult populations, and potential population life shortening would be increased if the new, albeit limited, evidence from infant mortality studies was considered (EPA, 2004, p. 8–335). The Criteria Document also observes that the risk estimates reported for long-term fine particle exposures and lung cancer mortality are in about the same range as the risk seen for a nonsmoker living with a smoker (EPA, 2004, p. 9–94).

Large subgroups of the U.S. population are included in subpopulations considered to be potentially sensitive to effects related to fine particle exposures (EPA, 2004, section 9.2.5.1). While individual epidemiologic effect estimates may be small in size, the public health impact of the mortality and morbidity associations can be quite large. In addition, it appears that mortality risks are not limited to the very frail. Taken together, these results suggest that exposure to ambient PM, especially $PM_{2.5}$, can have substantial public health impacts (EPA, 2004, p. 9–93).

B. Quantitative Risk Assessment

This section discusses the approach used to develop quantitative risk estimates associated with exposures to $PM_{2.5}$ building upon a more limited risk assessment that was conducted during the last review.[20] At that time, EPA conducted a very limited risk assessment covering a portion of two cities (i.e., Philadelphia County and Southeast Los Angeles County) for which ambient $PM_{2.5}$ data were available. For short-term exposure mortality and morbidity health effects, the prior assessment relied on either pooled analyses that combined the results from several studies of individual cities or individual single- and multi-city studies, none of which included the two urban counties for which risks were estimated, to estimate concentration-response relationships for these two cities. EPA recognized that the lack of city-specific relative risks introduced substantial uncertainties in the risk estimates due to inherent differences (e.g., different population characteristics, PM size distributions) that might influence the concentration-response relationships. For long-term exposure mortality, the prior assessment relied on the concentration-response relationship reported in the original ACS study (Pope et al., 1995). Additional important uncertainties noted at the time of that assessment with respect to all health effects included: (1) The absence of clear evidence regarding mechanisms of

[19] Health studies that have suggested that children are susceptible to PM-related effects include varying age ranges, for example, for hospital admissions in children up to 18 years of age, or respiratory symptoms in panels of 4th and 5th grade children.

[20] The methodology, scope, and results from the risk assessment conducted in the last review are described in Chapter 6 of the 1996 Staff Paper (EPA, 1996b) and in several technical reports (Abt Associates, 1996; Abt Associates, 1997a,b) and publications (Post et al., 2000; Deck et al., 2001).

action for the various effects of interest, (2) uncertainties about the shape of the concentration-response relationships; and (3) concern about whether the use of ambient $PM_{2.5}$ fixed-site monitoring data adequately reflected the relevant population exposures to PM that are responsible for the reported health effects (61 FR 65650).

In light of the substantial uncertainties in the prior risk estimates, EPA placed greater weight on the overall conclusions derived from the health effect studies—that ambient PM was likely causing or contributing to significant adverse effects at levels below those permitted by the then-existing PM_{10} standards—than on the specific concentration-response functions and quantitative risk estimates derived from them. Nevertheless, EPA judged that the assessment provided reasonable estimates as to the possible extent of risk for those effects given the available information (62 FR at 38656).

1. Overview

The updated risk assessment conducted as part of this review includes estimates of (1) risks of mortality, morbidity, and symptoms associated with recent ambient $PM_{2.5}$ levels; (2) risk reductions and remaining risks associated with just meeting the current suite of $PM_{2.5}$ NAAQS; and (3) risk reductions and remaining risks associated with just meeting various alternative $PM_{2.5}$ standards in a number of example urban areas. This risk assessment is more fully described and presented in the Staff Paper (EPA, 2005a, Chapter 4) and in a technical support document, *Particulate Matter Health Risk Assessment for Selected Urban Areas* (Abt Associates, 2005a). The scope and methodology for this risk assessment were developed over the last few years with considerable input from the CASAC PM Panel and the public.[21] The information presented in these documents included specific criteria for the selection of health endpoints and studies to include in the assessment. It also addressed which alternative statistical models (e.g., for control of time-varying factors such as weather and for various lags) to include in the assessment, recognizing that some of the health studies presented results from a large number of alternative models. In an advisory letter sent by CASAC to the Administrator documenting its advice in May 2002 (Hopke, 2002), CASAC concluded that the general methodology and framework to be used in the assessment were appropriate.

The goals of the $PM_{2.5}$ risk assessment were: (1) To provide estimates of the potential magnitude of mortality and morbidity effects associated with current $PM_{2.5}$ levels, and with meeting the current suite of $PM_{2.5}$ NAAQS and alternative $PM_{2.5}$ standards, in specific urban areas; (2) to develop a better understanding of the influence of various inputs and assumptions on the risk estimates; and (3) to gain insights into the distribution of risks and patterns of risk reductions associated with meeting alternative suites of $PM_{2.5}$ standards. EPA recognizes that there are many sources of uncertainty and variability inherent in the inputs to this assessment and that there is a high degree of uncertainty in the resulting $PM_{2.5}$ risk estimates. While some of these uncertainties have been addressed quantitatively in the form of estimated confidence ranges around central risk estimates, other uncertainties and the variability in key inputs are not reflected in these confidence ranges, but rather have been addressed through separate sensitivity analyses or characterized qualitatively.

2. Scope and Key Components

The risk assessment estimates risks of various health effects associated with exposure to ambient $PM_{2.5}$ in nine urban areas selected to illustrate the public health impacts associated with a recent year of air quality and potential reductions in risk associated with just meeting the current suite of $PM_{2.5}$ standards and alternative suites of standards. The selection of urban areas was largely determined by identifying areas in the U.S. for which acceptable epidemiological studies were available that estimated concentration-response relationships for $PM_{2.5}$, which were then used in assessing the risks. Thus, unlike the prior risk assessment, the current risk assessment for short-term exposure mortality and morbidity health effects used concentration-response relationships reported in studies that included the urban areas for which risks were estimated. Based on a review of the evidence evaluated in the Criteria Document and Staff Paper, as well as the criteria discussed in Chapter 4 of the Staff Paper, the following broad categories of health endpoints were included in the risk assessment for $PM_{2.5}$ associated with short-term exposure: Total (non-accidental), cardiovascular, and respiratory mortality; hospital admissions for cardiovascular and respiratory causes; and respiratory symptoms not requiring hospitalization. Also included in the $PM_{2.5}$ risk assessment were total, cardiopulmonary, and lung cancer mortality associated with long-term exposure.

The available long-term exposure mortality concentration-response functions are all based on cohort studies, in which a cohort of individuals is followed over time. Based on the evaluation contained in the Criteria Document and EPA's assessment of the complete data base addressing mortality associated with long-term exposure to $PM_{2.5}$, studies based on the following two cohorts were identified as being particularly relevant for the $PM_{2.5}$ risk assessment: (1) The Six Cities study cohort (referred to as Krewski et al. (2000)—Six Cities) and (2) the ACS cohort (referred to Krewski et al. (2000)—ACS), which includes a much larger number of individuals from many more cities. In addition, Pope et al. (2002) extended the follow-up period for the ACS cohort to sixteen years and published findings on the relation of long-term exposure to $PM_{2.5}$ and all-cause mortality as well as cardiopulmonary and lung cancer mortality (referred to as Pope et al. (2002)—ACS extended).[22]

The available short-term exposure morbidity and mortality concentration-response functions used in the risk assessment are all from time series studies. The risk assessment included only those health endpoints for which the the Criteria Document concluded that there is likely to be a causal relationship with short-term exposure to $PM_{2.5}$ based on the overall weight of the evidence from the collective body of available studies. Also, given the large number of endpoints and studies addressing $PM_{2.5}$-related effects, the assessment only included the more severe and better understood (in terms of health consequences) health effects. As noted above, in contrast to the prior risk assessment, the concentration-response functions used in this assessment for each urban area are

[21] In June 2001, OAQPS released a draft document, PM NAAQS Risk Analysis Scoping Plan (EPA, 2001), for CASAC consultation and public comment, which described staff's general plan for this assessment. In January 2002, OAQPS released a more detailed draft document, Proposed Methodology for Particulate Matter Risk Analyses for Selected Urban Areas (Abt Associates, 2002), for CASAC review and public comment, which described staff's plans to assess (a) $PM_{2.5}$-related risks for several health endpoints, including mortality, hospital admissions, and respiratory symptoms and (b) $PM_{10-2.5}$-related risks for hospital admissions and respiratory symptoms (as discussed below in Section III.B).

[22] The use of these particular cohort studies to estimate health risks associated with long-term exposure to $PM_{2.5}$ is consistent with the views expressed in the National Academy of Sciences (2002) report, ''Estimating the Public Health Benefits of Proposed Air Pollution Regulations,'' and the Science Advisory Board Clean Air Act Compliance Council review of the proposed methodology to estimate the health benefits associated with the Clean Air Act (SAB, 2004).

based on results of studies for that specific area or from a multi-city study that included that specific area.

The concentration-response relationships used in the assessment were based on findings from human epidemiological studies that have relied on fixed-site, population-oriented, ambient monitors as a surrogate for actual ambient $PM_{2.5}$ exposures. The risk assessment addresses risks attributable to anthropogenic sources and activities (i.e., risk associated with concentrations above policy-relevant background [23] or above various selected higher cutpoints intended as surrogates for alternative assumed population thresholds). This approach of estimating risks in excess of background was judged to be more relevant to policy decisions regarding ambient air quality standards than risk estimates that include effects potentially attributable to uncontrollable background PM concentrations. For the base case analyses, an estimate of the annual average background level was used, rather than a maximum 24-hour value, since estimated risks were aggregated for each day throughout the year.

In order to estimate the incidence of a particular health effect associated with recent conditions in a specific county or set of counties attributable to ambient $PM_{2.5}$ exposures in excess of background or various alternative cutpoints, as well as the change in incidence corresponding to a given change in $PM_{2.5}$ levels resulting from just meeting a specified set of alternative $PM_{2.5}$ standards, three elements are required. These elements are: (1) Air quality information (including recent air quality data for $PM_{2.5}$ from ambient monitors for the selected location, estimates of background $PM_{2.5}$ concentrations appropriate for that location, and a method for adjusting the recent data to reflect patterns of air quality estimated to occur when the area just meets a given set of $PM_{2.5}$ standards); (2) relative risk-based concentration-response functions that provide an estimate of the relationship between the health endpoints of interest and ambient PM concentrations; and (3) annual or seasonal baseline health effects incidence rates and population data, which are needed to provide an estimate of the annual or seasonal baseline incidence of health effects in an area before any changes in PM air quality.

The risk assessment for $PM_{2.5}$ included a series of base case analyses that characterized the uncertainty associated with the form of the concentration-response relationship drawn from the studies used in the assessment—this uncertainty had by far the greatest impact on estimated risks. Other uncertainties addressed in various sensitivity analyses (e.g., the use of single-versus multi-pollutant models, single-versus multi-city models, use of a distributed lag model, alternative assumptions about the relevant air quality for long-term exposure mortality, and alternative constant or varying background levels) all have a more moderate and often variable impact on the risk estimates in some or all of the cities.

In estimating health risks remaining upon just meeting the current and alternative $PM_{2.5}$ standards, the assessment includes a series of base cases, while noting that the confidence ranges in the estimates do not reflect all the identified uncertainties. As discussed above in section II.A.3, additional uncertainty for short-term exposure mortality is related to the use of alternative statistical models and methods to control for time-varying effects, such as weather or season, and to address alternative lag structures. To provide a consistent basis for comparison across studies and locations, the risk assessment used concentration-response functions based on the most common type of analysis (''generalized additive methods'') and on lag structures judged to be most appropriate for each specific health endpoint, as discussed in the Staff Paper (EPA, 2005a, p. 4–24). The risk assessment included a sensitivity analysis for one location where a wide array of statistical models and lags was reported in the health study for that location (Los Angeles, as reported in Moolgavkar, 2003). EPA recognizes that there is additional uncertainty associated with choices about appropriate modeling strategy (EPA, 2004, 8.4.2) and that this uncertainty is not included in the confidence ranges presented for the risk estimates.

As noted earlier, EPA recognizes that while there are likely biological thresholds in individuals for specific health endpoints, the available epidemiologic studies do not support or refute the existence of thresholds at the population level for either long-term or short-term $PM_{2.5}$ exposures within the range of air quality observed in the studies (EPA, 2004, 9.2.2.5). Thus, base case risks were estimated using not only the linear or log-linear concentration-response functions reported in the studies, but also using a series of modified linear functions, as discussed below, as surrogates for assumed non-linear functions that would reflect the possibility that thresholds may exist in the reported associations within the range of air quality observed in the studies.

For short-term exposure mortality and morbidity outcomes associated with $PM_{2.5}$, the initial base case includes linear or log-linear concentration-response models reported in the epidemiology studies which are applied down to the estimated policy-relevant background concentration level. Generally, the lowest measured concentrations in the short-term exposure studies were relatively near or below the estimated policy-relevant background levels such that little or no extrapolation was required beyond the range of data in the studies. In the case of the long-term exposure mortality studies for $PM_{2.5}$ that have been included in the risk assessment, the lowest measured levels were in the range 7.5 to 11 $\mu g/m^3$. For the initial base case scenario for this endpoint, the reported linear models were applied down to 7.5 $\mu g/m^3$, which is the lowest measured level reported in the long-term studies. Going down to an estimated policy-relevant background level for short-term exposure studies and to 7.5 $\mu g/m^3$ for long-term studies provides a consistent framework which facilitates comparison of risk estimates across urban locations within each group of studies and avoids significant extrapolation beyond the range of concentrations included in these studies.

Additional base case scenarios for both short- and long-term exposure health endpoints involved the use of alternative concentration-response functions that incorporated a modified linear slope with an imposed cutpoint (i.e., an assumed threshold). For mortality associated with short-term exposure, the base case analyses included risk estimates associated with cutpoints of 10, 15, and 20 $\mu g/m$. For mortality associated with long-term $PM_{2.5}$ exposure, cutpoints of 10 and 12 $\mu g/m^3$ were included. For the base case scenarios involving alternative cutpoints, the approach used to develop alternative functions incorporates a modified linear slope with an imposed cutpoint (i.e., an assumed population threshold) that is intended to reflect a

[23] Background PM concentrations used in the PM risk assessment were defined in Chapter 2 of the Staff Paper as the PM concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of PM and its precursors in the U.S., Canada, and Mexico. For the initial base case risk estimates, the midpoints of the appropriate ranges of annual average estimates for $PM_{2.5}$ background presented in the Staff Paper were used (i.e., eastern values were used for eastern study locations and western values were used for western study locations). Estimated policy-relevant background concentrations are 3.5 $\mu g/m^3$ in eastern cities, and 2.5 $\mu g/m^3$ in western cities.

hypothetical inflection point in a typical non-linear, ''hockey-stick'' shaped function, below which there is little or no population response. More specifically, the slope of the concentration-response relationship has been adjusted assuming that the upward-sloping portion of the ''hockey stick'' would be the slope estimated in the original epidemiologic study adjusted by the inverse of the proportion of the range of PM levels observed in the study that was above the cutpoint. The Staff Paper concludes that this simple slope adjustment approach represents a reasonable approach to illustrating the potential impact of possible non-linear concentration-response relationships. In its review of the Staff Paper and risk assessment, the CASAC PM Panel commented that for the purpose of estimating public health impacts, it ''favored the primary use of an assumed threshold of 10 μg/m^3'' and that ''a major research need is for more work to determine the existence and level of any thresholds that may exist or the shape of nonlinear concentration-response curves at low levels of exposure that may exist'' (Henderson, 2005a).

3. Risk Estimates and Key Observations

In focusing on the five study areas that do not meet the current $PM_{2.5}$ standards based on 2001–2003 air quality data (Detroit, Los Angeles, Philadelphia, Pittsburgh, and St. Louis), the total mortality risk estimates associated with simulating air quality reductions to just meet the current $PM_{2.5}$ standards (based on associations with long-term $PM_{2.5}$ exposure, and using the lowest cutpoint of 7.5 μg/m^3) range from several hundred to over 1500 deaths per year, which translate into an incidence rate of approximately 16 to 35 deaths per year per hundred thousand population.[24] These estimated risks associated with long-term exposure represent approximately 2.6 to 3.2 percent of total mortality in those areas. Estimated risks associated with long-term exposure based on an assumed cutpoint of 10 μg/m^3 are roughly half as large as the estimates based on a cutpoint of 7.5 μg/m^3. In the same five areas, the estimates of mortality risk associated with short-term $PM_{2.5}$ exposure, based on a cutpoint equal to policy-relevant background or 10 μg/m, range from less than 20 percent to over 50 percent of the estimates associated with long-term exposure.[25]

Reductions in risk associated with simulating air quality to just meet a range of lower alternative annual and 24-hour $PM_{2.5}$ standards were also estimated in this assessment. The estimated risk reductions are depicted graphically in the Staff Paper (EPA, 2005a, Figures 5–1 and 5–2 and Figures 5A–1 and 5A–2), showing patterns of estimated risk reductions associated with alternative suites of standards for all the various assumed cutpoints. As would be expected, patterns of increasing estimated risk reductions are observed as either the annual or 24-hour standard, or both, are reduced over the range considered in this assessment, and the estimated percentage reductions in risk are strongly influenced by the assumed cutpoint level.

The discussion below highlights additional observations and insights from this $PM_{2.5}$ risk assessment, together with important caveats and limitations.

(1) With respect to short-term exposure mortality and morbidity, this risk assessment provides the basis for greater confidence in the results as compared to the prior assessment, given that studies are now available using $PM_{2.5}$ as the indicator in a much greater number of locations, and the assessment is able to use city-specific functions that are matched to the locations for which risks are estimated. This contrasts with the use of pooled concentration-response functions in the prior assessment which did not include studies for the specific cities included in that assessment. However, EPA recognizes that the confidence ranges, which only reflect uncertainty associated with the precision of the study (related to the population size and duration of the study), may be larger for the current risk estimates due to the use of concentration-response functions from smaller, city-specific studies now versus the use of concentration-response functions from pooled sets of studies that have greater statistical precision. Comparing the risk estimates for the only two specific locations that were included in both the prior and current assessments, the magnitude of the estimates associated with just meeting the current annual standard, in terms of percentage of total incidence, is similar in one of the locations (Philadelphia) and the current estimate is lower in the other location (Los Angeles).

(2) With respect to long-term exposure mortality risk estimates, the prior risk assessment focused on the estimates based on the original ACS study (Pope et al., 1995). Since that time additional cohort analyses have been published and evaluated in the Criteria Document. EPA has greater confidence in the current risk estimates for long-term exposure mortality, given the extensive review of these studies and the extension of the ACS study to additional years of data, as well as improvements in the statistical approach. However, ACS-based risk estimates remain sensitive to plausible changes in statistical model specifications. The choice of studies and concentration-response functions to use for the base case risk estimates is discussed in the Staff Paper (EPA, 2005a, p. 4–25) and risk assessment report (Abt Associates, 2005, pp.49–50) and is consistent with the advice provided by both the National Academy of Sciences and the Science Advisory board Clean Air Act Compliance Council (see footnote 22). At the same time, EPA recognizes that alternative statistical models were examined in the reanalysis of the ACS and Six-Cities studies, and that the uncertainty associated with model selection (such as multipollutant models and different effect estimates associated with different educational levels) is not reflected in the confidence ranges presented in this assessment. Thus, for long-term exposure mortality risk estimates there are additional unquantified uncertainties associated with a lack of understanding as to which statistical model best represents the actual concentration-response function. The relative risk estimates used in the current risk assessment from the ACS extended study are only slightly smaller (1.06 with 95 percent confidence interval of 1.02–1.11) compared to the original ACS study (1.07 with 95 percent confidence interval 1.04–1.10) used in the prior assessment. In terms of the magnitude of the risk estimates, the estimates in terms of percentage of total incidence are very similar for the two specific locations included in both the prior and current assessments.

(3) A fairly wide range of risk estimates are observed for $PM_{2.5}$-related morbidity and mortality risk associated with recent air quality across the urban areas analyzed. The impact of adding additional co-pollutants to the models was variable; sometimes there was relatively little difference, while in other cases there were larger differences. The wide variability in risk estimates associated with a recent year of air

[24] The full range of quantitative risk estimates associated with just meeting the current $PM_{2.5}$ standards are presented in Tables 4–9, 4–10, 4–12, and 4–13 in Chapter 4 of the Staff Paper.

[25] In some areas, the 95 percent confidence ranges associated with the risk estimates for short-term exposure (but not long-term exposure) extend to below zero, reflecting appreciably more uncertainty in estimates based on positive but not statistically significant associations.

quality is to be expected given the wide range of $PM_{2.5}$ levels across the urban areas analyzed and the variation observed in the concentration-response relationships obtained from the original epidemiologic studies. Among other factors, this variability may reflect differences in the mixture of components or sources of fine particles, populations, exposure considerations (e.g., degree of air conditioning use), differences in co-pollutants and/or other stressors, differences in study design, and differences related to exposure and monitor measurement error.

(4) The single most important factor influencing the quantitative estimates of risk is which of the alternative concentration-response functions included in this assessment are considered to best represent the unknown ''true'' concentration-response relationships. In comparison, the following uncertainties have only a moderate impact on the risk estimates in some or all of the cities: choice of an alternative estimated constant background level, use of a distributed lag model, and alternative assumptions about the relevant air quality for estimating exposure levels for long-term exposure mortality. Use of a distribution of daily background concentrations had very little impact on the risk estimates.

The overall pattern of risk associated with short-term $PM_{2.5}$ exposures across the distribution of $PM_{2.5}$ air quality, as typically observed in urban areas, is similar to that observed in the last review. That is, on an annual basis, the very highest days (which pose the greatest risk in terms of deaths per day) contribute less to the total annual health risk associated with short-term exposures than the middle of the distribution, due to the much greater number of days that occur in this part of the air quality distribution.

(5) Risk estimates associated with just meeting the current suite of $PM_{2.5}$ standards in five urban areas that do not meet the current $PM_{2.5}$ standards showed a wide range of $PM_{2.5}$-related risk estimates for short-term exposure mortality and morbidity. This is likely due, in large part, to differences in concentration-response relationships among single-location short-term exposure studies, differences in baseline incidence rates, and varying population sizes. Results of a sensitivity analysis which applied one multi-city concentration-response function to all five urban areas analyzed narrowed considerably the range of risk estimates when a risk metric was used that normalized for different population sizes. However, it is still unknown whether the wider range of estimates observed using single-city concentration-response functions reflect methodological differences between studies and/or real city-to-city differences related to exposure, population, composition of the particles, or other factors.

(6) For the risk estimates associated with just meeting the current suite of $PM_{2.5}$ standards and alternative suites of standards, the single most important factor influencing the short- and long-term exposure mortality and morbidity estimates is again which of the alternative concentration-response functions included in this assessment are considered to best represent the unknown ''true'' concentration-response relationships. Several additional sources of uncertainty are introduced into this portion of the risk assessment, including: (1) Uncertainty in the degree to which the pattern of air quality concentration reductions estimated for the risk assessment cities represents the distribution of actual PM concentration changes that would be observed in a given area (''rollback uncertainty'') and (2) uncertainty concerning the degree to which current PM risk coefficients may reflect contributions from other pollutants, or uncertainty concerning whether all of the constituents of $PM_{2.5}$ would be reduced in similar proportion to the reduction in $PM_{2.5}$ as a whole, and, if not, what impact this would have on estimated reductions in risk. For areas where the current annual standard is the controlling standard, one alternative approach to rolling back the distribution of daily $PM_{2.5}$ concentrations, in which the upper end of the distributions of concentrations was reduced by a greater amount than the rest of the distribution, had little impact on the risk estimates. This approach or alternative approaches to rolling back the distribution of daily concentrations may have a greater impact on the risk estimates in areas where the daily standard is the controlling standard.

(7) For the risk estimates associated with just meeting the current or alternative suites of $PM_{2.5}$ standards, there is a significant decrease in the mortality risk estimates based on short-term $PM_{2.5}$ exposure remaining as one considers alternative higher cutpoints. There also is a significant increase observed in the percent reduction in estimated risk upon just meeting alternative standards with higher alternative cutpoints. These findings are even more pronounced for the mortality risk estimates associated with long-term $PM_{2.5}$ exposure as higher alternative cutpoint levels are considered.

C. Need for Revision of the Current Primary $PM_{2.5}$ Standards

The initial issue to be addressed in the current review of the primary $PM_{2.5}$ standards is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the existing standards should be revised. Based on the information and conclusions presented in the Criteria Document, summarized above in section II.A., the Staff Paper concludes that the newly available information generally reinforces the associations between $PM_{2.5}$ and mortality and morbidity effects observed in the last review. While important uncertainties and research questions remain, much progress has been made in reducing some key uncertainties since the last review. The examination of specific components, properties, and sources of fine particles that are linked with health effects remains an important research need. Other important research needs include better characterizing the shape of concentration-response functions, including identification of potential threshold levels, and methodological issues such as those associated with selecting appropriate statistical models in time-series studies to address time-varying factors (such as weather) and other factors (such as other pollution variables), and better characterizing population exposures. Nonetheless, important progress has been made in advancing our understanding of potential mechanisms by which ambient $PM_{2.5}$, alone and in combination with other pollutants, is causally linked with cardiovascular, respiratory, and lung cancer associations observed in epidemiologic studies. In addition, health effects associations reported in epidemiologic studies have been found to be generally robust to confounding by co-pollutants, there is now greater confidence in the results of long-term exposure studies due to reanalyses and extensions of the critical studies, and there is an increased understanding of susceptible populations. Based on these considerations, the Staff Paper finds clear support in the available evidence for fine particle standards that are at least as protective as the current $PM_{2.5}$ standards (EPA, 2005a, p. 5–6).

Having reached this initial conclusion, the Staff Paper addresses the question of whether the available evidence supports consideration of standards that are more protective than the current $PM_{2.5}$ standards. In so doing, the Staff Paper considers whether there is now evidence (1) that statistically significant health effects associations

with short-term exposures to fine particles occur in areas that would likely meet the current $PM_{2.5}$ standards or (2) that such associations with long-term exposures to fine particles extend down to lower air quality levels than had previously been observed.[26] This takes into consideration the bases for the decisions made in 1997 in setting the current $PM_{2.5}$ standards. In generally considering what areas would likely meet the current $PM_{2.5}$ standards, the focus is principally on comparing the long-term average $PM_{2.5}$ level in an area with the level of the current annual $PM_{2.5}$ standard, since in 1997 that standard was set to be the ''generally controlling'' standard to provide protection against health effects related to both short- and long-term exposures to fine particles. In conjunction with such an annual standard, the current 24-hour standard was set to provide only supplemental protection against days with high peak $PM_{2.5}$ concentrations, localized ''hotspots,'' or risks arising from seasonal emissions that might not be well controlled by a national annual standard.

In first considering the available epidemiologic evidence related to short-term exposures, the Staff Paper focuses on specific epidemiologic studies that show statistically significant associations between $PM_{2.5}$ and health effects for which the Criteria Document judges associations with $PM_{2.5}$ to be likely causal (EPA, 2005a, section 5.3.1.1). Many more U.S. and Canadian studies are now available that provide evidence of associations between short-term exposure to $PM_{2.5}$ and serious health effects in areas with air quality at and above the level of the current annual $PM_{2.5}$ standard (15 μg/m3). Moreover, a few newly available short-term exposure mortality studies provide evidence of statistically significant associations with $PM_{2.5}$ in areas with air quality levels below the levels of the current $PM_{2.5}$ standards. In considering these studies, the Staff Paper focuses on those that include adequate gravimetric $PM_{2.5}$ mass measurements, and where the associations are generally robust to alternative model specification and to the inclusion of potentially confounding co-pollutants. Three such studies conducted in Phoenix (Mar et al., 2003), Santa Clara County, CA (Fairley, 2003) and eight Canadian cities (Burnett and Goldberg, 2003) report statistically significant associations between short-term $PM_{2.5}$ exposure and total and cardiovascular mortality in areas in which long-term average $PM_{2.5}$ concentrations ranged between 13 and 14 μg/m^3 and 98th percentile concentrations ranged between 32 and 59 μg/m^3.[27]

In also considering the new epidemiologic evidence available from U.S. and Canadian studies of long-term exposure to fine particles, the Criteria Document notes that new studies have built upon studies available in the last review and concludes that these studies have confirmed and strengthened the evidence of associations for both mortality and respiratory morbidity (EPA, 2004, section 9.2.3). For mortality, the Criteria Document places greatest weight on the reanalyses and extensions of the Six Cities and ACS studies, finding that these studies provide strong evidence for associations with fine particles (EPA, 2004, p. 9–34), notwithstanding the lack of consistent results in other long-term exposure studies. For morbidity, the Criteria Document finds that new studies of a cohort of children in Southern California have built upon earlier limited evidence to provide fairly strong evidence that long-term exposure to fine particles is associated with development of chronic respiratory disease and reduced lung function growth (EPA, 2004, pp. 9–33 to 9–34). In addition to strengthening the evidence of association, the new extended ACS mortality study observed statistically significant associations with cardiorespiratory mortality (including lung cancer mortality) across a range of long-term mean $PM_{2.5}$ concentrations that was lower than was reported in the original ACS study available in the last review.

Beyond the epidemiologic studies using $PM_{2.5}$ as an indicator of fine particles, a large body of newly available evidence from studies that used PM_{10}, as well as other indicators or components of fine particles (e.g., sulfates, combustion-related components), provides additional support for the conclusions reached in the last review as to the likely causal role of ambient PM, and the likely importance of fine particles in contributing to observed health effects. Such studies notably include new multi-city studies, intervention studies (that relate reductions in ambient PM to observed improvements in respiratory or cardiovascular health), and source-oriented studies (e.g., suggesting associations with combustion- and vehicle-related sources of fine particles). The Criteria Document also notes that new epidemiologic studies of asthma-related increased physicians visits and symptoms, as well as new studies of cardiac-related risk factors, suggest likely much larger public health impacts due to ambient fine particles than just those indexed by the mortality and morbidity effects considered in the last review (EPA, 2004, p. 9–94).

In reviewing this information, the Staff Paper recognizes that important limitations and uncertainties associated with this expanded body of evidence for $PM_{2.5}$ and other indicators or components of fine particles, noted above in section II.A.2, need to be carefully considered in determining the weight to be placed on the body of studies available in this review. For example, the Criteria Document notes that while PM-effects associations continue to be observed across most new studies, the newer findings do not fully resolve the extent to which the associations are properly attributed to PM acting alone or in combination with other gaseous co-pollutants, particularly SO_2, or to the gaseous co-pollutants themselves. The Criteria Document concludes, however, that overall the various approaches that have now been used to evaluate this issue substantiate that associations for various PM indicators with mortality and morbidity are generally robust to confounding by co-pollutants (EPA, 2004, p. 9–37).

While the limitations and uncertainties in the available evidence suggest caution in interpreting the epidemiologic studies at the lower levels of air quality observed in the studies, the Staff Paper concludes that the evidence now available provides strong support for considering fine particle standards that would provide increased protection beyond that afforded by the current $PM_{2.5}$ standards. The Staff Paper notes that a more protective suite of $PM_{2.5}$ standards would reflect the generally stronger and broader body of evidence of associations with mortality and morbidity now available in this review, both at levels

[26] In addressing this question, the Staff Paper first recognizes, as discussed above in section II.A.3, that although there are likely biologic threshold levels in individuals for specific health responses, the available epidemiologic evidence neither supports nor refutes the existence of thresholds at the population level for the effects of $PM_{2.5}$ on mortality across the range of concentrations in the studies, for either long-term or short-term $PM_{2.5}$ exposures (EPA, 2004, section 9.2.2.5).

[27] As noted in the Staff Paper, these studies were reanalyzed to address questions about the application of the statistical software used in the original analyses, and the study results from Phoenix and Santa Clara County were little changed in alternative models (Mar et al., 2003; Fairley, 2003), although Burnett and Goldberg (2003) reported that their results were sensitive to using different temporal smoothing methods. Two of these studies also reported significant associations with gaseous pollutants (Mar et al., 2003; Fairley, 2003), and the other study included multi-pollutant model results in reanalyses, reporting that associations with $PM_{2.5}$ remained significant with gaseous pollutants (Fairley, 2003).

below the current standards and extending to lower levels of air quality than in earlier studies, as well as increased understanding of possible underlying mechanisms.

In addition to this evidence-based evaluation, the Staff Paper also considers the extent to which health risks estimated to occur upon attainment of the current $PM_{2.5}$ standards may be judged to be important from a public health perspective, taking into account key uncertainties associated with the quantitative health risk estimates. In so doing, the Staff Paper first notes that the risk assessment addresses a number of key uncertainties through various base case analyses, as well as through several sensitivity analyses, as discussed above in section II.B. In considering the health risks estimated to occur upon attainment of the current $PM_{2.5}$ standards, the Staff Paper focuses in particular on a series of base case risk estimates, while recognizing that the confidence ranges in the selected base case estimates do not reflect all the identified uncertainties. These risks were estimated using not only the linear or log-linear concentration-response functions reported in the studies,[28] but also using alternative modified linear functions as surrogates for assumed non-linear functions that would reflect the possibility that thresholds may exist in the reported associations within the range of air quality observed in the studies. Regardless of the relative weight placed on the risk estimates associated with the concentration-response functions reported in the studies or with the modified functions favored by CASAC,[29] the risk assessment indicates the possibility that thousands of premature deaths per year would occur in urban areas across the U.S. upon attainment of the current $PM_{2.5}$ standards.[30] Beyond the estimated incidences of premature mortality, the Staff Paper also recognizes that similarly substantial numbers of incidences of hospital admissions, emergency room visits, aggravation of asthma and other respiratory symptoms, and increased cardiac-related risk are also likely in many urban areas, based on risk assessment results (EPA, 2005a, Chapter 4) and on the discussion related to this pyramid of effects in the Criteria Document (EPA, 2004, section 9.2.5). Based on these considerations, the Staff Paper concludes that the estimates of risks likely to remain upon attainment of the current $PM_{2.5}$ standards are indicative of risks that can reasonably be judged to be important from a public health perspective.

In considering available evidence, risk estimates, and related limitations and uncertainties, the Staff Paper concludes that the available information clearly calls into question the adequacy of the current suite of $PM_{2.5}$ standards and provides strong support for revising the current $PM_{2.5}$ standards to provide increased public health protection. Also taking into account these considerations, the CASAC advised the Administrator that a majority of CASAC Panel members were in agreement that the primary 24-hour and annual $PM_{2.5}$ standards ''should be modified to provide increase public health protection'' (Henderson, 2005a). The CASAC further advised that changes to either the annual standard or the 24-hour standard, or both, could be recommended, and expressed reasons that formed the basis for the consensus among the Panel members for placing more emphasis on lowering the 24-hour standard (Henderson, 2005a).[31]

In considering whether the suite of primary $PM_{2.5}$ standards should be revised to provide requisite public health protection, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator places primary consideration on the evidence obtained from the studies, and provisionally finds the evidence of serious health effects reported in short-term exposure studies conducted in areas that would attain the current standards to be compelling, especially in light of the extent to which such studies are part of an overall pattern of positive and frequently statistically significant associations across a broad range of studies that collectively represent a strong and robust body of evidence. As discussed in the Criteria Document and Staff Paper, the Administrator recognizes that much progress has been made since the last review in addressing some of the key uncertainties that were important considerations in establishing the current $PM_{2.5}$ standards. In considering the risk assessment presented in the Staff Paper, the Administrator notes that the assessment contained a sensitivity analysis but not a formal uncertainty analysis, making it difficult to use the risk assessment to form a judgment of the probability of various risk estimates. Instead, the Administrator views the risk assessment in light of his evaluation of the underlying studies. Seen in this light, the risk assessment informs the determination of the public health significance of risks to the extent that the evidence is judged to support an effect at a particular level of air quality. Based on these considerations, the Administrator provisionally concludes that the current primary $PM_{2.5}$ standards, taken together, are not requisite to protect public health with an adequate margin of safety and that revision is needed to provide increased public health protection.

D. Indicator of Fine Particles

In 1997, EPA established $PM_{2.5}$ as the indicator for fine particles. In reaching this decision, the Agency first considered whether the indicator should be based on the mass of a size-differentiated sample of fine particles or on one or more components within the mix of fine particles. Secondly, in establishing a size-based indicator, a size cut needed to be selected that would appropriately distinguish fine particles from particles in the coarse mode.

In addressing the first question in the last review, EPA determined that it was appropriate to control fine particles as a group, as opposed to singling out any particular component or class of fine particles. Community health studies had found significant associations between various indicators of fine particles (including $PM_{2.5}$ or PM_{10} in areas dominated by fine particles) and health effects in a large number of areas that had significant mass contributions of differing components or sources of fine particles, including sulfates, wood smoke, nitrates, secondary organic compounds and acid sulfate aerosols. In addition, a number of animal

[28] As discussed above in section II.B.2, the reported linear or log-linear concentration-response functions were applied down to 7.5 $\mu g/m^3$ in estimating risk associated with long-term exposure (i.e., the lowest measured level in the extended ACS study), and down to the estimated policy-relevant background level in estimating risk associated with short-term exposure (i.e., 3.5 $\mu g/m^3$ for eastern urban areas and 2.5 $\mu g/m^3$ for western urban areas).

[29] The CASAC PM Panel generally favored the primary use of an assumed threshold of 10 $\mu g/m^3$ for the various concentration-response functions used in the risk assessment (Henderson, 2005a).

[30] The Staff Paper recognizes how highly dependent any specific risk estimates are on the assumed shape of the underlying concentration-response functions, noting nonetheless that mortality risks are not completely eliminated when current $PM_{2.5}$ standards are met in a number of example urban areas even using the highest assumed cutpoint levels considered in the risk assessment (EPA, 2005a, p. 5–15).

[31] Of the individual Panel members who submitted written comments expressing views on appropriate levels of the $PM_{2.5}$ standards, only one did not suppport changes to either the 24-hour or annual standard to provide additional public health protection (Henderson, 2005a). In written comments, the health scientists on the CASAC Panel did not agree on whether the annual standard should be lowered.

toxicologic and controlled human exposure studies had reported health effects associations with high concentrations of numerous fine particle components (e.g., sulfates, nitrates, transition metals, organic compounds), although such associations were not consistently observed. It also was not possible to rule out any component within the mix of fine particles as not contributing to the fine particle effects found in epidemiologic studies. For these reasons, EPA concluded that total mass of fine particles was the most appropriate indicator for fine particle standards rather than an indicator based on PM composition (62 FR 38667, July 18, 1997).

Having selected a size-based indicator for fine particles, the Agency then based its selection of a specific size cut on a number of considerations. In focusing on a size cut within the size range of 1 to 3 μm (i.e., the intermodal range between fine and coarse mode particles), the Agency noted that the available epidemiologic studies of fine particles were based largely on $PM_{2.5}$; only very limited use of PM_1 monitors had been made. While it was recognized that using PM_1 as an indicator of fine particles would exclude the tail of the coarse mode in some locations, in other locations it would miss a portion of the fine PM, especially under high humidity conditions, which would result in falsely low fine PM measurements on days with some of the highest fine PM concentrations. The selection of a 2.5 μm size cut reflected the regulatory importance that was placed on defining an indicator for fine particle standards that would more completely capture fine particles under all conditions likely to be encountered across the U.S., especially when fine particle concentrations are likely to be high, while recognizing that some small coarse particles would also be captured by $PM_{2.5}$ monitoring. Thus, EPA's selection of 2.5 μm as the size cut for the fine particle indicator was based on considerations of consistency with the epidemiologic studies, the regulatory importance of more completely capturing fine particles under all conditions, and the potential for limited intrusion of coarse particles in some areas; it also took into account the general availability of monitoring technology (62 FR 38668).

In this current review, the same considerations continue to apply for selection of an appropriate indicator for fine particles. As an initial matter, the available epidemiologic studies linking mortality and morbidity effects with short- and long-term exposures to fine particles continue to be largely indexed by $PM_{2.5}$. Some epidemiologic studies also have continued to implicate various components within the mix of fine particles that have been more commonly studied (e.g., sulfates, nitrates, carbon, organic compounds, and metals) as being associated with adverse effects (EPA, 2004, p. 9–31, Table 9–3). In addition, several recent studies have used $PM_{2.5}$ speciation data to evaluate the association between mortality and particles from different sources (Schwartz, 2003a; Mar et al., 2003; Tsai et al., 2000; EPA, 2004, section 8.2.2.5). Schwartz (2003a) reported statistically significant associations for mortality with factors representing fine particles from traffic and residual oil combustion that were little changed in reanalysis to address statistical modeling issues, and also an association between mortality and coal combustion-related particles that was reduced in size and lost statistical significance in reanalysis. In Phoenix, significant associations were reported between mortality and fine particles from traffic emissions, vegetative burning, and regional sulfate sources that remained unchanged in reanalysis models (Mar et al., 2003). Finally, a small study in three New Jersey cities reported significant associations between mortality and fine particles from industrial, oil burning, motor vehicle and sulfate aerosol sources, though the results were somewhat inconsistent between cities (Tsai et al., 2000).[32] No significant increase in mortality was reported with a source factor representing crustal material in fine particles (CD, p. 8–85). Recognizing that these three studies represent a very preliminary effort to distinguish effects of fine particles from different sources, and that the results are not always consistent across the cities, the Criteria Document found that these studies indicate that exposure to fine particles from combustion sources, but not crustal material, is associated with mortality (EPA, 2004, p. 8–77). Animal toxicologic and controlled human exposure studies have continued to link a variety of PM components or particle types (e.g., sulfates, notably primary metal sulfate emissions from residual oil burning, metals, organic constituents, bioaerosols, diesel particles) with health effects, though often at high concentrations (EPA, 2004, section 7.10.2). In addition, some recent studies have suggested that the ultrafine subset of fine particles (generally including particles with a nominal mean aerodynamic diameter less than 0.1 μm) may also be associated with adverse effects (EPA, 2004, pp. 8–67 to 68).

The Criteria Document recognizes that, for a given health response, some fine particle components are likely to be more closely linked with that response than others. The presumption that different PM constituents may have differing biological responses is toxicologically plausible and an important source of uncertainty in interpreting such epidemiologic evidence. For specific effects there may be stronger correlation with individual PM components than with aggregate particle mass. In addition, particles or particle-bound water can act as carriers to deliver other toxic agents into the respiratory tract, suggesting that exposure to particles may elicit effects that are linked with a mixture of components more than with any individual PM component (EPA, 2004, section 9.2.3.1.3).

Thus, epidemiologic and toxicologic studies have provided evidence for effects associated with various fine particle components or size-differentiated subsets of fine particles. The Criteria Document concludes: ''These studies suggest that many different chemical components of fine particles and a variety of different types of source categories are all associated with, and probably contribute to, mortality, either independently or in combinations'' (EPA, 2004, p. 9–31). Conversely, the Criteria Document provides no basis to conclude that any individual fine particle component cannot be associated with adverse health effects (EPA, 2005a, p. 5–17). In short, there is not sufficient evidence that would lead toward the selection of one or more PM components as being primarily responsible for effects associated with fine particles, nor is there sufficient evidence to suggest that any component should be eliminated from the indicator for fine particles. The Staff Paper continues to recognize the importance of an indicator that not only captures all of the most harmful components of fine particles (i.e., an effective indicator), but also emphasizes control of those constituents or fractions, including sulfates, transition metals, and organics that have been associated with health effects in epidemiologic and/or toxicologic studies, and is thus most likely to result in the largest risk reduction (i.e., an efficient indicator). Taking into account the above considerations, the Staff Paper concludes that it remains appropriate to

[32] More specifically, statistically significant associations were reported with factors representing fine particles from oil burning, industrial and sulfate aerosol sources in Newark and with particles from oil burning and motor vehicle sources in Camden, and no statistically significant associations were reported in Elizabeth.

control fine particles as a group; i.e., that total mass of fine particles is the most appropriate indicator for fine particle standards (EPA, 2005a, p. 5–17).

With regard to an appropriate size cut for a size-based indicator of total fine particle mass, the Criteria Document concludes that advances in our understanding of the characteristics of fine particles continue to support the use of particle size as an appropriate basis for distinguishing between these subclasses, and that a nominal size cut of 2.5 μm remains appropriate (EPA, 2004, p. 9–22). This conclusion follows from a recognition that within the intermodal range of 1 to 3 μm there is no unambiguous definition of an appropriate size cut for the separation of the overlapping fine and coarse particle modes. Within this range, the Staff Paper considered size cuts of both 1 μm and 2.5 μm. Consideration of these two size cuts took into account that there is generally very little mass in this intermodal range, although in some circumstances (*e.g.*, windy, dusty areas) the coarse mode can extend down to and below 1 μm, whereas in other circumstances (*e.g.*, high humidity conditions, usually associated with very high fine particle concentrations) the fine mode can extend up to and above 2.5 μm. The same considerations that led to the selection of a 2.5 μm size cut in the last review—that the epidemiologic evidence was largely based on $PM_{2.5}$ and that it was more important from a regulatory perspective to capture fine particles more completely under all conditions likely to be encountered across the U.S. (especially when fine particle concentrations are likely to be high) than to avoid some coarse-mode intrusion into the fine fraction in some areas—led to the same recommendation by the Staff Paper (EPA, 2005a, p. 5–18) and CASAC (Henderson, 2005a) in this review. In addition, the Staff Paper recognizes that particles can act as carriers of water, oxidative compounds, and other components into the respiratory system, which adds to the importance of ensuring that larger accumulation-mode particles are included in the fine particle size cut (EPA, 2005a, p. 5–18).

Consistent with the Staff Paper and CASAC recommendations, the Administrator proposes to retain $PM_{2.5}$ as the indicator for fine particles. Further, the Administrator provisionally concludes that currently available studies do not provide a sufficient basis for supplementing mass-based fine particle standards with standards for any specific fine particle component or subset of fine particles, or for eliminating any individual component or subset of components from fine particle mass standards. Addressing the current uncertainties in the evidence of effects associated with various fine particle components and types of source categories is an important element in EPA's ongoing PM research program.

The Administrator notes that some commenters have expressed views about the importance of evaluating health effect associations with various fine particle components and types of source categories as a basis for focusing ongoing and future research to reduce uncertainties in this area and for considering whether alternative indicator(s) are now or may be appropriate for standards intended to protect against the array of health effects that have been associated with fine particles as indexed by $PM_{2.5}$.[33] Information from such studies could also help inform the development of strategies that emphasize control of specific types of emission sources so as to address particles of greatest concern to public health. While recognizing that the studies evaluated in the Criteria Document provide some limited evidence of such associations that is helping to focus research activities, the Administrator solicits broad public comment on issues related to studies of fine particle components and types of source categories and their usefulness as a basis for consideration of alternative indicator(s) for fine particle standards. In general, comment is solicited on relevant new published research, recommendations for studies that would be appropriate for inclusion in future research activities, and approaches to assessing the available and future research results to determine whether alternative indicators for fine particles are warranted to provide effective protection of public health from effects associated with long- and short-term exposure to ambient fine particles.

More specifically, comment is also solicited on a number of related issues. One such issue is the extent to which reducing particular types of PM (differentiated by either size or chemistry) might alter the size and toxicity of remaining particles, and on the extent to which fine particles in urban and rural areas can be differentiated by size or chemistry. Another issue deals with assessment of human exposure and its relationship with pollution measurements at monitors (EPA, 2004, chapter 5); comment is solicited on the extent to which the latest scientific information can be used to improve our understanding of the relationship of monitored pollution levels to human exposure. Comment is also solicited on studies using concentrated ambient particles (CAPs) and their use in examining the toxicity of specific mixtures of pollutants or of particular source categories.

E. Averaging Time of Primary $PM_{2.5}$ Standards

In the last review, EPA established two $PM_{2.5}$ standards, based on annual and 24-hour averaging times, respectively (62 FR at 38668–70). This decision was based in part on evidence of health effects related to both short-term (from less than 1 day to up to several days) and long-term (from a year to several years) measures of PM. EPA noted that the large majority of community epidemiologic studies reported associations based on 24-hour averaging times or on multiple-day averages. Further, EPA noted that a 24-hour standard could also effectively protect against episodes lasting several days, as well as providing some degree of protection from potential effects associated with shorter duration exposures. EPA also recognized that an annual standard would provide effective protection against both annual and multi-year, cumulative exposures that had been associated with an array of health effects, and that a much longer averaging time would complicate and unnecessarily delay control strategies and attainment decisions. EPA considered the possibility of seasonal effects, although the very limited available evidence of such effects and the seasonal variability of sources of fine particle emissions across the country did not provide an adequate basis for establishing a seasonal averaging time.

In considering whether the information available in this review supports consideration of different averaging times for $PM_{2.5}$ standards, the Staff Paper concludes that the available information is generally consistent with and supportive of the conclusions reached in the last review to set $PM_{2.5}$ standards with both annual and 24-hour averaging times. In considering the new information, the Staff Paper makes the following observations (EPA, 2005a, section 5.3.3):

(1) There is a growing body of studies that provide additional evidence of effects associated with exposure periods shorter than 24-hours (*e.g.*, one to several hours) (EPA, 2004, section 3.5.5.1). While the Staff Paper concludes

[33] Such comments have focused in part on newer studies that have become available since the close of the Criteria Document, which EPA intends to include in its assessment of potentially significant new studies discussed above in section I.D.

that this information remains too limited to serve as a basis for establishing a shorter-than-24-hour fine particle primary standard at this time, it also noted that this information gives added weight to the importance of a standard with a 24-hour averaging time.

(2) Some recent PM_{10} studies have used a distributed lag over several days to weeks preceding the health event, although this modeling approach has not been extended to studies of fine particles (EPA, 2004, section 3.5.5). While such studies continue to suggest consideration of a multiple day averaging time, the Staff Paper notes that limiting 24-hour concentrations of fine particles will also protect against effects found to be associated with PM averaged over many days in health studies. Consistent with the conclusion reached in the last review, the Staff Paper concludes that a multiple-day averaging time would add complexity without providing more effective protection than a 24-hour average.

(3) While some newer studies have investigated seasonal effects (EPA, 2004, section 3.5.5.3), the Staff Paper concludes that currently available evidence of such effects is still too limited to serve as a basis for considering seasonal standards.

Based on the above considerations, the Staff Paper and CASAC (Henderson, 2005a) recommend retaining the current annual and 24-hour averaging times for $PM_{2.5}$ primary standards. The Administrator concurs with the staff and CASAC recommendations and proposes that averaging times for $PM_{2.5}$ standards should continue to include annual and 24-hour averages to protect against health effects associated with short-term (hours to days) and long-term (seasons to years) exposure periods.

F. Form of Primary $PM_{2.5}$ Standards

1. 24-Hour $PM_{2.5}$ Standard

In 1997 EPA established the form of the 24-hour $PM_{2.5}$ standard as the 98th percentile of the annual 24-hour concentrations at each population-oriented monitor within an area, averaged over three years (62 FR at 38671–74). EPA selected such a concentration-based form because of its advantages over the previously used expected-exceedance form.[34] A concentration-based form is more reflective of the health risk posed by elevated $PM_{2.5}$ concentrations because it gives proportionally greater weight to days when concentrations are well above the level of the standard than to days when the concentrations are just above the standard. Further, a concentration-based form better compensates for missing data and less-than-every-day monitoring; and, when averaged over 3 years, it has greater stability and, thus, facilitates the development of more stable implementation programs.[35] After considering a range of concentration percentiles from the 95th to the 99th, EPA selected the 98th percentile as an appropriate balance between adequately limiting the occurrence of peak concentrations and providing increased stability and robustness. Further, by basing the form of the standard on concentrations measured at population-oriented monitoring sites (as specified in 40 CFR part 58), EPA intended to provide protection for people residing in or near localized areas of elevated concentrations.

In this review, the Staff Paper concludes that it is appropriate to retain a concentration-based form that is defined in terms of a specific percentile of the distribution of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area, averaged over 3 years. This staff recommendation is based on the same reasons that were the basis for EPA's selection of this type of form in the last review. As to the specific percentile value to be considered, the Staff Paper took into consideration (1) the relative risk reduction afforded by alternative forms at the same standard level, (2) the relative year-to-year stability of the air quality statistic to be used as the basis for the form of a standard, and (3) the implications from a public health communication perspective of the extent to which either form allows different numbers of days in a year to be above the level of the standard in areas that attain the standard. Based on these considerations, the Staff Paper recommends either retaining the 98th percentile form or revising it to be based on the 99th percentile form, and notes that primary consideration should be given to the combination of form and level, as compared to looking at the form in isolation (EPA, 2005a, p. 5–44).

In considering the information provided in the Staff Paper, most CASAC Panel members favored continued use of the 98th percentile form because it is more robust than the 99th percentile form, such that it would provide more stability to prevent areas from bouncing in and out of attainment from year to year (Henderson 2005a). In recommending retention of the 98th percentile form, the CASAC Panel recognized that it is the link between the form and level of a standard that determines the degree of public health protection afforded by a standard.

In considering the available information and the Staff Paper and CASAC recommendations, the Administrator proposes that the form of the 24-hour standard should be based on the 98th percentile form. In so doing, the Administrator has focused on the relative stability of the 98th and 99th percentile forms as a basis for selecting the 98th percentile form, while recognizing that the degree of public health protection likely to be afforded by a standard is a result of the combination of the form and the level of the standard.

2. Annual $PM_{2.5}$ Standard

In 1997 EPA established the form of the annual $PM_{2.5}$ standard as an annual arithmetic mean, averaged over 3 years, from single or multiple community-oriented monitors. This form of the annual standard was intended to represent a relatively stable measure of air quality and to characterize area-wide $PM_{2.5}$ concentrations in conjunction with a 24-hour standard designed to provide adequate protection against localized peak or seasonal $PM_{2.5}$ levels. The current annual $PM_{2.5}$ standard level is to be compared to measurements made at the community-oriented monitoring site recording the highest level, or, if specific constraints are met, measurements from multiple community-oriented monitoring sites may be averaged (Part 50 App. N section 2.1(a) and (b) and Part 58 App. D at 2.8.1.6.1; 62 FR 38,672, July 18, 1997). Community-oriented monitoring sites were specified to be consistent with the intent that a spatially averaged annual standard protect those in smaller communities, as well as those in larger population centers. The constraints on allowing the use of spatially averaged measurements were intended to limit averaging across poorly correlated or widely disparate air quality values.[36] This approach was judged to be consistent with the epidemiologic studies on which the $PM_{2.5}$ standard

[34] The form of the 1987 24-hour PM_{10} standard is based on the expected number of days per year (averaged over 3 years) on which the level of the standard is exceeded; thus, attainment of the one-expected exceedance form is determined by comparing the fourth-highest concentration in 3 years with the level of the standard.

[35] See *American Trucking Associations* v. *EPA*, 283 F. 3d at 374–75 (legitimate for EPA to consider promotion of overall effectiveness of NAAQS implementation programs, including their overall stability, in setting a standard that is requisite to protect the public health).

[36] The current constraints include the criteria that the correlation coefficient between monitor pairs to be averaged be at least 0.6, and that differences in mean air quality values between monitors to be averaged not exceed 20 percent (Part 58 App. D at 2.8.1.6.1).

was primarily based, in which air quality data were generally averaged across multiple monitors in an area or were taken from a single monitor that was selected to represent community-wide exposures, not localized ''hot spots'' (62 FR 38672). These criteria and constraints were intended to ensure that spatial averaging would not result in inequities in the level of protection afforded by the $PM_{2.5}$ standards (*Id.*).

In this review, there now exist much more $PM_{2.5}$ air quality data than were available in the last review. Consideration in the Staff Paper of the spatial variability across urban areas that is revealed by this new database has raised questions as to whether an annual standard that allows for spatial averaging, within currently specified or alternative constraints, would provide appropriate public health protection. Analyses in the Staff Paper to assess these questions, as discussed below, have taken into account both aggregate population risk across an entire urban area and the potential for disproportionate impacts on potentially vulnerable subpopulations within an area.

The effect of allowing the use of spatial averaging on aggregate population risk was considered in sensitivity analyses included in the health risk assessment (EPA, 2005a). In particular, analyses were done in several urban areas that compared estimated mortality risks based on calculating compliance with alternative standards (1) using air quality values from the highest community-oriented monitor in an area and (2) using air quality values averaged across all such monitors within the constraints allowed by the current standard.[37] As expected, estimated risks associated with long-term exposures remaining upon just meeting the current annual standard are greater when spatial averaging is used than when the highest monitor is used (*i.e.*, the estimated reductions in risk associated with just attaining the current or alternative annual standards are less when spatial averaging is used), as the use of the highest monitor leads to greater modeled reductions in ambient $PM_{2.5}$ concentrations.[38]

In considering the potential for disproportionate impacts on potentially vulnerable subpopulations, analyses were done to assess whether any such groups are more likely to live in census tracts in which the monitors recording the highest air quality values in an area are located. Data were obtained for demographic parameters measured at the census tract level, including education level, income level, and percent minority population. Data from the census tract in each area in which the highest air quality value was monitored were compared to the area-wide average value (consistent with the constraints on spatial averaging provided by the current standard) in each area. (Schmidt *et al.*, 2005). Recognizing the limitations of such cross-sectional analyses, the Staff Paper observes that the results suggest that the highest concentrations in an area tend to be measured at monitors located in areas where the surrounding population is more likely to have lower education and income levels, and higher percentage minority levels (EPA, 2005a, p. 5–41).[39] Noting the intended purposes of the form of the annual standard, as discussed above, the Staff Paper concludes that the existing constraints on spatial averaging may not be adequate to avoid substantially greater exposures in some areas, potentially resulting in disproportionate impacts on potentially vulnerable subpopulations.

In considering whether more stringent constraints on the use of spatial averaging may be appropriate, the Staff Paper presents results of an analysis of recent air quality data on the correlations and differences between monitor pairs in metropolitan areas across the country (Schmidt et al., 2005). For all pairs of $PM_{2.5}$ monitors, the median correlation coefficient based on annual air quality data is approximately 0.9, which is substantially higher than the current criterion for correlation of at least 0.6, which was met by nearly all monitor pairs. Similarly, the current criterion that differences in mean air quality values between monitors not exceed 20 percent was met for most monitor pairs, while the annual median and mean differences for all monitor pairs are 5 percent and 8 percent, respectively. This analysis also shows that in some areas with highly seasonal air quality patterns (e.g., due to seasonal wood smoke emissions), substantially lower seasonal correlations and larger seasonal differences can occur relative to those observed on an annual basis. This analysis provides some perspective on the constraints on spatial averaging that were put in place in the last review, before data were widely available on spatial distributions of $PM_{2.5}$ air quality levels, based on the extensive air quality data and related analyses that have become available since the last review.

In considering the results of the analyses discussed above, the Staff Paper concludes that it is appropriate to consider either eliminating the provision that allows for spatial averaging from the form of an annual $PM_{2.5}$ standard or revising the allowance for spatial averaging to be based on more restrictive criteria. More specifically, based on the analyses discussed above, the Staff Paper recommends consideration of revised criteria such that the correlation coefficient between monitor pairs to be averaged be at least 0.9, determined on a seasonal basis, with differences between monitor values not to exceed 10 percent (EPA, 2005a, p. 5–42).

In considering the Staff Paper recommendations based on the results of the analyses discussed above, and focusing on a desire to be consistent with the epidemiologic studies on which the $PM_{2.5}$ health effects are based and concern over the evidence of potential disproportionate impact on potentially vulnerable subpopulations, the Administrator proposes to revise the form of the annual $PM_{2.5}$ standard consistent with the Staff Paper recommendation to change the criteria for use of spatial averaging such that the correlation coefficient between monitor pairs must be at least 0.9, determined on a seasonal basis, with differences between monitor values not to exceed 10 percent. The Administrator also solicits comment on the other Staff Paper-recommended alternative of revising the form of the annual $PM_{2.5}$

[37] As discussed in the Staff Paper, section 4.2.2, the monitored air quality values were used to determine the design value for the annual standard in each area, as applied to a ''composite'' monitor to reflect area-wide exposures. Changing the basis of the annual standard design value from the concentration at the highest monitor to the average concentration across all monitors changes the ambient $PM_{2.5}$ levels that are needed to just meet the current or alternative annual standards. With averaging, less overall reduction in ambient $PM_{2.5}$ is needed to just meet the standards.

[38] For example, based on analyses conducted in three example urban areas, estimated mortality incidence associated with long-term exposure based on the use of spatial averaging is about 10 to over 40 percent higher than estimated incidence based on the use of the highest monitor (EPA, 2005a, p. 5–41).

[39] As summarized in section II.A.4 above, the Criteria Document notes that some epidemiologic study results, most notably the associations between mortality and long-term $PM_{2.5}$ exposure in the ACS cohort, have shown larger effect estimates in the cohort subgroup with lower education levels (EPA, 2004, p. 8–103). The Criteria Document also notes that lower education level can be a marker for lower socioeconomic status that may be related to increased vulnerability to the effects of fine particle exposures, for example, as a result of greater exposure to sources such as roadways. Lower education level may be associated with other potential risk factors, such as poorer health status or access to health care, that may also result in increased susceptibility to the effects of air pollution exposure (EPA, 2004, section 9.2.4.5)

standard to one based on the highest community-oriented monitor in an area, with no allowance for spatial averaging.

G. Level of Primary $PM_{2.5}$ Standards

In the last review, having concluded that both 24-hour and annual $PM_{2.5}$ standards were appropriate, EPA selected a level for each standard that was appropriate for the function to be served by such standard (62 FR 38652). As discussed above, EPA concluded at that time that the suite of $PM_{2.5}$ standards could most effectively and efficiently protect public health by treating the annual standard as the generally controlling standard for lowering both short- and long-term $PM_{2.5}$ concentrations.[40] In conjunction with such an annual standard, the 24-hour standard was intended to provide protection against days with high peak $PM_{2.5}$ concentrations, localized ''hotspots,'' and risks arising from seasonal emissions that would not be well controlled by an annual standard.[41]

In selecting the level for the annual standard in the last review, EPA used an evidence-based approach that considered the evidence from both short- and long-term exposure studies. The risk assessment conducted in the last review, while providing qualitative insights about the distribution of risks, was considered to be too limited to serve as a quantitative basis for decisions on the standard levels. In accordance with Staff Paper and CASAC views on the relative strengths of the short- and long-term exposure studies, greater emphasis was placed on the short-term exposure studies. In so doing, EPA first determined a level for the annual standard based on the short-term exposure studies, and then considered whether the long-term exposure studies suggested the need for a lower level. While recognizing that health effects could occur over the full range of concentrations observed in the studies, EPA concluded that the strongest evidence for short-term $PM_{2.5}$ effects occurs at concentrations near the long-term (e.g., annual) average in those studies reporting statistically significant health effects. Thus, in the last review, EPA selected a level for the annual standard that was below the lowest long-term average $PM_{2.5}$ concentration in a short-term exposure study that reported statistically significant health effects. Further consideration of the average $PM_{2.5}$ concentrations across the cities in the key long-term exposure studies available at that time did not provide a basis for establishing a lower annual standard level.

In this review, the approach used in the Staff Paper as a basis for staff recommendations on standard levels builds upon and broadens the general approach used by EPA in the last review. This broader approach reflects the more extensive and stronger body of evidence now available on health effects related to both short- and long-term exposure to $PM_{2.5}$, together with the availability of much more extensive $PM_{2.5}$ air quality data. This newly available information has been used to conduct a more comprehensive risk assessment for $PM_{2.5}$. As a consequence, the broader approach used in the Staff Paper discusses ways to take into account both evidence-based and quantitative risk-based considerations and places relatively greater emphasis on evidence from long-term exposure studies than was done in the last review.

Given the extensive body of new evidence based specifically on $PM_{2.5}$ that is now available, and the resulting broader approach presented in the Staff Paper, the Administrator considers it appropriate to use a different approach from that used in the last review to select appropriate standard levels. More specifically, the Administrator's proposal relies on an evidence-based approach that considers the much expanded body of evidence from short-term exposure $PM_{2.5}$ studies as the principal basis for selecting the level of the 24-hour standard and the stronger and more robust body of evidence from the long-term exposure $PM_{2.5}$ studies as the principal basis for selecting the level of the annual standard. In the Administrator's view, the very large number of health effect studies that are now available provide the most reliable basis for standard setting. With respect to the quantitative risk assessment, the Administrator recognizes that it rests on a more extensive body of data and is more comprehensive in scope than the assessment conducted in the last review, but is mindful that significant uncertainties continue to underlie the resulting risk estimates. Such uncertainties generally relate to a lack of clear understanding of a number of important factors, including for example: The shape of concentration-response functions, particularly when, as here, effect thresholds can neither be discerned nor determined not to exist; issues related to selection of appropriate statistical models for the analysis of the epidemiologic data; the role of potentially confounding and modifying factors in the concentration-response relationships; issues related to simulating how $PM_{2.5}$ air quality distributions will likely change in any given area upon attaining a particular standard, since strategies to reduce emissions are not yet defined; and whether there would be differential reductions in the many components within $PM_{2.5}$ and if so whether this would result in differential reductions in risk. In the case of fine particles, the Administrator recognizes that such uncertainties are likely to be unusually large due to the complexity in the composition of the mix of fine particles generally present in the ambient air. Further, in the Administrator's view, a risk assessment based on studies that do not resolve the issue of a threshold is inherently limited as a basis for standard setting, since it will necessarily predict that ever lower standards result in ever lower risks, which has the effect of masking the increasing uncertainty inherent as lower levels are considered. As a result, while the Administrator views the risk assessment as providing supporting evidence for the conclusion that there is a need to revise the current suite of $PM_{2.5}$ standards, he judges that it does not provide a reliable basis to determine what specific quantitative revisions are appropriate.

1. 24-Hour $PM_{2.5}$ Standard

Based on the approach discussed above, the Administrator has relied upon evidence from the short-term exposure $PM_{2.5}$ studies as the principal basis for selecting the level of the 24-hour standard. In considering these studies as a basis for the level of a 24-hour standard, and having selected a 98th percentile form for the standard, the Administrator agrees with the focus in the Staff Paper of looking at the 98th percentile values in these studies. In so doing, the Administrator recognizes that these studies provide no evidence of clear effect thresholds or lowest-observed-effects levels. Thus, in focusing on 98th percentile values in these studies, the Administrator is seeking to establish a standard level that will require improvements in air quality generally in areas in which short-term exposure to $PM_{2.5}$ can reasonably be expected to be associated with serious

[40] In so doing, EPA noted that an annual standard would focus control programs on annual average $PM_{2.5}$ concentrations, which would generally control the overall distribution of 24-hour exposure levels, as well as long-term exposure levels, and would also result in fewer and lower 24-hour peak concentrations. Alternatively, a 24-hour standard that focused controls on peak concentrations could also result in lower annual average concentrations. Thus, EPA recognized that either standard could provide some degree of protection from both short- and long-term exposures, with the other standard serving to address situations where the daily peaks and annual averages are not consistently correlated (62 FR 38669).

[41] See also *American Trucking Associations* v. *EPA*, 283 F.3d at 373 (endorsing this reasoning).

health effects. While strategies that may be employed in the future to bring about such improvements in air quality in any particular area are not yet defined, most such strategies are likely to move the broad distribution of $PM_{2.5}$ air quality values in an area lower, resulting in reductions in risk associated with exposures to $PM_{2.5}$ levels across a wide range of concentrations.

Based on the information in the Staff Paper and a supporting staff memo,[42] the Administrator observes an overall pattern of statistically significant associations reported in studies of short-term exposure to $PM_{2.5}$ across a wide range of 98th percentile values. More specifically, there is a strong predominance of studies with 98th percentile values down to about 39 μg/m³ (in Burnett and Goldberg, 2003) reporting statistically significant associations with mortality, hospital admissions, and respiratory symptoms. For example, within this range of air quality, statistically significant associations were reported for mortality in the combined Six City study (and three of the individual cities within that study) (Klemm and Mason, 2003), the Canadian 8-City Study (Burnett and Goldberg, 2003), and in studies in Santa Clara County, CA (Fairley, 2003) and Philadelphia (Lipfert, 2000); for hospital admissions and emergency department visits in Seattle (Sheppard et al., 2003), Toronto (Burnett et al., 1997; Thurston et al., 1994), Detroit (Ito, 2003, for ischemic heart disease and pneumonia, but not for other causes), and Montreal (Delfino et al., 1998, 1997, for some but not all age groups and years); for respiratory symptoms in panel studies in a combined Six City study (Schwartz et al., 1994) and in two Pennsylvania cities (Uniontown in Neas et al., 1995; State College in Neas et al., 1996); and for lung function in Philadelphia (Neas et al., 1999).[43] Studies in this air quality range that reported positive but not statistically significant associations with mortality include studies in Detroit (Ito, 2003), Pittsburgh (Chock et al., 2000), and Montreal (Goldberg and Burnett, 2003).

Within the range of 98th percentile $PM_{2.5}$ concentrations of about 35 to 30 μg/m³, this strong predominance of statistically significant results is no longer observed. Rather, within this range, some studies report statistically significant results (Mar et al., 2003; Ostro et al., 2003), other studies report mixed results in which some associations reported in the study are statistically significant and others are not (Delfino et al., 1997; Peters et al., 2000),[44] and another study reports associations in two of six cities that are not statistically significant (Klemm and Mason, 2003). Further, the very limited number of studies in which the 98th percentile values are below this range do not provide a basis for reaching conclusions about associations at such levels (Stieb et al., 2000; Peters et al., 2001). Thus, in the Administrator's view, this body of evidence provides confidence that statistically significant associations are occurring down close to this range, and it provides a clear basis for concluding that this range represents a range of reasonable values and thus for selecting a 24-hour standard level from within this range. The Administrator further notes that focusing on the range of 35 to 30 μg/m³ is consistent with the interpretation of the evidence held by most CASAC Panel members as reflected in their recommendation to select a 24-hour $PM_{2.5}$ standard level within this range (Henderson, 2005a). The Administrator recognizes, however, the separate point that most CASAC Panel members favored the range of 35 to 30 μg/m³ for the 24-hour $PM_{2.5}$ standard in concert with an annual standard set in the range of 14 to 13 μg/m3 (Henderson, 2005a), as discussed in section II.G.2 below.

In considering what 24-hour standard is requisite to protect public health with an adequate margin of safety, the Administrator is mindful that this choice requires judgment based on an interpretation of the evidence that neither overstates nor understates the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. In the absence of evidence of any clear effect thresholds, the Administrator may select a specific standard level from within a range of reasonable values. In making this judgment, the Administrator notes that the general uncertainties related to the shape of the concentration-response functions and the selection of appropriate statistical models affect the likelihood that observed associations are causal down to the lowest concentrations in the studies. Further, and more specifically, the variation in results found in the short-term exposure studies in which the 98th percentile values were below 35 μg/m³ indicates an increase in uncertainty as to whether likely causal associations extend down below this level.

In considering the extent to which the quantitative risk assessment inform his selection of a 24-hour $PM_{2.5}$ standard, the Administrator recognizes that risk estimates based on simulating the attainment of standards set at lower levels within this range will inevitably suggest some additional reductions in risk at each lower standard level considered. However, these quantitative risk estimates largely depend upon assumptions made about the lowest level at which reported associations will likely persist and remain causal in nature. Thus, the Administrator is hesitant to use such risk estimates as a basis for proposing a standard level below 35 μg/m³, and instead prefers to rely on inferences that are based directly on the evidence in the studies themselves.

Taking the above considerations into account, the Administrator proposes to set the level of the primary 24-hour $PM_{2.5}$ standard at 35 μg/m³. In the Administrator's judgment, based on the currently available evidence, a standard set at this level would protect public health with an adequate margin of safety from serious health effects including premature mortality and hospital admissions for cardiorespiratory causes that are likely causally associated with short-term exposure to $PM_{2.5}$. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. Being mindful that the available evidence does not provide a basis for identifying a bright line within the range of 35 to 30 μg/m³ that clearly provides the appropriate degree of public health protection, the Administrator also

[42] As discussed in the Staff Paper (EPA, 2005a, p. 5–30) and supporting staff memo (Ross and Langstaff, 2005), staff focused on U.S. and Canadian short-term exposure $PM_{2.5}$ studies that had been reanalyzed as appropriate to address statistical modeling issues and considered the extent to which the reported associations are robust to co-pollutant confounding and alternative modeling approaches and the extent to which the studies used relatively reliable air quality data.

[43] Of the studies within this group that evaluated multipollutant associations, as discussed above in section II.A.3, the results reported in Fairley (2003), Sheppard et al. (2003), and Ito (2003) were generally robust to inclusion of gaseous co-pollutants, whereas the effect estimate in Thurston et al. (1994) was substantially reduced with the inclusion of O_3.

[44] For example, Delfino et al. (1997) report statistically significant associations between $PM_{2.5}$ and respiratory emergency department visits for elderly people (>64 years old), but not children (<2 years old) in one part of the study period (summer 1993) but not the other (summer 1992). Peters et al. (2000) report new findings of associations between fine particles and cardiac arrhythmia, but the Criteria Document observes that the strongest associations were reported for a small subset of the study population that had experienced 10 or more defibrillator discharges (EPA, 2004, p. 8–164).

solicits comment on selecting a lower level within this range.

Having reached this decision to propose a level of 35 μg/m³ for the 24-hour $PM_{2.5}$ standard based on the approach to interpreting the available evidence described above, the Administrator recognizes that other approaches to selecting a standard level have been presented to the Agency. These other approaches reflect alternative views, principally expressed in public comments to date, as to the appropriate interpretation of the scientific evidence and the appropriate policy response in light of that interpretation. One such view focuses very strongly on the uncertainties inherent in the epidemiologic and toxicologic studies and the quantitative risk assessment as the basis for concluding that no change to the current 24-hour $PM_{2.5}$ standard of 65 μg/m³ is warranted. Such commenters prefer greater weight, for example, on issues related to the sensitivity in the magnitude and statistical significance of relative risks reported in studies using different statistical models, noting that further research is needed to inform modeling strategies that will appropriately adjust for temporal trends and weather variables in time-series studies. Additional uncertainties arise from the potential confounding by co-pollutants, and the potential differential toxicity of components within the mix of fine particles. These commenters suggest that the magnitude of risks associated with fine particle exposures have decreased since the last review. Some such commenters also focus on considerations such as the absence of clear evidence from toxicologic studies and from studies focused on elucidating specific physiologic mechanisms by which $PM_{2.5}$ may be causing the observed effects. Such commenters recognize a need for a 24-hour $PM_{2.5}$ standard, but consider the evidence to be too uncertain overall to warrant any tightening of the standard and instead believe the appropriate policy response in light of this uncertainty is to retain the current level of the 24-hour standard.

Other commenters who also focus strongly on the uncertainties inherent in the epidemiologic and toxicologic studies and the quantitative risk assessment reach a somewhat different conclusion as to the appropriate policy response in light of these uncertainties. This group of commenters sees a basis for lowering the level of the 24-hour $PM_{2.5}$ standard, but does not believe that a level as low as 35 μg/m³ is warranted. Such commenters note that while many of the studies within the range of air quality from approximately 39 μg/m³ up to the level of the current standard of 65 μg/m³ report statistically significant results, only a few such studies independently evaluated confounding by co-pollutants. This lack of a broader assessment of co-pollutants, together with other types of uncertainties as noted above, leads such commenters to conclude that a standard level selected from below this range is not warranted, and that the appropriate policy response is to select a standard level from within the range of about 40 to 65 μg/m³.

In sharp contrast, others view the epidemiologic evidence and other health studies as strong and robust, and generally place much weight on the results of the quantitative risk assessment as a basis for concluding that a much stronger policy response is warranted, generally consistent with a standard level at or below 25 μg/m³. While recognizing that important uncertainties are inherently present in both the evidence and estimated risks, these commenters generally support a view that such uncertainties warrant a highly precautionary policy response, particularly in view of the serious nature of the health effects at issue, and should be addressed by selecting a standard level that incorporates a large margin of safety.

The Administrator recognizes that these sharply divergent views on the appropriate level of the standard are based on very different interpretations of the science itself including its relative strengths and limitations and on very different judgments as to how such scientific evidence should be used in making policy decisions on proposed standards. Consistent with the goal of soliciting comments on a wide array of views, the Administrator also solicits broad public comment on these and other alternative approaches and on the related standard levels, such as levels from 35 μg/m³ up to 65 μg/m³ or from 30 μg/m³ down to 25 μg/m³, that commenters may believe are appropriate, along with the rationale supporting such approaches and levels. In addition, the Administrator solicits comments on issues related to the interpretation of relevant epidemiologic and toxicologic studies, including approaches to addressing uncertainties related to the sensitivity of results to alternative statistical modeling approaches, co-pollutant confounding, and the lack of a discernable threshold of effects, as well as approaches to more fully characterize uncertainties in quantitative risk assessments based on epidemiologic studies.

2. Annual $PM_{2.5}$ Standard

Based on the approach discussed at the beginning of this section, the Administrator has relied upon evidence from the long-term exposure $PM_{2.5}$ studies as the principal basis for selecting the level of the annual standard. In considering these studies as a basis for the level of an annual standard, the Administrator agrees with the focus in the Staff Paper of looking at the long-term mean $PM_{2.5}$ concentrations across the cities included in such studies. In so doing, the Administrator recognizes that these studies, like the short-term exposure studies, provide no evidence of clear effect thresholds or lowest-observed-effects levels. Thus, in focusing on the cross-city long-term mean concentrations in these studies, the Administrator is seeking to establish a standard level that will require improvements in air quality in areas in which long-term exposure to $PM_{2.5}$ can reasonably be expected to be associated with serious health effects.

Based on the characterization and assessment of the long-term exposure $PM_{2.5}$ studies presented in the Criteria Document and Staff Paper, the Administrator recognizes the importance of the validation efforts and reanalysis that have been done since the last review of the original Six Cities and ACS mortality studies. These new assessments provide evidence of generally robust associations and provide a basis for greater confidence in the reported associations than in the last review, for example, in the extent to which they have made progress in understanding the importance of issues related to co-pollutant confounding and the specification of statistical models. Consistent with the information available in the last review, these two key long-term exposure mortality studies reported long-term mean $PM_{2.5}$ concentrations across all the cities included in the studies of 18 and 21 μg/m³, respectively. The Administrator also particularly recognizes the importance of the extended ACS mortality study, published since the last review, which provides new evidence of mortality related to lung cancer and further substantiates the statistically significant associations with cardiorespiratory-related mortality observed in the original studies. The Administrator notes that the statistically significant associations reported in the extended ACS study, in a large number of cities across the U.S., provide evidence of effects at a lower long-term mean $PM_{2.5}$ concentration (17.7 μg/m³) than had been observed in the original study,

although the relative risk estimates are somewhat smaller in magnitude than those reported in the original study. The assessment in the Criteria Document of these mortality studies, taking into account study design, the strength of the study (in terms of statistical significance and precision of result), and the consistency and robustness of results, concludes that it would be appropriate to give the greatest weight to the reanalyses of the Six Cities and ACS studies, and in particular to the results of the extended ACS study (EPA, 2004, p. 9–33) in weighing the evidence of mortality effects associated with long-term exposure to $PM_{2.5}$. Consistent with that assessment, the Administrator places greatest weight on these studies as a basis for selecting the level of the annual $PM_{2.5}$ standard.

In addition to these mortality studies, the Administrator also recognizes the availability of relevant morbidity studies providing evidence of respiratory morbidity, including decreased lung function growth, in children with long-term exposure to $PM_{2.5}$. Studies conducted in the U.S. and Canada include the 24-city study considered in the last review and new studies of cohorts of children in southern California, in which the long-term mean $PM_{2.5}$ concentrations in all the cities included in the studies are approximately 14.5 and 15 μg/m^3, respectively. As discussed in section II.A. above, in the 24-city study, statistically significant associations were reported between long-term fine particle exposures and lung function measures at a single point in time, whereas positive but not statistically significant associations were reported with prevalence of several respiratory conditions. As interpreted in the last review, the results from the 24-city study are uncertain as to the extent to which the association extends below a long-term mean $PM_{2.5}$ concentration of approximately 15 μg/m^3. The new southern California children's cohort study provides evidence of important respiratory morbidity effects in children, including evidence for a new measure of morbidity, decreased growth in lung function. Reports from this study suggest that long-term $PM_{2.5}$ exposure is associated with decreases in lung function growth, as measured over a four-year follow-up period, although statistically significant associations are not consistently reported. The Administrator recognizes that these are important new findings, indicating that long-term $PM_{2.5}$ exposure may be associated with respiratory morbidity in children. However, the Administrator also observes this is the only study reporting decreased lung function growth, conducted in just one area of the country, such that further study of this health endpoint in other areas of the country would be needed to increase confidence in the reported associations. Thus, at this time, the Administrator provisionally concludes that this study provides an uncertain basis for establishing the level of a national standard.

As discussed in the Staff Paper (EPA, 2005a, p. 5–22), the Administrator generally agrees that it is appropriate to consider a level for an annual $PM_{2.5}$ standard that is below the averages of the long-term $PM_{2.5}$ concentrations across the cities in the key long-term exposure mortality studies, recognizing that the evidence of an association in any such study is strongest at and around the long-term average where the data in the study are most concentrated. The Administrator is mindful that considering what standard is requisite to protect public health with an adequate margin of safety requires policy judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. The Administrator provisionally concludes that these key mortality studies, together with the morbidity studies, provide a basis for considering a standard level no higher than 15 μg/m^3. This level is somewhat below the long-term mean concentrations in the key mortality studies and consistent with the interpretation of the evidence from the morbidity studies discussed above. Further, in the Administrator's view, these studies do not provide a clear basis for selecting a level lower than the current standard of 15 μg/m^3.

In considering the extent to which the quantitative risk assessment can help to inform these judgments with regard to the annual $PM_{2.5}$ standard, the Administrator again recognizes that risk estimates based on simulating the attainment of standards set at lower levels, as expected, continue to suggest some additional reductions in risk at the lower standard level considered in the assessment, and that these estimates largely depend upon assumptions made about the lowest level at which reported associations will likely persist and remain causal in nature. Thus, the Administrator is again hesitant to use such risk estimates as a basis for proposing a lower annual standard level than 15 μg/m^3, the level that is based directly on the evidence in the studies themselves, as discussed above.

Taking the above considerations into account, the Administrator proposes to retain the level of the primary annual $PM_{2.5}$ standard at 15 μg/m^3. In the Administrator's judgment, based on the currently available evidence, a standard set at this level would be requisite to protect public health with an adequate margin of safety from serious health effects including premature mortality and respiratory morbidity that are likely causally associated with long-term exposure to $PM_{2.5}$. This judgment by the Administrator appropriately considers the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In so doing, the Administrator recognizes that the CASAC Panel did not endorse retaining the annual standard at the current level of 15 μg/m^3 (Henderson, 2005a, p. 7). In weighing the recommendation of the CASAC Panel, the Administrator has carefully considered the stated reasons for it. In discussing its recommendation (Henderson, 2005a), the CASAC Panel first noted that changes to either the annual or 24-hour $PM_{2.5}$ standard, or both, could be recommended. Three reasons were then given for placing more emphasis on lowering the 24-hour standard than the annual standard: (1) The vast majority of studies indicating effects of short-term $PM_{2.5}$ exposure were carried out in settings in which $PM_{2.5}$ concentrations were largely below the current 24-hour standard level of 65 μg/m^3; (2) the amount of evidence on short-term exposure effects, at least as reflected by the number of reported studies, is greater than for long-term exposure effects; and (3) toxicologic findings are largely related to the effects of short-term, rather than long-term, exposures. In not endorsing the option of retaining the level of the current annual standard in conjunction with lowering the 24-hour standard, the CASAC Panel observed that some cities have relatively high annual $PM_{2.5}$ concentrations without much day-to-day variation and that such cities would only rarely exceed a 24-hour standard, even if it were set at a level below the current standard. In such a city, attaining a 24-hour standard would likely have minimal if any effect on the long-term mean $PM_{2.5}$ concentration and consequently would be less likely to reduce health effects associated with long-term exposures. These observations

were taken as an indication of the desirability of lowering the level of the annual $PM_{2.5}$ standard as well as that of the 24-hour standard. Based on these considerations and taking into account the results of the risk assessment, most CASAC Panel members favored setting an annual standard in the range of 14 to 13 μg/m³, along with lowering the 24-hour standard (Henderson, 2005a).

In considering these views, the Administrator notes that the appropriateness of setting an annual standard that would lower annual $PM_{2.5}$ concentrations in cities across the country depends upon a policy judgment as to what annual level is required to protect public health with an adequate margin of safety from long-term exposures to $PM_{2.5}$ in light of the available evidence. In considering the evidence of effects associated with long-term $PM_{2.5}$ exposure as a basis for selecting an adequately health protective annual standard, as discussed above, the Administrator provisionally concludes that the evidence does not provide a basis for requiring annual levels below 15 μg/m³. Thus, the Administrator agrees conceptually with the CASAC Panel that any particular 24-hour standard may not result in reductions in the level of long-term exposures to $PM_{2.5}$ in all areas with relatively higher than typical annual $PM_{2.5}$ concentrations and lower than typical ratios of peak-to-mean values. Further, the Administrator agrees that this general advice supports relying on the annual standard, and not the 24-hour standard, to achieve the appropriate level of protection from long-term exposures to $PM_{2.5}$. However, the Administrator does not believe that this advice necessarily translates into a reason for setting the annual $PM_{2.5}$ standard at a level below the current level of 15 μg/m³. As discussed above, the Administrator believes the principal basis for selecting the appropriate level of an annual standard should be the evidence provided by the long-term studies, in conjunction with judgments concerning whether and over what range of concentrations reported associations are likely causal, and this evidence reasonably supports retaining the current level of the annual standard.

The Administrator places great importance on the advice of CASAC, and therefore solicits broad public comment on the range of 15 down to 13 μg/m³, the low end of the range recommended by CASAC, for the level of the annual $PM_{2.5}$ standard as well as on the reasoning that formed the basis for that recommendation. A decision to select a standard from within this range would place greater weight on the strength of the associations reported in the key epidemiologic mortality and morbidity long-term exposure studies down to the lower part of the range of $PM_{2.5}$ concentrations observed across all the cities included in these studies. Such a standard could also reflect greater reliance on the results of the quantitative risk assessment that suggested increased reductions in risk associated with meeting an annual standard at such lower levels.

The Administrator recognizes that an even stronger view of the appropriate policy response to the currently available evidence has been expressed by some public commenters. These commenters have focused principally on the strength of the long-term exposure studies, including the new children's cohort study conducted in southern California, as well as on those results from the quantitative risk assessment that are based on the assumption that there is no threshold of effects down to the lowest levels observed in those studies. Such considerations generally have led these commenters to express views that support a highly precautionary policy response and the selection of a standard level that incorporates a large margin of safety, consistent with an annual $PM_{2.5}$ standard level of 12 μg/m³. The Administrator recognizes that this view is based on a different interpretation of the science itself including its relative strengths and limitations and on different judgments as to how such scientific evidence should be used in making policy decisions on proposed standards. Consistent with the goal of soliciting comments on a wide array of views, the Administrator also solicits broad public comment on this alternative approach and on the related standard level of 12 μg/m³.

The Administrator also recognizes a contrasting view as to the interpretation of and weight to be accorded to the results from the ACS-based studies (Pope et al., 1995; Krewski et al., 2000; Pope et al., 2002). In this view, the ACS-based studies are not sufficiently robust to support a policy response that would tighten the annual $PM_{2.5}$ standard based on the evidence. This view emphasizes the sensitivity of the results of these studies to plausible changes in model specification with regard to accounting for the geographical proximity of cities and the correlation of air pollutant concentrations within a region, effect modification by education level, and inclusion of SO_2 in the model. In this view, these sensitivities suggest potential confounding or effect modification that has not been taken into account. For example, concern has been raised about the sensitivity of results in the reanalysis of data from the ACS cohort study (Krewski et al., 2000) to inclusion of SO_2 in the models. As discussed in section II.A.2.b above, the reanalysis found that $PM_{2.5}$, sulfates, and SO_2 were each associated with mortality in single-pollutant models. However, in two-pollutant models with SO_2 and $PM_{2.5}$, the relative risk for $PM_{2.5}$ was substantially smaller and no longer statistically significant, whereas the effect estimates for SO_2 were not sensitive to inclusion of $PM_{2.5}$ or sulfates in two-pollutant models. In this view, the ACS-based risk estimates are more robust for SO_2 than for $PM_{2.5}$ or sulfates. In further extended analyses, Pope et al. (2002) reported that effect estimates were not highly sensitive to spatial smoothing approaches intended to address spatial autocorrelation, while findings of effect modification by education level were reaffirmed. Results of multi-pollutant models were not reported by Pope et al. (2002). Because the correlation coefficient between $PM_{2.5}$ and SO_2 was 0.50 in the ACS data, in this view it is plausible to believe that the independent effects of the two pollutants could be disentangled with additional study.

In this view, there is a separate but related concern that tightening the annual standard now, without a clear understanding of which specific PM-related pollutants are most toxic, will have very uncertain public health payoffs. In response to the advice of the National Research Council (NRC) and other scientists, the Agency is undertaking, as one of its higher priorities, a substantial research program to clarify which aspects of PM-related pollution are responsible for elevated risks of mortality and morbidity. For example, the Health Effects Institute has issued a request for applications to analyze the largest database on specific components of PM that has ever been assembled for public health and medical researchers. The time line for this multi-million dollar research program is well designed to inform the Agency's next periodic reevaluation of the primary ambient air quality standard for $PM_{2.5}$. In light of the degree of sensitivity of the ACS-based relative risk estimates to model specifications and the significant research underway, in this view, it would be wiser to consider modification of the annual standard with a fuller body of information in hand rather than initiate a change in the annual standard at this time.

The Administrator solicits comment on this view and on the issues raised in interpreting the results of the ACS-based

studies. For example, comment is solicited on the extent to which the associations reported in the ACS-based studies suggest that SO_2 should be considered as a surrogate for fine particles and/or the broader mix of air pollutants or as an independent pollutant exhibiting separate effects. Comment is also solicited on relevant research that would improve our understanding of issues related to model specification and alternative analytic approaches that would better inform judgments based on such epidemiologic studies in the future.

H. Proposed Decisions on Primary $PM_{2.5}$ Standards

For the reasons discussed above, and taking into account the information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and public comments to date, the Administrator proposes to revise the current primary $PM_{2.5}$ standards. Specifically, the Administrator proposes to revise (1) the level of the 24-hour $PM_{2.5}$ standard to 35 μg/m^3, and (2) the form of the annual $PM_{2.5}$ standard by changing the constraints on the use of spatial averaging to include the criterion that the minimum correlation coefficient between monitor pairs to be averaged be 0.9 or greater, determined on a seasonal basis, and the criterion that differences between monitor values not exceed 10 percent. Data handling conventions are specified in proposed revisions to Appendix N, as discussed in Section V below, and the reference method for monitoring PM as $PM_{2.5}$ is specified in proposed minor revisions to Appendix L, as discussed in Section VI below.

In recognition of alternative views of the science and the appropriate policy response based on the currently available information, the Administrator also solicits comments on (1) alternative levels of the 24-hour $PM_{2.5}$ standard within the range of 35 to 30 μg/m^3, and alternative approaches for selecting the level of the 24-hour $PM_{2.5}$ standard, and related levels (such as approaches that suggest retaining the current level of 65 μg/m^3, setting a level no higher than 25 μg/m^3, or setting a level within the range of 65 down to 35 μg/m^3); (2) alternative levels of the annual $PM_{2.5}$ standard below 15 μg/m^3 down to12 μg/m^3; (3) issues related to consideration of alternative indicators of fine particle components; and (4) an alternative form of the annual $PM_{2.5}$ standard based on the highest community-oriented monitor in an area. Based on the comments received and the accompanying rationales, the Administrator may adopt other standards within the range of the alternatives identified above in lieu of the standards he is proposing today.

The Administrator solicits comment on all aspects of this proposed decision. Comment is specifically invited on the methodology for evaluating the uncertainty and significance of risks to public health. The Administrator believes that it is important to further develop ways of addressing uncertainty when estimating such risk, recognizing the wide variety of information available in the underlying health effects and other studies. The Agency seeks comment on methods and approaches for conducting a more formalized uncertainty analysis. In addition, the Agency seeks comment on how to evaluate the results from a formalized uncertainty analysis or from the Staff Paper's risk assessment, which addresses multiple health effects across multiple populations, in the context of judging the public health importance of such risks and determining the requisite level of public health protection for the PM standards.

To address issues related to the transition from the current $PM_{2.5}$ standards to revised $PM_{2.5}$ standards, the Administrator intends to seek public comment on EPA's implementation plans for the revised $PM_{2.5}$ standards, including its plans for assuring an effective transition, as part of an advance notice of proposed rulemaking (ANPR) on NAAQS implementation that will be published in an early in 2006. In this ANPR, EPA will be discussing issues related to the timing and regulatory implications of this transition. The EPA intends to present and take comment on the need and potential approaches for revocation of the current 24-hour $PM_{2.5}$ standard, and on issues related to the establishment of no-backsliding requirements, such as those adopted by the Agency in 1997 with respect to the ozone NAAQS. The EPA also expects to address a variety of implementation issues concerning revised $PM_{2.5}$ standards in the ANPR. The ANPR will explain the designation process and its timing, and the timing of SIP submittals for both attainment and nonattainment areas. The EPA also expects to address issues regarding the attainment dates for areas designated nonattainment. The EPA will also discuss new source permitting requirements for both attainment and nonattainment areas, i.e., the PSD and Part D NSR programs. If the Administrator promulgates a revised $PM_{2.5}$ standard, EPA will determine the final implementation approach for that standard.

III. Rationale for Proposed Decisions on Primary PM_{10} Standards

This action presents the Administrator's proposed decisions on revision to the primary NAAQS for PM_{10}. The rationale for the proposed revisions of the primary PM_{10} NAAQS includes consideration of: (1) Evidence of health effects related to short- and long-term exposures to thoracic coarse particles; (2) insights gained from a quantitative risk assessment prepared by EPA; and (3) specific conclusions regarding the need for revisions to the current standards and the elements of PM_{10} standards (i.e., indicator, averaging time, form, and level) that, taken together, would be requisite to protect public health with an adequate margin of safety.

In developing this rationale, EPA has taken into account the information available from a growing, but still limited, body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10\text{-}2.5}$ as a measure of thoracic coarse particles. The EPA has drawn upon an integrative synthesis of the body of evidence on associations between exposure to ambient thoracic coarse particles and a range of health endpoints (EPA, 2004, Chapter 9), focusing on those health endpoints for which the Criteria Document concludes that the associations are suggestive of possible causal relationships. In its policy assessment of the evidence judged to be most relevant to making decisions on elements of the standards, EPA has placed greater weight on U.S. and Canadian epidemiological studies using thoracic coarse particles measurements, since studies conducted in other countries may well reflect different demographic and air pollution characteristics.

While there is little question that particles in the thoracic coarse particle size range can present a risk of adverse effects to the most sensitive regions of the respiratory tract, the characterization of health effects attributable to various levels of exposure to ambient thoracic coarse particles is subject to uncertainties that are markedly greater than is the case for fine particles. As discussed below, however, there is a growing body of evidence available since the last review of the PM NAAQS, with important new information coming from epidemiologic, toxicologic, and dosimetric studies. Moreover, the newly available research studies have undergone intensive scrutiny through multiple layers of peer review and extended opportunities for public review and comment. While

important uncertainties remain, the review of the health effects information has been extensive and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence has provided an adequate basis for proposing regulatory decisions at this time. This review also provides important input to EPA's research plan for improving our future understanding of the relationships between exposures to ambient thoracic coarse particles and health effects.

A. Evidence of Health Effects Related to Thoracic Coarse Particle Exposure

The first PM NAAQS (36 FR 8186) used an indicator based solely on a preexisting monitor for total suspended particles (TSP) that was not designed to focus on particles of greatest risk to health. In preparing for the initial review of those standards, EPA placed a major emphasis on developing a new indicator that considered the significant amount of evidence on particle size, composition, and relative risk of effects from penetration and deposition to the major regions of the respiratory tract (Miller et al., 1979). The development and assessment of these lines of evidence in the PM Criteria Document and PM Staff Paper published between 1979 and 1986 culminated in revised standards for PM that used PM_{10} as the indicator (52 FR 24634). The major conclusion from that review, which remained unchanged in the 1997 review, was that ambient particles smaller than or equal to 10 μm in aerodynamic diameter are capable of penetrating to the deeper ''thoracic'' [45] regions of the respiratory tract and present the greatest concern to health (61 FR 65648). While considerable advances have been made, the available evidence in this review continues to support the basic conclusions reached in the 1987 and 1997 reviews regarding penetration and deposition of fine and thoracic coarse particles. As discussed in the Criteria Document, both fine and thoracic coarse particles penetrate to and deposit in the alveolar and tracheobronchial regions. For a range of typical ambient size distributions, the total deposition of thoracic coarse particles to the alveolar region can be comparable to or even larger than that for fine particles. For areas with appreciable coarse particle concentrations, thoracic coarse particles would tend to dominate particle deposition to the tracheobronchial region for mouth breathers (EPA, 2004, p. 6–16). Deposition of particles to the tracheobronchial region is of particular concern with respect to aggravation of asthma.

In the last review, little new toxicologic evidence was available on potential effects of thoracic coarse particles and there were few epidemiologic studies that had included direct measurements of thoracic coarse particles. Evidence of associations between health outcomes and PM_{10} that were conducted in areas where PM_{10} was predominantly composed of thoracic coarse particles was an important part of the basis for reaching conclusions about the requisite level of protection provided against coarse particles for the final standards. The new studies available in this review include a number of epidemiologic studies that have reported associations with health effects using direct measurements of $PM_{10\text{-}2.5}$, as well as a number of new toxicologic studies.

This section outlines key information contained in the Criteria Document (Chapters 6–9 and the Staff Paper (Chapter 3) on known or potential effects associated with exposure to thoracic coarse particles and their major constituents. The information highlighted here summarizes: (1) New information available on potential mechanisms for health effects associated with exposure to thoracic coarse particles or their constituents; (2) the nature of the effects that have been associated with ambient thoracic coarse particles or their constituents; (3) an integrative assessment of the evidence on health effects related to thoracic coarse particles; (4) subpopulations that appear to be sensitive to effects of exposure to thoracic coarse particles; and (5) the public health impact of exposure to ambient thoracic coarse particles.

1. Mechanisms

As summarized above, the first review of the PM NAAQS found a strong basis for concluding that thoracic coarse particles could be plausibly linked to health effects. This was based on an integrated assessment of the physical and chemical characteristics of ambient coarse particles, the evidence regarding health effects that could be associated with deposition of coarse particulate substances in the different regions of the respiratory tract, and the relative potential for penetration and deposition of ambient distributions of coarse particles in the human respiratory tract (52 FR 24634). In the 1987 review, EPA found that occupational and toxicologic studies provided ample cause for concern related to higher levels of thoracic coarse particles. Such findings indicated that elevated levels of thoracic coarse particles were linked with effects such as aggravation of asthma and increases in upper respiratory illness, which was consistent with dosimetric evidence of enhanced deposition of thoracic coarse particles in the respiratory tract (61 FR 65649).

Toxicologic and controlled human exposure studies available in previous reviews have generally used particle exposures at levels higher than ambient levels, relying on various particle components or surrogates. Such studies reported some effects on the respiratory tract, indicative of inflammatory or irritant effects for particles in both the fine and thoracic coarse particle size range (EPA, 1982, chapters 12 and 13; EPA, 1996, chapters 10 and 11). As discussed above in section II.A, the results of numerous new toxicologic and controlled human exposure studies have implicated a number of potential mechanisms or pathways for effects associated with PM. Many of these studies have used particle exposures that are generally more relevant to studying the effects of fine particles than those of thoracic coarse particles. However, several studies, discussed more fully below, have suggested mechanisms or pathways for thoracic coarse particles to cause inflammatory and other effects on the respiratory system. This evidence generally supports previous conclusions that thoracic coarse particles can affect the respiratory system.

Some limited evidence is available from recent toxicologic studies on effects of exposure to thoracic coarse particles, specifically using $PM_{10\text{-}2.5}$, for either acute or chronic exposures (EPA, 2004, p. 9–55). This toxicologic evidence includes results from studies where respiratory cell cultures were exposed to ambient particles, thus providing insight into potential mechanisms for respiratory effects of thoracic coarse particles. The types of effects reported include inflammatory and allergic effects. For example, two recent studies report inflammatory responses in cells exposed to extracts of water-soluble and water-insoluble materials from thoracic coarse particles and fine particles collected in Chapel Hill, NC (Monn and Becker, 1999; Soukup and Becker, 2001). One study focused on water-soluble materials, and reported significant immune system effects with water-soluble extracts of ambient $PM_{10\text{-}2.5}$, in contrast to the lack of effects observed with extracts from

[45] The 'thoracic' regions of the respiratory tract are located in the chest (thorax) and are comprised of the tracheo-bronchial region with connecting airways and the alveolar, or gas-exchange region of the lung. For ease of communications, 'thoracic' particles penetrating to these regions are often called 'inhalable' particles.

ambient $PM_{2.5}$ as well as indoor-collected $PM_{10-2.5}$ and $PM_{2.5}$. The authors report that different components of $PM_{10-2.5}$ appeared to have different effects, with endotoxin implicated in inflammatory effects, while coarse particulate metals appeared to have a role in cytotoxicity effects (Monn and Becker, 1999). A followup study in the same laboratory (Soukup and Becker, 2001) reports that the insoluble materials from thoracic coarse particles resulted in several effects on immune system cells.[46] In this extract of thoracic coarse particles, endotoxin appeared to be the most pro-inflammatory component, but components other than endotoxin or metals appeared to contribute to other effects. Using particles collected in two urban areas in the Netherlands, Becker et al. (2003) reported that thoracic coarse particles, but not fine or ultrafine particles, resulted in effects related to inflammation and decreased pulmonary defenses. This small group of studies thus suggests that exposure to thoracic coarse particles may cause pro-inflammatory effects, as well as cytotoxicity and oxidant generation (EPA, 2004, section 7.4.2). While still limited, these emerging new studies provide additional insight into potential mechanisms for respiratory effects of thoracic coarse particles. The results also indicate that different health responses may be linked with different components of thoracic coarse particles.

In contrast, one recent study exposed human red blood cell cultures to ambient coarse particles collected in Italy and found only limited effects on blood cells (Diociaiuti et al., 2001). The addition of thoracic coarse particles that were collected in Italy to human respiratory tract cell cultures produced only limited evidence of carcinogenic effects; some response was seen with thoracic coarse particles but greater response was reported with fine particle exposures (Hornberg et al., 1998). These latter results are consistent with the evidence from epidemiologic studies, which provide no direct evidence for carcinogenicity of thoracic coarse particles.

As noted in past reviews (EPA, 1981b, 1996b), deposition of a variety of particle types in the tracheobronchial region, including resuspended urban dust and coarse-fraction organic materials, has the potential to affect lung function and aggravate symptoms, particularly in asthmatics. Of particular note are limited toxicologic studies that found urban road dust can produce cellular and immunological effects (e.g., Kleinman et al., 1995; Steerenberg et al., 2003). Road dust is a major source of thoracic coarse particles in urban areas and is therefore representative of the components expected to be found in resuspended thoracic coarse particles. In the 1996 Staff Paper, results from the study by Kleinman and colleagues (1995) were highlighted in which effects were observed in rats with inhalation exposure to road dust. These effects included changes in the structure of the rat airways as well as effects on immune cells. Higher concentrations of road dust were needed to cause effects, compared with exposures to fine particle components (e.g., sulfates, nitrates), in part because of the limited penetration of coarse-sized particles past the nose of the rats studied (EPA, 1996b, p. V–70).[47] Another study used a standard toxicologic approach to studying allergic responses, and the authors concluded that exposure to road tunnel dust particles resulted in greater allergy-related effects than did exposure to several other particle samples, including residual oil fly ash and diesel exhaust particles (Steerenberg et al., 2003).[48] In this study, the particles were collected in a road tunnel and placed directly in the animal respiratory tract, so differences in inhalability of larger particles in rodents was not an issue. In contrast, a number of studies have reported that Mt. St. Helens volcanic ash, which is generally in the size range of thoracic coarse particles, has very little toxicity in animal or in vitro toxicologic studies (EPA, 2004, p. 7–216).

The Criteria Document finds that the limited number of recent toxicologic studies using $PM_{10-2.5}$ provide some evidence that coarse fraction particle exposures can result in effects primarily linked to the respiratory system, related to inflammation or aggravation of allergic effects. Toxicologic studies have suggested potential pathways for effects from a few sources or components of thoracic coarse particles, such as road dust particles, metals or organic constituents. The need to better understand the relationship between different components or sources of thoracic coarse particles remains a key area of uncertainty with regard to the effects of thoracic coarse particles.

2. Nature of Effects

In the last review, EPA considered a substantial number of epidemiological studies using PM_{10}, which contains both fine and coarse particles, as a measure of exposure to PM. In many such studies in which fine and coarse particles occur at similar levels, it is difficult or impossible to determine whether fine and coarse particles both played major roles in the associations. Accordingly, considerable emphasis was placed on the more limited body of evidence from PM_{10} studies in locations where coarse particles were a much greater fraction of PM_{10} than were fine particles. These findings indicated that short-term exposure to thoracic coarse particles in such areas was linked with respiratory morbidity effects, such as aggravation of asthma, increases in respiratory symptoms and respiratory infections (62 FR 38677). The single available short-term exposure study that compared associations between mortality and fine and coarse particles reported a significant association between short-term exposure to $PM_{10-2.5}$ and mortality in one of six cities (Steubenville, OH). In this location, an unusually high correlation between high levels of fine and thoracic coarse particles suggested a common industrial source, and a clear conclusion about the relative contribution was not possible. The study found no association with thoracic coarse particles in a combined multi-city analysis (Schwartz et al., 1996; CD, p. 8–40 to 8–41).[49] No studies in the past review provided clear epidemiologic evidence of mortality or morbidity effects related to long-term exposure to $PM_{10-2.5}$. EPA observed that toxicologic studies offered some qualitative evidence suggesting the potential for effects on the respiratory system with long-term exposure to coarse particles or coarse particle constituents (62 FR 38678).

In this review, epidemiologic studies have continued to support a relationship between short-term exposure to thoracic coarse particles and respiratory morbidity, with effects ranging from increased respiratory symptoms to hospitalization for respiratory diseases. As discussed below, the new studies also suggest associations with effects on the cardiovascular system and possibly with

[46] Examples of such effects include cytokine production, decreased phagocytic ability and oxidant generation.

[47] The particles used in this study were collected by vacuum sweeping of freeway surfaces in California, and were generally 5 μm in diameter or lower (Kleinman et al., 1995).

[48] This approach, using ovalbumin-sensitized mice, is commonly used for comparing allergic potency of air pollutants. The authors also tested responses in an additional toxicologic model, based on pollen-sensitized rats, and reported responses only with diesel exhaust particles (Steerenberg et al., 2003, p. 1436).

[49] Note that in more recent reanalyses of this study to investigate statistical modeling issues, the association for Steubenville was not statistically significant in most models reported in the two reanalyses (Klemm and Mason, 2003; Schwartz, 2003a).

mortality. Figure 2 summarizes results from both multi-city and single-city epidemiologic studies using short-term exposures to $PM_{10-2.5}$, including all U.S. and Canadian studies that used direct measurements of $PM_{10-2.5}$[50] and for which effect estimates and confidence intervals were reported. Consistent with the presentation of fine particle study results in Figure 1, the central effect estimate is indicated by a diamond for each study result, with the vertical bar representing the 95 percent confidence interval around the estimate. The results of these epidemiologic studies are discussed below.

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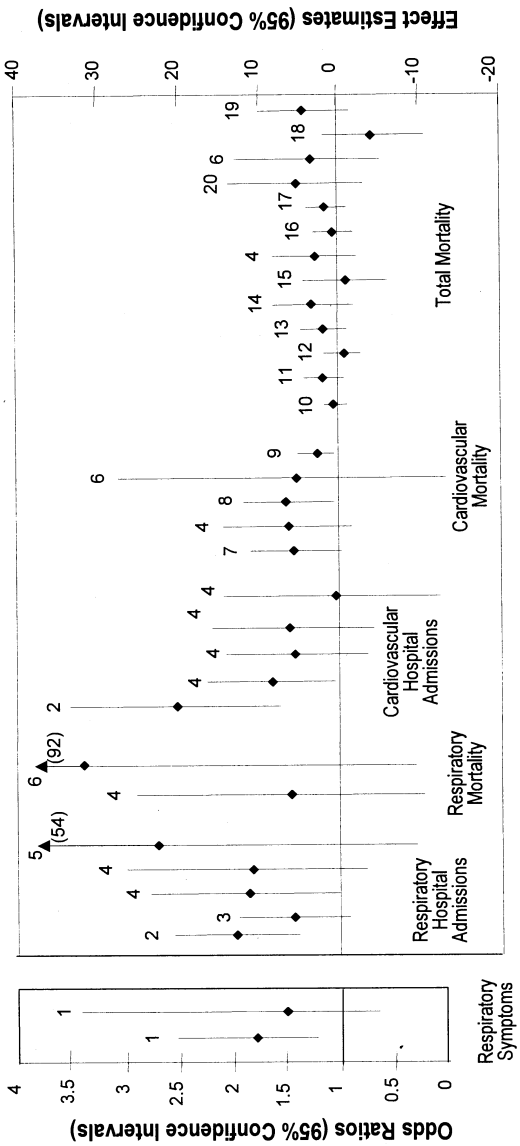

Figure 2. Effect estimates for associations between short-term exposure to $PM_{10-2.5}$ and mortality or morbidity health outcomes in U.S. and Canadian Studies; multi-city studies noted by bold text below.

1. Schwartz and Neas (2000), 6 U.S. cities
2. Burnett et al. (1997), Toronto
3. Sheppard et al. (2003), Seattle
4. Ito (2003), Detroit
5. Thurston et al. (1994), Toronto
6. Fairley (2003), Santa Clara County
7. Lipfert et al. (2000), Philadelphia
8. Mar et al. (2003), Phoenix
9. Ostro et al. (2003), Coachella Valley
10. Klemm and Mason (2003), 6 U.S. cities
11. Burnett and Goldberg (2003), 8 Canadian cities
12. Klemm and Mason (2003), St. Louis
13. Klemm and Mason (2003), Boston
14. Klemm and Mason (2003), Kingston-Harriman
15. Klemm and Mason (2003), Portage
16. Chock et al. (2000), Pittsburgh (<75 y.o.)
17. Chock et al. (2000), Pittsburgh (75+ y.o.)
18. Klemm and Mason (2003), Topeka
19. Klemm and Mason (2003), Steubenville
20. Klemm and Mason (2000), Atlanta

Results presented are from time-series studies that did not use generalized additive models or were reanalyzed using general linear models. For consistency across studies, effect estimates are from single-pollutant, general linear models, based on an increment of 25 $\mu g/m^3$ $PM_{10-2.5}$, and have been plotted in order of decreasing study power, using as an indicator the natural log of the product of the number of study days and number of health events per day. Results for studies of respiratory symptoms are presented as odds ratios; an odds ratio of 1.0 is equivalent to no effect, and thus is presented as equivalent to the zero effect estimate line.

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a. Effects Associated With Short-Term Exposure to Thoracic Coarse Particles

The discussion below focuses first on evidence related to respiratory morbidity effects, since information available in the previous review provided plausible evidence that short-term exposure to thoracic coarse particles was associated with such effects. This is followed by a discussion of new findings on potential cardiovascular effects of thoracic coarse particles, as well as new evidence from studies of mortality.

i. Morbidity

(a) Effects on the Respiratory System

Evidence available in the last review suggested that aggravation of asthma

[50] All epidemiologic studies discussed below included measurements of thoracic coarse particles either through monitors that collected thoracic coarse particles separately (e.g., dichotomous monitors) or using data from side-by-side (co-located) monitors for fine particles and PM_{10}. Investigators have sometimes also used prediction models to ''fill'' or estimate PM concentrations where measurements are not available (most often where data are collected less frequently than daily). In one particular study in Coachella Valley, measurements were made of fine and thoracic coarse particle concentrations for two and a half years. The investigators predicted $PM_{10-2.5}$ concentrations for a longer time series, based on a ten-year data set for PM_{10} for use in the health study (Ostro et al., 2003).

and respiratory infections and symptoms were associated with PM_{10} in areas where thoracic coarse particles were a much greater fraction of PM_{10} than were fine particles, such as Anchorage, AK, and southeast Washington (62 FR 38679). Only one epidemiologic study had used $PM_{10-2.5}$ data; it reported a positive, but not statistically significant, association between respiratory hospital admissions and $PM_{10-2.5}$ in Toronto (Thurston et al., 1994).

Several new studies of respiratory symptoms and lung function have included both $PM_{10-2.5}$ and $PM_{2.5}$ data, and these results suggest a role for thoracic coarse particles as well as for fine particles in associations with respiratory symptoms (EPA, 2004, p. 8–311). In the Six Cities study, a statistically significant increase in cough for children was found with $PM_{10-2.5}$ but not with $PM_{2.5}$, while the reverse was true for lower respiratory symptoms. When both $PM_{10-2.5}$ and $PM_{2.5}$ were included in models, the effect estimates were reduced for each, but $PM_{10-2.5}$ retained significance in the association with cough and $PM_{2.5}$ retained significance in the association with lower respiratory symptoms (Schwartz and Neas, 2000).[51] Changes in lung function were evaluated in three cities in Pennsylvania, and in all three, short-term exposure to thoracic coarse particles was not significantly associated with peak flow rate, although some statistically significant associations were found with exposure to fine particles (EPA, 2004, p. 8–312).

Three new U.S. and Canadian epidemiologic studies have reported associations between short-term exposure to $PM_{10-2.5}$ with hospital admissions for respiratory diseases, including asthma, pneumonia and COPD (Burnett et al., 1997; Ito, 2003; Sheppard et al., 2003). As shown in Figure 2, the effect estimates for these associations are positive and some are statistically significant. In these associations with respiratory hospitalization, the risk estimates tend to fall in the range of 5 to 15 percent per 25 $\mu g/m^3$ $PM_{10-2.5}$ (EPA, 2004, p. 8–193).

Because fine particles and ozone, as well as other gaseous air pollutants, are known to cause respiratory effects, a key consideration for assessing this body of studies is assessment of potential confounding by these co-pollutants, as discussed in detail in Section 8.4.3 of the Criteria Document. The associations reported between respiratory hospital admissions and short-term exposure to $PM_{10-2.5}$ were largely unchanged in most cases when gaseous co-pollutants were included in the models (EPA, 2004, Figure 8–18; Burnett et al., 1997; Ito, 2003).[52] Few investigators have evaluated potential confounding of $PM_{10-2.5}$ effects with adjustment for $PM_{2.5}$ in multi-pollutant models. Only the study conducted in Detroit included such multi-pollutant models for respiratory hospitalization and was reanalyzed to address potential statistical modeling questions. In this study, the simultaneous consideration of $PM_{10-2.5}$ and $PM_{2.5}$ resulted in reduction in the size of the effect estimate, as well as loss of statistical significance, for both pollutants. The authors report that the correlation between the two pollutants was ''modest'' (correlation coefficient of 0.42) (Lippmann et al., 2000, p. 33). The results in this study vary by health outcome; for example, for pneumonia hospitalization, effect estimates for $PM_{2.5}$ were little changed but those for $PM_{10-2.5}$ decreased substantially in magnitude in two-pollutant models. In contrast, effect estimates for $PM_{2.5}$ with COPD hospitalization decreased dramatically, whereas those for $PM_{10-2.5}$ were only slightly decreased in size in two-pollutant models (Ito, 2003, pp. 152, 153).

Additional insight into the respiratory effects of coarse particles is provided by studies using PM_{10} in locations where thoracic coarse particles were a much greater fraction of PM_{10} than were fine particles. This review includes new PM_{10} studies in such relatively high coarse-fraction areas, such as Reno, NV and Anchorage, AK.[53] In these areas, statistically significant associations have been reported between PM_{10} and hospitalization for respiratory diseases (Chen et al., 2000) and outpatient medical visits for asthma (Choudhury et al., 1997). These findings support the evidence from the limited group of studies discussed above that have reported associations between measured $PM_{10-2.5}$ and respiratory morbidity.

Considering evidence from across a range of respiratory morbidity health outcomes, the Criteria Document concludes that the epidemiologic evidence indicates that both fine and thoracic coarse particles impact respiratory health (EPA, 2004, p. 8–311).

(b) Effects on the Cardiovascular System

Two new studies conducted in the U.S. and Canada have also reported associations between short-term exposure to $PM_{10-2.5}$ and hospital admissions for various cardiovascular diseases. The results of these studies are included in Figure 2, where it can be seen that the associations are generally positive and the results of the larger studies with more statistical power are statistically significant (Burnett et al., 1997, cardiovascular disease hospitalization; Ito, 2003, ischemic heart disease hospitalization). The excess risks for hospital admissions for cardiovascular diseases range from about 1 to 10 percent per 25 $\mu g/m^3$ $PM_{10-2.5}$, as seen in the Detroit study (EPA, 2004, p. 8–310). In addition, a statistically significant association was reported between PM_{10} and increased hospitalization for cardiovascular diseases in Tucson, AZ, an urban area where thoracic coarse particles are a much greater fraction of PM_{10} than are fine particles (Schwartz, 1997).[54] The Criteria Document finds that associations between cardiovascular hospitalization and short-term $PM_{10-2.5}$ exposure were relatively unchanged when gaseous co-pollutants were included in the models (EPA, 2004, Figure 8–17; Burnett et al., 1997; Ito, 2003).[55] In assessing potential confounding between $PM_{2.5}$ and $PM_{10-2.5}$, one new study in Detroit reported that simultaneous consideration of $PM_{10-2.5}$ and $PM_{2.5}$ resulted in a reduction in effect estimate

[51] The authors conclude that for acute asthma-related responses as well as daily mortality, fine particles are a stronger predictor of health response that are thoracic coarse particles (Schwartz and Neas, 2000, p. 8).

[52] More specifically, the effect estimates for associations between $PM_{10-2.5}$ and hospitalization for COPD and pneumonia in Detroit are largely unchanged with the addition of gaseous co-pollutants to the models, except in one case where the $PM_{10-2.5}$ effect estimate for COPD hospitalization is substantially reduced in size with the inclusion of O_3 in the model (Ito, 2003). Results for the study in Toronto also show relatively consistent effect estimate size for associations between $PM_{10-2.5}$ and respiratory hospitalization, except for the models including NO_2 and all four gaseous pollutants (Burnett et al., 1997).

[53] For example, Anchorage, AK and Reno, NV do not currently attain the PM_{10} 24-hour standard which is set at 150 $\mu g/m^3$. Based on 2002–2004 data, the 98th percentile $PM_{2.5}$ concentrations in these areas were 21 and 25 $\mu g/m^3$, respectively. As noted in the fine particle discussion above, no short-term exposure studies to date have shown statistically significant associations between fine particles and effects with 98th percentile values this low. This suggests that coarse particles either caused or contributed to the observed PM_{10} associations.

[54] Tucson currently attains the PM_{10} standard, and the 98th percentile 24-hour average concentrations reported for $PM_{2.5}$ are 15 and 17$\mu g/m^3$ at two monitoring sites in the area.

[55] The effect estimates for associations between $PM_{10-2.5}$ and hospitalization for ischemic heart disease and heart failure in Detroit are largely unchanged with the addition of gaseous co-pollutants to the models (Ito, 2003). Results presented for the study in Toronto also show relatively consistent effect estimate size for associations between $PM_{10-2.5}$ and cardiovascular hospitalization, except for the models including NO_2 and all four gaseous pollutants (Burnett et al., 1997).

size and a lack of statistical significance for both PM indicators (Ito, 2003). In the reanalysis for this study, for example, a significant association was reported between $PM_{10-2.5}$ and hospitalization for ischemic heart disease in a single-pollutant model, and in a two-pollutant model the effect estimates for $PM_{2.5}$ and $PM_{10-2.5}$ were both reduced in magnitude and neither remained statistically significant (Ito, 2003, pp. 152, 153).

Epidemiologic studies have also reported associations between short-term exposures to ambient PM (generally using PM_{10} or $PM_{2.5}$) and more subtle cardiovascular health outcomes (e.g., changes in heart rhythm or cardiovascular biomarkers) (EPA, 2004, p. 8–169). Only one of this new set of epidemiologic studies included $PM_{10-2.5}$, and no significant associations were reported between onset of myocardial infarction and short-term $PM_{10-2.5}$ exposures (EPA, 2005a, p. 8–165; Peters et al., 2001).

ii. Mortality

In the few epidemiologic studies available for the last review, only the Six City study summarized above evaluated the relationship between short-term exposure to $PM_{10-2.5}$ and mortality. That study provided a suggestion of a potential effect of thoracic coarse particles only in the city with the highest coarse and fine particle concentrations, but it was not possible to separate fine and thoracic coarse particle contributions.

As shown in Figure 2 for U.S. and Canadian studies, effect estimates for associations between mortality and short-term exposure to $PM_{10-2.5}$ are generally positive and similar in magnitude to those for $PM_{2.5}$ and PM_{10} though most are not statistically significant. In general, the confidence intervals (indicating uncertainty) are greater for associations between mortality and $PM_{10-2.5}$ than for associations with $PM_{2.5}$, as is apparent when directly comparing results from numerous studies as shown in Figure 8–5 of the Criteria Document (EPA, 2004, p. 8–61). In the same comparison, it can be seen that the size of the effect estimates for the associations are in the same range. In general, effect estimates are somewhat larger for respiratory and cardiovascular mortality than for total mortality. Two of the five effect estimates for cardiovascular mortality with short-term $PM_{10-2.5}$ exposure are positive and statistically significant (Mar et al., 2003; Ostro et al., 2003) while none of the effect estimates for total mortality reach statistical significance. The new studies include a multi-city study that uses data from the eight largest Canadian cities and reported associations between total mortality and $PM_{10-2.5}$ as well as $PM_{2.5}$ and PM_{10}. The effect estimates were of similar magnitude for each PM indicator (Burnett and Goldberg, 2003), but the association with $PM_{10-2.5}$ did not reach statistical significance. The magnitude of the effect estimates for $PM_{10-2.5}$ are similar to those for $PM_{2.5}$, generally falling in the range of 3 to 8 percent for cardiovascular mortality per 25 $\mu g/m^3$ $PM_{10-2.5}$.

Potential confounding by co-pollutant gases has been assessed in some of these mortality studies. As shown in Figures 8–16 through 8–18 of the Criteria Document, the associations reported with $PM_{10-2.5}$ are generally unchanged in effect size when co-pollutant gases are included in multi-pollutant models. The evidence available on potential confounding between $PM_{2.5}$ and $PM_{10-2.5}$ is limited, but the Criteria Document includes results from two studies that showed effects of the two PM indicators to be relatively independent in multi-pollutant models, however, these particular analyses were not included in reanalyses to address statistical modeling questions.[56]

iii. Effects of Thoracic Coarse Particle Components or Sources in Epidemiologic Studies

In considering the epidemiologic evidence on morbidity or mortality associations with short-term exposure to thoracic coarse particles, EPA recognizes that the issue of the relative toxicity of different PM components, discussed above in section II.A.1 for fine particles, is an important uncertainty for thoracic coarse particles as well. Several toxicologic studies, discussed above in section III.A.1, have reported evidence of effects with different components or sources of thoracic coarse particles. However, the available epidemiologic studies that have used $PM_{10-2.5}$ did not evaluate associations with specific components of thoracic coarse particles (EPA, 2004, section 8.2.2.5.2). As discussed in section II.A, several studies have reported that $PM_{2.5}$ from combustion-related sources is more strongly linked with mortality than $PM_{2.5}$ of crustal origin. However, these findings are not directly relevant to findings related to thoracic coarse particles. Combustion sources are a major contributor to $PM_{2.5}$ emissions, but not to emissions of $PM_{10-2.5}$, while crustal material is an important component of $PM_{10-2.5}$ but only a small portion of $PM_{2.5}$ (EPA, 2005a, Table 2–2).

One study that does have relevance to considering the effects of $PM_{10-2.5}$ from different sources assessed the contribution of dust storms to PM_{10}-related mortality. The authors focused on days when dust storms or high wind events occurred in Spokane, during which thoracic coarse particles from surrounding rural soils are the dominant fraction of PM_{10}. No evidence was reported of increased mortality on days with high PM_{10} levels related to these dust storms (average PM_{10} level was 221 $\mu g/m^3$ higher on dust storm days than on other study days) (Schwartz, et al., 1999), suggesting that $PM_{10-2.5}$ from wind-blown rural dust is also not likely associated with mortality.[57] EPA has also observed that the available epidemiologic studies using $PM_{10-2.5}$ have been conducted in urban areas, such as Phoenix, Detroit and Seattle. Coarse particles are generally not distributed over broad areas, but rather reflect contributions from more localized sources, thus it is more difficult than for fine particles to generalize the results of these studies to areas with other types of sources.

The Criteria Document finds that the new epidemiologic studies support the conclusions drawn in the previous review, and indicate that short-term exposure to thoracic coarse particles is likely associated with respiratory morbidity. The epidemiologic studies report statistically significant associations between short-term $PM_{10-2.5}$ exposure and outcomes ranging from respiratory symptoms to hospitalization for respiratory diseases (EPA, 2004, p. 8–312). A limited body of new

[56] One study was the Canadian 8-city study, in which multi-pollutant models included $PM_{2.5}$ and $PM_{10-2.5}$ and gaseous co-pollutants, with moderate reductions in the effect estimate size for both PM indicators (Burnett et al., 2000). Moolgavkar (2000) presented results of two-pollutant models for $PM_{2.5}$ and $PM_{10-2.5}$ with COPD hospitalization in Los Angeles, and again, effect estimates for both pollutants were generally reduced somewhat in size. The author also reports that associations with $PM_{10-2.5}$ were generally reduced in size and lost statistical significance in two-pollutant models including CO. These two studies were reanalyzed to address potential issues with statistical model specification, but these multi-pollutant model results were not included in the reanalysis reports.

[57] In addition, studies conducted in several areas in the western U.S. have reported that associations between PM_{10} and mortality or morbidity remained unchanged or became larger and more precise when days indicative of wind-blown dust or high PM_{10} concentration days were excluded from the analyses (Pope et al., 1999; Schwartz, 1997; Chen et al., 2000; Hefflin et al., 1994). This group of studies does not provide conclusive evidence of any effects or lack of effects associated with wind-blown dust or high concentration days, nor were the studies designed specifically for that purpose. The results do, however, indicate that associations between PM_{10} and health outcomes in these western areas are not overly influenced or ''driven by'' such days.

epidemiologic evidence suggests that short-term exposure to thoracic coarse particles is associated with effects on the cardiovascular system. Finally, the Criteria Document finds that evidence from health studies on associations between short-term exposure to $PM_{10-2.5}$ and mortality is ''limited and clearly not as strong'' as evidence for associations with $PM_{2.5}$ or PM_{10} but nonetheless is suggestive of associations with mortality (EPA, 2004, p. 9–28, 9–32). As discussed briefly above, some epidemiologic evidence suggests that there are components of thoracic coarse particles (e.g., crustal material in non-urban areas) that are less likely to have adverse effects, at least at lower concentrations, than other components. Based on the epidemiologic evidence, the Criteria Document concluded that the limited body of evidence provided suggestive evidence for associations between throacic coarse particles and various mortality and morbidity effects ''in some locations'' (EPA, 2004, p. 8–338).

b. Effects Related to Long-Term Exposure to Thoracic Coarse Particles

In the last review, the available prospective cohort study results had shown no evidence of associations between long-term exposure to thoracic coarse particles and either mortality (Dockery et al., 1993; Pope et al., 1995) or morbidity (Dockery et al., 1996; Raizenne et al., 1996). As discussed above for $PM_{2.5}$, new studies available in this review include the reanalyses and extended analyses for the Six Cities and ACS cohort studies of mortality, and new analyses from the southern California children's cohorts of morbidity effects.

In both the reanalyses and extended analyses of the ACS cohort study, long-term exposure to $PM_{10-2.5}$ was not significantly associated with mortality (CD, p. 8–105; Krewski et al., 2000; Pope et al., 2002). Based on evidence from reanalyses and extended analyses using ACS cohort data, the Criteria Document concludes that the long-term exposure studies find no associations between long-term exposure to thoracic coarse particles and mortality (EPA, 2004, p. 8–307).

In the previous review, results from the Harvard 24-city study had shown associations between respiratory illness prevalence and decreased lung function in children with fine particles or fine particle indicators, but not with the larger size fractions (Dockery et al., 1996; Raizenne et al., 1996). Further EPA staff evaluation of the data from this study that suggested that lung function decrements were not associated with long-term exposure to thoracic coarse particles (EPA, 1996b, p. V–67a) . In this group of cities, mean thoracic coarse particle concentrations ranged from approximately 4 to 15 μg/m³. Several new studies have used data from the Southern California children's cohorts, one of which included $PM_{10-2.5}$ data; in these cities, mean thoracic coarse particle concentrations ranged from 6 to 39 μg/m³. In this study, decreases in several measures of lung function growth were associated with long-term exposure to $PM_{10-2.5}$ (as well as PM_{10} and $PM_{2.5}$) though not all associations reached statistical significance (Gauderman et al., 2000). Further, in analyses for a second cohort of children, no statistically significant associations were reported between lung function growth and long-term $PM_{10-2.5}$ exposure (Gauderman et al., 2002, p. 81). The correlation reported between $PM_{10-2.5}$ and $PM_{2.5}$ in this area was unusually high (r=0.76); in two-pollutant models, the authors observe that the effects reported with both pollutants were reduced in magnitude, and did not remain statistically significant, with somewhat larger reductions for $PM_{10-2.5}$ associations than for $PM_{2.5}$ (Gauderman et al., 2000, p. 1387). Thus, results from one children's cohort study provide no evidence of associations between long-term to exposure to $PM_{10-2.5}$ and respiratory morbidity, while findings from a more recent cohort study provide only very limited evidence for such effects. Overall, EPA finds that the available evidence provides little support to link long-term exposures to thoracic coarse particles with respiratory morbidity (EPA, 2004, p. 9–34).

3. Integration and Interpretation of the Health Evidence

As discussed in section II.A.3, the Criteria Document and Staff Paper focused on well-recognized criteria in evaluating the epidemiologic evidence, including the strength of associations; robustness of reported associations to the use of alternative model specifications, potential confounding by co-pollutants, and exposure misclassification related to measurement error; consistency of findings in multiple studies of adequate power, and in different persons, places, circumstances and times; and the nature of concentration-response relationships. These evaluations addressed key methodological issues that are relevant to interpretation of evidence from epidemiologic studies. Further, findings from epidemiologic studies were integrated with available experimental evidence (e.g., dosimetric and toxicologic), in considering the extent of coherence and biological plausibility of effects observed in epidemiologic studies. This integrative assessment formed the basis for the Criteria Document and Staff Paper to draw judgments about the extent to which causal inferences can be made about observed associations between health endpoints and thoracic coarse particles combination with other pollutants. The key elements of these evaluations are summarized below. Many of these issues are discussed in section II.A.3 above for fine particles, and are thus only briefly summarized here with regard to implications for thoracic coarse particles.

(1) Effect estimates from associations between short-term exposures to thoracic coarse particles and various health outcomes are generally small in size. The Criteria Document observes that the associations are similar in size to those reported for $PM_{2.5}$, but with less precision as the measurement error for $PM_{10-2.5}$ is greater than that for $PM_{2.5}$. Thus, the Criteria Document concludes that the magnitude of $PM_{10-2.5}$ associations is similar to those for fine particles, but the lesser precision of the associations reduces the strength of the evidence for thoracic coarse particles (EPA, 2004, p. 9–41).

(2) EPA has evaluated the robustness of epidemiologic associations in part by considering the effect of differences in statistical model specification, exposure error on PM-health associations, and potential confounding by co-pollutants.

Sensitivity to model specification was discussed above for fine particles, and, in general, similar conclusions apply to studies using $PM_{10-2.5}$. Section 8.4.2 of the Criteria Document discusses a series of reanalyses that address issues related to a specific type of statistical model (''generalized additive methods'') used in some recent epidemiologic studies. The results of the reanalyses showed little change in effect estimates for some studies; in others the effect estimates were reduced in size though it was observed that the reductions were often not substantial (EPA, 2004, p. 9–35). Overall, the Criteria Document concludes that associations between short-term exposure to PM and various health outcomes are generally robust to the use of alternative modeling strategies, recognizing that further evaluation of alternative modeling strategies is warranted. It was also observed that the results of reanalyses indicated that effect estimates were more sensitive to the modeling approach used to account for temporal effects and weather variables than to the specific model specifications, and thus

recommended further exploration of alternative modeling approaches for time-series analyses (EPA, 2004, pp. 8–236 to 8–237).

Recent epidemiologic studies have also evaluated the influence of exposure error on PM-health associations. This includes both consideration of error in measurements of PM, and the degree to which measurements from an individual monitor reflect exposures to the surrounding community. As discussed in section 8.4.5 of the Criteria Document, several studies have shown that fairly extreme conditions (e.g., very high correlation between pollutants and no measurement error in the ''false'' pollutant) are needed for complete ''transfer of causality'' of effects from one pollutant to another (EPA, 2004, p. 9–38). Exposure error is likely to be more important for associations with $PM_{10-2.5}$ than with $PM_{2.5}$, since there is generally greater error in $PM_{10-2.5}$ measurements, $PM_{10-2.5}$ concentrations are less evenly distributed across a community, and thoracic coarse particles are less likely to penetrate into buildings (EPA, 2004, p. 9–38). Thus, factors related to exposure error likely result in reduced precision for epidemiologic associations with $PM_{10-2.5}$.

There are two key implications of this uncertainty for this review. First, for an individual epidemiologic association, the increased uncertainty in measurements would tend to increase the standard error about the effect estimate, possibly reducing statistical significance of the findings. This would mean that a set of positive but generally not statistically significant associations between $PM_{10-2.5}$ and a health outcome could be reflecting a true association that is measured with error (EPA, 2004, p. 5–126). Second, this uncertainty about measurements is an important consideration in evaluating the air quality concentrations with which a statistical association is reported. The air quality levels reported in these studies, as measured by ambient concentrations at monitoring sites within the study areas, are not necessarily good surrogates for the population exposures that are likely associated with the observed effects in the study areas or that would likely be associated with effects in other urban areas across the country. The concentrations measured at one particular site may over-or under-estimate air quality levels in other parts of the area. In evaluating the air quality data from the locations in which epidemiologic associations were reported, as discussed in the Staff Paper and below in section III.G, examples of both cases are seen. For example, in Coachella Valley, mortality was statistically significantly associated with $PM_{10-2.5}$ measurements made at one site (Ostro et al., 2003), but these air quality measurements appear to represent concentrations on the high end of $PM_{10-2.5}$ levels for Coachella Valley communities. In contrast, statistically significant associations were reported with $PM_{10-2.5}$ measurements in Detroit (Ito, 2003), and in this case the data appear to represent concentrations on the low end of $PM_{10-2.5}$ levels for the Detroit area (EPA, 2005a, p. 5–65, 5–66).

Finally, some investigators have assessed the robustness of associations between health outcomes and short-term exposures to $PM_{10-2.5}$ in multi-pollutant models to potential confounding by the gaseous co-pollutants or fine particles. A high degree of correlation between the concentrations of thoracic coarse particles and other pollutants (either gaseous co-pollutants or fine particles) can make interpretation of the study results difficult. Multi-pollutant models including $PM_{10-2.5}$ and gaseous co-pollutants are included in Figures 8–16 through 8–18 of the Criteria Document, where it can be seen that associations with $PM_{10-2.5}$ are largely unchanged when gaseous co-pollutants are added to the models (EPA, 2004, section 8.4.3). Further, in the available epidemiologic studies, it can be seen that correlations between the gaseous co-pollutants (CO, NO_2, O_3, SO_2) and $PM_{10-2.5}$ concentrations are often lower than correlations between the gases and fine particles.[58] While recognizing that disentangling the effects attributable to various pollutants within an air pollution mixture is challenging, the Criteria Document concludes that effect estimates for associations between PM, including $PM_{10-2.5}$, and health endpoints are generally robust to confounding by gaseous co-pollutants (EPA, 2004, p. 9–37).

Less information is available from studies that specifically assessed potential confounding between fine and thoracic coarse particles, as noted above. The reported correlation coefficients between $PM_{10-2.5}$ and $PM_{2.5}$ are in the low to moderate range for most such studies, i.e., generally in a range of below 0.3 to 0.5, with some notably higher correlation coefficients reported in Phoenix (0.59) and Steubenville (0.69). As observed previously, one study in Detroit evaluated the effects of both $PM_{2.5}$ and $PM_{10-2.5}$ simultaneously where the correlation between the two pollutants was ''modest'' (correlation coefficient of 0.42). The authors report a reduction in coefficients for both $PM_{10-2.5}$ and $PM_{2.5}$ in associations with mortality and hospital admissions for respiratory or cardiovascular diseases (Ito, 2003, pp. 152–153); the degree of reduction in size varied for different health outcomes. Similarly, Schwartz and Neas (2000) report some reduction in effect estimate size for both $PM_{10-2.5}$ and $PM_{2.5}$ associations across six cities in two-pollutant models, but the association reported between $PM_{10-2.5}$ and cough remains statistically significant.[59] Two studies reported associations between $PM_{10-2.5}$ and mortality (Ostro et al., 2003, Coachella Valley; Mar et al., 2003, Phoenix); stronger associations were reported with $PM_{10-2.5}$ than $PM_{2.5}$ by Ostro et al., although the authors note the reduced sample size for $PM_{2.5}$ may have influenced the statistical power (Ostro et al., 2003). Both areas have relatively low fine particle concentrations, with 98th percentile $PM_{2.5}$ concentrations of about 32 $\mu g/m^3$ in Phoenix and 34 $\mu g/m^3$ in Coachella Valley, while the correlation coefficient reported between $PM_{2.5}$ and $PM_{10-2.5}$ was low in Coachella Valley (0.28) and fairly high in Phoenix (0.59). This limited body of evidence suggests that $PM_{10-2.5}$ and $PM_{2.5}$ have associations with health outcomes that are likely independent of one another, but further work is needed to help distinguish the contributions of thoracic coarse particles on health outcomes from those of fine particles.

Overall, the Criteria Document concludes that associations reported between health outcomes and short-term exposure to $PM_{10-2.5}$ are generally robust to the use of alternative modeling strategies, to adjustment for the potential confounding effects of gaseous co-pollutants, and in terms of exposure error (EPA, 2004, p. 9–46). However, the remaining uncertainties are larger in assessing the degree to which effects observed with thoracic coarse particle exposures are independent from effects of fine particles. In addition, in interpreting the results of epidemiologic studies, it is difficult to determine how well $PM_{10-2.5}$ concentrations measured at ambient monitoring stations

[58] For example, from the studies included in Figures 8–16 through 8–18, correlation coefficients reported in Detroit between $PM_{10-2.5}$ and the four gaseous co-pollutants ranged from 0.13 to 0.32, whereas the correlation coefficients between $PM_{2.5}$ and the gaseous co-pollutants range from 0.38–0.49 (Ito, 2003).

[59] The correlation coefficients between $PM_{10-2.5}$ and $PM_{2.5}$ range from 0.23 to 0.45 in five of the six cities (Boston, Knoxville, Portage, Topeka, and St. Louis), with a correlation coefficient of 0.69 in Steubenville.

characterize the magnitude of population exposures to thoracic coarse particles.

(3) In assessing consistency in effect estimates, the epidemiologic study results suggest that effect estimates may differ from one location to another, but the extent of variation is not clear. For example, in one multi-city study, some limited evidence was reported in the reanalysis to address model specification issues that suggested some heterogeneity among the 8 largest Canadian cities for associations with $PM_{10-2.5}$, although there had been no evidence of heterogeneity in initial study findings (Burnett and Goldberg, 2003; EPA, 2004, p. 9–39). As was observed for fine particles, there are a number of factors that would be likely to cause variation in PM-health outcomes in different populations and geographic areas. The Criteria Document discusses such factors, including the mix of PM sources and composition, the mix of other gaseous pollutants, geographic features that would affect the spatial distribution of ambient PM, and population characteristics that affect susceptibility or exposure levels (EPA, 2004, p. 9–41). In addition, the use of data collected on a 1-in-6 or 1-in-3 day schedule results in reduced statistical power, resulting in less precision for estimated effect estimates for the individual cities and increased potential variability in results (EPA, 2004, p. 9–40). Overall, the Criteria Document concludes that there is some consistency in effect estimates for hospitalization for respiratory and cardiovascular causes with short-term exposure to thoracic coarse particles, though fewer studies are available on which to make such an assessment than are available for fine particles (EPA, 2004, p. 9–47).

(4) Of the group of new epidemiologic studies that have evaluated the shape of concentration-response functions, many (generally using PM_{10}) have been unable to detect threshold levels in the relationship between short-term PM exposure and mortality. One single-city study used $PM_{10-2.5}$ and $PM_{2.5}$ measurements in Phoenix and reported that there was no indication of a threshold in the association between $PM_{10-2.5}$ and mortality (Smith et al., 2000; EPA, 2004, p. 8–322). However, a few analyses have provided suggestions of some potential threshold levels, generally at fairly low ambient concentrations. Thus, the Criteria Document concludes that the evidence did not support selecting any particular population threshold for $PM_{10-2.5}$, recognizing that there may be thresholds for specific health responses in individuals, and that it is possible that such thresholds exist toward the lower end of the range of air quality measurements in the health studies, but cannot be detected due to variability in susceptibility across a population. Even in those few studies with suggestive evidence of such thresholds, the potential thresholds are at fairly low concentrations (EPA, 2004, sections 8.4.7 and 9.2.2.5).

(5) Several issues related to exposure time periods were assessed in the Criteria Document, as summarized in section 3.6.5 of the Staff Paper. One key issue is the lag period between thoracic coarse particle exposure and health outcome in short-term exposure studies. In many epidemiologic studies, the authors have reported a pattern of positive associations across several consecutive lag periods for thoracic coarse particles, such that an effect estimate for any individual lag day for thoracic coarse particles likely underestimates the magnitude of the PM-health response. A number of recent studies that have investigated associations with distributed lags provide effect estimates for health responses that persist over a period of time (days to weeks) after the exposure period and the effect estimates are often, but not always, larger in size that those for single-day lag periods; however, available studies have generally not included $PM_{10-2.5}$ (EPA, 2004, p. 8–281). As reported for fine particles, the Criteria Document concludes that it is likely that the most appropriate lag period for a study will vary, depending on the health outcome and the specific pollutant under study. (EPA, 2004, p. 8–279).

(6) In integrating evidence from across scientific disciplines, the Criteria Document and Staff Paper observed that the body of epidemiologic evidence on thoracic coarse particles is smaller than that for fine particles and the evidence available from toxicologic studies is also more limited. The clearest case for a causal relationship for coarse particles is for effects on the respiratory system. The epidemiologic results showing respiratory effects is consistent with the assessment of regional particle penetration and deposition, as well the observations from more limited toxicologic studies. The fractional deposition of elevated coarse particle concentrations is significant in the tracheobronchial region, which is particularly sensitive in asthmatic individuals. From the limited number of toxicologic studies using $PM_{10-2.5}$, as noted above in section III.A.1, there is some evidence that exposure to thoracic coarse particles results in respiratory-related effects such as inflammation or oxidative stress. In addition, allergic adjuvant effects were linked with road dust exposures. These findings are generally consistent with epidemiologic evidence linking $PM_{10-2.5}$ with respiratory morbidity, such as increased respiratory symptoms and hospitalization for respiratory diseases such as asthma or COPD.

The evidence is less coherent for effects on the cardiovascular system. Some epidemiologic studies have reported significant associations with hospital admissions for cardiovascular diseases, and associations reported with cardiovascular mortality are positive and some are statistically significant (see Figure 2). However, the very limited available evidence from toxicologic studies or epidemiologic studies on more subtle cardiovascular effects has not provided evidence that demonstrates plausible mechanisms or pathways for these effects.

Based on an integrative assessment of the evidence, the Criteria Document concludes that this growing but still limited body of health evidence is suggestive of causality in associations between short-term (but not long-term) exposures to thoracic coarse particles and health effects, particularly for associations with respiratory morbidity.

(7) In summary, based on the available evidence and the evaluation of that evidence in the Criteria Document and Staff Paper, the Criteria Document concludes that the body of evidence on effects related to exposure to thoracic coarse particles is less strong than that for fine particles, but provides suggestive evidence of causality for short-term exposure to $PM_{10-2.5}$ and morbidity, including hospitalization for respiratory diseases, increased respiratory symptoms and decreased lung function, and possibly mortality (EPA, 2004, pp. 9–79, 9–80). The Staff Paper recognizes, however, that the substantial uncertainties associated with this limited body of evidence suggest that it should be interpreted with a high degree of caution (EPA, 2005a, p. 5–70).

4. Sensitive Subgroups for Effects of Thoracic Coarse Particle Exposure

As described in section II.A.4, there are several population groups that may be susceptible or vulnerable to PM-related effects. These groups include those with preexisting lung diseases, such as asthma, and children and older adults. Emerging evidence indicates that people from lower socioeconomic strata or who have particularly elevated exposures may be more vulnerable to PM-related effects. However, the available evidence does not generally

allow distinctions to be drawn between the PM indicators, in terms of which groups might have greater susceptibility or vulnerability to $PM_{2.5}$ or $PM_{10-2.5}$ (EPA, 2005a pp. 3–35 to 36).

5. Impacts on Public Health From Thoracic Coarse Particle Exposure

While recognizing that the health evidence regarding effects of thoracic coarse particles is more limited, the Criteria Document has concluded that the evidence suggests causal associations between short-term exposure to thoracic coarse particles and morbidity effects, such as respiratory symptoms or hospital admissions for respiratory diseases, and possibly mortality. As observed above, the potentially susceptible populations for such effects include people with preexisting respiratory diseases, including asthma, and children and older adults. In focusing on respiratory effects likely associated with $PM_{10-2.5}$, it can be observed that population groups with respiratory diseases such as asthma or COPD include tens of millions of people (EPA, 2004; Tables 9–4 and 9–5). Considering the magnitude of these subpopulations and risks identified in health studies, the Criteria Document concludes that exposure to thoracic coarse particles can have an important public health impact.

B. Quantitative Risk Assessment

The general overview and discussion of key components of the risk assessment used to develop risk estimates for $PM_{2.5}$ presented in section II.B above is also applicable to the assessment done for $PM_{10-2.5}$ in this review. However, the scope of the risk assessment for $PM_{10-2.5}$ is much more limited than that for $PM_{2.5}$, reflecting the much more limited body of epidemiologic evidence and air quality information available for $PM_{10-2.5}$. As discussed in chapter 4 of the Staff Paper, the $PM_{10-2.5}$ risk assessment includes risk estimates for just three urban areas for two categories of health endpoints related to short-term exposure to $PM_{10-2.5}$: hospital admissions for cardiovascular and respiratory causes and respiratory symptoms.

Consistent with the approach used in the $PM_{2.5}$ risk assessment, discussed above in section II.B, $PM_{10-2.5}$-related health risks attributable to anthropogenic sources and activities (i.e., risk associated with concentrations above background or above various selected higher cutpoints intended as surrogates for alternative assumed population thresholds) were estimated by using the reported linear or log-linear concentration-response functions from epidemiologic studies and available air quality data from the locations in which the studies had been conducted. A series of base case analyses were conducted, using the same assumed cutpoints as were used in the assessment of short-term exposures to $PM_{2.5}$.

Estimates of hospital admissions attributable to short-term exposure to $PM_{10-2.5}$ have been developed for Detroit (cardiovascular and respiratory admissions) and Seattle (respiratory admissions), and estimates of respiratory symptoms have been developed for St. Louis.[60] Base case estimates of respiratory-related hospital admissions under recent air quality levels in Detroit are on the order of several hundred admissions per year across the range of assumed cutpoints considered in this assessment. The Detroit estimates are roughly one to two orders of magnitude greater than the range of estimated asthma-related admissions in Seattle, which can be attributed in part to differences in baseline risks related to respiratory-related health endpoints as well as to differences in $PM_{10-2.5}$ air quality levels in these two areas. More specifically, recent (e.g., 2001-2003) $PM_{10-2.5}$ concentrations are substantially higher in Detroit, where the current 24-hour PM_{10} standard is not met, than they are in Seattle (where the 24-hour PM_{10} design value is well below the level of the current PM_{10} standard). In considering risk estimates for respiratory symptoms in St. Louis, the number of days of cough in children living in St. Louis associated with recent $PM_{10-2.5}$ levels range from approximately 27,000 days per year[61] at the lowest assumed cutpoint to almost 3,000 days per year at the highest assumed cutpoint. For the same time period, $PM_{10-2.5}$ air quality levels in St. Louis are high, where, like Detroit, the current 24-hour PM_{10} standard is not met.

While one of the goals of the $PM_{10-2.5}$ risk assessment was to provide estimates of the risk reductions associated with just meeting alternative $PM_{10-2.5}$ standards, the nature and magnitude of the uncertainties and concerns associated with this portion of the risk assessment weigh against use of these risk estimates as a basis for recommending specific standard levels (EPA, 2005a, p. 5–69). These uncertainties and concerns include, but are not limited to the following:

(1) As noted above in section II.A and discussed more fully below in section III.G, the $PM_{10-2.5}$ levels measured at ambient monitoring sites in recent years may be quite different from the levels used to characterize exposure in the original epidemiologic studies based on monitoring sites in different location, thus possibly over- or underestimating population risk levels.

(2) There is greater uncertainty about the reasonableness of the use of proportional rollback to simulate just meeting alternative $PM_{10-2.5}$ standards in any urban area relative to that for $PM_{2.5}$ due to the limited availability of historic $PM_{10-2.5}$ air quality data.

(3) The locations used in the $PM_{10-2.5}$ risk assessment are not representative of urban areas in the U.S. that experience the most significant 24-hour peak $PM_{10-2.5}$ concentrations, and thus, observations about relative risk reductions associated with alternative standards may not be relevant to the areas expected to have the greatest health risks associated with elevated ambient $PM_{10-2.5}$ levels.

(4) The health effects database that supplies the concentration-response relationships used in the $PM_{10-2.5}$ risk assessment is much smaller than that available for $PM_{2.5}$, which limits EPA's ability to evaluate the robustness of the risk estimates for the same health endpoints across different locations.

C. Need for Revision of the Current Primary PM_{10} Standards

The initial issue to be addressed in the current review of the primary PM_{10} standards is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the existing standards should be revised. The Staff Paper addresses this question by first considering the conclusions reached in the last review, the subsequent litigation of that decision, and the nature of the new information available in this review.

In 1997, in conjunction with establishing new $PM_{2.5}$ standards, EPA concluded that continued protection against potential effects associated with thoracic coarse particles in the size range of 2.5 to 10 μm was warranted based on particle dosimetry, toxicologic information, and limited epidemiologic evidence (62 FR 38,677). This information indicated that thoracic coarse particles can deposit in the sensitive regions of the lung of most concern (e.g., the tracheobronchial and alveolar regions, which together make

[60] Quantitative risk estimates associated with recent air quality levels for these three cities are presented in Figures 4–11 and 4–12 in Chapter 4 of the Staff Paper.

[61] This represents roughly 1100 days of cough per 100,000 people in the general population, of which approximately 12 percent are children.

up the thoracic region),[62] and that they can be expected to aggravate effects in individuals with asthma and contribute to increased upper respiratory illness (62 FR 38,666–8).

Further, EPA decided that the new function of PM_{10} standard(s) would be to provide such protection against effects associated with particles in this narrower size range between 2.5 to 10 μm. Although some consideration had been given to a more narrowly defined indicator that did not include fine particles (e.g., $PM_{10-2.5}$), EPA decided that it was more appropriate to continue to use PM_{10} as the indicator for standards to control thoracic coarse particles. This decision was based in part on the recognition that the only studies of clear quantitative relevance to health effects most likely associated with thoracic coarse particles used PM_{10} in areas where the coarse fraction was the dominant fraction of PM_{10}, namely two studies conducted in areas that substantially exceeded the 24-hour PM_{10} standard (62 FR 38,679). The decision also reflected the fact that there were only very limited ambient air quality data then available specifically on thoracic coarse particles, in contrast to the extensive monitoring network already in place for PM_{10}. In essence, EPA concluded at that time that it was appropriate to continue to control thoracic coarse particles, but that the only information available upon which to base such standards was indexed in terms of PM_{10}.

In subsequent litigation regarding the 1997 PM NAAQS revisions, however, the court held in part that PM_{10} is a ''poorly matched indicator'' for thoracic coarse particles in the context of a rule that also includes $PM_{2.5}$ standards because PM_{10} includes $PM_{2.5}$. *American Trucking Associations* v. *EPA*, 175 F.3d. at 1054. Although the court found ''ample support'' (*id.*) for EPA's decision to regulate thoracic coarse particles, it vacated the 1997 revised PM_{10} standards for that reason. The result of subsequent EPA actions, discussed above in section I.C, is that the 1987 PM_{10} standards remain in place (65 FR 80776, 80777, Dec. 22, 2000) and the present review is consequently of those 1987 standards.

In this review, the Staff Paper focuses on the information now available from a growing, but still limited, body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ as the measure of thoracic coarse particles. In addition, there is now much more information available to characterize air quality in terms of $PM_{10-2.5}$ than was available in the last review.[63] In considering this information, the Staff Paper finds that the major considerations that formed the basis for EPA's 1997 decision to retain PM_{10} as the indicator for thoracic coarse particles, rather than a more narrowly defined indicator that does not include fine particles, no longer apply. More specifically, the continued use of PM_{10} as an indicator for standards intended to protect against health effects associated with thoracic coarse particles is no longer appropriate since information is now available that supports the use of a more directly relevant indicator, $PM_{10-2.5}$. Further, continuing to rely principally on health effects evidence indexed by PM_{10} to determine the appropriate averaging time, form, and level of a standard is no longer necessary or appropriate since a number of more directly relevant studies, indexed by $PM_{10-2.5}$, are also now available. Thus, separate from any legal considerations, the Staff Paper concludes it is appropriate to revise the current PM_{10} standards in part by revising the indicator for thoracic coarse particles, and by basing any such revised standard principally on the currently available evidence and air quality information indexed by $PM_{10-2.5}$, but also considering evidence from studies using PM_{10} in locations where $PM_{10-2.5}$ is the predominant fraction (EPA, 2005a, section 5.4.1).

Recognizing that dosimetric evidence formed the principal basis for the initial establishment of the PM_{10} indicator in 1987, and supported the decision in 1997 to retain the PM_{10} indicator, the Staff Paper also considers whether currently available dosimetric evidence continues to support the basic conclusions reached in those reviews of the standards. In particular, consideration is given to available information about patterns of penetration and deposition of thoracic coarse particles in the sensitive thoracic region of the lung and to whether an aerodynamic size of 10 μm remains a reasonable separation point for particles that penetrate and potentially deposit in the thoracic regions. The Staff Paper concludes that while considerable advances have been made in understanding particle dosimetry, the available evidence continues to support those basic conclusions from past reviews. More specifically, both fine particles, indexed by $PM_{2.5}$, and thoracic coarse particles, indexed by $PM_{10-2.5}$, penetrate to and deposit in the thoracic regions. Further, for a range of typical ambient size distributions, the total deposition of thoracic coarse particles to the alveolar region can be comparable to or even larger than that for fine particles (EPA, 2004, p. 6–16).

Beyond the dosimetric evidence, as noted in past reviews (EPA, 1981b, 1996b), toxicologic studies show that the deposition of a variety of particle types in the tracheobronchial region, including resuspended urban dust and coarse-fraction organic materials, has the potential to affect lung function and aggravate respiratory symptoms, particularly in asthmatics. Of particular note are limited toxicologic studies that found urban road dust can produce cellular and immunological effects (e.g., Kleinman, et al., 1995; Steerenberg et al., 2003).[64] In addition, some very limited in vitro toxicologic studies show some evidence that coarse particles may elicit pro-inflammatory effects (EPA, 2004, section 7.4.4). Further, the Staff Paper assessment of the physicochemical properties and occurrence of ambient coarse particles suggests that both the chemical makeup and the spatial distribution of coarse particles are likely to be more heterogeneous than for fine particles (EPA, 2005a, chapter 2). In particular, as discussed below in section III.D, coarse particles in urban areas can contain all of the components found in more rural areas, but be contaminated by a number of additional materials, from motor vehicle-related emissions to metals and transition elements associated with industrial operations. The Staff Paper concludes that the weight of the dosimetric, limited toxicologic, and atmospheric science evidence, taken together, lends support to the plausibility of the $PM_{10-2.5}$-related effects reported in urban epidemiologic studies, and provides support for retaining some standard for thoracic coarse particles so as to continue programs to protect public health from such effects (EPA, 2005a, p. 5–49).

The available epidemiologic evidence, discussed above in section III.A, includes studies of associations between short-term exposure to thoracic coarse particles, indexed by $PM_{10-2.5}$, and

[62] EPA further concluded at that time that the risks of adverse health effects associated with deposition of particles in the thoracic region are ''markedly greater than for deposition in the extrathoracic (head) region,'' and that risks from extrathoracic deposition are ''sufficiently low that particles which deposit only in that region can safely be excluded from the standard indicator'' (62 FR 38,666).

[63] Coarse particle concentrations from EPA's monitoring network are currently determined using a difference method in locations with same-day data from co-located PM_{10} and $PM_{2.5}$ FRM monitors.

[64] The Criteria Document notes that toxicologic studies, in general, use exposure concentrations that are generally much higher than ambient concentrations (EPA, 2004, p. 9–51).

health endpoints, as well as evidence from PM_{10} studies conducted in areas in which the coarse fraction is dominant. More specifically, several U.S. and Canadian studies now provide evidence of associations between short-term exposure to $PM_{10-2.5}$ and various morbidity endpoints. Three such studies conducted in Toronto (Burnett et al., 1997), Seattle (Sheppard et al., 2003), and Detroit (Ito, 2003) report statistically significant associations between short-term $PM_{10-2.5}$ exposure and respiratory- and cardiac-related hospital admissions, and a fourth study (Schwartz and Neas, 2000) conducted in six U.S. cities including Boston, St. Louis, Knoxville, Topeka, Portage, and Steubenville reports statistically significant associations across these six areas with respiratory symptoms in children. These studies were mostly done in areas in which $PM_{2.5}$, rather than $PM_{10-2.5}$, is the larger fraction of ambient PM_{10}, and they are not representative of areas with relatively high levels of thoracic coarse particles (EPA, 2005a, p. 5–49).

In evaluating the epidemiologic evidence from health studies on associations between short-term exposure to $PM_{10-2.5}$ and mortality, the Criteria Document concluded that such evidence was ''limited and clearly not as strong'' as that for associations with $PM_{2.5}$ or PM_{10} but nonetheless was suggestive of associations with mortality (EPA, 2004, p. 9–28, 9–32). Statistically significant mortality associations were reported in short-term exposure studies conducted in areas with relatively high $PM_{10-2.5}$ concentrations, including Phoenix (Mar et al., 2003), Coachella Valley, CA (Ostro et al., 2003), and in the initial analysis of data from Steubenville (as part of the Six Cities study, Schwartz et al., 1996), although in a reanalysis of this study, the results were generally not statistically significant (Klemm and Mason, 2003). In areas with lower $PM_{10-2.5}$ concentrations, no statistically significant associations were reported with mortality, though most were positive.

The Staff Paper also considers relevant epidemiologic studies indexed by PM_{10} that were conducted in areas where the coarse fraction of PM_{10} is typically much greater than the fine fraction. Such studies include findings of associations between short-term exposure to PM_{10} and hospitalization for cardiovascular diseases in Tucson, AZ (Schwartz, 1997), hospitalization for COPD in Reno/Sparks, NV (Chen et al., 2000), and medical visits for asthma or respiratory diseases in Anchorage, AK (Gordian et al., 1996; Choudhury et al., 1997). In addition, a number of epidemiologic studies have reported significant associations with mortality, respiratory hospital admissions and respiratory symptoms in the Utah Valley area (e.g., Pope et al., 1989; 1991; 1992). This group of studies provides additional supportive evidence for associations between short-term exposure to thoracic coarse particles and health effects, particularly morbidity effects, generally in areas not meeting the PM_{10} standards (EPA, 2005a, p. 5–50).[65]

In contrast to the findings from the short-term exposure studies discussed above, available epidemiologic studies do not provide evidence that long-term exposure to thoracic coarse particles is associated with mortality or morbidity (EPA, 2005a, p. 3–25). More specifically, no association is found between long-term exposure to thoracic coarse particles and mortality in the reanalyses and extended analysis of the ACS cohort (EPA, 2005a, p. 8–307). Further, little evidence is available on potential respiratory and cardiovascular morbidity effects of long-term exposure to thoracic coarse particles (EPA, 2005a, p. 3–23–24).

Taken together, the Staff Paper concludes that the health evidence, including dosimetric, toxicologic and epidemiologic study findings, supports retaining some standard to protect against effects associated with short-term exposure to thoracic coarse particles. However, the substantial uncertainties associated with this limited body of epidemiologic evidence on health effects related to exposure to $PM_{10-2.5}$, including the difficulty in separating the effects of fine and thoracic coarse particles, suggest a high degree of caution in interpreting this evidence, especially at the lower levels of ambient particle concentrations in the morbidity studies discussed above (EPA, 2004, p. 5–50).

Beyond this evidence-based evaluation, the Staff Paper also considers the extent to which $PM_{10-2.5}$-related health risks estimated to occur at current levels of ambient air quality may be judged to be important from a public health perspective, taking into account key uncertainties associated with the estimated risks. Consistent with the approach used to address this issue for $PM_{2.5}$-related health risks, discussed above in section II.B, the Staff Paper considers the results of a series of base case analyses that reflect in part the uncertainty associated with the form of the concentration-response functions drawn from the studies used in the assessment. In this assessment, which is much more limited than the risk assessment conducted for $PM_{2.5}$, health risks were estimated for three urban areas by using the reported linear or log-linear concentration-response functions as well as modified functions that incorporate alternative assumed cutpoints as surrogates for potential population thresholds (discussed above in section III.B). In considering the risk estimates from this limited assessment, and recognizing the very substantial uncertainties inherent in basing an assessment on such limited information, the Staff Paper concludes that the results for the two areas in the assessment that did not meet the current PM_{10} standards are indicative of risks that can reasonably be judged to be important from a public health perspective, in contrast to the appreciably lower risks estimated for the area that did meet the current standards (EPA, 2005a, p. 5–52).

The Staff Paper recognizes the substantial uncertainties associated with the limited available epidemiologic evidence and the inherent difficulties in interpreting the evidence for purposes of setting appropriate standards for thoracic coarse particles. Nonetheless, in considering the available evidence, the public health implications of estimated risks associated with current levels of air quality, and the related limitations and uncertainties, the Staff Paper concludes that this information supports (1) revising the current PM_{10} standards in part by revising the indicator for thoracic coarse particles, and (2) consideration of a standard that will continue to provide public health protection from short-term exposure to thoracic coarse particles of concern that have been associated with morbidity effects and possibly mortality at current levels in some urban areas (EPA, 2005a, p. 5–52).

In CASAC's review of these Staff Paper recommendations, there was general concurrence among CASAC Panel members that there is a need to revise the current PM_{10} standards and establish a primary standard specifically targeted to address particles in the size range of 2.5 to 10 μm (Henderson, 2005b). In making this recommendation, CASAC indicated its agreement with the summary of the scientific data regarding the potential adverse health effects from exposures to thoracic coarse particles in

[65] Based on recent air quality data, as well as the summary information provided for PM concentrations used in the studies, the existing PM_{10} standards are not met in any of these study cities except Tucson, AZ. Based on 2002–2004 air quality data, the 98th percentile $PM_{2.5}$ concentrations in three of these areas range from 15 to 25 $\mu g/m^3$, while in Utah Valley the concentrations range from 37 to 54 $\mu g/m^3$.

section 5.4 of the Staff Paper upon which the EPA staff recommendations were based.

In considering whether the primary PM_{10} standards should be revised, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations of CASAC, and public comments to date on this issue. The Administrator provisionally concludes that the health evidence, including dosimetric, toxicologic and epidemiologic study findings, supports retaining a standard to protect against effects associated with short-term exposure to thoracic coarse particles. Further, the Administrator believes that the new evidence on health effects from studies that use $PM_{10-2.5}$ as a measure of thoracic coarse particles, together with the much more extensive data now available to characterize air quality in terms of $PM_{10-2.5}$, provide an appropriate basis for revising the current PM_{10} standards in part by revising the indicator to focus more narrowly on particles between 2.5 and 10 μm. The Administrator also notes that the need for a standard for thoracic coarse particles has already been upheld based upon evidence of health effects considerably more limited than now available. *American Trucking Associations* v. *EPA*, 175 F. 3d at 1054. Based on these considerations, the Administrator provisionally concludes that the current suite of PM_{10} standards should be revised, and that the revised standard(s) should provide more targeted protection from short-term exposure to those thoracic coarse particles that are of concern to public health.

D. Indicator of Thoracic Coarse Particles

In considering an appropriate indicator for a standard intended to afford protection from health effects associated with exposure to thoracic coarse particles of concern, the Staff Paper starts by making the following observations:

(1) The most obvious choice for a thoracic coarse particle standard is the size-differentiated, mass-based indicator used in the epidemiologic studies that provide the most direct evidence of such health effects, $PM_{10-2.5}$.

(2) The upper size cut of a $PM_{10-2.5}$ indicator is consistent with dosimetric evidence that continues to reinforce the finding from past reviews that an aerodynamic size of 10 μm is a reasonable separation point for particles that penetrate to and potentially deposit in the thoracic regions of the respiratory tract.

(3) The lower size cut of such an indicator is consistent with the choice of 2.5 μm as a reasonable separation point between fine and coarse fraction particles.

(4) Further, the limited available information is not sufficient to define an indicator for thoracic coarse particles solely in terms of metrics other than size-differentiated mass, such as specific chemical components.

(5) The available epidemiologic evidence for effects of $PM_{10-2.5}$ exposure is quite limited and is inherently characterized by large uncertainties, reflective in part of the more heterogeneous nature of the spatial distribution and chemical composition of thoracic coarse particles and the more limited and generally uncertain measurement methods that have historically been used to characterize their ambient concentrations.

In evaluating relevant information from atmospheric sciences, toxicology, and epidemiology related to thoracic coarse particles, the Staff Paper notes that there appears to be clear distinctions between (1) the character of the ambient mix of particles generally found in urban areas as compared to that found in nonurban and, more specifically, rural areas, and (2) the nature of the evidence concerning health effects associated with thoracic coarse particles generally found in urban versus rural areas. Based on such information, and on specific initial advice from CASAC (Henderson, 2005a), the Staff Paper considers a more narrowly defined indicator for thoracic coarse particles that focuses on the mix of such particles that is characteristic of that generally found in urban areas where thoracic coarse particles are strongly influenced by traffic-related or industrial sources. In so doing, the Staff Paper focuses on comparing the potential health effects associated with thoracic coarse particles in urban and rural settings, as discussed below.

Atmospheric science and monitoring information indicates that exposures to thoracic coarse particles tend to be higher in urban areas than in nearby rural locations. Further, the mix of thoracic coarse particles typically found in urban areas contains a number of contaminants that are not commonly present to the same degree in the mix of natural crustal particles that is typical of rural areas. The elevation of $PM_{10-2.5}$ levels in urban locations as compared to those at nearby rural sites suggests that sources located within urban areas are generally the cause of elevated urban concentrations; conversely, $PM_{10-2.5}$ concentrations in such urban areas are not largely composed of particles blown in from more distant regions (EPA, 2005a, sections 2.4.5 and 5.4.2.1). Important sources of thoracic coarse particles in urban areas include dense traffic that suspends significant quantities of dust from paved roads, as well as industrial and combustion sources and construction activities that contribute to ambient coarse particles both directly and through deposition to soils and roads (EPA, 2005a, Table 2–2). It follows that the mix of thoracic coarse particles in urban areas would differ in composition from that in rural areas, being influenced to a relatively greater degree by components from urban mobile and stationary source emissions.

While detailed composition data are more limited for $PM_{10-2.5}$ than for $PM_{2.5}$, available measurements from some areas as well as studies of road dust components do show a significant influence of urban sources on both the composition and mass of thoracic coarse particles generally found in urban areas. Although crustal elements and natural biological materials represent a significant fraction of thoracic coarse particles in urban areas, both their relative quantity and character may be altered by urban sources. For example, in industrial cities, primary particle emissions from industrial sources and resuspended road dust can increase the relative amount of iron in the mix of $PM_{10-2.5}$, one of the metals that has been noted as being of some interest in the studies of mechanisms of toxicity for PM, as well as other industrial process-related and potentially toxic materials such as nickel, cadmium, and chromium (EPA, 2005a, p. 5–54). Traffic-related activities can also grind and resuspend vegetative materials into forms not as common in more natural areas (Rogge et al., 1993). Studies of urban road dusts find that levels of a variety of components are increased from traffic as well as from other anthropogenic urban sources, including products of incomplete combustion (e.g. polycyclic aromatic hydrocarbons) from motor vehicle emissions and other sources, brake and tire wear, rust, salt and biological materials (EPA, 2004, p. 3D–3). Limited ambient coarse fraction composition data from various comparisons find that metals and sometimes elemental carbon contribute a greater proportion of thoracic coarse particle mass in urban areas than in nearby rural areas. In addition, while large uncertainties exist in emissions inventory data, the Staff Paper observes that major sources of $PM_{10-2.5}$ emissions in the urban counties in which epidemiologic studies have been conducted are paved roads and ''other''

sources (largely construction), and that such areas also have larger contributions from industrial emissions, whereas unpaved roads and agriculture are the main sources of $PM_{10-2.5}$ emissions outside of urban areas.

Toxicologic studies, although quite limited, support the view that thoracic coarse particles from sources common in urban areas are of greater concern than uncontaminated materials of geologic origin. One major source of thoracic coarse particles in urban areas is paved road dust; the Criteria Document discusses results from a recent toxicologic study in which road tunnel dust particles had greater allergic adjuvant activity than several other particle samples (Steerenberg et al., 2003; EPA, 2004, pp. 7–136, 137). This study supports evidence available in the last review regarding potential effects of road dust particles (EPA, 1996b, p. V–70). In contrast, a number of studies have reported that Mt. St. Helens volcanic ash, an example of natural crustal material of geologic origin, has very little toxicity in animal or in vitro toxicologic studies (EPA, 2004, p. 7–216).

A few toxicologic studies have used ambient thoracic coarse particles from urban/suburban locations ($PM_{10-2.5}$), and the results suggest that effects can be linked with several components of $PM_{10-2.5}$. These in vitro toxicologic studies linked thoracic coarse particles with effects including cytotoxicity, oxidant formation, and inflammatory effects (EPA, 2005a, sections 3.2 and 5.4.1). These studies suggest that several components (e.g., metals, endotoxin, other materials) may have roles in various health responses but do not suggest a focus on any individual component.

Although largely focused on undifferentiated PM_{10}, the series of epidemiologic observations and toxicologic experiments related to the Utah Valley suggest that directly emitted (fine and coarse) and resuspended (coarse) urban industrial emissions are of concern. Of particular interest are area studies spanning a 13-month period when a major source of PM_{10} in the area, a steel mill, was not operating. Observational studies found that respiratory hospital admissions for children were lower when the plant was shut down (Pope et al., 1989). More recently, a set of toxicologic and controlled human exposure studies have used particles extracted from filters from ambient PM_{10} monitors from periods when the plant did and did not operate. In both human volunteers and animals, greater lung inflammatory responses were reported with particles collected when the source was operating, as compared to the period when the plant was closed (EPA, 2004, p. 9–73). In addition, in some studies it was suggested that the metal content of the particles was most closely related to the effects reported (EPA, 2004, p. 9–74). While peak days in the Utah Valley occur in conditions that enhance fine particle concentrations, over the long run, over half of the PM_{10} was in the coarse fraction. The aggregation of particles collected on the filters during the study period reflect this long-term composition and represent the kinds of industrial components that would be incorporated in road dusts in the area.

Epidemiologic studies that have examined exposures to thoracic coarse particles generally found in urban environments, together with studies that have taken into account exposures to natural crustal materials typical of rural areas, generally support the view that the mix of thoracic coarse particles generally found in urban areas is of concern to public health, in contrast to natural crustal dusts of geologic origin. With respect to the urban results, several recent studies have shown associations between $PM_{10-2.5}$ and health outcomes in a few sites across the U.S. and Canada. Associations have been reported with morbidity in a few urban areas, some of which had relatively low $PM_{10-2.5}$ concentrations. For mortality, statistically significant associations have been reported only for two urban areas that have notably higher ambient $PM_{10-2.5}$ concentrations. These associations are with short-term exposures to aggregated $PM_{10-2.5}$ mass, and no epidemiologic evidence is available on associations with different components or sources of $PM_{10-2.5}$. However, these studies have all been conducted in urban areas of the U.S., and thus reflect effects associated with the ambient mix of thoracic coarse particles generally present in urban environments.

In contrast, recent evidence from epidemiologic studies has suggested that mortality and possibly other health effects are not associated with thoracic coarse particles from dust storms or other such wind-related events that result in suspension of natural crustal materials of geologic origin. The clearest example is provided by a study in Spokane, WA, which specifically assessed whether mortality was increased on dust-storm days using case-control analysis methods. The average PM_{10} level was more than 200 $\mu g/m^3$ higher on dust storm days than on control days, and the authors report no evidence of increased mortality on these specific days (Schwartz et al., 1999). One caveat of note is the possibility that people may reduce their exposure to ambient particles on the most dusty days (e.g., Gordian et al., 1996; Ostro et al., 2000). Nevertheless, these studies provide no suggestion of significant health effects from uncontaminated natural crustal materials that would typically form a major fraction of coarse particles in non-urban or rural areas.

Beyond the urban and rural distinctions discussed above, the Staff Paper also considers the extent to which there is evidence of effects with exposure to the ambient thoracic coarse particles in communities predominantly influenced by agricultural or mining sources.[66] For example, in the last review, EPA considered health evidence related to long-term silica exposures from mining activities, but found that there was a lack of evidence that such emissions contribute to effects linked with ambient PM exposures (EPA, 1996b, p. V–28). Similarly in this review, there is an absence of evidence related to such community exposures. While crustal and organic dusts generated from agricultural activity can include a variety of biological materials, and some occupational studies discussed in the Criteria Document report effects at occupational exposure levels (EPA, 2004, Table 7B–3, p. 7B–11), such studies do not provide relevant evidence for effects at much lower levels of community exposures. Further, it is unlikely that such sources contribute to the effects that have been observed in the recent urban epidemiologic studies.

The Criteria Document concludes its integrated assessment of the effects of natural crustal materials as follows:

> Certain classes of ambient particles appear to be distinctly less toxic than others and are unlikely to exert human health effects at typical ambient exposure concentrations (or perhaps only under special circumstances). For example, particles of crustal origin, which are predominately in the coarse fraction, are relatively non-toxic under most circumstances, compared to combustion-related particles (such as from coal and oil combustion, wood burning, etc.) However, under some conditions, crustal particles may become sufficiently toxic to cause human health effects. (EPA, 2004, p. 8–344)

The Staff Paper assessment of the available evidence relevant to the appropriate scope of an indicator for coarse particles can be summarized as follows. Ambient concentrations of thoracic coarse particles generally

[66] Mining sources are intended to include all activities that encompass extraction and/or mechanical handling of natural geologic crustal materials.

reflect contributions from local sources, and the limited information available from speciation of thoracic coarse particles and emissions inventory data indicate that the sources of thoracic coarse particles in urban areas generally differ from those found in nonurban areas. As a result, the mix of thoracic coarse particles people are typically exposed to in urban areas can be expected to differ appreciably from the mix typically found in non-urban or rural areas. Ambient $PM_{10-2.5}$ exposure is associated with health effects in studies conducted in urban areas, and the limited available health evidence more strongly implicates the ambient mix of thoracic coarse particles that is dominated by traffic-related and industrial sources than that from uncontaminated soil or geologic sources. The limited evidence does not support either the existence or the lack of causative associations for community exposures to thoracic coarse particles from agricultural or mining industries. Given the apparent differences in composition and in the epidemiologic evidence, the Staff Paper concludes that it is not appropriate to generalize the available evidence of associations with health effects that have been related to thoracic coarse particles generally found in urban areas and apply it to the mix of particles typically found in nonurban or rural areas (EPA, 2005a, p. 5–57).

Collectively, this evidence suggests that a more narrowly defined indicator for thoracic coarse particles should be considered that would protect public health against effects that have been linked with the mix of thoracic coarse particles generally present in urban areas. Such an indicator would be principally based on particle size, but also reflect a focus on the mix of thoracic coarse particles that is generally present in urban environments and the sources that principally generate that mix. The Staff Paper recommends consideration of thoracic coarse urban particulate matter[67] as an indicator for a thoracic coarse particle standard, referring to the mix of airborne particles between 2.5 and 10 μm in diameter that are generally present in urban environments, which, as discussed above, are principally comprised of resuspended road dust typical of high traffic-density areas and emissions from industrial sources and construction activities (EPA, 2005a, p. 5–54, 5–57–58). The Staff Paper concludes that such an indicator would more likely be an effective indicator for standards to protect against health effects that have been associated with thoracic coarse particles than a more broadly focused $PM_{10-2.5}$ indicator. This indicator would also be consistent with an appropriately cautious interpretation of the epidemiologic evidence that does not potentially over-generalize the results of the limited available studies.

In conjunction with this recommendation of an indicator defined in terms of the mix of thoracic coarse particles that are generally present in urban areas, the Staff Paper also discusses the importance of a monitoring network designed so as to be consistent with the intent of such an indicator and that would facilitate implementation of such a standard. EPA has historically used implementation policies to address elevations in thoracic coarse particle levels that may occur in urban areas as a result of dust storms or other such events for which this staff-recommended indicator is not intended to apply. Both new criteria for monitor network design and revised natural/exceptional events policies should work in concert with a revised thoracic coarse particle indicator to ensure the most effective application of a thoracic coarse particle standard.

In its review of the Staff Paper recommendation for a thoracic coarse particle indicator (Henderson, 2005b), the CASAC generally agreed that ''thoracic coarse particles in urban areas can be expected to differ in composition from those in rural areas;'' that ''coarse particles in urban or industrial areas are likely to be enriched by anthropogenic pollutants that tend to be inherently more toxic than the windblown crustal material which typically dominates coarse particle mass in arid rural areas;'' and that ''evidence of associations with health effects related to urban coarse-mode particles would not necessarily apply to non-urban or rural coarse particles.'' Further, most CASAC Panel members concurred that ''the current scarcity of information on the toxicity of rural dusts makes it necessary'' for EPA to base its standard for thoracic coarse particles ''on the known toxicity of urban-derived coarse particles.'' While most Panel members concurred with the thoracic coarse particle indicator recommended in the Staff Paper, a few members recommended specifying a $PM_{10-2.5}$ indicator in conjunction with monitoring network design criteria and natural/exceptional events policies that would emphasize urban influences. In either case, CASAC indicated that the intent of any such indicator should be to ''provide protection against those components of $PM_{10-2.5}$ that arise from anthropogenic activities occurring in or near urban and industrial areas.''

In considering an appropriate indicator for a standard intended to afford protection from health effects associated with exposure to thoracic coarse particles of concern, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator believes, despite the substantial limitations and uncertainties in the relevant information available, that it is appropriate to propose a new indicator for such particles at this time. Further, the Administrator believes that any such indicator should be defined not only by particle size, to generally include those particles between 2.5 and 10 μm in diameter, but also by qualifications that narrow the scope of the indicator. In considering an indicator that is intended to focus on the mix of thoracic coarse particles generally present in urban environments and commonly derived from sources typically found in urban environments, consistent with Staff Paper and CASAC recommendations, the Administrator notes that identifying it as an ''urban'' thoracic coarse particle indicator could be misconstrued as meaning that the standard is limited to certain geographic locations and, thus, not a national standard. To avoid this semantic problem, the Administrator has sought to define the indicator in a way that more clearly focuses on the nature of the mix of thoracic coarse particles intended to be included and the sources that principally generate that mix, rather than just where they are found, and that also explicitly focuses on what would be excluded from such an indicator. In so doing, the Administrator intends the proposed indicator to be equivalent to the one recommended in the Staff Paper and endorsed by CASAC, but to do so in a manner that will be more clearly understood and less likely to be misinterpreted.

Taking into account the considerations discussed above, the Administrator proposes to establish a new indicator for thoracic coarse particles in terms of $PM_{10-2.5}$, the definition of which includes qualifications that identify both the mix of such particles that are of concern to public health, and are thus included in the indicator, and those for which currently available information is not sufficient to infer a public health concern, and are thus excluded. More specifically, the proposed $PM_{10-2.5}$ indicator is qualified so as to include any ambient mix of $PM_{10-2.5}$ that is

[67] The acronym ''$UPM_{10-2.5}$'' is used in the Staff Paper to refer to this indicator.

dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. In short, the indicator is not defined by nor limited to any specific geographic area, but includes the mix of $PM_{10-2.5}$ in any location that is dominated by these sources.

With the indicator as defined above, each area in the country would fall into one or the other of these two categories: (1) Either the majority of the ambient mix of $PM_{10-2.5}$ in an area is resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, or (2) the majority of the ambient mix is rural windblown dust and soils and PM generated by agricultural and mining sources. The indicator would apply when $PM_{10-2.5}$ generated by one or more of these named sources in the first category constitutes a majority of the ambient mix of $PM_{10-2.5}$. The EPA recognizes that in many cases it will be clear which of these two categories applies, while in other cases it may be difficult to determine the appropriate category. As described in more detail in the preamble to EPA's proposed monitor network design rule, published elsewhere in today's **Federal Register**, the proposed minimum monitor siting criteria would provide guidance on distinguishing between areas where the mix of $PM_{10-2.5}$ of concern would likely be dominated by the named sources in the first category and those areas where it would not. Consequently, all $PM_{10-2.5}$ captured by a monitor that is properly sited in light of the indicator described above, as discussed in the proposed monitoring rule, would be considered in applying the standard, since the monitor would be capturing the mix of ambient $PM_{10-2.5}$ covered by the proposed indicator. As such, the proposed indicator does not present the type of over-inclusion or under-inclusion problems noted by the court with respect to a PM_{10} indicator (see *American Trucking Associations* v. *EPA*, 175 F.3d at 1054), since the application of the proposed indicator would result in compliance being based on measurement of the mix of ambient $PM_{10-2.5}$ at which the standard is directed.

The regulation for the proposed thoracic coarse particle indicator states that ''[a]gricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard.'' This proposed language reflects that the information supporting the proposed standard for thoracic coarse particles does not support extending controls to thoracic coarse particles from agricultural, mining sources, and other similar sources of crustal material. This statement in the regulations therefore is designed to make clear that there is no need nor basis to control these sources to obtain the public health benefits intended by the proposed indicator.

Although the Administrator believes that an indicator qualified through reference to these categories and named sources appropriately identifies the ambient mixes that the epidemiologic studies indicate are of concern to public health, he solicits comment as to whether there may be other classes of sources which should also be included or excluded from the indicator. More generally, comment is also solicited on the approach of defining the indicator in terms of both particle size and categories of named sources.

The Administrator recognizes that the proposed indicator, which includes considerations beyond particle size in its definition, represents a shift in the way in which PM indicators have been defined historically, and thus poses new challenges in ensuring a common understanding of how it can be appropriately and consistently implemented in areas across the country. In the Administrator's view, the application of this proposed indicator in conjunction with the proposed monitoring network design criteria, published elsewhere in today's **Federal Register**, and proposed rules for the treatment of air quality data influenced by exceptional events that will be published in the near future, will facilitate appropriate and consistent implementation.

E. Averaging Time of Primary $PM_{10-2.5}$ Standard

In the last review, EPA retained both 24-hour and annual PM_{10} standards to provide protection against the known and potential effects of short- and long-term exposures to thoracic coarse particles (62 FR at 38,677–79). That decision was based in part on qualitative considerations related to the expectation that deposition of thoracic coarse particles in the respiratory system could aggravate effects in individuals with asthma. In addition, quantitative support for retaining a 24-hour standard came from limited epidemiologic evidence suggesting that aggravation of asthma and respiratory infection and symptoms may be associated with daily or episodic increases in PM_{10}, where dominated by thoracic coarse particles including fugitive dust. The decision to retain an annual standard as well was generally based on considerations of the plausibility of the potential build-up of insoluble thoracic coarse particles in the lung after long-term exposures to high levels of such particles.

New information available in this review on thoracic coarse particles, discussed above, includes several epidemiologic studies that report statistically significant associations between short-term (24-hour) exposure to $PM_{10-2.5}$ and various morbidity effects and mortality. With regard to long-term exposure studies, while one recent study conducted in southern California reported a link between reduced lung function growth and long-term exposure to $PM_{10-2.5}$ and $PM_{2.5,}$ other such studies reported no associations (EPA, 2005a, p. 3–19, 3–23–24). Thus, the Criteria Document concludes that the available evidence does not suggest an association with long-term exposure to $PM_{10-2.5}$ (EPA, 2004, p. 9–79).

Based on these considerations, the Staff Paper concludes that the newly available evidence continues to support a 24-hour averaging time for a standard intended to control thoracic coarse particles, based primarily on evidence suggestive of associations between short-term (24-hour) exposure and morbidity effects and, to a lesser degree, mortality. Noting the absence of evidence judged to be suggestive of an association with long-term exposures, the Staff Paper concludes that there is no quantitative evidence that directly supports an annual standard, while recognizing that it could be appropriate to consider an annual standard to provide a margin of safety against possible effects related to long-term exposure to thoracic coarse particles that future research may reveal. The Staff Paper observes, however, that a 24-hour standard that would reduce 24-hour exposures would also likely reduce long-term average exposures, thus providing some margin of safety against the possibility of health effects associated with long-term exposures (EPA, 2005a, p. 5–61).

Based on its review of the Staff Paper, CASAC recommends retention of a 24-hour averaging time and agrees that an annual averaging time for $PM_{10-2.5}$ is not currently warranted (Henderson, 2005b). Based on these considerations, the Administrator concurs with staff and CASAC recommendations, and provisionally concludes that the newly available evidence continues to support a 24-hour averaging time for a $PM_{10-2.5}$ standard, based primarily on evidence suggestive of associations between

short-term (24-hour) exposure and morbidity effects and, to a lesser degree, mortality. Further, the Administrator agrees that an annual $PM_{10-2.5}$ standard is not warranted at this time. Thus, the Administrator proposes to revoke the annual PM_{10} standard and is not proposing an annual $PM_{10-2.5}$ standard.

F. Form of Primary $PM_{10-2.5}$ Standard

For reasons similar to those discussed above in section II.F.2 on the form of the 24-hour $PM_{2.5}$ standard, the Staff Paper also recommends consideration of either the 98th or 99th percentile form for a 24-hour $PM_{10-2.5}$ standard. The relative year-to-year stability of the air quality statistic to be used as the basis for the form of a $PM_{10-2.5}$ standard is of particular importance for a $PM_{10-2.5}$ standard, since the nature and magnitude of the uncertainties in the risk assessment conducted for thoracic coarse particles weighed against considering risk estimates as a basis for comparing alternative combinations of specific forms and levels of standards.

In considering the information provided in the Staff Paper, CASAC strongly recommends use of the 98th percentile form because it is more statistically robust than the 99th percentile form, together with the use of a three-year average of this statistic (Henderson 2005b). In making this recommendation, CASAC notes that the use of this statistic will tend to minimize ''measurement error and spatial variability, which are larger for coarse-mode particles than for fine PM'' as well as ''the influence in arid areas of occasional but extreme excursion contributions from rural, coarse-mode dust sources that are thought to be inherently less toxic than coarse-mode particles heavily enriched with urban source contaminants'' (Henderson, 2005b).

In considering the available information, the Administrator concurs with the CASAC recommendation and proposes that the form of the 24-hour $PM_{10-2.5}$ standard be based on the annual 98th percentile statistic, averaged over three years.

G. Level of Primary $PM_{10-2.5}$ Standard

In considering the available evidence on associations between short-term $PM_{10-2.5}$ concentrations and morbidity and mortality effects as a basis for setting a 24-hour standard for thoracic coarse particles, the Staff Paper focuses on relevant U.S. and Canadian epidemiologic studies, as discussed above in section II.A. As an initial matter, the Staff Paper recognizes that these individual short-term exposure studies provide no evidence of clear population thresholds, or lowest-observed-effects levels, in terms of 24-hour average concentrations. As a consequence, this body of evidence is difficult to translate directly into a specific 24-hour standard that would protect against the range of effects that have been associated with short-term exposures.

In considering the evidence, the Staff Paper notes the significant uncertainties and the limited nature of the available evidence. In examining the available evidence to identify a basis for a range of standard levels that would be appropriate for consideration, the Staff Paper focuses on the upper end of the distributions of daily $PM_{10-2.5}$ concentrations in the relevant studies in terms of the 98th and 99th percentile values.[68]

In looking first at the morbidity studies that report statistically significant associations with respiratory- and cardiac-related hospital admissions in Toronto (Burnett et al., 1997), Seattle (Sheppard et al., 2003), and Detroit (Ito, 2003), the 98th percentile values reported in these studies range from approximately 30 to 36 $\mu g/m^3$. To provide some perspective on these $PM_{10-2.5}$ levels, the Staff Paper notes that the level of the 24-hour PM_{10} standard was exceeded only on a few occasions during the time periods of the studies in Detroit and Seattle.[69] In looking also at the mortality studies that report statistically significant and generally robust associations with short-term exposures to $PM_{10-2.5}$ in Phoenix (Mar et al., 2003) and Coachella Valley, CA (Ostro et al., 2003), the reported 98th percentile values were approximately 70 and 107 $\mu g/m^3$, respectively. These studies were conducted in areas with air quality levels that did not meet the current PM_{10} standards. In addition, a statistically significant association was reported between $PM_{10-2.5}$ and mortality in Steubenville as part of the original Six Cities study (Schwartz et al., 1996), although in more recent reanalyses, the association did not remain statistically significant in most models (Schwartz, 2003a; Klemm and Mason, 2003)—the $PM_{10-2.5}$ concentrations in this eastern city were fairly high, with a reported 98th percentile value of 53 $\mu g/m^3$. In contrast to the statistically significant mortality associations with $PM_{10-2.5}$ reported in these studies, the Staff Paper notes that no such associations were reported in a number of other studies, including those in the five other cities that were part of the Six Cities study (Boston, St. Louis, Knoxville, Topeka, and Portage), Santa Clara County, CA, Detroit, Philadelphia, and Pittsburgh. With the exception of Pittsburgh, these cities had much lower 98th percentile $PM_{10-2.5}$ values, ranging from 18 to 49 $\mu g/m^3$. Thus, in mortality studies that reported statistically significant associations, the reported 98th percentile $PM_{10-2.5}$ values were all above 50 $\mu g/m^3$, whereas in the mortality studies that reported no statistically significant associations, the reported 98th percentile $PM_{10-2.5}$ values were generally below 50 $\mu g/m^3$.

In looking more closely at air quality data used in the morbidity and mortality studies discussed above, however, the Staff Paper recognizes that the uncertainty related to exposure measurement error associated with using ambient concentrations to represent area-wide population exposure levels can be potentially quite large. For example, in looking specifically at the Detroit study, the Staff Paper notes that the $PM_{10-2.5}$ air quality values were based on air quality monitors located in Windsor, Canada. While the study authors concluded that these monitors were appropriate for use in exploring the association between air quality and hospital admissions in Detroit, a close examination of air quality levels at Detroit and Windsor sites in recent years led to the conclusion that the statistically significant, generally robust association with hospital admissions in Detroit likely reflects population exposures that may be appreciably higher in the central city area, but not necessarily across the broader study area, than would be estimated using data from the Windsor monitors (EPA, 2005a, p. 5–64).

The EPA staff also looked more specifically at the Coachella Valley mortality study (Ostro et al., 2003), in which data were used from a single monitoring site in one city, Indio, within the study area where daily measurements were available. A close examination of air quality levels across the Coachella Valley suggests that while the association of mortality with $PM_{10-2.5}$ measurements made at the Indio site was statistically significant, a portion of the study population would have been expected to experience appreciably lower ambient exposure levels. In contrast to the Detroit study, air quality data used in the mortality

[68] This examination of the evidence is based on air quality information and analyses presented in two staff memos which were part of the materials reviewed by CASAC (Ross and Langstaff, 2005; Ross, 2005).

[69] As shown in air quality data trends reports: for Seattle, 1997 Air Quality Annual Report for Washington State, p. 17, at *http://www.ecy.wa.gov/pubs/97208.pdf*; for Detroit, Michigan's 2003 Annual Air Quality Report, p. 46, at *http://www.deq.state.mi.us/documents/deq-aqd-air-reports-03AQReport.pdf.*

study conducted in Coachella Valley appear to represent concentrations on the high end of $PM_{10-2.5}$ levels for Coachella Valley communities. On the other hand, a close examination of the air quality data used in the other studies discussed above generally shows less disparity between air quality levels at the monitoring sites used in the studies and the broader pattern of air quality levels across the study areas than that described above in the Detroit and Coachella Valley studies.

This close examination of air quality information generally reinforces the view that exposure measurement error is potentially quite large in these $PM_{10-2.5}$ studies. As a consequence, the air quality levels reported in these studies, as measured by ambient concentrations at monitoring sites within the study areas, are not necessarily good surrogates for population exposures that are likely associated with the observed effects in the study areas or that would likely be associated in other urban areas across the country. The Detroit example suggests that population exposures were probably appreciably underestimated in the Detroit morbidity study, such that the observed effects are likely associated with higher $PM_{10-2.5}$ levels than reported. In contrast, the Coachella Valley mortality study provides an example in which population levels were probably appreciably overestimated, such that the observed effects may well be associated with lower $PM_{10-2.5}$ levels than reported. At relatively low levels of air quality, population exposures implied by these studies as being associated with the observed effects likely become more uncertain, suggesting a high degree of caution in interpreting the group of morbidity studies as a basis for identifying a standard level that would protect against the observed effects.

Taking into account this close examination of the studies, the Staff Paper concludes that this evidence suggests that EPA could consider a standard for urban thoracic coarse particles at a $PM_{10-2.5}$ level at least down to 50 μg/m³, in conjunction with a 98th percentile form. This view takes into account the conclusion that this evidence is particularly uncertain as to population exposures, especially from the morbidity studies reporting effects at relatively low concentrations, as well as the general lack of evidence of associations from the group of mortality studies with reported concentrations below these levels.

Another view that reflects a more cautious or restrained approach to interpreting the limited body of $PM_{10-2.5}$ epidemiologic evidence would be to judge that the uncertainties in this whole group of studies as to population exposures that are associated with the observed effects are too large to use the reported air quality levels directly as a basis for setting a specific standard level. Such a judgment would be consistent with concluding that these studies, together with other dosimetric and toxicologic evidence, provide support for retaining standards for thoracic coarse particles at some level to protect against the morbidity and mortality effects observed in the studies, regardless of whether an associated population exposure level can be clearly discerned from the studies.

Based on this more cautious approach, the Staff Paper concludes that it would be reasonable to interpret the available epidemiologic evidence more qualitatively. Considering the available evidence in this way leads to the following observations:

(1) The statistically significant mortality associations with short-term exposure to $PM_{10-2.5}$ reported in the Phoenix and Coachella Valley studies were observed in areas that did not meet the current PM_{10} standards.

(2) The statistically significant morbidity associations with short-term exposure to $PM_{10-2.5}$ reported in the Detroit and Seattle studies were observed in areas that exceeded the level of the current 24-hour PM_{10} standard on just a few occasions during the time periods of the studies.

(3) All but one of the statistically significant morbidity and mortality associations with short-term exposure to PM_{10} reported in areas in which the thoracic coarse particle fraction of PM_{10} was much greater than was the fine fraction (including Reno/Sparks, NV, Tucson, AZ, Anchorage, AK, and the Utah Valley area) were observed in areas that did not meet the current PM_{10} standards.

Based on these considerations, the Staff Paper finds little basis for concluding that the degree of protection afforded by the current PM_{10} standards in urban areas is greater than warranted, since potential mortality effects have been associated with air quality levels not allowed by the current standards, but have not been associated with air quality levels that would generally meet the current standards, and morbidity effects have been associated with air quality levels that exceeded the current standards only a few times. Further, the Staff Paper finds little basis for concluding that a greater degree of protection is warranted in light of the very high degree of uncertainty in the relevant population exposures implied by the morbidity studies. The Staff Paper concludes, therefore, that it is reasonable to interpret the available evidence as supporting consideration of a short-term standard for thoracic coarse particles, so as to provide generally ''equivalent'' protection to that afforded by the current PM_{10} standards, recognizing that no one $PM_{10-2.5}$ level will be strictly equivalent to a specific PM_{10} level in all areas (EPA, 2005a, p. 5–67). Such a standard would likely provide protection against morbidity effects especially in urban areas where, unlike the study areas, PM_{10} is generally dominated by coarse-fraction rather than fine-fraction particles. Such a standard would also likely provide protection against the more serious, but more uncertain, $PM_{10-2.5}$-related mortality effects generally observed at somewhat higher air quality levels.

To identify a range of levels for consideration for a 24-hour $PM_{10-2.5}$ standard, based on the indicator proposed above and set so as to afford generally ''equivalent'' protection as the current PM_{10} standards, the Staff Paper presents the results of analyses of relevant data on $PM_{10-2.5}$ and PM_{10} 24-hour average concentrations.[70] In one such analysis of 205 monitoring sites (Schmidt et al., 2005),[71] a $PM_{10-2.5}$ level of approximately 60 μg/m³, in terms of a 98th percentile form, would be roughly equivalent on average across the U.S. to the current PM_{10} standard level of 150 μg/m³, in terms of the current one-expected-exceedance form.[72] While noting appreciable variability in the estimated point of equivalence across individual sites, these levels of approximate average equivalence are quite consistent across each of the five regions in which all of the areas that do not meet the current PM_{10} standards are located (including the southern California, southwest, northwest, upper mid-west, and southeast regions). Notably different average equivalence

[70] Consistent with $PM_{10-2.5}$ monitoring network design criteria discussed in section 5.4.2.2 of the Staff Paper, monitors included in this analysis are those in CBSAs with at least 100,000 population and in census block groups with a population density of at least 500, and that also had 3 years of complete data in each quarter for both PM_{10} and $PM_{10-2.5}$ (EPA, 2005a, p. 5–67).

[71] These analyses were based on collocated PM_{10} and $PM_{10-2.5}$ data, and used linear regression methods to predict $PM_{10-2.5}$ concentrations (98th percentile form) equivalent to the 24-hour PM_{10} standard level of 150 μg/m³ (one expected exceedence form) at a national and at regional levels.

[72] Across the U.S., the 95 percent confidence intervals around these point estimates are approximately ±3 μg/m³, while region-specific intervals are approximately ±10 μg/m³ in the five regions in which all of the areas that do not meet the current PM_{10} standards are located (EPA, 2005a, p. 5–68).

levels were observed in the other two regions, i.e., approximately 40 μg/m³ in the northeast and over 70 μg/m³ in the industrial mid-west.

Another such analysis was based on comparing the number of areas, and the population in those areas, that would likely not meet a specific $PM_{10-2.5}$ standard, set at a given level and form, with the same measures in areas that do not meet the current PM_{10} standards. This analysis, based on 2001 to 2003 data, provides some rough indication of the breadth of protection potentially afforded by alternative standards. The results of this analysis indicate that a $PM_{10-2.5}$ standard of about 70 or 65 μg/m³, 98th percentile form, would impact approximately the same number of counties or number of people, respectively, as would the current PM_{10} standards.[73]

In considering the relevant dosimetric, toxicologic, and epidemiologic evidence, related limitations and uncertainties, and analyses of relevant air quality information, the Staff Paper concludes that it is appropriate to consider a 24-hour $PM_{10-2.5}$ standard in the range of 50 to 70 μg/m³, with a 98th percentile form.[74] The lower end of this range is based on a close examination of the air quality patterns related to the limited number of relevant epidemiologic studies. The upper part of this range is based on a more cautious approach to interpreting the available information and reflects a generally ''equivalent'' degree of protection to that afforded by the current PM_{10} standards. The upper end of this range is also below the 98th percentile $PM_{10-2.5}$ concentrations in the two mortality studies that reported statistically significant associations. Consideration of a generally ''equivalent'' $PM_{10-2.5}$ standard would reflect a judgment that while the epidemiologic evidence supports establishing a short-term standard for urban thoracic coarse particles at such a generally ''equivalent'' level, the evidence concerning air quality levels of thoracic coarse particles in the studies is not strong enough to provide a basis for changing the level of protection generally afforded by the current PM_{10} standards.

Based on its review of the Staff Paper, there was general agreement among the CASAC Panel members that the Staff Paper-recommended range of 50 to 70 μg/m³, with a 98th percentile form, for a 24-hour $PM_{10-2.5}$ standard was reasonably justified. Most CASAC Panel members favored levels at the upper end of that range, while several members supported the lower end of the range (Henderson, 2005b). Because of the significant uncertainties resulting from the limited number of studies to date in which $PM_{10-2.5}$ has been measured and the potentially large exposure measurement errors in such studies, the CASAC Panel did not generally support a level below the Staff Paper-recommended range.

In considering an appropriate level for a 24-hour $PM_{10-2.5}$ standard intended to afford requisite protection of public health from health effects associated with exposure to thoracic coarse particles of concern, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations of CASAC, and public comments to date on this issue. Taking these considerations into account, the Administrator proposes to set the level of the primary 24-hour $PM_{10-2.5}$ standard at 70 μg/m³. In the Administrator's provisional judgment, based on the currently available evidence, a standard set at this level would be requisite to protect public health with an adequate margin of safety from the morbidity and possibly mortality effects that have been associated with short-term exposures to thoracic coarse particles of concern. This proposed standard is expected to have the most impact in areas that do not meet the current 24-hour PM_{10} standard.

In reaching this judgment, the Administrator recognizes that the epidemiologic evidence on morbidity and possible mortality effects related to $PM_{10-2.5}$ exposure is very limited at this time, and that there are potentially quite large uncertainties inherent in interpreting the available evidence for $PM_{10-2.5}$ as compared with the evidence related to fine particles. For example, $PM_{10-2.5}$ concentrations can vary substantially across a metropolitan area and thoracic coarse particles are less able to penetrate into buildings than fine particles; thus, the ambient concentrations reported in epidemiologic studies may not well represent area-wide population exposure levels. It may also be difficult to disentangle effects associated with $PM_{10-2.5}$ and $PM_{2.5}$ in epidemiologic studies. Further, the Administrator is mindful that considering what standard is requisite to protect public health with an adequate margin of safety requires judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the evidence. Thus, the Administrator provisionally concludes that the selection of a level that provides generally equivalent protection to that provided by the current PM_{10} standards is an appropriate policy response to the very limited body of evidence that is available at this time. The EPA intends to address the considerable uncertainties in the currently available information on thoracic coarse particles as part of the Agency's ongoing PM research program.

The Administrator also recognizes that there is no one level for a $PM_{10-2.5}$ standard that would be equivalent to the current PM_{10} standards in every area across the country, and that there are likely additional approaches to identifying a generally equivalent standard level beyond those approaches considered in the Staff Paper upon which the proposed level is based. Thus, the Administrator also solicits comment on alternative approaches to identifying a generally ''equivalent'' standard level. While proposing to set the $PM_{10-2.5}$ standard at a level that is generally equivalent to the 1987 PM_{10} standard, the Administrator solicits comment on whether it would be more appropriate to set the $PM_{10-2.5}$ standard at a level that is generally equivalent to the PM_{10} standard set in 1997.

Having decided to propose the 24-hour $PM_{10-2.5}$ standard described above, the Administrator recognizes that there are important views on the information relating to the effects of coarse fraction PM that warrant consideration. For example, an alternative interpretation of the available health evidence presented in the Criteria Document and the Staff Paper questions the conclusions about $PM_{10-2.5}$ associations drawn from one-pollutant models. This interpretation of the available epidemiological evidence suggests that the results from one-pollutant $PM_{10-2.5}$ models are confounded by fine particles and gaseous co-pollutants.

The key $PM_{10-2.5}$ epidemiologic results discussed in the Criteria Document and

[73] As shown in Tables 5B–2(a) and (b) of the Staff Paper, there are 585 counties with PM_{10} monitoring sites used in determining compliance with the PM_{10} standards, whereas only 309 of those counties have monitor sites that would be included in the monitoring network design criteria discussed in section 5.4.2.2 of the Staff Paper. Of these 309 counties, 259 have PM_{10} and $PM_{10-2.5}$ air quality data that meet the data completeness criteria defined for this analysis, which are somewhat less restrictive than the criteria that were applied in the regression analysis described above.

[74] Beyond looking directly at the relevant epidemiologic evidence and related air quality information, the Staff Paper also considers the extent to which the $PM_{10-2.5}$ risk assessment, discussed above in section III.B, can help inform consideration of alternative 24-hour $PM_{10-2.5}$ standards. The Staff Paper concludes that the nature and magnitude of the uncertainties and concerns associated with this portion of the risk assessment weigh against use of these risk estimates as a basis for recommending specific standard levels (EPA, 2005a, p. 5–69).

Staff Paper are drawn from one-pollutant models; i.e., $PM_{10-2.5}$ is the only variable used in the statistical model reflecting exposure to air pollution. There are four studies cited in these documents as being suggestive of a statistically significant role for $PM_{10-2.5}$ in the reported associations: Ito (2003), Burnett et al. (1997), Mar et al. (2003), and Ostro et al. (2003). However, there is strong evidence that adverse health effects similar to those observed in these studies, including both cardiovascular and/or respiratory health effects are associated with exposure to $PM_{2.5}$. The authors of several of these studies focus on fine particles (and in some cases one or more of the gaseous pollutants) as playing an important role in ''explaining'' the association between PM and various health endpoints. For example, in these key epidemiologic studies, the correlation coefficients between $PM_{2.5}$ and $PM_{10-2.5}$ concentrations range from moderate to high (i.e., 0.4 to 0.7), which increases the likelihood that associations between health effects and $PM_{10-2.5}$ identified in one-pollutant models may instead simply reflect the effects of exposure to $PM_{2.5}$ rather than independent health effects. With the positive correlations between pollutants and similar health effects, it generally would be appropriate for any assessment of the effect of exposure to $PM_{10-2.5}$ to control for exposure to the $PM_{2.5}$.

In this light, it is important to review how the authors of the four key $PM_{10-2.5}$ epidemiology studies have accounted for co-pollutants in their analysis. Ito (2003) noted significant estimates of the health effects of associations in one-pollutant models, but in a two-pollutant model with $PM_{2.5}$ the $PM_{10-2.5}$ associations lost statistical significance. Burnett et al. (1997) concluded that the effect of $PM_{10-2.5}$ in a one-pollutant model could be explained by gaseous co-pollutants. Mar et al. (2003) found $PM_{10-2.5}$ to be positively associated with adverse health effects in a one-pollutant model, but also found similar associations with a range of other air pollutants. In addition, Mar et al. (2003) noted that even though all PM mass metrics included in the study were associated with an excess risk of cardiovascular death, the strongest associations were with $PM_{2.5}$, followed by PM_{10} and $PM_{10-2.5}$. Ostro et al. (2003) used a one-pollutant model to estimate the association between $PM_{10-2.5}$ on mortality using an effectively linear construct of PM_{10} (as observed in Indio, CA) to represent $PM_{10-2.5}$ for the entire study area. By using such a construct of PM_{10}, the estimated associations simply reflect a PM_{10} association (i.e., the construct does not provide additional information on the effect of $PM_{10-2.5}$). Moreover, roughly 75 percent of the cardiovascular mortality in this study occurred in or near Palm Springs, CA and PM characteristics differ significantly between Palm Springs and Indio (e.g., average PM_{10} concentrations are roughly 30 percent lower in Palm Springs and $PM_{2.5}$ represents a higher fraction of PM_{10}, with a correlation coefficient between $PM_{2.5}$ and $PM_{10-2.5}$ of 0.46 in Palm Springs). Thus, the Ostro et al. (2003) study suggests a positive association between PM_{10} monitored in Indio and mortality in Palm Springs, but some view this study as offering little basis for attributing significant mortality association to $PM_{10-2.5}$ as observed in either city.

The Criteria Document and Staff Paper also present and discuss other epidemiology studies in support of the proposal for both the $PM_{2.5}$ and $PM_{10-2.5}$ standards (as shown in Figure 2 and discussed in Section III.A above): Burnett (1997), Fairley (2003), Ito (2003), Lipfert et al (2000), Mar et al (2003), Moolgavkar (2000), Sheppard et al (2003), Thurston et al (1994), Burnett (2000, 2003), Klemm and Mason (2003), and Schwartz and Neas (2000). However, these studies report positive, statistically significant associations with $PM_{2.5}$ that are more consistent and robust than the associations thus far identified for $PM_{10-2.5}$. Indeed, several of these and other studies that specifically considered $PM_{10-2.5}$, but did not find statistically significant associations, including Schwartz et al (1996), Thurston et al. (1994), Sheppard et al. (2003), Fairley (2003), Schwartz et al (1996) and Lipfert et al. (2000). With respect to mortality effects in the Six-City study, Schwartz et al. (1996) concluded that the PM associations (in the six metropolitan areas—including Steubenville) were specifically associated with $PM_{2.5}$, with little additional contribution from the $PM_{10-2.5}$. Sheppard et al. (2003) noted that bias in model selection and reporting can result in inflated excess risk estimates for PM. Fairley (1999) noted that $PM_{10-2.5}$ effects become negative and insignificant when modeled jointly with $PM_{2.5}$. Lipfert et al. (2000) showed insignificant effects for $PM_{10-2.5}$ in one- and two-pollutant models with O_3. The authors also caution against drawing causal interpretations from results when comparing health effects from one region in a metropolitan area to air quality observations in another region. In addition, several of these studies also report positive, statistically significant associations with one or more of the gaseous pollutants. Both Thurston et al. (1994) and Burnett et al. (1997) reported substantial confounding with gaseous co-pollutants in Toronto, and Thurston et al. (1994, p. 282) reported that ''it seems clear that these apparent associations were merely a statistical by-product of interpollutant confounding resulting from the shared day-to-day variations in dispersion conditions.'' In addition, Burnett et al. (2000) concluded that gaseous pollutants played an important role in explaining the effect of urban air pollution on health. Similarly, Moolgavkar (2000) concludes that gases were more strongly associated with respiratory effects than PM in Los Angeles.

Taken as a whole, evidence from $PM_{10-2.5}$ epidemiologic studies could be interpreted to suggest that one-pollutant $PM_{10-2.5}$ models suffer from bias due to omitting co-pollutants in the statistical model, especially given the much stronger evidence (discussed above) that these effects are associated with exposure to $PM_{2.5}$. As noted by many of the aforementioned authors, while significant health associations may be noted for coarse fraction PM in one-pollutant models, the actual association may be insignificant from zero due to confounding co-pollutants. Of course, the Administrator must conclude in the final rule that the evidence about the health effects of $PM_{10-2.5}$ is sufficiently robust to finalize a standard for $PM_{10-2.5}$.

The Administrator, recognizing notably large uncertainties in the underlying evidence and information that formed the basis for this proposal as well as the challenges associated with moving toward a new $PM_{10-2.5}$ indicator and a related new monitoring network, solicits comment on this and other alternative interpretations of the available health evidence and alternative policy responses. Several such alternative interpretations and policy responses are discussed below.

(1) In light of the large uncertainties in the evidence and the challenges of moving to a new indicator, and provisionally recognizing the need for a standard to provide a requisite level of protection from the risks associated with thoracic coarse particles, the Administrator also believes it appropriate to consider a policy option that would retain the current 24-hour PM_{10} standard (with a one-expected-exceedance form), while addressing issues such as the appropriateness of the indicator and the level of the standard.

As discussed in section I.D, in response to a challenge to the 1997 standards for thoracic coarse PM, the

U.S. Court of Appeals for the District of Columbia vacated the Agency's 1997 PM_{10} standards. In its decision the Court noted that use of PM_{10} as an indicator to protect against the public health risks associated with thoracic coarse particles resulted in double regulation of $PM_{2.5}$, since this size fraction is both a component of PM_{10} and the subject of its own standard. The Court further reasoned that, since $PM_{2.5}$ concentrations vary from area to area, use of PM_{10} as a thoracic coarse particle indicator results in an arbitrary level of protection in public health from the risks associated with thoracic coarse particles on a national basis, as the level of protection would vary based on the concentration of $PM_{2.5}$ in an area. See *American Trucking Associations* v. *EPA*, 175 F.3d at 1054–55.

Under this option to retain the 24-hour PM_{10} standard, EPA would modify the standard to exclude the double-counted $PM_{2.5}$ contribution in circumstances where this could present a concern. First, there will be some areas that may be in nonattainment with the PM_{10} standard because, and only because, they are in nonattainment with the $PM_{2.5}$ standard. To remedy the double counting in this situation, EPA is requesting comment on subtracting from a daily measured PM_{10} concentration the value by which the concentration of $PM_{2.5}$ measured at a collocated monitor is in excess of 35 μg/m³ (i.e., the proposed level for the 24-hour $PM_{2.5}$ standard). This adjustment would need to be made only on days when a 24-hour average PM_{10} concentration is measured in excess of 150 μg/m³. In such a case, the amount by which the $PM_{2.5}$ concentration exceeds 35 μg/m³ would be subtracted from the measured PM_{10} concentration. The EPA would then use this adjusted value in any comparison to the PM_{10} standard.

The second situation where the overlap between the $PM_{2.5}$ and PM_{10} standards may cause some concern is in areas where a daily $PM_{2.5}$ level is below 35 μg/m³. In those areas, the level of the PM_{10} standard would allow a higher concentration of thoracic coarse particles before triggering an exceedance than it would in other areas. The EPA is requesting comment on not requiring any adjustment to the daily measured PM_{10} concentration in this situation, on the basis that any additional risk to public health that may be associated with this higher allowable concentration of thoracic coarse particles would reasonably be expected to present less concern from a public health perspective than would the otherwise allowable equivalent increase in the concentration of $PM_{2.5}$.

The EPA also believes that it would be appropriate in this option to focus the PM_{10} standard in a manner similar to that proposed above for the $PM_{10\text{-}2.5}$ standard. While the indicator would remain specified as PM_{10}, the focus would be on including only the mix of ambient thoracic coarse particles that are of concern to public health (and to exclude the mix for which information is not sufficient to infer a public health concern) and would be achieved in practice through the data handling requirements associated with the standard, which are linked to the proposed monitoring network design criteria (in the part 58 rule proposed elsewhere in today's **Federal Register**).

The EPA invites comment on whether this option would provide the requisite level of public health protection from risks associated with thoracic coarse particles. Given the difference in form between the 24-hour PM_{10} standard (one-expected-exceedance form) and the proposed $PM_{10\text{-}2.5}$ standard (98th percentile form), and the adjustments noted above, in practice there may not be an appreciable difference in the degree of public health protection afforded by this option relative to that afforded by the proposed $PM_{10\text{-}2.5}$ standard. The EPA invites comment on whether this approach addresses one of the concerns about use of a PM_{10} indicator for thoracic coarse particles noted by the Court in its ATA decision, namely that the level of public health protection from thoracic coarse particles in an area would vary depending on the relative proportions of fine and thoracic coarse particles, by recognizing that the PM_{10} indicator and standard would cover both fine and thoracic coarse particles.

With respect to revocation of the 1987 24-hour PM_{10} standard, under this option EPA would apply the same approach to revocation as that proposed below in section III.H. in conjunction with the proposed $PM_{10\text{-}2.5}$ standard. Since the 24-hour PM_{10} standard would be focused in basically the same manner as the proposed $PM_{10\text{-}2.5}$ standard, it would be appropriate to follow the same approach to revocation of the current 24-hour PM_{10} standard under this option as well.

The EPA solicits comment on all aspects of this approach, including views on whether a 24-hour PM_{10} standard revised as noted above would be requisite to protect public health from the risks associated with thoracic coarse particles, with an adequate margin of safety, as well as views on any legal, scientific, or policy issues associated with this alternative, and including comments on the consistency of this option with CASAC's recommendations. The EPA also solicits comment on whether a 98th percentile form should be considered for a 24-hour PM_{10} standard and on the appropriate level of such a standard.

(2) The Administrator recognizes that some commenters hold the view that the uncertainties that exist at the present time are so great that no standards for thoracic coarse particles are warranted. Some such commenters point to conclusions reached in the Staff Paper in part as a basis for their view, including, for example, the conclusion that the ''substantial uncertainties associated with this limited body of epidemiological evidence on health effects related to $PM_{10\text{-}2.5}$ * * * suggests a high degree of caution in interpreting this evidence * * *.'' (EPA 2005, pp. 5–50). This view generally places significant weight on the issue of confounding between $PM_{2.5}$ and $PM_{10\text{-}2.5}$ (discussed above in section III.A), with some commenters stating that the correlation coefficients between fine and thoracic coarse particle levels are modest to high for all studies for which such data are available, increasing the possibility that the positive association identified in the $PM_{10\text{-}2.5}$ one-pollutant models may instead reflect the effects of fine particles. Noting that the Staff Paper puts little weight on the health risk assessment because of the significant uncertainties in the underlying health studies, some commenters suggest that the risk assessment therefore does not provide a basis for determining whether the health effects possibly associated with $PM_{10\text{-}2.5}$ constitute a meaningful public health risk. Some commenters take the view that, based either on the studies or the risk assessment, the magnitude of the health effects possibly associated with $PM_{10\text{-}2.5}$ do not constitute a meaningful risk to public health. These commenters also maintain that significant uncertainty remains as to an appropriate level of a standard, even assuming that a meaningful public health risk exists. In consideration of these views, the Administrator also solicits comment on revoking the current 24-hour PM_{10} standard at this time (as well as the current annual PM_{10} standard, as proposed above), not adopting a thoracic coarse particle standard at this time, and taking into account any new relevant research that becomes available as a basis for considering a more targeted standard for thoracic coarse particles in the next periodic review of the PM NAAQS.

(3) In sharp contrast to the views noted above, another view that the Administrator takes note of would place greater weight on the available epidemiologic evidence as a basis for selecting a level down to 50 μg/m^3 or below and/or for selecting an unqualified $PM_{10-2.5}$ indicator. While recognizing that important uncertainties are present in the available evidence, this view would support incorporating a larger margin of safety consistent with a more highly precautionary policy response. In soliciting comments on a wide array of views, the Administrator solicits comment on this view and on standard levels that are consistent with this view.

H. Proposed Decisions on Primary $PM_{10-2.5}$ Standard

For the reasons discussed above, and taking into account the information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and public comments to date, the Administrator proposes to revise the current primary PM_{10} standards. In particular, to provide more targeted protection from thoracic coarse particles that are of concern to public health, the Administrator proposes to establish a new indicator for thoracic coarse particles in terms of $PM_{10-2.5}$, the definition of which includes qualifications that identify both the mix of such particles that are of concern to public health, and are thus included in the indicator, and those for which currently available information is not sufficient to infer a public health concern, and are thus excluded. More specifically, the proposed $PM_{10-2.5}$ indicator is qualified so as to include any ambient mix of $PM_{10-2.5}$ that is dominated by particles generated by high-density traffic on paved roads, industrial sources, and construction sources, and to exclude any ambient mix of particles dominated by rural windblown dust and soils and agricultural and mining sources. The Administrator proposes to replace the current primary 24-hour PM_{10} standard with a 24-hour standard defined in terms of this new $PM_{10-2.5}$ indicator and set at a level of 70 μg/m^3, which would generally maintain the degree of public health protection afforded by the current PM_{10} standards from short-term exposure to thoracic coarse particles of concern. The proposed new standard would be met at an ambient air quality monitoring site [75] when the 3-year average of the annual 98th percentile 24-hour average $PM_{10-2.5}$ concentration is less than or equal to 70 μg/m^3.[76] The Administrator also proposes to revoke and not replace the annual PM_{10} standard.

In recognition of alternative views of the currently available scientific information and the appropriate policy response to this information, the Administrator also solicits comments on (1) alternative approaches to selecting the level of a 24-hour $PM_{10-2.5}$ standard or to selecting an unqualified $PM_{10-2.5}$ indicator, and (2) alternative approaches to providing continued protection from thoracic coarse particles based on retaining the current 24-hour PM_{10} standard. Alternatively, the Administrator also solicits comment on revoking and not replacing the 24-hour PM_{10} standard. Based on the comments received and the accompanying rationale, the Administrator may adopt other standards within the range of the alternatives identified above in lieu of the standard he is proposing today.

The Administrator is also proposing to revoke the current annual PM_{10} standard upon promulgation of this rule. Further, if EPA finalizes a 24-hour primary $PM_{10-2.5}$ standard, the Administrator is proposing to revoke the current 24-hour PM_{10} standard everywhere except in areas where there is at least one monitor that is located in an urbanized area [77] with a minimum population of 100,000 people and that violates the 24-hour PM_{10} standard based on the most recent three years of data.

EPA specifically proposes that the 24-hour PM_{10} standard would be revoked in this rulemaking in all areas except the following:

1. Birmingham urban area (Jefferson County, AL)
2. Maricopa and Pinal Counties; Phoenix planning area (AZ)
3. Riverside, Los Angeles, Orange and San Bernardino Counties; South Coast Air Basin (CA)
4. Fresno, Kern, Kings, Tulare, San Joaquin, Stanislaus, Maderia Counties; San Joaquin Valley planning area (CA)
5. San Bernardino County (part); excluding Searles Valley Planning Area and South Coast Air Basin (CA)
6. Riverside County; Coachella Valley Planning Area (CA)
7. Simi Valley urban area (CA)
8. Lake County; Cities of East Chicago, Hammond, Whiting, and Gary (IN)
9. Wayne County (part) (MI)
10. St. Louis urban area (MO)
11. Albuquerque urban area (NM)
12. Clark County; Las Vegas planning area (NV)
13. Columbia urban area (SC)
14. El Paso urban area (including those portions in TX and those portions in NM)
15. Salt Lake County (UT)

A separate memorandum explaining the factual basis for our proposed determinations regarding each PM_{10} area where we are proposing to retain the current 24-hour standard is part of the administrative record for this proposed rule (Rosendahl, 2005).

In essence, we are proposing to retain the current 24-hour PM_{10} standard only in areas which could be in violation of the proposed $PM_{10-2.5}$ standard. While it is possible that some existing PM_{10} monitors may not be sited in accordance with all of the criteria for $PM_{10-2.5}$ monitor siting proposed elsewhere in today's **Federal Register** (see section IV.E.2.b.ii of the preamble to the proposed changes to Part 53/58), it is not possible for EPA to make a case-by-case assessment of monitor placement within each area at this time. Therefore, EPA believes that all areas with violating PM_{10} monitors located in urbanized areas with a minimum population of 100,000 people should be considered areas that may violate the $PM_{10-2.5}$ standard.

For those areas where we propose to retain the 24-hour PM_{10} standard which were previously designated nonattainment for PM_{10} or which are currently designated nonattainment for PM_{10}, EPA proposes, in the alternative, either that the standard would continue to apply in the entire attainment/nonattainment area, or that the area to which the standard would continue to apply should be limited to the urbanized area containing the violating monitor(s). For areas with violating monitor(s) which were never designated nonattainment, EPA proposes that the boundaries of the area to which the standard would continue to apply should be limited to the urbanized area containing the violating monitor(s). For

[75] Monitoring sites that are appropriate for determining compliance with this standard are those that are consistent with the proposed indicator. Guidance on this can be found in the proposed monitoring network design criteria published elsewhere in today's **Federal Register**.

[76] Data handling conventions are specified in a new proposed Appendix P, as discussed in Section V below, and the reference method for monitoring PM as $PM_{10-2.5}$ is specified in a new proposed Appendix L, as discussed in Section VI below.

[77] As defined by the U.S. Bureau of the Census, an urbanized area has ''a minimum residential population of at least 50,000 people'' and generally includes ''core census block groups or blocks that have a population density of at least 1,000 people per square mile and surrounding census blocks that have an overall density of at least 500 people per square mile.'' The Census Bureau notes that ''under certain conditions, less densely settled territory may be part of each UA.'' See *http://www.census.gov/geo/www/ua/ua_2k.html.*

all areas in which the 24-hour PM_{10} standard would be retained, EPA invites comments on the appropriate boundaries within which the standard should continue to apply.

Consistent with our request for comment in the Part 53/58 proposal, section IV.E.2.b.ii, on whether we should establish criteria for locating discretionary monitors appropriate for comparison with the proposed 24-hour $PM_{10-2.5}$ standard in locations other than urbanized areas with population of at least 100,000 people, we also request comment on whether the 24-hour PM_{10} standard should be retained in areas that are either urbanized areas with a population less than 100,000 people or non-urbanized areas (*i.e.* population less than 50,000) but where the majority of the ambient mix of $PM_{10-2.5}$ is generated by high density traffic on paved roads, industrial sources, and construction activities, and which have at least one monitor that violates the 24-hour PM_{10} standard. The EPA requests comment on the criteria that should be used to determine whether such an area with a violating monitor must retain the 24-hour PM_{10} standard. Such criteria could include whether the area has one (or more) industrial source(s) listed in either the National Emissions Inventory or the Toxics Release Inventory located within a certain radius of the violating monitor, and whether these sources are in industrial categories that do not include agricultural or mining sources. One approach to defining such categories would be to utilize the U.S. Census Bureau's North American Industry Classification System,[78] which defines separate classifications for agricultural and mining activities such as Crop Production (111), Animal Production (112), and Mining (112). The EPA requests comments on how this or another classification system, combined with information on the location of sources relative to the violating PM_{10} monitor, could be used to identify additional areas to which the 24-hour PM_{10} standard should continue to apply due to the presence of industrial sources. The EPA also requests comments on which areas would meet these criteria or other criteria that may be appropriate to determine in which, if any, areas the 24-hour PM_{10} standard should be retained, and the appropriate boundaries within which the standard should continue to apply for these areas. A more detailed example of criteria that could be used to identify areas to which the standard should continue to apply, along with a list of all areas with violating PM_{10} monitors that meet these criteria, are part of the administrative record for this proposed rule (Rosendahl, 2005). For all areas where the 24-hour PM_{10} standard would be retained under this proposal, we contemplate that the 24-hour PM_{10} standard would be revoked after designations are completed under a final 24-hour $PM_{10-2.5}$ standard.

The EPA also recognizes that it is possible that some areas for which we are proposing to retain the PM_{10} daily standard would, upon a case-specific investigation (see section IV.E.2.c of the Part 53/58 preamble), warrant revocation as not being an area where the ambient coarse PM mix is dominated by the type of coarse PM described by the proposed indicator. The EPA is not in a position to conduct such case-by-case evaluation for this proposal, but could address revocation in such situations in a future rulemaking. The EPA invites comment on this issue.

To address issues related to the transition from the current PM_{10} standards to a new $PM_{10-2.5}$ standard, the Administrator intends to seek public comment on EPA's plans for assuring an effective transition as part of an ANPR that EPA intends to issue by the end of January 2006. In the forthcoming ANPR dealing with transition issues, EPA intends to address, among other things, the timing for revocation of the PM_{10} standard in areas in which we are proposing to retain that standard, and the consequences of revoking the PM_{10} standards on the PM_{10} PSD program (including PM_{10} increments), on the PM_{10} nonattainment New Source Review (NSR) program, and on our existing policy of using PM_{10} as a surrogate for the $PM_{2.5}$ NSR program.

IV. Rationale for Proposed Decisions on Secondary PM Standards

The Criteria Document and Staff Paper examined the effects of PM on such aspects of public welfare as visibility, vegetation and ecosystems, materials damage and soiling, and climate change. The existing suite of secondary PM standards, which is identical to the suite of primary PM standards, includes annual and 24-hour $PM_{2.5}$ standards and annual and 24-hour PM_{10} standards. This existing suite of secondary standards is intended to address visibility impairment associated with fine particles and materials damage and soiling related to both fine and coarse particles. The following discussion of the rationale for the proposed decisions on secondary PM standards focuses on those considerations most influential in the Administrator's proposed decisions, first addressing visibility impairment followed by the other welfare effects considered in this review.[79]

A. Visibility Impairment

This section presents the rationale for the Administrator's proposed revision of the current secondary $PM_{2.5}$ standard to address PM-related visibility impairment. As discussed below, the rationale includes consideration of: (1) The latest scientific information on visibility effects associated with PM; (2) insights gained from assessments of correlations between ambient $PM_{2.5}$ and visibility impairment prepared by EPA staff; and (3) specific conclusions regarding the need for revisions to the current standards (i.e., indicator, averaging time, form, and level) that, taken together, would be requisite to protect the public welfare from adverse effects on visual air quality.

1. Visibility Impairment Related to Ambient PM

This section outlines key information contained in the Criteria Document and Staff Paper on: (1) The nature of visibility impairment, including trends in visual air quality and the characterization of current visibility conditions; (2) quantitative relationships between ambient PM and visibility; (3) the impacts of visibility impairment on public welfare; and (4) approaches to evaluating public perceptions and attitudes about visibility impairment.

a. Nature of Visibility Impairment

Visibility can be defined as the degree to which the atmosphere is transparent to visible light. Visibility conditions are determined by the scattering and absorption of light by particles and gases, from both natural and anthropogenic sources. Visibility is often described in terms of visual range, light extinction, or deciviews.[80] The classes of fine particles principally responsible for visibility impairment are sulfates, nitrates, organic matter, elemental carbon, and soil dust. Fine

[78] *http://www.census.gov/epcd/naics02/naicod02.htm#N21.*

[79] As noted in section I.A above, in establishing secondary standards that are requisite to protect the public welfare from any known or anticipated adverse effects, EPA may not consider the costs of implementing the standards.

[80] Visual range can be defined as the maximum distance at which one can identify a black object against the horizon sky. It is typically described in kilometers or miles. Light extinction is the sum of light scattering and absorption by particles and gases in the atmosphere. It is typically expressed in terms of inverse megameters (Mm^{-1}), with larger values representing poorer visibility. The deciview metric describes perceived visual changes in a linear fashion over its entire range, analogous to the decibel scale for sound.

particles are more efficient per unit mass at scattering light than coarse particles. The scattering efficiency of certain classes of fine particles, such as sulfates, nitrates, and some organics, increases as relative humidity rises because these particles can absorb water and grow to sizes comparable to the wavelength of visible light. In addition to limiting the distance that one can see, the scattering and absorption of light caused by air pollution can also degrade the color, clarity, and contrast of scenes.

Visibility impairment is manifested in two principal ways: As local visibility impairment and as regional haze. Local visibility impairment may take the form of a localized plume, a band or layer of discoloration appearing well above the terrain that results from complex local meteorological conditions. Alternatively, local visibility impairment may manifest as an urban haze, sometimes referred to as a ''brown cloud.'' A ''brown cloud'' is predominantly caused by emissions from multiple sources in the urban area and is not typically attributable to a single nearby source or to long-range transport from more distant sources. The second type of visibility impairment, regional haze, generally results from pollutant emissions from a multitude of sources located across a broad geographic region. Regional haze impairs visibility in every direction over a large area, in some cases over multi-state regions. It is regional haze that is principally responsible for impairment in national parks and wilderness areas across the country (NRC, 1993).

While visibility impairment in urban areas at times may be dominated by local sources, it often may be significantly affected by long-range transport of haze due to the multi-day residence times of fine particles in the atmosphere. Fine particles transported from urban and industrialized areas, in turn, may, in some cases, be significant contributors to regional-scale impairment in Class I areas [81] and other rural areas.

As discussed in the Staff Paper (EPA, 2004, section 6.2), in Class I areas, visibility levels on the 20 percent haziest days in the West are about equal to levels on the 20 percent best days in the East. Despite improvement through the 1990's, visibility in the rural East remains significantly impaired, with an average visual range of approximately 20 km on the 20 percent haziest days (compared to the naturally occurring visual range in the eastern U.S. of about 150 ± 45 km). In the rural West, the average visual range showed little change over this period, with an average visual range of approximately 100 km on the 20 percent haziest days (compared to the naturally occurring visual range in the western U.S. of about 230 ± 40 km).

In urban areas, visibility levels show far less difference between eastern and western regions. For example, the average visual ranges on the 20 percent haziest days in eastern and western urban areas are approximately 20 km and 27 km, respectively (Schmidt et al., 2005). Even more similarity is seen in considering 4-hour (12 to 4 p.m.) average $PM_{2.5}$ concentrations, for which the average visual ranges on the 20 percent haziest days in eastern and western urban areas are approximately 26 km and 31 km, respectively (Schmidt et al., 2005).

Data on visibility conditions indicate that urban areas generally have higher loadings of $PM_{2.5}$ and, thus, higher visibility impairment than monitored Class I areas. Since efforts are now underway to address all human-caused visibility in Class I areas through the regional haze program (EPA, 1999; 65 FR 35713), implemented under sections 169A and 169B of the CAA, and since the Clean Air Interstate Rule (CAIR) (70 FR 25162) is expected to result in improvements to visual air quality, particularly in eastern Class I and non-urban areas, new assessments included in the Staff Paper were primarily focused on visibility impairment in urban areas.

b. Correlations Between Urban Visibility and $PM_{2.5}$ Mass

Direct relationships exist between measured ambient pollutant concentrations and their contributions to light extinction and thus to visibility impairment. The contribution of each PM constituent to total light extinction is derived by multiplying the constituent concentration by its extinction efficiency to calculate a ''reconstructed'' light extinction.[82] For certain fine particle constituents, extinction efficiencies increase significantly with increases in relative humidity. As a consequence, while higher $PM_{2.5}$ mass concentrations generally indicate higher levels of visibility impairment, it is not as precise a metric as the light extinction coefficient. Nonetheless, by using historic averages, regional estimates, or actual day-specific measurements of the component-specific percentage of total mass, one can develop reasonable estimates of light extinction from PM mass concentrations. As discussed below, the Staff Paper concludes that fine particle mass concentrations can be used as a general surrogate for visibility impairment (EPA, 2005a, p. 2–74).

In an effort to better characterize urban visibility, the Staff Paper presents results of analyses of the extensive new data now available on $PM_{2.5}$ primarily in urban areas. This rapidly expanding national database includes federal reference method (FRM) [83] measurements of $PM_{2.5}$ mass, continuous measurements of hourly $PM_{2.5}$ mass, and $PM_{2.5}$ chemical speciation measurements. These data allowed for analyses that explored factors that have historically complicated efforts to address visibility impairment nationally, including regional differences related to levels of primarily fine particles and to relative humidity. These analyses show a consistently high correlation between visibility, in terms of reconstructed light extinction, and hourly $PM_{2.5}$ concentrations for urban areas in a number of regions across the U.S. and, more generally, in the eastern and western U.S. These correlations in urban areas are generally similar in the East and West, in sharp contrast to the East/West differences observed in rural areas.

While the average daily relative humidity levels are generally higher in the East than in the West, in both regions relative humidity levels are appreciably lower during daylight as compared to night time hours. The reconstructed light extinction coefficient, for a given mass and concentration, increases sharply as relative humidity rises. Thus, with lower relative humidity levels, visibility impacts related to East/West differences in average relative humidity are minimized during daylight hours, when relative humidity is generally lower.

Both 24-hour and shorter-term daylight hour averaging periods were

[81] There are 156 mandatory Class I Federal areas protected by the visibility provisions in sections 169A and 169B of the Act. These areas are defined in section 163 of the Act as those national parks exceeding 6000 acres, wilderness areas and memorial parks exceeding 5000 acres, and all international parks which were in existence on August 7, 1977.

[82] Extinction efficiencies vary by type of constituent and have been obtained for typical atmospheric aerosols by a combination of empirical approaches and theoretical calculations. As discussed in the Staff Paper, EPA's guidance for tracking progress under the regional haze program specifies an algorithm for calculating total light extinction as a function of the major fine particle components (EPA, 2005a, section 2.8.1). ''Reconstructed'' light extinction simply refers to the calculation of PM-related light extinction by the use of that formula.

[83] The $PM_{2.5}$ Federal Reference Method (FRM) monitoring network provides 24-hour average $PM_{2.5}$ concentrations.

considered in evaluations of correlations between $PM_{2.5}$ concentrations in urban areas and visibility in eastern and western areas, as well as nationwide. Clear and similarly strong correlations are found between visibility and 24-hour average $PM_{2.5}$ in eastern, western, and all urban areas (EPA, 2005a, Figure 6–3). Somewhat stronger correlations are observed between visibility and $PM_{2.5}$ concentrations averaged over a 4-hour time period (EPA, 2005a, Figure 6–5). The correlations between visibility and $PM_{2.5}$ concentrations during daylight hours in urban areas are relatively more reflective of $PM_{2.5}$ mass rather than relative humidity effects, in comparison to correlations based on a 24-hour averaging time.

c. Impacts of Urban Visibility Impairment on Public Welfare

EPA has long recognized that impairment of visibility is an important effect of PM on public welfare, and that it is experienced throughout the U.S. in urban areas as well as in remote Class I areas (62 FR 38680). Visibility is an important welfare effect because it has direct significance to people's enjoyment of daily activities in all parts of the country. Individuals value good visibility for the sense of well-being it provides them directly, both in places where they live and work, and in places where they enjoy recreational opportunities.

Survey research on public awareness of visual air quality using direct questioning typically reveals that 80 percent or more of the respondents are aware of poor visual air quality (Cohen et al., 1986). The importance of visual air quality to public welfare across the country has been demonstrated by a number of studies designed to quantify the benefits (or willingness to pay) associated with potential improvements in visibility (Chestnut and Dennis, 1997; Chestnut and Rowe, 1991). Economists have performed many studies in an attempt to quantify the economic benefits associated with improvements in current visibility conditions both in national parks and in urban areas (Chestnut and Dennis, 1997). These economic benefits may include the value of improved aesthetics during daily activities (e.g., driving or walking, daily recreations), for special activities (e.g., visiting parks and scenic vistas, hiking, hunting), and for viewing scenic photography. They may also include the value of improved road and air safety, and/or preservation of the resource for its own sake. As discussed in the Staff Paper and below, the value placed on protecting visual air quality is further demonstrated by the existence of a number of programs, goals, standards, and planning efforts that have been established in the U.S. and abroad to address visibility concerns in urban and non-urban areas.

Protection against visibility impairment in special areas is provided for in sections 169A, 169B, and 165 of the CAA, in addition to that provided by the secondary NAAQS. Section 169A, added by the 1977 CAA Amendments, established a national visibility goal to ''remedy existing impairment and prevent future impairment'' in 156 national parks and wilderness areas (Class I areas). The Amendments also called for EPA to issue regulations requiring States to develop long-term strategies to make ''reasonable progress'' toward the national goal. EPA issued initial regulations in 1980 focusing on visibility problems that could be linked to a single source or small group of sources. The 1990 CAA Amendments placed additional emphasis on regional haze issues through the addition of section 169B. In accordance with this section, EPA established the Grand Canyon Visibility Transport Commission (GCVTC) in 1991 to address adverse visibility impacts on 16 Class I national parks and wilderness areas on the Colorado Plateau. The GCVTC issued its recommendations to EPA in 1996, triggering a requirement in section 169B for EPA issuance of regional haze regulations.

EPA accordingly promulgated a final regional haze rule in 1999 (U.S. EPA, 1999; 65 FR 35713). Under the regional haze program, States are required to establish goals for improving visibility on the 20 percent most impaired days in each Class I area, and for allowing no degradation on the 20 percent least impaired days. Each state must also adopt emission reduction strategies which, in combination with the strategies of contributing States, assure that Class I area visibility improvement goals are met. The first State implementation plans are to be adopted in the 2003–2008 time period, with the first implementation period extending until 2018. Five multi-state planning organizations are evaluating the sources of $PM_{2.5}$ contributing to Class I area visibility impairment to lay the technical foundation for developing strategies, coordinated among many States, in order to make reasonable progress in Class I areas across the country.

A number of other programs, goals, standards, and planning efforts have also been established in the U.S. and abroad to address visibility concerns in urban and non-urban areas. These regulatory and planning activities are of interest because they are illustrative of the significant value that the public places on improving visibility, and because they have developed and applied methods for evaluating public perceptions and judgments about the acceptability of varying degrees of visibility impairment, as discussed below in the next section.

Several state and local governments have developed programs to improve visual air quality in specific urban areas, including Denver, CO; Phoenix, AZ; and, Lake Tahoe, CA. At least two States have established statewide standards to protect visibility. In addition, interest in visibility protection in other countries, including Canada, Australia, and New Zealand has resulted in various studies, surveys, and programs. Examples of these efforts are highlighted below.

In 1990, the State of Colorado adopted a visibility standard for the city of Denver. The Denver standard is a short-term standard that establishes a limit of a four-hour average light extinction level of 76 Mm^{-1} (equivalent to a visual range of approximately 50 km) during the hours between 8 a.m. and 4 p.m. (Ely et al., 1991). In 2003, the Arizona Department of Environmental Quality created the Phoenix Region Visibility Index, which focuses on an averaging time of 4 hours during actual daylight hours. This visibility index establishes visual air quality categories (i.e., excellent to very poor) and establishes the goals of moving days in the poor/very poor categories up to the fair category, and moving days in the fair category up to the good/excellent categories (Arizona Department of Environmental Quality, 2003). This approach results in a focus on improving visibility to a visual range of approximately 48–36 km. In 1989, the state of California revised the visibility standard for the Lake Tahoe Air Basin and established an 8-hour visibility standard equal to a visual range of 30 miles (approximately 48 km) (California Code of Regulations).

California and Vermont each have standards to protect visibility, though they are based on different measures. Since 1959, the state of California has had an air quality standard for particle pollution where the ''adverse'' level was defined as the ''level at which there will be * * * reduction in visibility or similar effects.'' California's general statewide visibility standard is a visual range of 10 miles (approximately 16 km) (California Code of Regulations). In 1985, Vermont established a state visibility standard that is expressed as a summer seasonal sulfate concentration of 2 $\mu g/m^3$, that equates to a visual range

of approximately 50 km. This standard was established to represent ''reasonable progress'' toward attaining the congressional visibility goal for the Class 1 Lye Brook National Wilderness Area, and applies to this Class 1 area and to all other areas of the state with elevations greater than 2500 ft.

Outside of the U.S., efforts have also been made to protect visibility. The Australian state of Victoria has established a visibility objective (State Government of Victoria, 1999 and 2000), and a visibility guideline is under consideration in New Zealand (New Zealand National Institute of Water & Atmospheric Research, 2000a and 2000b; New Zealand Ministry of Environment, 2000). A survey was undertaken for the Lower Fraser Valley in British Columbia, with responses from this pilot study being supportive of a standard in terms of a visual range of approximately 40 km for the suburban township of Chilliwack and 60 km for the suburban township of Abbotsford, although no visibility standard has been adopted for the Lower Fraser Valley at this time.

d. Approaches to Evaluating Public Perceptions and Attitudes

New methods and tools have been developed to communicate and evaluate public perceptions of varying visual effects associated with alternative levels of visibility impairment relative to varying pollution levels and environmental conditions. New survey methods have been applied and evaluated in various studies, such as those done in Denver, Phoenix, and the Lower Fraser Valley in British Columbia. These methods are intended to assess public perceptions as to the acceptability of varying levels of visual air quality, considered in these studies to be an appropriate basis for developing goals and standards for visibility protection. A pilot study was also conducted in Washington, DC by EPA staff.[84] Even with variations in each study's approaches, the public perception survey methods used for the Denver, Phoenix, and British Columbia studies produced reasonably consistent results from location to location, with each study indicating that a majority of participants find visual ranges within about 40 to 60 km to be acceptable.

These public perception studies use images of urban and distant scenic views under different visibility conditions together with survey techniques designed to elicit judgments from members of the public about the acceptability of differing levels of visual air quality. Images used are either photographs or computer simulations using the WinHaze program.[85] Examples of images that illustrate visual air quality in Denver, Phoenix, Washington, DC, and Chicago under a range of visibility conditions associated with a range of $PM_{2.5}$ concentrations are available at *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html* (labeled as Appendix 6A: Images of Visual Air Quality in Selected Urban Areas in the U.S.). These examples include simulated images for Denver, Phoenix, and Washington, DC, and photographs of Chicago.

Survey techniques were developed in conjunction with the Denver study and relied on citizen judgments of acceptable and unacceptable levels of visual air quality (Ely et al., 1991; EPA, 2005a, section 6.2.6.2). The studies in Phoenix and British Columbia, and the pilot study in Washington, DC used survey approaches based on that used in Denver. This approach involves conducting a series of meetings with civic and community groups to elicit individual ratings of a number of images of well-known local vistas having varying levels of visual air quality. Participants are told that the results are intended to provide input on setting a visibility standard, and they are asked to base their judgments on three factors: (1) The standard is for an urban area, not a pristine national park area where the standards might be more strict; (2) standard violations should be at visual air quality levels considered to be unreasonable, objectionable, and unacceptable visually; and (3) judgments of standard violations should be based on visual air quality only, not on any health effects that some may perceive as being linked with poor visual air quality. The Denver visibility survey process produced the following findings: (1) Individuals' judgments of an images's visual air quality and whether the image should be considered to violate a visibility standard are highly correlated with the group average; (2) when participants judged duplicate slides, group averages of the first and second ratings were highly correlated; and (3) group averages of visual air quality ratings and ''standard violations'' were highly correlated. The strong relationship of standard violation judgments with the visual air quality ratings is cited as the best evidence available from this study for the validity of this approach as input to a standard setting process (Ely et al., 1991).

The Denver visibility standard was established based on a 50 percent acceptability criterion. That is, under this approach, the standard was identified as the light extinction level that divides the images into two groups: those found to be acceptable and those found to be unacceptable by a majority of study participants. In fact, when researchers evaluated all citizen judgments made on all the photographic images at this level and above as a single group, more than 85 percent of the participants found visibility impairment at and above the level of the selected standard to be unacceptable.

Generally consistent results were found in the Phoenix study, which used simulated images from the WinHaze program. The study carefully selected participants to be demographically representative of the Phoenix population. The Phoenix survey demonstrates that the rating methodology developed for gathering citizen input for establishing the Denver visibility standard can be reliably transferred to another city while relying on updated imaging technology to simulate a range of visibility impairment levels. Similarly, the British Columbia study reinforces the conclusion that the methodology originally developed for the Denver standard setting process is a sound and effective one for obtaining public participation in a standard setting process (EPA, 2005a, p. 6–22).

2. Need for Revision of the Current Secondary PM Standards for Visibility Protection

The initial issue to be addressed in the current review of the secondary PM standards is whether, in view of the information now available, the existing secondary standards should be revised to provide requisite protection from PM-related adverse effects on visual air quality. As discussed in the Criteria Document and Staff Paper, while new research has led to improved understanding of the optical properties of particles and the effects of relative humidity on those properties, it has not changed the fundamental characterization of the role of PM, especially fine particles, in visibility impairment from the last review. However, extensive new information

[84] This small pilot study was briefly discussed in the preliminary draft staff paper (Abt Associates, 2001).

[85] The Criteria Document discusses methods available to represent different levels of visual air quality (EPA, 2004, p. 4–174). In particular, Molenar et al. (1994) describe a sophisticated visual air quality simulation technique, incorporated into the WinHaze program developed by Air Resources Specialists, Inc., which combined various modeling systems under development for the past 20 years to produce images that standardize non-pollution related effects on visibility so that perceptions of these images are not biased due to these other factors.

now available from visibility and fine particle monitoring networks has allowed for updated characterizations of visibility trends and current levels in urban areas, as well as Class I areas. As discussed above, these new data are a critical component of analyses that better characterize visibility impairment in urban areas and the relationships between visibility and $PM_{2.5}$ concentrations, finding that $PM_{2.5}$ concentrations can be used as a general surrogate for visibility impairment in urban areas.

Taking into account the most recent monitoring information and analyses, and recognizing that efforts are now underway to address all human-caused visibility impairment in Class I areas through the regional haze program implemented under sections 169A and 169B of the CAA, as discussed above, this review focuses on visibility impairment primarily in urban areas. In so doing, consideration is first given to the question of whether visibility impairment in urban areas allowed by the current 24-hour secondary $PM_{2.5}$ standard can be considered adverse to public welfare.

As discussed above, studies in the U.S. and abroad have provided the basis for the establishment of standards and programs to address specific visibility concerns in a number of local areas. These studies (e.g., in Denver, Phoenix, British Columbia) have produced reasonably consistent results in terms of the visual ranges found to be generally acceptable by the participants in the various studies, which ranged from approximately 40 to 60 km in visual range. Standards targeting protection within this range have also been set by the State of Vermont and by California for the Lake Tahoe area, in contrast to the statewide California standard that targets a visual range of approximately 16 km.

In addition to the information available from such programs, photographic representations (simulated images and actual photographs) of visibility impairment are available, as discussed above, to help inform judgments about the acceptability of varying levels of visual air quality in urban areas across the U.S. In considering these images for Phoenix, Washington, DC, and Chicago (for which $PM_{2.5}$ concentrations are reported), the Staff Paper observes that:

(1) At concentrations at or near the level of the current 24-hour $PM_{2.5}$ standard (65 $\mu g/m^3$), which equates to visual ranges roughly around 10 km, scenic views (e.g., mountains, historic monuments), as depicted in these images around and within the urban areas, are significantly obscured from view.

(2) Appreciable improvement in the visual clarity of the scenic views depicted in these images occurs at $PM_{2.5}$ concentrations below 35 to 40 $\mu g/m^3$, which equate to visual ranges generally above 20 km for the urban areas considered (EPA, 2005a, p. 7–6).

(3) Visual air quality appears to be good in these images at $PM_{2.5}$ concentrations generally below 20 $\mu g/m^3$, corresponding to visual ranges of approximately 25 to 35 km (EPA, 2005a, p. 7–8).

While being mindful of the limitations in using visual representations from a small number of areas as a basis for considering national visibility-based secondary standards, the Staff Paper nonetheless concludes that these observations, together with information from the analyses and other programs discussed above, support revising the current secondary $PM_{2.5}$ standards to improve visual air quality, particularly in urban areas. As discussed in the following sections, the Staff Paper recommends the establishment of a new short-term secondary $PM_{2.5}$ standard to provide increased and more targeted protection primarily in urban areas from visibility impairment related to fine particles (EPA, 2005a, p. 7–12). Based on its review of the Staff Paper, the CASAC advised the Administrator that most CASAC PM Panel members strongly supported the Staff Paper recommendation to establish a new, secondary $PM_{2.5}$ standard to protect urban visibility (Henderson, 2005a).[86] Most Panel members considered such a standard to be a reasonable complement to the Regional Haze Rules that protect Class I areas.

In considering whether the secondary PM standards should be revised to target PM-related visibility impairment primarily in urban areas, the Administrator has carefully considered the rationale and recommendation in the Staff Paper, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator first recognizes that PM-related visibility impairment is principally related to fine particle levels, such that it is appropriate to focus in this review on the current secondary $PM_{2.5}$ standards to provide such targeted protection. The Administrator also recognizes that visibility is most directly related to instantaneous levels of visual air quality, such that it is appropriate to focus on a standard with a short-term averaging time (e.g., 24-hours or less). Thus, the Administrator has considered whether the current 24-hour secondary $PM_{2.5}$ standard should be revised to provide a requisite level of protection from visibility impairment, principally in urban areas, in conjunction with the regional haze program for protection of visual air quality in Class I areas. The Administrator observes that at concentrations at or near the level of the current 24-hour $PM_{2.5}$ standard (65 $\mu g/m^3$), corresponding to visual ranges of about 10 km, images of scenic views (e.g., mountains, historic monuments, urban skylines) around and within a number of urban areas are significantly obscured from view. Further, the Administrator notes the various State and local standards and programs that have been established protect visual air quality beyond the degree of protection that would be afforded by the current 24-hour secondary $PM_{2.5}$ standard. Based on all of the above considerations, the Administrator provisionally concludes that it is appropriate to revise the current 24-hour secondary $PM_{2.5}$ standard to provide requisite protection from visibility impairment principally in urban areas.

3. Indicator of PM for Secondary Standard To Address Visibility Impairment

As discussed in the Staff Paper, fine particles contribute to visibility impairment directly in proportion to their concentration in the ambient air. Hygroscopic components of fine particles, in particular sulfates and nitrates, contribute disproportionately to visibility impairment under high humidity conditions. Particles in the coarse mode generally contribute only marginally to visibility impairment in urban areas. In analyzing how well $PM_{2.5}$ concentrations correlate with visibility in urban locations across the U.S. (see EPA, 2005a, section 6.2.3), the Staff Paper concludes that the observed correlations are strong enough to support the use of $PM_{2.5}$ as the indicator for such standards. More specifically, clear correlations exist between 24-hour average $PM_{2.5}$ concentrations and reconstructed light extinction, which is directly related to visual range. These correlations are similar in the eastern and western regions of the U.S.. Further, these correlations are less influenced by relative humidity and more consistent across regions when $PM_{2.5}$ concentrations are averaged over shorter, daylight time periods (e.g., 4 to

[86] A dissenting view was expressed in one Panel member's invididual review comments to the effect that any urban visibility standard should be voluntary and locally adopted (Henderson, 2005a).

8 hours). Thus, the Staff Paper concludes that it is appropriate to use $PM_{2.5}$ as an indicator for standards to address visibility impairment in urban areas, especially when the indicator is defined for a relatively short period of daylight hours. Based on its review of the Staff Paper, most CASAC PM Panel members endorsed a $PM_{2.5}$ indicator for a secondary standard to address visibility impairment.

The Administrator concurs with the EPA staff and CASAC recommendations, and concludes that $PM_{2.5}$ should be retained as the indicator for fine particles as part of a secondary standard to address visibility protection. In the Administrator's view, $PM_{2.5}$ is the appropriate indicator for any such standard, whether averaged over 24-hours or over a shorter, sub-daily time period.

4. Averaging Time of a Secondary $PM_{2.5}$ Standard for Visibility Protection

As discussed in the Staff Paper, averaging times from 24 to 4 hours have been considered for a standard to address visibility impairment. Within this range, as noted above, clear and similarly strong correlations are found between visibility and 24-hour average $PM_{2.5}$ concentrations in eastern and western areas, while somewhat stronger correlations are found with $PM_{2.5}$ concentrations averaged over a 4-hour time period. In general, correlations between $PM_{2.5}$ concentrations and light extinction are generally less influenced by relative humidity and more consistent across regions as shorter, sub-daily averaging times, within daylight hours from approximately 10 a.m. to 6 p.m., are considered. The Staff Paper concludes that an averaging time from 4 to 8 hours, generally within this daylight time period, should be considered for a standard to address visibility impairment.

In reaching this conclusion, the Staff Paper recognizes that the $PM_{2.5}$ Federal Reference Method (FRM) monitoring network provides 24-hour average concentrations, and, in some cases, on a third- or sixth-day sample schedule, such that implementing a standard with a less-than-24-hour averaging time would necessitate the use of continuous monitors that can provide hourly time resolution. Given that the data used in the analysis discussed above are from commercially available $PM_{2.5}$ continuous monitors, such monitors clearly could provide the hourly data that would be needed for comparison with a potential visibility standard with a less-than-24-hour averaging time.[87]

Most CASAC PM Panel members supported the Staff Paper recommendation of a sub-daily (4 to 8 daylight hours) averaging time, finding it to be an innovative approach that strengthens the quality of the $PM_{2.5}$ indicator by targeting the driest part of the day (Henderson, 2005a). In its advice to the Administrator, CASAC noted an indirect but important benefit to advancing EPA's monitoring program goals that would come from the direct use of hourly data from a network of continuous $PM_{2.5}$ mass monitors.

In considering the Staff Paper recommendation and CASAC's advice, the Administrator provisionally concludes that averaging times from 24 hours to 4 daylight hours would represent a reasonable range of choices for a standard to address urban visibility impairment. A 24-hour averaging time could be selected and applied based on the extensive data base currently available from the existing $PM_{2.5}$ FRM monitoring network, whereas a sub-daily averaging time would necessarily depend upon an expanded network of continuous $PM_{2.5}$ mass monitors. While the Administrator agrees that broader deployment of continuous $PM_{2.5}$ mass monitors is a desirable goal, working toward that goal does not depend upon nor provide a basis for setting a sub-daily standard. The Administrator believes that it is appropriate to evaluate averaging time in conjunction with reaching decisions on the form and level of a standard, as discussed below.

5. Elements of a Secondary $PM_{2.5}$ Standard for Visibility Protection

In considering $PM_{2.5}$ standards that would provide requisite protection against PM-related impairment of visibility primarily in urban areas, the Administrator has taken into account the results of public perception and attitude surveys in the U.S. and Canada, State and local visibility standards within the U.S., and visual inspection of photographic representations of several urban areas across the U.S. In the Administrator's judgment, these sources provide useful but still quite limited information on the range of levels appropriate for consideration in setting a national visibility standard primarily for urban areas, given the generally subjective nature of the public welfare effect involved. In considering alternative forms for such standards, the Administrator has also taken into account the same general factors that were considered in selecting an appropriate form for the 24-hour primary $PM_{2.5}$ standard, as well as additional information on the percent of areas not likely to meet various alternative $PM_{2.5}$ standards, consistent with CASAC advice to consider such information (Henderson, 2005a).

In considering elements of a secondary $PM_{2.5}$ standard, the Administrator has looked to the rationale presented in the Staff Paper and to CASAC's advice and recommendations for such a standard. Based on photographic representations of varying levels of visual air quality, public perception studies, and local and State visibility standards, as discussed above, the Staff Paper concludes that 30 to 20 $\mu g/m^3$ $PM_{2.5}$ represents a reasonable range for a national visibility standard primarily for urban areas, based on a sub-daily averaging time. The upper end of this range is below the levels at which the illustrative scenic views are significantly obscured, and the lower end is around the level at which visual air quality generally appears to be good based on observation of the illustrative views. Analyses of 4-hour average $PM_{2.5}$ concentrations indicate that this concentration range can be expected generally to correspond to median visual ranges in urban areas within regions across the U.S. of approximately 25 to 35 km (see EPA, 2005a, Figure 7–1).[88] This range of visual range values is bounded above by the visual range targets selected in specific areas where State or local agencies placed particular emphasis on protecting visual air quality.

In considering a reasonable range of forms for a $PM_{2.5}$ standard within this range of levels, the Staff Paper concludes that a concentration-based percentile form is appropriate for the same reasons as discussed above in section II.F.1 (on the form of the 24-hour primary $PM_{2.5}$ standard). The Staff Paper also concludes that the upper end of the range of concentration percentiles should be consistent with the percentile used for the primary standard, which is proposed to be the 98th percentile, and that the lower end of the range should be the 92nd percentile, which represents the mean of the distribution

[87] Decisions as to which $PM_{2.5}$ continuous monitors are providing data of sufficient quality to be used in a sub-daily visibility standard would follow protocols for approval of Federal equivalent methods (FEMs) that can provide data in at least hourly intervals, as proposed in the revisions to Part 53, published elsewhere in today's **Federal Register**.

[88] The Staff Paper notes that a standard set at any specific $PM_{2.5}$ concentration will necessarily result in visual ranges that vary somewhat in urban areas across the country, reflecting the variability in the correlations between $PM_{2.5}$ concentrations and light extinction (EPA, 2005a, p. 7–8).

of the 20 percent worst day, as targeted in the regional haze program (EPA, 2005a, p. 7–11 to 12).

In its letter to the Administrator (Henderson, 2005a), the CASAC PM Panel recognizes that it is difficult to select any specific level and form based on currently available information. Some Panel members felt that the range of levels recommended in the Staff Paper was on the high side, but recognized that developing a more specific (and more protective) level in future reviews would require updated and refined public visibility valuation studies, which CASAC strongly encouraged the Agency to support prior to the next review. With regard to the form of the standard, the recommendations in the final Staff Paper reflected CASAC's advice to consider percentiles in the range of the 92nd to the 98th percentile. Some Panel members recommend considering a percentile within this range in conjunction with a level toward the upper end of the range recommended in the Staff Paper.[89]

Based on the above considerations, the Administrator believes that it is appropriate to first consider the level of protection that would be afforded by the suite of primary $PM_{2.5}$ standards proposed today. The limited and uncertain evidence currently available for use in evaluating the appropriate level of protection suggests that a cautious approach is warranted in establishing a secondary standard. While significantly more information is available since the last review concerning the relationship between fine PM levels and visibility across the country, there is still little available information for use in making the relatively subjective value judgment needed in setting the secondary standard. Given this, it is appropriate to first evaluate the level of protection that the proposed primary standards would likely provide, and then determine whether the available evidence warrants adopting a standard with a different level, form, or averaging time. In comparing the extent to which the proposed suite of primary standards would require areas across the country to improve visual air quality with the extent of increased protection likely to be afforded by a standard based on a sub-daily averaging time, the Administrator has looked to information on the predicted percent of areas not likely to meet various alternative secondary and primary $PM_{2.5}$ standards (EPA, 2005a, Tables 7A–1 and 5B–1(a)[90]). In so doing, the Administrator observes that the predicted percent of counties with monitors not likely to meet the proposed suite of primary $PM_{2.5}$ standards (i.e., a 24-hour standard set at 35 $\mu g/m^3$, with a 98th percentile form, and an annual standard of 15 $\mu g/m^3$) is somewhat higher (27 percent) than the predicted percent of counties with monitors not likely to meet a sub-daily secondary standard with an averaging time of 4 to 8 daylight hours, a level toward the upper end of the range recommended in the Staff Paper (e.g., up to 30 $\mu g/m^3$), and a form within the recommended range (e.g., around the 95th percentile) (24 percent). A similar comparison is seen in considering the predicted percentages of the population living in such areas.

The Administrator provisionally concludes that revising the current secondary $PM_{2.5}$ to be identical to the proposed suite of primary $PM_{2.5}$ standards is a reasonable policy approach to addressing visibility protection primarily in urban areas. Such an approach would result in improvements in visual air quality in as many or more urban areas across the country as would the alternative approach of setting a sub-daily standard consistent with that generally recommended by CASAC. Such an approach also takes into account the substantial limitations in the available hourly air quality data and in available studies of public perception and attitudes with regard to the acceptability of various degrees of visibility impairment in urban areas across the country. Given these limitations, the Administrator concludes, subject to consideration of public comment, that a secondary standard with a different averaging time, level, or form is not warranted, because the available evidence does not support a decision to achieve a level of protection different from that provided by the current primary standards, and because no change in averaging time, level, or form appears needed to achieve a comparable level of protection.

The Administrator believes that a secondary NAAQS should be considered in conjunction with the regional haze program as a means of achieving appropriate levels of protection against PM-related visibility impairment in urban, non-urban, and Class I areas across the country. Programs implemented to meet a national standard focused primarily on urban areas can be expected to improve visual air quality in surrounding non-urban areas as well, as would programs now being developed to address the requirements of the regional haze rule established for protection of visual air quality in Class I areas. The Administrator further believes that the development of local programs continues to be an effective and appropriate approach to provide additional protection for unique scenic resources in and around certain urban areas that are particularly highly valued by people living in those areas. Based on these considerations, and taking into account the observations, analyses, and recommendations discussed above, the Administrator proposes to revise the current secondary $PM_{2.5}$ standards by making them identical in all respects to the proposed suite of primary $PM_{2.5}$ standards.

As discussed above, most CASAC PM Panel members strongly supported a sub-daily (4- to 8-hour averaging time) $PM_{2.5}$ standard. The Administrator places great importance on the advice of CASAC, and therefore solicits public comment on such a standard.

B. Other PM-Related Welfare Effects

This section presents the rationale for the Administrator's proposed revision of the current secondary PM standards to address PM-related effects other than visibility impairment, including vegetation and ecosystems, materials damage and soiling, and climate change. In considering the currently available evidence on each of these types of PM-related welfare effects, the Staff Paper notes that there is much information linking ambient PM to potentially adverse effects on materials and ecosystems and vegetation, and on characterizing the role of atmospheric particles in climatic and radiative processes. However, given the evaluation of this information in the Criteria Document and Staff Paper which highlighted the substantial limitations in the evidence, especially the lack of evidence linking various effects to specific levels of ambient PM, the Administrator provisionally concludes that the available evidence does not provide a sufficient basis for establishing distinct secondary standards for PM based on any of these effects alone.

[89] Some CASAC Panel members also recommend that such a standard be implemented in conjunction an ''exceptional events'' policy so as to avoid having non-compliance with the standard be driven by natural source influences such as dust storms and wild fires (Henderson, 2005a).

[90] The information in these Tables is based on analysis of 2001–2003 air quality data, including 562 counties with FRM monitors that met specific data completeness criteria for developing predicted percentages of counties not likely to meet the suite of primary $PM_{2.5}$ standards and 168 counties with continuous $PM_{2.5}$ monitors that met less restrictive data completeness criteria for developing predicted percentages for a 4-hour secondary $PM_{2.5}$ standard.

The Administrator has also addressed the question of whether reductions in PM likely to result from the current secondary PM standards, or from the range of proposed revisions to the primary PM standards, would provide requisite protection against any of these PM-related welfare effects. As discussed below, these considerations include the latest scientific information characterizing the nature of these PM-related effects and judgments as to whether revision of the current secondary standards are appropriate based on that information.

1. Nature of Effects

Particulate matter contributes to adverse effects on a number of welfare effects categories other than visibility impairment, including vegetation and ecosystems, soiling and materials damage and climate. These welfare effects result predominantly from exposure to excess amounts of specific chemical species, regardless of their source or predominant form (particle, gas or liquid). Reflecting this fact, the Criteria Document concludes that regardless of size fraction, particles containing nitrates and sulfates have the greatest potential for widespread environmental significance, while effects are also related to other chemical constituents found in ambient PM, such as trace metals and organics.[91] The following characterizations of the nature of these welfare effects are based on the information contained in the Criteria Document and Staff Paper.

a. Effects on Vegetation and Ecosystems

Potentially adverse PM-related effects on vegetation and ecosystems are principally associated with particulate nitrate and sulfate deposition. In characterizing such effects, it is important to recognize that nitrogen and sulfur are necessary and beneficial nutrients for most organisms that make up ecosystems, with optimal amounts of these nutrients varying across organisms, populations, communities, ecosystems and time scales. Therefore, it is impossible to generalize to all species in all circumstances as to the amount at which inputs of these nutrients or acidifying compounds become stressors. The Staff Paper recognizes that the public welfare benefits from the use of nitrogen (N) and sulfur (S) nutrients in fertilizers in managed agricultural and commercial forest settings. The focus of this review, therefore, is on identifying risks to sensitive species and ecosystems where unintentional additions of these atmospherically derived nutrient and acidifying compounds may be contributing to undesired change in the nation's ecosystems and resulting in adverse impacts on essential ecological attributes such as species shifts, loss of species richness and diversity, impacts on threatened and endangered species, and alteration of native fire cycles. In these cases, deposited particulate nitrate and sulfate are appropriately termed ecosystem ''stressors.''

i. Vegetation Effects

At current ambient levels, risks to vegetation from short-term exposures to dry deposited particulate nitrate or sulfate are low. However, when found in acid or acidifying deposition, such particles do have the potential to cause direct foliar injury. Specifically, the responses of forest trees to acid precipitation (rain, snow) include accelerated weathering of leaf cuticular surfaces, increased permeability of leaf surfaces to toxic materials, water, and disease agents; increased leaching of nutrients from foliage; and altered reproductive processes—all which serve to weaken trees so that they are more susceptible to other stresses (e.g., extreme weather, pests, pathogens). Acid deposition with levels of acidity associated with the foliar effects described above are currently found in some locations in the eastern U.S. (EPA, 2003). Even higher concentrations of acidity can be present in occult deposition (e.g. fog, mist or clouds) which more frequently impacts higher elevations. Thus, the risks of foliar injury occurring from acid deposition in some areas of the eastern U.S. is high. However, based on currently available information, the contribution of particulate sulfates and nitrates to the total acidity found at these locations is not clear.

ii. Ecosystem Effects

The N- and S-containing components of PM have been associated with a broad spectrum of terrestrial and aquatic ecosystem impacts that result from either the nutrient or acidifying characteristics of the deposited compounds.

Reactive nitrogen (Nr) is the form of N that is available to support the growth of plants and microorganisms. Since the mid-1960's, Nr creation through natural terrestrial processes has been overtaken by Nr creation as a result of human processes, and is now accumulating in the environment on all spatial scales—local, regional and global. Some Nr emissions are transformed into ambient PM and deposited onto sensitive ecosystems. Some of the most significant detrimental effects associated with excess Nr deposition are those associated with a syndrome known as ''nitrogen saturation.'' These effects include: (1) Decreased productivity, increased mortality, and/or shifts in terrestrial plant community composition, often leading to decreased biodiversity in many natural habitats wherever atmospheric Nr deposition increases significantly and critical thresholds are exceeded; (2) leaching of excess nitrate and associated base cations from terrestrial soils into streams, lakes and rivers and mobilization of soil aluminum; and (3) alteration of ecosystem processes such as nutrient and energy cycles through changes in the functioning and species composition of beneficial soil organisms (Galloway and Cowling 2002). Thus, through its effects on habitat suitability, genetic diversity, community dynamics and composition, nutrient status, energy and nutrient cycling, and frequency and intensity of natural disturbance regimes (fire), excess Nr deposition is having profound and adverse impact on the essential ecological attributes associated with terrestrial ecosystems. In the U.S., numerous forests now show severe symptoms of nitrogen saturation. For other forested locations, ongoing expansion in nearby urban areas will increase the potential for nitrogen saturation unless there are improved emission controls.

Excess nutrient inputs into aquatic ecosystems (e.g., streams, rivers, lakes, estuaries or oceans) either from direct atmospheric deposition, surface runoff, or leaching from nitrogen saturated soils into ground or surface waters can contribute to conditions of severe water oxygen depletion (hypoxia); eutrophication and algae blooms; altered fish distributions, catches, and physiological states; loss of biodiversity; habitat degradation; and increases in the incidence of disease. Estuaries are among the most intensely fertilized systems on Earth.

Reactive nitrogen moves from one environmental reservoir to another through a number of sequential environmental processes. Though strong correlation between the stressor and adverse environmental response exists in many locations, and N-addition studies have confirmed the relationship between stressor and response, the ability to determine the temporal and spatial distribution of environmental effects for a given input of Nr are extremely limited by the large uncertainties associated with the rates at which Nr cascades through and

[91] The Staff Paper notes that some of these other components are regulated under separate statutory authorities, e.g., section 112 of the CAA.

accumulates in various environmental reservoirs.

Acid and acidifying deposition is another significant source of stress to forest and aquatic ecosystems. It changes the chemical composition of soils by depleting the content of available plant nutrient cations such as calcium (Ca^{2+}), increasing the mobility of aluminum (Al), and increasing the S and N content (Driscoll et al., 2001).

Leaching of soil nutrients is often of major importance in cation cycles, and many forest ecosystems show a net loss of base cations. In sensitive forest soils, acid deposition leads to a shift in chemical speciation of Al from organic to inorganic forms that are toxic to terrestrial and aquatic biota, and increases inorganic Al mobilization and transport into surface waters. The toxic effect of Al on forest vegetation is attributed to its interference with plant uptake of essential nutrients, such as Ca and Mg. There are large variations in Al sensitivity among ecotypes, between and within species, due to differences in nutritional demands and physiological status, that are related to age and climate, and which change over time.

Acid deposition has been firmly implicated as a causal factor in the decline of red spruce in high elevation sites in the Northeast. Red spruce is valued commercially, for recreation and aesthetics, and as habitat for unique and endangered species. Dieback of red spruce trees has also been observed in mixed hardwood-conifer stands at relatively low elevations in the western Adirondack Mountains, where inputs of acid deposition are high. Exposure to acidic mist or cloud water reduces foliar calcium levels in red spruce needles, leading to increased susceptibility to freezing (winter injury). There is also the strong possibility that acid deposition altering of foliar calcium levels leading to reduced cold tolerance is not unique to red spruce but has been demonstrated in many other northern temperate forest tree species including yellow birch, white spruce, red maple, eastern white pine, and sugar maple. Less sensitive forests throughout the U.S. are experiencing gradual losses of base cation nutrients, which in many cases will reduce the quality of forest nutrition in the future (National Science and Technology Council, 1998).

Inputs of acid deposition to regions with base-poor soils have also resulted in the acidification of soil waters, shallow ground waters, streams, and lakes in a number of locations within the U.S. Acidification has marked effects on the trophic structure of surface waters. Decreases in pH and increases in Al concentrations contribute to declines in species richness and in the abundance of zooplankton, macroinvertebrates, and fish. Numerous studies have shown that decreases in pH result in decreases in fish species richness (the number of fish species in a water body) by eliminating acid-sensitive species including important recreational fishes plus ecologically important minnows that serve as forage for sport fishes.

Though significant decreases in sulfur emissions have occurred in the U.S. and Europe in recent decades, these decreases have not been accompanied by equivalent declines in net acidity related to sulfate in precipitation, and may have, to varying degrees, been offset by steep declines in atmospheric base cation concentrations over the past 10 to 20 years (Hedin et al., 1994; Driscoll et al. 2001). Projections made using an acidification model (PnET-BGC) [92] indicate that full implementation of the 1990 CAA Amendments will not afford substantial chemical recovery at Hubbard Brook Experimental Forest and at many similar acid-sensitive locations (Driscoll et al., 2001). Model calculations indicate that the magnitude and rate of recovery from acid deposition in the northeastern U.S. are directly proportional to the magnitude of emissions reductions. Model evaluations of policy proposals calling for additional reductions in utility SO_2 and NO_X emissions, year round emissions controls, and early implementation indicate greater success in facilitating the recovery of sensitive ecosystems (Driscoll et al., 2001).

Driscoll et al. (2001) envision a recovery process that will involve two phases: chemical and biological. Initially, a decrease in acid deposition following emissions controls will facilitate a phase of chemical recovery in forest and aquatic ecosystems. Recovery time for this phase will vary widely across ecosystems and will be a function of a number of factors. In most cases, it seems likely that chemical recovery will require decades, even with additional controls on emissions. The second phase in ecosystem recovery is biological recovery, which can occur only if chemical recovery is sufficient to allow survival and reproduction of plants and animals. The time required for biological recovery is uncertain. For terrestrial ecosystems, it is likely to be at least decades after soil chemistry is restored because of the long life of tree species and the complex interactions of soil, roots, microbes, and soil biota. For aquatic systems, research suggests that stream macroinvertebrate populations may recover relatively rapidly (approximately 3 years), whereas lake populations of zooplankton are likely to recover more slowly (approximately 10 years) (Gunn and Mills, 1998). Some fish populations may recover in 5 to 10 years after the recovery of zooplankton populations, perhaps sooner with fish stocking (Driscoll et al., 2001).

iii. Ecosystem Exposure to PM Deposition

In order to establish exposure-response profiles useful in ecological risk assessments, two types of monitoring networks need to be in place. First, a deposition network is needed that can track changes in deposition rates of PM stressors (nitrates/sulfates) occurring in sensitive or symptomatic areas/ecosystems. Secondly, a network or system of networks should be established that measures the response of key sensitive ecological indicators over time to changes in atmospheric deposition of PM stressors.

Data from existing deposition networks in the U.S. demonstrate that N and S compounds are being deposited in amounts known to be sufficient to affect sensitive terrestrial and aquatic ecosystems over time. Though the percentages of N and S containing compounds in PM vary spatially and temporally, nitrates and sulfates make up a substantial portion of the chemical composition of PM. In the future, speciated data from these networks may allow better understanding of the specific components of total deposition that are most strongly influencing PM-related ecological effects.

At this time, however, there are only a few sites where long-term monitoring of sensitive indicators of ecosystem response to excess nitrogen and/or acidic and acidifying deposition is taking place within the U.S. Because the complexities of ecosystem response make predictions of the magnitude and timing of chemical and biotic recovery uncertain, it is important that this type of long-term monitoring network be continued, and that biological monitoring be enhanced to support future evaluations of the response of forested watersheds and surface waters to a host of research and regulatory issues related to nutrient and acid and acidifying deposition.

[92] PnET–BGC is designed to simulate element cycling in forest and interconnected aquatic ecosystems. The model PnET is a simple, generalized, and well validated model that provides estimates of forest net primary productivity, nutrient uptake by vegetation, and water balances. Recently, PnEt was coupled with a soil model that simulates abiotic soil processes, resulting in a comprehensive forest-soil-water model, PnET–BGC (Driscoll et al., 2001).

iv. Critical Loads

The critical load (CL) has been defined as a ''quantitative estimate of an exposure to one or more pollutants below which significant harmful effects on specified sensitive elements of the environment do not occur according to present knowledge'' (Lokke et al., 1996). The concept is useful for estimating the amounts of pollutants that ecosystems can absorb on a sustained basis without experiencing measurable degradation. The estimation of ecosystem critical loads requires an understanding of how an ecosystem will respond to different loading rates in the long term and is a direct function of the level of sensitivity of the ecosystem to the pollutants in question and its ability to ameliorate pollutant stress.

The CL approach is very data-intensive, and, at the present time, there is a paucity of ecosystem-level data for most sites. However, for a limited number of areas which already have a long-term record of ecosystem monitoring, (e.g., Rocky Mountain National Park in Colorado and the Lye Brook Wilderness in Vermont), Federal Land Managers may be able to develop site specific CLs. More specifically, with respect to PM deposition, there are insufficient data for the vast majority of U.S. ecosystems that differentiate the PM contribution to total N or S deposition to allow for practical application of this approach as a basis for developing national standards to protect sensitive U.S. ecosystems from adverse effects related to PM deposition. Though atmospheric sources of Nr and acidifying compounds, including ambient PM, are clearly contributing to the overall excess load or burden entering ecosystems annually, insufficient data are available at this time to quantify the contribution of ambient PM to total Nr or acid deposition as its role varies both temporally and spatially along with a number of other factors. Thus, at the present time, a CL could not be developed that would address the portion of the total N or S input that is contributed by ambient PM.

b. Effects on Materials Damage and Soiling

As discussed in the Staff Paper, the effects of the deposition of atmospheric pollution, including ambient PM, on materials are related to both physical damage and impaired aesthetic qualities. The deposition of PM (especially sulfates and nitrates) can physically affect materials, adding to the effects of natural weathering processes, by potentially promoting or accelerating the corrosion of metals, by degrading paints, and by deteriorating building materials such as concrete and limestone. As noted in the last review, only chemically active fine-mode or hygroscopic coarse-mode particles contribute to these physical effects. In addition, the deposition of ambient PM can reduce the aesthetic appeal of buildings and culturally important articles through soiling. Particles consisting primarily of carbonaceous compounds cause soiling of commonly used building materials and culturally important items such as statues and works of art. Available data indicate that particle-related soiling can result in increased cleaning frequency and repainting, and may reduce the useful life of the soiled materials. However, to date, no quantitative relationships between particle characteristics (e.g., concentrations, particle size, and chemical composition) and the frequency of cleaning or repainting have been established. Thus, the Administrator concludes that PM effects on materials can play no quantitative role in considering whether any revisions of the secondary PM standards are appropriate at this time.

c. Effects on Climate

As discussed in the Staff Paper, atmospheric particles can alter the earth's energy balance by both scattering and absorbing radiation transmitted through the earth's atmosphere. Most components of ambient PM (especially sulfates) scatter and reflect incoming solar radiation back into space, thus tending to have a cooling effect on climate. In contrast, some components of ambient PM (especially black carbon) absorb incoming solar radiation or outgoing terrestrial radiation, thus tending to have a warming effect on climate. Other impacts of atmospheric particles are associated with their role in affecting the radiative properties of clouds, through changes in the number and size distribution of cloud droplets (which can have an effect on the climate in either direction), and by altering the amount of ultraviolet solar radiation (especially UV–B) penetrating through the atmosphere to ground level, where it can exert a variety of effects on human health, plant and animal biota, and other environmental components.

The available information, however, provides no basis for estimating how localized changes in the temporal, spatial, and composition patterns of ambient PM likely to occur as a result of expected future emissions of particles and their precursor gases across the U.S., would affect local, regional, or global changes in climate or UV–B radiation penetration. Even the direction of such effects on a local scale remains uncertain. Moreover, similar concentrations of different particle components can produce opposite net effects, depending on other atmospheric parameters such as humidity. The Administrator thus concludes that, given this uncertainty, the potential indirect effects of ambient PM on public health and welfare, secondary to potential PM-related changes in climate and UV–B radiation, can play no quantitative role in considering whether any revisions of the primary or secondary PM standards are appropriate at this time.

2. Need for Revision of Current Secondary PM Standards To Address Other PM-Related Welfare Effects

In considering the currently available evidence on each type of PM-related welfare effects discussed above, the Administrator notes that there is much information linking the S- and N-containing components of ambient PM to potentially adverse effects on ecosystems and vegetation, materials damage and soiling, and on climatic and radiative processes. However, after reviewing the extent of relevant studies and other information provided since the 1997 review of the PM standards, which highlighted the substantial limitations in the evidence, especially with regard to the lack of evidence linking various effects to specific levels of ambient PM, the Administrator concurs with conclusions reached in the Staff Paper and by CASAC (Henderson, 2005a) that the available data do not provide a sufficient basis for establishing separate and distinct secondary PM standards based on any of these non-visibility PM-related welfare effects.

While recognizing that PM-related impacts on vegetation and ecosystems and PM-related soiling and materials damage are associated with chemical components in both fine and coarse-fraction PM, the Administrator provisionally concludes that sufficient information is not available at this time to consider either an ecologically based indicator or an indicator based distinctly on soiling and materials damage, in terms of specific chemical components of PM. Further, consistent with the rationale and recommendations in the Staff Paper, the Administrator agrees that it is appropriate to continue control of ambient fine and coarse-fraction particles, especially long-term deposition of particles such as particulate nitrates and sulfates that contribute to adverse impacts on vegetation and ecosystems and/or to

materials damage and soiling. The Administrator also agrees with the Staff Paper that the available information does not provide a sufficient basis for the development of distinct national secondary standards to protect against such effects beyond the protection likely to be afforded by the proposed suite of primary PM standards. In considering those proposed standards in combination, including the proposed more protective 24-hour standard for $PM_{2.5}$ and the proposed 24-hour standard for $PM_{10-2.5}$, which is intended to provide an equivalent degree of protection to the current PM_{10} standards in areas where the proposed $PM_{10-2.5}$ indicator applies (which tend to be more densely populated areas where materials damage would be of greater concern), the Administrator believes that this proposed suite of standards would afford at least the degree of protection as that afforded by the current secondary PM standards.

Finally, the Administrator believes, as noted above, that such standards should be considered in conjunction with the protection afforded by other programs intended to address various aspects of air pollution effects on ecosystems and vegetation, such as the Acid Deposition Program and other regional approaches to reducing pollutants linked to nitrate or acidic deposition. Based on these considerations, and taking into account the information and recommendations discussed above, the Administrator therefore proposes to revise the current secondary $PM_{2.5}$ and PM_{10} standards to address these other welfare effects by making them identical in all respects to the proposed suite of primary $PM_{2.5}$ and $PM_{10-2.5}$ standards.

C. Proposed Decisions on Secondary PM Standards

For the reasons discussed above, and taking into account the information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and public comments to date, the Administrator proposes to revise the current secondary $PM_{2.5}$ and PM_{10} standards by making them identical in all respects to the proposed primary $PM_{2.5}$ and $PM_{10-2.5}$ standards to address PM-related welfare effects including visibility impairment, effects on vegetation and ecosystems, materials damage and soiling, and effects on climate change. In recognition of an alternative view expressed by most members of the CASAC PM Panel, the Administrator also solicits comments on a sub-daily (4- to 8-hour averaging time) $PM_{2.5}$ standard to address visibility impairment, within the range of 20 to 30 $\mu g/m^3$ and with a form within the range of the 92nd to 98th percentile. Based on the comments received and the accompanying rationale, the Administrator may adopt other standards within the range of alternatives identified above in lieu of the standards he is proposing today.

V. Interpretation of the NAAQS for PM

A. Proposed Amendments to Appendix N—Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$

The EPA is proposing to revise the data handling procedures for the annual and 24-hour primary $PM_{2.5}$ standards in appendix N to 40 CFR part 50. The proposed amendments to appendix N would detail the computations necessary for determining when the proposed primary and secondary $PM_{2.5}$ national ambient air quality standards (NAAQS) are met. The proposed amendments also would address data reporting, monitoring considerations, and rounding conventions. Key elements of the proposed revisions to appendix N are summarized below in sections V.A.1 through V.A.5 of this preamble.

1. General

Several new definitions would be added to section 1.0 and utilized throughout the appendix, most notably ones for ''design values''. Also, the 24-hour time would be clarified as representing ''local *standard* (word inserted) time''. This proposal reflects EPA's previous intent as well as majority practice, and also avoids ambiguity since local *clock* time varies according to daylight savings periods.

2. $PM_{2.5}$ Monitoring and Data Reporting Considerations

Two new sections would be added to appendix N to more specifically stipulate and highlight monitoring and data considerations. New section 2.0 would include statistical requirements for spatial averaging (which is part of the form of the current and proposed annual standard for $PM_{2.5}$). As explained in section II.F.2 above, we are proposing to tighten the constraints on use of spatial averaging to reflect enhanced knowledge of typical monitor correlation coefficients in metropolitan areas. As also set out in section II.F.2, the Administrator is further soliciting comment on the other staff-recommended alternative of revising the form of the annual $PM_{2.5}$ standard to one based on the highest community-oriented monitor in an area, with no allowance for spatial averaging.

New section 3.0 would codify aspects of raw data reporting and raw data time interval aggregation including specifications of number of decimal places. Previously, these reporting instructions resided only in associated guidance documents. Section 3.0 would also note the process for assimilating monitored concentration data from collocated instruments into a single ''site'' record; data for the site record would originate mainly from the designated ''primary'' monitor at the site location, but would be augmented with collocated Federal reference method (FRM) or Federal equivalent method (FEM) monitor data whenever valid data are not generated by the primary monitor. This procedure would enhance the opportunity for sites to meet data completeness requirements. This proposed language likewise would codify existing practice, since the technique was previously documented in guidance documentation and implemented as EPA standard operating procedure.

3. $PM_{2.5}$ Computations and Data Handling Conventions

The EPA is proposing a spatially-averaged annual mean as the form of the annual $PM_{2.5}$ standard and a 98th percentile concentration as the form of the 24-hour $PM_{2.5}$ standard. Although no actual computational change is proposed for a spatially-averaged annual mean, the proposed Appendix N now differentiates, in language and formulae, between a spatial average of more than one site and a spatial average of only one site. The intent of this change is to alleviate confusion caused by the current ''catch-all'' generic reference. The proposed revisions to appendix N would identify the NAAQS metrics and explain data capture requirements and comparisons to the standards for the annual $PM_{2.5}$ standard and the 24-hour standard (in sections 4.1, and 4.2, respectively); data rounding conventions (in section 4.3); and formulas for calculating the annual and 24-hour metrics (in sections 4.4 and 4.5, respectively).

With regard to the annual $PM_{2.5}$ standard, we are proposing to retain current data capture requirements for the annual standard with two exceptions. Current appendix N has reduced data capture requirements for years that exceed the level of the annual NAAQS; specifically, a minimum of 11 valid samples per quarter as opposed to a more stringent 75 percent (of scheduled samples) is currently considered sufficient in those instances where the annual mean exceeded the NAAQS level. See existing Part 50 App.

N 2.1(b). The EPA is proposing to also allow 11 or more samples per quarter as an acceptable minimum if the calculated annual standard design value exceeds the level of the standard. The EPA solicits comments on this proposed change.

A second proposed change in the data completeness requirements would incorporate data substitution logic for situations where the proposed 11 sample per quarter minimum is not met. Consistent with existing guidance and practice (implementing current App. N 2.1(c)), EPA proposes to incorporate the following requirement into appendix N: a quarter with less than 11 samples would be complete and valid if, by substituting a historically low 24-hr value for the missing samples (up to the 11 minimum), the results yield an annual mean, spatially averaged annual mean, and/or annual standard design value that exceeds the levels of the standard. The EPA proposes to implement this procedure for making comparisons to the NAAQS and not to permanently alter the reported data. The EPA considers this a very conservative means of inputing data (and increasing the opportunities for using monitoring data that otherwise are valid), but solicits comment on the proposed approach.

With regard to the 24-hour $PM_{2.5}$ standard, the proposed revisions to appendix N would include a special formula (Equation 6 in the proposed rule) for computing annual 98th percentile values when a site operates on an approved seasonal sampling schedule. This formula was previously stated only in guidance documentation (''Guideline on Data Handling Conventions for the PM NAAQS'', April 1999) but was utilized, where appropriate, in official OAQPS design value calculations. Seasonal sampling has traditionally been implemented in periods that do not divide months; this criterion is explicitly stated in the proposed amendments.

The proposed revisions to appendix N would also incorporate language explicitly stating that 98th percentiles (for both regular and seasonal sampling schedules) is to be based on the *applicable* number of samples rather than the *actual* number of samples. Both annual 98th percentile equations (proposed Equations 5 and 6) would now reflect this approach. To accommodate seasonal sampling, the calculation of ''annual applicable number of samples'' would be changed from the sum of the ''quarterly applicable number of samples'' to a sum of the ''monthly applicable number of samples''. The EPA welcomes comment on the ''applicable number of samples'' concept and calculation.

To simplify the regulatory language, another proposed change to appendix N would eliminate the equation computational examples. The EPA will provide extensive computational examples in forthcoming guidance documents.

4. Secondary Standard

The EPA is proposing that the secondary standards for $PM_{2.5}$ be the same as the primary standards. However, the Administrator is soliciting comment on the alternative of a distinct 4-hour secondary standard for visibility protection with a form of an annual percentile, in the range 92nd to 98th, for a 12 p.m. to 4 p.m. local standard time daily average, averaged over 3 years. The same basic data handling approach as used for the 24-hour 98th percentile primary standard would also be utilized for a 4-hour percentile-based secondary standard (should EPA ultimately adopt such a standard). For example, 75 percent of the hours in the averaging time (i.e., 3 hours) would be required to produce a valid daily measurement. Also, 75 percent capture of sample days in a quarter would always make a complete quarter and four complete quarters, a complete year. Reduced capture (i.e., as little as one sample per year) would also suffice for high concentration years or 3-year periods. However, the percentile computational variation permitted for seasonal sampling for the 24-hour 98th percentile would not be needed for the 4-hour 95th percentile since the predominant (if not only) monitoring instrument used for this standard would be a continuous $PM_{2.5}$ sampler and EPA expects these continuous instruments to operate throughout the entire year. For this same reason, distinction between *applicable* number of samples and *actual* number of samples would not be necessary.

5. Conforming Revisions

Terminology and data handling procedures associated with exceptional events would be revised to conform to rules which EPA plans to propose in the near future to implement the recent amendment to CAA section 319 (42 U.S.C. 7619) by section 6013 of the Safe, Accountable, Flexible Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) (PL 109–59). At this time, EPA is proposing to replace the term currently used in Appendix N.1.(b)—''uncontrollable or natural events''—with ''exceptional events,'' corresponding with the term used in the recent amendment. (Because this proposal would make only a semantic change to existing Appendix N, EPA believes the proposal is consistent with section 6013 (b) (4) of SAFETEA–LU, which provides that EPA shall continue to apply existing Appendix N of part 50 (among others) until the effective date of rules implementing the exceptional event provisions in amended section 319 of the CAA.)

B. Proposed Appendix P—Interpretation of the National Ambient Air Quality Standards for $PM_{10\text{-}2.5}$

The EPA is proposing to add appendix P to 40 CFR part 50 in order to add data handling procedures for the proposed 24-hour $PM_{10\text{-}2.5}$ standard. The proposed appendix P would detail the computations necessary for determining when the proposed $PM_{10\text{-}2.5}$ NAAQS is met. The proposed appendix also would address data reporting, sampling frequency considerations, and rounding conventions. The protocols described in proposed appendix P would mirror the general and 24-hour specific protocols proposed for the $PM_{2.5}$ NAAQS in appendix N of 40 CFR part 50. Key elements of the proposed appendix P are summarized below in sections V.B.1 through V.B.3 of this preamble.

1. General

Terms utilized throughout the proposed appendix would be defined in section 1.0.

2. $PM_{2.5}$ Data Reporting Considerations

Section 2.0 of the proposed appendix P would specify the input data to be used in the NAAQS computations. The section would address raw data reporting and raw data time interval aggregation (i.e., report/calculate to one decimal place, truncate additional digits). Section 2.0 would also note the process for assimilating monitored concentration data into a ''site'' record; data for the site record would originate mainly from the designated ''primary'' monitor at the site location, but would be augmented with collocated Federal reference method or Federal equivalent method monitor data whenever valid data are not generated by the primary monitor. This procedure would enhance the opportunity for sites to meet data completeness requirements.

3. $PM_{10\text{-}2.5}$ Computations and Data Handling Conventions

The EPA is proposing a site-based 98th percentile concentration as the form of the 24-hour $PM_{2.5}$. The proposed appendix P would explain data handling conventions and computations for the 24-hour primary (and secondary) $PM_{10\text{-}2.5}$ standards in section 3.1; data

rounding conventions in section 3.2; and sampling frequency considerations in section 3.3. The formulas used for calculating the 24-hour NAAQS metric would be specified in section 3.4.

The proposed appendix would include a special formula (Equation 2) for use in computing annual 98th percentile values when a site operates on an approved seasonal sampling schedule. The proposed appendix P also would incorporate language explicitly stating that 98th percentiles (for both regular and seasonal sampling schedules) is to be based on the *applicable* number of samples rather than *actual* number of samples. Both annual 98th percentile equations (Equations 1 and 2 of proposed appendix P) would reflect this approach. This approach parallels that proposed in appendix N for $PM_{2.5}$ described in V.A.3. above, and is based on the same considerations.

4. Exceptional Events

The EPA plans to use the terminology and adopt the data handling procedures associated with exceptional events consistent with rules which would implement the recent amendment to CAA section 319 discussed in section V.A.5 above. The EPA expects to propose such rules in the near future. In the present proposal, the term ''exceptional events'' is used, consistent with the term used in the recent amendment as well as the term EPA proposes to use in the parallel provision in Appendix N (see section V.A.5).

VI. Reference Methods for the Determination of Particulate Matter As $PM_{2.5}$ and $PM_{10-2.5}$

A. Proposed Appendix O: Reference Method for the Determination of Coarse Particulate Matter (as $PM_{10-2.5}$) in the Atmosphere

1. Purpose of the New Reference Method

The EPA is proposing a new Federal reference method (FRM) for the measurement of coarse particles (as $PM_{10-2.5}$) in ambient air for the purpose of determining attainment of the proposed new $PM_{10-2.5}$ standards. The FRM would also serve as the standard of comparison for determining the adequacy of alternative ''equivalent'' methods for use in lieu of the FRM. The method is described in a proposed new appendix O to 40 CFR part 50, where it would join other FRM (or measurement principles) specified for the other criteria pollutants.

2. Rationale for Selection of the New Reference Method

The proposed FRM for measuring $PM_{10-2.5}$ is based on the combination of two conventional low-volume methods, one for measuring PM_{10} and the other for measuring $PM_{2.5}$, and determining the $PM_{10-2.5}$ measurement by subtracting the $PM_{2.5}$ measurement from the concurrent PM_{10} measurement. The proposed $PM_{2.5}$ measurement method is identical to the $PM_{2.5}$ FRM currently specified in appendix L to 40 CFR part 50, and the proposed PM_{10} measurement method is similar, utilizing the same sampler but without the $PM_{2.5}$ particle size separator. (Both samplers use identical PM_{10} size-selective inlets.) Thus, this $PM_{10-2.5}$ FRM is based on the same aerodynamic particle size separation and filter-based, gravimetric technology that is also the basis for FRMs for $PM_{2.5}$ and (in a somewhat less rigorously specified form) for PM_{10}.

In selecting the FRM methodology, EPA's primary considerations were the ability of the method to provide: (1) Credible and reliable measurements of $PM_{10-2.5}$; (2) reliable assessment of the quality of monitoring data; and (3) a credible and practical reference standard of comparison for candidate alternative measurement methods to determine their qualification as equivalent methods. In concept, a direct method for measuring $PM_{10-2.5}$ would seem to be desirable for the FRM, rather than the indirect method proposed. The EPA tested and evaluated various types of direct measurement technology (Vanderpool et al., 2005), including other conventional, filter-based gravimetric methods. The results of these tests and other evaluations indicate that none of the available methods or alternative technologies was more suitable as a reference method for $PM_{10-2.5}$ than the method proposed.

Perhaps the most fundamental requirement for the $PM_{10-2.5}$ FRM is the capability of the method to measure the subject particulate matter with a high degree of fidelity and faithfulness to the definition of $PM_{10-2.5}$. In proposed appendix O, $PM_{10-2.5}$ is defined as the mass concentration of ambient particles in the coarse-mode fraction of PM_{10}, specifically the (nominal) size range of 2.5 to 10 micrometers. The lower and upper limits of this size range are formally defined by the existing FRMs for $PM_{2.5}$ (40 CFR part 50, appendix L) and for PM_{10} (40 CFR part 50, appendix J). In both cases, the particle sizes are defined in terms of aerodynamic size, not actual physical size. Further, the particle size limits are not simple step functions but instead are defined by the corresponding $PM_{2.5}$ and PM_{10} measurement methodologies, which have inherent size fractionation curves with characteristic shapes and cutoff sharpness. The proposed $PM_{10-2.5}$ FRM would utilize these same measurement methodologies to determine the $PM_{10-2.5}$ concentration as the difference between separate PM_{10} and $PM_{2.5}$ measurements, thereby preserving and replicating the same particular PM_{10} and $PM_{2.5}$ aerodynamic particle size limit characteristics previously established by the PM_{10} and $PM_{2.5}$ FRMs.

Also, the proposed $PM_{10-2.5}$ FRM utilizes the same conventional integrated-sample, filter-collection, and mass-based gravimetric measurement technology that has been chosen for all previous FRM for the various formal particulate matter indicators. This well-established and reliable technology provides a high degree of credibility in the $PM_{10-2.5}$ measurements, derived from its gravimetric basis and its extensive track record from wide utilization over many years in many government monitoring networks. Further, it allows for maximum compatibility and comparability among new and existing $PM_{10-2.5}$, PM_{10}, and $PM_{2.5}$ data sets and thus to much of the health effects data used as a basis for the proposed NAAQS. No costly studies are needed to assess the impact, effect, or degree of comparability of a new or changed measurement technology relative to previously acquired measurement data. Extensive wind tunnel tests have shown that the inlet, used on both the $PM_{2.5}$ and PM_{10} samplers, is capable of aspirating large particles efficiently, even at high wind speeds. The presence of $PM_{2.5}$ aerosols on the PM_{10} sample collection filter increases the adhesion of larger particles to the filter to minimize losses of large particles from the PM_{10} filters during handling and transport. Such losses can be a problem with filter samples collected with a virtual impactor-type sampler, where the $PM_{2.5}$ aerosols are not present on the $PM_{10-2.5}$ filter in sufficient quantities to eliminate loss of coarse mode particles.

An inherent advantage of a difference method is that some (additive) biases may be eliminated or substantially reduced by the subtraction. In the proposed $PM_{10-2.5}$ FRM, the two samplers and their operational procedures are very closely matched (except for the particle size separator) to take maximum advantage of this feature, which helps to compensate for the additional variability resulting from dual measurement systems. Although a difference method could produce negative measurements on occasion,

considerable field testing of the method indicates that negative readings are rare, due in substantial part to the excellent precision of the base methods (Vanderpool et al., 2005). Moreover, measured negative $PM_{10-2.5}$ concentrations, if observed, would likely occur only at low concentrations near the detection limit of the method and would thus be unlikely to adversely affect the accuracy of $PM_{10-2.5}$ attainment decisions based on the proposed 24-hour NAAQS.

The proposed method also has a number of secondary advantages. The samplers and operational procedures of the proposed FRM are similar to those of the $PM_{2.5}$ FRM and will be familiar to most State monitoring agencies. In fact, the nature of the method allows for the possibility of readily and economically obtaining $PM_{10-2.5}$ samplers (actually sampler pairs) by reconfiguring existing $PM_{2.5}$ samplers. $PM_{10-2.5}$ sampler pairs based on currently designated $PM_{2.5}$ FRM samplers could be quickly designated by EPA as $PM_{10-2.5}$ FRM, as no additional qualification testing would be required. Existing $PM_{2.5}$ FRM samplers can be easily reconfigured as $PM_{10-2.5}$ FRM sampler pairs by converting some of them to the special PM_{10} (PM_{10c}) samplers by simply replacing the WINS impactor with the specified straight downtube adaptor. Thus, the $PM_{10-2.5}$ method could be rapidly and economically implemented into new or existing monitoring networks to begin collection of $PM_{10-2.5}$ monitoring data expeditiously, with minimal requirements for operator retraining or pilot operational periods.

The proposed FRM provides readily accessible aerosol samples for subsequent chemical analyses, and the sampler's design allows use of a wide variety of filter materials including Teflon, quartz, nylon, and polycarbonate. Compared to $PM_{2.5}$, the chemical composition of coarse-mode aerosols has not yet been extensively evaluated. The ability of the proposed FRM to provide speciated analyses of coarse aerosol samples would be an important tool for the States during development of effective implementation plans.

In developing this new FRM for $PM_{10-2.5}$, EPA staff consulted with a number of individuals and groups in the monitoring community, including instrument manufacturers, academics, consultants, and experts in State and local agencies. The approach and key specifications of the method were submitted for peer review to the Clean Air Scientific Advisory Committee (CASAC) Ambient Air Monitoring and Methods Subcommittee, which held public meetings to discuss methods and related monitoring issues on July 22, 2004 and September 21 and 22, 2005. Comments on the proposed method were provided orally and in writing by Subcommittee members and by interested public entities. In a letter dated November 30, 2005 (Henderson, 2005c) forwarded by the CASAC to the Administrator, the CASAC provided its peer review consensus report stating that ''in general, the CASAC agrees that there are several important scientific or operational strengths of the proposed difference method $PM_{10-2.5}$ to be used as the FRM, while noting that there are several prominent weaknesses as well. Despite these weaknesses, no other better, currently available candidate FRM method has been identified.'' The CASAC report noted that ''A majority of the Subcommittee members expressed the opinion that the demonstrated data quality of the $PM_{10-2.5}$ difference method and its documented value in correlations with health effects data support its being proposed as the PM coarse FRM''. However, the CASAC also indicated that the proposed FRM should not be intended for extensive implementation in national monitoring networks. Instead, it should be used primarily as a benchmark for evaluating the performance of continuous as well as other direct-measuring, filter-based, integrated methods and determining their acceptability for use in routine monitoring of $PM_{10-2.5}$. As explained more fully below, this is the approach we intend to adopt for the national monitoring network.

3. Consideration of Other Methods for the Federal Reference Method

Other measurement technologies considered for the FRM include a variety of alternative integrated-sample, filter-based methods as well as various automated methods providing continuous or semi-continuous measurements of $PM_{10-2.5}$. One methodology that warranted particular consideration is integrated, filter sampling using a virtual impactor particle size separator (also known as a dichotomous fractionator). This technology provides for measuring $PM_{10-2.5}$ more directly than the proposed difference method and also provides associated $PM_{2.5}$ measurements, as well as PM_{10} measurements by addition. Like the proposed difference method, dichotomous samplers have been used in health studies that supported the basis for both the $PM_{2.5}$ and proposed $PM_{10-2.5}$ NAAQS. A dichotomous sampler can utilize the same PM_{10} sampler inlet, the same types of filters and filter processing, and similar quality assurance procedures as the proposed method. It also has a very important advantage in providing $PM_{10-2.5}$ filter samples for chemical analysis. Such ''speciation'' analysis is a critical tool used by States for developing effective $PM_{10-2.5}$ control strategies. Speciated $PM_{2.5}$ and $PM_{10-2.5}$ data have supported epidemiological studies used to develop associations between exposure to ambient particulate matter and increased mortality and morbidity (Dockery, et al., 1993, Schwartz, 1994). Collected speciated samples from dichotomous samplers can also be used to conduct toxicological studies of the adverse health effects of PM exposure as a function of particle size (Demokritou, et al., 2003).

However, some aspects of virtual impactor technology raise concerns regarding the technology's current suitability for use as a $PM_{10-2.5}$ reference method. Various versions of virtual impactors have been designed and used, but their particle size separation characteristics have not been fully evaluated and independently characterized as extensively as those of the proposed method, resulting in considerable uncertainty about their performance relative to the conventional low-volume $PM_{2.5}$ and PM_{10} FRMs. There is also concern about the impact and potential need to compensate for some inherent fine particle contamination on the $PM_{10-2.5}$ filter. For example, for a virtual impactor which employs a 10 to 1 total flow rate to coarse flow rate ratio, 10 percent of the fine particles deposit on the coarse filter. Following each sampling event, the presence of these fine particles must be accounted for during subsequent calculation of the $PM_{10-2.5}$ mass concentration. Depending upon the analyte of interest, the collected mass of the analyte, and the method detection limit of the analytical technique for that analyte, proper compensation for fine particle contamination will also need to be made when conducting speciation analysis of the coarse channel filter. Allen et al. (1999) also reported the tendency for some fraction (up to 16 percent) of coarse mode particles to penetrate to the fine channel filter and thus positively bias calculated $PM_{2.5}$ mass concentrations as well as concentrations of specific analytes. Because the level of coarse particle contamination depends upon the size distribution of the sampled aerosol and the physical nature of the coarse particles, this contamination cannot be accurately predicted and thus cannot be

accounted for during subsequent calculations.

Loss of particles within virtual impactors is also well documented (Forney et al., 1982, Chen et al., 1985, Loo and Cork, 1988, Li and Lundgren, 1997, Allen, et al., 1999, Kim and Lee, 2000) and can substantially bias measured mass and species concentrations. As reported by Loo and Cork (1988), losses up to 50 percent have been reported during laboratory calibration of various virtual impactor designs when using liquid calibration aerosols. Moreover, these losses cannot be predicted and are very sensitive to virtual impactor geometry and component misalignment. Unlike conventional impactors where internal particle loss can be readily minimized, the design of virtual impactors must be optimized to ensure that particle loss is sufficiently low to enable accurate mass and species measurements during field use.

In the proposed difference method, the high concentration of fine particles on the PM_{10} filter provides additional adhesive force for retaining large particles to the filter's surface. In the dichotomous sampler, however, the low concentration of fine particles on the coarse channel filter results in a significantly reduced adhesive force. If inertial forces (applied to the filter during its post-sampling handling and transport) are greater than the adhesive force, then coarse particles will be dislodged from the coarse channel filter and not be subsequently quantified. Depending upon the virtual impactor design, the nature of the collected aerosol, and the magnitude of the applied inertial force, large particle losses up to 50 percent have been documented (Dzubay and Barbour, 1983, Spengler and Thurston, 1983). As in the case of coarse particle intrusion into the fine channel, the magnitude of this measurement bias is variable and cannot be accurately predicted nor compensated for.

The CASAC, in their peer review report (Hendersen, 2005c) supports ''* * * the possibility of specifying more than one FRM for $PM_{10-2.5}$ (as it did for PM_{10}) , if one or more of the current or evolving dichotomous sampler designs shows reasonable agreement with the difference method (assuming filter-handling procedures can be developed to minimize losses of coarse-only particles prior to weighing).'' We agree that the filter-handling procedures need to be investigated in addition to other issues described above. Therefore, at this point we believe the proposed FRM, based on the difference method, offers less uncertainty in $PM_{10-2.5}$ measurements and is the more prudent choice for the reference method. However, CASAC and EPA are both interested in utilizing dichotomous samplers in support of other monitoring objectives, such as providing samples for chemical speciation analysis, once a number of issues are worked through. Therefore, the Agency wishes to solicit public comment regarding consideration of a $PM_{10-2.5}$ reference method or equivalent method based on the use of the virtual impactors to aerodynamically separate fine mode aerosols from coarse mode aerosols.

Concerns have been expressed to EPA regarding the fact that the size separation devices of both the $PM_{2.5}$ and PM_{10} FRMs, which are the basis of the proposed difference-based $PM_{10-2.5}$ FRM, have inherent size fractionation curves with characteristic shapes and cutoff sharpness rather than creating a perfectly sharp cutpoint at a specific aerodynamic particle size. For example, a portion of all ambient particles larger than 10 micrometers are included in the $PM_{10-2.5}$ sample, while some particles smaller than 10 micrometers are not. A larger effect on measured $PM_{10-2.5}$ will occur in environments with high concentrations of particles above 10 micrometers than in environments with low concentrations.

Some commenters who have been concerned about this aspect of the $PM_{2.5}$ and PM_{10} FRMs have supported the adoption of a $PM_{10-2.5}$ FRM that would directly measure the coarse fraction of particles. We invite comment on this topic, in the context of today's proposal for a $PM_{10-2.5}$ NAAQS and a FRM that would employ both $PM_{2.5}$ and PM_{10} size separators.

4. Consideration of Automated Methods for the Federal Reference Method

Other measurement technologies considered for the FRM included various types of automated analyzer methods that provide continuous or semi-continuous measurements of $PM_{10-2.5}$. Such methods are particularly desirable for use in $PM_{10-2.5}$ monitoring networks because they potentially offer substantially lower operational and maintenance costs, hourly averages or other short-term measurements in addition to 24-hour averages, and nearly real-time electronic, remote reporting of measurement data. However, recent field testing of many of these instruments (Vanderpool et al., 2005) indicated that none can yet achieve performance commensurate to that of the proposed method. The technologies employed by these methods usually represent a substantial, if not radical, departure from the well-characterized, conventional filter-collection and gravimetric determination. This departure raises inevitable questions of representativeness of particle size discrimination, treatment of volatile components, variability with differing site and climatic conditions, and the degree of comparability to conventionally obtained measurements. Also, since EPA is proposing a daily standard for $PM_{10-2.5}$, hourly measurements are not required to support such a standard, although they would be of value to more closely investigate impacts of sources and exceptional events.

Most, if not all, of these automated measurement technologies are proprietary. While that alone is not sufficient reason to preclude their consideration as FRM or as a ''reference measurement principle,'' it would be in the best interest of all stakeholders if multiple manufacturers could compete for this market. Adoption of the proposed FRM along with reasonable qualification requirements for equivalent methods leaves a fair and level playing field for any manufacturer to either produce the specified FRM samplers or to pursue the development and EPA approval of innovative new methods and technologies to strive for competitive marketing advantages.

5. Use of the Proposed Federal Reference Method

The EPA acknowledges that the proposed FRM is quite labor-intensive and has other disadvantages that make it less than ideal for routine use in large monitoring networks. At the same time, as just described, alternative, automated methods are under continuing research and development, and some may soon demonstrate adequate performance and comparability to the FRM for use in monitoring networks. Accordingly, and consistent with the recommendations of the CASAC (Hendersen, 2005c), EPA is providing for the possible designation of alternative methods as equivalent methods for $PM_{10-2.5}$, as set forth in proposed amendments to 40 CFR part 53 published elsewhere in this **Federal Register.** Under these proposed equivalent method provisions, EPA anticipates that alternative methods—particularly filter based, virtual-impactor samplers as well as self-contained, automated analyzers—can be designated as equivalent methods. The dichotomous samplers could potentially lead to better speciation data, while automated equivalent methods would ease the potential $PM_{10-2.5}$ monitoring burdens of monitoring agencies and would potentially provide substantial

monitoring advantages such as reduced operational cost, availability of 1-hour (or other less-than-24-hour) average concentration measurements, and near real-time telemetered monitoring data. As explained in the preamble to the proposed Part 58 rule, if such automated methods are designated as equivalent, they would likely be used predominantly for much of the required $PM_{10-2.5}$ network monitoring. The new $PM_{10-2.5}$ FRM would thus be used primarily as the reference standard for designating qualified equivalent methods and for quality assurance activities, but used only minimally for routine network monitoring.

Encouraging the further development of automated analyzers by providing for their designation as equivalent methods for $PM_{10-2.5}$ could eventually lead to commercial, direct-reading instruments that would meet multiple monitoring objectives better than the FRM proposed today. In that event, the Agency may consider adopting such an automated method for the FRM (or as a ''measurement principle and calibration procedure'') under the provisions of 40 CFR 53.16, ''Supersession of reference methods.''

6. Relationship of Proposed FRM to SAFETEA–LU Requirements

Section 6012 of the SAFETEA–LU in part requires the Administrator, within two years, to ''develop a Federal reference method to measure directly particles that are larger than 2.5 micrometers in diameter without reliance on subtracting from coarse particle measurements those particles that are equal to or smaller than 2.5 micrometers in diameter.'' We believe that our proposed action today is consistent with the goals of the new legislation, in that it actively promotes use of non-difference methods through the Part 53 equivalency designation process, and states our ultimate expectation that the monitoring network for $PM_{10-2.5}$ will utilize primarily non-difference method monitors. Furthermore, we are actively investigating the possibility that a dichotomous method could be an alternative FRM within the time frame prescribed by this Act. However, we are proposing a difference method as the FRM for $PM_{10-2.5}$, for the reasons explained above as we believe this is the only approach technically justified at this time. Since the new statutory language does not require that EPA promulgate a non-difference method as either the sole or alternative FRM, we believe this proposed approach is consistent with the express language of the provision as well as with its objectives.

7. Basic Requirements of the Proposed Federal Reference Method Sampler

The proposed $PM_{10-2.5}$ FRM ''sampler'' is actually a collocated pair of samplers, one for PM_{10} and one for $PM_{2.5}$, operated simultaneously. The $PM_{2.5}$ sampler is exactly as specified in the $PM_{2.5}$ FRM (appendix L to 40 CFR part 50). The operational and procedural requirements would be the same as those for $PM_{2.5}$ FRM measurements. $PM_{2.5}$ measurements obtained as part of $PM_{10-2.5}$ FRM measurements would be indistinguishable from conventional $PM_{2.5}$ FRM measurements and would be usable for any $PM_{2.5}$ monitoring purpose, provided they are sited at the appropriate spatial scale (e.g., neighborhood scale).

In contrast, the PM_{10} sampler of the $PM_{10-2.5}$ sampler pair would be required to be identical in design and construction to the $PM_{2.5}$ sampler, except that the $PM_{2.5}$ particle size separator (WINS impactor) would be removed from the sampler and replaced with a straight downtube, thereby converting it to a PM_{10} sampler. This PM_{10} sampler would have to meet the higher standards of manufacture and performance of appendix L to 40 CFR part 50 rather than the standards for conventional PM_{10} FRM samplers (which meet the lesser requirements of appendix J to 40 CFR part 50). Thus, PM_{10} measurements obtained as part of or incidental to the $PM_{10-2.5}$ FRM measurements must be distinguished from conventional PM_{10} measurements and need to be identified by a unique descriptor such as ''PM_{10c}.'' Since PM_{10c} measurements would meet a higher standard than conventional PM_{10} measurements, such measurements would also be acceptable for any conventional PM_{10} monitoring purpose. However, one subtle issue regarding conventional PM_{10} measurements and new PM_{10c} measurements needs clarification. Conventional PM_{10} measurement flow systems operate on conditions of standard temperature and pressure (STP). Flow systems for $PM_{2.5}$ and the new $PM_{10-2.5}$ FRM as proposed today and peer reviewed by the CASAC, all operate under conditions of actual local conditions.

$PM_{10-2.5}$ sampler pairs would be required to be specifically designated as $PM_{10-2.5}$ FRM samplers by EPA under amendments to 40 CFR 53 proposed elsewhere in this **Federal Register**. The two samplers of the $PM_{10-2.5}$ FRM sampler pair would be required to be of like manufacturer and of matched design and fabrication so that they are essentially identical, except that one would have a $PM_{2.5}$ particle size separator while the other would not. Either single-filter samplers or multiple-filter, sequential samplers could constitute a $PM_{10-2.5}$ sampler pair, as long as both were of the same type and design. For a manufacturer's sampler model that has already been designated as a $PM_{2.5}$ FRM, no further testing would be required for designation as a $PM_{10-2.5}$ FRM, although the sampler manufacturer would have to submit a formal application under 40 CFR part 53. Users could assemble their own $PM_{10-2.5}$ sampler pair using existing $PM_{2.5}$ samplers of the same model or design by converting one of the samplers to a PM_{10c} sampler, provided the specific sampler pair has been previously designated by the EPA as a $PM_{10-2.5}$ FRM under 40 CFR part 53.

Pairings of qualified $PM_{2.5}$ samplers that are dissimilar or have some minor design or model variations (and one sampler is converted to a PM_{10c} sampler) could be designated by the EPA as Class I equivalent methods under proposed amendments to 40 CFR part 53. Again, an application for an equivalent method determination for the sampler combination would have to be submitted to the EPA under 40 CFR part 53, and not all combinations would necessarily be designated without further testing. For example, supplemental test or operational performance information would likely be required for designation of a $PM_{10-2.5}$ sampler pair consisting of a single-filter sampler and a multiple-filter, sequential sampler. A pairing of dissimilar $PM_{2.5}$ samplers that has not been designated as a Class I equivalent method for $PM_{10-2.5}$ under 40 CFR part 53 could be considered by the EPA for approved use in $PM_{10-2.5}$ monitoring networks as a user modification under section 2.8 of appendix C to 40 CFR part 58.

8. Other Important Aspects of the Proposed Federal Reference Method Sampler

The proposed method would require that both samplers of the $PM_{10-2.5}$ sampler pair be located in close proximity and operated simultaneously. Operational procedures for both samplers of the pair would be similar or identical to those specified for $PM_{2.5}$ FRM, and both samplers should be operated, serviced, and maintained similarly. Quality assurance procedures would parallel those for the $PM_{2.5}$ FRM, although data quality assessment procedures would apply to the calculated $PM_{10-2.5}$ measurement data rather than (or in addition to) the individual PM_{10} and $PM_{2.5}$

measurements. The proposed sample period would be nominally 24 hours (±1 hour).

Expected performance of the $PM_{10-2.5}$ FRM—as measured by precision, lower concentration limit, and completeness—is similar to that of the $PM_{2.5}$ FRM, but may be somewhat inferior because of the dual measurement components. Precision, defined as a goal for acceptable measurement uncertainty, is given as 15 percent coefficient of variation, as assessed according to quality assurance procedures for $PM_{10-2.5}$ monitoring described in proposed revisions to appendix A of 40 CFR part 58, published elsewhere in this **Federal Register**.

The lower concentration limit proposed for the method is 3 μg/m³. This value can vary with the level of quality control and precision achieved in implementing the method. It should not be interpreted as a specification but rather as a simple guide to the general significance of low-level measured concentrations. However, this proposed value may be used as a lower range limit for excluding low-concentration data from composite performance calculations that use percentages (where very low values in a denominator need to be avoided) or in types of statistical calculations of monitoring data that cannot accept zero or negative values (such as geometric distributions, where ½ of this lower concentration limit may be substituted for any measurements less than that value). Comments are solicited on the usefulness of this lower concentration limit, its value, or how its value should be established and interpreted.

B. Proposed Amendments to Appendix L—Reference Method for the Determination of Fine Particulate Matter (as $PM_{2.5}$) in the Atmosphere

In connection with the proposal of a new Federal reference method (FRM) for $PM_{10-2.5}$, EPA is proposing minor changes to the FRM for $PM_{2.5}$ in appendix L to 40 CFR part 50. These proposed changes are based on new test information and extensive operational experience with the $PM_{2.5}$ FRM acquired subsequent to its promulgation in 1997. Through the increased flexibility afforded by the proposed changes, significant improvements in the efficiency of the $PM_{2.5}$ method in monitoring network operations are expected without altering the performance of the method. In fact, the changes have already been implemented in the national $PM_{2.5}$ monitoring network through designated equivalent methods or duly approved user modifications. Further, the changes would also apply to the proposed $PM_{10-2.5}$ FRM, so the benefits would be realized for $PM_{10-2.5}$ measurements as well, and uniformity between the $PM_{2.5}$ FRM and the $PM_{2.5}$ portion of the $PM_{10-2.5}$ FRM would be maintained.

The most significant proposed change is the addition of an alternative $PM_{2.5}$ particle size separator. Since the promulgation of the $PM_{2.5}$ FRM in 1997, a new, very sharp cut cyclone separator (VSCC™) manufactured by BGI Incorporated, Waltham, MA has been shown to have performance equivalent to that of the originally specified separator (WINS impactor) (Kenny, et al., 2001; Kenny et al., 2004; EPA, 2002b). Although the original WINS impactor continues to show fully adequate performance in $PM_{2.5}$ samplers, the new VSCC provides the same level of performance and has a considerably longer service interval. Generally, the VSCC separator is also physically interchangeable with the WINS where both are manufactured for the same sampler. The proposed change would allow either the WINS or the VSCC separator to be used in a $PM_{2.5}$ FRM sampler. Currently, EPA has designated seven $PM_{2.5}$ samplers configured with VSCC separators as Class II equivalent methods.[93] Upon promulgation of this change to appendix L, those seven methods would be re-designated as $PM_{2.5}$ FRM.

Another minor change proposed for the $PM_{2.5}$ FRM (and, hence, also applicable to the proposed $PM_{10-2.5}$ FRM) would require an improved impactor oil for the $PM_{2.5}$ WINS impactor particle size separator. The new oil corrects an occasional problem of crystallization of the original oil during sampling in cold and damp weather and has been tested and approved as a national user modification (EPA, 2000b). Also, the time limit specified for sample filter retrieval time would be increased from 96 hours to 177 hours following the end of the sample period. This change would allow the filter to be retrieved by the morning of the eighth day after sampling to permit recovery of up to three samples from a sequential sampler operating on a 1-in-3 day sample schedule. Based on a study (Papp, et al., 2002) at six sampling sites, this change has already been approved as a national user modification (EPA, 2002a). An associated change to ease the filter retrieval burden on monitoring agencies would modify the current requirement that retrieved filters be weighed within 10 days after sampling, unless they are maintained at a temperature of 4°C or less at all times during transport. The filter recovery extension study (Papp, et al., 2002) showed that these limits can be relaxed somewhat (EPA, 2000a) to allow up to 30 days for weighing the filter if it is maintained below the average ambient temperature during the sampling period prior to the post-collection sample equilibration.

Finally, some of the sampler data output reporting requirements specified in Table L–1 of appendix L to 40 CFR part 50 (e.g. flow rate CV, sample volume, minimum and maximum temperature, minimum and maximum pressure) have been determined to be unnecessary to report to the Air Quality System, and the reporting requirement for these data would be deleted. These data will be retained and available at the monitoring agency, if needed.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

1. Have an annual effect on the economy of $100 million or more or 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;

2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

In view of its important policy implications and potential effect on the economy of over $100 million, this action has been judged to be an economically ''significant regulatory action'' within the meaning of the Executive Order. As a result, today's action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations

[93] List of designated reference and equivalent methods available at *http://www.epa.gov/ttn/amtic/criteria.html.*

will be documented in the public record.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. There are no information collection requirements directly associated with the establishment of a NAAQS under section 109 of the CAA.

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.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute 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 organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of particulate matter in ambient air as required by section 109 of the CAA. See also *American Trucking Associations* v. *EPA*. 175 F. 3d at 1044–45 (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or Tribal governments or the private sector. The rule imposes no new expenditure or enforceable duty on any State, local or Tribal governments or the private sector, and EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Furthermore, as indicated previously, in setting a NAAQS EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards, although such factors may be considered to a degree in the development of State plans to implement the standards. See also *American Trucking Associations* v. *EPA*, 175 F. 3d at 1043 (noting that because EPA is precluded from considering costs of implementation in establishing NAAQS, preparation of a Regulatory Impact Analysis pursuant to the Unfunded Mandates Reform Act would not furnish any information which the court could consider in reviewing the NAAQS). Accordingly, EPA has determined that the provisions of sections 202, 203, and 205 of the UMRA do not apply to this proposed decision. The EPA acknowledges, however, that any corresponding revisions to associated SIP requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively, might result in such effects. Accordingly, EPA has addressed unfunded mandates in the notice that announces the proposed revisions to 40 CFR part 58, and will, as appropriate, address unfunded mandates when it proposes any revisions to 40 CFR part 51.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), 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 proposed rule does not have federalism implications. It 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. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, this rule does not impact CAA section 107 which establishes that the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or Tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this rule.

However, as also noted in section E (above) on UMRA, EPA recognizes that States will have a substantial interest in this rule and any corresponding revisions to associated SIP requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively. Therefore, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175: Consultation and 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.'' This rule concerns the establishment of PM NAAQS. The Tribal Authority Rule gives Tribes the opportunity to develop and implement CAA programs such as the PM NAAQS, but it leaves to the discretion of the Tribe whether to develop these programs and which programs, or appropriate elements of a program, they will adopt.

This proposed rule does not have Tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes, since Tribes are not obligated to adopt or implement any NAAQS. Thus, Executive Order 13175 does not apply to this rule.

Although Executive Order 13175 does not apply to this rule, EPA contacted tribal environmental professionals during the development of this rule. The EPA staff participated in the regularly scheduled Tribal Air call sponsored by the National Tribal Air Association during the summer and fall of 2005 as this proposal was under development. Also, EPA is sending notice and an opportunity for comment to Tribal Leaders within the lower 48 states. Specifically, EPA solicits additional comment on this proposed rule from Tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045, ''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 rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is subject to Executive Order 13045 because it is an economically significant regulatory action as defined by Executive Order 12866, and we believe that the environmental health risk addressed by this action may have a disproportionate effect on children. The proposed NAAQS will establish uniform, national standards for PM pollution; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. However, the protection offered by these standards may be especially important for children because children, along with other sensitive population subgroups such as the elderly and people with existing heart or lung disease, are potentially susceptible to health effects resulting from PM exposure. Because children are considered a potentially susceptible population, we have carefully evaluated the environmental health effects of exposure to PM pollution among children. These effects and the size of the population affected are summarized in section 9.2.4 of the Criteria Document and section 3.5 of the Staff Paper, and the results of our evaluation of the effect of PM pollution on children are discussed in sections II.A, B, and C and III.A, B, and C of this preamble.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This proposed rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this rule is to establish NAAQS for PM. The rule does not prescribe specific pollution control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects and does not constitute a significant energy action as defined in Executive Order 13211.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer Advancement Act of 1995 (NTTAA), Public Law No. 104–113, § 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The proposed rule establishes requirements for environmental monitoring and measurement. Specifically, it would establish the FRM for $PM_{10-2.5}$ measurement (and slightly amend the FRM for $PM_{2.5}$). The FRM is the benchmark against which all ambient monitoring methods are measured. While the FRM is not a voluntary consensus standard, the proposed revisions to the FEM in 40 CFR part 53 do allow for the utilization of voluntary consensus standards if they meet the specified performance criteria.

To the extent feasible, EPA employs a Performance-Based Measurement System (PBMS), which does not require the use of specific, prescribed analytic methods. The PBMS is defined as a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner. It is intended to be more flexible and cost effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. Though the FRM defines the particular specifications for ambient monitors, there is some variability with regard to how monitors measure PM, depending on the type and size of PM and environmental conditions. Therefore, it is not practically possible to fully define the FRM in performance terms. Nevertheless, our approach in the past has resulted in multiple brands of monitors qualifying as FRM for PM, and we expect this to continue. Also, the FRM described in this proposal and the equivalency criteria contained in the proposed revisions to 40 CFR part 53 do constitute performance based criteria for the instruments that will actually be deployed for monitoring $PM_{10-2.5}$. Therefore, for most of the measurements that will be made and most of the measurement systems that make them, EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the specified performance criteria.

The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' requires Federal agencies to consider the impact of programs, policies, and activities on minority populations and low-income populations. According to EPA guidance, agencies are to assess whether minority or low income populations face risks or a rate of exposure to hazards that are significant and that ''appreciably exceed or is likely to appreciably exceed the risk or rate to the general population or to the appropriate comparison group.'' (EPA, 1998)

In accordance with Executive Order 12898, the Agency has considered whether these proposals, if promulgated, may have disproportionate negative impacts on minority or low income populations. The Agency expects these proposals would lead to the establishment of uniform NAAQS for PM.

References

Abbey, D. E.; Nishino, N.; McDonnell, W. F.; Burchette, R. J.; Knutsen, S. F.; Beeson, L.; Yang, J. X. (1999) Long-term inhalable particles and other air pollutants related to mortality in nonsmokers. Am. J. Respir. Crit. Care Med. 159:373–382.

Abt Associates Inc. (1996). ''A Particulate Matter Risk Assessment for Philadelphia and Los Angeles.'' Bethesda, MD. Prepared for the Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Contract No. 68–W4–0029. July 3 (revised November). Available: *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_pr_td.html*.

Abt Associates Inc. (1997a). Abt Associates Memorandum to U.S. EPA. Subject: Revision of Mortality Incidence Estimates Based on Pope et al. (1995) in the Abt Particulate Matter Risk Assessment Report. June 5, 1997.

Abt Associates Inc. (1997b). Abt Associates Memorandum to U.S. EPA. Subject: Revision of Mortality Incidence Estimates Based on Pope et al. (1995) in the December 1996 Supplement to the Abt Particulate Matter Risk Assessment Report. June 6, 1997.

Abt Associates, Inc. (2001). Assessing Public Opinions on Visibility Impairment Due to Air Pollution: Summary Report. Prepared for EPA Office of Air Quality Planning and Standards; funded under EPA Contract No. 68–D–98–001. Bethesda, Maryland. January 2001.

Abt Associates Inc. (2002). Proposed Methodology for Particulate Matter Risk Analyses for Selected Urban Areas: Draft Report. Bethesda, MD. Prepared for the Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Contract No. 68–D–03–002. Available: *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_td.html*.

Abt Associates Inc. (2005). Particulate Matter Health Risk Assessment for Selected Urban Areas. Draft Report. Bethesda, MD. Prepared for the Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Contract No. 68–D–03–002. Available: *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_td.html*.

Allen, G., Oh, J., Koutrakis, P., Sioutus, C. (1999). Techniques for High-Quality Ambient Coarse Particle Mass Measurements. J. Air Waste Manage. Assoc. 49:133–141.

Arizona Department of Environmental Quality (2003). Visibility Index Oversight Committee Final Report: Recommendation for a Phoenix Area Visibility Index. March 5, 2003. *http://www.phoenixvis.net/PDF/vis_031403final.pdf*.

Becker, S.; Soukup, J. M.; Sioutas, C.; Cassee, F. R. (2003). Response of human alveolar macrophages to ultrafine, fine and coarse urban air pollution particles. Exp. Lung Res. 29: 29–44.

Burnett, R. T.; Cakmak, S.; Brook, J. R.; Krewski, D. (1997). The role of particulate size and chemistry in the association between summertime ambient air pollution and hospitalization for cardiorespiratory diseases. Environ. Health Perspect. 105:614–620.

Burnett, R. T.; Brook, J.; Dann, T.; Delocla, C.; Philips, O.; Cakmak, S.; Vincent, R.; Goldberg, M. S.; Krewski, D. (2000). Association between particulate- and gas-phase components of urban air pollution and daily mortality in eight Canadian cities. Inhalation Toxicol. 12 (suppl. 4): 15–39.

Burnett, R. T.; Goldberg, M. S. (2003). Size-fractionated particulate mass and daily mortality in eight Canadian cities. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 85–90. Available: *http://www.healtheffects.org/news.htm*. May 16, 2003.

California Code of Regulations. Title 17, Section 70200, Table of Standards.

Centers for Disease Control and Prevention (2004). The health consequences of smoking: a report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Available: *http://www.cdc.gov/tobacco/sgr/sgr_2004/chapters.htm*. August 18, 2004.

Chen, B.T., Yeh, H.C., Cheng, Y.S. (1985). A Novel Virtual Impactor: Calibration and Use. J. Aerosol Sci. 16:343–354.

Chen, L.; Yang, W.; Jennison, B. L.; Omaye, S. T. (2000). Air particulate pollution and hospital admissions for chronic obstructive pulmonary disease in Reno, Nevada. Inhalation Toxicol. 12:281–298.

Chestnut , L. G.; Rowe, R. D. (1991). Economic valuation of changes in visibility: A state of the science assessment. Sector B5 Report 27. In Acidic Depositions: State of Science and Technology Volume IV Control Technologies, Future Emissions and Effects Valuation. P.M. Irving (ed.). The U.S. National Acid Precipitation Assessment Program. GPO, Washington, DC.

Chestnut, L. G.; Dennis, R. L. (1997). Economic benefits of improvements in visibility: acid rain provisions of the 1990 clean air act amendments. J. Air Waste Manage. Assoc. 47:395–402.

Chock, D. P.; Winkler, S.; Chen, C. (2000). A study of the association between daily mortality and ambient air pollutant concentrations in Pittsburgh, Pennsylvania. J. Air Waste Manage. Assoc. 50:1481–1500.

Choudhury, A. H.; Gordian, M. E.; Morris, S. S. (1997) Associations between

respiratory illness and PM_{10} air pollution. Arch. Environ. Health 52:113–117.

Cohen, S.; Evans, G.W.; Stokols, D.; Krantz, D.S. (1986). Behavior, Health, and Environmental Stress. Plenum Press. New York, NY.

Deck, L. B.; Post, E.S.; Smith, E.; Wiener, M.; Cunningham, K.; Richmond, H. (2001). Estimates of the health risk reductions associated with attainment of alternative particulate matter standards in two U.S. cities. Risk Anal. 21(5):821–835.

Delfino, R. J.; Murphy-Moulton, A. M.; Burnett, R. T.; Brook, J. R.; Becklake, M. R. (1997). Effects of air pollution on emergency room visits for respiratory illnesses in Montreal, Quebec. Am. J. Respir. Crit. Care Med. 155:568–576.

Delfino, R. J.; Zeiger, R. S.; Seltzer, J. M.; Street, D. G. (1998). Symptoms in pediatric asthmatic and air pollution: differences in effects by symptom severity, anti-inflammatory medication use and particulate averaging time. Environ. Health Perspect. 106:751–761.

Demokritou, P., Tarun, G., Ferguson, S., Koutrakis, P. (2003). Development of a High-Volume Concentrated Ambient Particles System (CAPS) for Human and Animal Inhalation Toxicological Studies. Inhalation Toxicol. 15:111–129.

Diociaiuti, M.; Balduzzi, M.; De Berardis, B.; Cattani, G.; Stacchini, G.; Ziemacki, G.; Marconi, A.; Paoletti, L. (2001) The two $PM_{2.5}$ (fine) and $PM_{2.5-10}$ (coarse) fractions: evidence of different biological activity. Environ. Res. A 86:254–262.

Dockery, D. W.; Pope, C. A., III; Xu, X.; Spengler, J. D.; Ware, J. H.; Fay, M. E.; Ferris, B. G., Jr.; Speizer, F. E. (1993). An association between air pollution and mortality in six U.S. cities. N. Engl. J. Med. 329:1753–1759.

Dockery, D. W.; Cunningham, J.; Damokosh, A. I.; Neas, L. M.; Spengler, J. D.; Koutrakis, P.; Ware, J. H.; Raizenne, M.; Speizer, F. E. (1996). Health effects of acid aerosols on North American children: respiratory symptoms. Environ. Health Perspect. 104:500–505.

Dominici, F.; McDermott, A.; Daniels, M.; Zeger, S. L.; Samet, J. M. (2003). Mortality among residents of 90 cities. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 9–24. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf.* May 12, 2004.

Driscoll, C. T.; Lawrence, G. B.; Bulger, A. J.; Butler, T. J.; Cronan, C. S.; Eagar, C.; Lambert, K. F.; Likens, G. E.; Stoddard, J. L.; Weathers, K. C. (2001). Acidic deposition in the northeastern United States: sources and inputs, ecosystem effects, and management strategies. BioScience 51:180–198.

Dzubay, T.G., Barbour, R.K. (1983). A Method to Improve the Adhesion of Aerosol Particles on Teflon Filters. JAPCA, 33: 692–695.

Ely, D.W.; Leary, J.T.; Stewart, T.R.; Ross, D.M. (1991). The Establishment of the Denver Visibility Standard. For presentation at the 84th Annual Meeting & Exhibition of the Air and Waste Management Association, June 16–21, 1991.

Environmental Protection Agency (1996a). Air Quality Criteria for Particulate Matter. Research Triangle Park, NC: National Center for Environmental Assessment-RTP Office; report no. EPA/600/P–95/001aF–cF. 3v

Environmental Protection Agency (1996b). Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Research Triangle Park, NC 27711: Office of Air Quality Planning and Standards; report no. EPA–452\R–96–013.

Environmental Protection Agency (1999). Regional Haze Regulations. 40 CFR Part 51.300–309. 64 **Federal Register** 35713.

Environmental Protection Agency (2000a). Memorandum from David Mobley, EPA–OAQPS to EPA Regional Office Air Directors, dated January 19, regarding Additional Guidance on $PM_{2.5}$ Cassette Handling and Transportation. Available: *http://www.epa.gov/ttn/amtic/files/ambient/pm25/pm25caset.pdf.*

Environmental Protection Agency (2000b). Memorandum from Elizabeth Hunike, EPA–NERL–Process Modeling Research Branch to Lee Ann Byrd, EPA–OAQPS–MQAG, dated November 30, regarding Alternative WINS oil. Available: *http://www.epa.gov/ttn/amtic/files/cfr/recent/letter.pdf.*

Environmental Protection Agency (2001). Particulate Matter NAAQS Risk Analysis Scoping Plan, Draft. Research Triangle Park, NC: Office of Air Quality Planning and Standards. Available: *http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_td.html.*

Environmental Protection Agency (2002a). Memorandum from David Mobley, EPA–OAQPS to EPA Regional Office Air Directors, dated February 22, regarding ''Extension of Filter Retrieval Time for $PM_{2.5}$ Samples.'' Available: *http://www.epa.gov/ttn/amtic/files/ambinet/pm25/filtere.pdf.*

Environmental Protection Agency (2002b). 67 **Federal Register** 15566. April 2, 2002.

Environmental Protection Agency (2003). Response Of Surface Water Chemistry to the Clean Air Act Amendments of 1990. National Health and Environmental Effects Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency. Research Triangle Park, NC. EPA 620/R–03/001.

Environmental Protection Agency (2004). Air Quality Criteria for Particulate Matter. Research Triangle Park, NC: National Center for Environmental Assessment-RTP Office; report no. EPA/600/P–99/002aD.

Environmental Protection Agency. (2005a) Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Research Triangle Park, NC 27711: Office of Air Quality Planning and Standards; report no. EPA–452/R–05–005. June 2005.

Environmental Protection Agency. (2005b) Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Research Triangle Park, NC 27711: Office of Air Quality Planning and Standards; report no. EPA EPA–452/R–05–005a. December 2005.

Fairley, D. (2003). Mortality and air pollution for Santa Clara County, California, 1989–1996. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 97–106. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf.* October 18, 2004.

Forney, L.J., Ravenhall, D.G., Lee, S.S. (1982). Experimental and Theoretical Study of a Two-Dimensional Virtual Impactor. Environ. Sci. Technol. 16: 492–497.

Galloway, J. N.; Cowling, E. B. (2002). Reactive nitrogen and the world: 200 years of change. Ambio 31: 64–71.

Gauderman, W. J.; McConnell, R.; Gilliland, F.; London, S.; Thomas, D.; Avol, E.; Vora, H.; Berhane, K.; Rappaport, E. B.; Lurmann, F.; Margolis, H. G.; Peters, J. (2000). Association between air pollution and lung function growth in southern California children. Am. J. Respir. Crit. Care Med. 162: 1383–1390.

Gauderman, W. J.; Gilliland, G. F.; Vora, H.; Avol, E.; Stram, D.; McConnell, R.; Thomas, D.; Lurmann, F.; Margolis, H. G.; Rappaport, E. B.; Berhane, K.; Peters, J. M. (2002). Association between air pollution and lung function growth in southern California children: results from a second cohort. Am. J. Respir. Crit. Care Med. 166: 76–84.

Gold, D. R.; Litonjua, A.; Schwartz, J.; Lovett, E.; Larson, A.; Nearing, L.; Allen, G.; Verrier, M.; Cherry, R.; Verrier, R. (2000) Ambient pollution and heart rate variability. Circulation 101:1267–1273.

Goldberg, M. S.; Burnett, R. T. (2003) Revised analysis of the Montreal time-series study. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 113–132. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf* [18 October, 2004].

Gordian, M. E.; Özkaynak, H.; Xue, J.; Morris, S. S.; Spengler, J. D. (1996) Particulate air pollution and respiratory disease in Anchorage, Alaska. Environ. Health Perspect. 104:290–297.

Grand Canyon Visibility Transport Commission (1996). Report of the Grand Canyon Visibility Transport Commission to the United States Environmental Protection Agency.

Gunn, J.M. and Mills, K.H. (1998). The potential for restoration of acid-damaged lake trout lakes. Restoration Ecology. 6:390–397.

Health Effects Institute (2000). Commentary on the National Morbidity, Mortality and Air Pollution Study. Part II: morbidity, mortality and air pollution in the United States. Boston, MA: Health Effects Institute; research report no. 94, pp. 73–

81. Available: *http://www.healtheffects.org/Pubs/Samet2.pdf.* June, 2000.

Health Effects Institute (2003). Commentary on revised analyses of selected studies. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 255–290. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf.* October 18, 2004.

Hedin, L. O.; Granat, L.; Likens, G. E.; Buishand, T. A.; Galloway, J. N.; Butler, T. J.; Rodhe, H. (1994). Steep declines in atmospheric base cations in regions of Europe and North America. Nature (London) 367:351–354.

Hefflin, B. J.; Jalaludin, B.; McClure, E.; Cobb, N.; Johnson, C. A.; Jecha, L.; Etzel, R. A. (1994). Surveillance for dust storms and respiratory diseases in Washington State, 1991. Arch. Environ. Health 49:170–174.

Henderson, R. (2005a). EPA's Review of the National Ambient Air Quality Standards for Particulate Matter (Second Draft PM Staff Paper, January 2005): A review by the Particulate Matter Review Panel of the EPA Clean Air Scientific Advisory Committee. June 6, 2005. Available: *http://www.epa.gov/sab/pdf/casac-05007.pdf.*

Henderson, R. (2005b). Clean Air Scientific Advisory Committee (CASAC) Review of the EPA Staff Recommendations Concerning a Potential Thoracic Coarse PM Standard in the Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information (Final PM OAQPS Staff Paper, EPA–452/R–05–005). September 15, 2005. Available: *http://www.epa.gov/sab/panels/casacpmpanel.html.*

Henderson, R. (2005c). Letter to the EPA Administrator from the Clean Air Scientific Advisory Committee, dated November 30, 2005, regarding peer review of the proposed Federal reference method for $PM_{10-2.5}$. Available: *http://www.epa.gov/sab/pdf/casac_06001.pdf.*

Hopke, P. (2002). Letter from Dr. Phil Hopke, Chair, Clean Air Scientific Advisory Committee (CASAC) to Honorable Christine Todd Whitman, Administrator, U.S. EPA. Final advisory review report by the CASAC Particulate Matter Review Panel on the proposed particulate matter risk assessment. May 23, 2002. Available: *http://www.epa.gov/sab/pdf/casacadv02002.pdf.*

Hornberg, C.; Maciuleviciute, L.; Seemayer, N. H.; Kainka, E. (1998). Induction of sister chromatid exchanges (SCE) in human tracheal epithelial cells by the fractions PM_{-10} and $PM_{-2.5}$ of airborne particulates. Toxicol. Lett. 96/97: 215–220.

Ito, K. (2003). Associations of particulate matter components with daily mortality and morbidity in Detroit, Michigan. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 143–156. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf.* May 12, 2004.

Kenny L.C.; Thorp, A. (2001). Evaluation of VSCC Cyclones. Health & Safety Laboratory Report # IR/L/EXM/01/01 (2001). Available: *http://www.bgiusa.com/aam/vsccref6.pdf.*

Kenny, L; Merrifield, T.; Gussman, R.; Thorp, A. (2004). The Development and Designation of a New USEPA-Approved Fine Particle Inlet: A Study of the USEPA Designation Process. Aerosol Science & Technology, 38 (supplement 2): 15–22.

Kim, M.C., Lee, K.W. (2000). Design Modification of Virtual Impactor for Enhancing Particle Concentration Performance. Aerosol Sci. Technol. 32: 233–242.

Kleinman, M.T.; Bhalla, D.K.; Mautz, W.J.; Phalen, R.F. (1995) Cellular and immunologic injury with PM–10 inhalation. Inhalation Toxicol. 7:589–602.

Klemm, R. J.; Mason, R. (2003). Replication of reanalysis of Harvard Six-City mortality study. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 165–172. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf. May 12, 2004.*

Krewski, D.; Burnett, R. T.; Goldberg, M. S.; Hoover, K.; Siemiatycki, J.; Jerrett, M.; Abrahamowicz, M.; White, W. H. (2000). Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of particulate air pollution and mortality. A special report of the Institute's particle epidemiology reanalysis project. Cambridge, MA: Health Effects Institute.

Li, S., Lundgren, D.A. (1997). Effect of Clean Air Core Geometry on Fine Particle Contamination and Calibration of a Virtual Impactor. Aerosol Sci. Technol. 27: 625–635.

Lipfert, F. W.; Morris, S. C.; Wyzga, R. E. (2000a). Daily mortality in the Philadelphia metropolitan area and size-classified particulate matter. J. Air Waste Manage. Assoc. 50:1501–1513.

Lipfert, J. W.; Perry, H. M., Jr.; Miller, J. P.; Baty, J. D.; Wyzga, R. E.; Carmody, S. E. (2000b). The Washington University-EPRI veteran's cohort mortality study: preliminary results. Inhalation Toxicol. 12(Suppl. 4):41–73.

Lippmann, M.; Ito, K.; Nadas, A.; Burnett, R. T. (2000). Association of particulate matter components with daily mortality and morbidity in urban populations. Cambridge, MA: Health Effects Institute; research report 95.

Lokke, H.; Bak, J.; Falkengren-Grerup, U.; Finlay, R. D.; Ilvesniemi, H.; Nygaard, P. H.; Starr, M. (1996). Critical loads of acidic deposition for forest soils: is the current approach adequate. Ambio 25: 510–516.

Loo, B.W.; Cork, C.P. (1988). Development of High Efficiency Virtual Impactors. Aerosol Sci. Technol. 9: 167–176.

Mar, T. F.; Norris, G. A.; Larson, T. V.; Wilson, W. E.; Koenig, J. Q. (2003). Air pollution and cardiovascular mortality in Phoenix, 1995–1997. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 177–182. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf.* October 18, 2004.

Mauderly, J.; Neas, L.; Schlesinger, R. (1998) PM monitoring needs related to health effects. In: Atmospheric observations: helping build the scientific basis for decisions related to airborne particulate matter; Report of the PM measurements research workshop, July 22–23, 1998. Available from ''PM Measurements Report'', Health Effects Institute, 955 Massachusetts Ave., Cambridge, MA 02139.

McConnell, R.; Berhane, K.; Gilliland, F.; London, S. J.; Vora, H.; Avol, E.; Gauderman, W. J.; Margolis, H. G.; Lurmann, F.; Thomas, D. C.; Peters, J. M. (1999). Air pollution and bronchitic symptoms in southern California children with asthma. Environ. Health Perspect. 107: 757–760.

McDonnell, W. F.; Nishino-Ishikawa, N.; Petersen, F. F.; Chen, L. H.; Abbey, D. E. (2000). Relationships of mortality with the fine and coarse fractions of long-term ambient PM_{10} concentrations in nonsmokers. J. Exposure Anal. Environ. Epidemiol. 10:427–436.

Miller, F.J.; Gardner, D.E.; Graham, J.A.; Lee, R.E.; Wilson, W.E.; Bachmann, J.D. (1979) Size considerations for establishing a standard for inhalable particles. J Air Pollution Control Assoc. 29:610–615.

Molenar, J.V. (2000). Visibility Science and Trends in the Lake Tahoe Basin: 1989–1998. Report by Air Resource Specialists, Inc., to Tahoe Regional Planning Agency. February 15, 2000.

Monn, C.; Becker, S. (1999). Cytotoxicity and induction of proinflammatory cytokines from human monocytes exposed to fine ($PM_{2.5}$) and coarse particles ($PM_{10-2.5}$) in outdoor and indoor air. Toxicol. Appl. Pharmacol. 155: 245–252.

Moolgavkar, S. H. (2000c). Air pollution and hospital admissions for chronic obstructive pulmonary disease in three metropolitan areas of the United States. Inhalation Toxicol. 12 (Suppl. 4):75–90.

Moolgavkar, S. H. (2003). Air pollution and daily deaths and hospital admissions in Los Angeles and Cook counties. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 183–198. Available: *http://www.healtheffects.org/news.htm.* May 16, 2003.

National Academy of Sciences (2002). Estimating the Public Health Benefits of Proposed Air Pollution Regulations. Washington, D.C.: The National Academy Press. Available: *http://www.nap.edu/books/0309086094/html/.*

National Research Council (1993). Protecting Visibility in National Parks and Wilderness Areas. National Academy of Sciences Committee on Haze in National Parks and Wilderness Areas. National Academy Press: Washington, DC.

National Science and Technology Council (1998). National acid precipitation

assessment program biennial report to Congress: an integrated assessment; executive summary. Silver Spring, MD: U.S. Department of Commerce, National Oceanic and Atmospheric Administration. Available: *http://www.nnic.noaa.gov/CENR/NAPAP/NAPAP_96.htm.* November 24, 1999.

Nauenberg, E.; Basu, K. (1999). Effect of insurance coverage on the relationship between asthma hospitalizations and exposure to air pollution. Public Health Rep. 114: 135–148.

Neas, L. M.; Dockery, D. W.; Koutrakis, P.; Tollerud, D. J.; Speizer, F. E. (1995). The association of ambient air pollution with twice daily peak expiratory flow rate measurements in children. Am. J. Epidemiol. 141: 111–122.

Neas, L. M.; Dockery, D. W.; Burge, H.; Koutrakis, P.; Speizer, F. E. (1996). Fungus spores, air pollutants, and other determinants of peak expiratory flow rate in children. Am. J. Epidemiol. 143: 797–807.

Neas, L. M.; Dockery, D. W.; Koutrakis, P.; Speizer, F. E. (1999). Fine particles and peak flow in children: acidity versus mass. Epidemiology 10:550–553.

New Zealand Ministry for the Environment. (2000). Proposals for Revised and New Ambient Air Quality Guidelines: Discussion Document. Air Quality Report No. 16. December.

New Zealand National Institute of Water & Atmospheric Research (NIWAR) (2000a). Visibility in New Zealand: Amenity Value, Monitoring, Management and Potential Indicators. Air Quality Technical Report 17. Prepared for New Zealand Ministry for the Environment. Draft report.

New Zealand National Institute of Water & Atmospheric Research (NIWAR) (2000b). Visibility in New Zealand: National Risk Assessment. Air Quality Technical Report 18. Prepared for New Zealand Ministry for the Environment. Draft report.

Ostro, B. (1995). Fine particulate air pollution and mortality in two Southern California counties. Environ. Res. 70: 98–104.

Ostro, B. D.; Lipsett, M. J.; Mann, J. K.; Braxton-Owens, H.; White, M. C. (1995). Air pollution and asthma exacerbations among African-American children in Los Angeles. Inhalation Toxicol. 7:711–722.

Ostro, B. D.; Broadwin, R.; Lipsett, M. J. (2000). Coarse and fine particles and daily mortality in the Coachella Valley, CA: a follow-up study. J. Exposure Anal. Environ. Epidemiol. 10:412–419.

Ostro, B. D.; Broadwin, R.; Lipsett, M. J. (2003). Coarse particles and daily mortality in Coachella Valley, California. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 199–204. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf.* October 18, 2004.

Papp, M.; Eberly, S.; Hanley, T.; Watkins, N.; Barden, H.; Noah, G.; Bermudez, R.; Eden, R.; Franks, B.; Johnson, A. Marriner, R.; Michel, E. (2002). Evaluation of Filter Recovery Period for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere. EPA-OAQPS Test Report. Available: *http://www.epa.gov/ttn/amtic/files/ambient/pm25/qa/initdraft.pdf.*

Peters, A.; Liu, E.; Verrier, R. L.; Schwartz, J.; Gold, D. R.; Mittleman, M.; Baliff, J.; Oh, J. A.; Allen, G.; Monahan, K.; Dockery, D. W. (2000). Air pollution and incidence of cardiac arrhythmia. Epidemiology 11:11–17.

Peters, A.; Dockery, D. W.; Muller, J. E.; Mittleman, M. A. (2001). Increased particulate air pollution and the triggering of myocardial infarction. Circulation 103:2810–2815.

Peters, J. M.; Avol, E.; Navidi, W.; London, S. J.; Gauderman, W. J.; Lurmann, F.; Linn, W. S.; Margolis, H.; Rappaport, E.; Gong, H., Jr.; Thomas, D. C. (1999a). A study of twelve southern California communities with differing levels and types of air pollution. I. Prevalence of respiratory morbidity. Am. J. Respir. Crit. Care Med. 159: 760–767.

Peters, J. M.; Avol, E.; Navidi, W.; London, S. J.; Gauderman, W. J.; Lurmann, F.; Linn, W. S.; Margolis, H.; Rappaport, E.; Gong, H., Jr.; Thomas, D. C. (1999b). A study of twelve southern California communities with differing levels and types of air pollution. II. Effects on pulmonary function. Am. J. Respir. Crit. Care Med. 159: 768–775.

Pope, C. A., III. (1989). Respiratory disease associated with community air pollution and a steel mill, Utah Valley. Am. J. Public Health 79: 623–628.

Pope, C. A., III. (1991). Respiratory hospital admissions associated with PM_{10} pollution in Utah, Salt Lake, and Cache Valleys. Arch. Environ. Health 46: 90–97.

Pope, C. A., III; Schwartz, J.; Ransom, M. R. (1992). Daily mortality and PM_{10} pollution in Utah valley. Arch. Environ. Health 47: 211–217.

Pope, C. A., III; Thun, M. J.; Namboodiri, M. M.; Dockery, D. W.; Evans, J. S.; Speizer, F. E.; Heath, C. W., Jr. (1995). Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. Am. J. Respir. Crit. Care Med. 151: 669–674.

Pope, C. A., III; Hill, R. W.; Villegas, G. M. (1999). Particulate air pollution and daily mortality on Utah's Wasatch Front. Environ. Health Perspect. 107: 567–573.

Pope, C. A., III; Burnett, R. T.; Thun, M. J.; Calle, E. E.; Krewski, D.; Ito, K.; Thurston, G. D. (2002). Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution. J. Am. Med. Assoc. 287:1132–1141.

Post, E.; Deck, L.; Larntz, K.; Hoaglin. D. (2001). An application of an empirical Bayes estimation technique to the estimation of mortality related to short-term exposure to particulate matter. Risk Anal. 21(5): 837–842.

Raizenne, M.; Neas, L. M.; Damokosh, A. I.; Dockery, D. W.; Spengler, J. D.; Koutrakis, P.; Ware, J. H.; Speizer, F. E. (1996). Health effects of acid aerosols on North American children: pulmonary function. Environ. Health Perspect. 104: 506–514.

Rogge, W.F.; Hildemann, L.M.; Mazurek, M.A.; Cass, G.R.; Simoneit, B.R.T. (1993). Sources of fine organic aerosol. 3. Road dust, tire debris, and organometallic brake lining dust: roads as sources and sinks. Environ. Sci. Technol. 27:1982–1904.

Rosendahl, T. (2005). Basis for proposed determinations regarding retention of the existing 24-hour PM_{10} standard. Memorandum to the PM NAAQS review docket, EPA–HQ–OAR–2001–0017. December 20, 2005.

Ross, M. (2005). Updated information on air quality monitoring data for thoracic coarse particles used in epidemiologic studies. Memorandum to the PM NAAQS review docket, EPA–HQ–OAR–2001–0017. June 30, 2005.

Ross, M.; Langstaff, J. (2005). Updated statistical information on air quality data from epidemiologic studies. Memorandum to PM NAAQS review docket EPA–HQ–OAR–2001–0017. January 31, 2005.

Schlesinger, R.B., Cassee, F. (2003) Atmospheric secondary inorganic particulate matter: the toxicological perspective as a basis for health effects risk assessment. Inhalation Toxicol. 15:197–235.

Schmidt. M; Frank, N.; Mintz, D.; Rao, T.; McCluney, L. (2005). Analyses of particulate matter (PM) data for the PM NAAQS review. Memorandum to PM NAAQS review docket EPA–HQ–OAR–2001–0017. June 30, 2005.

Schwartz, J. (1997). Air pollution and hospital admissions for cardiovascular disease in Tucson. Epidemiology 8: 371–377.

Schwartz, J. (2003a). Daily deaths associated with air pollution in six U.S. cities and short-term mortality displacement in Boston. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 219–226. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf.* October 18, 2004.

Schwartz, J. (2003b). Airborne particles and daily deaths in 10 U.S. cities. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 211–218. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf.* October 18, 2004.

Schwartz, J.; Dockery, D. W.; Neas, L. M. (1996). Is daily mortality associated specifically with fine particles? J. Air Waste Manage. Assoc. 46:927–939.

Schwartz, J.; Norris, G.; Larson, T.; Sheppard, L.; Claiborne, C.; Koenig, J. (1999). Episodes of high coarse particle concentrations are not associated with increased mortality. Environ. Health Perspect. 107: 339–342.

Schwartz, J.; Neas, L. M. (2000). Fine particles are more strongly associated than coarse particles with acute respiratory health effects in schoolchildren. Epidemiology 11:6–10.

Science Advisory Board (2004). Advisory for plans on health effects analysis in the analytical plan for EPA's second prospective analysis—benefits and costs of the clean air act, 1990–2000. Advisory by the Health Effects Subcommittee of the Advisory Council for Clean Air Compliance Analysis. EPA SAB Council—ADV–04–002. March, 2004. Available: *http://www.epa.gov/science1/pdf/council_adv_04002.pdf.*

Sheppard, L. (2003). Ambient air pollution and nonelderly asthma hospital admissions in Seattle, Washington, 1987–1994. In: Revised analyses of time-series studies of air pollution and health. Special report. Boston, MA: Health Effects Institute; pp. 227–230. Available: *http://www.healtheffects.org/Pubs/TimeSeries.pdf.* October 18, 2004.

Smith, R. L.; Spitzner, D.; Kim, Y.; Fuentes, M. (2000). Threshold dependence of mortality effects for fine and coarse particles in Phoenix, Arizona. J. Air Waste Manage. Assoc. 50: 1367–1379.

Soukup, J. M.; Becker, S. (2001). Human alveolar macrophage responses to air pollution particulates are associated with insoluble components of coarse material, including particulate endotoxin. Toxicol. Appl. Pharmacol. 171: 20–26.

Spengler, J.D., Thurston, G.D. (1983). Mass and Elemental Composition of Fine and Coarse Particles in Six U.S. Cities. J. Air & Waste Manage. Assoc. 33: 1162–1171.

State Government of Victoria, Australia (2000a). Draft Variation to State Environment Protection Policy (Air Quality Management) and State Environment Protection Policy (Ambient Air Quality) and Draft Policy Impact Assessment. Environment Protection Authority. Publication 728. Southbank, Victoria.

State Government of Victoria, Australia (2000b). Year in Review. Environment Protection Authority. Southbank, Victoria.

Steerenberg, P. A.; Withagen, C. E.; Dormans, J. A. M. A.; Van Dalen, W. J.; Van Loveren, H.; Casee, F. R. (2003). Adjuvant activity of various diesel exhaust and ambient particle in two allergic models. J. Toxicol. Environ. Health A 66: 1421–1439.

Stieb, D. M.; Beveridge, R. C.; Brook, J. R.; Smith-Doiron, M.; Burnett, R. T.; Dales, R. E.; Beaulieu, S.; Judek, S.; Mamedov, A. (2000). Air pollution, aeroallergens and cardiorespiratory emergency department visits in Saint John, Canada. J. Exposure Anal. Environ. Epidemiol.: 10: 461–477.

Thurston, G. D.; Ito, K.; Hayes, C. G.; Bates, D. V.; Lippmann, M. (1994). Respiratory hospital admissions and summertime haze air pollution in Toronto, Ontario: Consideration of the role of acid aerosols. Environ. Res. 65:271–290.

Tsai, F. C.; Apte, M. G.; Daisey, J. M. (2000). An exploratory analysis of the relationship between mortality and the chemical composition of airborne particulate matter. Inhalation Toxicol. 12 (suppl.): 121–135.

Vanderpool, R.; Hanley, T.; Dimmick, F.; Hunike, E. (2005). Multi-Site Evaluations of Candidate Methodologies for Determining Coarse Particulate Matter ($PM_{10-2.5}$) Concentrations: August 2005. Updated Report Regarding Second-Generation and New $PM_{10-2.5}$ Samplers. In press.

List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: December 20, 2005.

Stephen L. Johnson,

Administrator.

For the reasons set forth in the preamble, part 50 of chapter 1 of title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

1. The authority citation for part 50 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

2. Section 50.3 is revised to read as follows:

§ 50.3 Reference conditions.

All measurements of air quality that are expressed as mass per unit volume (*e.g.*, micrograms per cubic meter) other than for the particulate matter ($PM_{2.5}$ and $PM_{10-2.5}$) standards contained in §§ 50.7 and 50.13 shall be corrected to a reference temperature of 25 [deg] C and a reference pressure of 760 millimeters of mercury (1,013.2 millibars). Measurements of $PM_{2.5}$ and $PM_{10-2.5}$ for purposes of comparison to the standards contained in §§ 50.7 and 50.13 shall be reported based on actual ambient air volume measured at the actual ambient temperature and pressure at the monitoring site during the measurement period.

3. Section 50.6 is amended by adding new paragraphs (d) and (e) to read as follows:

§ 50.6 National primary and secondary ambient air quality standards for PM_{10}.

* * * * *

(d) The national primary and secondary 24-hour ambient air quality standards for particulate matter set forth in paragraph (a) of this section will no longer apply except in the following areas as of [effective date of final rule]:

(1) Birmingham urban area (Jefferson County, AL).

(2) Maricopa and Pinal Counties; Phoenix planning area (AZ).

(3) Riverside, Los Angeles, Orange and San Bernardino Counties; South Coast Air Basin (CA).

(4) Fresno, Kern, Kings, Tulare, San Joaquin, Stanislaus, Maderia Counties; San Joaquin Valley planning area (CA).

(5) San Bernardino County (part); excluding Searles Valley Planning Area and South Coast Air Basin (CA).

(6) Riverside County; Coachella Valley Planning Area (CA).

(7) Simi Valley urban area (CA).

(8) Lake County; Cities of East Chicago, Hammond, Whiting, and Gary (IN).

(9) Wayne County (part) (MI).

(10) St. Louis urban area (MO).

(11) Albuquerque urban area (NM).

(12) Clark County; Las Vegas planning area (NV).

(13) Columbia urban area (SC).

(14) El Paso urban area (including those portions in TX and those portions in NM).

(15) Salt Lake County (UT).

(e) The national primary and secondary annual ambient air quality standards for particulate matter set forth in paragraph (b) of this section will no longer apply in an area as of [effective date of final rule.]

4. A new § 50.13 is added, to read as follows:

§ 50.13 National primary and secondary ambient air quality standards for $PM_{2.5}$ and $PM_{10-2.5}$.

(a) The national primary and secondary ambient air quality standards for particulate matter are:

(1) 15.0 micrograms per cubic meter ($\mu g/m^3$) annual arithmetic mean concentration, and 35 $\mu g/m^3$ 24-hour average concentration measured in the ambient air as $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers) by either:

(i) A reference method based on appendix L of this part and designated in accordance with part 53 of this chapter; or

(ii) An equivalent method designated in accordance with part 53 of this chapter.

(2)(i) 70 $\mu g/m^3$ 24-hour average concentration measured in the ambient air as $PM_{10-2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers and greater than a nominal 2.5 micrometers) by either:

(A) A reference method based on appendix O of this part and designated in accordance with part 53 of this chapter; or

(B) An equivalent method designated in accordance with part 53 of this chapter.

(ii) The standard for $PM_{10-2.5}$ includes any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and

PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. Agricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard.

(b) The annual primary and secondary $PM_{2.5}$ standards are met when the annual arithmetic mean concentration, as determined in accordance with appendix N of this part, is less than or equal to 15.0 μg/m³.

(c) The 24-hour primary and secondary $PM_{2.5}$ standards are met when the 98th percentile 24-hour concentration, as determined in accordance with appendix N of this part, is less than or equal to 35 μg/m³. The 24-hour primary and secondary $PM_{10-2.5}$ standards are met when the 98th percentile 24-hour concentration, as determined in accordance with appendix P of this part, is less than or equal to 70 μg/m³. ′

5. Appendix L to part 50 is amended by:

a. Revising section 1.1;

b. Revising the heading of section 7.3.4 and adding introductory text; revising paragraph (a) of section 7.3.4.3, adding section 7.3.4.4; and revising Table L–1 in section 7.4.19;

c. Revising section 8.3.6;

d. Revising the first sentence in section 10.10 and revising section 10.13; and

e. Revising reference 2 in section 13.0. The revisions and addition read as follows:

Appendix L to Part 50—Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere

1.0 *Applicability.*

1.1 This method provides for the measurement of the mass concentration of fine particulate matter having an aerodynamic diameter less than or equal to a nominal 2.5 micrometers ($PM_{2.5}$) in ambient air over a 24-hour period for purposes of determining whether the primary and secondary national ambient air quality standards for fine particulate matter specified in § 50.7 and § 50.13 of this part are met. The measurement process is considered to be nondestructive, and the $PM_{2.5}$ sample obtained can be subjected to subsequent physical or chemical analyses. Quality assessment procedures are provided in part 58, appendix A of this chapter, and quality assurance guidance are provided in references 1, 2, and 3 in section 13.0 of this appendix.

* * * * *

7.3 *Design specifications.* * * *

* * * * *

7.3.4 *Particle size separator.* The sampler shall be configured with either one of the two alternative particle size separators described in this section 7.3.4. One separator is an impactor-type separator (WINS impactor) described in sections 7.3.4.1, 7.3.4.2, and 7.3.4.3 of this appendix. The alternative separator is a cyclone-type separator (VSCC™) described in section 7.3.4.4 of this appendix.

* * * * *

7.3.4.3 Impactor oil specifications:

(a) Composition. Dioctyl sebacate (DOS), single-compound diffusion oil.

* * * * *

7.3.4.4 The cyclone-type separator is identified as a BGI VSCC™ Very Sharp Cut Cyclone particle size separator specified as part of EPA-designated equivalent method EQPM–0202–142 (67 FR 15567, April 2, 2002) and as manufactured by BGI Incorporated, 58 Guinan Street, Waltham, Massachusetts 20451.

* * * * *

7.4.19 Data reporting requirements. * * *

TABLE L–1 TO APPENDIX L OF PART 50.—SUMMARY OF INFORMATION TO BE PROVIDED BY THE SAMPLER

Information to be provided	Appendix L section reference	Availability				Format	
		Anytime [1]	End of period [2]	Visual display [3]	Data output [4]	Digital reading [5]	Units
Flow rate, 30 second maximum interval	7.4.5.1	✔		✔	(*)	XX.X	L/min
Flow rate, average for the sample period	7.4.5.2	(*)	✔	(*)	✔	XX.X	L/min
Flow rate, CV, for sample period	7.4.5.2	(*)	✔	(*)	✔	XX.X	%
Flow rate, 5-min. average out of spsec. (FLAG [6])	7.4.5.2	✔	✔	✔	✔■	On/Off	
Sample volume, total	7.4.5.2	(*)	✔	✔	✔	XX.X	m³
Temperature, ambient, 30-second interval	7.4.8	✔		✔		XX.X	°C
Temperature, ambient, min., max., average for the sample period.	7.4.8	(*)	✔	✔	✔■	XX.X	°C
Baro. pressure, ambient, 30-second interval	7.4.9	✔		✔		XXX	mm Hg
Baro. pressure, ambient, min., max., average for the sample period.	7.4.9	(*)	✔	✔	✔■	XXX	mm Hg
Filter temperature, 30-second interval	7.4.11	✔		✔		XX.X	°C
Filter temp. differential, 30-second interval, out of spec. (FLAG [6]).	7.4.11	(*)	✔	✔	✔■	On/Off	
Filter temp., maximum differential from ambient, date, time of occurrence.	7.4.11	(*)	(*)	(*)	(*)	X.X, YY/MM/DD HH.mm	°C Yr/Mon/Day Hrs.min
Date and Time	7.4.12	✔		✔		YY/MM/DD HH.mm	Yr/Mon/Day Hrs.min
Sample start and stop time settings	7.4.12	✔	✔	✔	✔	YY/MM/DD HH.mm	Yr/Mon/Day Hrs.min
Sample period start time	7.4.12		✔	✔	✔	YY/MM/DD HH.mm	Yr/Mon/Day Hrs.min
Elapsed sample time	7.4.13	(*)	✔	✔	✔	HH.mm	Hrs.min
Elapsed sample time, out of spec. (FLAG [6])	7.4.13		✔	✔	✔■	On/Off	
Power interruptions ≤1 min., start time of first 10	7.4.15.5	(*)	✔	(*)	✔	1HH.mm, 2HH.mm, etc* * *	Hrs.min
User-entered information, such as sampler and site identification.	7.4.16	✔	✔	✔	✔■	As entered	

✔ Provision of this information is required.

* Provision of this information is optional. If information related to the entire sample period is optionally provided prior to the end of the sample period, the value provided should be the value calculated for the portion of the sampler period completed up to the time the information is provided.

■ Indicates that this information is also required to be provided to the Air Quality System (AQS) data bank; see § 58.16 of this chapter. For ambient temperature and barometric pressure, only the average for the sample period must be reported.

1. Information is required to be available to the operator at any time the sampler is operating, whether sampling or not.

2. Information relates to the entire sampler period and must be provided following the end of the sample period until reset manually by the operator or automatically by the sampler upon the start of a new sample period.

3. Information shall be available to the operator visually.

4. Information is to be available as digital data at the sampler's data output port specified in section 7.4.16 of this appendix following the end of the sample period until reset manually by the operator or automatically by the sampler upon the start of a new sample period.

5. Digital readings, both visual and data output, shall have not less than the number of significant digits and resolution specified.

6. Flag warnings may be displayed to the operator by a single flag indicator or each flag may be displayed individually. Only a set (on) flag warning must be indicated; an off (unset) flag may be indicated by the absence of a flag warning. Sampler users should refer to section 10.12 of this appendix regarding the validity of samples for which the sampler provided an associated flag warning.

* * * * *

8.3 *Weighing procedure.*

* * * * *

8.3.6 The post-sampling conditioning and weighing shall be completed within 240 hours (10 days) after the end of the sample period, unless the filter sample is maintained at temperatures below the average ambient temperature during sampling (or 4°C or below for average sampling temperatures less than 4°C) during the time between retrieval from the sampler and the start of the conditioning, in which case the period shall not exceed 30 days. Reference 2 in section 13.0 of this appendix has additional guidance on transport of cooled filters.

* * * * *

10.0 *$PM_{2.5}$ Measurement Procedure.*

* * *

* * * * *

10.10 Within 177 hours (7 days, 9 hours) of the end of the sample collection period, the filter, while still contained in the filter cassette, shall be carefully removed from the sampler, following the procedure provided in the sampler operation or instruction manual and the quality assurance program, and placed in a protective container. * * *

* * * * *

10.13 After retrieval from the sampler, the exposed filter containing the $PM_{2.5}$ sample should be transported to the filter conditioning environment as soon as possible, ideally to arrive at the conditioning environment within 24 hours for conditioning and subsequent weighing. During the period between filter retrieval from the sampler and the start of the conditioning, the filter shall be maintained as cool as practical and continuously protected from exposure to temperatures over 25°C to protect the integrity of the sample and minimize loss of volatile components during transport and storage. See section 8.3.6 of this appendix regarding time limits for completing the post-sampling weighing. See reference 2 in section 13.0 of this appendix for additional guidance on transporting filter samplers to the conditioning and weighing laboratory.

* * * * *

13.0 *References.*

* * * * *

2. Quality Assurance Guidance Document 2.12. Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods. U.S. EPA, National Exposure Research Laboratory. Research Triangle Park, NC, November 1988 or later edition. Currently available at: *http://www.epa.gov/ttn/amtic/pmqainf.html.*

* * * * *

6. Appendix N to part 50 is revised to read as follows:

Appendix N to Part 50—Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$

1. *General.*

(a) This appendix explains the data handling conventions and computations necessary for determining when the annual and 24-hour primary and secondary national ambient air quality standards (NAAQS) for $PM_{2.5}$ specified in § 50.7 and § 50.13 of this part are met. $PM_{2.5}$, defined as particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers, is measured in the ambient air by a Federal reference method (FRM) based on appendix L of this part, as applicable, and designated in accordance with part 53 of this chapter, or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Data handling and computation procedures to be used in making comparisons between reported $PM_{2.5}$ concentrations and the levels of the $PM_{2.5}$ NAAQS are specified in the following sections.

(b) Data resulting from exceptional events, for example structural fires or high winds, may be given special consideration. In some cases, it may be appropriate to exclude these data in whole or part because they could result in inappropriate values to compare with the levels of the $PM_{2.5}$ NAAQS. In other cases, it may be more appropriate to retain the data for comparison with the levels of the $PM_{2.5}$ NAAQS and then for EPA to formulate the appropriate regulatory response.

(c) The terms used in this appendix are defined as follows:

Annual mean refers to a weighted arithmetic mean, based on quarterly means, as defined in section 4.4 of this appendix.

Daily values for $PM_{2.5}$ refers to the 24-hour average concentrations of $PM_{2.5}$ calculated (averaged from hourly measurements) or measured from midnight to midnight (local standard time).

Designated monitors are those monitoring sites designated in a State or local agency PM Monitoring Network Description in accordance with part 58 of this chapter.

Design values are the metrics (i.e., statistics) that are compared to the NAAQS levels to determine compliance, calculated as shown in section 4 of this appendix:

(1) The 3-year average of annual means for a single monitoring site or a group of monitoring sites (referred to as the *''annual standard design value''*). If spatial averaging has been approved by EPA for a group of sites which meet the criteria specified in section 2(b) of this appendix and section 4.7.5 of appendix D of 40 CFR part 58, then 3 years of spatially averaged annual means will be averaged to derive the *annual standard design value* for that group of sites (further referred to as the *''spatially averaged annual standard design value''*). Otherwise, the annual standard design value will represent the 3-year average of annual means for a single site (further referred to as the *''single site annual standard design value''*).

(2) The 3-year average of annual 98th percentile 24-hour average values recorded at each monitoring site (referred to as the *''24-hour standard design value''*).

98th percentile is the daily value out of a year of $PM_{2.5}$ monitoring data below which 98 percent of all daily values fall.

Year refers to a calendar year.

2.0 *Monitoring Considerations.*

(a) Section 58.30 of this chapter specifies which monitoring locations are eligible for making comparisons with the $PM_{2.5}$ standards.

(b) To qualify for spatial averaging, monitoring sites must meet the criterion specified in section 4.7.5 of appendix D of 40 CFR part 58 as well as the following requirements:

(1) The annual mean concentration at each site shall be within 10 percent of the spatially averaged annual mean.

(2) The daily values for each site pair shall yield a correlation coefficient of at least 0.9 for each calendar quarter.

(3) All of the monitoring sites should principally be affected by the same major emission sources of $PM_{2.5}$. This can be demonstrated by site-specific chemical speciation profiles confirming all major component concentration averages to be within 10 percent for each calendar quarter.

(4) The requirements in paragraphs (b)(1) through (3) of this section shall be met for 3 consecutive years in order to produce a valid spatially averaged annual standard design value. Otherwise, the individual (single) site annual standard design values shall be compared directly to the level of the annual NAAQS.

(c) Section 58.12 of this chapter specifies the required minimum frequency of sampling for $PM_{2.5}$. Exceptions to the specified sampling frequencies, such as a reduced frequency during a season of expected low concentrations (i.e., ''seasonal sampling''), are subject to the approval of EPA. Annual 98th percentile values are to be calculated according to equation 6 in section 4.5 of this appendix when a site operates on a ''seasonal sampling'' schedule.

3.0 *Requirements for Data Used for Comparisons With the $PM_{2.5}$ NAAQS and Data Reporting Considerations.*

(a) Except as otherwise provided in this appendix, only valid FRM/FEM $PM_{2.5}$ data required to be submitted to EPA's Air Quality System (AQS) shall be used in the design value calculations.

(b) $PM_{2.5}$ measurement data (typically hourly for continuous instruments and daily for filter-based instruments) shall be reported to AQS in micrograms per cubic meter (μg/m³) to one decimal place, with additional digits to the right being truncated.

(c) Block 24-hour averages shall be computed from available hourly $PM_{2.5}$ concentration data for each corresponding day of the year and the result shall be stored in the first, or start, hour (i.e., midnight, hour '0') of the 24-hour period. A 24-hour average shall be considered valid if at least 75 percent (i.e., 18) of the hourly averages for the 24-hour period are available. In the event that less than all 24 hourly averages are available (i.e., less than 24, but at least 18), the 24-hour average shall be computed on the basis of the hours available using the number of available hours as the divisor (e.g., 19). 24-hour periods with seven or more missing hours shall be considered valid if, after substituting zero for all missing hourly concentrations, the 24-hour average concentration is greater than the level of the standard. The computed 24-hour average $PM_{2.5}$ concentrations shall be reported to one decimal place (the insignificant digits to the right of the third decimal place are truncated, consistent with the data handling procedures for the reported data).

(d) Except for calculation of spatially averaged annual means and spatially averaged annual standard design values, all other calculations shown in this appendix shall be implemented on a site-level basis. Site level data shall be processed as follows:

(1) The default dataset for a site shall consist of the measured concentrations recorded from the designated primary FRM/FEM monitor. The primary monitor shall be designated in the appropriate State or local agency PM Monitoring Network Description.

(2) Data for the primary monitor shall be augmented as necessary with data from collocated FRM/FEM monitors. If a valid 24-hour measurement is not produced from the primary monitor for a particular required sampling day, but a valid sample is generated by a collocated FRM/FEM instrument (and recorded in AQS), then that collocated value shall be considered part of the site data record. If more than one valid collocated FRM/FEM value is available, the average of those valid collocated values shall be used as the site value for the day.

4.0 *Comparisons with the $PM_{2.5}$ NAAQS.*

4.1 *Annual $PM_{2.5}$ NAAQS.*

(a) The annual $PM_{2.5}$ NAAQS is met when the annual standard design value is less than or equal to 15.0 micrograms per cubic meter (μg/m³).

(b) For single site comparisons, 3 years of valid annual means are required to produce a valid annual standard design value. In the case of spatial averaging, 3 years of valid spatially averaged annual means are required to produce a valid annual standard design value. Designated sites with less than 3 years of data shall be included in annual spatial averages for those years that data completeness requirements are met. A year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. However, years with high concentrations and at least 11 samples in each quarter shall be considered valid, notwithstanding quarters with less than complete data, if the resulting annual mean, spatially averaged annual mean concentration, or resulting annual standard design value concentration (rounded according to the conventions of section 4.3 of this appendix) is greater than the level of the standard. Furthermore, where the explicit 11 sample per quarter requirement is not met, the site annual mean shall still be considered valid if, by substituting a low value (described below) for the missing data in the deficient quarters (substituting enough to meet the 11 sample minimum), the computation still yields a recalculated annual mean, spatially averaged annual mean concentration, or annual standard design value concentration over the level of the standard. The low value used for this substitution test shall be the lowest reported value in the site data record for that calendar quarter over the most recent 3-year period. If an annual mean is deemed complete using this test, the original annual mean (without substituted low values) shall be considered the official mean value for this site, not the result of the recalculated test using the low values.

(c) The use of less than complete data is subject to the approval of EPA, which may consider factors such as monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

(d) The equations for calculating the annual standard design values are given in section 4.4 of this appendix.

4.2 *24-Hour $PM_{2.5}$ NAAQS.*

(a) The 24-hour $PM_{2.5}$ NAAQS is met when the 24-hour standard design value at each monitoring site is less than or equal to 35 μg/m³. This comparison shall be based on 3 consecutive, complete years of air quality data. A year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. However, years with high concentrations shall be considered valid, notwithstanding quarters with less than complete data (even quarters with less than 11 samples), if the resulting annual 98th percentile value or resulting 24-hour standard design value (rounded according to the conventions of section 4.3 of this appendix) is greater than the level of the standard.

(b) The use of less than complete data is subject to the approval of EPA which may consider factors such as monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

(c) The equations for calculating the 24-hour standard design values are given in section 4.5 of this appendix.

4.3 *Rounding Conventions.* For the purposes of comparing calculated values to the applicable level of the standard, it is necessary to round the final results of the calculations described in sections 4.4 and 4.5 of this appendix. Results for all intermediate calculations shall not be rounded.

(a) Annual $PM_{2.5}$ standard design values shall be rounded to the nearest 0.1 μg/m³ (decimals 0.05 and greater are rounded up to the next 0.1, and any decimal lower than 0.05 is rounded down to the nearest 0.1).

(b) 24-hour $PM_{2.5}$ standard design values shall be rounded to the nearest 1 μg/m³ (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

4.4 *Equations for the Annual $PM_{2.5}$ NAAQS.*

(a) An annual mean value for $PM_{2.5}$ is determined by first averaging the daily values of a calendar quarter using equation 1 of this appendix:

Equation 1

$$\overline{X}_{q,y,s} = \frac{1}{n_q}\sum_{i=1}^{n_q} X_{i,q,y,s}$$

Where:

$\bar{x}_{q,\,y,\,s}$ = the mean for quarter q of year y for site s;

n_q = the number of monitored values in the quarter; and

$x_{i,\,q,\,y,\,s}$ = the ith value in quarter q for year y for site s.

(b) Equation 2 of this appendix is then used to calculate the site annual mean:

Equation 2

$$\overline{X}_{y,s} = \frac{1}{4}\sum_{q=1}^{4} \overline{X}_{q,y,s}$$

Where:

$\bar{x}_{y,s}$ = the annual mean concentration for year y (y = 1, 2, or 3) and for site s; and

$\bar{x}_{q,y,s}$ = the mean for quarter q of year y for site s.

(c) If spatial averaging is utilized, the site-based annual means will then be averaged together to derive the spatially averaged annual mean using equation 3 of this appendix. Otherwise (i.e., for single site comparisons), skip to equation 4.b of this appendix.

Equation 3

$$\bar{x}_y = \frac{1}{n_s}\sum_{s=1}^{n_s}\bar{x}_{y,s}$$

Where:

$\bar{x}_y$ = the spatially averaged mean for year y,
$\bar{x}_{y,s}$ = the annual mean for year y and site s, and
n_s = the number of sites designated to be averaged.

(d) The annual standard design value is calculated using equation 4A of this appendix when spatial averaging and equation 4B of this appendix when not spatial averaging:

Equation 4A

When spatial averaging

$$\bar{x} = \frac{1}{3}\sum_{y=1}^{3}\bar{x}_y$$

Equation 4B

When not spatial averaging

$$\bar{x} = \frac{1}{3}\sum_{y=1}^{3}\bar{x}_{y,s}$$

Where:

$\bar{x}$ = the annual standard design value (the spatially averaged annual standard design value for equation 4A of this appendix and the single site annual standard design value for equation 4B of this appendix); and
x_y = the spatially averaged annual mean for year y (result of equation 3 of this appendix) when spatial averaging is used, or
$\bar{x}_{y,s}$ = the annual mean for year y and site s (result of equation 2 of this appendix) when spatial averaging is not used.

(e) The annual standard design value is rounded according to the conventions in section 4.3 of this appendix before a comparison with the standard is made.

4.5 *Equations for the 24-Hour $PM_{2.5}$ NAAQS.*

(a) When the data for a particular site and year meet the data completeness requirements in section 4.2 of this appendix, calculation of the 98th percentile is accomplished by the steps provided in this subsection. Equation 5 of this appendix shall be used to compute annual 98th percentile values, except that where a site operates on an approved seasonal sampling schedule, equation 6 of this appendix shall be used instead. Seasonal sampling, when approved, will be implemented in periods of calendar quarters or months; seasonal sampling seasons shall not divide months. Calculations of all annual 98th percentile values are based on the *applicable* number of samples (as described below), rather than on the *actual* number of samples. For the 24-hour NAAQS, credit will not be granted for more samples than the maximum number of scheduled sampling days in the sampling period. For each month, the *applicable* number of samples is the lower of the *actual* number of samples and the scheduled number of samples. The applicable number of samples for a year is the sum of the twelve monthly ''applicable number of samples'; the applicable number of samples for a season is the sum of the corresponding monthly ''applicable number of samples''. 98th percentile values shall be calculated as in equations 5 or 6 of this appendix using the *applicable* number of samples for the year or season. [The *applicable number of samples* will determine how deep to go into the data distribution, but all samples (scheduled or not) will be considered when making the percentile assignment.]

(1) *Regular formula for computing annual 98th percentile values.* Sort all the daily values from a particular site and year by ascending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the smallest number and x[n] is the largest value.) The 98th percentile is determined from this sorted series of daily values which is ordered from the lowest to the highest number. Compute (0.98) × (an) as the number ''i.d'', where 'an' is the annual applicable number of samples, ''i'' is the integer part of the result, and ''d'' is the decimal part of the result. The 98th percentile value for year y, $P_{0.98,y}$, is calculated using equation 5 of this appendix:

Equation 5

$$P_{0.98,y} = X_{[j+1]}$$

Where:

$P_{0.98,y}$ = 98th percentile for year y;
x[i+1] = the (i+1)th number in the ordered series of numbers; and
i = the integer part of the product of 0.98 and an.

(2) *Formula for computing annual 98th percentile values when sampling frequencies are seasonal.* Calculate the annual 98th percentiles by determining the smallest measured concentration, x, that makes *W(x)* greater than 0.98 using equation 6 of this appendix:

Equation 6

$$W(x) = \frac{d_{High}}{d_{High}+d_{Low}}F_{High}(x) + \frac{d_{Low}}{d_{High}+d_{Low}}F_{Low}(x)$$

Where:

d_{High} = number of calendar days in the ''High'' season;
d_{Low} = number of calendar days in the ''Low'' season;
$d_{High} + d_{Low}$ = days in a year; and

$$F_a(x) = \frac{\text{number of samples in season a that are} \le x}{\text{applicable number of samples in season a}}$$

Such that ''a'' can be either ''High'' or ''Low'' ''x'' is the measured concentration; and ''$d_{High}/(d_{High} + d_{Low})$ and $d_{Low}/(d_{High} + d_{Low})$'' are constant and are called seasonal ''weights.''

(b) The 24-hour standard design value is then calculated by averaging the annual 98th percentiles using equation 7 of this appendix:

Equation 7

$$P_{0.98} = \frac{\sum_{y=1}^{3} P_{0.98,y}}{3}$$

(c) The 24-hour standard design value (3-year average 98th percentile) is rounded according to the conventions in section 4.3 of this appendix before a comparison with the standard is made.

7. Appendix O to part 50 is added to read as follows:

Appendix O to Part 50—Reference Method for the Determination of Coarse Particulate Matter as $PM_{10-2.5}$ in the Atmosphere

1.0 *Applicability and Definition.*

1.1 This method provides for the measurement of the mass concentration of coarse particulate matter ($PM_{10-2.5}$) in ambient air over a 24-hour period for purposes of determining whether the primary and secondary NAAQS for coarse particulate matter specified in § 50.13 of this chapter are met.

1.2 For the purpose of this method, $PM_{10-2.5}$ is defined as particulate matter having an aerodynamic diameter in the nominal range of 2.5 to 10 micrometers, inclusive.

1.3 For this reference method, $PM_{10-2.5}$ concentrations shall be measured as the arithmetic difference between separate but concurrent, collocated measurements of PM_{10} and $PM_{2.5}$, where the PM_{10} measurements are obtained with a specially approved sampler, identified as a ''PM_{10c} sampler,'' that meets more demanding performance requirements than conventional PM_{10} samplers described in appendix J of this part. Measurements obtained with a PM_{10c} sampler are identified as ''PM_{10c} measurements'' to distinguish them from conventional PM_{10} measurements obtained with conventional PM_{10} samplers. Thus, $PM_{10-2.5} = PM_{10c} - PM_{2.5}$.

1.4 The PM_{10c} and $PM_{2.5}$ gravimetric measurement processes are considered to be nondestructive, and the PM_{10c} and $PM_{2.5}$ samples obtained in the $PM_{10-2.5}$ measurement process can be subjected to subsequent physical or chemical analyses.

1.5 Quality assessment procedures are provided in part 58, appendix A of this chapter. The quality assurance procedures and guidance provided in reference 1 in section 13 of this appendix, although written specifically for $PM_{2.5}$, are generally applicable for PM_{10c}, and, hence, $PM_{10-2.5}$ measurements under this method, as well.

1.6 A method based on specific model PM_{10c} and $PM_{2.5}$ samplers will be considered a reference method for purposes of part 58 of this chapter only if:

(a) The PM_{10c} and $PM_{2.5}$ samplers and the associated operational procedures meet the requirements specified in this appendix and all applicable requirements in part 53 of this chapter, and

(b) The method based on the specific samplers and associated operational procedures has been designated as a reference method in accordance with part 53 of this chapter.

1.7 $PM_{10-2.5}$ methods based on samplers that meet nearly all specifications set forth in this method but have one or more significant but minor deviations or modifications from those specifications may be designated as ''Class I'' equivalent methods for $PM_{10-2.5}$ in accordance with part 53 of this chapter.

1.8 $PM_{2.5}$ measurements obtained incidental to the $PM_{10-2.5}$ measurements by this method shall be considered to have been obtained with a reference method for $PM_{2.5}$ in accordance with appendix L of this part.

1.9 PM_{10c} measurements obtained incidental to the $PM_{10-2.5}$ measurements by this method shall be considered to have been obtained with a reference method for PM_{10} in accordance with appendix J of this part, provided that:

(a) The PM_{10c} measurements are adjusted to EPA reference conditions (25°C and 760 millimeters of mercury), and

(b) Such PM_{10c} measurements are appropriately identified to differentiate them from PM_{10} measurements obtained with other (conventional) methods for PM_{10} designated in accordance with part 53 of this chapter as reference or equivalent methods for PM_{10}.

2.0 *Principle.*

2.1 Separate, collocated, electrically powered air samplers for PM_{10c} and $PM_{2.5}$ concurrently draw ambient air at identical, constant volumetric flow rates into specially shaped inlets and through one or more inertial particle size separators where the suspended particulate matter in the PM_{10} or $PM_{2.5}$ size range, as applicable, is separated for collection on a polytetrafluoroethylene (PTFE) filter over the specified sampling period. The air samplers and other aspects of this $PM_{10-2.5}$ reference method are specified either explicitly in this appendix or by reference to other applicable regulations or quality assurance guidance.

2.2 Each PM_{10c} and $PM_{2.5}$ sample collection filter is weighed (after moisture and temperature conditioning) before and after sample collection to determine the net weight (mass) gain due to collected PM_{10c} or $PM_{2.5}$. The total volume of air sampled by each sampler is determined by the sampler from the measured flow rate at local ambient temperature and pressure and the sampling time. The mass concentrations of both PM_{10c} and $PM_{2.5}$ in the ambient air are computed as the total mass of collected particles in the PM_{10} or $PM_{2.5}$ size range, as appropriate, divided by the total volume of air sampled by the respective samplers, and expressed in micrograms per cubic meter (μ/m^3)at local temperature and pressure conditions. The mass concentration of $PM_{10-2.5}$ is determined as the PM_{10c} concentration value less the corresponding, concurrently measured $PM_{2.5}$ concentration value.

2.3 Most requirements for $PM_{10-2.5}$ reference methods are similar or identical to the requirements for $PM_{2.5}$ reference methods as set forth in appendix L to this part. To insure uniformity, applicable appendix L requirements are incorporated herein by reference in the sections where indicated rather than repeated in this appendix.

3.0 *$PM_{10-2.5}$ Measurement Range.*

3.1 *Lower concentration limit.* The lower detection limit of the mass concentration measurement range is estimated to be approximately 3 $\mu g/m^3$, based on the observed precision of $PM_{2.5}$ measurements in the national $PM_{2.5}$ monitoring network, the probable similar level of precision for the matched PM_{10c} measurements, and the additional variability arising from the differential nature of the measurement process. This value is provided merely as a guide to the significance of low $PM_{10-2.5}$ concentration measurements.

3.2 *Upper concentration limit.* The upper limit of the mass concentration range is determined principally by the PM_{10c} filter mass loading beyond which the sampler can no longer maintain the operating flow rate within specified limits due to increased pressure drop across the loaded filter. This upper limit cannot be specified precisely because it is a complex function of the ambient particle size distribution and type, humidity, the individual filter used, the capacity of the sampler flow rate control system, and perhaps other factors. All PM_{10c} samplers are estimated to be capable of measuring 24-hour mass

concentrations of at least 200 μg/m^3 while maintaining the operating flow rate within the specified limits. The upper limit for the $PM_{10-2.5}$ measurement is likely to be somewhat lower because the $PM_{10-2.5}$ concentration represents only a fraction of the PM_{10} concentration.

3.3 *Sample period.* The required sample period for $PM_{10-2.5}$ concentration measurements by this method shall be at least 1,380 minutes but not more than 1,500 minutes (23 to 25 hours), and the start times of the $PM_{2.5}$ and PM_{10c} samples are within 10 minutes and the stop times of the samples are also within 10 minutes (see section 10.4 of this appendix). However, a $PM_{10-2.5}$ measured concentration where the actual sample period for PM_{10c} sample is less than 1,380 minutes, but the corresponding $PM_{2.5}$ sample period is at least 1,380 minutes, may be used as if it were a valid concentration measurement for the specific purpose of determining an exceedance of the NAAQS. For this purpose, the measured PM_{10c} concentration is determined as the PM_{10c} mass collected divided by the actual sampled air volume, multiplied by the actual number of minutes in the PM_{10c} sample period and divided by 1,440; the $PM_{10-2.5}$ concentration is then calculated as prescribed in section 12.4 of this appendix. This value represents the minimum nominal $PM_{10-2.5}$ concentration that could have been measured for the full sample period. Accordingly, if the value thus calculated is high enough to be an exceedance, such an exceedance would be a valid exceedance for the sample period. When reported to AQS, this data value should receive a special data qualifier code to identify it as having an insufficient sample period.

4.0 *Accuracy (bias).*

4.1 Because the size, density, and volatility of the particles making up ambient particulate matter vary over wide ranges and the mass concentration of particles varies with particle size, it is difficult to define the accuracy of $PM_{10-2.5}$ measurements in an absolute sense. Furthermore, generation of credible $PM_{10-2.5}$ concentration standards at field monitoring sites and presenting or introducing such standards reliably to samplers or monitors to assess accuracy is still generally impractical. The accuracy of $PM_{10-2.5}$ measurements is therefore defined in a relative sense as bias, referenced to measurements provided by other reference method samplers or based on flow rate verification audits or checks, or on other performance evaluation procedures.

4.2 Measurement system bias for monitoring data is assessed according to the procedures and schedule set forth in part 58, appendix A of this chapter. The goal for the measurement uncertainty (as bias) for monitoring data is defined in part 58, appendix A of this chapter as an upper 95 percent confidence limit for the absolute bias of 15 percent. Reference 1 in section 13 of this appendix provides additional information and guidance on flow rate accuracy audits and assessment of bias.

5.0 *Precision.*

5.1 Tests to establish initial measurement precision for each sampler of the reference method sampler pair are specified as a part of the requirements for designation as a reference method under part 53 of this chapter.

5.2 Measurement system precision is assessed according to the procedures and schedule set forth in appendix A to part 58 of this chapter. The goal for acceptable measurement uncertainty, as precision, of monitoring data is defined in part 58, appendix A of this chapter as an upper 95 percent confidence limit for the coefficient of variation (CV) of 15 percent. Reference 1 in section 13 of this appendix provides additional information and guidance on this requirement.

6.0 *Filters for PM_{10c} and $PM_{2.5}$ Sample Collection.* Sample collection filters for both PM_{10c} and $PM_{2.5}$ measurements shall be identical and as specified in section 6 of appendix L to this part.

7.0 *Sampler.* The $PM_{10-2.5}$ sampler shall consist of a PM_{10c} sampler and a $PM_{2.5}$ sampler, as follows:

7.1 The $PM_{2.5}$ sampler shall be as specified in section 7 of appendix L to this part.

7.2 The PM_{10c} sampler shall be of like manufacturer, design, configuration, and fabrication to that of the $PM_{2.5}$ sampler and as specified in section 7 of appendix L to this part, except as follows:

7.2.1 The particle size separator specified in section 7.3.4 of appendix L to this part shall be eliminated and replaced by a downtube extension fabricated as specified in Figure O–1 of this appendix.

7.2.2 The sampler shall be identified as a PM_{10c} sampler on its identification label required under § 53.9(d) of this chapter.

7.2.3 The average temperature and average barometric pressure measured by the sampler during the sample period, as described in Table L–1 of appendix L to this part, need not be reported to EPA's AQS data base, as required by section 7.4.19 and Table L–1 of appendix L to this part, provided such measurements for the sample period determined by the associated $PM_{2.5}$ sampler are reported as required.

7.3 In addition to the operation/instruction manual required by section 7.4.18 of appendix L to this part for each sampler, supplemental operational instructions shall be provided for the simultaneous operation of the samplers as a pair to collect concurrent PM_{10c} and $PM_{2.5}$ samples. The supplemental instructions shall cover any special procedures or guidance for installation and setup of the samplers for $PM_{10-2.5}$ measurements, such as synchronization of the samplers' clocks or timers, proper programming for collection of concurrent samples, and any other pertinent issues related to the simultaneous, coordinated operation of the two samplers.

7.4 Capability for electrical interconnection of the samplers to simplify sample period programming and further ensure simultaneous operation is encouraged but not required. Any such capability for interconnection shall not supplant each sampler's capability to operate independently, as required by section 7 of appendix L of this part.

8.0 *Filter Weighing.*

8.1 Conditioning and weighing for both PM_{10c} and $PM_{2.5}$ sample filters shall be as specified in section 8 of appendix L to this part. See reference 1 of section 13 of this appendix for additional, more detailed guidance.

8.2 Handling, conditioning, and weighing for both PM_{10c} and $PM_{2.5}$ sample filters shall be matched such that the corresponding PM_{10c} and $PM_{2.5}$ filters of each filter pair receive uniform treatment. The PM_{10c} and $PM_{2.5}$ sample filters should be weighed on the same balance, preferably in the same weighing session and by the same analyst.

8.3 Due care shall be exercised to accurately maintain the paired relationship of each set of concurrently collected PM_{10c} and $PM_{2.5}$ sample filters and their net weight gain data and to avoid misidentification or reversal of the filter samples or weight data. See Reference 1 of section 13 of this appendix for additional guidance.

9.0 *Calibration.* Calibration of the flow rate, temperature measurement, and pressure measurement systems for both the PM_{10c} and $PM_{2.5}$ samplers shall be as specified in section 9 of appendix L to this part.

10.0 *$PM_{10-2.5}$ Measurement Procedure.*

10.1 The PM_{10c} and $PM_{2.5}$ samplers shall be installed at the monitoring site such that their ambient air inlets differ in vertical height by not more than 0.2

meter, if possible, but in any case not more than 1 meter, and the vertical axes of their inlets are separated by at least 1 meter but not more than 4 meters, horizontally.

10.2 The measurement procedure for PM_{10c} shall be as specified in section 10 of appendix L to this part, with ''PM_{10c}'' substituted for ''$PM_{2.5}$'' wherever it occurs in that section.

10.3 The measurement procedure for $PM_{2.5}$ shall be as specified in section 10 of appendix L to this part.

10.4 For the $PM_{10-2.5}$ measurement, the PM_{10c} and $PM_{2.5}$ samplers shall be programmed to operate on the same schedule and such that the sample period start times are within 5 minutes and the sample duration times are within 5 minutes.

10.5 Retrieval, transport, and storage of each PM_{10c} and $PM_{2.5}$ sample pair following sample collection shall be matched to the extent practical such that both samples experience uniform conditions.

11.0 *Sampler Maintenance.* Both PM_{10c} and $PM_{2.5}$ samplers shall be maintained as described in section 11 of appendix L to this part.

12.0 *Calculations.*

12.1 Both concurrent PM_{10c} and $PM_{2.5}$ measurements must be available, valid, and meet the conditions of section 10.4 of this appendix to determine the $PM_{10-2.5}$ mass concentration.

12.2 The PM_{10c} mass concentration is calculated using equation 1 of this section:

Equation 1

$$PM_{10c} = (W_f - W_i)/V_a$$

Where:

PM_{10c} = mass concentration of PM_{10c}, $\mu g/m^3$;

W_f, W_i = final and initial masses (weights), respectively, of the filter used to collect the PM_{10c} particle sample, µg;

V_a = total air volume sampled by the PM_{10c} sampler in actual volume units measured at local conditions of temperature and pressure, as provided by the sampler, m^3.

Note: Total sample time must be between 1,380 and 1,500 minutes (23 and 25 hrs) for a fully valid PM_{10c} sample; however, see also section 3.3 of this appendix.

12.3 The $PM_{2.5}$ mass concentration is calculated as specified in section 12 of appendix L to this part.

12.4 The $PM_{10-2.5}$ mass concentration, in $\mu g/m^3$, is calculated using Equation 2 of this section:

Equation 2

$$PM_{10-2.5} = PM_{10c} - PM_{2.5}$$

13.0 *Reference.*

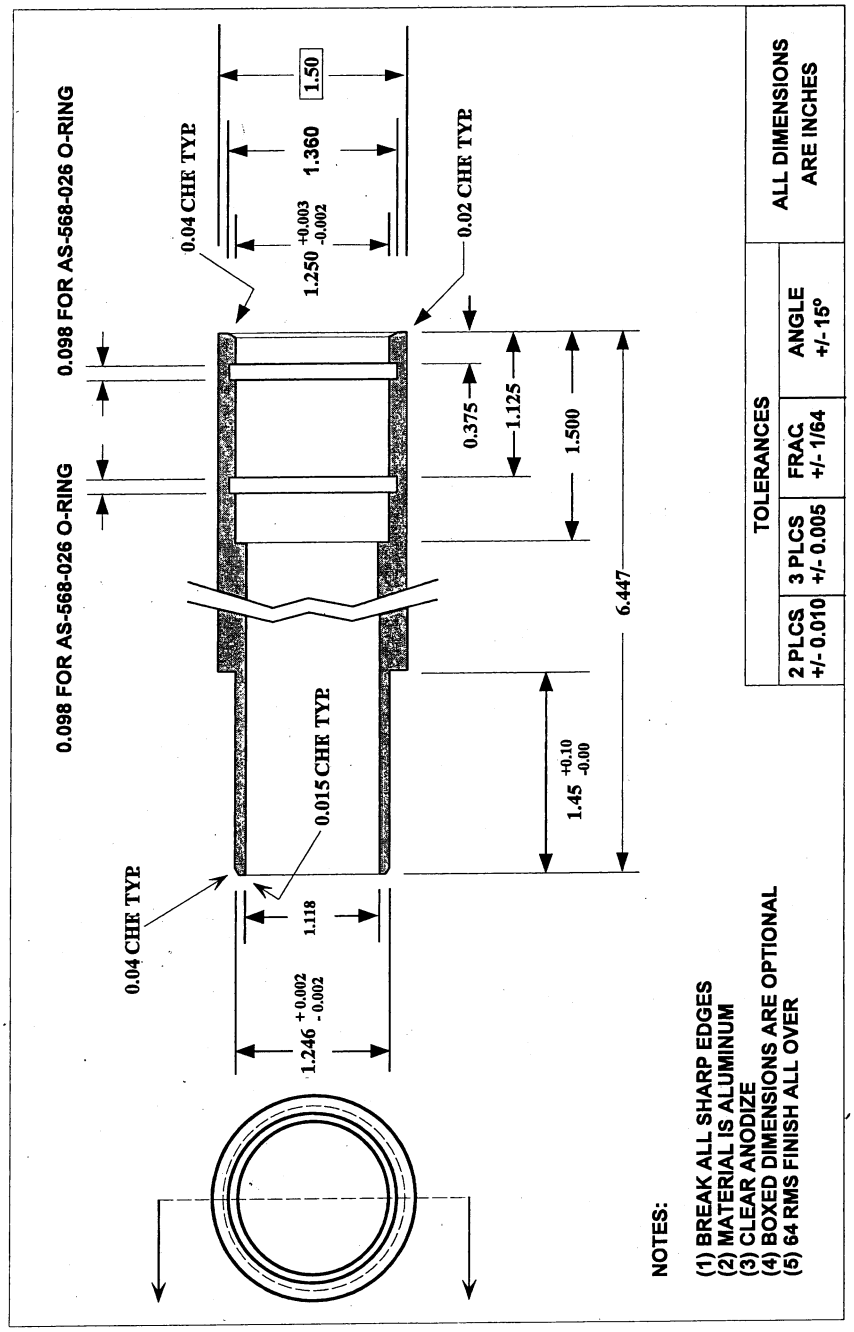
1. Quality Assurance Guidance Document 2.12. Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods. Draft, November 1998 (or later version or supplement, if available). Available at: *http://www.epa.gov/ttn/amtic/pgqa.html.*

14.0 *Figures.*

Figures O–1 is included as part of this appendix O.

BILLING CODE 6560–50–P

FIGURE O-1.DOWNTUBE-EXTENSION



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8. Appendix P is added to part 50 to read as follows:

Appendix P to Part 50—Interpretation of the National Ambient Air Quality Standards for $PM_{10\text{-}2.5}$

1.0 *General.*

(a) This appendix explains the data handling conventions and computations necessary for determining when the 24-hour primary and secondary national ambient air quality standards (NAAQS) for $PM_{10\text{-}2.5}$ specified in § 50.13 of this part are met. $PM_{10\text{-}2.5}$, defined as particles with an aerodynamic diameter more than a nominal 2.5 micrometers and less than or equal to a nominal 10.0 micrometers, is measured in the ambient air by a Federal reference method (FRM) based on appendix O of this part, as applicable, and designated in accordance with part 53 of this chapter, or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Data handling and computation procedures to be used in making comparisons between reported $PM_{10\text{-}2.5}$ concentrations and the levels of the $PM_{10\text{-}2.5}$ NAAQS are specified in the following sections.

(b) Data resulting from exceptional events, for example structural fires or high winds, may require special consideration. In some cases, it may be appropriate to exclude these data in whole or part because they could result in inappropriate values to compare with the levels of the $PM_{10\text{-}2.5}$ NAAQS. In other cases, it may be more appropriate to retain the data for comparison with the levels of the $PM_{10\text{-}2.5}$ NAAQS and then allow EPA to formulate the appropriate regulatory response.

(c) The terms used in this appendix are defined as follows:

Daily values for $PM_{10\text{-}2.5}$ refers to the 24-hour average concentrations of $PM_{10\text{-}2.5}$ calculated (averaged) or measured from midnight to midnight (local standard time).

Designated monitors are those monitoring sites designated in a State or local agency PM

Monitoring Network Description in accordance with part 58 of this chapter.

Design values are the metrics that are compared to the NAAQS levels to determine compliance and are comprised of the 3-year average of annual 98th percentile 24-hour average values recorded at each monitoring location, are referred to as ''24-hour standard design values,'' and are calculated as shown in section 3 of this appendix.

Geographic area design value (e.g., one for a county or defined metropolitan area) is the highest valid site-level design value in that area.

98th percentile means the daily value out of a year of $PM_{10-2.5}$ monitoring data below which 98 percent of all values in the group fall.

Year refers to a calendar year.

2.0 *Requirements for data used for comparisons with the $PM_{10-2.5}$ NAAQS and data reporting considerations.*

(a) Appendix D to part 58 of this chapter specifies which monitors are eligible for making comparisons with the $PM_{10-2.5}$ standards.

(b) Except as otherwise provided in this appendix, only valid FRM/FEM $PM_{10-2.5}$ data required to be submitted to EPA's Air Quality System (AQS) shall be used in the design value calculations.

(c) Raw concentration data (typically hourly for automated continuous instruments and daily for manual, filter-based instruments) shall be reported to AQS in micrograms per cubic meter (μg/m³) to one decimal place, with additional digits to the right being truncated.

(d) Block 24-hour averages shall be computed from available hourly $PM_{10-2.5}$ concentration data for each corresponding day of the year and the result shall be stored in the first, or start, hour (i.e., midnight, hour ''0'') of the 24-hour period. A 24-hour average shall be considered valid if at least 75 percent (i.e., 18) of the hourly averages for the 24-hour period are available. In the event that less than all 24 hourly averages are available (i.e., less than 24, but at least 18), the 24-hour average shall be computed on the basis of the hours available using the number of available hours as the divisor (e.g., 19). 24-hour periods with 7 or more missing hours shall be considered valid if, after substituting zero for the missing hourly concentrations, the 24-hour average concentration is greater than the level of the standard. The computed 24-hour average $PM_{10-2.5}$ concentrations shall be reported to one decimal place (the insignificant digits to the right of the third decimal place are truncated, consistent with the data handling procedures for the reported data).

(e) All calculations shall be implemented on a site-level basis. Site level data shall be processed as follows:

(1) The default dataset for a site shall consist of the measured concentrations recorded from the designated primary FRM/FEM monitor. The primary monitor shall be designated in the appropriate State or local agency PM Monitoring Network Description.

(2) Data for the primary monitor shall be augmented as necessary with data from collocated FRM/FEM monitors. If a valid 24-hour measurement is not produced from the primary monitor for a particular required sampling day, but a valid sample is generated by a collocated FRM/FEM instrument (and recorded in AQS), then that collocated value shall be considered part of the site data record. If more than one valid collocated FRM/FEM value is available, the average of those valid collocated values shall be used as the site value for the day.

3.0 *Comparisons with the $PM_{10-2.5}$ NAAQS.*

3.1 *24-Hour $PM_{10-2.5}$ NAAQS.*

(a) The 24-hour $PM_{10-2.5}$ NAAQS is met when the 24-hour standard design value at each monitoring site is less than or equal to 70 μg/m³. This comparison shall be based on 3 consecutive, complete years of air quality data. A year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. However, years or 3-year periods with high concentrations shall be considered valid, notwithstanding quarters with less than complete data (even quarters with less than 11 samples), if the resulting annual 98th percentile value or resulting 24-hour standard design value (rounded according to the conventions of section 3.2 of this appendix) is greater than the level of the standard.

(b) The use of less than complete data is subject to the approval of EPA, which may consider factors such as monitoring site closures/moves, monitoring diligence, and nearby concentrations in determining whether to use such data.

(c) The equations for calculating the 24-hour standard design values are given in section 3.4 of this appendix.

3.2 *Rounding Conventions.* For the purposes of comparing calculated values to the applicable level of the standard, it is necessary to round the final results of the calculations described in sections 3.4 of this appendix. 24-hour $PM_{10-2.5}$ standard design values shall be rounded to the nearest 1 μg/m³ (decimals 0.5 and greater are rounded up to nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

3.3 *Sampling Frequency Considerations.* Section 58.12 of this chapter specifies the required minimum frequency of sampling for $PM_{10-2.5}$. Exceptions to the specified sampling frequencies, such as a reduced frequency during a season of expected low concentrations (i.e., ''seasonal sampling''), are subject to the approval of EPA. Annual 98th percentile values are to be calculated according to equation 2 in section 3.4 of this appendix when a site operates on a ''seasonal sampling'' schedule.

3.4 *Equations for the 24-Hour $PM_{10-2.5}$ NAAQS.*

(a) When the data for a particular site and year meet the data completeness requirements in section 3.1 of this appendix, calculation of the 98th percentile is accomplished by the steps provided in paragraphs (a) through (c) of this section. Equation 1 of this appendix shall be used to compute annual 98th percentile values, except that where a site operates on an approved seasonal sampling schedule, equation 2 of this appendix shall be used instead. Seasonal sampling, when approved, will be implemented in periods of calendar quarters or months; seasonal sampling seasons shall not divide months. Calculations of all annual 98th percentile values are based on the *applicable* number of samples (as described below), rather than on the *actual* number of samples. For the 24-hour NAAQS, credit will not be granted for more samples than the maximum number of scheduled sampling days in the sampling period. For each month, the applicable number of samples is the lower of the actual number of samples and the scheduled number of samples. The applicable number of samples for a year is the sum of the twelve monthly ''applicable number of samples;'' the applicable number of samples for a season is the sum of the corresponding monthly ''applicable number of samples.'' 98th percentile values shall be calculated as in equations 5 or 6 of this appendix using the applicable number of samples for the year or season. The applicable number of samples will determine how deep to go into the data distribution, but all samples (scheduled or not) will be considered when making the percentile assignment.

(1) *Regular formula for computing annual 98th percentile values.* Sort all the daily values from a particular site and year by ascending value. (For example: x[1], x[2], x[3], * * *, x[n]. In this case, x[1] is the smallest number and x[n] is the largest value.) The 98th percentile is determined from this sorted series of daily values. Compute (0.98) x (an) as the number ''i.d,'' where ''an'' is the applicable number of samples, ''i'' is the integer part of the result, and ''d'' is the decimal part of the result. The 98th percentile value for year y, $P_{0.98,y}$, is calculated using equation 1 of this appendix:

Equation 1

$$P_{0.98,y} = X_{[i+1]}$$

Where:

$P_{0.98,y}$ = 98th percentile for year y;

x[i+1] = the (i+1)th number in the ascending ordered series of numbers for year y; and

i = the integer part of the product of 0.98 and an.

(2) *Formula for computing annual 98th percentile values when sampling frequencies are seasonal.* Calculate the annual 98th percentiles by determining the smallest measured concentration, x, that makes *W(x)* greater than 0.98 using equation 2 of this appendix:

Equation 2

$$W(x) = \frac{d_{High}}{d_{High} + d_{Low}} F_{High}(x) + \frac{d_{Low}}{d_{High} + d_{Low}} F_{Low}(x),$$

Where:

d_{High} = number of calendar days in the ''High'' season;

d_{Low} = number of calendar days in the ''Low'' season;

$d_{High} + d_{Low}$ = days in a year); and

$$F_a(x) = \frac{\text{number of samples in season a that are} \leq x}{\text{applicable number of samples in season a}}$$

Such that ''a'' can be either ''High'' or ''Low;'' ''x'' is the measured concentration; and ''$d_{High}/(d_{High} + d_{Low})$ and $d_{Low}/(d_{High} + d_{Low})$'' are constant and are called seasonal ''weights.''

(b) The 3-year average 98th percentile (24-hour standard design value) is then calculated by averaging the annual 98th percentiles using equation 3 of this appendix:

Equation 3

$$P_{0.98} = \frac{\sum_{y=1}^{3} P_{0.98,y}}{3}$$

(c) The 24-hour standard design value (3-year average 98th percentile) is rounded according to the conventions in section 3.2 of this appendix before a comparison with the standard is made.

[FR Doc. 06–177 Filed 1–13–06; 8:45 am]

BILLING CODE 6560–50–P

Federal Register

Tuesday,
January 17, 2006

Part III

Environmental Protection Agency

40 CFR Parts 53 and 58

Revisions to Ambient Air Monitoring Regulations; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 53 and 58

[EPA–HQ–OAR–2004–0018; FRL–8015–9]

RIN 2060–AJ25

Revisions to Ambient Air Monitoring Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; amendments.

SUMMARY: The EPA is proposing to revise the ambient air monitoring requirements for criteria pollutants. This proposal establishes ambient air monitoring requirements in support of the proposed revisions to the National Ambient Air Quality Standards (NAAQS) for particulate matter published elsewhere in today's **Federal Register**, including new minimum monitoring network requirements for $PM_{10-2.5}$ and criteria for approval of Federal reference and equivalent methods for $PM_{10-2.5}$ (to supplement the Federal reference method for $PM_{10-2.5}$ proposed elsewhere in today's **Federal Register**). This proposal also requires each State to operate one to three monitoring stations that take an integrated, multipollutant approach to ambient air monitoring. The proposed amendments modify the requirements for ambient air monitors by focusing requirements on populated areas with air quality problems and significantly reducing the requirements for criteria pollutant monitors that have measured ambient air concentrations well below the applicable NAAQS. Other proposed amendments revise the requirements for reference and equivalent method determinations (including specifications and test procedures) for fine particulate monitors, monitoring network descriptions and periodic assessments, quality assurance, and data certification. The purpose of the proposed amendments is to enhance ambient air quality monitoring to better serve current and future air quality management and research needs.

DATES: Comments must be received on or before April 17, 2006.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2004–0018, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- E-mail: *a-and-r-docket@epa.gov.*
- Fax: (202) 566–1741.
- Mail: Revisions to Ambient Air Monitoring Regulations, Docket No. EPA–HQ–OAR–2004–0018, Environmental Protection Agency, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.
- Hand Delivery: EPA Docket Center, 1301 Constitution Avenue, NW., Room B102, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2004–0018. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov index.* Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Revisions to the Ambient Air Monitoring Regulations Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The 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 Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For general questions concerning today's proposed amendments, please contact Mr. Lewis Weinstock, U.S. EPA, Office of Air Quality Planning and Standards, Emissions Monitoring and Analysis Division, Ambient Air Monitoring Group (D243–02), Research Triangle Park, North Carolina 27711; telephone number: (919) 541–3661; fax number: (919) 541–1903; e-mail address: *weinstock.lewis@epa.gov.* For technical questions, please contact Mr. Tim Hanley, U.S. EPA, Office of Air Quality Planning and Standards, Emissions Monitoring and Analysis Division, Ambient Air Monitoring Group (D243–02), Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4417; fax number: (919) 541–1903; e-mail address: *hanley.tim@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

Categories and entities potentially regulated by this action include:

Category	NAIC code [1]	Examples of regulated entities
Industry	334513 541380	Manufacturer, supplier, distributor, or vendor of ambient air monitoring instruments; analytical laboratories or other monitoring organizations that elect to submit an application for a reference or equivalent method determination under 40 CFR part 53.

Category	NAIC code [1]	Examples of regulated entities
Federal government	924110	Federal agencies (that conduct ambient air monitoring similar to that conducted by States under 40 CFR part 58 and that wish EPA to use their monitoring data in the same manner as State data) or that elect to submit an application for a reference or equivalent method determination under 40 CFR part 53.
State/local/tribal government	924110	State, territorial, and local, air quality management programs that are responsible for ambient air monitoring under 40 CFR part 58 or that elect to submit an application for a reference or equivalent method determination under 40 CFR part 53. The proposal also may affect Tribes that conduct ambient air monitoring similar to that conducted by States and that wish EPA to use their monitoring data in the same manner as State monitoring data.

[1] North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether your facility or Federal, State, local, or territorial agency would be regulated by this action, you should examine the requirements for reference or equivalent method determinations in 40 CFR part 53, subpart A (General Provisions) and the applicability criteria in 40 CFR 51.1 of EPA's requirements for State implementation plans. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. What Should I Consider as I Prepare My Comments for EPA?

Do not submit information containing Confidential Business Information (CBI) to EPA through *www.regulations.gov* or e-mail. Send or deliver information identified as CBI only to the following address: Roberto Morales, OAQPS Document Control Officer (C404–02), U.S. EPA, Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina 27711, Attention Docket ID EPA–HQ–OAR–2004–0018. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

C. Where Can I Get a Copy of This Document and Other Related Information?

In addition to being available in the docket, an electronic copy of today's proposed amendments is also available on the Worldwide Web (WWW) through the Technology Transfer Network (TTN). Following the Administrator's signature, a copy of the proposed amendments will be placed on the TTN's policy and guidance page for newly proposed or promulgated rules at *http://www.epa.gov/ttn/oarpg.* The TTN provides information and technology exchange in various areas of air pollution control.

D. Will There Be a Public Hearing?

Public hearings will be held concurrently with the public hearings on the proposed amendments to the NAAQS for particulate matter published elsewhere in this **Federal Register.** The EPA intends to hold public hearings during February 2006 in Philadelphia, Pennsylvania; Chicago, Illinois; and San Francisco, California. The EPA will announce the date, location, and time of the public hearings in a separate **Federal Register** notice.

E. Did EPA Conduct a Peer Review Before Issuing This Notice?

The EPA sought expert scientific review of the proposed methods, technologies, and approach for ambient air monitoring by the Clean Air Scientific Advisory Committee (CASAC). The CASAC is a Federal advisory committee established to review scientific and technical information and make recommendations to the EPA Administrator on issues related to the air quality criteria and corresponding NAAQS. CASAC constituted a National Ambient Air Monitoring Strategy (NAAMS) Subcommittee in 2003 to provide advice for a strategy for the national ambient air monitoring programs. This subcommittee, which operated over a one-year period, and a new subcommittee on Ambient Air Monitoring and Methods (AAMM), formed in 2004, provided the input for CASAC on its consultations, advisories, and peer-reviewed recommendations to the EPA Administrator.

In July 2003, the CASAC NAAMS Subcommittee held a public meeting to review EPA's draft National Ambient Air Monitoring Strategy document (dated September 6, 2002), which contained technical information underlying planned changes to the ambient air monitoring networks. The EPA continued to consult with the CASAC AAMM Subcommittee throughout the development of the proposed amendments. Public meetings were held in July 2004, December 2004, and September 2005 to discuss the CASAC review of nearly 20 documents concerning methods and technology for measurement of particulate matter (PM); data quality objectives for PM monitoring networks and related performance-based standards for approval of equivalent continuous PM monitors; reconfiguration of ambient air monitoring stations; [1] and other technical aspects of the proposed amendments. These documents, along with CASAC review comments and other information are available at: *http://www.epa.gov/ttn/amtic/casacinf.html.*

F. How Is This Document Organized?

The information presented in this preamble is organized as follows:

I. General Information
- A. Does this action apply to me?
- B. What should I consider as I prepare my comments for EPA?
- C. Where can I get a copy of this document and other related information?
- D. Will there be a public hearing?
- E. Did EPA conduct a peer review before issuing this notice?
- F. How is this document organized?

II. Overview

[1] "Station" and "site" are used somewhat interchangeably in this notice of proposed rulemaking. When there is a difference "site" generally refers to the location of a monitor, while "station" refers to a suite of measurements at a particular site.

A. What is the purpose of today's proposal?
B. What are the major changes proposed to the ambient air monitoring regulations?
C. When would the proposed amendments affect States, local governments, tribes, and other stakeholders?
D. How would EPA implement the new requirements?
III. Background
A. What is the role of ambient air monitoring in air quality management?
B. What is the history of ambient air monitoring?
C. What revisions to the National Ambient Air Quality Standards for particulate matter also are proposed today?
D. How do the monitoring data apply to attainment or nonattainment designations and findings?
IV. Proposed Monitoring Amendments
A. What are the proposed terminology changes?
B. What are the proposed requirements for approval of reference or equivalent methods?
C. What are the proposed requirements for quality assurance programs for the National Ambient Air Monitoring System?
D. What are the proposed monitoring methods for the National Ambient Air Monitoring System?
E. What are the proposed requirements for the number and location of monitors to be operated by State and local agencies?
F. What are the proposed probe and monitoring path siting criteria?
G. What are the proposed data reporting, data certification, and sample retention requirements?
V. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer Advancement Act
J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

II. Overview

A. What Is the Purpose of Today's Proposal?

The EPA is proposing a number of changes to the ambient air quality monitoring requirements of 40 CFR parts 53 and 58 to ensure that the national network of air monitors will meet the current and future data needs of EPA (and other Federal), State, local, and tribal air quality management agencies. While much of today's proposed rule outlines changes to the monitoring requirements for particulate matter (PM), there are additional changes relating to all the other criteria pollutants (ozone (O_3), carbon monoxide (CO), sulfur dioxide (SO_2), nitrogen dioxide (NO_2), and lead (Pb)) included in this proposal.

Some of these proposed changes are in support of the proposed revisions to the National Ambient Air Quality Standards (NAAQS) for PM in 40 CFR part 50 published elsewhere in today's **Federal Register**.[2] These changes are essential to implementation of the proposed NAAQS for PM. Included among these proposed PM-related changes are new provisions for addition to 40 CFR parts 53 and 58 which address approval of methods and $PM_{10-2.5}$ monitoring requirements. The added provisions would address federal reference method (FRM) equivalency determinations for continuous $PM_{10-2.5}$ monitors and the requirements for the number of $PM_{10-2.5}$ monitors a State must deploy. Another important element of the provisions for $PM_{10-2.5}$ is a proposal for the conditions under which a $PM_{10-2.5}$ monitor may be compared to the $PM_{10-2.5}$ NAAQS.

A number of amendments to existing provisions for $PM_{2.5}$ monitoring are also proposed. These would be important to the implementation of the revised $PM_{2.5}$ NAAQS because they take advantage of the experience and insight gained by EPA and the States during the past 7 years of $PM_{2.5}$ monitoring. One of the proposed $PM_{2.5}$ changes involves the criteria for FRM equivalency determinations for continuous $PM_{2.5}$ monitors. We anticipate that this change would allow States to operate continuous monitors at more required monitoring sites, providing more robust data for the $PM_{2.5}$ air quality program.

Other proposed changes are based on EPA's assessment that the monitoring regulations are not fully aligned with current data needs and opportunities across all the NAAQS pollutants—including PM but also including O_3, CO, SO_2, NO_2, and Pb. This misalignment has developed over time as ambient conditions have improved for some pollutants. Also, new monitoring technologies have been developed that provide attractive opportunities for obtaining more robust and useful data. The EPA recognized that changes were needed several years ago and since then, we have been developing the specifics of these changes with States and other stakeholders.[3] This group of proposed changes includes relaxation of some long-standing monitoring requirements which we believe are outdated or unnecessarily inflexible. This group of proposed changes also includes a new requirement for States to operate a new type of multipollutant monitoring station, which we plan to call National Core (NCore) stations. Other proposed changes relate to quality assurance requirements, monitor siting, special purpose monitoring, and data management.

We are proposing both the PM NAAQS review-related changes as well as the overarching NAAQS monitoring system changes together because they are strongly related in terms of regulatory language and in terms of implementation decision making. Resources for ambient monitoring are limited, and the cost of new types of monitoring to meet new requirements such as those for $PM_{10-2.5}$ must be offset, at least in part, by reducing resources for lower value types of monitoring. The proposed revisions to the monitoring regulations, when finalized, will improve EPA's and our monitoring partners' abilities to manage available funds to support monitoring activities and create a coordinated, integrated, multipurpose, and flexible monitoring system. In addition, it will be easier for the public to comment on the proposed changes if they are presented together rather than in sequential proposals.

The EPA notes that in the proposed regulatory language for 40 CFR parts 53 and 58, we are reprinting a number of existing provisions without change (for example, a number of definitions in current 58.1). We are doing so solely for the readers' convenience in order that the provisions we are proposing can appear in a single context. The EPA is not reproposing, reconsidering, or otherwise reopening any of these reprinted provisions. We will regard any comments as to these provisions as outside the scope of this proposal.

[2] The proposed amendments to the National Ambient Air Quality Standards include revised standards for $PM_{2.5}$ (particulate mater with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers) and new standards for $PM_{10-2.5}$ (particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers and greater than or equal to a nominal 2.5 micrometers).

[3] Our work with States and other monitoring program stakeholders has included the development of successive versions of a draft report, ''National Ambient Air Monitoring Strategy''. The most recent version, dated December 2005, is available in the public docket. The document describes in more depth the reasons for proposing many of the changes presented in this notice, excluding the changes related to $PM_{10-2.5}$. It also discusses strategy elements that are related to, but separate from, the regulatory provisions in 40 CFR parts 53 and 58 such as funding, training, *etc.*

B. What Are the Major Changes Proposed to the Ambient Air Monitoring Regulations?

The summary of each proposed change given here ends with a reference to the part(s) of section IV of this preamble that describes that change in detail.

• We propose to require States to operate from one to three National Core (NCore) multipollutant monitoring sites.[4] Monitors at NCore multipollutant sites would be required to measure particles ($PM_{2.5}$, speciated $PM_{2.5}$, $PM_{10-2.5}$), O_3, SO_2, CO, nitrogen oxides ($NO/NO_2/NO_Y$), and basic meteorology. Monitors for all the gases except for O_3 would be required to be more sensitive than standard Federal reference method (FRM)/Federal equivalent method (FEM) monitors, so they could accurately report concentrations that are well below the respective NAAQS but that can be important in the formation of O_3 and PM. We are not proposing specific locations for these sites, but instead would collaborate on site selection with States individually and through multistate organizations. Our objective is that sites be located in broadly representative urban (about 55 sites) and rural (about 20 sites) locations throughout the country to help characterize regional and urban patterns of air pollution. We expect that in many cases States would collocate these new stations with Photochemical Assessment Monitoring Station (PAMS) sites already measuring O_3 precursors and/or National Air Toxic Trends Station (NATTS) sites measuring air toxics.

These sites would still create points of integration among the existing networks for criteria pollutants, each of which was originally designed with only a single pollutant in mind. Where collocated with sites already measuring O_3 precursors or air toxics, the degree of integration across pollutants of concern would be even stronger. Data from these NCore sites would be used for several purposes that cannot be served as well using only data available from existing networks. Forecasting of the Air Quality Index (AQI) would be improved by feeding several collocated and interdependent pollutant concentration measurements into an air quality model in near real-time to better represent current conditions, from which the model could provide an improved forecast of O_3 and particle levels for the public. Studies that track long-term trends of criteria pollutants, and thereby help demonstrate the accountability of implemented emissions control programs, would be improved by utilizing higher-sensitivity monitoring equipment for pollutants whose measured levels are well below the NAAQS. Air quality model development and validation efforts would benefit by having a long-term network of several important and interdependent measurements at improved time-scales (e.g., hourly instead of daily sample concentrations on PM methods) at a network of sites expected to remain in place over many years to allow testing of how well models simulate co-pollutant interactions. Where applicable siting criteria for PM or O_3 monitoring stations are met, NCore sites could also be used to satisfy minimum monitoring requirements for PM and O_3 and data from these stations could be used in designation decisions and in development of control strategies.[5] The NCore proposals are described more fully in section IV.E.1 of this preamble.

• We propose monitoring requirements for $PM_{10-2.5}$ which are based on deploying a network of FEM monitors that would be approved based on criteria for comparability to monitors utilizing the FRM proposed elsewhere in today's **Federal Register**. Requirements for $PM_{10-2.5}$ Class I, Class II, and Class III candidate equivalent methods would be established. The definition of a ''Class III equivalent method'' would allow for designation of continuous and semi-continuous ambient air monitoring methods for $PM_{10-2.5}$.[6] Because we intend that most of the monitors used in the $PM_{10-2.5}$ network will use continuous or semi-continuous equivalent methods, the proposal for Class III approval requirements is particularly important for $PM_{10-2.5}$. We are also proposing minimum requirements for a $PM_{10-2.5}$ monitoring network, including criteria for the number of FRM/FEM monitoring sites in each metropolitan area (which would vary from zero to five) and criteria for how monitors should be placed within an area. Closely linked to the placement criteria is a proposed test for the suitability of a $PM_{10-2.5}$ monitoring site for comparison with the $PM_{10-2.5}$ NAAQS. We are also proposing that speciation monitoring of $PM_{10-2.5}$ be required in some areas. These proposals appear in sections IV.B.2, IV.B.3, IV.B.5, and IV.B.6 (dealing with equivalent methods) and section IV.E.2 (dealing with number of monitors, their placement, and the use of data from them in comparisons to the NAAQS) of this preamble.

• We propose amendments to facilitate the wider use of continuous $PM_{2.5}$ monitors by revising performance-based FEM equivalence standards for continuous $PM_{2.5}$ monitors and allowing for approved regional methods (ARM) for continuous $PM_{2.5}$ mass monitors. Existing requirements for $PM_{2.5}$ Class I and Class II candidate equivalent methods would be revised, and new requirements for $PM_{2.5}$ Class III candidate equivalent methods would be added. The definition of a Class III equivalent method would be revised to allow for designation of continuous and semi-continuous ambient air monitoring methods for $PM_{2.5}$. These proposals appear in sections IV.B.4, IV.B.5, and IV.B.6 (FEM equivalence standards) and in section IV.D.2 (approved regional methods) of this preamble.

• In association with the proposed requirements for new $PM_{10-2.5}$ stations and new NCore multipollutant stations, we propose to remove the existing requirements for certain numbers of State and local air FRM/FEM monitoring stations for CO, PM_{10}, SO_2, and NO_2, and reduce them for Pb.

[4] The National Core (NCore) multi-pollutant stations are part of an overall strategy to integrate multiple monitoring networks and measurements, including research grade sites and State and local air monitoring stations (SLAMS). Research grade sites would provide complex, research-grade monitoring data for special studies; the proposed amendments do not include requirements for these sites. SLAMS would include sites needed for National Ambient Air Quality Standard comparisons and other data needs of monitoring agencies. The number and placement of SLAMS monitors would vary according to the pollutant, population, and level of air quality problem. The April 2004 draft version of the National Ambient Air Monitoring Strategy presented a taxonomy in which monitoring stations belonged to three levels, called Level 1 (research sites), Level 2 (what are called NCore multipollutant sites in this notice), and Level 3 (what have been called SLAMS/NAMS (national air monitoring stations) in the past). The three Levels combined were referred to as the NCore System. We have decided to dispense with the three-level taxonomy because it does not encompass all relevant monitoring efforts. We now refer to the collection of all ambient air monitoring—including research sites, all types of monitoring by States and Tribes, and all types of ambient monitoring by Federal agencies—as the National Ambient Air Monitoring System (NAAMS). We are retaining the ''NCore'' label for the multipollutant sites in particular, because the term with this meaning has become part of the vocabulary of the State/local monitoring community.

[5] While not a part of our rationale for requiring States to operate these sites, we note that the data from them will also be of use in future health effects studies.

[6] Class I equivalent methods have only minor deviations or modifications from the specified reference method. Class II equivalent methods include other filter-based, integrated, gravimetric-type methods similar to the specified reference method but with greater deviations than allowed for a Class I method. Class III equivalent methods include all candidate $PM_{2.5}$ and $PM_{10-2.5}$ methods not classified as Class I or Class II. We expect that most candidate Class III equivalent methods will be continuous or semi-continuous methods.

However, States would still need EPA approval to move or remove existing monitoring stations for these pollutants.[7] To expedite reviews and provide more certainty to State planning, a specific process and several substantive criteria are proposed to govern EPA approval actions. Also, the requirement that EPA approval be obtained at the Administrator level (rather than the Regional Administrator level) for the subset of these monitors historically designated as NAMS would be eliminated, and all changes would be reviewed by the Regional Administrator.[8] In addition, the requirements for monitoring of O_3 precursors under the PAMS program would be reduced by about 50 percent. These proposed changes allow PAMS monitoring to be more customized to local data needs rather than meeting so many specific requirements common to all subject O_3 nonattainment areas; the PAMS changes would also give States the flexibility to reduce the overall size of their PAMS programs—within limits—and to use the associated resources for other types of monitoring they consider more useful. Requirements for minimum numbers of O_3 and $PM_{2.5}$ monitors would be retained, with small adjustments. The overall impact of these changes would be to retain comprehensive monitoring networks for $PM_{2.5}$ and O_3, and to reduce the number of SO_2, CO, NO_2, Pb, and PM_{10} monitors in areas that do not have air quality problems for these pollutants. $PM_{2.5}$ and O_3 monitoring would be mostly unaffected because $PM_{2.5}$ and O_3 are current nonattainment challenges and comprehensive monitoring is needed to support efforts to attain the NAAQS. Many existing monitors for SO_2, CO, NO_2, Pb, and PM_{10} can be discontinued because they are now well below the applicable NAAQS and the data from most of these monitors have low value for air quality management and research purposes. We expect reductions in the number of monitors for these pollutants nationally to be in the range of about 33 percent for SO_2 to about 90 percent for NO_2.[9] This would free up resources to go beyond minimum requirements for O_3, $PM_{2.5}$, $PM_{10\text{-}2.5}$, or other pollutants such as air toxics in areas where there are ongoing or new air quality management challenges. These proposed changes are described in sections IV.E.3 (number of $PM_{2.5}$ monitors), IV.E.4 (PM_{10} monitors), IV.E.5 (number of O_3 monitors), IV.E.6 (number of CO, SO_2, NO_2, and Pb monitors), IV.E.7 (PAMS monitors), and IV.E.8 (process and criteria for moving or removing monitors) of this preamble.

- We propose updated quality assurance (QA) requirements for all NAAQS pollutants, emphasizing the responsibility of each monitoring program for its data quality based on the use of data quality objectives for monitoring precision, data completeness, and bias. States would be required to provide for adequate, independent performance audits of FRM/FEM monitoring stations. We describe several options for how they could meet this audit responsibility. One way would be to agree to have appropriated State and Territorial Air Grant (STAG) funds retained by EPA to cover the cost of performing these audits; another option would be a partnership between State/local monitoring agencies (or independent subunits within one agency). The statistics for calculating precision and bias would also would be revised. Quality assurance requirements would be defined for $PM_{10\text{-}2.5}$ monitoring. See section IV.C of this preamble for details.
- We propose to revise the provisions regarding special purpose monitors (SPM) for all NAAQS pollutants. In certain restricted situations, data from SPM would not be usable for nonattainment designations. SPM that are FRM, FEM, or ARM monitors would be required to meet standard quality assurance requirements for their monitor type, and States would be required to report data from such SPM to the Air Quality System (AQS). See section IV.E.9 of this preamble for details.
- We propose to require that States conduct in-depth network assessments every 5 years. These assessments are intended to ensure that future gaps between data needs and monitoring operations are identified and filled in a timely manner. See section IV.E.11 of this preamble for specifics.
- We propose to move requirements for reporting certain operational data from PM samplers from 40 CFR part 50 to 40 CFR part 58, and to reduce the number of data elements required to be reported. This would put all similar data reporting requirements together in 40 CFR part 58 and allow them to apply to both FRM and FEM monitors. See section IV.G.1 of this preamble.
- We propose a new requirement for the reporting of $PM_{2.5}$ field blank data.[10] Only the data from field blanks which States are already taking into the field and weighing in their laboratories would be required to be reported under this proposal. Having the data from these field blanks available to the national monitoring community would help EPA and other researchers understand the relationship between the mass of PM that is sampled and weighed on a regular PM filter and the PM that is actually present in ambient air. See section IV.G.2 of this preamble or details.
- We propose to require State or local agencies to submit annual data certification letters, by May 1 of each year, to certify that the ambient air concentration and QA data submitted to EPA's AQS for the previous year are complete and accurate. These letters are now required on July 1 of each year. See section IV.G.3 of this preamble.
- We propose to require States to archive $PM_{2.5}$ and $PM_{10\text{-}2.5}$ filters for one year (the current requirement is only for $PM_{2.5}$ filters).[11] See section IV.G.4 of this preamble.
- We propose to increase the distance that ozone monitors should be placed downwind of roadways, to reduce the possibility that ozone readings will be artificially low due to ozone scavenging by NO emitted by vehicles on roadways. See section IV.F of this preamble.

C. When Would the Proposed Amendments Affect State and Local Governments, Tribes, and Other Stakeholders?

1. State and Local Governments

Only State governments, and those local governments that have been assigned responsibility for ambient air monitoring by their States, are subject to the mandatory requirements of 40 CFR part 58.[12]

The proposed compliance date for deployment of $PM_{10\text{-}2.5}$ monitors by States is January 1, 2009. A plan for this

[7] Where the PM_{10} annual and 24-hour NAAQS have both been revoked, the proposed rule does not require prior EPA approval for discontinuing a PM_{10} monitor.

[8] EPA Administrator approval would continue to be required for changes to some $PM_{2.5}$ speciation monitoring stations, to any required NCore multipollutant station, and to any PAMS station.

[9] Detailed estimates of the current and expected future number of each type of monitor over the 3 years following promulgation are given in the supporting statement to the Information Collection Request for this action, available in the docket.

[10] Field blanks are filters which are handled in the field as much as possible like actual filters except that ambient air is not pumped through them, to help quantify contamination and sampling artifacts.

[11] A $PM_{10\text{-}2.5}$ ''filter'' from a FRM monitor would actually consist of the separate PM_{10} and $PM_{2.5}$ filters. Some equivalent methods, if approved, could involve a single $PM_{10\text{-}2.5}$ filter. All filters from both types of monitors would be subject to the archiving requirement.

[12] Throughout this preamble, ''States'' is meant to also refer to local governments that have been assigned responsibility for ambient air monitoring within their respective jurisdiction by their States. We also use ''monitoring organization'' to refer to States, local agencies, and/or Tribes conducting monitoring under or guided by the provisions of 40 CFR part 58.

deployment would be due January 1, 2008, unless an extension is granted to July 1, 2008. These plans would be subject to EPA approval at the Regional Office level.

State (or local) agencies would also be required to submit earlier annual data certification letters and make electronic reports of QA data to the AQS, starting May 1, 2009.

The proposed amendments require that State (or local) agencies fully implement the required NCore multipollutant sites by January 1, 2011 (more than 4 years after the expected date of promulgation of the amendments). A plan for this implementation, including site selection, would be due July 1, 2009.

Network assessments would be required every 5 years starting July 1, 2009.

State and local agencies would be required to comply with existing requirements in 40 CFR part 58 (including annual network review and data reporting), until the compliance date for each new requirement is reached.

Some provisions in the proposed amendments to 40 CFR part 58 (those that do not involve deployment of new monitoring stations or new types of data handling) would be effective as of the effective date of the final rule.

2. Tribes

Under the Tribal Authority Rule (TAR) (40 CFR part 49), which implements section 301(d) of the CAA, Tribes may elect to be treated in the same manner as a State in implementing sections of the CAA. However, the EPA determined in the TAR that it was inappropriate to treat Tribes in a manner similar to a State with regard to specific plan submittal and implementation deadlines for NAAQS-related requirements, including, but not limited to, such deadlines in CAA sections 110(a)(1), 172(a)(2), 182, 187, and 191. See 40 CFR 49.4(a). For example, an Indian tribe may choose, but is not required, to submit implementation plans for NAAQS related requirements, nor are they required to monitor. If a Tribe elects to do an implementation plan, the plan can contain program elements to address specific air quality problems in a partial program. The EPA will work with the Tribe to develop an appropriate schedule which meets the needs of each Tribe.

Indian tribes have the same rights and responsibilities as States under the CAA to implement elements of air quality programs as they deem necessary. Tribes can choose to engage in ambient air monitoring activities. In many cases, Indian tribes are required by EPA regions to institute strict quality assurance programs, utilize FRM or FEM when comparing their data to the NAAQS, and to insure that the data collected is qualitative and representative of their respective airsheds. For FRM and FEM monitors used for NAAQS attainment or nonattainment determinations, quality assurance requirements of 40 CFR part 58 must be followed and would be viewed by EPA as an indivisible element of a regulatory air quality monitoring program.

3. Other Stakeholders

Manufacturers of continuous $PM_{2.5}$ and $PM_{10\text{-}2.5}$ instruments would be able to apply for designation of their instruments as FEM as soon as the notice of final rulemaking is signed. The EPA is eager to receive such applications as soon as manufacturers can collect and analyze the necessary supporting data.

D. How Would EPA Implement the New Requirements?

After promulgation, we would implement the new requirements using several mechanisms. We expect to work with each State to develop the monitoring plans for their new $PM_{10\text{-}2.5}$ and NCore multipollutant monitoring stations. For example, we would negotiate the selection of required new monitoring sites (or new capabilities at existing sites) and their schedules for start up as well as plans to discontinue sites that were no longer needed. The EPA would negotiate with each State its annual grants for air quality management activities, including ambient monitoring work. We would negotiate grants that provide funding to meet minimum requirements and which have milestones for completion of necessary changes. Once States have established a new monitoring infrastructure to meet the new requirements, we would review State monitoring activities, submitted data, and plans for further changes on an annual basis.

The EPA's support for and participation in enhancing the national ambient air monitoring system to serve current and future air quality management and research needs will extend beyond ensuring that States meet the minimum requirements of the monitoring rules, including the proposed amendments. We will work with each State or local air monitoring agency to determine what affordable monitoring activities above minimum requirements would best meet the diverse needs of the individual air quality management program as well as the needs of other data users. In particular, we may negotiate with some States, and possibly with some Tribes, for the establishment and operation of some additional rural NCore multipollutant monitoring stations to complement the multipollutant stations that would be required by the proposed changes to the monitoring regulations. We also expect to work with the States, and possibly with some Tribes, to establish and operate more $PM_{10\text{-}2.5}$ speciation sites than the minimums that would be required by the proposed amendments. We expect to work with the States, and possibly with some Tribes, to establish and operate rural $PM_{10\text{-}2.5}$ mass concentration sites in less urbanized locations.

An important element of implementing the new requirements will be EPA's role in encouraging the development and application of Federal equivalent methods (FEM), in particular for continuous methods of measuring $PM_{2.5}$ and $PM_{10\text{-}2.5}$. We have determined that continuous monitoring of $PM_{2.5}$ has many advantages over the filter-based Federal reference method. One of the proposed changes makes it more practical for manufacturers of continuous $PM_{2.5}$ instruments to obtain designation for them as FEM or approved regional methods. To ensure objectivity and sound science, EPA's Office of Research and Development would continue to review applications for FEM designations based on the criteria proposed today and would recommend approval or disapproval to the EPA Administrator.

We will also provide technical guidance documents and training opportunities for State, local, and Tribal monitoring staff to help them select, operate, and use the data from new types of monitoring equipment. We have already distributed a technical assistance document on the precursor gas monitors [13] that will be part of the multipollutant sites and we have conducted three training workshops on these monitors. Additional guidance will be developed and provided on some other types of monitors with which many State monitoring staff are currently unfamiliar, and on network design, site selection, quality assurance, and other topics. While Tribes are not to be subject to the requirements of the proposed monitoring amendments,

[13] Technical Assistance Document (TAD) for Precursor Gas Measurements in the NCore Multipollutant Monitoring Network. Version 4. U.S. Environmental Protection Agency. EPA–454/R–05–003. September 2005. Available at: *http://www.epa.gov/ttn/amtic/pretecdoc.html.*

these technical resources will also be available to them directly from EPA and via grantees, such as the Institute for Tribal Environmental Professionals and the Tribal Air Monitoring Support Center.

In partnership with States, we will also continue to plan and manage State technical assistance grants (STAG) to support the National Park Service's operation of the IMPROVE monitoring network, which provides important data for implementing both regional haze and $PM_{2.5}$ attainment programs.[14]

We will also continue to operate the Clean Air Status and Trends Network (CASTNET), which monitors for O_3, PM, and chemical components of PM in rural areas across the nation.[15] We are in the process of revising CASTNET to upgrade its monitoring capabilities to allow it to provide even more useful data to multiple data users. We expect that about 20 CASTNET sites will have new capabilities at least equivalent to the capabilities envisioned for NCore multipollutant sites. Those sites would reduce the number of, and complement, rural multipollutant sites funded with limited State/local grant funds.

We recognize that some air quality management issues require ambient concentration and deposition data that cannot be provided by the types of monitoring required by the proposed monitoring amendments and other activities addressed in today's proposal. These issues include near-roadway exposures to emissions from motor vehicles and mercury deposition. We are actively researching these issues and developing plans for monitoring programs to address them, but these issues are outside the scope of this proposal.

III. Background

A. What Is the Role of Ambient Air Monitoring in Air Quality Management?

Ambient air monitoring systems are a critical part of the nation's air quality management program infrastructure. We use the ambient air monitoring data for a wide variety of purposes as part of an iterative process in managing air quality. This iterative process involves a continuum of setting standards and objectives, designing and implementing control strategies, assessing the results of those control strategies, and measuring progress. The data have many uses throughout this system, such as: Determining compliance with the National Ambient Air Quality Standards (NAAQS); characterizing air quality status and trends; estimating health risks and ecosystem impacts; developing and evaluating emissions control strategies; and measuring overall progress for the air pollution control program. Ambient air monitoring data provide accountability for control strategy reductions by tracking long-term trends of criteria and noncriteria pollutants and their precursors. The data also form the basis for air quality forecasting and other public air quality reports.

More detailed ambient monitoring data are needed to meet current and future program and research needs. The data collected by State and local agencies under the proposed monitoring amendments would:

- Provide more timely Air Quality Index reporting to the public by supporting continuous particle measurements needed for AIRNow air quality forecasting and other public reporting mechanisms;
- Improve the development of emissions control strategies through more effective air quality model evaluation and other observational methods; and
- Support long-term health assessments that contribute to ongoing reviews of the NAAQS and other scientific studies ranging across technological, health, and atmospheric process disciplines.

B. What Is the History of Ambient Air Monitoring?

1. Statutory Authority

The EPA rules for ambient air monitoring are authorized under sections 110, 301(a), and 319 of the Clean Air Act (CAA). Section 110(a)(2)(B) of the CAA requires that each State implementation plan (SIP) provide for the establishment and operation of devices, methods, systems, and procedures needed to monitor, compile, and analyze data on ambient air quality and for the reporting of air quality data to EPA. Section 301(a) of the CAA authorizes EPA to develop regulations needed to carry out the Agency's mission and establishes rulemaking requirements. Uniform criteria to be followed when measuring air quality and provisions for daily air pollution index reporting are required by CAA section 319.

2. Ambient Air Monitoring Regulations

The EPA's procedures for determining and designating reference and equivalent methods (40 CFR part 53) have been in place since 1975 (40 FR 7049, February 18, 1975). Reference methods for criteria pollutants provide uniform, reproducible measurements of concentrations in the ambient air. Equivalent methods allow for the introduction of new and innovative technologies for the same purpose, provided the technologies produce measurements comparable to reference methods under a variety of monitoring conditions.

Subpart A of 40 CFR part 53 (General Provisions) establishes definitions; general requirements for designation of Federal reference methods (FRM) and Federal equivalent methods (FEM); procedures for submitting, processing, and approving applications; and associated provisions. The general requirements identify the applicable requirements or tests that a candidate method must meet to be approved as a FRM or FEM. All manual or automated methods must meet the applicable requirements in 40 CFR part 53, subpart C (Procedures for Determining Comparability Between Candidate Methods and Reference Methods). Automated equivalent methods for pollutants other than PM_{10} or $PM_{2.5}$ also must meet the requirements in 40 CFR part 53, subpart B (Procedures for Testing Performance Characteristics of Automated Methods for SO_2, CO, O_3, and NO_2). A manual sampler or automated method for PM_{10}, Class I equivalent method for $PM_{2.5}$, or Class II equivalent method for $PM_{2.5}$ also must meet the requirements in 40 CFR part 53, subpart D (Procedures for Testing Performance Characteristics of Methods for PM_{10}), subpart E (Procedures for Testing Physical (Design) and Performance Characteristics of Reference Methods and Class I Equivalent Methods for $PM_{2.5}$), or subpart F (Procedures for Testing Performance Characteristics of Class II Equivalent Methods for $PM_{2.5}$), as applicable. The existing rule adopts a case-by-case approach for $PM_{2.5}$ Class III candidate equivalent methods. The regulations in 40 CFR part 53 have been amended several times since 1975 to reflect the addition of new and revised reference methods and advances in monitoring methods and technologies for criteria pollutants.

In 1979 (44 FR 27558, May 10, 1979), EPA issued the first regulations for ambient air quality surveillance (40 CFR part 58) for all pollutants subject to NAAQS. Within 40 CFR part 58, subpart A (General Provisions) establishes definitions, and subpart B (Monitoring Criteria) sets requirements for quality assurance, methods, siting, operating

[14] Additional information on EPA/National Park Service IMPROVE (Interagency Monitoring of Protected Visual Environments) Visibility Program is available at: *http://www.epa.gov/ttn/amtic/visdata.html.*

[15] Additional information on CASTNET is available at: *http://www.epa.gov/castnet/.*

schedules, and special purpose monitors. Subpart C (State and Local Air Monitoring Stations), subpart D (National Air Monitoring Stations), and subpart E (Photochemical Assessment Monitoring Stations) generally define the current monitoring networks. Appendices A through G to 40 CFR part 58 contain more detailed requirements on quality assurance; monitoring methods, network design, and siting criteria; and air quality reporting. Subpart F (Air Quality Index Reporting), subpart G (Federal Monitoring), and appendices F and G to 40 CFR part 58 define annual and daily reporting requirements.

Most of the major amendments to the monitoring regulations made after 1979 coincide with the NAAQS revisions and include the addition of provisions for PM_{10} (52 FR 24740, July 1, 1987) and $PM_{2.5}$ (62 FR 38833, July 18, 1997). Photochemical assessment monitoring stations (PAMS) were established in 1993 to monitor ozone and visibility (58 FR 8468, February 12, 1993).

3. Monitoring Networks

More than 5,500 monitors at about 3,000 sites in the State and local air monitoring stations (SLAMS) and national air monitoring stations (NAMS) networks comprise the majority of monitors measuring criteria pollutants using FRM or FEM for direct comparison to the NAAQS. The NAMS are a subset of SLAMS that are designated as national trends sites. The $PM_{2.5}$ network consists of ambient air monitoring sites that make mass or chemical speciation measurements. Within the $PM_{2.5}$ network operated by State and local agencies, there are approximately 1,200 FRM filter-based samplers and about 450 continuous monitors for mass measurements. Chemical speciation measurements are made at 54 ''Speciation Trends Network'' sites that are intended to remain in operation indefinitely and about 200 other, potentially less permanent sites used to support SIP development and other monitoring objectives. These stations collect aerosol samples and analyze the filters for trace elements, major ions, and carbon fractions.

Ambient air monitors in the PAMS network measure ozone precursors at 109 stations in 25 serious, severe, or extreme ozone nonattainment areas. The PAMS monitors use near-research-grade measurement technologies to produce continuous data for more than 50 volatile organic compounds during summer ozone seasons.

In addition to the NAMS/SLAMS/PAMS sites, there are approximately 310 ambient air toxics monitoring sites, the majority of which are Federally funded and report data to EPA's Air Quality System (AQS).

Ambient air monitoring stations also are operated by Indian Tribes. Thirty-one Tribes are currently making data from 119 individual monitors available to EPA and others. Approximately 73 Tribal sites monitor for PM_{10} and $PM_{2.5}$, and about 16 monitor for ozone.

The Clean Air Status and Trends Network (CASTNET) is cooperatively operated and funded by EPA with the National Park Service. The EPA's Office of Air and Radiation operates a majority of the monitoring stations with contractor support; however, the National Park Service operates approximately 30 stations in cooperation with EPA. It the nation's primary source for data on dry acidic deposition and rural, ground-level ozone. Operating since 1987, CASTNET is used in conjunction with other national monitoring networks to provide information for evaluating the effectiveness of national emission control strategies. CASTNET consists of over 80 sites across the eastern and western U.S. The longest data records are primarily at eastern sites. CASTNET provides atmospheric data on the dry deposition component of total acid deposition, ground-level ozone and other forms of atmospheric pollution. More information is available from the CASTNET program Web site *http://www.epa.gov/castnet/.*

The EPA is also one of many sponsors of the National Atmospheric Deposition Program/National Trends Network. The National Atmospheric Deposition Program/National Trends Network (NADP/NTN) is a nationwide network of precipitation monitoring stations. The NADP/NTN has over 200 stations spanning the continental U.S., Alaska, and Puerto Rico, and the Virgin Islands. The purpose of the network is to collect data on the chemistry of precipitation for monitoring of geographical and temporal long-term trends. While distinct from ambient air monitoring, precipitation monitoring is related in that it shares same of the same objectives, including tracking the effects of emission reduction programs. More information on NADP is available at its Internet Web site, *http://nadp.sws.uiuc.edu/.*

The EPA is a major funding sponsor of the Interagency Monitoring of Protected Visual Environments (IMPROVE) program. IMPROVE is a cooperative measurement effort governed by a steering committee composed of representatives from EPA, National Park Service, other Federal agencies, and Regional-State organizations. A total of 110 monitoring stations in Class I visibility areas have particulate matter samplers to measure speciated $PM_{2.5}$ and PM_{10} mass. Select stations also deploy transmissometer and nephelometers to measure light extinction and scattering respectively, as well as automatic camera systems. Some IMPROVE stations include an O_3 monitor. The objectives of IMPROVE are: (1) To establish current visibility and aerosol conditions in mandatory Class I areas; (2) to identify chemical species and emission sources responsible for existing man-made visibility impairment; (3) to document long-term trends for assessing progress towards the national visibility goal; (4) and with the enactment of the Regional Haze Rule, to provide regional haze monitoring representing all visibility-protected Federal Class I areas where practical. The IMPROVE stations provide very useful information on regional-scale particulate matter concentrations which can help States and EPA attribute urban concentrations of $PM_{2.5}$ to local versus regional sources and to types of sources. More information on the IMPROVE program is available on its Internet Web site, *http://vista.cira.colostate.edu/improve/.*

4. Data Storage and Dissemination Systems

a. Air Quality System. The AQS stores data collected from over 10,000 monitors, about 5,500 of which are currently active for criteria pollutants. The AQS also contains meteorological data, air toxics data, descriptive information about each monitoring station (including its geographic location and its operator), and data quality assurance/quality control information. The EPA and other AQS users rely upon the system data to assess air quality, assist in attainment and non-attainment designations, evaluate SIP, perform modeling for permit review analysis, and other air quality management functions. The AQS information is also used to prepare reports for Congress as mandated by the CAA. The AQS Web site address is: *http://www.epa.gov/ttn/airs/airsaqs/index.htm.*

b. AIRNow. AIRNow is a cross-government Web site (*http://airnow.gov/*) that provides the public with easy access to national air quality information. The Web site offers a daily forecast of conditions and associated health effects, known as the Air Quality Index (AQI), as well as real-time conditions for more than 300 cities across country. The AQI focuses on health effects that may occur within a

few hours or days after breathing polluted air. The EPA calculates the AQI for ground-level ozone, particulate matter, carbon monoxide, sulfur dioxide, and nitrogen dioxide. The AIRNow Web site displays nationwide and regional real-time $PM_{2.5}$ and ozone air quality maps for 48 States and parts of Canada. The air quality data used in these maps and to generate forecasts are collected using either FRM, FEM, or techniques approved by State monitoring agencies.

c. Other existing data systems. Other existing data systems for ambient air quality-related data include EPA's National Emission Inventory (NEI) and AirData. The NEI database at *http://www.epa.gov/ttn/chief/eiinformation.html* provides information about sources that emit criteria air pollutants and estimates of annual air pollutant emissions from point, nonpoint, and mobile sources. The EPA compiles the NEI database from emissions inventories compiled by State and local environmental agencies based on State reporting requirements in 40 CFR part 51, agency rulemaking databases, and the Toxic Release Inventory data from industry. The EPA updates the NEI database every 3 years.

The AirData Web site at *http://www.epa.gov/air/data/* provides annual summaries of ambient monitoring and emissions inventory data from the AQS and NEI. The database includes emission estimates from all 50 States plus the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, and provides data in a variety of formats. Other web-based data systems related to ambient air concentration data include VIEWS (*http://vista.cira.colostate.edu/views/*) to support analysis of visibility-related data from the IMPROVE network, and Web sites to support analysis of CASTNET (*http://www.epa.gov/castnet/data.html*) and NADP (*http://nadp.sws.uiuc.edu/*) data sets.

5. EPA Funding

The EPA has historically funded part of the cost of installation and operation of monitors to meet Federal monitoring requirements to defray costs for State, local, and tribal governments. Sections 103 and 105 of the CAA allow EPA to provide grant funding for programs for preventing and controlling air pollution and for some research and development efforts. States must apply for section 103 grants and State agencies must provide nonfederal matching funds for section 105 grants.

C. What Revisions to the National Ambient Air Quality Standards for Particulate Matter Also Are Proposed Today?

1. $PM_{2.5}$: Primary Standards, Secondary Standard, and Federal Reference Method

Elsewhere in this **Federal Register**, we are proposing revisions to the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM). Under the proposal, the 24-hour primary standard for $PM_{2.5}$ would be reduced from the current level of 65 micrograms per cubic meter ($\mu g/m^3$) to 35 $\mu g/m^3$ (based on the three-year average of the annual 98th percentile concentrations). We also are proposing to retain the level of the current annual $PM_{2.5}$ standard at 15 $\mu g/m^3$ and to add additional constraints to the use of spatial averaging to demonstrate compliance with that standard. The EPA is also proposing to revise the current secondary standards for $PM_{2.5}$ by making them identical to the suite of proposed primary standards.

The NAAQS proposal would also make several changes to the Federal reference method (FRM) for $PM_{2.5}$ in 40 CFR part 50, appendix L. These changes would improve the operation and maintenance aspects of the $PM_{2.5}$ monitoring network. Specifically, we are proposing to adopt the ''very sharp cut cyclone'' (VSCC) as an approved second-stage impactor. The performance of the VSSC separator is equivalent to that of the WINS (Well Impactor Ninety Six) impactor currently specified in the proposed reference method and has a considerably longer service interval. We also are proposing to require dioctyl sebacate as an alternative oil approved for use in the WINS, to extend the maximum allowed time to recover filters from samplers, and to modify the filter transport temperature and post-sampling time requirements for final laboratory analysis.

2. $PM_{10\text{-}2.5}$: Primary Standard, Secondary Standard, and Federal Reference Method

The NAAQS proposal would also revise the current 24-hour primary standard for PM_{10} by replacing the indicator with a $PM_{10\text{-}2.5}$ indicator. The proposed $PM_{10\text{-}2.5}$ indicator is qualified so as to include any ambient mix of $PM_{10\text{-}2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and exclude any ambient mix of $PM_{10\text{-}2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. This standard shall not require control of agricultural sources and mining sources. The proposed level of the standard is 70 $\mu g/m^3$, based on the three-year average of the annual 98th percentile concentrations.

Accordingly, the proposed revisions to the NAAQS include a new FRM for measuring $PM_{10\text{-}2.5}$ (Reference Method for the Determination of Coarse Particulate Matter as $PM_{10\text{-}2.5}$ in the Atmosphere) to be codified in a new appendix O to 40 CFR part 50. The proposed FRM is based on the combination of two low-volume, filter-based methods, one for measuring PM_{10} and the other for measuring $PM_{2.5}$, and determines the $PM_{10\text{-}2.5}$ measurement by subtracting the $PM_{2.5}$ measurement from the concurrent PM_{10} measurement. The $PM_{2.5}$ measurement method is identical to the $PM_{2.5}$ FRM currently specified in 40 CFR part 50, appendix L (Reference Method for the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere), with the proposed changes described above. The PM_{10} measurement method is very similar and utilizes a sampler that is the same as the $PM_{2.5}$ sampler, except that it has no $PM_{2.5}$ particle size separator downstream of the PM_{10} separator. Thus, this proposed $PM_{10\text{-}2.5}$ FRM is based on the same aerodynamic particle size separation and filter-based, gravimetric technology that is also the basis of the FRM for $PM_{2.5}$ (with the proposed changes described above).

3. Data Handling Procedures for $PM_{2.5}$ and $PM_{10\text{-}2.5}$

In the PM NAAQS proposal published elsewhere in today's **Federal Register**, EPA is also proposing to revise the conditions under which spatial averaging of the annual primary $PM_{2.5}$ NAAQS would be permitted. We also propose to move the criteria for determining if spatial averaging is acceptable from section 2.8.1.6.1 of appendix D to 40 CFR part 58 to appendix N of 40 CFR part 50 (Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$). We also propose to add a new appendix P to 40 CFR part 50 (Interpretation of the National Ambient Air Quality Standards for $PM_{10\text{-}2.5}$) to provide data handling procedures for $PM_{10\text{-}2.5}$.

4. Revocation of National Ambient Air Quality Standards for PM_{10}

In the PM NAAQS proposal, we are proposing to revoke the current annual PM_{10} standard immediately should we finalize the primary standards for $PM_{10\text{-}2.5}$ proposed in that notice. Further, we propose that the current 24-hour PM_{10} standard be revoked in all

areas except for 20 areas listed in section III of the NAAQS proposal preamble.

D. How Do the Monitoring Data Apply to Attainment or Nonattainment Designations and Findings?

The criteria for determining when it is appropriate to compare ambient monitoring data from a specific monitor and period to a National Ambient Air Quality Standard (NAAQS) is an important element of the air quality management system because it can identify what geographic areas have air quality problems and may be designated as nonattainment.

Later sections of this preamble, discussing the proposed monitoring requirements for the proposed $PM_{10-2.5}$ NAAQS and the proposed provisions for special purpose monitors (SPM), discuss the use of monitoring data for attainment or nonattainment designations. We are also proposing a change related to the required spacing between ozone (O_3) monitors and roadways. Finally, we are proposing changes to some quality assurance requirements. This section of the preamble provides background information on current EPA policy and regulations in order to facilitate informed public comment on these aspects of today's proposal.

There are some preconditions to use of data from an ambient monitor for comparison to an NAAQS that generally apply to the current NAAQS for O_3, PM_{10}, $PM_{2.5}$, CO, SO_2, NO_2, and Pb, with a few exceptions and/or the opportunity for waiver by EPA.[16] These include the following:

- The monitoring site must represent ambient air, as defined in 40 CFR 50.1 (*i.e.*, ''that portion of the atmosphere, external to buildings, to which the general public has access''). In practical terms, this means that data from monitoring sites within the boundaries of a privately-owned facility to which public access is restricted, for example, a storage yard of a factory, are not eligible for comparison to the NAAQS. (On occasion, EPA has relied on data from such sites when the air sampled is ambient air, even though the monitor may be sited on a facility to which public access is restricted (*e.g.*, the monitor is very close to a fence line and is monitoring the conditions that are present in the adjacent publicly accessible property.) Data from a monitor in ambient air as so defined can be compared to the NAAQS even if members of the public infrequently come near the monitor's location (*e.g.*, O_3 monitors that are located on the ground on high elevation mountain sites). However, data from monitors located high above standing/walking ground level, such as on a high roof or tower, are not eligible for comparison to an NAAQS. It should be noted that although monitors are often sited with the intention to represent an area of a certain geographic scale, in general, a monitor need not be representative of the ambient air quality across an area of any specific size to be eligible for comparison to most NAAQS. However, as described in section IV.E.2 of this preamble, the current annual $PM_{2.5}$ NAAQS is an exception, and the proposed 24-hour $PM_{10-2.5}$ NAAQS would be an exception. (See also the item in this list regarding proximity of O_3 and CO monitors to roadways.)
- The monitor must use a Federal reference method (FRM) or Federal equivalent method (FEM).
- The monitoring data must be technically valid so as to be truly representative of the actual air quality at its location during the sampline period, subject to the normal limitations of the FRM or FEM when properly operating. Generally, this means that the monitor's operation and subsequent sample handling and laboratory analysis, if applicable, must observe minimum quality assurance (QA) procedures, as set forth in 40 CFR 58.10 and 40 CFR part 58, appendices A and B (consolidated into a single appendix A in the proposed amendments), to guard against equipment malfunction, miscalibration, drift, or operator error. When States document that these procedures have been followed, the data are presumed to be valid although specific evidence of instrument faults or procedural errors can cause EPA to disregard data from particular periods. When documentation on whether these specific procedures have been followed is not available to EPA, as may be the case if a State has not submitted QA data to the Air Quality System (AQS) or if the monitoring was performed by a non-State organization not subject to the QA requirements in 40 CFR part 58, appendices A and B, the validity of data is considered on a case-by-case basis if the issue is raised by EPA, the State, or another party during an NAAQS designation process.
- The monitoring probe inlet (or open path, for open path monitors) must meet certain requirements for distance from adjacent roadways. This is a feature of the current monitoring requirements in 40 CFR part 58, appendix E (Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring) and the proposed amendments.[17] Ozone monitors too close to a roadway may be measuring air in which O_3 has been scavenged by nitric oxide (NO). Carbon monoxide and NO_2 monitors that are too close to a roadway can measure concentrations that do not represent likely human exposures of any significant frequency or duration. Requirements regarding spacing from roadways can be waived if no other suitable site is available.
- The monitoring probe inlet (or open path, for open path monitors) must meet certain minimum distance limits for proximity to nearby obstructions, such as walls of buildings.
- The probe height above the surface on which the public would stand or walk nearby must be within a certain range so that the air it samples is reasonably representative of what the public breathes when near the monitor. This requirement can be waived for practicality reasons.
- The monitoring data must be sufficiently complete according to requirements defined for each NAAQS in 40 CFR part 50, appendices H, I, K, and N (a new appendix P proposed elsewhere in today's **Federal Register** would add completeness requirements for $PM_{10-2.5}$).[18]

In addition to these generally applicable preconditions or restrictions, the current requirements of 40 CFR part 58 contain the following special provisions for $PM_{2.5}$:

- Data from a $PM_{2.5}$ monitor can be compared to the annual or 24-hour $PM_{2.5}$ NAAQS only if its location is ''population-oriented.'' [19] ''Population-

[16] Monitors that have received waivers are eligible for comparison to their respective NAAQS.

[17] Minimum separation distance requirements in the current rule apply to O_3, NO_2, CO, Pb (for stations designed to assess concentrations from mobile sources) and PM (PM_{10} and $PM_{2.5}$). Under the proposed amendments, minimum separation distance requirements would apply to O_3, oxides of nitrogen (NO, NO_2, NO_X, NO_y), CO, PM (PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$) and Pb for stations designed to assess concentrations from stationary or mobile sources.

[18] Interpretation of the 1-Hour Primary and Secondary National Ambient Air Quality Standards for Ozone; Interpretation of the 8-Hour Primary and Secondary National Ambient Air Quality Standards for Ozone; Interpretation of the National Ambient Air Quality Standards for PM_{10}; Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$; and Interpretation of the National Ambient Air Quality Standards for $PM_{10-2.5}$, respectively.

[19] Section 2.8.1.2.3 of appendix D to 40 CFR part 58 states that $PM_{2.5}$ data from state or local air monitoring systems (SLAMS) and special purpose monitors (SPM) that are ''* * * representative of relatively unique population-oriented microscale or localized hot spot or unique population-oriented middle scale impact sites are only eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS.'' However, under certain circumstances, the Regional Administrator may approve population-oriented microscale or middlescale impact sites for comparison to the annual NAAQS.

oriented monitoring or sites'' is described in 40 CFR 50.1 as applying to residential areas, commercial areas, recreational areas, industrial areas, and other areas where a substantial number of people may spend a significant fraction of their day.

• Data from a $PM_{2.5}$ monitor that is located in a ''microscale'' location, meaning it is influenced by a nearby emissions source while locations somewhat further away would be much less influenced, can be compared to the annual $PM_{2.5}$ NAAQS only if its location is representative of many other locations in the surrounding urban area, such that significant numbers of people can be expected to have similar $PM_{2.5}$ concentration exposures as people living, working, or visiting the location of the monitor in question (section 2.8.1.2.3 of appendix D to 40 CFR part 58).

• Under certain conditions, a State may, with the approval of EPA, average data from specified monitors for purposes of comparing the data to the annual $PM_{2.5}$ NAAQS. To be approved for spatial averaging, as it is known, monitors must meet certain requirements for relative location and measure concentrations as specified in section 2.8 of appendix D to 40 CFR part 58 (section 4.7.5 of proposed appendix D to 40 CFR part 58).[20]

• The first two complete calendar years of data from an SPM for $PM_{2.5}$ may be excluded from comparisons to the $PM_{2.5}$ NAAQS, but only if the monitor is not continued beyond those 2 years (section 2.8.1.2.2 of appendix D to 40 CFR part 58).

The first three of these four special provisions for $PM_{2.5}$ are tied to the reliance by EPA on community epidemiology studies in setting the form and levels of the annual and 24-hour $PM_{2.5}$ NAAQS. In simple terms, EPA determined that the levels of these NAAQS would be appropriately protective of public health based on a presumption that NAAQS compliance determinations would be made using data only from monitors that represented concentrations to which a large portion of the population would be exposed, even though some individuals would have higher or lower exposures.

Finally, EPA has policies addressing situations in which natural events and exceptional events have, or may have, influenced monitored concentrations. Under these policies, States may make the case that data from an otherwise eligible monitor from a specific period should not be used in comparisons to the NAAQS. We expect to revise these policies and codify them in 40 CFR part 50 in a separate rulemaking.[21]

IV. Proposed Monitoring Amendments

A. What Are the Proposed Terminology Changes?

In 40 CFR 58.1, we propose to replace the definition of ''National Air Monitoring Stations (NAMS)'' with a new definition for the ''National Core (NCore)'' network. The NCore designation[22] structure would be based on a tiered system of measurements including complex research-oriented stations,[23] multipollutant stations equipped to support a better understanding of ozone, particulate matter (PM), and PM precursors, and sites with as few as one measured pollutant identified as State and Local Air Monitoring Stations (SLAMS) that are primarily intended to support compliance with the National Ambient Air Quality Standards (NAAQS).

We are proposing to add a definition for the term, ''approved regional methods'' (ARM) to 40 CFR 58.1. This term refers to alternative $PM_{2.5}$ methods that have been approved by EPA for use specifically within a State, local, or tribal air monitoring network for purposes of comparison to the NAAQS and to meet other monitoring objectives, but which may not have been approved as Federal equivalent methods (FEM) for nationwide use. The proposed testing criteria for approval of ARM are specified in 40 CFR part 58, appendix C (Ambient Air Monitoring Methodology).

In 40 CFR 53.1, we are proposing to revise the definition of the term ''Class III equivalent method'' to apply only to continuous or semi-continuous methods having 1-hour (or less) measurement resolution. The revised definition would read:

* * * an equivalent method for $PM_{2.5}$ or $PM_{10\text{-}2.5}$ that is an analyzer capable of providing $PM_{2.5}$ or $PM_{10\text{-}2.5}$ ambient air measurements representative of 1-hour or less integrated $PM_{2.5}$ or $PM_{10\text{-}2.5}$ concentrations as well as 24-hour measurements determined as, or equivalent to, the mean of 24 consecutive 1-hour measurements. Restricting the Class III definition as proposed would offer a technical advantage by allowing the establishment of more tolerant minimum performance limits than would be necessary if non-continuous methods were included.

We are also proposing to add a definition of the term ''PM_{10c}'' to 40 CFR 53.1. This term refers to PM_{10} measurements obtained with a specially-approved sampler that meets more demanding performance specifications than high-volume PM_{10} samplers described in 40 CFR part 50, appendix J (Reference Method for the Determination of Particulate Matter as PM_{10} in the Atmosphere). Measurements obtained with PM_{10c} samplers are intended to be paired with $PM_{2.5}$ measurements from Federal reference method (FRM) samplers as part of the difference measurement ($PM_{10\text{-}2.5}$ equals PM_{10c} minus $PM_{2.5}$) specified in the proposed appendix O to 40 CFR part 50 (Reference Method for the Determination of Coarse Particulate Matter as $PM_{10\text{-}2.5}$ in the Atmosphere) published elsewhere in today's **Federal Register**.

B. What Are the Proposed Requirements for Approval of Reference or Equivalent Methods?

The provisions of 40 CFR part 50 and related appendices define certain ambient air monitoring methods (or methodology) as reference methods for the purpose of determining attainment of the National Ambient Air Quality Standards (NAAQS). Under 40 CFR part 53, EPA designates specific commercial instruments or other versions of methods as Federal reference methods (FRM). Furthermore, to foster the development of improved alternative air monitoring methods, EPA also designates alternative methods that are shown to have comparable performance as Federal equivalent methods (FEM). Explicit performance tests, performance standards, and other requirements for designation of both FRM and FEM are provided in 40 CFR part 53 for each of the criteria pollutants. Only designated reference or equivalent methods may be used in the States' air surveillance monitoring networks. A list of all methods that EPA has designated as either FRM or FEM for all criteria pollutants is available at *www.epa.gov/ttn/amtic/criteria.html.*

Elsewhere in this **Federal Register**, EPA is proposing a new reference method (40 CFR part 50, appendix O) for the measurement of coarse

[20] Changes to the requirements for spatial averaging are proposed elsewhere in this **Federal Register**.

[21] These policies on natural and exceptional events will be discussed in the preamble to the Natural and Exceptional Events rule to be published in the near future.

[22] Because the terms, SLAMS and NAMS, are used extensively through the current rules, this terminology change results in numerous changes. For clarity, we are publishing the entire text of 40 CFR part 58, appendix D (Network Design Criteria for Ambient Air Quality Monitoring).

[23] The NCore research grade station designation is defined in the proposed amendments in anticipation that these stations will be initiated at some time in the future. We are not proposing to require (or to fund) NCore research grade stations in this notice.

particulate matter (PM) in the ambient air. Concurrent with the proposal of this new reference method, EPA is also proposing amendments to 40 CFR part 53 to extend the designation provisions to methods for $PM_{10-2.5}$. These proposed amendments would set forth explicit tests, performance standards, and other requirements for designation of specific commercial samplers, sampler configurations, or analyzers as either FRM or FEM for $PM_{10-2.5}$, as appropriate.

The EPA recognizes that the $PM_{10-2.5}$ reference method, while providing a good standard of performance for comparison to other methods, is not itself optimal for routine use in large $PM_{10-2.5}$ monitoring networks. Accordingly, EPA is specifically encouraging the development of alternative methods (and particularly continuous monitoring methods) for $PM_{10-2.5}$ by focusing on the explicit test and qualification requirements necessary for designation of such types of methods as equivalent methods for $PM_{10-2.5}$. Virtual-impactor technology provides a more direct measurement of $PM_{10-2.5}$ and can provide an integrated $PM_{10-2.5}$ sample filter for chemical species analyses that can be important in the development of $PM_{10-2.5}$ control strategies. Continuous (or semi-continuous) methods for $PM_{10-2.5}$ typically provide significant operational advantages over 24-hour integrated monitoring methods, such as a self-contained automatic measurement process for output of nearly real-time measurements, reduced on-site service and off-site filter analysis and support requirements, and measurement resolution of one-hour or less. In addition, corresponding provisions for considering the designation of continuous or semi-continuous equivalent methods for $PM_{2.5}$ are also being proposed, since such provisions are similar to those for $PM_{10-2.5}$ and are not currently included in 40 CFR part 53. The nature of the proposed new provisions for automated methods, which can accommodate a wide range of potential $PM_{10-2.5}$ or $PM_{2.5}$ measurement technologies, is based primarily on ambient air testing at diverse monitoring sites to demonstrate that the level of comparability to collocated reference method measurements is adequate to meet established data quality objectives. Furthermore, some existing requirements for designation of alternative, non-continuous methods for $PM_{2.5}$ would be modified to be more consistent with the more advanced new requirements for non-continuous methods for $PM_{10-2.5}$ and for continuous methods.[24]

1. Proposed Requirements for Candidate Reference Methods for $PM_{10-2.5}$

Because of the nearly complete similarity between the specifications of the proposed $PM_{10-2.5}$ reference method and the existing $PM_{2.5}$ reference method, the proposed designation requirements for $PM_{10-2.5}$ reference methods are essentially the same as those for $PM_{2.5}$ reference methods.[25] In fact, EPA proposes that a $PM_{10-2.5}$ sampler pair consisting of samplers that have been shown to meet the $PM_{2.5}$ reference method requirements (except for the $PM_{2.5}$ particle size separator in the case of the PM_{10c} sampler) may be designated as a $PM_{10-2.5}$ reference method without further testing.

2. Proposed Requirements for Candidate Equivalent Methods for $PM_{10-2.5}$

As noted, EPA will strive to encourage the development of improved alternative air monitoring methods by providing for their designation as equivalent methods. But developing suitable qualification requirements for equivalent methods for $PM_{10-2.5}$ is complicated by the complex physical and chemical nature of PM, the definition of $PM_{10-2.5}$ that to some extent incorporates the nature of the measurement technique defined in the reference method, and a wide variety of alternative $PM_{2.5}$ measurement techniques that are or may become available or may be technically feasible. Alternative methods must be shown to provide concentration measurements closely comparable to those obtained with reference methods. Thus, the requirements established for designation of equivalent methods must identify candidate methods that can achieve that goal, while also having reasonable testing protocols that are not so extensive or burdensome as to effectively inhibit approval of adequate and suitable improved or alternative candidate methods.

In light of these constraints, EPA previously defined three classes of $PM_{2.5}$ candidate equivalent methods in 40 CFR part 53 with progressively greater equivalent method qualification burdens. Class I equivalent methods are limited to methods having ''* * * only minor deviations or modifications * * *'' from the specified reference method and have the most modest requirements for equivalent method designation (in addition to the applicable reference method designation requirements). Class II equivalent methods include other filter-based, integrated, gravimetric-type methods similar to the reference method, but with greater deviation than allowed for Class I. Class III equivalent methods include all other candidate $PM_{2.5}$ methods not classified as Class I or II. The proposed amendments would extend the definition of Class I, Class II, and Class III candidate equivalent methods to $PM_{10-2.5}$.

Because Class I equivalent methods for $PM_{10-2.5}$ differ only very modestly from $PM_{10-2.5}$ reference methods, designation requirements would also be very similar. The EPA is proposing that $PM_{10-2.5}$ Class I equivalent methods be designated if the samplers of the $PM_{10-2.5}$ sampler pair are shown to meet all requirements for either $PM_{2.5}$ reference methods or Class I equivalent methods. As for $PM_{10-2.5}$ reference methods, no further tests would be required.

One type of Class II equivalent sampler for $PM_{10-2.5}$ could be based on virtual impactor technology, which is designed to separate coarse mode aerosols from fine mode aerosols. The resulting size-segregated filter samples could be of great importance to State, local, and tribal agencies to obtain $PM_{10-2.5}$ sample filters for chemical speciation analyses. Class II methods, having greater deviation from the reference method, would have more extensive designation requirements. These methods still typically have many similarities to the reference method, and therefore, many of the reference method designation requirements would apply to Class II candidate equivalent methods. Generally, these methods must be subject to extensive laboratory and wind-tunnel tests to determine their performance relative to the performance of the reference method. However, for methods that have only one substantial difference from the reference method specifications (such as a virtual impactor particle-size separator), only those laboratory tests pertaining to the

[24] For this reason, we view our proposal as consistent with the objectives of section 6102 of the Transportation Equity Act for the 21st Century. See section VI.5 of the preamble for the proposed amendments to the National Ambient Air Quality Standards for particulate matter published elsewhere in this **Federal Register**.

[25] The proposed $PM_{10-2.5}$ reference method specifies a pair of samplers consisting of a conventional $PM_{2.5}$ sampler and a special PM_{10} sampler. The $PM_{2.5}$ sampler must meet all requirements for a $PM_{2.5}$ reference method in 40 CFR part 50, appendix L. However, the PM_{10} sampler required by the proposed method is not a conventional PM_{10} sampler as described in 40 CFR part 50, appendix J; rather, it is a sampler specified to be identical to the $PM_{2.5}$ sampler of the pair, except that the $PM_{2.5}$ particle size separator is removed. This special PM_{10} sampler is identified as a ''PM_{10c}'' sampler to differentiate it from conventional PM_{10} samplers that meet the lesser requirements of 40 CFR part 50, appendix J.

performance of the deviating component would be required. Further, for methods that have more deviation from the reference method specifications, the proposed requirements would provide an option to substitute more extensive field comparison tests for some or all of the extensive laboratory tests that would otherwise be required. Since such additional field tests would be similar to field test requirements proposed for $PM_{10-2.5}$ methods, concurrent field testing for $PM_{2.5}$ and $PM_{10-2.5}$ methods could be carried out. Concurrent testing would substantially reduce the testing burden for candidate equivalent methods that measure both $PM_{2.5}$ and $PM_{10-2.5}$ (such as a dichotomous, virtual impactor sampler), which could be tested simultaneously for designation as an equivalent method for both PM indicators.

3. Continuous Methods for $PM_{10-2.5}$

The EPA recognizes that filter-based measurement methods for either $PM_{2.5}$ or $PM_{10-2.5}$ that require manual gravimetric analysis, as embodied in the corresponding reference methods, as well as Class I and Class II equivalent methods, are by nature very labor intensive. They are expensive to operate in routine monitoring networks and can generally provide only delayed reporting of multiple-hour integrated measurements. Self-contained, continuous-type automated monitoring methods (analyzers), such as those that are commonly used for monitoring various gaseous pollutants, overcome many of these shortcomings. Various types of continuous (or nearly continuous) analyzers have been developed or are under development for $PM_{2.5}$ and $PM_{10-2.5}$ that offer substantial advantages over manual methods for implementation in routine air monitoring. These advantages include reduced operational cost, greater practicality for daily operation, availability of short-term measurements such as one-hour averages, and the possibility for near real-time, telemetered measurement acquisition. Accordingly, EPA is very interested in encouraging the further development of these continuous-type methods by providing requirements for designating such methods as Class III equivalent methods, so that they can be used in monitoring networks. Because no such explicit requirements exist, EPA is today proposing new Class III designation requirements for both $PM_{2.5}$ and $PM_{10-2.5}$.

Unfortunately, the continuous-type methods for $PM_{2.5}$ and $PM_{10-2.5}$ often tend to have performance characteristics somewhat different than those of the corresponding reference method. Consequently, adequate comparability to the corresponding reference method measurements may be technically difficult to achieve. Thus, the comparability testing requirements for Class III candidate methods must be sufficiently sophisticated to effectively differentiate between a method that shows adequate comparability and one that does not. At the same time, the designation qualification requirements must not be impractically extensive or burdensome, such that monitoring instrument manufacturers seeking designation for their analyzers cannot afford or economically justify the testing regimen.

We are proposing to narrow the definition of Class III equivalent methods to apply only to continuous or semi-continuous analyzer methods having one-hour (or less) measurement resolution, because such methods are of the most interest to the air quality monitoring community. While it would be possible to develop new, noncontinuous (or non-semicontinuous) $PM_{2.5}$ or $PM_{10-2.5}$ methods that would be categorized as Class III as currently defined, there is little, if any, technical need or economic incentive for instrument manufacturers to do so. Restricting the Class III definition to continuous analyzers, as proposed, would offer a substantial technical advantage by allowing the establishment of somewhat more tolerant limits of adequate comparability than would be necessary if non-continuous methods were included. This statistical advantage arises because the analyzers are operated continuously rather than on an intermittent, one-in-six day or one-in-three day schedule, which is typical of manually operated sampler methods.

Any of the currently existing or proposed requirements for designation of reference methods and Class I and Class II equivalent methods for $PM_{2.5}$ or $PM_{10-2.5}$ that would or should reasonably apply to a specific Class III candidate method would be required for the candidate Class III equivalent method, as well. But because of the wide variety of measurement techniques or technologies possible for a Class III candidate method, many of these existing requirements would not, or may not, apply. Therefore, the proposed requirements for $PM_{2.5}$ and $PM_{10-2.5}$ Class III candidate equivalent methods are based largely on demonstrating comparability between candidate method measurements and concurrent reference method measurements when both methods are collocated at several diverse monitoring and during different seasonal periods. These proposed requirements would be added to subpart C of 40 CFR part 53. Because we intend that most of the $PM_{10-2.5}$ monitors in the network use continuous or semi-continuous methods, the proposal of Class III approval requirements is particularly important for $PM_{10-2.5}$.

Although candidate $PM_{2.5}$ and $PM_{10-2.5}$ Class III equivalent methods would have hourly measurement resolution, this capability would not be subject to comparability requirements because both $PM_{2.5}$ and $PM_{10-2.5}$ FRM have only 24-hour measurement capability.

In developing these proposed new requirements for $PM_{2.5}$ and $PM_{10-2.5}$ Class III candidate equivalent methods, EPA has attempted to provide requirements that effectively reject inadequately comparable methods while minimizing the testing burden to the extent possible. Because the performance characteristics of Class III methods are likely to vary at monitoring sites having differing climatic and aerosol conditions, comparison tests would be required at sites in three specified areas of the continental U.S. during winter and summer seasons (winter in only one of the areas). The EPA believes these requirements would provide the minimum of test venues necessary to represent an adequate degree of monitoring site diversity for designation of a candidate equivalent method. However, EPA specifically solicits comments on the adequacy of the proposed geographical test areas, the appropriateness of the proposed seasonal requirements, and whether an additional test site may be needed (including the nature of such an additional site).

4. Specific Requirements for Class III Equivalent Methods

The proposed amendments to 40 CFR part 53 would revise the requirements for comparison tests and the allowable quantitative deviation from reference method measurements that are based on statistical analyses. The EPA has previously used a documented procedure [26] and a special computer software aid [27] to establish data quality objectives (DQO) for $PM_{2.5}$ monitoring data so that such data can be used effectively in making decisions regarding attainment of the NAAQS for PM. Using these established DQO and the software, statistical analyses of both

[26] U.S. Environmental Protection Agency. Guidance for the Data Quality Objectives Process. EPA QA/G–4, EPA/600/R–96/055. August 2000.

[27] U.S. Environmental Protection Agency (2004b) DQO Companion Tool, Version 2.0. 2004. *http://www.epa.gov/ttn/amtic/dqotool.html.*

actual and simulated $PM_{2.5}$ monitoring data [28] [29] were carried out to confirm the suitability of the statistical parameters selected to describe a comparison relationship between the candidate and reference methods and to set appropriate and optimal limits for their values in the proposed Class III equivalent method tests. These quantitative requirements then define the minimum candidate method comparability performance that would be necessary to provide $PM_{2.5}$ monitoring data of sufficient quality to meet the established DQO.[30] The DQO for $PM_{10-2.5}$ monitoring data have recently been developed and are incorporated into 40 CFR part 58, appendix A. These DQO are similar to the DQO for $PM_{2.5}$. Accordingly, the requirements proposed for $PM_{10-2.5}$ methods are similar to those proposed for $PM_{2.5}$ methods.[31] Furthermore, similar or parallel requirements are also proposed for Class II equivalent methods for $PM_{10-2.5}$ as well as for $PM_{2.5}$. However, the proposed requirements for Class II equivalent methods for $PM_{10-2.5}$ are stricter with regard to additive bias (intercept) since this method would also support other monitoring objectives. These latter requirements proposed for $PM_{2.5}$ Class II methods would replace the existing test requirements with the more advanced, DQO-based requirements.

The parameters selected to estimate the performance of $PM_{2.5}$ and $PM_{10-2.5}$ Class II and Class III candidate method measurements relative to the performance of the reference method in the proposed field tests are precision, correlation, and the linear regression slope and intercept of a linear plot fitted to corresponding candidate and reference method mean measurement data pairs. Statistical analyses based on the DQO model show that the precision of a candidate method is not, statistically, very important to annual concentration averages used for NAAQS attainment decisions, but would be important for a daily standard. Precision is also consequential for other important aspects and applications of the $PM_{2.5}$ or $PM_{10-2.5}$ monitoring data. Accordingly, the proposed amendments would include a minimum requirement for an estimate of the candidate method precision for 24-hour measurements.

A minimum requirement for an estimate of reference method precision in the tests, as well as a test for possible anomalous reference method measurement values, also are proposed to ensure that the quality of the reference method measurements used for the test meets the expected reference method performance. The proposed numerical limits for the Class II and III precision test requirements for both the reference and candidate methods are somewhat larger than those currently prescribed for Class I $PM_{2.5}$ methods because the Class II and III precision would be calculated as the root mean square average, rather than the simple average, of the daily precision values determined from multiple samplers or instruments. This more statistically appropriate aggregation of precision is consistent with the way precision would be expressed under proposed revisions to the data quality assessment provisions in appendix A to 40 CFR part 58.

As noted above, the proposed revision to the definition for Class III equivalent methods would require such methods to provide one-hour (or less) concentration measurements, because such short-term measurements are useful for a variety of applications. The EPA proposes that hourly measurements from Class III comparability tests be recorded and submitted as part of the required test data. No requirement for the precision of these hourly measurements is included in the proposed amendments because no one-hour DQO have been established for either $PM_{2.5}$ or $PM_{10-2.5}$ measurements and neither of the $PM_{2.5}$ or $PM_{10-2.5}$ reference methods provide one-hour data or performance goals. Nevertheless, in view of the substantial potential utility of one-hour $PM_{2.5}$ and $PM_{10-2.5}$ measurements, EPA solicits comments on whether requirements for one-hour measurement precision should be included in the Class III equivalent method designation requirements. In particular, comments are requested on whether such requirements, if included, should provide merely an assessment of one-hour precision or a specified standard of performance, and if the latter, to what extent would it be appropriate to reject a candidate method that exhibited poor one-hour precision but adequate 24-hour precision.

The regression comparability parameters proposed for Class II and Class III candidate methods would be interpreted in ways somewhat different from those now used for determining candidate method comparability for other types of candidate equivalent methods for PM. The slope (multiplicative bias) and intercept (additive bias) are the performance parameters most critical in achieving the DQO for making correct attainment decisions. However, these parameters are interrelated, and statistical analyses of simulated $PM_{2.5}$ data [32] show that the allowable limits for the intercept can be somewhat less stringent if they are made to be variable and related to the value obtained for the slope. Accordingly, EPA is proposing variable, slope-dependant limits for the intercept.

Further, because Class III $PM_{2.5}$ and $PM_{10-2.5}$ equivalent methods would be redefined as continuous or semi-continuous methods, such methods would normally be operated continuously, just as continuous gaseous pollutant analyzers are, rather than on a one-day-in-six sampling schedule typically used for $PM_{2.5}$ reference method sampling. Again, statistical analyses [33] show that this more frequent (daily) sampling allows the intercept limits to be set even wider than would be needed for one-in-six day sampling and still meet the established DQO. The actual intercept limits for $PM_{10-2.5}$ methods proposed today are somewhat more restrictive than the analyses would indicate to provide a factor of safety to account for inherent differences between the way candidate methods would be operated in the proposed equivalent method tests and the way they would be operated routinely in State monitoring networks.

Another difference in the way the conventional comparison parameters would be interpreted relates to the proposed lower limit requirement for the comparison correlation. The correlation test is instrumental in detecting longer-term method variability, such as seasonal bias. By its nature, the correlation value calculated for the comparison is quite dependent on the range of concentrations measured in the tests. The comparison tests are subject to the actual $PM_{2.5}$ or $PM_{10-2.5}$ concentrations available at the test site, which are generally related to variable atmospheric conditions during the test period and consequently may

[28] Data Quality Objectives for PM Continuous Methods. Prepared for U.S. Environmental Protection Agency by ManTech Environmental Technology, Inc. EPA Contract 68–D–00–206, Report TR–4423–03–08, June 2003.

[29] Data Quality Objectives for PM Continuous Methods II. Prepared for U.S. Environmental Protection Agency by ManTech Environmental Technology, Inc. EPA Contract 68–D–00–206. Report TR–CAN–04–02, June 2004.

[30] Criteria for Designation of Equivalence Methods for Continuous Surveillance of $PM_{2.5}$ Ambient Air Quality. Prepared for U.S. Environmental Protection Agency by B. Coutant and J. Sanford, Battelle Columbus, EPA Contract 68–D–02–061, 2004.

[31] Method Equivalency Development for $PM_{10-2.5}$. Prepared for U.S. Environmental Protection Agency by B. Coutant, Battelle Columbus, 2005.

[32] Battelle Columbus (2004).

[33] ManTech Environmental Technology, Inc. (June 2003); ManTech Environmental Technology, Inc. (June 2004); Battelle Columbus (2004); Battelle Columbus (2005).

sometimes occur in a rather narrow range. Therefore, the minimum value proposed for this statistic is not a fixed value but rather a variable that is related to the concentration coefficient of variation (CCV), which is a measure of the range of the concentrations measured in the test. This variable limit for correlation would provide a more effective test without unnecessarily failing test data representative of an unfortunately limited range of test concentrations.

One minor difference from the reference method would be necessitated by the proposed Class III comparison tests. The proposed reference methods for $PM_{2.5}$ and $PM_{10-2.5}$ specify a sampling period tolerance of 23 to 25 hours. Experience has shown that in multiple-sampler candidate method tests, which may be frequently combined with tests of additional instruments to reduce overall testing costs, the time required to properly change sample filters and service the samplers and other instruments between sample periods often requires more than one hour. Accordingly, the proposed test protocol would allow a 22-hour minimum sample period for the reference method to allow complete sample set acquisition within a 24-hour period. This proposed revision in the reference method protocol should have very little, if any, adverse impact on the results of the comparability tests.

The proposed requirements for $PM_{10-2.5}$ and $PM_{2.5}$ Class II and Class III equivalent methods are the least stringent requirements that would provide reasonable assurance that candidate methods meeting these requirements will produce monitoring data of quality commensurate with the quality of reference method data and that the data will meet the DQO established for $PM_{2.5}$ and the proposed DQO for $PM_{10-2.5}$. While recent field studies suggest some potential $PM_{10-2.5}$ continuous methods look promising,[34] it is not certain at this time whether any current commercial continuous or nearly continuous methods can yet meet the proposed requirements for Class III methods. However, EPA believes that the establishment of these requirements would provide a definitive goal which instrument manufacturers could achieve.

5. Proposed Changes to Requirements for PM_{10} and $PM_{2.5}$ Class I and Class II Equivalent Methods

The proposed amendments would revise the existing provisions for PM_{10} and $PM_{2.5}$ Class I and II candidate equivalent methods. These changes would clarify or simplify current provisions or implement minor improvements to test protocols suggested by experience and information acquired in processing equivalent method applications for these methods. The proposed changes would have very little, if any, impact on the nature, efficacy, or extent of any of the test requirements.

In the tests for PM_{10} and $PM_{2.5}$ Class I and II candidate equivalent methods, the minimum separation distance between sampler or analyzer inlets is proposed to be reduced from 2 meters to 1 meter for instruments having flow rates less than 200 liters per minute. One meter separation has been found to be entirely adequate for such low-flow-rate instruments, and the change is consistent with a similar minimum separation allowance for audit samplers used in assessing the precision of network $PM_{2.5}$ samplers.[35] An identical change is also proposed for appendix A to 40 CFR part 58.

Another proposed change would replace existing requirements for Class II $PM_{2.5}$ equivalent methods with similar but new DQO-based requirements. These proposed requirements are similar to the Class III requirements and would be based on daily sampling. Therefore, $PM_{10-2.5}$ and $PM_{2.5}$ Class II equivalent methods used for determining compliance with the PM NAAQS would generally be restricted to daily operation. However, as discussed previously, filter-based integrated methods (such as Class II equivalent methods) are not likely to be widely used for compliance monitoring. These methods would be used more for chemical analysis of samples to characterize the species of PM in a monitoring area, which would not require daily operation of the samplers. For Class II methods (for either $PM_{2.5}$ and $PM_{10-2.5}$ methods), the test sites would be similar in character to those for Class III methods, but only two test sites (one eastern and one western) rather than three, and tests in only one season at any time of year rather than two seasons, would be required. These requirements would allow tests for $PM_{2.5}$ and $PM_{10-2.5}$ methods (or for Class II and Class III method) to be tested simultaneously, to reduced testing costs. Flow rates in the existing $PM_{2.5}$ FRM and proposed $PM_{10-2.5}$ FRM would be operated under conditions of actual ambient temperature and barometric pressure, ensuring compatibility of the measured sample flows. The EPA solicits comments on the adequacy and appropriateness of these tests requirements for Class II methods.

In addition, the proposed amendments would lower many of the minimum concentration limit specifications for various existing test requirements for PM_{10} and $PM_{2.5}$ Class I and Class II candidate equivalent methods. These minimum limits were established either to avoid possible difficulties with interpretation of test results due to increased measurement variability that often occurs at very low concentrations or to require a wide range of concentration measurements for the test. However, experience has shown that these lower limits are unnecessarily conservative and can be decreased considerably without encountering undue variability in the measurements or an insufficient range of concentrations. Further, applicants often have difficulty obtaining a sufficient number of measurement sets that meet some of these minimum limits. The proposed decreases in these minimum limits would reduce the number of test measurement sets that are rejected as unacceptable due to test concentration levels failing to meet the test requirements without compromising the efficacy of the tests. These changes would reduce the costs to applicants of conducting the tests.

6. Other Proposed Changes

The proposed amendments would make subpart C of 40 CFR part 53 easier to understand by consolidating the provisions for the various types of candidate equivalent methods. This reorganization results in numerous minor editorial and section number changes of no technical impact. The entire text of 40 CFR part 53, subpart C is reprinted in the proposed amendments.

We are proposing numerous minor changes which are needed to incorporate new provisions for $PM_{10-2.5}$ methods into subparts A, C, E, and F of 40 CFR part 53, as well as a few minor changes that would apply to methods for $PM_{2.5}$ or other pollutants. As noted above, the definition of a ''Class III equivalent method'' in 40 CFR 53.1 would be modified to include only methods that provide automated

[34] U.S. Environmental Protection Agency. Multi-Site Evaluations of Candidate Methodlogies for Determining Coarse Particulate Matter ($PM_{10-2.5}$) Concentrations: August 2005 Updated Report Regarding Second-generation and New $PM_{10-2.5}$ Samplers.

[35] Quality Assurance Guidance Document: Field Standard Operating Procedures for the $PM_{2.5}$ Performance Evaluation Program. U.S. Environmental Protection Agency. Office of Air Quality Planning and Standards, November 1998, Section 4, page 8.

continuous or semi-continuous measurements of $PM_{2.5}$ and $PM_{10-2.5}$ with one-hour or less resolution. We are also proposing definitions for the terms, ''PM'', ''$PM_{10-2.5}$ sampler'', and ''PM_{10C} sampler''. Another proposed change, to paragraph (4) of 40 CFR 53.3 (General requirements for an equivalent method), would clarify that Class III $PM_{10-2.5}$ and $PM_{2.5}$ candidate equivalent methods would be subject to applicable requirements for $PM_{10-2.5}$ or $PM_{2.5}$ reference methods contained in those reference methods (40 CFR part 50, appendixes L and O) and applicable requirements for Class I and Class II equivalent methods contained in subparts E and F of 40 CFR part 53, in addition to the proposed amendments to subpart C. The requirement in 40 CFR 53.5 (Processing of applications) to publish a notice in the **Federal Register** upon receipt of an application would be deleted, as would the requirements in 40 CFR 53.51(f)(2) and 53.2(a) for manufacturers of $PM_{2.5}$ designated method samplers to submit an annual Product Manufacturing Checklist. These requirements have proved to be of little value, and the significant cost burden to the Government and to applicants for these activities can therefore be eliminated. The proposed amendments would also delete the requirement in 40 CFR 53.8 (Designation of reference and equivalent methods) for publishing a notice of designation in the **Federal Register** no later than 15 days after the date of the determination. We are proposing to delete the 15-day requirement because it is not achievable within the confines of EPA's internal review process.

C. What Are the Proposed Requirements for Quality Assurance Programs of the National Ambient Air Monitoring System?

A quality system provides a framework for planning, implementing and assessing work performed by an organization and for carrying out required quality assurance (QA) and quality control (QC) activities. The proposed amendments to 40 CFR part 58, appendix A would provide the requirements necessary to develop quality systems for the NCore, State and Local Air Monitoring Stations (SLAMS), and Prevention of Significant Deterioration (PSD) networks. The proposed revisions address responsibilities for implementing the quality system for both EPA and monitoring organizations, as well as adherence to the Agency's QA policy, data quality objectives (DQO), and the minimum QC requirements and performance evaluations needed to assess the data quality indicators of precision, bias, detectability, and completeness. In addition, the proposed amendments would describe the required frequency of the QC requirements and performance evaluations, the data to be collected, and the statistical calculations for estimates of the data quality indicators at various levels of aggregation. The revised statistical calculations would be used to determine attainment of the DQO. The proposed amendments would also identify national programs that help determine data quality comparability across individual monitoring programs.

The EPA has not conducted a thorough review of the quality system for many years. Based on our review of the existing QA program in 40 CFR part 58, appendices A and B, we are proposing changes to make the requirements consistent with our current QA policy, meet the objectives of the NCore, SLAMS, and PSD monitoring networks, and make the requirements more user-friendly. These proposed changes would produce a more consistent QA program across pollutant categories that fosters use of new technologies by more directly linking instrument performance with programmatic objectives. The proposed revisions were developed with the assistance of a stakeholder group (QA Strategy Workgroup) composed of QA representatives from EPA, State, local, and tribal monitoring organizations. Recommendations from the workgroup are provided in one of the draft versions of the National Ambient Air Quality Strategy document.[36] We solicit comments on all of the following proposed amendments to 40 CFR part 58, appendix A.

1. Consolidation of Quality Assurance Requirements

The requirements for State and local air monitoring stations (SLAMS) and prevention of significant deterioration (PSD) monitoring stations have been combined from two separate appendices, 40 CFR part 58, appendices A and B, into one single appendix A because both programs have similar QA requirements.

[36] The National Ambient Air Monitoring Strategy (Final Draft). U.S. Environmental Protection Agency. Office of Air Quality Planning and Standards, APril 2004. Some of the detailed content of the April 2004 draft, including some of the workgroup recommendations are not included in the subsequent December 2005 version.

2. Realignment to Current EPA Quality Assurance Policies

EPA Order 5360.1 A2 requires agencies that accept Federal grant funding for their air monitoring programs to have a QA program with certain elements including quality management plans (QMP), quality assurance project plans (QAPP), and a person designated as the quality assurance manager. Many of these elements are not in the existing regulations, which predate EPA Order 5360.1 A2 (revised in 2000), but would now be added under today's proposal. Grantee agencies have been following the requirements of EPA Order 5360.1 A2 for several years, and as a result, we do not expect these proposed revisions would have a significant impact on resources beyond the existing program. Copies of EPA Order 5360.1 A2 are available in the docket for this proposal as well as on EPA's Internet site *http://www.epa.gov/quality1.*

A QMP is a document that describes an organization's quality system including its policy and procedures, functional responsibilities of management and staff, and other general practices of its data collection program. Project-specific details are documented in a QAPP. A QAPP would document, for example, how the $PM_{2.5}$ air monitoring network will be operated and how sampler performance will be controlled and data quality evaluated.

EPA Order 5360.1 A2 requires grantee agencies involved with data collection activities to identify a quality assurance manager. The proposed amendments to 40 CFR part 58, appendix A would require each State (or delegated monitoring agency) to identify and maintain a ''QA management function''. This proposed language captures the essence of the requirements in EPA Order 5360.1A2, while befitting the nature of the ambient air monitoring community which is made up of large and small (local and tribal) organizations.

The EPA also proposes to revise the QA program by emphasizing the DQO process. A DQO is a qualitative and quantitative statement that defines the appropriate quality of data needed for a particular decision—for example, the data quality necessary for EPA or a monitoring organization to make data comparisons against the National Ambient Air Quality Standards (NAAQS). The DQO help to establish the requirements for precision, bias, completeness, and detectability and the rationale for their acceptance criteria.

The proposed amendments would require monitoring organizations to

evaluate $PM_{10-2.5}$ and ozone monitoring system performance through the DQO process. This is consistent with the existing requirement for organizations to evaluate their $PM_{2.5}$ monitoring system performance using the DQO process. Priority for these evaluations is placed on $PM_{2.5}$, $PM_{10-2.5}$, and ozone as these are the pollutants of most concern across the country. Quality assurance procedures such as determining precision through collocated sampling and determining bias through an independent performance evaluation program for $PM_{10-2.5}$ are proposed to follow the same basic approach as the $PM_{2.5}$ monitoring network. The proposed precision and bias measurement uncertainty goals are identified in 40 CFR part 58, appendix A. The proposed amendments to appendix A would also specify that EPA is responsible for the development of the DQO for NCore multi-pollutant stations and State and local air monitoring stations (SLAMS).

3. Quality Assurance Requirements for PM_{10}, $PM_{10-2.5}$ and $PM_{2.5}$

The proposed QA requirements for $PM_{10-2.5}$ would follow the same approach as the requirements that currently apply to both automated and manual PM_{10} and $PM_{2.5}$ monitors. These requirements would include the implementation of flow rates audits conducted by the monitoring organization, collocated monitoring, and performance evaluations. Statistical evaluations have allowed us to reduce collocation and performance evaluation sampling frequencies without significant affects to data quality assessments.

We are proposing to amend the $PM_{2.5}$ and PM_{10} collocation sampling frequency requirement. Statistical assessments of the collocated $PM_{2.5}$ and PM_{10} data reveal that adequate estimates of precision at the primary quality assurance organization could be made at a reduced sampling frequency. Consequently, we are proposing to reduce the frequency from every 6 days to every 12 days. This change would reduce the burden on the monitoring organization without a significant effect on precision estimates. This proposal does not include a reduction in the collocation requirements for total suspended particulate (TSP) or PSD monitors. In addition, we are proposing to revise the concentration limits applicable to collocated pairs of monitors that are used to provide precision estimates. The concentration limits would be reduced from 6 micrograms per cubic meter ($\mu g/m^3$) to 3 $\mu g/m^3$ for $PM_{2.5}$ and from 20 $\mu g/m^3$ to 15 $\mu g/m^3$ for PM_{10} (high-volume samplers). Statistical evaluation of three years of $PM_{2.5}$ and PM_{10} data revealed comparable estimates of precision using data from both of these reduced concentration ranges, and that the addition of the data at these lower ranges will increase the level of confidence in the precision estimates. This proposed change would make the collocation sampling frequency requirement consistent for $PM_{2.5}$ PM_{10} and $PM_{10-2.5}$. A document describing the possible new approach is available in the docket.[37]

We are proposing to revise the sampling frequency for the implementation of the PM Performance Evaluation Program (PEP). This proposed approach used historical $PM_{2.5}$ precision and bias data to identify the minimum number of performance evaluations required for all primary quality assurance organizations to provide an adequate assessment of bias, rather than the current requirement that a uniform 25 percent of monitors in a primary quality assurance organization be evaluated each year. The revision would establish an equitable sampling frequency of five valid audits a year for organizations with less than or equal to five monitoring sites and eight valid audits a year for those organizations with greater than five monitoring sites. A valid performance evaluation audit means that both the primary monitor and PEP audit concentrations are valid and above 3 $\mu g/m^3$. As an example, if a primary quality assurance organization had 20 monitoring sites, the current requirement would require five sites (25 percent of network) to be audited four times each year (one each quarter) for a total of 20 audits. The new proposal would simply require eight audits be provided (distributed across each quarter) and that all monitoring sites be audited within a six year period in order to provide a representative estimate of bias for the monitoring network. This would equate to distributing eight audits (or five for networks less than or equal to 5) at 15 percent of the monitoring network sites. In addition, each method designation must be audited. Therefore, if a primary quality assurance organization had two different monitoring instruments in their network, both would need PEP audits each year. Since bias data quality objectives are evaluated on 3 years of PEP audits, both sampling frequencies should provide us with reasonable assessments of bias. Preliminary assessments of the impact of the possible new method show that organizations with smaller networks would need more audits but fewer audits would be needed at organizations with larger networks. The net result across all primary quality assurance organizations would be fewer audits, comparable bias results, and reduced resource burden. A document describing this possible approach is available in the docket.[38]

4. Requirements to Ensure Adequate Independent Quality Assurance for All Pollutants Subject to National Ambient Air Quality Standards

We are proposing to revise the current regulatory requirements dealing with responsibilities for independent assessments of monitoring system performance. These evaluations are the subject of sections 2.4 and 3.5.3.1 of the current appendix A to 40 CFR part 58. Section 2.4 of appendix A to 40 CFR part 58 applies to all National Ambient Air Quality Standards (NAAQS) pollutants and section 3.5.3.1 is applicable only to $PM_{2.5}$. Currently, section 2.4 of appendix A requires the monitoring organization to ''participate'' in EPA's National Performance Audit Program (NPAP). For the last few years, EPA has considered that monitoring organizations are in compliance with the requirements of section 2.4 if, at a minimum, the organizations made their monitoring sites and equipment accessible to EPA or contractors for conducting the performance evaluations. For continuous gas instruments, a performance evaluation involves the introduction of a gas or gases of independently known concentration to determine the bias of the local monitor.

Section 3.5.3.1 of appendix A to 40 CFR part 58 describes the Performance Evaluation Program (PEP) for $PM_{2.5}$. The PEP requirements are functionally similar to the NPAP requirements but differ in its specifics because of the nature of particulate matter sampling (i.e., it is not possible to introduce air with a known concentration of $PM_{2.5}$ into a monitor). Under the PEP for $PM_{2.5}$, a local monitor is evaluated by placing a second, independently-maintained Federal reference method (FRM) monitor next to the local monitor and allowing both monitors to sample for 24 hours. The filter from the independent FRM monitor is then shipped to an independent laboratory

[37] Proposal to Change the $PM_{2.5}$ and PM_{10} Collocation Sampling Frequency Requirement, *http://www.epa.gov/ttn/amtic/pmqainf.html*

[38] Review of the Potential to Reduce or Provide a More Cost Efficient Means to Implement the $PM_{2.5}$ Performance Evaluation Program, *http://www.epa.gov/ttn/amtic/pmpep.html.*

where it is weighed and the resulting independently calculated concentration is compared to the concentration from the local monitor. The resulting difference in concentrations between the independent FRM monitor and local monitor is used to calculate the bias between the sampler results.

The monitoring organization is responsible for having these $PM_{2.5}$ performance evaluations take place, or only for giving access to its sites for EPA staff or contractors to perform them. In practice, most monitoring organizations comply with the requirements in section 3.5.3.1 by giving access to EPA staff or contractors and by accepting that EPA funds this activity by holding back part of the grant funding that might otherwise go directly to the monitoring organization. One State complies with requirements in section 3.5.3.1 by having independent audits in one part of the State performed by personnel and laboratories from the monitoring organization that is responsible for daily operations in another part of the State.

The EPA proposes to revise the text of 40 CFR part 58, appendix A to clearly provide that it is the responsibility of each monitoring organization to make arrangements for, and to provide any necessary funding for, the conduct of adequate independent performance evaluations of all its FRM or Federal equivalent method (FEM) criteria pollutant monitors. The proposed language would also clearly indicate that it is the monitoring organization's choice whether to obtain its independent performance evaluations through EPA's NPAP and $PM_{2.5}$ PEP programs, or from some other independent organization. An independent organization could be another unit of the same agency that is sufficiently separated in terms of organizational reporting and which can provide for independent filter weighing and audit gas naming. This proposed approach would ensure that adequate and independent audits will be performed but would provide flexibility in the implementation approach.

Monitoring organizations that choose to comply with the revised provisions of appendix A to 40 CFR part 58 regarding performance evaluations by relying on EPA audits, for $PM_{2.5}$, $PM_{10\text{-}2.5}$, and/or other NAAQS pollutants, would be required to agree that EPA hold back part of the grant funds they would otherwise receive directly. The EPA intends to develop guidance for monitoring organizations that choose to comply by obtaining audit services from elsewhere. To ensure national consistency and effective audits, this guidance will include provisions for EPA certification of data comparability for audit services not provided by EPA and for traceability of gases and other audit standards to national standards maintained by the National Institute for Standards and Technology.

5. Revisions to Precision and Bias Statistics

We are also proposing to change the statistics for assessment of precision and bias for criteria pollutants. Two important data quality indicators that are needed to assess the achievement of DQO are bias and precision. Statistics in the current requirements of 40 CFR part 58, appendix A (with the exception of $PM_{2.5}$) combine precision and bias together into a probability limit at the primary quality assurance organization level of aggregation. In addition, the statistical calculations of precision and bias vary among criteria pollutants and between manual and automated methods within the same pollutant. Since the DQO process uses separate estimates of precision and bias, we examined assessment methods that were statistically reasonable and simple. The proposed assessment methods are based on the QA measurements that are currently required in 40 CFR part 58, appendix A.

For sulfur dioxide (SO_2), nitrogen dioxide (NO_2), carbon monoxide (CO), and ozone (O_3), we are proposing to estimate precision and bias on confidence intervals at the site level of data aggregation rather than the primary quality assurance organization. Estimates at the site level can be accomplished with the automated methods for SO_2, NO_2, CO and O_3 because there is sufficient QC information collected at the site level to perform adequate assessments. Since the criteria pollutant data are used for very important decisions (comparison to the NAAQS), providing precision and bias estimates at upper confidence limits would provide a higher probability of making appropriate decisions. The intent of this proposed change is to move organizations to a ''performance-based'' quality system. Organizations that demonstrate acceptable performance would be allowed the flexibility to reduce the frequency of certain QC checks. These agencies are expected to shift resources used for these QC checks into higher priority QA work. A document describing this possible new approach is available in the docket.[39]

[39] Proposal: New Method for Estimating Precision and Bais for Gaseous Automated Methods for Ambient Air Monitoring Program, *http://www.epa.gov/ttn/amtic/files/ambient/gagc/proprecision.pdf.*

The precision and bias statistics for PM measurements (PM_{10}, $PM_{10\text{-}2.5}$ and $PM_{2.5}$) would be generated at a primary quality assurance organization level because, unlike the gaseous pollutants, only a percentage of the sites have precision and bias checks performed in any year. As with the gaseous pollutants, the statistics would use the confidence limit approach. Using a consistent set of statistics would simplify procedures by removing a significant number of equations and confusing language in the appendix.

We are also proposing to change the precision and bias statistics for lead (Pb) to provide a framework for developing and assessing DQO. The QC checks for Pb come in three forms: flow rate audits, Pb audit strips, and collocation. The EPA proposes to combine information from the flow rate audits and the Pb audit strips to provide an estimate of bias. Precision estimates would still be made using collocated sampling but the estimates would be based on the upper 95 percent confidence limit of the coefficient of variation, similar to the method described for the automated instruments.

6. Program Updates

We are also proposing several QA program changes to update the existing requirements in 40 CFR part 58 to reflect current program needs and terminology:

- We are proposing to remove SO_2 and NO_2 manual audit checks. A review of all SLAMS/NAMS/PAMS sites by monitor type revealed that no monitoring organizations are using manual SO_2 or NO_2 methods, nor are any monitoring organizations expected to use these older technologies. Instead of the old manual methods, monitoring sites are using continuous methods to perform these audit checks. We are proposing to remove the manual method QC checks because the continuous check methods are covered by the current QA procedures.
- We are proposing to change the concentration ranges for QC checks and annual audit concentrations. The one-point QC check concentrations for the gaseous pollutants SO_2, NO_2, O_3 and CO would be expanded to include lower concentrations. Lower audit ranges would also be added to concentration ranges in the annual audit concentrations. Adding or expanding the required range to lower concentration ranges is appropriate due to the lower measured concentrations at many monitoring sites as well as the potential for NCore stations to monitor areas where concentrations are at trace ranges. In addition, EPA proposes that

the selection of QC check gas concentration must reflect the routine concentrations normally measured at sites within the monitoring network in order to appropriately estimate the precision and bias at these routine concentration ranges.

• We are proposing to revise the PM_{10} collocation requirement. Currently, 15 percent of all $PM_{2.5}$ sites are required to maintain collocated samplers. For consistency, the proposed amendments would change the PM_{10} collocation requirement to match the $PM_{2.5}$ requirement. This proposed change would make the collocation requirement consistent for $PM_{2.5}$ PM_{10} and $PM_{10\text{-}2.5}$.

• We are proposing to amend the $PM_{2.5}$ and PM_{10} collocation sampling frequency requirement. Statistical assessments of the collocated $PM_{2.5}$ and PM_{10} data reveal that adequate estimates of precision at the primary quality assurance organization could be made at a reduced sampling frequency. Consequently, we are proposing to reduce the frequency from every 6 days to every 12 days. This change would reduce the burden on the monitoring organization without a significant effect on precision estimates. This proposal does not include a reduction in the collocation requirements for total suspended particulate (TSP) or PSD monitors. In addition, we are proposing to revise the concentration limits applicable to collocated pairs of monitors that are used to provide precision estimates. The concentration limits would be reduced from 6 micrograms per cubic meter ($\mu g/m_3$) to 3 $\mu g/m_3$ for $PM_{2.5}$ and from 20 $\mu g/m_3$ to 15 $\mu g/m_3$ for PM_{10} (high-volume samplers). Statistical evaluation of 3 years of $PM_{2.5}$ and PM_{10} data revealed comparable estimates of precision using data from both of these reduced concentration ranges, and that the addition of the data at these lower ranges will increase the level of confidence in the precision estimates. This proposed change would make the collocation sampling frequency requirement consistent for $PM_{2.5}$ PM_{10} and $PM_{10\text{-}2.5}$.

• We are proposing to revise the requirements for $PM_{2.5}$ flow rate audits. Based on an evaluation of flow rate data and discussions within the QA Strategy Workgroup, we are proposing to reduce the frequency of flow rate audits from quarterly to semiannually and remove the alternative method which allows for obtaining the precision check from the analyzers internal flow meter without the use of an external flow rate transfer standard. Most monitoring organizations participating in the QA Strategy Workgroup considered auditing with a external transfer standard to be the preferred method and believed that the quarterly audit data demonstrates the instruments are sufficiently stable to reduce the audit frequency. The proposed amendments would provide an efficient and effective approach by reducing audit frequency to an adequate level while ensuring the use of a preferred approach.

D. What Are the Proposed Monitoring Methods for the National Ambient Air Monitoring System?

1. Federal Reference Methods and Federal Equivalent Methods

Monitoring methods used in the multi-pollutant NCore and SLAMS networks would include Federal reference methods (FRM), Federal equivalent methods (FEM), and other methods designed to meet the data quality objectives of the network being deployed. When appropriate, the proposed amendments place emphasis on continuous methods over filter-based methods to provide for highly time-resolved data for better characterization of diurnal patterns of air pollution and for timely public availability of data. While more emphasis is placed on continuous methods, a limited number of filter-based methods would still be retained in most networks to tie together historical data sets with new monitoring data. EPA's strategy for selecting the proposed monitoring methods for the National ambient air monitoring system was to select methods that meet data quality objectives for each pollutant and that have the most utility to support multiple monitoring objectives. Specifics on the monitoring methods proposed for use at each type of site are described below.

• A wide variety of research, FRM/FEM or other routine methods could be used at NCore research-grade stations. Maximum flexibility is provided in the proposed amendments for these sites because they would be used to investigate the atmospheric processes and air chemistry that go beyond the capabilities of characterizing the air with routine monitoring methods.

• NCore multi-pollutant stations would use FRM or FEM for criteria pollutants when the expected concentration of the pollutants are at or near the level of the National Ambient Air Quality Standards (NAAQS). For criteria pollutant measurements of carbon monoxide (CO) and sulfur dioxide (SO_2), where the level of the pollutant is well below the NAAQS, it may be more appropriate to operate higher sensitivity monitors than FRM or FEM. In these cases, the higher sensitivity methods are expected to support different monitoring objectives than the FRM or FEM. In some limited cases, higher-sensitivity gas monitors have also been approved as FEM and can serve both NAAQS and other monitoring objectives. Options for high-sensitivity measurements of CO, SO_2, and total reactive nitrogen (NO) are described in the report, ''Technical Assistance Document for Precursor Gas Measurements in the NCore Multipollutant Monitoring Network.''

• State and local air monitoring stations would use FRM or FEM for criteria pollutants. For $PM_{2.5}$, these sites could also use approved regional methods (ARM), which are described in section IV.D.2 of this preamble.

• Photochemical assessment monitoring stations (PAMS) would use the ozone (O_3) ultraviolet photometry FEM and the nitric oxide (NO) and nitrogen dioxide (NO_2) chemiluminescence FRM for criteria pollutant measurements. Methods for volatile organic compounds (VOC) including carbonyls, additional measurements of gaseous nitrogen, such as NO_y, and meteorological measurements are routinely operated at PAMS. Because these measurements are not of criteria pollutants, the methods are not subject to the requirements for reference or equivalent methods. However, these methods are described in detail in the report, ''Technical Assistance Document (TAD) for Sampling and Analysis of Ozone Precursors.''[40]

• Special purpose monitoring (SPM) sites have no restrictions on the type of method to be utilized. While FRM and FEM can be employed at SPM sites, other methods, not limited to continuous, high-sensitivity, and passive methods, may also be utilized. Because SPM sites are designed to encourage monitoring, agencies are expected to design SPM sites with methods to meet specific monitoring objectives that may not be achievable with FRM or FEM. For instance, a community may be concerned with a source impacting their neighborhood. Because many PM FRMs are filter-based manual methods, having a 24-hour sample may not indicate if the source impacted the neighborhood because of the meteorological variability during the sample collection period. However, a continuous method may be able to provide the high-time resolution

[40] Technical Assistance Document (TAD) for Sampling and Analysis of Ozone Precursors. U.S. Environmental Protection Agency. HUman Exposure and Atmospheric Sciences Division. EPA/600–R–98/161. September 1998. Available at: *http://www.epa.gov/ttn/amtic/pams.html.*

necessary to detect the short-term impacts of a plume on a neighborhood. Another example could be the utilization of passive monitors deployed at many locations to determine the location of maximum concentrations within a neighborhood. Additional information on SPM is included in section IV.E.9 of this preamble.

2. Approved Regional Methods for $PM_{2.5}$

The proposed amendments also expand the use of alternative $PM_{2.5}$ measurement methods through approved regional methods (ARM). The proposed amendments to 40 CFR part 58, appendix C extend the existing provisions for EPA approval of a nondesignated $PM_{2.5}$ method as a substitute for a FRM or FEM at a specific individual site to a network of sites. This approval would be extended on a network basis to allow for flexibility in operating a hybrid network of $PM_{2.5}$ FRM and continuous monitors. The size of the network, in which the ARM could be approved, would be based on the location of test sites operated during the testing of the candidate ARM. The proposed amendments require that test sites be located in urban and rural locations that characterize a wide range of aerosols expected across the network. A hybrid network of monitors would be operated to address monitoring objectives beyond just determining compliance with NAAQS. The hybrid network would lead to a reduced number of existing FRM samplers for direct comparison to NAAQS and an increase in continuous samplers that meet specified performance criteria related to their ability to produce sound comparisons to FRM data. Those ARM that meet the specified performance criteria would be approved for direct comparison to $PM_{2.5}$ NAAQS.

Performance criteria for approval of ARM would be used to determine whether the continuous measurements are sufficiently comparable for integration into the $PM_{2.5}$ network used in NAAQS decisions. These criteria are the same criteria for precision, correlation, and additive and multiplicative bias that are proposed for approval of continuous $PM_{2.5}$ Class III equivalent methods, described in section IV.B.3 of this preamble. These performance criteria would be demonstrated by monitoring agencies independently or in cooperation with instrument manufacturers under actual operational conditions using one to two FRM and one to two candidate monitors each. This would be a departure from the very tightly-controlled approach used for national equivalency demonstration in which three FRM and three candidate monitors are operated. The ARM would be validated periodically in recognition of changing aerosol composition and instrument performance. These validations would be performed on at least two levels: (1) Through yearly assessments of data quality provided for as part of the on-going quality assurance (QA) requirements in 40 CFR part 58, appendix A, and (2) through network assessments conducted at least every 5 years as described in section IV.E.11 of this preamble.

The testing criteria EPA is proposing for approval of $PM_{2.5}$ continuous methods as ARM are intended to be robust but not overly burdensome. The two main facets of testing are the duration and location(s) of testing. The duration is expected to be one year to provide understanding of the quality of the data on a seasonal basis. The locations for testing are expected to be a subset of sites in a network where the State desires the $PM_{2.5}$ continuous monitor to be approved as an ARM. Testing would be carried out in multiple locations to include up to two Core-based Statistical Area/Combined Statistical Areas (CBSA/CSA) and one rural area or small city for a new method. For methods that have already been approved by EPA in other networks, one CBSA/CSA and one rural area or small city would be required.

To ensure that approvals of new methods are made consistently on a national basis, the procedures for approval of methods would be similar to the requirements specified in 40 CFR part 53, i.e., the EPA Administrator (or delegated office) would approve the application. However, to optimize flexibility in the approval process, all other monitoring agencies seeking approval of a method that is already approved in another agency's monitoring network may seek approval through their own EPA Regional Administrator. This approach should provide a streamlined approval process, as well as an incentive for consistency in selection and operation of $PM_{2.5}$ continuous monitors across various monitoring agency networks.

The proposed QA requirements for approval of continuous $PM_{2.5}$ ARM at a network of sites would be the same as for FEM in 40 CFR part 58, appendix A, except that 30 percent of the required sites that utilize a $PM_{2.5}$ ARM would be collocated with an FRM and required to operate at a sample frequency of at least a one-in-six day schedule. The higher collocation requirement would support the main goal of the particulate matter continuous monitoring implementation plan, which is to have an optimized FRM and $PM_{2.5}$ continuous monitoring network that can serve several monitoring objectives. The current 15 percent collocation requirement in 40 CFR part 58, appendix A is adequate to provide an estimate of site and network precision; however, a higher amount of collocation is necessary to retain a minimum number of FRM for continued validation of the ARM, direct comparison to NAAQS, and for long-term trends that are consistent with the historical data set archived in the Air Quality System. The collocated sites are to be located at the highest concentration sites, starting with one site in each of the largest population CBSA or CSA in the network and working to the next highest-population CBSA or CSA with the second site and so forth.

E. What are the Proposed Requirements for the Number and Locations of Monitors To Be Operated by State and Local Agencies?

The proposed amendments modify the requirements in appendix D to 40 CFR part 58 for the number and locations of monitors necessary to support ambient air data objectives. This proposal requires States to deploy a new network of multipollutant monitoring stations called the National Core (NCore) network; requires States to maintain robust networks for $PM_{2.5}$ and ozone (O_3) and to establish a robust monitoring network for $PM_{10-2.5}$; allows States to make major reductions in monitoring for other criteria pollutants, where concentration data are well below the applicable National Ambient Air Quality Standards (NAAQS) and are not expected to pose future air quality problems; and allows States to reduce the number of stations required for the NCore photochemical assessment monitoring stations (PAMS) network. We also propose to establish or modify certain monitoring frequency requirements.

This proposal allows for reductions in air pollution monitoring for select pollutants in geographic areas that do not have or are not expected to have related air quality problems, while increasing or maintaining monitoring sites in areas with continuing or new air quality problems. The proposal allows for reductions in the carbon monoxide (CO), sulfur dioxide (SO_2), nitrogen dioxide (NO_2), PM_{10}, and lead (Pb) air monitoring networks in geographic areas with historically low concentrations of these specific pollutants, except cases in which the State implementation plan (SIP) or source permits specifically require

certain monitoring. However, monitoring requirements that are part of a SIP or permit should be revisited as part of the network assessments described in section IV.E.11 of this preamble. Overall, a limited number of these monitors are still expected, but not required, to be operated to support studies of air quality trends, to allow accountability for emissions control programs, and for health effects studies.

This proposal also requires States to increase or maintain monitoring sites in most areas with continuing or new air quality problems for O_3 and $PM_{2.5}$. However, with EPA agreement, States would be allowed to move some monitors to better characterize the spatial variability of these pollutants.

As discussed in section IV.E.2 of this preamble, we also are proposing requirements for the minimum monitoring network for the proposed $PM_{10\text{-}2.5}$ NAAQS published elsewhere in this **Federal Register**.[41]

Under the proposed monitoring amendments, the PAMS network would remain a requirement for serious, severe, and extreme ozone nonattainment areas. However, EPA is promoting the development of more individualized PAMS networks to suit the specific data needs for a PAMS area. We propose to make the PAMS requirements more flexible to allow for this redesign.

Minimum criteria pollutant monitoring requirements, where proposed for retention or addition, would be based in part on population statistics. The Office of Management and Budget (OMB) has established standards for defining metropolitan and micropolitan statistical areas that replace metropolitan statistical areas defined in the 1990 standards (65 FR 82227, December 27, 2000). The EPA has traditionally used the 1990 metropolitan statistical area definitions within many of the air monitoring requirements including the numbers of monitoring sites within a network and the Air Quality Index (AQI) reporting requirements. The proposed amendments use the new OMB standards for defining metropolitan and micropolitan areas, as well as the new standards for Core-based Statistical Areas (CBSA) and Combined Statistical Areas (CSA).

[41] Continuous $PM_{2.5}$ and $PM_{10\text{-}2.5}$ methods that can meet multiple monitoring objectives are being promoted by proposing new performance-based criteria for approval of these methods. See section IV.B of this preamble.

1. Proposed Requirements for Operation of Multipollutant Monitoring Stations Identified as the National Core Network (NCore).

The EPA is proposing requirements applicable to States individually that may, in the aggregate, cause the deployment of a new network of monitors in approximately 60 mostly urban multipollutant stations. Most States would be required to operate at least one urban station; however, rural stations could be substituted in States that have limited dense urban exposures. States with Core-Based Statistical Areas (CBSA) often also have multiple air sheds with unique characteristics and, often, elevated air pollution. These States include, at a minimum, California, Florida, Illinois, Michigan, New York, North Carolina, Ohio, Pennsylvania, and Texas. These States would be required to identify one to two additional NCore stations in order to account for their unique situations. These stations, combined with about 20 multipollutant rural stations, which are not specifically being required of the States, would form the new multipollutant NCore network. The rural NCore stations will be negotiated using grant authority as part of an overall design of the network that is expected to leverage existing rural networks such as IMPROVE, CASTNET and, in some cases, State-operated rural sites.

These multipollutant NCore stations are intended to track long-term trends for accountability of emissions control programs and health assessments that contribute to ongoing reviews of the NAAQS; support development of emissions control strategies through air quality model evaluation and other observational methods; support scientific studies ranging across technological, health, and atmospheric process disciplines; and support ecosystem assessments. Of course, these stations together with the more numerous $PM_{2.5}$ and O_3 sites would also provide data for use in the NAAQS decision making process and for public reporting and forecasting of the AQI.

The EPA proposes that these multipollutant NCore stations be required to measure O_3; high-sensitivity measurements, where appropriate, of CO, SO_2, and total reactive nitrogen (NO_y); $PM_{2.5}$ with both a Federal reference method (FRM) and a continuous monitor, $PM_{2.5}$ chemical speciation, and $PM_{10\text{-}2.5}$ with a continuous FEM; and meteorological measurements of temperature, wind speed, wind direction, and relative humidity. High-sensitivity measurements are necessary for CO, SO_2, and NO_y to adequately measure a signal for these pollutants in most air sheds for data purposes beyond NAAQS attainment determinations. For the other listed pollutants, conventional ambient air monitoring methods could be used.

At least one NCore station would be required in each State, unless a State determines through the network design process that a site which meets their obligation can be reasonably represented by a site in a second State, and the second State has committed to establishing and operating that site. Any State, local, or tribal agency could propose modifications to these requirements for approval by the Administrator. While the proposed amendments do not specify the cities in which the States must place their multipollutant NCore Level 2 monitoring stations, EPA anticipates that the overall result will be a network that has a diversity of locations to support the purposes listed earlier. For example, there would be sites with different levels and compositions of $PM_{2.5}$ and $PM_{10\text{-}2.5}$, allowing air quality strategies to be evaluated under a range of conditions.

These sites would be located in a manner that represents as large an area of relatively uniform land use and ambient air concentrations as possible (i.e., out of the area of influence of specific local sources, unless exposure to the local source(s) is typical of exposures across the urban area). Neighborhood-scale sites may be appropriate for multipollutant NCore monitoring stations in cases where the site is expected to be similar to many other neighborhood scale locations throughout the area. In some instances, State and local agencies may have a long-term record of several measurements at an existing location that deviates from the siting criteria in the proposed amendments. The State or local agency may propose utilizing these kinds of sites as the multipollutant NCore monitoring station to take advantage of that record. The EPA will approve these sites, considering both existing and expected new users of the data. The multipollutant NCore stations should be collocated, when appropriate, with other multipollutant air monitoring stations including PAMS, National Air Toxic Trends Station (NATTS) sites, and the $PM_{2.5}$ chemical Speciation Trends Network (STN) sites. Collocation would allow use of the same monitoring platform and equipment to meet the objectives of multiple programs where possible and advantageous.

The proposed amendments would require operation of the 60 NCore

stations by January 1, 2011. However, up to 35 of these stations are already being operated on a voluntary and EPA-funded basis with acquisition of high-sensitivity monitors for CO, SO_2, and NO_y. These three new measurements and other existing measurements for O_3,$PM_{2.5}$, and meteorology are the foundation of this highly leveraged network. $PM_{10-2.5}$ measurements would also be added to these stations once the continuous technologies are approved as FEM and are commercially available.

Once these multipollutant NCore stations are established, it is EPA's intention that they operate for many years in their respective locations. Therefore, State and local agencies are encouraged to insure long-term accessability to the sites proposed for NCore monitoring stations. Relocating these stations would require EPA approval, which would be based on the data needs of the host State and other clients of the information.

We may negotiate with some States, and possibly with some Tribes, for the establishment and operation of some additional rural NCore multipollutant monitoring stations to complement the multipollutant stations that would be required by the proposed changes to the monitoring regulations. We are in the process of revising CASTNET to upgrade its monitoring capabilities to allow it to provide even more useful data to multiple data users. We expect that about 20 CASTNET sites will have new capabilities at least equivalent to the capabilities envisioned for NCore multipollutant sites. Those sites would reduce the number of, and complement, rural multipollutant sites funded with limited State/local grant funds.

2. Proposed Monitoring Requirements for the Proposed Primary National Ambient Air Quality Standard for $PM_{10-2.5}$

The EPA is proposing elsewhere in today's **Federal Register** a new primary standard for coarse particulate matter (PM), and a new indicator for that standard: $PM_{10-2.5}$, qualified so as to include any mix of $PM_{10-2.5}$ dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. See section III.D of the 40 CFR part 50 proposal.[42]

Accordingly, EPA is proposing new provisions in 40 CFR Part 58 to establish the minimum requirements for States to deploy and monitor for this proposed NAAQS. A main goal of the minimum required network will be the support of NAAQS designation decisions. Other data objectives include the improved characterization of the composition of coarse particles to support source apportionment studies and the development of control strategies; support of epidemiological and toxicological research efforts; public reporting of real-time concentration levels through the AQI and particle pollution forecasting programs; the quantification of coarse particle trends over time; and identifying and quantifying the factors that have contributed to changes over time for purposes of program accountability.

Requirements for monitor placement by States that are specific, for example requirements regarding the target distances of monitors from sources of concern, will also ensure a level of consistency in network design that allows monitoring results to be generally comparable among areas where minimum monitoring requirements apply.

This section begins with a discussion of the monitoring methods, types, and sampling frequencies to be used in the proposed network. We then turn to the description of the proposed minimum requirements for the $PM_{10-2.5}$ monitoring network including the proposed number of monitors to be required in affected areas and proposed requirements for where those monitors should be located within the areas. States would have the discretion (and would be encouraged) to place additional monitors to supplement these minimum required monitors.

Monitoring for an indicator described in qualified terms poses issues regarding how and when to determine the sites at which the ambient mix of $PM_{10-2.5}$ would be dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and where it would not be dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. The proposed new provisions for 40 CFR part 58 described in this section address this issue.

a. *Monitor type, methods, and frequency of sampling.*

We are proposing a Federal reference method (FRM) for $PM_{10-2.5}$ in a new appendix 0 to 40 CFR part 50 (Reference Method for the Determination of Coarse Particulate Matter in the Atmosphere), in section VI of the preamble to the Part 50 proposal elsewhere in this **Federal Register**. See also section IV.B above. The proposed FRM for measuring $PM_{10-2.5}$ is based on the combination of two conventional low-volume filter-based methods, one for measuring PM_{10} and the other for measuring $PM_{2.5}$, and determining the $PM_{10-2.5}$ measurement by subtracting the $PM_{2.5}$ measurement from the concurrent PM_{10} measurement.[43]

The new filter-based FRM would not be required to be widely deployed in the operational $PM_{10-2.5}$ network, but rather would serve as the basis of comparison for the equivalency procedures in 40 CFR part 53 described in section IV.B of this preamble. The EPA intends (but would not require) that the majority of the monitors comprising the $PM_{10-2.5}$ network be based on continuous methods that will provide an hourly

[42] As explained in section III of the NAAQS proposal (published elsewhere in this **Federal Register**), the focus on coarse particles associated with these source types is derived from the available epidemiological studies that examined exposures to the ambient mix of $PM_{10-2.5}$ in urban areas, and the study which examined exposure to unenriched natural crustal materials, as well as dosimetric evidence and toxicological studies. Adverse health effects associated with $PM_{10-2.5}$ concentrations have been noted in studies conducted in urban areas, while limited evidence does not support the association of health effects with $PM_{10-2.5}$ concentrations resulting from the suspension by wind of uncontaminated natural crustal materials of geologic origin. Furthermore, available evidence does not support either the existence or the lack of causative associations for community exposures to coarse particle emissions from agricultural or mining sources.

[43] As noted in section VI.A.5 ''Relationship of Proposed FRM to Section 6012 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) (PL 109–59)'' of the part 50 NAAQS proposal, section 6012 of SAFETEA–LU requires the Administrator to ''develop a Federal reference method to measure directly particles that are larger than 2.5 micrometers in diameter without reliance on subtracting from coarse particle measurements those particles that are equal to or smaller than 2.5 micrometers in diameter.''

As explained above in section IV.B of this preamble and in the NAAQS proposal, EPA, consistent with Clean Air Scientific Advisory Committee (CASAC) Peer Review and recommendation, is proposing a difference method as the Federal reference method (FRM). We are doing so because other methods are not yet sufficiently developed to serve as an FRM. We have further explained, however, that we believe that other methods, notably certain types of continuous monitoring and dichotomous methods, are potential Federal equivalent methods, and indeed, that we expect actual monitoring networks to utilize these other means of monitoring. We are also continuing to investigate the possibility of promulgating the dichotomous method as an FRM, and if technically justified, will do so.

We view these actions as consistent with the new statutory provisions. We are taking the steps necessary to develop a compliance network using non-difference, continuous methods as the principal means of monitoring for $PM_{10-2.5}$. We are further devoting substantial effort to the possibility of promulgating dichotomous methods as an alternative FRM. The EPA will also submit the required reports by August 10, 2007, the deadline specified by SAFETEA–LU.

time resolution. At sites with locally measured wind data and continuous $PM_{10-2.5}$ monitors, hourly time resolution will help States and EPA understand the emission sources that are most important to control, by relating wind direction and source locations in particular hours with peaks, and/or by matching the hourly pattern of concentrations with known temporal patterns of sources such as traffic. It may also, in some cases, help in understanding whether natural events have influenced a day's 24-hour concentration. Whatever method a State chooses to deploy, all $PM_{10-2.5}$ monitors counted by a State as part of its compliance with the required minimum number of $PM_{10-2.5}$ monitoring sites (proposed below) would be required to sample every day. The EPA's data quality objective process has found daily sampling to be a key factor in reducing statistical uncertainty at concentration levels near the proposed daily $PM_{10-2.5}$ NAAQS. The automation inherent in continuous methods would provide a more cost-effective alternative to manual filter-based sampling for achieving this daily sampling frequency.

The EPA is proposing January 1, 2009, as the deadline for deployment of $PM_{10-2.5}$ monitors. This will provide over 2 years from promulgation of the final rule for one or more continuous $PM_{10-2.5}$ monitors to be approved by EPA as meeting the proposed Class III FEM requirements in 40 CFR part 53 and for the States to procure and deploy those instruments. We believe this will be sufficient time for the steps that are required by monitor vendors, EPA, and the States. At least two monitor vendors have already developed prototype continuous instruments expected to be candidates for approval as equivalent methods. These prototypes have already been the subject of field trials in cooperation with EPA. We expect vendors to make improvements based on this field experience so that final designs can be field tested in the winter of 2006/2007, after promulgation of the final rule, and in the summer of 2007. Under 40 CFR section 53.5, the Administrator has up to 120 days to act on equivalency applications. Thus, it is feasible for applications to be submitted and EPA to approve one or more applications in late 2007 or early 2008 and for States (or EPA on behalf of States) to place orders in time for monitors to be manufactured, shipped, and installed by January 1, 2009.

A small percentage of continuous $PM_{10-2.5}$ samplers (minimum of 15 percent) would be required to have a collocated filter-based FRM sampler or collocated continuous FEM monitor at the same site for QA purposes (see proposed 40 CFR part 58, appendix A, Quality Assurance Requirements for SLAMS, NCore, and Prevention of Significant Deterioration (PSD) Air Monitoring. While we have determined that all of the $PM_{10-2.5}$ monitors should be of the continuous type, except for these collocated FRM samplers, we are not requiring the sole use of continuous methods, in order to maintain flexibility in the use of manual sampling technology that can meet the proposed $PM_{10-2.5}$ FRM or FEM requirements, and potentially address additional goals such as speciation.

We have considered the issue of whether a State should be allowed to operate an appropriately sited PM_{10} monitor in lieu of a required $PM_{10-2.5}$ monitor in a situation in which the probability of a $PM_{10-2.5}$ NAAQS violation is small. Some State monitoring officials have expressed interest in such an option to save resources or to spread the need for monitor investments over time.[44] We expect that in the types of areas where $PM_{10-2.5}$ is dominated by emissions generated from high density traffic on paved roads, industrial sources, and construction activity, a substantial fraction of PM_{10} is likely to be $PM_{2.5}$. While a PM_{10} monitor will capture this $PM_{2.5}$ and thus would provide a conservative estimate (i.e., an overestimate) of $PM_{10-2.5}$ concentrations, there are complicating considerations.

Without data from FRM or FEM $PM_{10-2.5}$ monitors, an area would be initially designated unclassifiable for $PM_{10-2.5}$.[45] Some designated PM_{10} FRM instruments have relatively poor precision compared to the proposed requirements for the $PM_{10-2.5}$ FRM and FEMs. It is possible that an area might appear to meet the $PM_{10-2.5}$ NAAQS based on PM_{10} monitor readings but actually not be in compliance. It is also possible that a PM_{10} monitor might unexpectedly indicate a high enough concentration of PM_{10} as to suggest a possible violation of the $PM_{10-2.5}$ NAAQS. In such a situation, the result could be a delay in efforts to meet the $PM_{10-2.5}$ NAAQS relative to what would have been the case had an approved FRM or FEM $PM_{10-2.5}$ monitor been deployed initially.

On balance, EPA believes it is appropriate to allow use of any PM_{10} FRM or FEM monitor in lieu of a required $PM_{10-2.5}$ monitor, with restrictions, including the requirement for daily sampling at such PM_{10} monitors. This could only be initiated at monitoring sites where the 98th percentile value for the most recent complete calendar year of PM_{10} monitoring data[46], reported at local conditions of temperature and pressure as specified for $PM_{10-2.5}$, is less than the proposed $PM_{10-2.5}$ NAAQS.[47] During any calendar year of PM_{10} sampling in lieu of a required $PM_{10-2.5}$ sampler, if more than seven 24-hour average PM_{10} concentrations exceed the numerical value of the proposed $PM_{10-2.5}$ NAAQS, the State would have to deploy a FRM or FEM $PM_{10-2.5}$ monitor within a one year period. We invite comment on this subject, including other possible provisions for more limited use of PM_{10} monitors in lieu of $PM_{10-2.5}$ monitors, such as limiting the use of PM_{10} monitors to a period of 3 years after the first approval of a continuous FEM $PM_{10-2.5}$ method.

b. *Network design.*

i. Number of required monitors. The discussion of network design requirements for $PM_{10-2.5}$ begins with the questions of how to define the geographic units which should be separately subject to minimum monitoring requirements and how many monitors should be required in each such area. We propose that the geographic unit for individual application of monitoring requirements be the Metropolitan Statistical Area (MSA) (i.e., a CBSA which contains an urbanized area with a population of at least 50,000 persons).[48] We also propose that only those MSAs that contain all or part of an urbanized area with a population of at least 100,000 or more be required to have monitors.

[44] The Clean Air Scientific Advisory Committee (CASAC) also supported this concept, although without explicit discussion of the complicating implementation considerations discussed here.

[45] An area without a $PM_{10-2.5}$ monitor could in concept be included in an adjacent nonattainment area because of its contribution to concentrations in the latter area. Given the typically short transport distance of $PM_{10-2.5}$, this would be unusual.

[46] PM_{10} data used to qualify a site for PM_{10} monitoring in place of $PM_{10-2.5}$ monitoring must be based on a 1-in-3 day sampling frequency, or more frequent sampling.

[47] The EPA's intention regarding the substitution of PM_{10} monitors for required $PM_{10-2.5}$ monitors is that siting criteria would not be affected, i.e., the PM_{10} monitor that will substitute for a $PM_{10-2.5}$ monitor would have to be located at a site that would be appropriate for a required $PM_{10-2.5}$ monitor. (What sites are appropriate for required $PM_{10-2.5}$ monitors is addressed below.) Also, PM_{10} data used to qualify a site for PM_{10} monitoring in place of $PM_{10-2.5}$ monitoring must also be from—or clearly representative of—the site where a PM_{10} monitor will substitute for a $PM_{10-2.5}$ monitor.

[48] Defined metropolitan and micropolitan statistical areas based on application of 2000 standards (which appeared in the **Federal Register** on December 27, 2000) to 2000 decennial census data. *http://www.census.gov/population/www/estimates/00–32997.txt.*

Some MSAs contain multiple urbanized areas with populations of 100,000 people or more, each containing emission sources of interest for $PM_{10-2.5}$, which could be separately subject to monitoring requirements; however, we believe applying minimums at the urbanized area level is not necessary to support implementation of the proposed NAAQS.[49] Where more than one MSA is part of a Combined Statistical Area (CSA), each MSA would be treated separately. We believe separate treatment of MSAs is appropriate in light of the typically short transport distance of $PM_{10-2.5}$ and the diversity of situations that can exist in a CSA. For comparison, $PM_{2.5}$ and O_3 monitoring, minimum requirements apply at the CSA level, because a broader geographic frame is appropriate for those photochemically formed pollutants.

Consistent with both the current State and Local Air Monitoring Station (SLAMS) minimum requirements for $PM_{2.5}$ described in 40 CFR part 58, appendix D and the proposed minimum requirements for $PM_{2.5}$ described in section IV.E.3 of this preamble, EPA proposes that States be required to have more $PM_{10-2.5}$ monitors in higher-population MSA than in lower-population MSA. A higher-population MSA typically has more total roadway surface, higher traffic counts, more and larger industrial sources, and more ongoing construction at any given time, all of which make it more likely that the MSA contains more locations with high concentrations of coarse particles attributable to these sources. Also, a higher-population MSA potentially contains more distinct types of emissions situations causing $PM_{10-2.5}$ nonattainment, *i.e.*, more distinct mixes of emission sources affecting different locations, such that separate monitoring may be needed to identify these and to develop and track the success of control strategies for them. More monitors will also be useful in helping to define nonattainment boundaries in larger and potentially more complex MSAs. Accordingly, we are proposing minimum requirements for the number of $PM_{10-2.5}$ monitoring stations in each MSA based, in part, on the total population of the MSA.[50]

We are proposing that the actual or estimated $PM_{10-2.5}$ design value (three-year average of 98th percentile 24-hour concentrations) of an MSA, where one can be calculated, be used as a second factor to increase the minimum number of monitors in MSA with higher estimated ambient coarse particle levels and to reduce requirements in MSA with lower estimated levels. Given the imprecision of current estimates of $PM_{10-2.5}$ ambient concentrations and the resulting non-robust design value statistics that will initially be available to States when they develop their monitoring plans, we are proposing three categories of design values defined by percentages of the proposed 24-hour $PM_{10-2.5}$ NAAQS. The proposed amendments categorize MSA design values as either low (less than 50 percent of the proposed $PM_{10-2.5}$ NAAQS), medium (50 percent to 80 percent), or high (greater than 80 percent).

The EPA will assist States with the development of $PM_{10-2.5}$ design values by analyzing the concentrations from existing collocated or nearly collocated PM_{10} and $PM_{2.5}$ monitors in each MSA and identifying which pairs meet the proposed siting criteria appropriate for comparison to the proposed $PM_{10-2.5}$ NAAQS. Monitoring agencies may propose other procedures for calculating estimated $PM_{10-2.5}$ design values as a substitute for EPA-calculated values, subject to Regional Office approval of the monitoring methods, site characteristics, and data handling procedures being used to calculate substitute estimated design values. $PM_{10-2.5}$ design values for purposes of determining the number of required monitors would be calculated using data only from sites which are suitable for comparison to the NAAQS under the criteria presented later in this section. If no such sites exist, medium area MSA minimum requirements would apply. After actual data using FRM or FEM monitors is available to establish a true design value based on 3 years of data, a State would be allowed to reduce or be required to increase the number of monitors based on that design value. This process of adjustment would be ongoing, and would be a specific aspect of the periodic network assessment that would be required by the proposed amendments.

Table 1 of this preamble presents the specifics of the proposed requirements for the minimum number of monitors in an MSA, relating the minimum number of $PM_{10-2.5}$ monitors to total MSA population and design value. For example, an MSA with a total population of between 1 million and 5 million people that contains all or part of an urbanized area with a population of at least 100,000 people, with an actual or estimated $PM_{10-2.5}$ design value of between 50 percent and 80 percent of the proposed $PM_{10-2.5}$ NAAQS would be required to have at least two monitors. In another example, an MSA with a total population between 100,000 and 500,000 people with an actual or estimated $PM_{10-2.5}$ design value of less than 50 percent of the proposed $PM_{10-2.5}$ NAAQS would not be required to have any monitors, although States could deploy discretionary monitors.

We invite comment on whether there should be a different minimum size for an MSA required to have monitors, rather than applying the criteria in Table 1 of this preamble to all MSA that contain all or part of an urbanized area with a population of at least 100,000 persons. We also invite comment on whether factors in addition to MSA population and estimated design value should enter into the determination of the number of required monitors, for example, MSA or urbanized area(s) population density, and if so, in what way.

[49] Factors which contribute to this assessment include the consideration that multiple urbanized areas in a single Metropolitan statistical area (MSA) will tend to have similar situations affecting $PM_{10-2.5}$ concentrations, for example similar meteorological conditions which can favor or suppress emissions of $PM_{10-2.5}$ from paved roadways and construction sites. Also, applying monitoring requirements separately to urbanized areas would both increase the total number of required monitors and reduce State flexibility in siting the required monitors since any requirements would have to be met separately in each urbanized area.

[50] April 1, 2000 population in Metropolitan and Micropolitan Statistical Areas in Alphabetical Order and Numerical and Percent Change for the United States and Puerto Rico: 1990 and 2000, Source: U.S. Census Bureau, Census 2000 and 1990 Census. Internet Release date: December 30, 2003. *http://www.census.gov/population/cen2000/phc-t29/tab01a.xls.*

TABLE 1.—$PM_{10-2.5}$ MINIMUM MONITORING REQUIREMENTS

MSA total population [1] [5]	Most recent 3-year design value [2] >80% of $PM_{10-2.5}$ NAAQS [3]	Most recent 3-year design value 50%–80% of $PM_{10-2.5}$ NAAQS [3] [4]	Most recent 3-year design value <50% of $PM_{10-2.5}$ NAAQS [3]
> 5,000,000	5	3	2
1,000,000–<5,000,000	4	2	1
500,000–<1,000,000	3	1	0
100,000–<500,000	2	1	0

[1] Metropolitan Statistical Area (MSA) as defined by the Office of Management of Budget. The requirements of this table apply only to MSAs that contain all or part of an urbanized area with a population of at least 100,000 persons. Metropolitan and micropolitan statistical areas based on application of 2000 standards (which appeared in the **Federal Register** on December 27, 2000) to 2000 decennial census data.
[2] A database of estimated $PM_{10-2.5}$ design values will be provided by EPA until the network is fully deployed for 3 years.
[3] The proposed $PM_{10-2.5}$ National Ambient Air Quality Standards (NAAQS) levels and forms are defined in 40 CFR part 50.
[4] These minimum monitoring requirements would apply in the absence of a design value.
[5] Population based on latest available census figures.

The EPA estimates that the size of the minimum required $PM_{10-2.5}$ network will be approximately 250 monitors based on the proposed requirements and our current estimates of $PM_{10-2.5}$ design values. Figure 1 of this preamble illustrates our current estimates of how many monitors would be required in each MSA based on the criteria in Table 1, census data on MSA populations, and current estimates of design value.[51] We are not proposing a specific number of monitors for any MSA. The actual initial number of monitors required in a given MSA and the initial size of the minimum required national network may be different if monitoring agencies propose and we approve alternate approaches to estimating design values for this purpose. It may be that later review by States may determine that one or more of the PM_{10} monitors we have used to estimate $PM_{10-2.5}$ design values is not appropriate. Also, consideration of exceptional events may be appropriate and may affect estimated design values. The size of the required network may vary after its startup depending on long-term changes in total MSA population and design values.

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[51] A document listing the current estimate of $PM_{10-2.5}$ design values used in constructing figure 1 of this preamble is available in the docket.

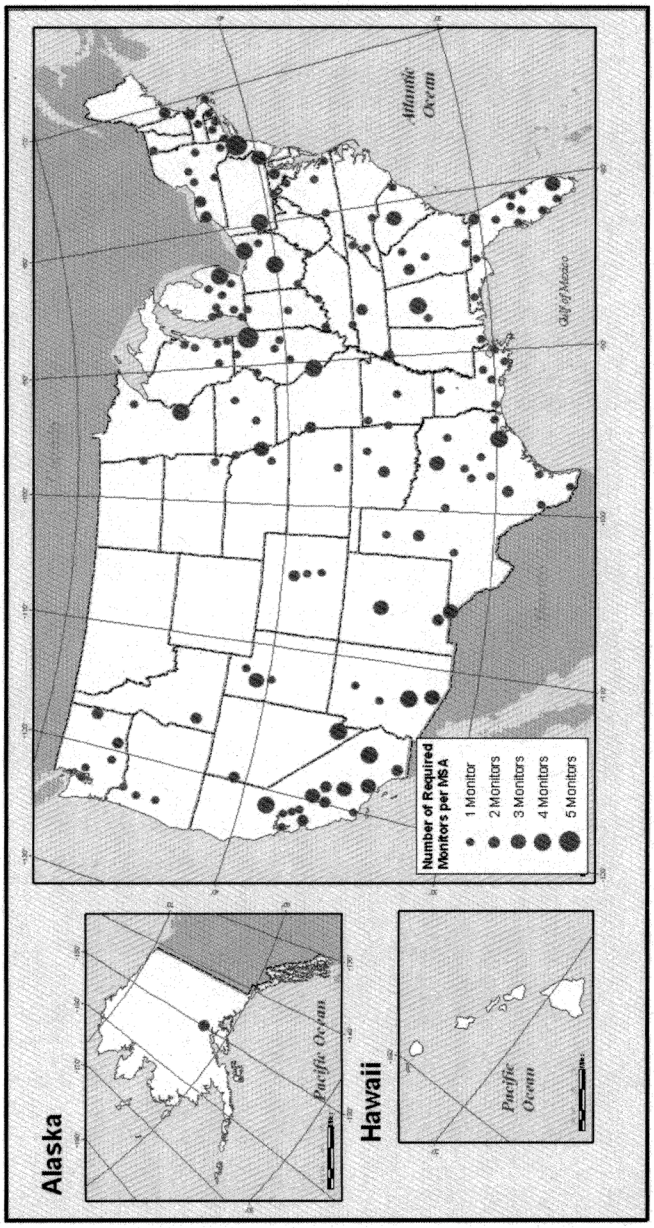

Figure 1. Illustration of Monitors That Could Be Required by the Proposed Requirements Listed in Table 1. The circles, which are sized to indicate the number of required monitors, appear at the centroid of MSA and do not imply the actual placement of any of the required monitors at particular locations within the MSA.

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Figure 1 of this preamble shows that the proposed minimum network criteria could (depending on estimated design values as of the time the States develop their monitor siting plans) have the effect of putting relatively more monitors in the eastern States than in western States. This occurs in part because of currently estimated design values but also in part because there are so many individual MSA in eastern States compared to western States. In western States, there are fewer small and medium-sized cities which are in separate MSA and thus qualify for separate monitoring under the proposed criteria, because the larger size of

counties in the western States means that many smaller cities are subsumed within relatively few MSA.

We request comment on whether the proposed minimum requirements appropriately address the need for monitoring data in both eastern and western States, whether additional or fewer monitors could be needed, and whether additional monitors in some areas, if needed, should be required by the regulations or deployed through collaborative planning and grant support. A possibility on which we request comment is to not adhere to the formal county-based definition of MSA in the West and in some way to require separate monitoring of more urbanized areas that are not distinct MSA and, therefore, would not be separately subject to the minimum monitoring requirements as proposed. For example, some MSA in some western states are divided into distinct nonattainment areas for ozone, reflecting natural barriers to transport between air basins. This division or similar divisions of a large MSA in a western state could perhaps play a role in determining which population centers should require separate monitoring for $PM_{10-2.5}$. We also request comment on approaches that would aggregate officially distinct MSAs in eastern States for the purpose of determining the required number of monitors.

ii. *Location of required monitors and comparability to the NAAQS.* We now turn to the criteria that should be used to locate required monitoring sites within an MSA (the number of monitors to be sited being determined by the total MSA population and estimated design value criteria as just described). As stated in the introduction to this section, a main goal of the minimum required monitors in a given MSA will be to support NAAQS designation decisions, including decisions on nonattainment area boundaries. As detailed in the NAAQS proposal also in today's **Federal Register**, the purpose of the proposed qualified coarse particle indicator and standard is to protect against coarse particle mixes that are likely to be similar to those present in the urban epidemiological studies upon which the proposed standard is based. The indicator for the NAAQS includes any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. In order to implement the proposed standard, it is necessary to separate where the mix is dominated by the emissions of PM from listed sources and where it is not. We have been mindful of this goal in developing the following proposals regarding monitor siting. In particular we have been mindful that the strategy for locating $PM_{10-2.5}$ monitors must be developed in light of the qualified indicator for the NAAQS. Monitors should therefore be placed in locations where concentrations of $PM_{10-2.5}$ are dominated by PM emissions generated from high density traffic on paved roads, industrial sources, and construction activities.

We have also been mindful that the strategy for locating $PM_{10-2.5}$ monitors must be developed in light of the approach used to set the level of the proposed $PM_{10-2.5}$ NAAQS. As explained in the NAAQS proposal notice elsewhere in today's **Federal Register**, the proposed level of 70 $\mu g/m^3$ for $PM_{10-2.5}$ (98th percentile form) was selected to be of equivalent stringency to the current 24-hour PM_{10} NAAQS of 150 $\mu g/m^3$ (one-expected exceedance form). As discussed below, the approach used to determine that these levels are equivalent in stringency has implications for $PM_{10-2.5}$ monitor placement.

The EPA recognizes that each MSA will be characterized by a unique mix of moderate to highly populated areas together with unique arrangements of paved roads, areas of construction, and industrial sources of coarse particles. Therefore, we are proposing network design requirements that leave room for later agreement between EPA and each State on specific sites but that provide the binding principles for those agreements.

We envision that a typical $PM_{10-2.5}$ monitoring network in a large MSA would include some sites with heavy impacts from PM emissions generated from highly traveled roadways and/or major industrial sources, but with a relatively small exposed population because the area around the site is not a dense residential or commercial area, and some sites in densely populated areas with somewhat less proximity to such sources. It could also include some sites in lower-density suburban-type population areas that are nonetheless affected by sources with emissions of concern. Within each of these three categories of sites, there are some sites that are not suitable for required monitors because the sites have a good possibility of not being dominated by PM emissions generated from high density traffic on paved roads, industrial sources, and construction activities, or because placement of monitors for comparison to the NAAQS in those locations would be inconsistent with the intended stringency of the NAAQS. The following proposal addresses both how the required number of monitors should be assigned to the three categories of sites, and what types of sites are suitable or unsuitable for placement of monitors.

We are proposing a five-part test of whether a potential monitoring site is suitable for comparison to the NAAQS, and two rules for how required monitors should be assigned among such suitable sites. All five parts of the suitability test must be met. The suitability test also would be used to determine whether non-required or special purpose monitors are suitable for comparison with the proposed $PM_{10-2.5}$ NAAQS.

The first two parts of the five-part suitability test are based on using readily available Census data to help ensure that $PM_{10-2.5}$ monitoring sites are located near and will be dominated by PM emissions from paved roads, construction, and industrial sources. The first part is that a monitoring site must be within a U.S. Census Bureau-defined urbanized area that has a population of at least 100,000 persons. Restricting suitable sites to only those within an urbanized area of this size increases the likelihood that the ambient mix of $PM_{10-2.5}$ will be dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, rather than rural windblown dust and soils and PM generated by agricultural and mining sources which are more typical of rural areas.

The second part of the suitability test is a minimum threshold for the population density of the block group containing the monitoring site. This provides more assurance that resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources will dominate in the vicinity of the monitoring site.

We propose to employ population density in addition to simple presence within an urbanized area because population density is highly correlated to traffic density and is available on a relevant geographic scale. It is appropriate to expect that mixes of $PM_{10-2.5}$ monitored at sites located in areas of sufficiently high population density are dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources.

Accordingly, we have based the proposed suitability test for a candidate monitoring site on the population

density of the census block group in which the site is located. There is a strong correlation of county-level estimates of Vehicle Miles Traveled (VMT) density with county-based population density.[52] It is reasonable to presume that this county-level correlation indicates an association between population density and vehicular traffic and resulting emissions of resuspended dust at smaller geographic scales also, although exceptions to the association no doubt become more common. To a lesser extent, there may also be associations between population density and the presence of other industrial sources and construction activities.[53] It is thus appropriate to expect that mixes of $PM_{10-2.5}$ monitored at sites located in areas of sufficiently high population density are dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and are not dominated by rural windblown dust and soils and PM generated by agricultural and mining sources.

The available census geographic entities for which population density is published by the U.S. Census are counties, urbanized areas, urban clusters, census tracts, and block groups. Block groups typically encompass one-half to two square miles, and thus they provide a spatial resolution of about one mile. On average, there are approximately 200 block groups for each of the 370 MSA in the U.S. In a State such as Michigan, for example, the average land area in a county is 700 square miles as compared to just over 20 square miles for a census tract and to about 0.5 square miles for a block group. A large-scale unit of density analysis, say the urbanized area level, would not be as helpful for guiding monitor placement since it would be a mix of low and high density sub-units that could have quite different source mixes.

We considered a range of block group population density thresholds for use in identifying block groups within an urbanized area that may be suitable for comparison to the NAAQS, depending on other parts of the suitability test. A low population density threshold would tend to identify as suitable low density ''edge'' block groups, which because of their proximity to surrounding non-urbanized lands could tend to have $PM_{10-2.5}$ concentrations that are from emission sources that are not of concern, as these are explicitly rural sources (windblown rural dust and soil) or sources that are more typical in rural lands (agriculture and mining). A low population density threshold would also tend to identify internal or ''enclave'' low density block groups which may well have significant paved road, industrial, and construction emission sources but happen not to have many residences; later we return to such ''enclave'' block groups as an exceptional case. A population density threshold that is too high could leave out areas where $PM_{10-2.5}$ concentrations are dominated by PM emissions from high density traffic on paved roads, industrial sources, and construction activities.

We first noted that the U.S. Census Bureau uses a population density of 500 persons per square mile in one step of defining the ''Initial Core'' of an urbanized area. The initial core of an urbanized area always includes core census block groups or blocks with a density of at least 1,000 persons per square mile and contiguous block groups that have a density of at least 500 persons per square mile.[54]

We have investigated for comparison the population densities of block groups in which States and EPA have agreed in the past to place PM_{10} monitors. We observe that States have typically located PM_{10} monitors in block groups of population densities that are higher than 500 people per square mile. The median block group population density of the approximately 1,200 PM_{10} monitoring sites active in the U.S. between 2002 and 2004 is 1,390 people per square mile. Sixty-three percent of the approximately 1,200 PM_{10} monitoring sites are in block groups with a density higher than 500 persons per square mile.

We have also investigated for comparison the block group population densities for those PM_{10} monitors which are sited with or near a $PM_{2.5}$ monitor. The $PM_{2.5}$ monitoring program was set up to be more urban oriented than the PM_{10} monitoring program. Thus, this smaller set is of more relevance to the structure of a $PM_{10-2.5}$ monitoring program. Among the 710 such monitors, the median block group density is 2,306 persons per square mile. Seventy-eight percent of the 710 monitoring sites are in block groups with a density higher than 500 persons per square mile.

After examining on an empirical basis in a sampling of MSA the block groups identified by population density thresholds of 500 persons per square mile, values lower than 500, and values above 500, and in light of the practices of the U.S. Census Bureau, we selected 500 as the proposed threshold value for the second part of the suitability test because it appears to result in inclusion of most of the related urbanized area while omitting fringe areas where paved roads, construction sites, and industrial sources are few in number and/or low in emissions mass, and whose emissions and ambient impact could be exceeded by the impact of rural soil, dust, and emissions from agricultural and mining sources.

Regarding the above-mentioned issue of enclaves within an urbanized area, we are concerned not to exclude low population density block groups that contain paved roads, construction sites, and/or industrial sources and do not contain significant agricultural or mining sources. The Census incorporates enclaves consisting of block groups with population density below 500 persons per square mile if certain conditions are satisfied. Enclaves of less than five square miles are always incorporated. Even larger enclaves can be included as well. We are concerned that such large enclaves may not be industrial zones or transportation corridors that happen to have little resident population (which could be appropriate for monitoring) but instead could contain agricultural or mining operations (which could make them inappropriate for monitoring). Therefore, we propose that block group(s) with population densities less than 500 persons per square mile, even if part of an urbanized area, will be considered to pass the second part of the suitability test if those block groups comprise an enclave of less than five square miles in land area. We invite comment on this special exception.

We propose that the third necessary condition for siting a required monitor and comparing any $PM_{10-2.5}$ monitor to the $PM_{10-2.5}$ NAAQS be that the monitor be population-oriented. The term

[52] Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper, EPA–452/R–05–005, June 2005, p. 5–59. Counties are the geographic unit at which vehicle miles traveled (VMT) is most readily available from State departments of transportation. The Federal Highway Administration maintains VMT statistics at a higher level of aggregation.

[53] Manufacturing and service industry facilities, and areas of long-term construction such as commercial development and roadway construction, tend—with exceptions—to be in the general area of populated areas that create the demand for such activities and provide their workers.

[54] See Urban Area Criteria for Census 2000, March 15, 2002, 51 FR 11663. The Census Bureau adds to each urbanized area additional non-contiguous block groups below and above 500 persons per square mile using detailed ''hop'' and ''jump'' criteria. Any additional block groups below 500 persons per square mile would not be included in our proposed suitability test because such areas are less likely to have a dense concentration of paved roads, construction, and industrial sources and may be in close proximity to sources of emissions that are not of concern.

''population-oriented sites'' is presently defined in 40 CFR 58.1 as sites in residential areas, recreational areas, industrial areas, and other areas where a substantial number of people may spend a significant fraction of their day.[55] The concept plays an important role in the $PM_{2.5}$ monitoring network in that a $PM_{2.5}$ monitor must be population-oriented to be appropriate for comparison to either the annual or 24-hour $PM_{2.5}$ NAAQS. We believe that this restriction is also appropriate for $PM_{10\text{-}2.5}$ for the same reasons as for $PM_{2.5}$.

The fourth part of the five-part suitability test is a restriction against monitoring sites that are adjacent to a large emissions source or otherwise within the micro scale environment affected by a large source.[56] This restriction is intended to help ensure that monitor siting is consistent with the intended stringency of the proposed NAAQS. The relatively large size of coarse particles and resulting high rate of deposition under most weather conditions, and the fact that nearly all coarse particles are primary[57], mean that the ambient concentration of $PM_{10\text{-}2.5}$ measured in a specific location will be more dependent on the distance of that monitor from coarse particle sources than would typically be the case for ambient $PM_{2.5}$ and associated sources of fine particles.[58] Monitors placed adjacent to coarse particle sources would typically measure higher ambient concentrations than monitors placed farther away. A $PM_{10\text{-}2.5}$ monitoring site located adjacent to a high emitting industrial source or a heavily traveled highway, for example, might measure high ambient concentrations, but these concentrations could be characteristic only of the relatively small area around the monitor, notably a smaller area than in the case of a similarly sited $PM_{2.5}$ monitor. Even if there are people living or working at the monitor site, thus qualifying it as population-oriented, applying the proposed NAAQS level to the concentration level measured at such a monitor would be inconsistent with the level of community protection intended through the proposed NAAQS. As explained in section III.G of the NAAQS preamble, the EPA intends that the proposed 24-hour $PM_{10\text{-}2.5}$ NAAQS be equivalent in stringency to the current 24-hour PM_{10} NAAQS. In determining the level for the $PM_{10\text{-}2.5}$ NAAQS that would achieve this equivalency, we relied on the relationship between $PM_{10\text{-}2.5}$ and PM_{10} observed at PM_{10} monitoring sites all or most of which were not adjacent to large emission sources. If $PM_{10\text{-}2.5}$ monitors were placed at sites that are adjacent to emission sources, the effect would be to make the proposed NAAQS less community-oriented and more stringent than intended. The EPA therefore believes it is appropriate to have a restriction that $PM_{10\text{-}2.5}$ monitors in source-influenced micro-environments, such as on facility fence lines or along the edge of traffic lanes, are not appropriate for comparison to the NAAQS even if there is some population subject to exposure in that location (even if EPA or the State believes that there are other micro-environments similarly affected by other sources of the same type). $PM_{10\text{-}2.5}$ monitors placed in such micro environment-types of situations thus would not be eligible for comparison to the NAAQS[59] and would not count toward meeting minimum EPA monitoring requirements.

The fifth part of the suitability test, which would only need to be considered for sites that satisfy all of the first four parts, is that a site-specific assessment shows that the ambient mix of $PM_{10\text{-}2.5}$ sampled at that site would be dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and would not be dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. The first four parts of the suitability test make it unlikely that a candidate site would be dominated by rural windblown dust (other than perhaps during exceptional events), but the site-specific assessment may determine otherwise. The site-specific assessment may also reveal the presence of a dominant agricultural or mining operation, for example, a gravel or sand extraction and material handling operation.

As an example of how this five-part suitability test would work, consider the Riverside-San Bernardino-Ontario, California MSA. The first part of the test excludes any site outside the Census-designated urbanized areas within the MSA, of which there are several. The second part of the test would indicate that a monitoring site within a certain boundary around the densest parts of the Riverside-San Bernardino urbanized area, the Indio-Cathedral City-Palm Springs urbanized area, or any of the other urbanized areas in the MSA that have a population of at least 100,000 persons, is possibly suitable for comparison with the NAAQS, while a monitoring site in the small Yucca Valley urban cluster would definitely not be suitable. Each boundary would follow block group borders, and would leave out less dense parts of its associated urbanized area. The third part of the test (population-orientation) would disqualify some sites within these boundaries because of the small number of people subject to exposure in the vicinity that has concentrations similar to what would be monitored at the site. The fourth part would disqualify sites adjacent to major roadways (a source-influenced microenvironment). The fifth part would assess the remaining candidate sites to verify that they are not exposed to windblown rural dust and soils or PM generated by agriculture and mining sources to such an extent that emissions from those sources would dominate the mix of $PM_{10\text{-}2.5}$ sampled at that site.

We invite comment on possible variations of the proposed test for suitability for comparison to the NAAQS, for example the use of census tracts in place of block groups or different values for population density or total population of a aggregation of block groups or tract groups. Census

[55] Population density of a block group and population-orientation of a monitoring site are distinct concepts. A monitoring site may not be population-oriented even though it is within a block group of high population density. Population-orientation refers to the presence of people in a geographic area around a monitoring site that may be much smaller than the block group. If there is not a substantial number of people spending a significant fraction of their day in the area around the monitor with ambient concentrations of about the magnitude indicated by a monitor, the monitor is not population oriented, regardless of the population density of the surrounding census block group. For example, there could be a portion of a high-density block group that is near a source but which has few residents or visitors because of its land use type, for example.

[56] A microscale environment is one in which there are significant differences in concentrations between locations that are 10 meters to 100 meters apart, and generally are areas that are impacted by immediately adjacent sources such as industrial sites, roadways, or construction sites.

[57] i.e., coarse particles typically are deposited in the form most recently emitted by their original source (or in the form they had when resuspended after having deposited to a roadway or construction site) rather than being created or modified by atmospheric chemical reactions during their generally short transport from the point of original emission (or resuspension). Particles that have been resuspended may have incorporated secondarily formed compounds at some time in their prior history.

[58] Air Quality Criteria for Particulate Matter, Volume I of II, EPA/600/P–99/002aF, October 2004, p. 2–49. See also section III.G in the NAAQS proposal elsewhere in today's **Federal Register**.

[59] We note that this proposed language is more restrictive for the proposed 24-hour $PM_{10\text{-}2.5}$ NAAQS than parallel language for the 24-hour $PM_{2.5}$ NAAQS (which allows such data to be used for comparison with the 24-hour $PM_{2.5}$ NAAQS, see present 40 CFR part 58, appendix D, section 2.8.1.2.3). As explained in the text above, this is because coarse PM is transported over shorter distances such that a microscale $PM_{10\text{-}2.5}$ monitor would not be representative of community-wide conditions.

tracts are defined as combinations of (usually a few) block groups, and would provide a somewhat larger scale of analysis around a candidate monitoring site.

While the issue of setting boundaries for nonattainment areas is not a subject of this rulemaking, we note that the considerations that underlie the proposed suitability test, having to do with the influence of sources on measured concentrations, may also be relevant to the setting of such boundaries.

The five-part suitability test will leave as suitable many sites in a MSA, falling into the three broad categories described earlier. We believe that States should be given further direction on placement of the required monitors among these sites. A network design strategy should not allow all required $PM_{10-2.5}$ monitoring sites to be located so far from large emissions sources that they measure ambient concentrations lower than would be representative of the impact of coarse particle sources on well populated urban areas. We propose to address this issue by adopting some of the elements of the monitoring siting approach that has been used for the PM_{10} NAAQS. We propose that 50 percent of required $PM_{10-2.5}$ monitors [60] be required to represent population-oriented middle scale-sized areas [61] [62] near but not adjacent to large sources of PM (i.e., heavily traveled paved roadways, long-term construction sites, large industrial sources) to characterize air quality in significant-sized areas that are affected by emissions from these sources where people may spend a greater part of their day.[63] The placement of a monitor on the grounds of a school within a residential community that is near but not adjacent to an industrial facility would be an example of such a site. With this requirement for middle scale $PM_{10-2.5}$ sites, EPA's proposal provides the intended degree of protection in populated areas with high coarse particle concentrations by requiring sites that are likely to measure the maximum concentrations (among sites meeting the suitability test) in one or more of the populated areas that are impacted by the heaviest PM emissions from roadways and/or industrial/construction sources.

For those areas with monitoring requirements greater than one required monitor, we propose that at least one of the required monitors must be sited in a neighborhood scale-sized area [64] that is highly populated and which may be somewhat further away from emission sources but is still expected to have elevated levels of coarse particles of concern. These sites would typically still be impacted by roadway and/or industrial/construction source emissions, but to a lesser extent than sites expected to measure maximum concentrations. Among such sites, the State should select a site characterized by a very large number of people subject to exposure; typically, this population number would be higher than the population at sites expected to record maximum concentrations. A site located within a heavily populated residential and commercial area that is in proximity to roadways with high vehicular traffic would be an example of this type of monitor placement. A site of this type is useful for several reasons. It will help define the spatial gradients of $PM_{10-2.5}$ concentrations, which may be useful in setting nonattainment area boundaries. It likely will provide concentration data that are relevant for informing a large segment of the population of their exposure levels on a given day. Also, areas of this type may have $PM_{10-2.5}$ nonattainment problems that are caused by a different source mix than problems found at the first type of site, and require a different approach to reducing concentrations. For example, the mix of industrial and paved road emissions may be different or the mix of types of vehicles on paved roads may be different.

For MSA with a requirement for one, two, or three monitors, the above two siting provisions address the siting of all required monitors with respect to proximity to specific sources and populations. For MSA with a requirement for four or five monitors, there is one remaining required monitor not yet addressed. We propose that the siting of this monitor be left to the discretion of the State or local monitoring agency, subject to a restriction that the site satisfy the suitability test described above. This site could be placed in locations similar to those that would be eligible as monitoring sites for the other required monitors, i.e., at other sites that meet one of the above two proposed siting requirements. A State may also choose to place the site in a location that is somewhat more distant from downtown areas, main industrial source regions, or areas of highest traffic density, such as in a highly populated suburban residential community. The comparison of ambient $PM_{10-2.5}$ concentrations between such suburban monitors and those monitors located at the previously described maximum exposure-type of sites would provide comparative data for assessing the spatial variation of $PM_{10-2.5}$ concentrations over a metropolitan area.

While we expect the proposed suitability test described above will appropriately identify areas where the ambient mix of $PM_{10-2.5}$ is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, it may not identify them all. We recognize that it does not address the possibility that high density traffic on paved roads, large industrial emission sources, and/or construction activities may be located outside an urbanized area (including outside any MSA) or in parts of an urbanized area that do not satisfy the second part of the suitability test (related to population density) such that monitoring sites near these sources would not meet the proposed test, yet persons living or working near the source could be exposed to concentrations of $PM_{10-2.5}$ which are dominated by the PM emissions from these sources. We invite comment on alternative approaches that would examine areas where States may wish to place non-required monitors that do not meet the proposed suitability test, but are locations of industrial emissions or high traffic on paved roads which create the potential for ambient mixes of coarse particles of the type intended to be included by the indicator. In particular, EPA solicits comment on a modification of the proposed test that would specify that a site meeting only the third, fourth, and fifth parts of the

[60] Fractional monitor requirements would round up. MSA with one, two, three, four, or five required monitors would place one, one, two, two, or three monitors in this manner, respectively.

[61] A middle scale-sized area is one in which there are significant differences in concentrations between locations that are 100 meters to 500 meters apart, and generally are areas that are impacted by nearly adjacent (but not immediately adjacent) sources, such as industrial sites, roadways, or construction sites. Middle scale sites are common in PM_{10} monitoring (see present 40 CFR part 58, appendix D, section 2.8.0.2) and typical of the PM_{10} sites used to establish the equivalency of the proposed $PM_{10-2.5}$ NAAQS to the current PM_{10} NAAQS.

[62] Additional information on middle-scale siting, and on all such monitoring scales, can be found in the document: Guidance For Network Design and Optimum Site Exposure For $PM_{2.5}$ and PM_{10}. U.S. Environmental Protection Agency. EPA–454/R–99–022. December 1997. Available on the web at: *http://www.epa.gov/ttn/amtic/files/ambient/pm25/network/r-99–022.pdf.*

[63] If only one monitor is required, then that monitor would need to conform to this siting requirement (if the monitor is to be considered as part of the minimum network design).

[64] A neighborhood scale-sized are is one in which there are not typically significant differences in concentrations between locations that are 500 meters to four kilometers apart, and generally are areas that are impacted by the more well-mixed emissions of urban industrial and mobile sources in the general vicinity of the site.

suitability test could be compared to the NAAQS if it were close enough to an industrial source of coarse particles of a defined high enough emissions level (for example, 100 tons per year or more of emissions) that the ambient mix would be dominated by PM generated by that industrial source. The term ''industrial'' would be made operational by using a source's assigned industry code under the North American Industry Classification System (NAICS) and excluding sources with codes corresponding to agricultural or mining industries.[65] As noted, the site would have to population-oriented and could not be in the micro-scale environment affected by a large source. A site-specific assessment (the fifth part of the suitability test) would still be required, and would consider the local mix of emission source types and sizes, their relative locations to the potential monitoring site, and local factors affecting transport and deposition of $PM_{10-2.5}$. Such monitors, even if determined to be comparable to the NAAQS through the site-specific assessment, would not count toward the minimum number of monitors required for each MSA.

We also invite comment on the possibility of another, similar modification to the proposed suitability test as that just described for industrial sources, but addressing emissions from vehicle traffic on roadways. Non-required State sites otherwise excluded from comparison to the NAAQS, based on their location outside of a U.S. Census Bureau-defined urbanized area and/or their location in block groups with population density below the proposed threshold, but are population oriented and within some distance of a roadway with a certain traffic volume per day, could be the subject of site-specific analysis to determine if they are in fact suitable for comparison to the NAAQS based on the PM emissions from sources that dominate $PM_{10-2.5}$ concentrations at those sites. Such sites would have to be population-oriented and could not be in the micro-scale environment affected by the roadway. The site-specific assessment would consider the local mix of emission source types and sizes, their relative locations to the potential monitoring site, and local factors affecting transport and deposition of $PM_{10-2.5}$. We seek comment on whether such sites would be appropriate for comparison to the NAAQS, and, if so, what levels of VMT must occur and/or other conditions exist before comparison to the NAAQS could be considered. We note that traffic volume alone is not a direct predictor of emissions of resuspended dust and other $PM_{10-2.5}$ emissions, since the load of dust on the highway and the mix of vehicle types matter also. Such monitors, even if determined to be comparable to the NAAQS through the site-specific assessment, would not count toward the minimum number of monitors required for each MSA.

iii. *Non-required monitoring.* States may deploy $PM_{10-2.5}$ monitors in addition to those that would be required. For example, additional monitors in areas that are required to have one or more monitors may be very useful for determining nonattainment area boundaries. States might also want to site monitors near large point sources, if the final rule provides for the suitability of monitoring sites near such sources. The EPA will work with States as they consider what additional monitors to deploy and operate.

The proposed suitability test for comparison with the $PM_{10-2.5}$ NAAQS applies to all non-required monitors (as well as all required monitors). Data from monitors that do not meet the suitability test could not be used for nonattainment determinations. For example, as with required monitors, non-required monitors must also be population-oriented as defined above in order to be used for nonattainment designations. Also, as with required monitors, non-required monitors could not be compared to the NAAQS if they are located in source-influenced micro-environments, such as on facility fence lines or along the edge of traffic lanes.

iv. *Speciation monitoring.* In addition to sites measuring $PM_{10-2.5}$ mass concentration, our experience with $PM_{2.5}$ suggests that it would be useful to have a long-term $PM_{10-2.5}$ speciation network of 50 to 100 sites to assess physical and chemical characteristics at a nationally diverse set of locations. Speciation data would help identify the specific source types, address the relative contribution of anthropogenic and natural sources to ambient concentrations, and support future research concerning the health risks of coarse particles of various compositions and source origins. We propose that one speciation site be located in each of the MSAs with total population greater than 500,000 people and that also have an estimated $PM_{10-2.5}$ design value greater than 80 percent of the proposed $PM_{10-2.5}$ NAAQS. We expect that approximately 25 MSAs will be required to have speciation monitors based on these proposed criteria. These sites will gather data in areas that have a higher probability of exceeding the proposed NAAQS and also have larger exposed populations at risk, and would support the characterization of coarse particles concentrations that control the attainment/nonattainment status of the area. States would be required to operate any of these speciation sites that were located inside their borders. In some cases, monitors could be collocated with $PM_{2.5}$ speciation monitors at urban NCore multipollutant monitoring stations to provide comparative chemical characterization studies between fine and coarse particles. The $PM_{10-2.5}$ mass concentration data obtained with speciation monitors would be comparable to the NAAQS only in situations where the underlying sampling method used to obtain the filters was an approved FRM or FEM and the site met the suitability test described earlier in this section.

We will collaborate with States to select and fund additional sites based on data requirements, individual State needs, and availability of funds. The EPA solicits comment on all aspects of the $PM_{10-2.5}$ speciation network including the number of required sites, the total size of the network, the criteria for choosing the number of required monitors in each area, the sampling method used to obtain filters, and frequency and types of analyses that would be performed on those filters.

c. Monitoring plan requirements and approval process.

We propose that each State be required to submit to the respective EPA Regional Administrator a plan proposing how all affected monitoring organizations within the State will comply with the requirements described above for the type, sampling schedule, number, and location of $PM_{10-2.5}$ monitoring stations. The plan would also provide supporting information for why each monitoring site which the State proposes to count towards the requirement for a minimum number of monitors is suitable for comparison to the $PM_{10-2.5}$ NAAQS, based on the criteria described above. In addition, for each non-required monitoring site which the State intends to deploy and which the State considers would be appropriate for comparison to the proposed $PM_{10-2.5}$ NAAQS, the plan would also provide evidence that the monitor is suitable for comparison, based on the criteria described above. The State would be required to make this plan available for public inspection for at least 30 days prior to submission to EPA.

This plan would be due to EPA January 1, 2008. The EPA Regional Administrator may extend this due date

[65] Information on the NAICS is avaialble at *http://www.census.gov/epcd/naics02/.*

to July 1, 2008, for example to allow it to be consolidated with the overall annual monitoring review and plan due at that time.

The EPA Regional Administrator will review the submitted plan and approve or disapprove it by a letter to the submitting State official within 120 days of submittal. The EPA Regional Administrator will be required to invite public comment; he/she must consider relevant public comments, if any are received in response to the invitation. We are not proposing a specific mechanism for the Regional Administrator to make the plan available for public comment, but we invite comment now on mechanisms that would be practical for the Regional Administrators and effective for persons likely to want to comment. The approval, if given, will include confirmation that EPA will treat each planned monitoring site as suitable or not suitable for comparison to the $PM_{10-2.5}$ NAAQS, along with the reasons for each determination. This confirmation will be a final EPA action applicable to subsequent determinations of attainment or nonattainment. This status will then be recorded in AQS for each monitor by the State.

Elsewhere in this notice (section IV.E.11), we are proposing a new requirement for States to conduct and submit to EPA a comprehensive monitoring system assessment at five-year intervals. The status of each $PM_{10-2.5}$ monitoring site with respect to comparability to the NAAQS should be re-examined during these assessments, starting with the first assessment which is submitted not less than 5 years after EPA Regional Administrator approval of the initial $PM_{10-2.5}$ monitoring plan. The State may also propose a change in the status of a $PM_{10-2.5}$ monitor whenever a large existing source of $PM_{10-2.5}$ near the monitor ceases (or begins) operation and is expected to remain shut down (or to continue operation)for three or more years, if the type of source involved is such that its shut down or start up could materially affect what types of emissions dominate the $PM_{10-2.5}$ measured at the site.

We invite comment on this proposed process and possible alternatives or additions to it, for example on whether there should be review by the EPA Administrator before the approval or disapproval is considered a final Agency action, or an opportunity for appeal to the Administrator to alter the final action.

3. Monitoring Requirements for the Proposed Primary and Secondary National Ambient Air Quality Standards for $PM_{2.5}$

The current $PM_{2.5}$ network includes over 1,200 FRM samplers at approximately 900 sites that are operated to determine compliance with the NAAQS; track trends, development, and accountability of emission control programs; and provide data for health and ecosystem assessments that contribute to periodic reviews of the NAAQS. Over 450 continuous $PM_{2.5}$ monitors are operated to support public reporting and forecasting of the AQI.

For $PM_{2.5}$, EPA proposes to modify the network minimum requirements for $PM_{2.5}$ monitoring so that multiple urban monitors in the same CBSA are not required if they are redundant or measuring concentrations well below the NAAQS. We propose to base minimum monitoring requirements for $PM_{2.5}$ on $PM_{2.5}$ concentrations as represented by a design value, and on the census population of the CBSA. Overall, this is expected to result in a lower number of required sites; however, we recommend and anticipate that States continue to operate a high percentage of the existing sites now utilizing FRM, but with FEM and ARM continuous methods replacing the FRM monitors at many of these sites.[66]

We are proposing to require that all sites counted by a State towards meeting the minimum requirement for the number of $PM_{2.5}$ sites have an FRM, FEM, or ARM monitor. We are also proposing that at least one-half of all the required $PM_{2.5}$ sites be required to operate $PM_{2.5}$ continuous monitors of some type even if not an FEM or ARM. This requirement would ensure that continuous methods continue to be well utilized throughout the network to support monitoring objectives such as public reporting and forecasting of the AQI not readily addressed by FRM and filter-based FEM.

As noted, EPA proposes to use design value and population as inputs in deciding the minimum required $PM_{2.5}$ monitoring sites in each CSA/CBSA. We are proposing these inputs so that monitoring resources are prioritized based on the number of people who may be exposed to a problem and the level of exposure of that population. Metropolitan areas with smaller populations would not be required to perform as much monitoring as larger areas. If ambient air concentrations as indicated by historical monitoring are low enough, these smaller population areas would not be required to continue to perform any $PM_{2.5}$ monitoring.

The proposed amendments would require fewer sites when design values are well above (rather than near) the NAAQS to allow more flexibility in the use of monitoring resources in these areas where States and EPA are already more certain of the severity and extent of the $PM_{2.5}$ problem and possibly in more need of other types of data to address it. For instance, an agency may wish to operate more speciation samplers rather than FRM to get a better understanding of the atmospheric chemistry of an area. We invite comments on this approach, versus requiring more FRM/FEM monitors in areas well above the NAAQS.

The proposed siting criteria for $PM_{2.5}$ monitors would remain the same as current requirements, which have an emphasis on population-oriented sites at neighborhood scale and larger. Population-oriented middle scale sites would remain a part of the network for comparison to both the daily and annual standard when a site can represent many other middle-scale locations where people are exposed. For middle-scale sites that are unique, only the daily NAAQS would be considered when comparing data to the standard.

Background and transport sites would remain a required part of each State's network to support characterization of regional transport and regional scale episodes of $PM_{2.5}$. To meet these requirements, IMPROVE samplers may be used even though they would not be eligible for comparison to the $PM_{2.5}$ NAAQS; these samplers are currently used in visibility monitoring programs in Class I areas and national parks. Sites in other States which are located at places that make them appropriate as background and transport sites can also fulfill these minimum siting requirements.

The proposed change in the primary 24-hour $PM_{2.5}$ NAAQS from 65 $\mu g/m^3$ to 35 $\mu g/m^3$ raises the issue of whether any commensurate changes would be needed in the $PM_{2.5}$ ambient monitoring network regulations. The current specific network design criteria for $PM_{2.5}$ in appendix D to 40 CFR part 58 directs States to select sites mostly representative of community-oriented area-wide $PM_{2.5}$ exposure levels at locations of neighborhood or larger scale, except in cases where a certain population-oriented microscale or middle-scale $PM_{2.5}$ site is determined to represent similar locations that

[66] An approved regional method (ARM) is a $PM_{2.5}$ method that has been approved specifically within a State, local, or tribal air monitoring network for purposes of comparison to the National Ambient Air Quality Standards and to meet other monitoring objectives. See section IV.D.2 of this preamble.

collectively form a larger region of localized high ambient $PM_{2.5}$ concentrations. The EPA believes that these current design criteria remain appropriate for implementation of the proposed primary $PM_{2.5}$ NAAQS. The existing minimum requirements effectively ensure that monitors are placed in locations that appropriately reflect the community-oriented area-wide concentrations levels used in the epidemiological studies that support the proposed lowering of the 24-hour NAAQS.

Most often, the current location of maximum monitors around $PM_{2.5}$ concentrations is the same as the location of maximum monitored 24-hour $PM_{2.5}$ concentrations, suggesting that no shifts in monitors would be needed to implement the proposed 24-hour NAAQS. In a relatively small number of cases [67], certain microscale $PM_{2.5}$ monitors that have not been eligible for comparison to the annual $PM_{2.5}$ NAAQS and that have been complying with the 24-hour $PM_{2.5}$ NAAQS, and therefore have not impacted the attainment status, may become more influential to attainment status under a more stringent 24-hour form of the NAAQS. Some sites that have not measured high concentrations relative to the current 24-hour NAAQS may also become more influential to attainment status under the proposed more stringent 24-hour NAAQS. In these cases, States may choose to move accompanying speciation and continuous monitors to the new site of particular interest to get a better characterization of PM at that location. States and EPA may also agree on changing the location of some $PM_{2.5}$ FRM/FEM sites to insure measurements at the population-oriented location(s) of most interest.

In proposed changes to 40 CFR 58.10 (Monitoring Network Description and Periodic Assessments), monitoring agencies would be required to provide a network plan that includes the identification of any $PM_{2.5}$ sites that are not suitable for comparison against the annual $PM_{2.5}$ NAAQS. The proposed requirements would also provide for a public hearing and review of changes to a $PM_{2.5}$ monitoring network that impact the location of a violating $PM_{2.5}$ monitor, prior to requesting EPA approval of the changes. Through this process, monitoring agencies would be able to consider changes to their $PM_{2.5}$ monitoring networks made in response to the proposed NAAQS, and inform the public about the potential implications on design values and resulting attainment and nonattainment decisions.

In today's NAAQS proposal (published elsewhere in this **Federal Register**), EPA requests comments on the alternative of basing a $PM_{2.5}$ secondary standard on a shorter-term averaging interval of less than 24-hours to provide protection against visibility impairment primarily in urban areas.

If the alternative short-term secondary standard is promulgated, EPA envisions that compliance would be assessed with data from continuous $PM_{2.5}$ monitoring methods capable of providing hourly time resolution. Continuous monitors would be required to comply with FEM or ARM requirements. Hourly $PM_{2.5}$ data values would be averaged over the appropriate short-term averaging interval (*e.g.*, four to eight hours) to assess compliance with the proposed short-term secondary NAAQS. The alternative short-term secondary NAAQS would also require minor additions to the current $PM_{2.5}$ siting requirements. Some continuous monitors would likely be required to be sited on a neighborhood and urban scale to form the basis of a network representing ambient $PM_{2.5}$ conditions along corridors that influence visibility of important scenic resources in and around urban areas. Sites might also want to consider collocating such monitors with automated haze-cam systems to quantify local relationships between short-term $PM_{2.5}$ concentrations and visual range.

4. Proposed Monitoring Requirements for PM_{10}

In the PM NAAQS proposal published elsewhere in this **Federal Register**, EPA proposes to revoke the PM_{10} annual standard. Further, consistent with the more targeted nature of the proposed new $PM_{10\text{-}2.5}$ indicator, the Administrator proposes to revoke the current 24-hour PM_{10} standard everywhere except in areas where there is at least one monitor that violates the 24-hour PM_{10} standard. In areas where both applicable PM_{10} NAAQS are revoked, we propose to have no minimum PM_{10} monitoring requirements and to allow discontinuation of PM_{10} monitors without prior EPA approval, although monitoring organizations would have the option of funding and operating PM_{10} monitors as needed to satisfy any still-applicable SIP commitments or to monitor compliance with non-Federal air quality standards. In areas where the PM_{10} NAAQS are not both revoked, we propose to have no minimum requirements, but to require prior EPA approval for changes to existing monitors. See also section IV.E.8 of this preamble.

5. Proposed Requirements for Operation of Ozone Monitoring Sites

Ozone (O_3) monitoring sites are operated to determine compliance with the NAAQS; to track trends, development, and accountability of emission control programs; to provide data for health and ecosystem assessments that contribute to ongoing reviews of the NAAQS; and to support public reporting and forecasting of the AQI. For O_3, EPA proposes to change the minimum network requirement from at least two sites in ''any urbanized area having a population of more than 200,000'' to an approach that considers the level of exposure of O_3, as indicated by the design value and the census population of an area. Larger population CSA and CBSA with design values near the O_3 NAAQS would be required to operate at least four sites. Smaller CSA and CBSA would be required to operate as few as one site, provided the design values were sufficiently low enough. Similar to the proposal for $PM_{2.5}$, EPA proposes that areas with measured ambient concentrations significantly above the NAAQS be required to operate fewer sites than areas with measured ambient concentrations near the NAAQS to allow flexibility of resources in those areas. We invite comments on this approach.

The O_3 monitoring network is primarily based on continuous FEM using ultraviolet analysis. The network is well deployed throughout the country at about 1,100 sites with most metropolitan areas already operating more O_3 monitors than would be required by today's proposed amendments. The EPA does not anticipate or recommend significant changes to the size of this network because O_3 remains a pollutant with measured levels near or above the NAAQS in many areas throughout the country. However, the proposed amendments would help to better prioritize monitoring resources depending on the population and relative levels of O_3 in an area.

6. Proposed Requirements for Operation of Carbon Monoxide, Sulfur Dioxide, Nitrogen Dioxide, and Lead Monitoring Sites

Criteria pollutant monitoring networks for the measurement of CO, SO_2, NO_2, and Pb are primarily operated to determine compliance with the NAAQS and to track trends and accountability of emission control

[67] EPA is presently aware of less than 10 $PM_{2.5}$ monitors that are sited in a manner that is unsuitable for comparison to the annual NAAQS.

programs as part of a SIP. Because these criteria pollutant concentrations are typically well below the NAAQS, there is limited use for public reporting to the AQI, except for a very small number of locations with on-going local air quality issues.

Gas measurements of CO, SO_2, and NO_2 utilize continuous technologies. Lead (Pb) is sampled by collecting total suspended particulates (TSP) on a high-volume sampler and analyzed in a laboratory.

We are proposing to revoke all minimum requirements for CO, SO_2, and NO_2, monitoring networks, and reduce the requirements for Pb. This proposal allows for reductions in ambient air monitoring for CO, SO_2, NO_2, and Pb, particularly where measured levels are well below the applicable NAAQS and air quality problems are not expected, except in cases with ongoing regulatory requirements for monitoring such as SIP or permit provisions. In these cases, EPA encourages States to comment on ways to reduce these potentially unnecessary monitors. We will also work with some States on a voluntary basis to make sure that at least some monitors for these pollutants remain in place in each EPA region. Measurement of CO, SO_2, and NO_y are being proposed as required measurements at NCore sites. There may be little regulatory purpose for keeping many other sites showing low concentrations, other than specific State, local, or tribal commitments to do so. However, in limited cases, some of these monitors may be part of a long-term record utilized in a health effects study. The EPA expects State and local agencies to seek input on which monitors are being used for heath effects studies prior to shutting down a monitor. See also section IV.E.8 of this preamble (Proposed criteria and process for discontinuing monitors).

7. Proposed Changes to Minimum Requirements for Ozone Precursor Monitoring

Section 182(c)(1) of the CAA required us to promulgate rules requiring enhanced monitoring of ozone, oxides of nitrogen, and volatile organic compounds in ozone nonattainment areas classified as serious, severe, or extreme. On February 12, 1993, we promulgated requirements for State and local monitoring agencies to establish Photochemical Assessment Monitoring Stations (PAMS) as part of their SIP monitoring networks in ozone nonattainment areas classified as serious, severe, or extreme. During 2001, we formed a workgroup consisting of EPA, State, and local monitoring experts to evaluate the existing PAMS network. The PAMS workgroup recommended that the existing PAMS requirements be streamlined to allow for more individualized PAMS networks to suit the specific data needs for a PAMS area.

We are proposing changes to the minimum PAMS monitoring requirements in 40 CFR part 58 to implement the recommendations of the PAMS workgroup. Specifically, we are proposing the following changes:

- The number of required PAMS sites would be reduced. Only one Type 2 site would be required per area regardless of population and Type 4 sites would not be required. Only one Type 1 or one Type 3 site would be required per area.
- The requirements for speciated VOC measurements would be reduced. Speciated VOC measurements would only be required at Type 2 sites and one other site (either Type 1 or Type 3) per PAMS area.
- Carbonyl sampling would only be required in areas classified as serious or above for the 8-hour O_3 standard.
- NO_2/NO_X monitors would only be required at Type 2 sites.
- NO_y will be required at one site per PAMS area (either Type 1 or Type 3).
- Trace level CO would be required at Type 2 sites.

Note that on April 15, 2004, we revised some O_3 nonattainment classifications, under the 8-hour O_3 standard (69 FR 23951). While the number of areas classified as serious, severe, or extreme ozone nonattainment under the 8-hour O_3 standard has been greatly reduced (69 FR 23857), areas that had previously been classified as serious, severe, or extreme ozone nonattainment under the 1-hour O_3 standard are required to comply with the PAMS monitoring requirements until they achieve compliance with the 8-hour ozone standard. See 40 CFR 51.900(f)(9). In addition, the PAMS requirements would apply to any new areas that are classified or reclassified as serious, severe, or extreme O_3 nonattainment under the 8-hour O_3 standard.

We solicit comments on the proposed revisions to the PAMS monitoring program requirements including the measurements to be made, the sampling frequencies, and the location and numbers of required monitoring sites proposed.

8. Proposed Criteria and Process for Discontinuing Monitors

The EPA has determined that many single-pollutant monitors operated by State and local agencies, specifically many of those measuring CO, Pb, PM_{10}, SO_2, and NO_2, are providing data that have limited usefulness in air quality management. This is likely the case for monitors whose data indicate current attainment of the corresponding NAAQS with little prospect for future nonattainment. Accordingly, consistent with the draft National Ambient Air Monitoring Strategy (NAAMS), we are proposing to eliminate the current requirements for operation of a certain minimum number of monitors for CO, PM_{10}, SO_2, and NO_2, and to reduce the requirements for Pb monitors, as described in section IV.E.6 of this preamble. We are also proposing changes to loosen the minimum requirements for monitoring of O_3 precursors in the PAMS program, as described in section IV.E.7 of this preamble. We are also proposing changes to the minimum requirements for O_3 and $PM_{2.5}$ monitoring that may have the effect of reducing the minimum number of these monitors in some areas. We note that the remaining specific minimum requirements (limited to O_3, $PM_{2.5}$, and $PM_{10\text{-}2.5}$) are intended to be necessary but are not always sufficient to meet the requirement in section 110(a)(2)(B) of the Clean Air Act (CAA) that SIP provide for operation of appropriate systems to monitor, compile, and analyze data on ambient air quality. We intend to require many States to operate some monitors for these pollutants, but to determine what monitoring is appropriate on a more case-by-case basis. The EPA encourages, and in fact the proposed amendments to 40 CFR part 58 would require, all States to assess their monitoring networks periodically to determine what changes should be made, including which monitors should be discontinued and which retained. Local situations will differ, and should be considered individually. Reducing low-value monitoring expenditures would allow resources to be devoted to under-served and new monitoring purposes.

Some monitors in excess of the remaining minimums may be necessary to the State/local air quality management process, or for other uses, such as development and validation of air quality models. We are proposing to continue to require States to propose changes in their monitoring networks and obtain EPA approval before making changes, even when the remaining minimum requirements for number of monitors would still be met. This EPA review and approval can take place through the mechanism of the annual monitoring plan. The current rule already requires State agencies to prepare and submit the plan on July 1

of each year for EPA approval at the Regional Office level. We are proposing to retain this current requirement. We will approve proposed changes to a monitoring plan provided the proposed network will still meet any applicable SIP provisions related to ambient monitoring and will provide data needed to support the air quality control program. Based on assessments that we and individual States have done to date, we generally expect to find that a large percentage—between 33 percent for SO_2 and 90 percent for NO_2—of current monitors for CO, PM_{10}, SO_2, and NO_2 can be removed; that most O_3 monitors should continue although some should be moved to more productive locations; that some filter-based $PM_{2.5}$ monitors can be removed; and that some filter-based $PM_{2.5}$ monitors should be replaced by continuous instruments when models that have been approved as FEM or ARM are available.

While local situations need to be considered individually, we believe that certain general principles can be articulated regarding reductions in monitoring networks. We have incorporated these principles in the proposed amendments to reduce uncertainties in the process and thereby facilitate an efficient and timely process for review and approval or disapproval of proposed changes. These principles would apply independently. A monitor meeting any one of them would qualify for EPA approval for discontinuation. Situations not addressed by these criteria would be considered on a case-by-case basis. The EPA Regional Offices would have more time to give this case-by-case consideration to the exceptional cases because cases meeting one of the following criteria could be disposed of more quickly.

- Any $PM_{2.5}$, O_3, CO, PM_{10}, SO_2, Pb, or NO_2 monitor which has shown attainment during the previous 5 years, that has a probability of less than 10 percent of exceeding 80 percent of the NAAQS during the next 3 years based on the levels, trends, and variability observed in the past, and which is not specifically required by an attainment plan or maintenance plan, can be removed or moved to another location.[68, 69] Few if any O_3 monitors in urban areas would likely meet this criterion, but some $PM_{2.5}$ monitors may do so. This criterion would not apply to a $PM_{2.5}$ monitor that is part of a spatial averaging plan.
- A monitor for CO, PM_{10}, SO_2, or NO_2, which has consistently measured lower concentrations than another monitor for the same pollutant in the same county and same nonattainment area during the previous 5 years, and which is not specifically required by an attainment plan or maintenance plan, could be removed or moved to another location, if control measures scheduled to be implemented or discontinued during the next 5 years would apply to the areas around both monitors and have similar effects on measured concentrations, such that the retained monitor would remain the higher reading of the two monitors being compared.[70]
- For any pollutant, the highest reading monitor (which may be the only monitor) in a county (or portion of a county within a distinct nonattainment or maintenance area) could be removed or moved to a new location provided the monitor has not measured NAAQS violations in the previous 5 years, the CBSA within which the county lies (if in any) would still meet requirements for the minimum number of monitors for the applicable pollutant if any, and the approved SIP provides for a specific, reproducible approach to representing the air quality of the affected county in the absence of actual monitoring data. For example, the SIP could provide that a continuing monitor in a neighboring county will always be taken by the State and EPA to represent both counties for purposes of nonattainment and other regulatory determinations. Because EPA would review and approve any SIP revision that provides such an approach to representing air quality in the affected county, EPA can ensure its technical validity and protectiveness. We intend to take a cautious approach to allowing removal of such monitors, particularly in urban areas. While approval of such SIP revisions would be delegated to the Regional Offices, EPA Headquarters officials would participate in the review of proposed revisions that present the first instance of specific approaches, and would resolve issues of national consistency if such issues arise.
- A monitor, which EPA has determined cannot be compared to the relevant NAAQS because of the siting of the monitor, could be moved or removed. For example, a $PM_{2.5}$ monitor must be population-oriented to be comparable to the daily or annual NAAQS, and one that is not population-oriented could be removed.[71]
- A monitor that is designed to measure concentrations upwind of an urban area for purposes of characterizing transport into the area and that has not recorded violations of the relevant NAAQS in the previous 5 years could be moved to another location where information on transport will be more useful to SIP development.
- A monitor not eligible for removal under any of the above criteria could be moved to a nearby location with the same scale of representation if logistical problems beyond the State's control make it impossible to continue operation at its current site. For example, the State may lose access to a monitoring site not owned by the State itself, and this criterion would ensure approval of a new site that was nearby and that had the same scale of representation (e.g., middle-scale or neighborhood-scale). A move to a more distant site would require case-by-case EPA review of the appropriateness of the new location compared to other alternatives.

In the situations covered by these proposed criteria, the State would need to make a factual showing that the specified conditions are met. Once the EPA Regional Office accepts that showing, the proposed amendments would require approval of the State's request as part of the Regional Office action on the annual monitoring plan. We may issue guidance suggesting appropriate ways these showings can be made.

We invite comments on the specific details of these proposed criteria, and on other criteria that would be appropriate.

In order to help information be available to the State and to EPA that could be relevant to the appropriateness of monitoring network changes, we propose that each State be required to make available for public inspection its draft annual monitoring plan for a

[68] The concept of using historical data to statistically predict the probability of a future violation is an element of EPA's current policy memo on ''Limited Maintenance Plan Option for Moderate PM_{10} Nonattainment Areas,'' August 9, 2001. See *http://www.epa.gov/ttn/oarpg/t1/fact_sheets/lmp_fs.pdf* and *http://www.epa.gov/ttn/oarpg/t1/memoranda/cdv.pdf*. EPA believes that this concept can be generalized to the other pollutants listed in this paragraph, but the details of the probability estimation method(s) will likely differ.

[69] Five years of historical data means five successive calendar years of data sufficient for making an attainment determination.

[70] $PM_{2.5}$ and O_3 are not included in this proposed criterion because of the value of even low-reading monitors in understanding the causes of nonattainment and in informing the public about potential exposures. Lead (Pb) is not included because Pb concentrations are often very dependent on effective control of Pb emissions of individual sources very close to the monitor and we believe it would be too risky to depend on area-wide generalizations about the effect of scheduled controls. Also, we believe the effectiveness of emission controls on Pb sources may be more variable over time than of CO, SO_2, PM_{10}, and NO_2 emission controls on sources of those pollutants.

[71] Section 2.8.1.2.3 of appendix D to 40 CFR part 58 (Network Design for State and Local Air Monitoring Stations (SLAMS)).

period of at least 30 days prior to submitting it to the EPA Regional Office for approval. The State could, for example, satisfy this proposed requirement by making the draft plan available for download via the air agency's Internet Web site. We also propose that when submitting the annual monitoring plan for EPA approval, the State provide evidence that: (1) The State has considered the ability of the proposed network to support air quality characterization for areas with relatively high populations of susceptible individuals (e.g., children with asthma); and (2) if the State proposes to discontinue any monitoring sites, the State has considered how discontinuing monitoring sites would affect data users other than the monitoring agency itself, such as nearby States and tribes or health effects research studies. We invite comment on where EPA should provide opportunity to examine and comment on monitoring plans after they are reviewed by the Regional Office.

9. Special Purpose Monitors

The development of today's proposed amendments has given EPA occasion to re-examine the longstanding issue of whether the ambient air monitoring rules and current policies regarding use of monitoring data for regulatory determinations have the effect of creating undue and counterproductive disincentives to States and other organizations deploying discretionary monitors that overall and in the long run would benefit air quality management efforts. The EPA is proposing a limited change in the monitoring rules on this issue.

At present, each State at any given time is required to operate a certain set of monitors under the monitoring regulations and its own approved monitoring plan, or to meet commitments it has made in its SIP and/or grant agreement(s) with EPA. If a State chooses to deploy an additional monitor, it may designate it as a special purpose monitor (SPM). Such designation can afford the State certain flexibility it would not have if the monitor were designated as an NCore station or State and local air monitoring station (SLAMS).[72] However, regardless of whether a monitor is designated as an SPM, if it is an appropriately-sited FRM or FEM monitor and if its operation meets the QA requirements of 40 CFR part 58, or if the data are otherwise determined to be technically valid, EPA considers all available data from that monitor whenever we make a determination of attainment or nonattainment. The possibility that data from an SPM could result in a nonattainment designation of an area that would otherwise not be so designated may discourage the State from deploying a new monitor or supporting the deployment of a monitor by another organization, such as a university, even when the monitor would provide useful information for determining the extent, severity, causes, and possible solutions of a known or suspected air quality problem. Thus, a State that might have voluntarily addressed a nonattainment problem may never become aware of the problem. Also, affected persons may also be left unaware and unable to reduce their own exposures by modifying their behavior or to advocate for State action to address the problem.

We addressed this issue in the 1997 rulemaking that established the current requirements for $PM_{2.5}$ monitoring, and created a narrow exception to the practice that all known, good air quality data be considered in such determinations. (See preamble discussion at 62 FR 38770, July 18, 1997 and in existing 40 CFR 58.14(b).) That narrow exception addressed only new SPM for $PM_{2.5}$ concentrations. It provides that $PM_{2.5}$ NAAQS violation determinations shall not be exclusively made based on data produced at a population-oriented SPM site during the first two complete years of its operation, but only if monitoring is not continued beyond those 2 years. More recently, during the development of the draft NAAMS and today's proposal, EPA has received input from various parties, including the Clear Air Act Advisory Committee, to the effect that EPA ''should promote policies to avoid disincentives to monitoring'' by limiting the regulatory use of data from such monitoring.[73] A moratorium on any use of data from the first 3 years after the deployment of a discretionary monitor, applicable to all NAAQS pollutants, was a specific approach discussed in some of our consultations with State and local monitoring officials during the development of this proposal. Such a moratorium would give States time to address the air quality problem with more flexibility than it would have if the area were designated nonattainment and subject to CAA requirements for nonattainment areas.

We understand and, to some degree, sympathize with the States' perception that the current requirements create disincentives to monitoring. We agree that it is conceivable, and perhaps likely, that it might ultimately be more protective of public health to have more monitoring data in hand even if the early years of data from each additional, discretionary monitor could not be used for regulatory purposes, compared to never having that data at all. However, we believe we may not ignore technically valid air quality data from FRM and FEM monitors when making attainment or nonattainment determinations. If we know that an area is actually not meeting an NAAQS based on valid data, we cannot ignore those data. This is premised on the provisions of the CAA that the Agency must follow in determining whether an area is attainment or nonattainment. Section 107(d)(1)(A)(i) of the CAA defines ''nonattainment'' as ''any area that does not meet'' an NAAQS and CAA section 107(d)(1)(A)(ii) defines ''attainment'' as any area ''that meets'' an NAAQS. In light of this explicit language, EPA does not believe we could affirmatively determine an area to be an attainment area for a particular criteria pollutant, (*i.e.*, an area ''that attains'' the NAAQS) if we had the requisite years of valid data from appropriately sited FRM or FEM monitors showing that the area was in fact not attaining the standard.

In light of this legal requirement, we believe that two limited exclusions on use of data from SPM are possible. We are proposing that: (1) The limited two-year moratorium on the use of data from SPM in determinations of NAAQS violations established in the 1997 rulemaking for $PM_{2.5}$ be extended to the annual PM_{10} NAAQS (if it is retained rather than revoked as proposed

[72] A special purpose monitor (SPM) is one which the State does not count when showing compliance with the minimum requirements for the number and siting of monitors and which it has designated as an SPM by so labeling it in the Air Quality System (AQS) data system and/or in its monitoring plan. In common practice EPA does not overrule such designations provided the rest of the monitoring network meets minium requirements. Monitors carrying special purpose status need not use Federal reference or equivalent methods, are not subject to the quality system requirements of 40 CFR part 58 that apply to State and local air monitoring stations (SLAMS), and are not subject to siting requirements such as probe height or distance from nearby obstructions (or, in this proposal, the proposed siting suitability requirements for monitors which can be used for comparison with the proposed 24-hour $PM_{10-2.5}$ standard. Their data are not required to be submitted to AQS, and they may be discontinued at will by the State (assuming no grant commitment exists for their continued operation). States start up and designate monitors as special purpose as a flexible and economical way to meet various local monitoring objectives, such as exploring a possible air quality problem in response to citizen concerns.

[73] See recommendation 1.4 in Recommendations to the Clean Air Act Advisory Committee (CAAAC), Air Quality Management Workgroup, January 2005, transmitted by the CAAAC as a Committee recommendation to Administrator Michael O. Leavitt on January 19, 2005.

elsewhere in today's **Federal Register**), the O_3 NAAQS, and the proposed 24-hour $PM_{10-2.5}$ NAAQS, rather than any more extensive data exclusion approach; and (2) for CO, SO_2, NO_2, Pb, and 24-hour PM_{10}, that data from the first 2 years of a SPM would not be used for nonattainment designations but would be used in making findings of whether a nonattainment area has attained the NAAQS. In both cases, data from the first 2 years of operation of a new SPM would not be used provided the monitor does not continue operation beyond those 2 years. If the monitor does continue operation beyond 2 years, all years of data will be given full consideration. This policy would in some situations facilitate special purpose monitoring that would otherwise be discouraged by the risk of a nonattainment finding, but we acknowledge that these situations will be limited.

This proposed approach would have no practical effect for those NAAQS for which three consecutive years of data are always required before a determination of attainment/nonattainment can be made, *i.e.*, the 24-hour and annual $PM_{2.5}$ NAAQS, the annual PM_{10} NAAQS, the proposed $PM_{10-2.5}$ NAAQS, and the O_3 NAAQS. For these NAAQS, the proposed rule provision would make it clear that there is no risk of a nonattainment outcome based on a two-year period of SPM operation.

The CO, SO_2, NO_2, 24-hour PM_{10}, and Pb NAAQS present a different issue, because under the form of these NAAQS a single year of data can be sufficient to make a finding of nonattainment. We note that until such time as we revise one of these NAAQS, we are under no mandatory duty to designate an area from attainment or unclassifiable to nonattainment, so it is within our discretion to simply not take such an action if the critical data indicating nonattainment is from the first 2 years of an SPM.

However, if we are requested by a State to redesignate a nonattainment area to attainment, we do have a mandatory duty to act on that request. Consequently, we cannot overlook some SPM data that is contrary to the redesignation request by simply not taking an action. We must respond to a request for redesignation from nonattainment to attainment, and if there are valid data indicating that nonattainment still exists we could not approve the redesignation request. Therefore, we can use the fact that future designation of any new CO, SO_2, NO_2, 24-hour PM_{10}, or Pb nonattainment areas is discretionary to protect States from use of 2 years of data from a new SPM for one of these pollutants resulting in a nonattainment designation, but we cannot protect an area from use of such data in a finding on whether an already designated nonattainment area has subsequently attained the relevant NAAQS. Consequently, the proposed two-year data moratorium should remove the disincentive to place new monitors in attainment areas for CO, SO_2, NO_2, 24-hour PM_{10}, or Pb, but may leave in place disincentives to add monitors in nonattainment areas that may appear to have reached attainment or be approaching attainment.

Despite the limited nature of the proposed moratorium, States and other organizations would still be able to perform many useful types of discretionary monitoring without fear of triggering a near-term nonattainment designation. In the case of $PM_{2.5}$, PM_{10}, and the proposed $PM_{10-2.5}$ NAAQS, many of the most useful types of monitors for purposes of understanding the causes and possible solutions to a nonattainment problem are not FRM, FEM, or ARM monitors, and therefore these monitors can be deployed for two or even more years without any concern about use of the data in nonattainment designations. This includes a number of filter-based sampler models including the samplers used in the IMPROVE program, all types of speciation samplers for $PM_{2.5}$, PM_{10}, and the proposed $PM_{10-2.5}$, and all existing continuous monitors for $PM_{2.5}$. There are also non-FRM/FEM for some of the other NAAQS that currently can be deployed indefinitely to characterize air quality problems better without fear of nonattainment designation consequences (*e.g.*, passive monitors).

Another situation in which the limited nature of the proposed two-year moratorium would have no practical disincentive effect is when the siting of a monitor precludes comparison to the applicable NAAQS, even though it is an FRM or FEM monitor that meets quality system requirements. It could, for example, be placed in an location that is not ambient air and does not represent ambient air. It could also be placed inconsistently with siting criteria found in the rules which specify when monitoring data can be used for comparison with the NAAQS. See existing 40 CFR part 58, appendix D, section 2.8.1.2.3 and the suitability criteria proposed for the $PM_{10-2.5}$ monitoring network discussed in section IV.E.2 of this preamble.

The limited nature of the moratorium would have a disincentive effect on discretionary monitoring relative to a hypothetically more encompassing moratorium. For example, a State could still be discouraged from operating an O_3 or $PM_{2.5}$ monitor beyond 2 years, and thus may miss becoming aware of an actual public health problem. Therefore, we invite comment on the Agency's legal interpretation, which has shaped today's proposal for the described limited moratorium, and on what provisions for SPM data we should adopt if EPA was to change the legal interpretation in light of public comments. In particular, we invite comments on an approach in which the first 3 years of data from any SPM would be permanently protected from use in nonattainment determinations regardless of whether it operates beyond 3 years, but any monitor showing a violation in the first 3 years would be required to continue operation unless its discontinuation is approved as part of EPA's review of the State's annual monitoring plan. This approach would result in the State having some time to address the NAAQS violation before three usable years of data became available to make an official nonattainment/attainment determination from the fourth through sixth year of operation.

Special purpose monitors are presently not subject to the quality system requirements of 40 CFR part 58. With respect to data quality, EPA wishes to encourage all State and local monitoring agencies to adhere to the quality system requirements of 40 CFR part 58 for all FRM, FEM, and ARM monitors (the monitor types to which such requirements are applicable). Substandard quality system practices should not be deliberately used as a way to prevent EPA from using data from an SPM beyond the protection offered by the proposed two-year moratorium. However, under the current monitoring rules, States may do so and some have done so. Accordingly, EPA proposes to amend 40 CFR part 58 to require that all FRM, FEM, and ARM monitors operated by States (or delegated local agencies) comply with the quality system requirement in 40 CFR part 58 relevant to the monitor type(s) being used. We propose that this requirement take effect 2 years after the date of publication of the final rule, to provide States time to prepare to meet the requirement and to choose transition dates that fit with other network plans. We also invite comment on the alternative of using grant agreements to attempt to achieve quality system objectives for SPM instead of including a specific requirement in the proposed amendments.

We also propose that States be required to submit to the Air Quality System (AQS) all data collected by all FRM, FEM, and ARM special purpose monitors, starting no later than 2 years after the date of publication of the final amendments. In the past, when SPM were not required to follow quality system requirements, the uncertain data quality from such monitors was a reason to allow States discretion regarding submission of data to AQS. With the proposed requirement that FRM, FEM, and ARM special purpose monitors follow quality system requirements, there is no rationale for their data not being submitted to AQS to provide transparency in the air quality management process.

We propose to retain and clarify that a State may discontinue use of an SPM at any time, without need for EPA approval. However, we encourage States to continue the use of monitors that have gone beyond the two-year point of operation if they have recorded a violation of a NAAQS. Otherwise, EPA may designate the area as nonattainment and the State would lack clear evidence to show subsequent attainment.

10. Flexibility and Resources for Non-Required Monitoring

The EPA wishes to clarify that while 40 CFR part 58, including the proposed amendments, contains a number of minimum requirements for States to operate ambient monitors, ensure data quality, and report data, these requirements are not a complete blueprint for the monitoring networks that we believe should and we hope will be operated by State and local agencies. Many specific features of minimum requirements for these networks, such as selection of specific monitoring sites for $PM_{10-2.5}$, are left to be made later at the State level with EPA Regional Office approval, so that the best information and local insights can be applied to deciding those features. Also, not every type of monitoring that is needed can be required through the provisions of 40 CFR part 58 in this rulemaking because, in some cases, the specific State that should be responsible for a monitoring activity cannot be identified with confidence at this time. For example, the proposed amendments to 40 CFR part 58 do not require any State to operate a rural NCore multipollutant NCore monitoring station, even though we estimate that the Nation needs about 20 such sites, because it would be premature and too rigid at this time to select those sites. Instead, we will work with States as they determine the location of their required urban NCore multipollutant site or sites, and we will most likely negotiate for the voluntary operation of some rural sites as well.

The provisions of 40 CFR part 58 can and should only require the number and types of monitoring activities that will surely be needed in any State over a reasonably long time period, to avoid the need for frequent amendments to allow States to stop the use of obsolete monitors. However, aggregation of hypothetical State networks that just met the minimum requirements of 40 CFR part 58, including the proposed amendments, would be inadequate to meet the needs of air quality management at the State and national levels. We will negotiate with States for monitoring activities that go beyond the minimum requirements of 40 CFR part 58 using the draft National Ambient Air Monitoring Strategy as a starting point for those negotiations. The EPA will generally provide at least partial funding for such additional monitoring through grants, sometimes very specifically and sometimes though more general air quality management support grants. Where current monitoring activities by a State exceed the final minimum requirements in 40 CFR part 58, EPA may need to negotiate reductions in is funding for those activities if the data they produce are not sufficiently valuable to the air quality management process.

In particular, we anticipate that we will be negotiating with States in the next several years the specifics of the following directional changes in their networks:

- Creation and operation of rural NCore multipollutant stations. We expect that some of the need for rural monitoring data can be met by required stations that some states choose to place in suitable rural areas and/or by planned federally-operated rural monitoring stations. We will identify the remaining needed sites and recruit and fund specific States to establish and operate them.
- Creation and operation of more $PM_{10-2.5}$ speciation sites than the minimum required in the proposed amendments.
- Creation and operation of rural $PM_{10-2.5}$ mass concentration sites. In addition to the urban $PM_{10-2.5}$ sites required by this proposal, having some $PM_{10-2.5}$ mass concentration sites in rural areas may be useful to provide ambient data to compare with the higher coarse particle concentrations that are typically found in urban locations. Since these rural sites would typically be located outside of any MSA and would be characterized by lower population densities than in metropolitan areas, most would likely not be appropriate for NAAQS comparisons. We may work with selected States to establish such rural sites, taking into account existing siting opportunities such as the CASTNET and IMPROVE networks, and we solicit comment on the need for and siting strategy for such rural monitors. We note that monitoring sites in rural areas may be useful in future health effects research.
- Reduction in the number of $PM_{2.5}$ filter-based monitors and replacement of some such monitors with continuous instruments.
- Reduction in the number of CO, SO_2, NO_2, PM_{10}, and Pb monitoring sites.
- Changes in the number and/or locations of $PM_{2.5}$ speciation monitoring sites. The EPA and the States have been assessing these sites in the last year or so, and some changes are underway. A new factor to consider will be the speciation data needs of areas that may now be attaining the current $PM_{2.5}$ NAAQS but appear likely to be nonattainment with the proposed NAAQS.
- Changes in PAMS networks. The proposed minimum requirements for PAMS monitoring would mean that many current State networks exceed minimum requirements, providing the opportunity for reassessment and redesign to better meet local conditions and data needs.
- Other changes that would result in networks that better meet State data goals, which can be so individualistic that they cannot be given consideration in a rulemaking such as this, or even in a nonbinding national strategy.

11. Proposed Requirements for Network Assessments

In addition to annual network reviews, EPA proposes to require periodic and detailed network assessments as a way to maintain relevancy of ambient air monitoring to emerging air program needs and scientific findings. The EPA proposes that State and local agencies conduct a technical network assessment every 5 years to consider whether stations should be removed or added, or whether new program elements should be adopted to account for changes in air quality, population growth, emission sources, and other parameters. The first assessments would be due July 1, 2009. These assessments would also evaluate the adequacy of existing technologies deployed in the network compared to commercially available methods that could potentially be deployed to improve the network. Network assessments are intended to probe the

current and expected relevancy of air monitoring networks through a combination of stakeholder participation and technical analyses. This would be accomplished, in part, by periodically questioning the overall usefulness of the existing sites and identifying locations where additional monitoring may be necessary. Typical topics addressed in network assessments would include reviewing data objectives and data quality, prioritizing measurement needs, identifying redundant monitoring, and identifying specific gaps in location and measurement parameters. The EPA anticipates developing non-binding guidance on how to conduct these proposed network assessments. We solicit comment on the proposed requirements and schedule for network assessments.

12. Related Federal Monitoring

The EPA conducts or supports three ambient monitoring programs directly, related to but separate from, the State, local, and tribal monitoring programs that are the subject of today's proposal. These are CASTNET, NADP, and IMPROVE programs, described in section III.B.3 of this preamble. Today's proposals do not apply to these programs, but the following brief description of these programs may assist the public in commenting on today's proposal.

The EPA plans to upgrade the monitoring capabilities of many of the CASTNET sites in the next couple of years in ways that would allow them to meet the same multipollutant monitoring objectives as the proposed State-operated rural NCore stations. As these plans become more developed, EPA expects to adjust its targets for the number of rural NCore stations that are voluntarily operated by States under grant agreements with EPA.

The EPA is exploring with the National Atmospheric Deposition Network (NADP) sponsors the possibility of expanding NADP's objectives and monitoring infrastructure to investigate measurement of spatial monitoring concentrations, from which dry deposition could be estimated. Also, NADP stations potentially provide efficient opportunities to site ambient air monitors for other purposes.

At present, the IMPROVE program employs different sampling hardware and laboratory analytical procedures to measure speciated $PM_{2.5}$ compared to most $PM_{2.5}$ speciation monitoring in urban areas. The EPA is working to achieve more consistency between the two programs, so that monitoring results at the two types of stations are more directly comparable. We are also reviewing the current IMPROVE site list to determine which are of higher versus lower priority for long-term continuation.

F. What Are the Proposed Probe and Monitoring Path Siting Criteria?

The EPA is proposing minor organizational changes to 40 CFR 58, appendix E (Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring). The EPA also is proposing specific criteria for the placement of $PM_{10\text{-}2.5}$ samplers. Current vertical placement requirements permit microscale PM_{10} and $PM_{2.5}$ monitors to be located 2 to 7 meters above ground level to allow for security, instrument servicing, and operator safety, as well as sampling particulate matter at the breathing height. The EPA is proposing that the same 2- to 7-meter vertical placement requirements apply to microscale $PM_{10\text{-}2.5}$ sites.[74] The EPA is also proposing that the 2- to 7-meter vertical placement requirement apply to middle-scale $PM_{10\text{-}2.5}$ sites, which differs from the existing $PM_{2.5}$ vertical placement requirement permitting middle-scale sites to have samplers placed 2 to 15 meters above ground. We recognize that significant $PM_{10\text{-}2.5}$ vertical concentration gradients may exist due to re-entrainment of coarse particles from the surfaces that typically surround monitoring sites, such as adjacent streets, parking lots, and landscaped surfaces, and such vertical gradients may introduce additional complexities in the comparison of data from samplers at widely varying heights. The EPA seeks to reduce this variability by restricting the vertical placement of $PM_{10\text{-}2.5}$ samplers at middle-scale sites to the 2 to 7 meter requirement while recognizing that $PM_{10\text{-}2.5}$ monitors that would have been at a higher level (e.g., 15 meters above ground) would have likely measured lower ambient concentrations. The EPA proposes that $PM_{10\text{-}2.5}$ sites with neighborhood, urban, and regional scales have identical horizontal and vertical requirements with $PM_{2.5}$ sites in consideration of the lesser gradients of coarse particle ambient concentrations likely with sites representing larger, more homogeneous conditions. The EPA acknowledges the logistical complexity of having different vertical placement requirements for middle-scale $PM_{10\text{-}2.5}$ and $PM_{2.5}$ sites, and solicits comment on all aspects of $PM_{10\text{-}2.5}$ probe siting criteria.

Motor vehicle nitric oxide emissions are known to scavenge ozone, and EPA recognizes the difficulty that monitoring agencies face when trying to locate ozone air monitors in areas with multiple roadways and streets. Based upon concern about the scavenging effects of motor vehicle emissions on ozone, EPA proposes to increase the minimum distances between ozone monitors and roadways in certain cases. Recent field studies have shown significant effects of roadway emissions at the distances currently listed in 40 CFR part 58, appendix E. Summary information on this work is included in the docket for this proposal. The EPA solicits comments on these proposed minimum distance requirements.

G. What Are the Proposed Data Reporting, Data Certification, and Sample Retention Requirements?

1. Reduction of $PM_{2.5}$ Supplemental Data Reporting Requirements

The EPA is proposing to reduce the data reporting requirements associated with $PM_{2.5}$ Federal Reference Methods (FRM) to reduce the data management burden for monitoring agencies. The following Air Quality System (AQS) reporting requirements are proposed for elimination: Maximum and minimum ambient temperature, maximum and minimum ambient pressure, flow rate coefficient of variation (C_V), total sample volume, and elapsed sample time. AQS reporting requirements are being retained for average ambient temperature and average ambient pressure, and any applicable sampler flags.

Supplemental monitoring parameters were required to be reported to AQS along with FRM mass concentration data to evaluate the performance of the FRM as implemented through the newly developed sampler hardware that was purchased by EPA for State and local agencies at the beginning of the $PM_{2.5}$ monitoring program. Since that time, these supplemental data, along with statistical analyses conducted on data from collocated sampling and independent Performance Evaluation Program (PEP) audits, have confirmed that the $PM_{2.5}$ FRM samplers are producing data that meet or exceed the data quality objectives developed for the method. As a result, the AQS reporting requirement for many of the supplemental data parameters can be discontinued with no adverse effect on $PM_{2.5}$ data quality. Monitoring agencies would still be expected to retain supplemental data as required by their

[74] The proposed network design criteria for $PM_{10\text{-}2.5}$ would consider such data to be ineligible for comparison to the NAAQS (see preamble section IV.E.2.B.ii).

approved Quality Assurance Program Plans (QAPP).

AQS reporting requirements for average ambient temperature and average ambient pressure are being retained to provide data useful for the comparison of mass concentrations based on actual and standard operating conditions.

EPA is also proposing amendments to 40 CFR 58.16 (Data submittal) to add the remaining $PM_{2.5}$ supplemental data reporting requirements, which presently are only found in the FRM requirements (Table L–1 of appendix L of part 50). This change will ensure that supplemental data are reported for future $PM_{2.5}$ samplers designated as a Class I or Class II Federal equivalent method under the proposed amendments to 40 CFR part 53.

2. $PM_{2.5}$ Field Blank Data Reporting Requirement

We are proposing amendments to 40 CFR part 58.16 to require the submission of data on $PM_{2.5}$ field blank mass in addition to $PM_{2.5}$ filter-based measurements. Field blanks are filters which are handled in the field as much as possible like actual filters except that ambient air is not pumped through them, to help quantify contamination and sampling artifacts. Only the data from field blanks which States are already taking into the field and weighing in their laboratories would be required to be reported under this proposal. Quantifying field blank mass is important in order to complete the material balance of the major components of sampled $PM_{2.5}$. In addition, fluctuations of the field blank value are a useful quality control metric which can be used to help evaluate the performance of filter-based samplers and the quality of the sampled $PM_{2.5}$ values. However, there is currently limited information available to EPA and other users of ambient air quality data on the magnitude and trends in the blank concentrations from $PM_{2.5}$ Federal reference method (FRM) samplers. These data are produced by State and local air pollution agencies on a regular basis throughout the year, but the data are not currently submitted to EPA. Having the data from these field blanks available to the national monitoring community would help EPA and other researchers better understand the relationship between the mass of PM that is sampled and weighed on a regular PM filter and the PM that is actually present in ambient air. The EPA solicits comment on this additional $PM_{2.5}$ reporting requirement.

3. Data Certification Schedule

To enhance timely certification of each year's air quality data to allow more timely reporting to the public and more timely regulatory findings and actions based on those data, EPA proposes to speed up official certification of air quality data by moving the annual data certification date from July 1 to May 1 of each year. We believe it can be met through more expeditious administrative clearance processes with State/local agencies and will not require significant changes in monitoring practices or equipment. The EPA solicits comments on this proposed change to the certification schedule. The EPA solicits comments identifying possible barriers to meeting the proposed certification date and information on how agencies that presently certify their data ahead of the current schedule accomplish this.

4. Particulate Matter Filter Archive

During the regulatory development process, various governmental agencies and health scientists indicated that archiving particulate matter filters for FRM and Federal equivalent methods would be useful for later chemical speciation analyses, mass analyses, or other analyses. Therefore, we propose to require archiving $PM_{2.5}$, $PM_{10\text{-}2.5}$, and PM_{10C} filters for one year (the current requirement is only for $PM_{2.5}$ filters). The EPA solicits comment on this proposed requirement, specifically from those agencies or scientists interested in using these filters.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and to the requirements of the Executive Order. The Executive Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or 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;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, OMB has notified EPA that it considers this a ''significant regulatory action'' within the meaning of the Executive Order. EPA has submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

The information collection requirements in the proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) documents prepared by EPA have been assigned EPA ICR No. 0559.09 (2080–0005) for 40 CFR part 53 and 0940.19 (2060–0084) for 40 CFR part 58. The provisions in 40 CFR parts 53 and 58 have been previously approved by OMB under control numbers 2080–0005 (EPA ICR number 0559.07) and 2060–0084 (EPA ICR number 0940.17), respectively.

The monitoring, record keeping, and reporting requirements in 40 CFR parts 53 and 58 are specifically authorized by section 319 of the CAA (42 U.S.C. 7619). All information submitted to EPA pursuant to the monitoring, record keeping, and reporting requirements for which a claim of confidentiality is made is safeguarded according to Agency policies in 40 CFR part 2, subpart B.

The information collected under 40 CFR part 53 (e.g., test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the National Ambient Air Quality Standards (NAAQS) in 40 CFR part 50 will meet the design, performance, and/or comparability requirements for designation as a Federal reference method (FRM) or Federal equivalent method (FEM). The proposed amendments would add requirements for $PM_{10\text{-}2.5}$ FEM and FRM determinations, Class II equivalent methods for $PM_{10\text{-}2.5}$ and Class III equivalent methods for $PM_{2.5}$ and $PM_{10\text{-}2.5}$; reduce certain monitoring and data collection requirements; and streamline EPA administrative requirements.

The incremental annual reporting and record keeping burden for this collection of information under 40 CFR part 53 (averaged over the first 3 years of this ICR) for one additional respondent per year is estimated to increase by a total of 2,774 labor hours per year with an increase in costs of $32,000/year. The capital/startup costs for test equipment and qualifying tests are estimated at $3,832 with operation and maintenance costs of $27,772.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health and ecosystems impacts, to develop emission control strategies, and to measure progress for the air pollution program. The proposed amendments would revise the technical requirements for certain types of sites, add provisions for monitoring of $PM_{10-2.5}$, and reduce certain monitoring requirements for criteria pollutants of than particulate matter and ozone. Monitoring agencies would be required to submit annual monitoring network plans, establish $PM_{2.5}$ sites by January 1, 2009, establish NCore sites by January 1, 2011, conduct network assessments every 5 years, and perform quality assurance activities.

The annual average reporting burden for the collection under 40 CFR part 58 (averaged over the first 3 years of this ICR) for 168 respondents is estimated to decrease by a total of 336,650 labor hours per year with a decrease in costs of $31,600,362. State, local, and tribal entities are eligible for State assistance grants provided by the Federal government under the CAA for monitors and related activities.

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.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR parts 53 and 58 are listed in 40 CFR part 9.

To comment on the Agency's need for the information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for the proposed amendments, which includes the ICR for 40 CFR part 58, under Docket ID number EPA–HQ–OAR–2004–0018. Submit any comments related to the ICR for the proposed amendments to 40 CFR part 58 to EPA and OMB. See the **ADDRESSES** section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after January 17, 2006, a comment to OMB is best assured of having its full effect if OMB receives it by February 16, 2006. The final amendments will respond to any OMB or public comments on the information collection requirements for 40 CFR part 58 contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute 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.

For the purposes of assessing the impacts of today's proposed amendments on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration; (2) a government jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and that is not dominant in its field.

After considering the economic impacts of today's proposed amendments on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The proposed requirements in 40 CFR part 53 for applications for designation of equivalent methods do not address small entities. The requirement to apply is voluntary and, the criteria for approval are the minimum necessary to ensure that alternative methods meet the same technical standards as the proposed federal method. The proposed amendments to 40 CFR part 58 would reduce annual ambient air monitoring costs for State and local agencies by approximately $8.5 million and 40,000 labor hours from present levels. State assistance grant funding provided by the federal government can be used to defray the costs of new or upgraded monitors for the NCore and $PM_{10-2.5}$ networks. We continue to be interested in the potential impacts of the proposed amendments on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory

proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that the proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. The proposed amendments to 40 CFR part 58 would reduce annual ambient air monitoring costs for State and local agencies by approximately $8.5 million and 40,000 labor hours from present levels. The costs for reconfiguring the existing ambient air monitoring requirements to implement the NCore network would be borne by the Federal government in the form of State assistance grants. Thus, the proposed amendments are not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that the proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. Small governments that may be affected by the proposed amendments are already meeting similar requirements under the existing rules, the proposed amendments would substantially reduce the costs of the existing rules, and the costs of changing the network design requirements would be borne by the Federal government through State assistance grants. Therefore, the proposed rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132 (64 FR 43255, August 10, 1999), 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 proposed rule does not have federalism implications. It 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. States currently implement similar ambient air monitoring requirements under 40 CFR parts 53 and 58, and the costs of implementing new requirements would be borne by the Federal government through State assistance grants. Thus, Executive Order 13132 does not apply to this proposed rule.

Although section 6 of the Executive Order does not apply to this proposed rule, EPA did consult with representatives of State and local governments early in the process of developing this proposed rule. In 2001, EPA organized a National Monitoring Steering Committee (NMSC) to provide oversight and guidance in reviewing the existing air pollution monitoring program and in developing a comprehensive national ambient air monitoring strategy. The NMSC membership includes representatives EPA, State and local agencies, State and Territorial Air Pollution Program Administrators/Association of Local Air Pollution Control Officials (STAPPA/ALAPCO), and tribal governments to reflect the partnership between EPA and governmental agencies that collect and use ambient air data. The NMSC formed workgroups to address quality assurance, technology, and regulatory review of the draft ambient air monitoring strategy (NAAMS). These workgroups met several times by phone and at least once in a face-to-face workshop to detail out recommendations for improving the ambient air monitoring program. A record of the Steering Committee members, workgroup members, and workshop are available on the web at: *http://www.epa.gov/ttn/amtic/monitor.html*.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comments on the proposed rule from State and local officials.

F. Executive Order 13175: Consultation and 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.'' This proposed rule does not have tribal implications, as specified in Executive Order 13175. The proposed amendments would not directly apply to Tribal governments. However, a tribal government may elect to conduct ambient air monitoring and report the data to AQS. Since it is possible that tribal governments may choose to establish and operate NCore sites as part of the national monitoring program, EPA consulted with tribal officials early in the process of developing the proposed rule to permit them to have meaningful and timely input into its development. As discussed in section V.E of this preamble, tribal agencies were represented on both the NMSSC and the workgroups that developed the NAAMS document and proposed monitoring requirements. Tribal monitoring programs were represented on both the Quality Assurance and Technology work groups. Participation was also open to tribal monitoring programs on the regulatory review workgroup. EPA specifically solicits additional comment on the proposed amendments from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045 (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 rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. The proposed rule is not subject to Executive Order 13045 because it is based on technology and not on health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

The proposed rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use'' (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. No significant change in the use of energy is expected because the total number of monitors for ambient air

quality measurements will not increase above present levels. Further, we have concluded that this proposed rule is not likely to have any adverse energy effects.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The proposed amendments involve environmental monitoring and measurement. Ambient air concentrations of $PM_{2.5}$ are currently measured by the Federal reference method in 40 CFR part 50, appendix L (Reference Method for the Determination of Fine Particulate as $PM_{2.5}$ in the Atmosphere) or by an a Federal reference or equivalent method that meets the requirements in 40 CFR part 53. Ambient air concentrations of $PM_{10\text{-}2.5}$ would be measured by the proposed Federal reference method in 40 CFR part 50, appendix O (Reference Method for the Determination of Coarse Particulate Matter as $PM_{10\text{-}2.5}$ in the Atmosphere) published elsewhere in this **Federal Register** or by a Federal reference or equivalent method that meets the requirements in 40 CFR part 53. As discussed in section IV.B of this preamble, the proposed Federal reference method for $PM_{10\text{-}2.5}$ is similar to the existing methods for $PM_{2.5}$ and PM_{10}.

In the preamble to the proposed NAAQS revisions published elsewhere in this **Federal Register**, EPA requests comments on selection of an alternative filter-based dichotomous sampler as the Federal reference method for $PM_{10\text{-}2.5}$. Procedures are included in the proposed monitoring amendments that would allow for approval of a candidate equivalent method for $PM_{10\text{-}2.5}$ that is similar to the proposed Federal reference method or to the alternative method proposed for comment. Any method that meets the performance criteria for a candidate equivalent method could be approved for use as a Federal reference or equivalent method.

This approach is consistent with the Agency's Performance-Based Measurement System (PBMS). The PBMS approach is intended to be more flexible and cost effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the specified performance criteria. EPA welcomes comments on this aspect of the proposed amendments and, specifically invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in the regulation.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12848 (58 FR 7629, February 11, 1994) requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. These requirements have been addressed to the extent practicable in the Regulatory Impact Analysis for the proposed revisions to the NAAQS for particulate matter.

List of Subjects in 40 CFR Parts 53 and 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: December 20, 2005.

Stephen L. Johnson,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, parts 53 and 58 of the Code of Federal Regulations are proposed to be amended as follows:

PART 53—[AMENDED]

1. The authority citation for part 53 continues to read as follows:

Authority: Sec. 301(a) of the Clean Air Act (42 U.S.C. sec. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91–604, 84 Stat. 1713, unless otherwise noted.

Subpart A—[Amended]

2. Revise §§ 53.1 through 53.5 to read as follows:

§ 53.1 Definitions.

Terms used but not defined in this part shall have the meaning given them by the Act.

Act means the Clean Air Act (42 U.S.C. 1857–1857l), as amended.

Additive and multiplicative bias means the linear regression intercept and slope of a linear plot fitted to corresponding candidate and reference method mean measurement data pairs.

Administrator means the Administrator of the Environmental Protection Agency (EPA) or his or her authorized representative.

Agency means the Environmental Protection Agency.

Applicant means a person or entity who submits an application for a reference or equivalent method determination under § 53.4, or a person or entity who assumes the rights and obligations of an applicant under § 53.7. Applicant may include a manufacturer, distributor, supplier, or vendor.

Automated method or analyzer means a method for measuring concentrations of an ambient air pollutant in which sample collection (if necessary), analysis, and measurement are performed automatically by an instrument.

Candidate method means a method for measuring the concentration of an air pollutant in the ambient air for which an application for a reference method determination or an equivalent method determination is submitted in accordance with § 53.4, or a method tested at the initiative of the Administrator in accordance with § 53.7.

Class I equivalent method means an equivalent method for $PM_{2.5}$ or $PM_{10\text{-}2.5}$ which is based on a sampler that is very similar to the sampler specified for reference methods in appendix L or appendix O (as applicable) of part 50 of this chapter, with only minor deviations or modifications, as determined by EPA.

Class II equivalent method means an equivalent method for $PM_{2.5}$ or $PM_{10\text{-}2.5}$ that utilizes a $PM_{2.5}$ sampler or $PM_{10\text{-}2.5}$ sampler in which integrated $PM_{2.5}$ samples or $PM_{10\text{-}2.5}$ samples are obtained from the atmosphere by filtration and subjected to a subsequent filter conditioning process followed by a gravimetric mass determination, but which is not a Class I equivalent method because of substantial deviations from the design specifications of the sampler specified for reference methods in appendix L or appendix O (as

applicable) of part 50 of this chapter, as determined by EPA.

Class III equivalent method means an equivalent method for $PM_{2.5}$ or $PM_{10-2.5}$ that is an analyzer capable of providing $PM_{2.5}$ or $PM_{10-2.5}$ ambient air measurements representative of one-hour or less integrated $PM_{2.5}$ or $PM_{10-2.5}$ concentrations as well as 24-hour measurements determined as, or equivalent to, the mean of 24 one-hour consecutive measurements.

CO means carbon monoxideide.

Collocated means two or more air samplers, analyzers, or other instruments that are operated simultaneously while located side by side, separated by a distance that is large enough to preclude the air sampled by any of the devices from being affected by any of the other devices, but small enough so that all devices obtain identical or uniform ambient air samples that are equally representative of the general area in which the group of devices is located.

Equivalent method means a method for measuring the concentration of an air pollutant in the ambient air that has been designated as an equivalent method in accordance with this part; it does not include a method for which an equivalent method designation has been canceled in accordance with § 53.11 or § 53.16.

ISO 9001-registered facility means a manufacturing facility that is either:

(1) An International Organization for Standardization (ISO) 9001-registered manufacturing facility, registered to the ISO 9001 standard (by the Registrar Accreditation Board (RAB) of the American Society for Quality Control (ASQC) in the United States), with registration maintained continuously.

(2) A facility that can be demonstrated, on the basis of information submitted to the EPA, to be operated according to an EPA-approved and periodically audited quality system which meets, to the extent appropriate, the same general requirements as an ISO 9001-registered facility for the design and manufacture of designated reference and equivalent method samplers and monitors.

ISO-certified auditor means an auditor who is either certified by the Registrar Accreditation Board (in the United States) as being qualified to audit quality systems using the requirements of recognized standards such as ISO 9001, or who, based on information submitted to the EPA, meets the same general requirements as provided for ISO-certified auditors.

Manual method means a method for measuring concentrations of an ambient air pollutant in which sample collection, analysis, or measurement, or some combination thereof, is performed manually. A method for PM_{10} or $PM_{2.5}$ which utilizes a sampler that requires manual preparation, loading, and weighing of filter samples is considered a manual method even though the sampler may be capable of automatically collecting a series of sequential samples.

NO means nitrogen oxide.

NO_2 means nitrogen dioxide.

NO_X means oxides of nitrogen and is defined as the sum of the concentrations of NO_2 and NO.

O_3 means ozone.

Operated simultaneously means that two or more collocated samplers or analyzers are operated concurrently with no significant difference in the start time, stop time, and duration of the sampling or measurement period.

Pb means lead.

PM means PM_{10}, PM_{10C}, $PM_{2.5}$, $PM_{10-2.5}$, or particulate matter of unspecified size range.

PM_{10} means particulate matter as defined in section 1.1 of appendix J to part 50 of this chapter.

$PM_{2.5}$ means particulate matter as defined in section 1.1 of appendix L to part 50 of this chapter.

$PM_{10-2.5}$ means particulate matter as defined in section 1.1 of appendix O to part 50 of this chapter.

PM_{10C} means PM_{10} particulate matter or PM_{10} measurements obtained with a PM_{10C} sampler.

$PM_{2.5}$ sampler means a device, associated with a manual method for measuring $PM_{2.5}$, designed to collect $PM_{2.5}$ from an ambient air sample, but lacking the ability to automatically analyze or measure the collected sample to determine the mass concentrations of $PM_{2.5}$ in the sampled air.

PM_{10} sampler means a device, associated with a manual method for measuring PM_{10}, designed to collect PM_{10} from an ambient air sample, but lacking the ability to automatically analyze or measure the collected sample to determine the mass concentrations of PM_{10} in the sampled air.

PM_{10C} sampler means a PM_{10} sampler that meets the special requirements for a PM_{10C} sampler that is part of a $PM_{10-2.5}$ reference method sampler, as specified in appendix O to part 50 of this chapter, or a PM_{10} sampler that is part of a $PM_{10-2.5}$ sampler that has been designated as an equivalent method for $PM_{10-2.5}$.

$PM_{10-2.5}$ sampler means a sampler, or a collocated pair of samplers, associated with a manual method for measuring $PM_{10-2.5}$ and designed to collect either $PM_{10-2.5}$ directly or PM_{10C} and $PM_{2.5}$ separately and simultaneously from concurrent ambient air samples, but lacking the ability to automatically analyze or measure the collected sample(s) to determine the mass concentrations of $PM_{10-2.5}$ in the sampled air.

Reference method means a method of sampling and analyzing the ambient air for an air pollutant that is specified as a reference method in an appendix to part 50 of this chapter, or a method that has been designated as a reference method in accordance with this part; it does not include a method for which a reference method designation has been canceled in accordance with § 53.11 or § 53.16.

Sequential samples for PM samplers means two or more PM samples for sequential (but not necessarily contiguous) time periods that are collected automatically by the same sampler without the need for intervening operator service.

SO_2 means sulfur dioxide.

Test analyzer means an analyzer subjected to testing as part of a candidate method in accordance with subparts B, C, D, E, or F of this part, as applicable.

Test sampler means a PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler subjected to testing as part of a candidate method in accordance with subparts C, D, E, or F of this part.

Ultimate purchaser means the first person or entity who purchases a reference method or an equivalent method for purposes other than resale.

§ 53.2 General requirements for a reference method determination.

The following general requirements for a reference method determination are summarized in table A–1 of this subpart.

(a) *Manual methods.* (1) *Sulfur dioxide* (SO_2) *and lead.* For measuring SO_2 and lead, appendices A and G of part 50 of this chapter specify unique manual reference methods for measuring these pollutants. Except as provided in § 53.16, other manual methods for SO_2 and lead will not be considered for reference method determinations under this part.

(2) *PM_{10}.* A reference method for measuring PM_{10} must be a manual method that meets all requirements specified in appendix J of part 50 of this chapter and must include a PM_{10} sampler that has been shown in accordance with this part to meet all requirements specified in this subpart A and subpart D of this part.

(3) *$PM_{2.5}$.* A reference method for measuring $PM_{2.5}$ must be a manual method that meets all requirements specified in appendix L of part 50 of

this chapter and must include a $PM_{2.5}$ sampler that has been shown in accordance with this part to meet the applicable requirements specified in this subpart A and subpart E of this part. Further, reference method samplers must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

(4) *$PM_{10-2.5}$.* A reference method for measuring $PM_{10-2.5}$ must be a manual method that meets all requirements specified in appendix O of part 50 of this chapter and must include PM_{10C} and $PM_{2.5}$ samplers that have been shown in accordance with this part to meet the applicable requirements specified in this subpart A and subpart E of this part. Further, $PM_{10-2.5}$ reference method samplers must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

(b) *Automated methods.* An automated reference method for measuring CO, O_3, or NO_2 must utilize the measurement principle and calibration procedure specified in the appropriate appendix to part 50 of this chapter and must have been shown in accordance with this part to meet the requirements specified in this subpart A and subpart B of this part.

§ 53.3 General requirements for an equivalent method determination.

(a) *Manual methods.* A manual equivalent method must have been shown in accordance with this part to satisfy the applicable requirements specified in this subpart A and subpart C of this part. In addition, a PM sampler associated with a manual equivalent method for PM_{10}, $PM_{2.5}$, or $PM_{10-2.5}$ must have been shown in accordance with this part to satisfy the following additional requirements, as applicable:

(1) *PM_{10}.* A PM_{10} sampler associated with a manual method for PM_{10} must satisfy the requirements of subpart D of this part.

(2) *$PM_{2.5}$ Class I.* A $PM_{2.5}$ Class I equivalent method sampler must also satisfy all requirements of subpart E of this part, which shall include appropriate demonstration that each and every deviation or modification from the reference method sampler specifications does not significantly alter the performance of the sampler.

(3) *$PM_{2.5}$ Class II.* (i) A $PM_{2.5}$ Class II equivalent method sampler must also satisfy the applicable requirements of subparts E and F of this part or the alternative requirements in paragraph (a)(3)(ii) of this section.

(ii) In lieu of the applicable requirements specified for Class II $PM_{2.5}$ methods in subparts C and F of this part, a Class II $PM_{2.5}$ equivalent method sampler may alternatively meet the applicable requirements in paragraphs (b)(3)(i) through (iii) of this section and the testing, performance, and comparability requirements specified for Class III equivalent methods for $PM_{2.5}$ in subpart C of this part.

(4) *$PM_{10-2.5}$ Class I.* A $PM_{10-2.5}$ Class I equivalent method sampler must also satisfy the applicable requirements of subpart E of this part (there are no additional requirements specifically for Class I $PM_{10-2.5}$ methods in subpart C of this part).

(5) *$PM_{10-2.5}$ Class II.* (i) A $PM_{10-2.5}$ Class II equivalent method must also satisfy the applicable requirements of subpart C of this part and also the applicable requirements and provisions of paragraphs (b)(3)(i) through (iii) of this section, or the alternative requirements in paragraph (a)(5)(ii) of this section.

(ii) In lieu of the applicable requirements specified for Class II $PM_{10-2.5}$ methods in subpart C of this part and in paragraph (b)(3)(iii) of this section, a Class II $PM_{10-2.5}$ equivalent method sampler may alternatively meet the applicable requirements in paragraphs (b)(3)(i) and (ii) of this section and the testing, performance, and comparability requirements specified for Class III equivalent methods for $PM_{10-2.5}$ in subpart C of this part.

(6) *ISO 9001.* All designated equivalent methods for $PM_{2.5}$ or $PM_{10-2.5}$ must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

(b) *Automated methods.* All types of automated equivalent methods must have been shown in accordance with this part to satisfy the applicable requirements specified in this subpart A and subpart C of this part. In addition, an automated equivalent method must have been shown in accordance with this part to satisfy the following additional requirements, as applicable:

(1) An automated equivalent method for pollutants other than PM must be shown in accordance with this part to satisfy the applicable requirements specified in subpart B of this part.

(2) An automated equivalent method for PM_{10} must be shown in accordance with this part to satisfy the applicable requirements of subpart D of this part.

(3) A Class III automated equivalent method for $PM_{2.5}$ or $PM_{10-2.5}$ must be shown in accordance with this part to satisfy the requirements in paragraphs (b)(3)(i) through (iii) of this section, as applicable.

(i) All pertinent requirements of 40 CFR part 50, appendix L, including sampling height, range of operational conditions, ambient temperature and pressure sensors, outdoor enclosure, electrical power supply, control devices and operator interfaces, data output port, operation/instruction manual, data output and reporting requirements, and any other requirements that would be reasonably applicable to the method, unless adequate (as determined by the Administrator) rationale can be provided to support the contention that a particular requirement does not or should not be applicable to the particular candidate method.

(ii) All pertinent tests and requirements of subpart E of this part, such as instrument manufacturing quality control; final assembly and inspection; manufacturer's audit checklists; leak checks; flow rate accuracy, measurement accuracy, and flow rate cut-off; operation following power interruptions; effect of variations in power line voltage, ambient temperature and ambient pressure; and aerosol transport; unless adequate (as determined by the Administrator) rationale can be provided to support the contention that a particular test or requirement does not or should not be applicable to the particular candidate method.

(iii) Candidate methods shall be tested for and meet any performance requirements, such as inlet aspiration, particle size separation or selection characteristics, change in particle separation or selection characteristics due to loading or other operational conditions, or effects of surface exposure and particle volatility, determined by the Administrator to be necessary based on the nature, design, and specifics of the candidate method and the extent to which it deviates from the design and performance characteristics of the reference method. These performance requirements and the specific test(s) for them will be determined by Administrator for each specific candidate method or type of candidate method and may be similar to or based on corresponding tests and requirements set forth in subpart F of this part or may be special requirements and tests tailored by the Administrator to the specific nature, design, and operational characteristics of the candidate method. For example, a candidate method with an inlet design deviating substantially from the design of the reference method inlet would likely be subject to an inlet aspiration test similar to that set forth in § 53.63. Similarly, a candidate method having an inertial fractionation system substantially different from that of the reference method would likely be

subject to a static fractionation test and a loading test similar to those set forth in §§ 53.64 and 53.65, respectively. A candidate method with more extensive or profound deviations from the design and function of the reference method may be subject to other tests, full wind-tunnel tests similar to those described in § 53.62, or to special tests adapted or developed individually to accommodate the specific type of measurement or operation of the candidate method.

(4) All designated equivalent methods for $PM_{2.5}$ or $PM_{10-2.5}$ must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

§ 53.4 Applications for reference or equivalent method determinations.

(a) Applications for reference or equivalent method determinations shall be submitted in duplicate to: Director, National Exposure Research Laboratory, Reference and Equivalent Method Program (MD–D205–03), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711 (Commercial delivery address: 4930 Old Page Road, Durham, North Carolina 27703).

(b) Each application shall be signed by an authorized representative of the applicant, shall be marked in accordance with § 53.15 (if applicable), and shall contain the following:

(1) A clear identification of the candidate method, which will distinguish it from all other methods such that the method may be referred to unambiguously. This identification must consist of a unique series of descriptors such as title, identification number, analyte, measurement principle, manufacturer, brand, model, etc., as necessary to distinguish the method from all other methods or method variations, both within and outside the applicant's organization.

(2) A detailed description of the candidate method, including but not limited to the following: The measurement principle, manufacturer, name, model number and other forms of identification, a list of the significant components, schematic diagrams, design drawings, and a detailed description of the apparatus and measurement procedures. Drawings and descriptions pertaining to candidate methods or samplers for $PM_{2.5}$ or $PM_{10-2.5}$ must meet all applicable requirements in reference 1 of appendix A of this subpart, using appropriate graphical, nomenclature, and mathematical conventions such as those specified in references 3 and 4 of appendix A of this subpart.

(3) A copy of a comprehensive operation or instruction manual providing a complete and detailed description of the operational, maintenance, and calibration procedures prescribed for field use of the candidate method and all instruments utilized as part of that method (under § 53.9(a)).

(i) As a minimum this manual shall include:

(A) Description of the method and associated instruments.

(B) Explanation of all indicators, information displays, and controls.

(C) Complete setup and installation instructions, including any additional materials or supplies required.

(D) Details of all initial or startup checks or acceptance tests and any auxiliary equipment required.

(E) Complete operational instructions.

(F) Calibration procedures and descriptions of required calibration equipment and standards.

(G) Instructions for verification of correct or proper operation.

(H) Trouble-shooting guidance and suggested corrective actions for abnormal operation.

(I) Required or recommended routine, periodic, and preventative maintenance and maintenance schedules.

(J) Any calculations required to derive final concentration measurements.

(K) Appropriate references to any applicable appendix of part 50 of this chapter; reference 6 of appendix A of this subpart; and any other pertinent guidelines.

(ii) The manual shall also include adequate warning of potential safety hazards that may result from normal use and/or malfunction of the method and a description of necessary safety precautions. (See § 53.9(b).) However, the previous requirement shall not be interpreted to constitute or imply any warranty of safety of the method by EPA. For samplers and automated methods, the manual shall include a clear description of all procedures pertaining to installation, operation, preventive maintenance, and troubleshooting and shall also include parts identification diagrams. The manual may be used to satisfy the requirements of paragraphs (b)(1) and (2) of this section to the extent that it includes information necessary to meet those requirements.

(4) A statement that the candidate method has been tested in accordance with the procedures described in subparts B, C, D, E, and/or F of this part, as applicable.

(5) Descriptions of test facilities and test configurations, test data, records, calculations, and test results as specified in subparts B, C, D, E, and/or F of this part, as applicable. Data must be sufficiently detailed to meet appropriate principles described in part B, sections 3.3.1 (paragraph 1) and 3.5.1 and part C, section 4.6 of reference 2 of appendix A of this subpart; and in paragraphs 1 through 3 of section 4.8 (Records) of reference 5 of appendix A of this subpart. Salient requirements from these references include the following:

(i) The applicant shall maintain and include records of all relevant measuring equipment, including the make, type, and serial number or other identification, and most recent calibration with identification of the measurement standard or standards used and their National Institute of Standards and Technology (NIST) traceability. These records shall demonstrate the measurement capability of each item of measuring equipment used for the application and include a description and justification (if needed) of the measurement setup or configuration in which it was used for the tests. The calibration results shall be recorded and identified in sufficient detail so that the traceability of all measurements can be determined and any measurement could be reproduced under conditions close to the original conditions, if necessary, to resolve any anomalies.

(ii) Test data shall be collected according to the standards of good practice and by qualified personnel. Test anomalies or irregularities shall be documented and explained or justified. The impact and significance of the deviation on test results and conclusions shall be determined. Data collected shall correspond directly to the specified test requirement and be labeled and identified clearly so that results can be verified and evaluated against the test requirement. Calculations or data manipulations must be explained in detail so that they can be verified.

(6) A statement that the method, analyzer, or sampler tested in accordance with this part is representative of the candidate method described in the application.

(c) For candidate automated methods and candidate manual methods for PM_{10}, $PM_{2.5}$, and $PM_{10-2.5}$ the application shall also contain the following:

(1) A detailed description of the quality system that will be utilized, if the candidate method is designated as a reference or equivalent method, to ensure that all analyzers or samplers offered for sale under that designation will have essentially the same

performance characteristics as the analyzer(s) or samplers tested in accordance with this part. In addition, the quality system requirements for candidate methods for $PM_{2.5}$ and $PM_{10-2.5}$ must be described in sufficient detail, based on the elements described in section 4 of reference 1 (Quality System Requirements) of appendix A of this subpart. Further clarification is provided in the following sections of reference 2 of appendix A of this subpart: part A (Management Systems), sections 2.2 (Quality System and Description), 2.3 (Personnel Qualification and Training), 2.4 (Procurement of Items and Services), 2.5 (Documents and Records), and 2.7 (Planning); part B (Collection and Evaluation of Environmental Data), sections 3.1 (Planning and Scoping), 3.2 (Design of Data Collection Operations), and 3.5 (Assessment and Verification of Data Usability); and part C (Operation of Environmental Technology), sections 4.1 (Planning), 4.2 (Design of Systems), and 4.4 (Operation of Systems).

(2) A description of the durability characteristics of such analyzers or samplers (see § 53.9(c)). For methods for $PM_{2.5}$ and $PM_{10-2.5}$ the warranty program must ensure that the required specifications (see Table A–1 to this subpart) will be met throughout the warranty period and that the applicant accepts responsibility and liability for ensuring this conformance or for resolving any nonconformities, including all necessary components of the system, regardless of the original manufacturer. The warranty program must be described in sufficient detail to meet appropriate provisions of the ANSI/ASQC and ISO 9001 standards (references 1 and 2 in appendix A of this subpart) for controlling conformance and resolving nonconformance, particularly sections 4.12, 4.13, and 4.14 of reference 1 in appendix A of this subpart.

(i) Section 4.12 in reference 1 of appendix A of this subpart requires the manufacturer to establish and maintain a system of procedures for identifying and maintaining the identification of inspection and test status throughout all phases of manufacturing to ensure that only instruments that have passed the required inspections and tests are released for sale.

(ii) Section 4.13 in reference 1 of appendix A of this subpart requires documented procedures for control of nonconforming product, including review and acceptable alternatives for disposition; section 4.14 in reference 1 of appendix A of this subpart requires documented procedures for implementing corrective (4.14.2) and preventive (4.14.3) action to eliminate the causes of actual or potential nonconformities. In particular, section 4.14.3 requires that potential causes of nonconformities be eliminated by using information such as service reports and customer complaints to eliminate potential causes of nonconformities.

(d) For candidate reference or equivalent methods for $PM_{2.5}$ and Class II or Class III equivalent methods for $PM_{10-2.5}$, the applicant, if requested by EPA, shall provide to EPA for test purposes one sampler or analyzer that is representative of the sampler or analyzer associated with the candidate method. The sampler or analyzer shall be shipped FOB destination to Director, National Exposure Research Laboratory, Reference and Equivalent Method Program (MD–D205–03), U.S. Environmental Protection Agency, 4930 Old Page Road, Durham, North Carolina 27703, scheduled to arrive concurrent with or within 30 days of the arrival of the other application materials. This analyzer or sampler may be subjected to various tests that EPA determines to be necessary or appropriate under § 53.5(f), and such tests may include special tests not described in this part. If the instrument submitted under this paragraph malfunctions, becomes inoperative, or fails to perform as represented in the application before the necessary EPA testing is completed, the applicant shall be afforded an opportunity to repair or replace the device at no cost to EPA. Upon completion of EPA testing, the analyzer or sampler submitted under this paragraph shall be repacked by EPA for return shipment to the applicant, using the same packing materials used for shipping the instrument to EPA unless alternative packing is provided by the applicant. Arrangements for, and the cost of, return shipment shall be the responsibility of the applicant. EPA does not warrant or assume any liability for the condition of the analyzer or sampler upon return to the applicant.

§ 53.5 Processing of applications.

After receiving an application for a reference or equivalent method determination, the Administrator will, within 120 calendar days after receipt of the application, take one or more of the following actions:

(a) Send notice to the applicant, in accordance with § 53.8, that the candidate method has been determined to be a reference or equivalent method.

(b) Send notice to the applicant that the application has been rejected, including a statement of reasons for rejection.

(c) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 120-day period shall commence upon receipt of the additional information).

(d) Send notice to the applicant that additional test data must be submitted and specify what tests are necessary and how the tests shall be interpreted (in such cases, the 120-day period shall commence upon receipt of the additional test data).

(e) Send notice to the applicant that the application has been found to be substantially deficient or incomplete and cannot be processed until additional information is submitted to complete the application and specify the general areas of substantial deficiency.

(f) Send notice to the applicant that additional tests will be conducted by the Administrator, specifying the nature of and reasons for the additional tests and the estimated time required (in such cases, the 120-day period shall commence 1 calendar day after the additional tests have been completed).

2a. Revise §§ 53.8 and 53.9 to read as follows:

§ 53.8 Designation of reference and equivalent methods.

(a) A candidate method determined by the Administrator to satisfy the applicable requirements of this part shall be designated as a reference method or equivalent method (as applicable) by and upon publication of a notice of the designation in the **Federal Register**.

(b) Upon designation, a notice indicating that the method has been designated as a reference method or an equivalent method shall be sent to the applicant.

(c) The Administrator will maintain a current list of methods designated as reference or equivalent methods in accordance with this part and will send a copy of the list to any person or group upon request. A copy of the list will be available for inspection or copying at EPA Regional Offices and may be available via the Internet or other sources.

§ 53.9 Conditions of designation.

Designation of a candidate method as a reference method or equivalent method shall be conditioned to the applicant's compliance with the following requirements. Failure to comply with any of the requirements shall constitute a ground for

cancellation of the designation in accordance with § 53.11.

(a) Any method offered for sale as a reference or equivalent method shall be accompanied by a copy of the manual referred to in § 53.4(b)(3) when delivered to any ultimate purchaser, and an electronic copy of the manual suitable for incorporating into user specific standard operating procedure documents shall be readily available to any users.

(b) Any method offered for sale as a reference or equivalent method shall generate no unreasonable hazard to operators or to the environment during normal use or when malfunctioning.

(c) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as part of a reference or equivalent method shall function within the limits of the performance specifications referred to in § 53.20(a), § 53.30(a), § 53.50, or § 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).

(d) Any analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler offered for sale as a reference or equivalent method shall bear a prominent, permanently affixed label or sticker indicating that the analyzer or sampler has been designated by EPA as a reference method or as an equivalent method (as applicable) in accordance with this part and displaying any designated method identification number that may be assigned by EPA.

(e) If an analyzer is offered for sale as a reference or equivalent method and has one or more selectable ranges, the label or sticker required by paragraph (d) of this section shall be placed in close proximity to the range selector and shall indicate clearly which range or ranges have been designated as parts of the reference or equivalent method.

(f) An applicant who offers analyzers, PM_{10} samplers, $PM_{2.5}$ samplers, or $PM_{10-2.5}$ samplers for sale as reference or equivalent methods shall maintain an accurate and current list of the names and mailing addresses of all ultimate purchasers of such analyzers or samplers. For a period of 7 years after publication of the reference or equivalent method designation applicable to such an analyzer or sampler, the applicant shall notify all ultimate purchasers of the analyzer or sampler within 30 days if the designation has been canceled in accordance with § 53.11 or § 53.16 or if adjustment of the analyzer or sampler is necessary under § 53.11(b).

(g) If an applicant modifies an analyzer, PM_{10} sampler, $PM_{2.5}$ sampler, or $PM_{10-2.5}$ sampler that has been designated as a reference or equivalent method, the applicant shall not sell the modified analyzer or sampler as a reference or equivalent method nor attach a label or sticker to the modified analyzer or sampler under paragraph (d) or (e) of this section until the applicant has received notice under § 53.14(c) that the existing designation or a new designation will apply to the modified analyzer or sampler or has applied for and received notice under § 53.8(b) of a new reference or equivalent method determination for the modified analyzer or sampler.

(h) An applicant who has offered $PM_{2.5}$ or $PM_{10-2.5}$ samplers or analyzers for sale as part of a reference or equivalent method may continue to do so only so long as the facility in which the samplers or analyzers are manufactured continues to be an ISO 9001-registered facility, as set forth in subpart E of this part. In the event that the ISO 9001 registration for the facility is withdrawn, suspended, or otherwise becomes inapplicable, either permanently or for some specified time interval, such that the facility is no longer an ISO 9001-registered facility, the applicant shall notify EPA within 30 days of the date the facility becomes other than an ISO 9001-registered facility, and upon such notification, EPA shall issue a preliminary finding and notification of possible cancellation of the reference or equivalent method designation under § 53.11.

(i) An applicant who has offered $PM_{2.5}$ or $PM_{10-2.5}$ samplers or analyzers for sale as part of a reference or equivalent method may continue to do so only so long as updates of the Product Manufacturing Checklist set forth in subpart E of this part are submitted annually. In the event that an annual Checklist update is not received by EPA within 12 months of the date of the last such submitted Checklist or Checklist update, EPA shall notify the applicant within 30 days that the Checklist update has not been received and shall, within 30 days from the issuance of such notification, issue a preliminary finding and notification of possible cancellation of the reference or equivalent method designation under § 53.11.

Table A–1 to subpart A of part 53 is revised to read as follows:

TABLE A–1 TO SUBPART A OF PART 53.—SUMMARY OF APPLICABLE REQUIREMENTS FOR REFERENCE AND EQUIVALENT METHODS FOR AIR MONITORING OF CRITERIA POLLUTANTS

Pollutant	Ref. or equivalent	Manual or automated	Applicable part 50 appendix	Applicable subparts of part 53					
				A	B	C	D	E	F
SO_2	Reference	Manual	A						
	Equivalent	Manual		✔		✔			
		Automated		✔	✔	✔			
CO	Reference	Automated	C	✔	✔				
	Equivalent	Manual		✔		✔			
		Automated		✔	✔	✔			
O_3	Reference	Automated	D	✔	✔				
	Equivalent	Manual		✔		✔			
		Automated		✔	✔	✔			
NO_2	Reference	Automated	F	✔	✔				
	Equivalent	Manual		✔		✔			
		Automated		✔	✔	✔			
Pb	Reference	Manual	G						
	Equivalent	Manual		✔		✔			
PM_{10}	Reference	Manual	J	✔			✔		
	Equivalent	Manual		✔		✔	✔		
		Automated		✔		✔	✔		
$PM_{2.5}$	Reference	Manual	L	✔				✔	
	Equivalent Class I	Manual	L	✔		✔		✔	
	Equivalent Class II	Manual	L[1]	✔		[2]✔		✔	[1 2]✔

TABLE A–1 TO SUBPART A OF PART 53.—SUMMARY OF APPLICABLE REQUIREMENTS FOR REFERENCE AND EQUIVALENT METHODS FOR AIR MONITORING OF CRITERIA POLLUTANTS—Continued

Pollutant	Ref. or equivalent	Manual or automated	Applicable part 50 appendix	Applicable subparts of part 53					
				A	B	C	D	E	F
$PM_{10-2.5}$	Equivalent Class III	Automated	L[1]	✔		✔		[1]✔	[1]✔
	Reference	Manual	O[2]	✔				✔	
	Equivalent								
	Equivalent Class II	Manual	O[2]	✔		[2]✔		[1]✔	[1 2]✔
	Equivalent Class III	Automated	L[1], O[1 2]	✔		✔		[1]✔	[1]✔

[1] Some requirements may apply, based on the nature of each particular candidate method, as determined by the Administrator.
[2] Alternative Class III requirements may be substituted.

4. Paragraph (6) of appendix A to subpart A of part 53 is revised to read as follows:

Appendix A to Subpart A of Part 53—References

* * * * *

(6) Quality Assurance Guidance Document 2.12. Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods. U.S. EPA, National Exposure Research Laboratory, Research Triangle Park, NC, November 1998 or later edition. Currently available at *http://www.epa.gov/ttn/amtic/pmqainf.html.*

Subpart C—[Amended]

5. Section 53.30 is revised to read as follows:

§ 53.30 General provisions.

(a) *Determination of comparability.* The test procedures prescribed in this subpart shall be used to determine if a candidate method is comparable to a reference method when both methods measure pollutant concentrations in ambient air. Minor deviations in testing requirements and acceptance requirements set forth in this subpart, in connection with any documented extenuating circumstances, may be determined by the Administrator to be acceptable, at the discretion of the Administrator.

(b) *Selection of test sites.* (1) Each test site shall be in an area which can be shown to have at least moderate concentrations of various pollutants. Each site shall be clearly identified and shall be justified as an appropriate test site with suitable supporting evidence such as a description of the surrounding area, characterization of the sources and pollutants typical in the area, maps, population density data, vehicular traffic data, emission inventories, pollutant measurements from previous years, concurrent pollutant measurements, meteorological data, and other information useful in supporting the suitability of the site for the comparison test or tests.

(2) If approval of one or more proposed test sites is desired prior to conducting the tests, a written request for approval of the test site or sites must be submitted to the address given in § 53.4. The request should include information identifying the type of candidate method and one or more specific proposed test sites along with a justification for each proposed specific site as described in paragraph (b)(1) of this section. The EPA will evaluate each proposed site and approve the site, disapprove the site, or request more information about the site. Any such pre-test approval of a test site by the EPA shall indicate only that the site meets the applicable test site requirements for the candidate method type; it shall not indicate, suggest, or imply that test data obtained at the site will necessarily meet any of the applicable data acceptance requirements. The Administrator may exercise discretion in selecting a different site (or sites) for any additional tests the Administrator decides to conduct.

(c) *Test atmosphere.* Ambient air sampled at an appropriate test site or sites shall be used for these tests. Simultaneous concentration measurements shall be made in each of the concentration ranges specified in tables C–1, C–3, or C–4 of this subpart, as appropriate.

(d) *Sampling or sample collection.* All test concentration measurements or samples shall be taken in such a way that both the candidate method and the reference method obtain air samples that are alike or as nearly identical as practical.

(e) *Operation.* Set-up and start-up of the test analyzer(s), test sampler(s), and reference method analyzers or samplers shall be in strict accordance with the applicable operation manual(s).

(f) *Calibration.* The reference method shall be calibrated according to the appropriate appendix to part 50 of this chapter (if it is a manual method) or according to the applicable operation manual(s) (if it is an automated method). A candidate method (or portion thereof) shall be calibrated according to the applicable operation manual(s), if such calibration is a part of the method.

(g) *Submission of test data and other information.* All recorder charts, calibration data, records, test results, procedural descriptions and details, and other documentation obtained from (or pertinent to) these tests shall be identified, dated, signed by the analyst performing the test, and submitted. For candidate methods for $PM_{2.5}$ and $PM_{10-2.5}$, all submitted information must meet the requirements of the ANSI/ASQC E4 Standard, sections 3.3.1, paragraphs 1 and 2 (reference 1 of appendix A of this subpart).

§ 53.31 [Removed]

6. Section 53.31 is removed and reserved.

7. Section 53.32 is revised to read as follows:

§ 53.32 Test procedures for methods for SO_2, CO, O_3, and NO_2.

(a) *Comparability.* Comparability is shown for SO_2, CO, O_3, and NO_2 methods when the differences between:

(1) Measurements made by a candidate manual method or by a test analyzer representative of a candidate automated method, and;

(2) Measurements made simultaneously by a reference method are less than or equal to the values for maximum discrepancy specified in table C–1 of this subpart.

(b) *Test measurements.* All test measurements are to be made at the same test site. If necessary, the concentration of pollutant in the sampled ambient air may be augmented with artificially generated pollutant to facilitate measurements in the specified ranges, as described under paragraph (f)(4) of this section.

(c) *Requirements for measurements or samples.* All test measurements made or test samples collected by means of a

sample manifold as specified in paragraph (f)(4) of this section shall be at a room temperature between 20° and 30°C, and at a line voltage between 105 and 125 volts. All methods shall be calibrated as specified in § 53.30(f) prior to initiation of the tests.

(d) *Set-up and start-up.* (1) Set-up and start-up of the test analyzer, test sampler(s), and reference method shall be in strict accordance with the applicable operation manual(s). If the test analyzer does not have an integral strip chart or digital data recorder, connect the analyzer output to a suitable strip chart or digital data recorder. This recorder shall have a chart width of at least 25 centimeters, a response time of 1 second or less, a deadband of not more than 0.25 percent of full scale, and capability of either reading measurements at least 5 percent below zero or offsetting the zero by at least 5 percent. Digital data shall be recorded at appropriate time intervals such that trend plots similar to a strip chart recording may be constructed with a similar or suitable level of detail.

(2) Other data acquisition components may be used along with the chart recorder during the conduct of these tests. Use of the chart recorder is intended only to facilitate visual evaluation of data submitted.

(3) Allow adequate warmup or stabilization time as indicated in the applicable operation manual(s) before beginning the tests.

(e) *Range.* (1) Except as provided in paragraph (e)(2) of this section, each method shall be operated in the range specified for the reference method in the appropriate appendix to part 50 of this chapter (for manual reference methods), or specified in table B–1 of subpart B of this part (for automated reference methods).

(2) For a candidate method having more than one selectable range, one range must be that specified in table B–1 of subpart B of this part, and a test analyzer representative of the method must pass the tests required by this subpart while operated on that range. The tests may be repeated for a broader range (*i.e.*, one extending to higher concentrations) than the one specified in table B–1 of subpart B of this part, provided that the range does not extend to concentrations more than two times the upper range limit specified in table B–1 of subpart B of this part and that the test analyzer has passed the tests required by subpart B of this part (if applicable) for the broader range. If the tests required by this subpart are conducted or passed only for the range specified in table B–1 of subpart B of this part, any equivalent method determination with respect to the method will be limited to that range. If the tests are passed for both the specified range and a broader range (or ranges), any such determination will include the broader range(s) as well as the specified range. Appropriate test data shall be submitted for each range sought to be included in such a determination.

(f) *Operation of automated methods.* (1) Once the test analyzer has been set up and calibrated and tests started, manual adjustment or normal periodic maintenance, as specified in the manual referred to in § 53.4(b)(3), is permitted only every 3 days. Automatic adjustments which the test analyzer performs by itself are permitted at any time. The submitted records shall show clearly when manual adjustments were made and describe the operations performed.

(2) All test measurements shall be made with the same test analyzer; use of multiple test analyzers is not permitted. The test analyzer shall be operated continuously during the entire series of test measurements.

(3) If a test analyzer should malfunction during any of these tests, the entire set of measurements shall be repeated, and a detailed explanation of the malfunction, remedial action taken, and whether recalibration was necessary (along with all pertinent records and charts) shall be submitted.

(4) Ambient air shall be sampled from a common intake and distribution manifold designed to deliver homogenous air samples to both methods. Precautions shall be taken in the design and construction of this manifold to minimize the removal of particulate matter and trace gases, and to insure that identical samples reach the two methods. If necessary, the concentration of pollutant in the sampled ambient air may be augmented with artificially generated pollutant. However, at all times the air sample measured by the candidate and reference methods under test shall consist of not less than 80 percent ambient air by volume. Schematic drawings, physical illustrations, descriptions, and complete details of the manifold system and the augmentation system (if used) shall be submitted.

(g) *Tests.* (1) Conduct the first set of simultaneous measurements with the candidate and reference methods:

(i) Table C–1 of this subpart specifies the type (1- or 24-hour) and number of measurements to be made in each of the three test concentration ranges.

(ii) The pollutant concentration must fall within the specified range as measured by the reference method.

(iii) The measurements shall be made in the sequence specified in table C–2 of this subpart, except for the 1-hour SO_2 measurements, which are all in the high range.

(2) For each pair of measurements, determine the difference (discrepancy) between the candidate method measurement and reference method measurement. A discrepancy which exceeds the discrepancy specified in table C–1 of this subpart constitutes a failure. Figure C–1 of this subpart contains a suggested format for reporting the test results.

(3) The results of the first set of measurements shall be interpreted as follows:

(i) Zero failures: The candidate method passes the test for comparability.

(ii) Three or more failures: The candidate method fails the test for comparability.

(iii) One or two failures: Conduct a second set of simultaneous measurements as specified in table C–1 of this subpart. The results of the combined total of first-set and second-set measurements shall be interpreted as follows:

(A) One or two failures: The candidate method passes the test for comparability.

(B) Three or more failures: The candidate method fails the test for comparability.

(iv) For SO_2, the 1-hour and 24-hour measurements shall be interpreted separately, and the candidate method must pass the tests for both 1- and 24-hour measurements to pass the test for comparability.

(4) A 1-hour measurement consists of the integral of the instantaneous concentration over a 60-minute continuous period divided by the time period. Integration of the instantaneous concentration may be performed by any appropriate means such as chemical, electronic, mechanical, visual judgment, or by calculating the mean of not less than 12 equally-spaced instantaneous readings. Appropriate allowances or corrections shall be made in cases where significant errors could occur due to characteristic lag time or rise/fall time differences between the candidate and reference methods. Details of the means of integration and any corrections shall be submitted.

(5) A 24-hour measurement consists of the integral of the instantaneous concentration over a 24-hour continuous period divided by the time period. This integration may be performed by any appropriate means such as chemical, electronic, mechanical, or by calculating the mean

of twenty-four (24) sequential 1-hour measurements.

(6) For O_3 and CO, no more than six 1-hour measurements shall be made per day. For SO_2, no more than four 1-hour measurements or one 24-hour measurement shall be made per day. One-hour measurements may be made concurrently with 24-hour measurements if appropriate.

(7) For applicable methods, control or calibration checks may be performed once per day without adjusting the test analyzer or method. These checks may be used as a basis for a linear interpolation-type correction to be applied to the measurements to correct for drift. If such a correction is used, it shall be applied to all measurements made with the method, and the correction procedure shall become a part of the method.

8. Section 53.33 is revised to read as follows:

§ 53.33 Test procedure for methods for Pb.

(a) *Comparability.* Comparability is shown for Pb methods when the differences between:

(1) Measurements made by a candidate method, and

(2) Measurements made by the reference method on simultaneously collected Pb samples (or the same sample, if applicable), are less than or equal to the value specified in table C–3 of this subpart.

(b) *Test measurements.* Test measurements may be made at any number of test sites. Augmentation of pollutant concentrations is not permitted, hence an appropriate test site or sites must be selected to provide Pb concentrations in the specified range.

(c) *Collocated samplers.* The ambient air intake points of all the candidate and reference method collocated samplers shall be positioned at the same height above the ground level, and between 2 meters (1 meter for samplers with flow rates less than 200 liters per minute (L/min)) and 4 meters apart. The samplers shall be oriented in a manner that will minimize spatial and wind directional effects on sample collection.

(d) *Sample collection.* Collect simultaneous 24-hour samples (filters) of Pb at the test site or sites with both the reference and candidate methods until at least 10 filter pairs have been obtained. A candidate method which employs a sampler and sample collection procedure that are identical to the sampler and sample collection procedure specified in the reference method, but uses a different analytical procedure, may be tested by analyzing common samples. The common samples shall be collected according to the sample collection procedure specified by the reference method and each shall be divided for respective analysis in accordance with the analytical procedures of the candidate method and the reference method.

(e) *Audit samples.* Three audit samples must be obtained from the address given in § 53.4(a). The audit samples are 3/4 × 8-inch glass fiber strips containing known amounts of Pb at the following nominal levels: 100 micrograms per strip (µg/strip); 300 µg/strip; 750 µg/strip. The true amount of Pb, in total µg/strip, will be provided with each audit sample.

(f) *Filter analysis.* (1) For both the reference method samples and the audit samples, analyze each filter extract three times in accordance with the reference method analytical procedure. The analysis of replicates should not be performed sequentially, i.e., a single sample should not be analyzed three times in sequence. Calculate the indicated Pb concentrations for the reference method samples in micrograms per cubic meter (µg/m³) for each analysis of each filter. Calculate the indicated total Pb amount for the audit samples in µg/strip for each analysis of each strip. Label these test results as R_{1A}, R_{1B}, R_{1C}, R_{2A}, R_{2B}, * * *, Q_{1A}, Q_{1B}, Q_{1C}, * * * ., where R denotes results from the reference method samples; Q denotes results from the audit samples; 1, 2, 3 indicate the filter number, and A, B, C indicate the first, second, and third analysis of each filter, respectively.

(2) For the candidate method samples, analyze each sample filter or filter extract three times and calculate, in accordance with the candidate method, the indicated Pb concentration in µg/m³ for each analysis of each filter. Label these test results as C_{1A}, C_{1B}, C_{2C}, . . ., where C denotes results from the candidate method. For candidate methods which provide a direct measurement of Pb concentrations without a separable procedure, $C_{1A}=C_{1B}=C_{1C}$, $C_{2A}=C_{2B}=C_{2C}$, etc.

(g) *Average Pb concentration.* For the reference method, calculate the average Pb concentration for each filter by averaging the concentrations calculated from the three analyses using equation 1 of this section:

Equation 1

$$R_{i\ ave} = \frac{R_{iA} + R_{iB} + R_{iC}}{3}$$

where, i is the filter number.

(h) *Accuracy.* (1)(i) For the audit samples, calculate the average Pb concentration for each strip by averaging the concentrations calculated from the three analyses using equation 2 of this section:

Equation 2

$$Q_{i\ ave} = \frac{Q_{iA} + Q_{iB} + Q_{iC}}{3}$$

where, i is audit sample number.

(ii) Calculate the percent difference (D_q) between the indicated Pb concentration for each audit sample and the true Pb concentration (T_q) using equation 3 of this section:

Equation 3

$$D_{qi} = \frac{Q_{i\ ave} - T_{qi}}{T_{qi}} \times 100\%$$

(2) If any difference value (D_{qi}) exceeds ±5 percent, the accuracy of the reference method analytical procedure is out-of-control. Corrective action must be taken to determine the source of the error(s) (e.g., calibration standard discrepancies, extraction problems, etc.) and the reference method and audit sample determinations must be repeated according to paragraph (f) of this section, or the entire test procedure (starting with paragraph (d) of this section) must be repeated.

(i) *Acceptable filter pairs.* Disregard all filter pairs for which the Pb concentration, as determined in paragraph (g) of this section by the average of the three reference method determinations, falls outside the range of 0.5 to 4.0 µg/m³. All remaining filter pairs must be subjected to the tests for precision and comparability in paragraphs (j) and (k) of this section. At least five filter pairs must be within the 0.5 to 4.0 µg/m³ range for the tests to be valid.

(j) *Test for precision.* (1) Calculate the precision (P) of the analysis (in percent) for each filter and for each method, as the maximum minus the minimum divided by the average of the three concentration values, using equation 4 or equation 5 of this section:

Equation 4

$$P_{Ri} = \frac{R_{i\ max} - R_{i\ min}}{R_{i\ ave}} \times 100\%$$

or

Equation 5

$$P_{Ci} = \frac{C_{i\ max} - C_{i\ min}}{C_{i\ ave}} \times 100\%$$

where, i indicates the filter number.

(2) If any reference method precision value (P_{Ri}) exceeds 15 percent, the precision of the reference method analytical procedure is out-of-control. Corrective action must be taken to determine the source(s) of imprecision, and the reference method determinations must be repeated according to paragraph (f) of this section, or the entire test procedure (starting with paragraph (d) of this section) must be repeated.

(3) If any candidate method precision value (P_{Ci}) exceeds 15 percent, the candidate method fails the precision test.

(4) The candidate method passes this test if all precision values (*i.e.*, all P_{Ri}'s and all P_{Ci}'s) are less than 15 percent.

(k) *Test for comparability.* (1) For each filter or analytical sample pair, calculate all nine possible percent differences (D) between the reference and candidate methods, using all nine possible combinations of the three determinations (A, B, and C) for each method using equation 6 of this section:

Equation 6

$$D_{in} = \frac{C_{ij} - R_{ik}}{R_{ik}} \times 100\%$$

where, i is the filter number, and n numbers from 1 to 9 for the nine possible difference combinations for the three determinations for each method (j = A, B, C, candidate; k = A, B, C, reference).

(2) If none of the percent differences (D) exceeds ±20 percent, the candidate method passes the test for comparability.

(3) If one or more of the percent differences (D) exceed ±20 percent, the candidate method fails the test for comparability.

(4) The candidate method must pass both the precision test (paragraph (j) of this section) and the comparability test (paragraph (k) of this section) to qualify for designation as an equivalent method.

9. Section 53.34 is revised to read as follows:

§ 53.34 Test procedure for methods for PM_{10} and Class I methods for $PM_{2.5}$.

(a) *Comparability.* Comparability is shown for PM_{10} methods and for Class I methods for $PM_{2.5}$ when the relationship between:

(1) Measurements made by a candidate method, and

(2) Measurements made by a corresponding reference method on simultaneously collected samples (or the same sample, if applicable) at each of one or more test sites (as required) is such that the linear regression parameters (slope, intercept, and correlation coefficient) describing the relationship meet the requirements specified in table C–4 of this subpart.

(b) *Methods for PM_{10}.* Test measurements must be made, or derived from particulate samples collected, at not less than two test sites, each of which must be located in a geographical area characterized by ambient particulate matter that is significantly different in nature and composition from that at the other test site(s). Augmentation of pollutant concentrations is not permitted, hence appropriate test sites must be selected to provide the minimum number of test PM_{10} concentrations in the ranges specified in table C–4 of this subpart. The tests at the two sites may be conducted in different calendar seasons, if appropriate, to provide PM_{10} concentrations in the specified ranges.

(c) *PM_{10} methods employing the same sampling procedure as the reference method but a different analytical method.* Candidate methods for PM_{10} which employ a sampler and sample collection procedure that are identical to the sampler and sample collection procedure specified in the reference method, but use a different analytical procedure, may be tested by analyzing common samples. The common samples shall be collected according to the sample collection procedure specified by the reference method and shall be analyzed in accordance with the analytical procedures of both the candidate method and the reference method.

(d) *Methods for $PM_{2.5}$.* Augmentation of pollutant concentrations is not permitted, hence appropriate test sites must be selected to provide the minimum number of test measurement sets to meet the requirements for $PM_{2.5}$ concentrations in the ranges specified in table C–4 of this subpart. Only one test site is required, and the site need only meet the $PM_{2.5}$ ambient concentration levels required by table C–4 of this subpart. A total of 10 valid measurement sets is required.

(e) *Collocated measurements.* (1) Set up three reference method samplers collocated with three candidate method samplers or analyzers at each of the number of test sites specified in table C–4 of this subpart.

(2) The ambient air intake points of all the candidate and reference method collocated samplers or analyzers shall be positioned at the same height above the ground level, and between 2 meters (1 meter for samplers or analyzers with flow rates less than 200 L/min) and 4 meters apart. The samplers shall be oriented in a manner that will minimize spatial and wind directional effects on sample collection.

(3) At each site, obtain as many sets of simultaneous PM_{10} or $PM_{2.5}$ measurements as necessary (see table C–4 of this subpart), each set consisting of three reference method and three candidate method measurements, all obtained simultaneously.

(4) Candidate PM_{10} method measurements shall be nominal 24-hour (±1 hour) integrated measurements or shall be averaged to obtain the mean concentration for a nominal 24-hour period. $PM_{2.5}$ measurements may be either nominal 24- or 48-hour integrated measurements. All collocated measurements in a measurement set must cover the same nominal 24- or 48-hour time period.

(5) For samplers, retrieve the samples promptly after sample collection and analyze each sample according to the reference method or candidate method, as appropriate, and determine the PM_{10} or $PM_{2.5}$ concentration in µg/m3. If the conditions of paragraph (c) of this section apply, collect sample sets only with the three reference method samplers. Guidance for quality assurance procedures for $PM_{2.5}$ methods is found in ''Quality Assurance Document 2.12'' (reference (2) in appendix A to this subpart).

(f) *Sequential samplers.* For sequential samplers, the sampler shall be configured for the maximum number of sequential samples and shall be set for automatic collection of all samples sequentially such that the test samples are collected equally, to the extent possible, among all available sequential channels or utilizing the full available sequential capability.

(g) *Calculation of reference method averages and precisions.* (1) For each of the measurement sets, calculate the average PM_{10} or $PM_{2.5}$ concentration obtained with the reference method samplers, using equation 7 of this section:

Equation 7

$$\overline{R}_j = \frac{\sum_{i=1}^{3} R_{i,j}}{3}$$

Where:

R = The concentration measurements from the reference methods;

i = The sampler number; and

j = The measurement set number.

(2) For each of the measurement sets, calculate the precision of the reference method PM_{10} or $PM_{2.5}$ measurements as the standard deviation, PR_j, using equation 8 of this section:

Equation 8

$$P_{Rj} = \sqrt{\frac{\sum_{i=1}^{3} R_{i,j}^2 - \frac{1}{3}\left(\sum_{i=1}^{3} R_{i,j}\right)^2}{2}}$$

(3) For each measurement set, also calculate the precision of the reference method PM_{10} or $PM_{2.5}$ measurements as the relative standard deviation, RP_{Rj}, in percent, using equation 9 of this section:

Equation 9

$$RP_{Rj} = \frac{P_{Rj}}{\bar{R}_j} \times 100\%$$

(h) *Acceptability of measurement sets.* Each measurement set is acceptable and valid only if the three reference method measurements and the three candidate method measurements are obtained and are valid, $\bar{R}_j$ falls within the acceptable concentration range specified in table C–4 of this subpart, and either PR_j or RP_{Rj} is within the corresponding limit for reference method precision specified in table C–4 of this subpart. For each site, table C–4 of this subpart specifies the minimum number of measurement sets required having $\bar{R}_j$ above and below specified concentrations for 24- or 48-hour samples. Additional measurement sets shall be obtained, as necessary, to provide the minimum number of acceptable measurement sets for each category and the minimum total number of acceptable measurement sets for each test site. If more than the minimum number of measurement sets are collected that meet the acceptability criteria, all such measurement sets shall be used to demonstrate comparability.

(i) *Candidate method average concentration measurement.* For each of the acceptable measurement sets, calculate the average PM_{10} or $PM_{2.5}$ concentration measurements obtained with the candidate method samplers, using equation 10 of this section:

Equation 10

$$\bar{C}_j = \frac{\sum_{i=1}^{3} C_{i,j}}{3}$$

Where:

C = The concentration measurements from the candidate methods;

i = The measurement number in the set; and

j = The measurement set number.

(j) *Test for comparability.* (1) For each site, plot all of the average PM_{10} or $PM_{2.5}$ measurements obtained with the candidate method ($\bar{C}_j$) against the corresponding average PM_{10} or $PM_{2.5}$ measurements obtained with the reference method ($\bar{R}_j$). For each site, calculate and record the linear regression slope and intercept, and the correlation coefficient.

(2) To pass the test for comparability, the slope, intercept, and correlation coefficient calculated under paragraph (j)(1) of this section must be within the limits specified in table C–4 of this subpart for all test sites.

10. Section 53.35 is added to read as follows:

§ 53.35 Test procedure for Class II and Class III methods for $PM_{2.5}$ and $PM_{10\text{-}2.5}$.

(a) *Overview.* Class II and Class III candidate equivalent methods shall be tested for comparability of $PM_{2.5}$ or $PM_{10\text{-}2.5}$ measurements to corresponding collocated $PM_{2.5}$ or $PM_{10\text{-}2.5}$ reference method measurements at each of multiple field sites, as required. Comparability is shown for the candidate method when simultaneous collocated measurements made by candidate and reference methods meet the comparability requirements specified in this section § 53.35 and in table C–4 of this subpart at each of the required test sites.

(b) *Test sites and seasons.* (1) *Test sites.* Comparability testing is required at each of the applicable test sites required by this paragraph (b). Each test site must also meet the general test site requirements specified in § 53.30(b).

(i) *$PM_{2.5}$ Class II and Class III candidate methods.* Test sites should be chosen to provide representative chemical and meteorological characteristics with respect to nitrates, sulfates, organic compounds, and various levels of humidity, wind, and elevation. For Class III methods, one test site shall be selected in each of the following general locations. For Class II methods, two test sites, one eastern site and one western site, shall be selected from these locations. Test site A shall be in the Los Angeles basin area in a location that is characterized by relatively high $PM_{2.5}$, nitrates, and semi-volatile organic pollutants. Test site B shall be in a northeastern or mid-Atlantic U.S. city that is seasonally characterized by high sulfate concentrations, high relative humidity, and wintertime conditions. Test site C shall be in a western U.S. city such as Denver, Salt Lake City, or Albuquerque in a location that is in an area characterized by cold weather, higher elevation, winds, and dust.

(ii) *$PM_{10\text{-}2.5}$ Class II and Class III candidate methods.* Test sites shall be chosen to provide modest to high levels of $PM_{10\text{-}2.5}$ representative of locations in proximity to urban sources of $PM_{10\text{-}2.5}$ such as high-density traffic on paved roads, industrial sources, and construction activities. For Class III methods, one test site shall be selected in each of the following general locations. At least one of the test sites shall have characteristic wintertime temperatures of 0°C or lower. For Class II methods, two test sites, one eastern site and one western site, shall be selected from these locations. Test site A shall be in the Los Angeles basin or the California Central Valley area. Test site B shall be in a large U.S. city east of the Mississippi River, having characteristically high humidity levels. Test site C shall be in a western U.S. city characterized by a high ratio of $PM_{10\text{-}2.5}$ to $PM_{2.5}$, with exposure to rural windblown dust, such as Las Vegas or Phoenix.

(2) *Test seasons.* (i) For $PM_{2.5}$ and $PM_{10\text{-}2.5}$ Class III candidate methods, test campaigns are required in both summer and winter seasons at test sites A and B. A test campaign is required only in the winter season at test site C. (A total of 5 test campaigns is required.) The summer season shall be defined as the typically warmest 3 or 4 months of the year at the site; the winter season shall be defined as the typically coolest 3 or 4 months of the year at the site.

(ii) For Class II $PM_{2.5}$ and $PM_{10\text{-}2.5}$ candidate methods, only one test campaign is required at each site, at any time of year (total of 2 test campaigns).

(3) *Test concentrations.* The test sites should be selected to provide ambient concentrations within the concentration limits specified in table C–4 of this subpart, and also to provide a wide range of test concentrations. A narrow range of test concentrations may result in a low concentration coefficient of variation statistic for the test measurements, making the test for correlation coefficient more difficult to pass (see paragraph (h) of this section, test for comparison correlation).

(4) *Pre-approval of test sites.* The EPA recommends that the applicant seek EPA approval of each proposed test site prior to conducting test measurements at the site. To do so, the applicant should submit a request for approval as described in § 53.30(b)(2).

(c) *Collocated measurements.* (1) For each test campaign, three reference method samplers and three candidate method samplers or analyzers shall be installed and operated concurrently at each test site within each required season (if applicable), as specified in paragraph (b) of this section. All reference method samplers shall be of single-filter design (not multi-filter, sequential sample design). Each candidate method shall be setup and operated in accordance with its associated manual referred to in § 53.4(b)(3) and in accordance with applicable guidance in ''Quality Assurance Document 2.12'' (reference (2) in appendix A to this subpart). All samplers or analyzers shall be placed so that they sample or measure air representative of the surrounding area (within one kilometer) and are not unduly affected by adjacent buildings, air handling equipment, industrial operations, traffic, or other local influences. The ambient air inlet points of all samplers and analyzers shall be positioned at the same height above the ground level and between 2 meters (1 meter for instruments having sample inlet flow rates less than 200 L/min) and 4 meters apart.

(2) A minimum of 23 valid and acceptable measurement sets of $PM_{2.5}$ or $PM_{10\text{-}2.5}$ 24-hour (nominal) concurrent concentration measurements shall be obtained during each test campaign at each test site. To be considered acceptable for the test, each measurement set shall consist of at least two valid reference method measurements and at least two valid candidate method measurements, and the $PM_{2.5}$ or $PM_{10\text{-}2.5}$ measured concentration, as determined by the average of the reference method measurements, must fall within the acceptable concentration range specified in table C–4 of this subpart. Each measurement set shall include all valid measurements obtained. For each measurement set containing fewer than three reference method measurements or fewer than three candidate method measurements, an explanation and appropriate justification shall be provided to account for the missing measurement or measurements.

(3) More than 23 valid measurement sets may be obtained during a particular test campaign to provide a more advantageous range of concentrations, more representative conditions, additional higher or lower measurements, or to otherwise improve the comparison of the methods. All valid data sets obtained during each test campaign shall be submitted and shall be included in the analysis of the data.

(4) The integrated-sample reference method measurements shall be of at least 22 hours and not more than 25 hours duration. Each reference method sample shall be retrieved promptly after sample collection and analyzed according to the reference method to determine the $PM_{2.5}$ or $PM_{10\text{-}2.5}$ measured concentration in $\mu g/m^3$. Guidance and quality assurance procedures applicable to $PM_{2.5}$ or $PM_{10\text{-}2.5}$ reference methods are found in ''Quality Assurance Document 2.12'' (reference (2) in appendix A to this subpart).

(5) Candidate method measurements shall be timed or processed and averaged as appropriate to determine an equivalent mean concentration representative of the same time period as that of the concurrent integrated-sample reference method measurements, such that all measurements in a measurement set shall be representative of the same time period. In addition, hourly average concentration measurements shall be obtained from each of the Class III candidate method analyzers for each valid measurement set and submitted as part of the application records.

(6) In the following tests, all measurement sets obtained at a particular test site, from both seasonal campaigns if applicable, shall be combined and included in the test data analysis for the site. Data obtained at different test sites shall be analyzed separately. All measurements should be reported as normally obtained, and no measurement values should be rounded or truncated prior to data analysis. In particular, no negative measurement value, if otherwise apparently valid, should be modified, adjusted, replaced, or eliminated merely because its value is negative. Calculated mean concentrations or calculated intermediate quantities should retain at least one order-of-magnitude greater resolution than the input values. All measurement data and calculations shall be recorded and submitted in accordance with § 53.30(g), including hourly test measurements obtained from Class III candidate methods.

(d) *Calculation of mean concentrations.* (1) *Reference method outlier test.* For each of the measurement sets for each test site, check each reference method measurement to see if it might be an anomalous value (outlier) as follows, where $R_{i,j}$ is the measurement of reference method sampler i on test day j. In the event that one of the reference method measurements is missing or invalid due to a specific, positively-identified physical cause (e.g., sampler malfunction, operator error, accidental damage to the filter, etc.; see paragraph (c)(2) of this section), then substitute zero for the missing measurement, *for the purposes of this outlier test only.*

(i) Calculate the quantities $2 \times R_{1,j}/(R_{1,j} + R_{2,j})$ and $2 \times R_{1,j}/(R_{1,j} + R_{3,j})$. If both quantities fall outside of the interval, (0.93, 1.07), then $R_{1,j}$ is an outlier.

(ii) Calculate the quantities $2 \times R_{2,j}/(R_{2,j} + R_{1,j})$ and $2 \times R_{2,j}/(R_{2,j} + R_{3,j})$. If both quantities fall outside of the interval, (0.93, 1.07), then $R_{2,j}$ is an outlier.

(iii) Calculate the quantities $2 \times R_{3,j}/(R_{3,j} + R_{1,j})$ and $2 \times R_{3,j}/(R_{3,j} + R_{2,j})$. If both quantities fall outside of the interval, (0.93, 1.07), then $R_{3,j}$ is an outlier.

(iv) If this test indicates that one of the reference method measurements in the measurement set is an outlier, the outlier measurement shall be eliminated from the measurement set, and the other two measurements considered valid. If the test indicates that more than one reference method measurement in the measurement set is an outlier, the entire measurement set (both reference and candidate method measurements) shall be excluded from further data analysis for the tests of this section.

(2) For each of the measurement sets for each test site, calculate the mean concentration for the reference method measurements, using equation 11 of this section:

Equation 11

$$\overline{R}_j = \frac{1}{n}\sum_{i=1}^{n} R_{i,j}$$

Where:

$\bar{R}_j$ = The mean concentration measured by the reference method for the measurement set;

$R_{i,j}$ = The measurement of reference method sampler i on test day j; and

n =The number of valid reference method measurements in the measurement set (normally 3).

(3) Any measurement set for which $\bar{R}_j$ does not fall in the acceptable concentration range specified in table C–4 of this subpart is not valid, and the entire measurement set (both reference and candidate method measurements) must be eliminated from further data analysis.

(4) For each of the valid measurement sets at each test site, calculate the mean concentration for the candidate method measurements, using equation 12 of this section. (The outlier test in paragraph (d)(1) of this section shall not be applied to the candidate method measurements.)

Equation 12

$$\overline{C}_j = \frac{1}{m}\sum_{i=1}^{m} C_{i,j}$$

where:

C_j = The mean concentration measured by the candidate method for the measurement set;

$C_{i,j}$ = The measurement of candidate method analyzer i on test day j; and

m = The number of valid candidate method measurements in the measurement set (normally 3).

(e) *Test for reference method precision.* (1) For each of the measurement sets for each site, calculate an estimate for the relative precision of the reference method measurements, RP_j, using equation 13 of this section:

Equation 13

$$RP_j = \frac{1}{\overline{R}_j}\sqrt{\frac{\sum_{i=1}^{n} R_{i,j}^2 - \frac{1}{n}\left(\sum_{i=1}^{n} R_{i,j}\right)^2}{n-1}} \times 100\%$$

(2) For each site, calculate an estimate of reference method relative precision for the site, RP, using the *root mean square* calculation of equation 14 of this section:

Equation 14

$$RP = \sqrt{\frac{1}{J}\sum_{j=1}^{J}\left(RP_j\right)^2}$$

where, J is the total number of valid measurement sets for the site.

(3) Verify that the estimate for reference method relative precision for the site, RP, is not greater than the value specified for reference method precision in table C–4 of this subpart. A reference method relative precision greater than the value specified in table C–4 of this subpart indicates that quality control for the reference method is inadequate, and corrective measures must be implemented before proceeding with the test.

(f) *Test for candidate method precision.* (1) For each of the measurement sets, for each site, calculate an estimate for the relative precision of the candidate method measurements, CP_j, using equation 15 of this section:

Equation 15

$$CP_j = \frac{1}{\overline{C}_j}\sqrt{\frac{\sum_{i=1}^{m} C_{i,j}^2 - \frac{1}{m}\left(\sum_{i=1}^{m} C_{i,j}\right)^2}{m-1}} \times 100\%$$

(2) For each site, calculate an estimate of candidate method relative precision for the site, CP, using the *root mean square* calculation of equation 16 of this section:

Equation 16

$$CP = \sqrt{\frac{1}{J}\sum_{j=1}^{J}\left(CP_j\right)^2}$$

where, J is the total number of valid measurement sets for the site.

(3) To pass the test for precision, the mean candidate method relative precision at each site must not be greater than the value for candidate method precision specified in table C–4 of this subpart.

(g) *Test for additive and multiplicative bias (comparative slope and intercept).* (1) For each test site, calculate the mean concentration measured by the reference method, $\bar{R}$, using equation 17 of this section:

Equation 17

$$\overline{R} = \frac{1}{J}\sum_{j=1}^{J}\overline{R}_j$$

(2) For each test site, calculate the mean concentration measured by the candidate method, $\bar{C}$, using equation 18 of this section:

Equation 18

$$\overline{C} = \frac{1}{J}\sum_{j=1}^{J}\overline{C}_j$$

(3) For each test site, calculate the linear regression slope and intercept of the mean candidate method measurements ($\bar{C}_j$) against the mean reference method measurements ($\bar{R}_j$), using equations 19 and 20 of this section, respectively:

Equation 19

$$\text{Slope} = \frac{\sum_{j=1}^{J}\left(\overline{R}_j - \overline{R}\right)\left(\overline{C}_j - \overline{C}\right)}{\sum_{j=1}^{J}\left(\overline{R}_j - \overline{R}\right)^2}$$

Equation 20

$$\text{Intercept} = \overline{C} - \text{slope} \times \overline{R}$$

(4) To pass this test, at each test site:

(i) The slope must be in the interval specified for regression slope in table C–4 of this subpart; and

(ii) The intercept must be in the interval specified for regression intercept in table C–4 of this subpart.

(iii) The slope and intercept limits are illustrated in figures C–2 and C–3 of this subpart.

(h) *Tests for comparison correlation.* (1) For each test site, calculate the (Pearson) correlation coefficient, r (not the coefficient of determination, r^2), using equation 21 of this section:

Equation 21

$$r = \frac{\sum_{j=1}^{J}\left(\overline{R}_j - \overline{R}\right)\left(\overline{C}_j - \overline{C}\right)}{\sqrt{\sum_{j=1}^{J}\left(\overline{R}_j - \overline{R}\right)^2 \sum_{j=1}^{J}\left(\overline{C}_j - \overline{C}\right)^2}}$$

(2) For each test site, calculate the concentration coefficient of variation, CCV, using equation 22 of this section:

Equation 22

$$CCV = \frac{1}{\overline{R}}\sqrt{\frac{\sum_{j=1}^{J}\left(\overline{R}_j - \overline{R}\right)^2}{J-1}}$$

(3) To pass the test, the correlation coefficient, r, for each test site must not be less than the values, for various values of CCV, specified for correlation in table C–4 of this subpart. These limits are illustrated in figure C–4 of this subpart.

11. Tables C–1, C–2, C–3, and C–4 to subpart C are revised to read as follows:

TABLE C–1 TO SUBPART C OF PART 53.—TEST CONCENTRATION RANGES, NUMBER OF MEASUREMENTS REQUIRED, AND MAXIMUM DISCREPANCY SPECIFICATION

Pollutant	Concentration range parts per million	Simultaneous measurements required				Maximum discrepancy specification, parts per million
		1-hr		24-hr		
		First set	Second set	First set	Second set	
Ozone	Low 0.06 to 0.10	5	6			0.02
	Med 0.15 to 0.25	5	6			.03
	High 0.35 to 0.45	4	6			.04
	Total	14	18			
Carbon monoxide	Low 7 to 11	5	6			1.5
	Med 20 to 30	5	6			2.0
	High 35 to 45	4	6			3.0
	Total	14	18			
Sulfur dioxide	Low 0.02 to 0.05			3	3	0.02
	Med 0.10 to 0.15			2	3	.03
	High 0.30 to 0.50	7	8	2	2	.04
	Total	7	8	7	8	
Nitrogen dioxide	Low 0.02 to 0.08			3	3	0.02
	Med 0.10 to 0.20			2	3	.03
	High 0.25 to 0.35			2	2	.03
	Total			7	8	

TABLE C–2 TO SUBPART C OF PART 53.—SEQUENCE OF TEST MEASUREMENTS

Measurement	Concentration range	
	First set	Second set
1	Low	Medium.
2	High	High.
3	Medium	Low.
4	High	High.
5	Low	Medium.
6	Medium	Low.
7	Low	Medium.
8	Medium	Low.
9	High	High.

TABLE C–2 TO SUBPART C OF PART 53.—SEQUENCE OF TEST MEASUREMENTS—Continued

Measurement	Concentration range	
	First set	Second set
10	Medium	Low.
11	High	Medium.
12	Low	High.
13	Medium	Medium.
14	Low	High.
15		Low.
16		Medium.
17		Low.
18		High.

TABLE C–3 TO SUBPART C OF PART 53.—TEST SPECIFICATIONS FOR PB METHODS

Concentration range, μg/m³	0.5–4.0
Minimum number of 24-hr measurements	5
Maximum analytical precision, percent	15
Maximum analytical accuracy, percent	±5
Maximum difference, percent of reference method	±20

TABLE C–4 TO SUBPART C.—TEST SPECIFICATIONS FOR PM_{10}, $PM_{2.5}$ AND $PM_{10-2.5}$ CANDIDATE EQUIVALENT METHODS

Specification	PM_{10}	$PM_{2.5}$			$PM_{10-2.5}$	
		Class I	Class II	Class III	Class II	Class III
Acceptable concentration range (R_j), μg/m³.	15–300	3–200	3–200	3–200	3–200	3–200
Minimum number of test sites	2	1	2	3	2	3
Minimum number of candidate method samplers or analyzers per site.	3	3	3 [1]	3 [1]	3 [1]	3 [1]
Number of reference method samplers per site.	3	3	3 [1]	3 [1]	3 [1]	3 [1]
Minimum number of acceptable sample sets per site for PM_{10} methods:.						
R_j < 60 μg/m³	3					
R_j > 60 μg/m³	3					
Total	10					
Minimum number of acceptable sample sets per site for $PM_{2.5}$ and $PM_{10-2.5}$ candidate equivalent methods:.						
R_j < 30 μg/m³ for 24-hr or R_j < 20 μg/m³ for 48-hr samples.		3				

TABLE C–4 TO SUBPART C.—TEST SPECIFICATIONS FOR PM_{10}, $PM_{2.5}$ AND $PM_{10-2.5}$ CANDIDATE EQUIVALENT METHODS—Continued

Specification	PM_{10}	$PM_{2.5}$			$PM_{10-2.5}$	
		Class I	Class II	Class III	Class II	Class III
R_j > 30 μg/m³ for 24-hr or R_j > 20 μg/m³ for 48-hr samples.		3				
Each season		10	23	23	23	23
Total, each site		10	23	46 (23 for single season site).	23	46 (23 for single season site)
Precision of replicate reference method measurements, P_{Rj} or RP_{Rj}, respectively; RP for Class II or III $PM_{2.5}$ or $PM_{10-2.5}$, maximum.	5 μg/m³ or 7%	2 μg/m³ or 5%	10% [2]	10% [2]	10% [2]	10% [2]
Precision of $PM_{2.5}$ or $PM_{10-2.5}$ candidate method, CP, each site.			10% [2]	15% [2]	15% [2]	15% [2]
Slope of regression relationship.	1±0.1	1±0.05	1±0.10	1±0.10	1±0.10	1±0.12
Intercept of regression relationship, μg/m³.	0±5	0±1	Between: 13.55 − (15.05 × slope), but not less than −1.5; and 16.56 − (15.05 × slope), but not more than +1.5.	Between: 15.05 − (17.32 × slope); and 15.05 − (13.20 × slope).	Between: 59.93 − (70.50 × slope), but not less than −7.0; and 81.08 − (70.50 × slope), but not more than +7.0.	Between: 70.50 − (82.93 × slope); and 70.50 − (61.16 × slope)
Correlation of reference method and candidate method measurements.	≥0.97	≥0.97	≥0.93 for CCV≤0.4; ≥0.85+0.2×CCV for 0.4≤CCV≤0.5; ≥0.95 for CCV≥0.5			

[1] Some missing daily measurement values may be permitted; see test procedure.
[2] Calculated as the root mean square over all measurement sets.

11. Figure C–1 to subpart C is revised to read as follows:

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Figure C-1 to Subpart C of Part 53—-Suggested Format for Reporting Test Results for Methods for SO_2, CO, O_3, NO_2

Candidate Method _____

Reference Method _____

Applicant _____

☐ First Set ☐ Second Set ☐ Type ☐ 1 Hour ☐ 24 Hour

Concentration Range		Date	Time	Concentration, ppm		Difference	Table C-1 Spec.	Pass or Fail
				Candidate	Reference			
Low _____ ppm to _____ ppm	1							
	2							
	3							
	4							
	5							
	6							
Medium _____ ppm to _____ ppm	1							
	2							
	3							
	4							
	5							
	6							
High _____ ppm to _____ ppm	1							
	2							
	3							
	4							
	5							
	6							
	7							
	8							
							Total Failures:	

13. Figures C–2, C–3, and C–4 are added to subpart C to read as follows:

FIGURE C-2 TO SUBPART C OF PART 53–ILLUSTRATION OF THE SLOPE AND INTERCEPT LIMITS FOR CLASS II AND CLASS III $PM_{2.5}$ CANDIDATE EQUIVALENT METHODS.

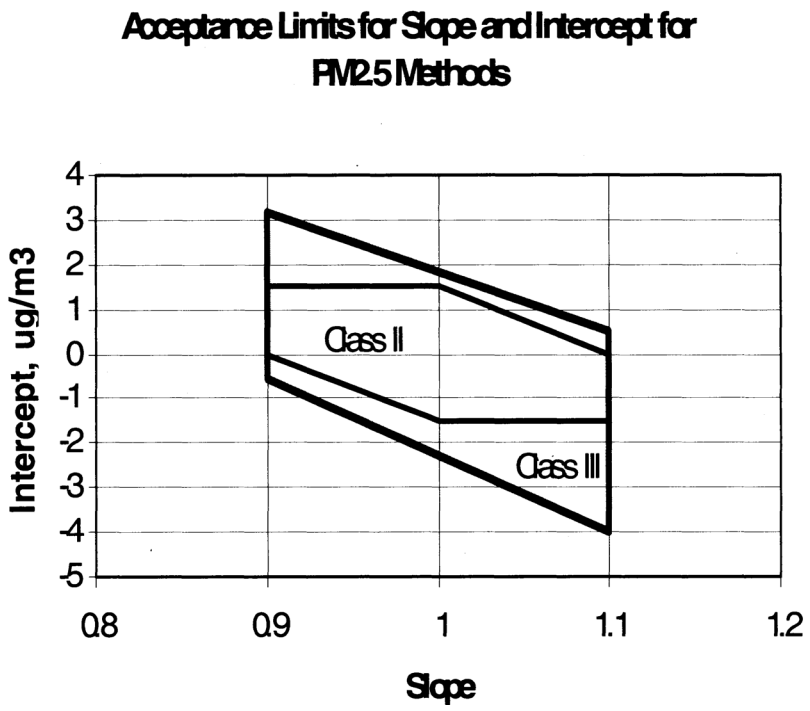


FIGURE C-3 TO SUBPART C OF PART 53–ILLUSTRATION OF THE SLOPE AND INTERCEPT LIMITS FOR CLASS II AND CLASS III $PM_{10-2.5}$ CANDIDATE EQUIVALENT METHODS.

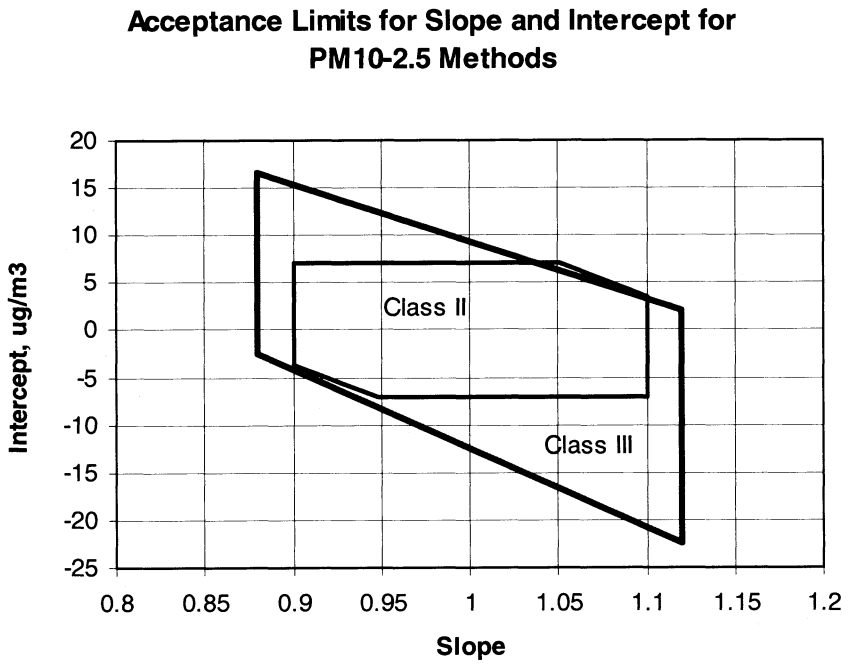
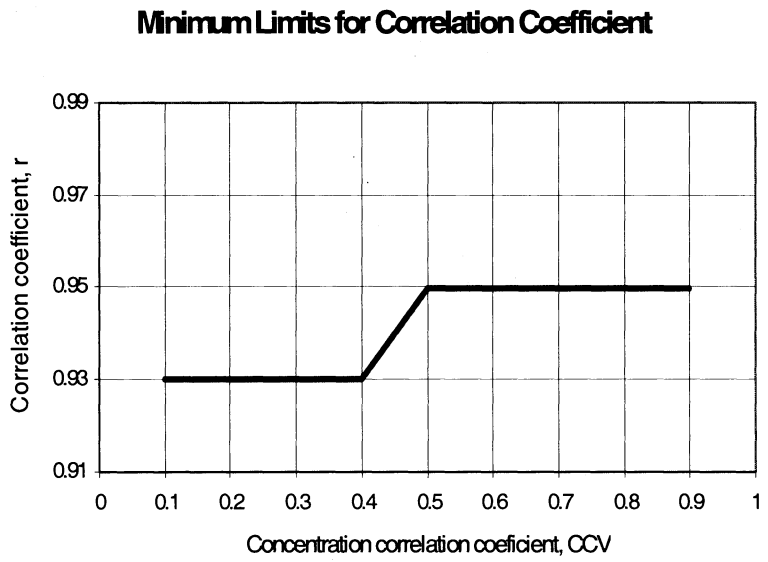


FIGURE C-4 TO SUBPART C OF PART 53–ILLUSTRATION OF THE MINIMUM LIMITS FOR CORRELATION COEFFICIENT FOR $PM_{2.5}$ AND $PM_{10-2.5}$ CLASS II AND III METHODS.



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14. Appendix A to subpart C is amended by adding reference (2) to read as follows:

Appendix A to Subpart C—References

* * * * *

(2) Quality Assurance Guidance Document 2.12. Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods. U.S. EPA, National Exposure Research Laboratory, Research Triangle Park, NC, November 1998 or later edition. Currently available at *http://www.epa.gov/ttn/amtic/pmqainf.html.*

Subpart E—Procedures for Testing Physical (Design) andPerformance Characteristics of Reference Methods and Class I and Class II Equivalent Methods for PM2.5 or PM10-2.5

15. The heading for subpart E is revised as set out above.

16. Section 53.50 is revised to read as follows:

§ 53.50 General provisions.

(a) A candidate method for $PM_{2.5}$ or $PM_{10-2.5}$ described in an application for a reference or equivalent method determination submitted under § 53.4 shall be determined by the EPA to be a reference method or a Class I, II, or III equivalent method on the basis of the definitions for such methods given in § 53.1. This subpart sets forth the specific tests that must be carried out and the test results, evidence, documentation, and other materials that must be provided to EPA to demonstrate that a $PM_{2.5}$ or $PM_{10-2.5}$ sampler associated with a candidate reference method or Class I or Class II equivalent method meets all design and performance specifications set forth in appendix L or O, respectively, of part 50 of this chapter as well as additional requirements specified in this subpart E. Some or all of these tests may also be applicable to a candidate Class III equivalent method or analyzer, as may be determined under § 53.3(b)(3).

(b) *$PM_{2.5}$ methods.* (1) *Reference method.* A sampler associated with a candidate reference method for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in §§ 53.51 through 53.58.

(2) *Class I method.* A sampler associated with a candidate Class I equivalent method for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in all sections of this subpart.

(3) *Class II method.* A sampler associated with a candidate Class II equivalent method for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in all applicable sections of this subpart, as specified in subpart F of this part or as specified in § 53.3(a)(3).

(c) *$PM_{10-2.5}$ methods.* (1) *Reference method.* A sampler associated with a reference method for $PM_{10-2.5}$, as specified in appendix O to part 50 of this chapter, shall be subject to the requirements in this paragraph (c)(1).

(i) The $PM_{2.5}$ sampler of the $PM_{10-2.5}$ sampler pair shall be verified to be either currently designated under this part 53 as a reference method for $PM_{2.5}$, or shown to meet all requirements for designation as a reference method for $PM_{2.5}$, in accordance with this part 53.

(ii) The PM_{10c} sampler of the $PM_{10-2.5}$ sampler pair shall be verified to be of like manufacturer, design, configuration, and fabrication to the $PM_{2.5}$ sampler of the $PM_{10-2.5}$ sampler pair, except for replacement of the particle size separator specified in

section 7.3.4 of appendix L to part 50 of this chapter with the downtube extension as specified in Figure O–1 of appendix O to part 50 of this chapter.

(iii) For samplers that meet the provisions of paragraphs (c)(1)(i) and (ii) of this section, the candidate $PM_{10-2.5}$ reference method may be determined to be a reference method without further testing.

(2) *Class I method.* A sampler associated with a Class I candidate equivalent method for $PM_{10-2.5}$ shall meet the requirements in this paragraph (c)(2).

(i) The $PM_{2.5}$ sampler of the $PM_{10-2.5}$ sampler pair shall be verified to be either currently designated under this part 53 as a reference method or Class I equivalent method for $PM_{2.5}$, or shown to meet all requirements for designation as a reference method or Class I equivalent method for $PM_{2.5}$, in accordance with this part 53.

(ii) The PM_{10c} sampler of the $PM_{10-2.5}$ sampler pair shall be verified to be of similar design to the $PM_{10-2.5}$ sampler and to meet all requirements for designation as a reference method or Class I equivalent method for $PM_{2.5}$, in accordance with this part 53, except for replacement of the particle size separator specified in section 7.3.4 of appendix L to part 50 of this chapter with the downtube extension as specified in Figure O–1 of appendix O to part 50 of this chapter.

(iii) For samplers that meet the provisions of paragraphs (c)(2)(i) and (ii) of this section, the candidate $PM_{10-2.5}$ method may be determined to be a Class I equivalent method without further testing.

(3) *Class II method.* A sampler associated with a Class II candidate equivalent method for $PM_{10-2.5}$ shall be subject to the applicable requirements of this subpart E, as described in § 53.3(a)(5).

(d) The provisions of § 53.51 pertain to test results and documentation required to demonstrate compliance of a candidate method sampler with the design specifications set forth in 40 CFR part 50, appendix L or O, as applicable. The test procedures prescribed in §§ 53.52 through 53.59 pertain to performance tests required to demonstrate compliance of a candidate method sampler with the performance specifications set forth in 40 CFR part 50, appendix L or O, as applicable, as well as additional requirements specified in this subpart E. These latter test procedures shall be used to test the performance of candidate samplers against the performance specifications and requirements specified in each procedure and summarized in table E–1 of this subpart.

(e) Test procedures prescribed in § 53.59 do not apply to candidate reference method samplers. These procedures apply primarily to candidate Class I or Class II equivalent method samplers for $PM_{2.5}$ or $PM_{10-2.5}$ that have a sample air flow path configuration upstream of the sample filter that is modified from that specified for the reference method sampler, as set forth in 40 CFR part 50, appendix L, Figures L–1 to L–29 or 40 CFR part 50 appendix O, Figure O–1, if applicable, such as might be necessary to provide for sequential sample capability. The additional tests determine the adequacy of aerosol transport through any altered components or supplemental devices that are used in a candidate sampler upstream of the filter. In addition to the other test procedures in this subpart, these test procedures shall be used to further test the performance of such an equivalent method sampler against the performance specifications given in the procedure and summarized in table E–1 of this subpart.

(f) A 10-day operational field test of measurement precision is required under § 53.58 for both reference and Class I equivalent method samplers for $PM_{2.5}$. This test requires collocated operation of 3 candidate method samplers at a field test site. For candidate equivalent method samplers, this test may be combined and carried out concurrently with the test for comparability to the reference method specified under § 53.34, which requires collocated operation of three reference method samplers and three candidate equivalent method samplers.

(g) All tests and collection of test data shall be performed in accordance with the requirements of reference 1, section 4.10.5 (ISO 9001) and reference 2, part B, section 3.3.1, paragraphs 1 and 2 and Part C, section 4.6 (ANSI/ASQC E4) in appendix A of this subpart. All test data and other documentation obtained specifically from or pertinent to these tests shall be identified, dated, signed by the analyst performing the test, and submitted to EPA in accordance with subpart A of this part.

17. Section 53.51 is revised to read as follows:

§ 53.51 Demonstration of compliance with design specifications and manufacturing and test requirements.

(a) *Overview.* (1) The subsequent paragraphs of this section specify certain documentation that must be submitted and tests that are required to demonstrate that samplers associated with a designated reference or equivalent method for $PM_{2.5}$ or $PM_{10-2.5}$ are properly manufactured to meet all applicable design and performance specifications and have been properly tested according to all applicable test requirements for such designation. Documentation is required to show that instruments and components of a $PM_{2.5}$ or $PM_{10-2.5}$ sampler are manufactured in an ISO 9001-registered facility under a quality system that meets ISO–9001 requirements for manufacturing quality control and testing.

(2) In addition, specific tests are required by paragraph (d) of this section to verify that critical features of reference method samplers—the particle size separator and the surface finish of surfaces specified to be anodized—meet the specifications of 40 CFR part 50, appendix L or appendix O, as applicable. A checklist is required to provide certification by an ISO-certified auditor that all performance and other required tests have been properly and appropriately conducted, based on a reasonable and appropriate sample of the actual operations or their documented records. Following designation of the method, another checklist is required initially to provide an ISO-certified auditor's certification that the sampler manufacturing process is being implemented under an adequate and appropriate quality system.

(3) For the purposes of this section, the definitions of ISO 9001-registered facility and ISO-certified auditor are found in § 53.1. An exception to the reliance by EPA on ISO-certified auditors is the requirement for the submission of the operation or instruction manual associated with the candidate method to EPA as part of the application. This manual is required under § 53.4(b)(3). The EPA has determined that acceptable technical judgment for review of this manual may not be assured by ISO-certified auditors, and approval of this manual will therefore be performed by EPA.

(b) *ISO registration of manufacturing facility.* The applicant must submit documentation verifying that the samplers identified and sold as part of a designated $PM_{2.5}$ or $PM_{10-2.5}$ reference or equivalent method will be manufactured in an ISO 9001-registered facility and that the manufacturing facility is maintained in compliance with all applicable ISO 9001 requirements (reference 1 in appendix A of this subpart). The documentation shall indicate the date of the original ISO 9001 registration for the facility and shall include a copy of the most recent certification of continued ISO 9001 facility registration. If the manufacturer

does not wish to initiate or complete ISO 9001 registration for the manufacturing facility, documentation must be included in the application to EPA describing an alternative method to demonstrate that the facility meets the same general requirements as required for registration to ISO–9001. In this case, the applicant must provide documentation in the application to demonstrate, by required ISO-certified auditor's inspections, that a quality system is in place which is adequate to document and monitor that the sampler system components and final assembled samplers all conform to the design, performance and other requirements specified in this part and in 40 CFR part 50, appendix L.

(c) *Sampler manufacturing quality control.* The manufacturer must ensure that all components used in the manufacture of $PM_{2.5}$ or $PM_{10-2.5}$ samplers to be sold as part of a reference or equivalent method and that are specified by design in 40 CFR part 50, appendix L or O (as applicable), are fabricated or manufactured exactly as specified. If the manufacturer's quality records show that its quality control (QC) and quality assurance (QA) system of standard process control inspections (of a set number and frequency of testing that is less than 100 percent) complies with the applicable QA provisions of section 4 of reference 4 in appendix A of this subpart and prevents nonconformances, 100 percent testing shall not be required until that conclusion is disproved by customer return or other independent manufacturer or customer test records. If problems are uncovered, inspection to verify conformance to the drawings, specifications, and tolerances shall be performed. Refer also to paragraph (e) of this section-final assembly and inspection requirements.

(d) *Specific tests and supporting documentation required to verify conformance to critical component specifications.* (1) *Verification of $PM_{2.5}$ (WINS) impactor jet diameter.* For samplers utilizing the WINS impactor particle size separator specified in paragraphs 7.3.4.1, 7.3.4.2, and 7.3.4.3 of appendix L to part 50 of this chapter, the diameter of the jet of each impactor manufactured for a $PM_{2.5}$ or $PM_{10-2.5}$ sampler under the impactor design specifications set forth in 40 CFR part 50, appendix L, shall be verified against the tolerance specified on the drawing, using standard, NIST-traceable ZZ go/no go plug gages. This test shall be a final check of the jet diameter following all fabrication operations, and a record shall be kept of this final check. The manufacturer shall submit evidence that this procedure is incorporated into the manufacturing procedure, that the test is or will be routinely implemented, and that an appropriate procedure is in place for the disposition of units that fail this tolerance test.

(2) *VSCC separator.* For samplers utilizing the BGI VSCC™ Very Sharp Cut Cyclone particle size separator specified in paragraph 7.3.4.4 of appendix L to part 50 of this chapter, the VSCC manufacturer shall identify the critical dimensions and manufacturing tolerances for the device, develop appropriate test procedures to verify that the critical dimensions and tolerances are maintained during the manufacturing process, and carry out those procedures on each VSCC manufactured to verify conformance of the manufactured products. The manufacturer shall also maintain records of these tests and their results and submit evidence that this procedure is incorporated into the manufacturing procedure, that the test is or will be routinely implemented, and that an appropriate procedure is in place for the disposition of units that fail this tolerance test.

(3) *Verification of surface finish.* The anodization process used to treat surfaces specified to be anodized shall be verified by testing treated specimen surfaces for weight and corrosion resistance to ensure that the coating obtained conforms to the coating specification. The specimen surfaces shall be finished in accordance with military standard specification 8625F, Type II, Class I (reference 4 in appendix A of this subpart) in the same way the sampler surfaces are finished, and tested, prior to sealing, as specified in section 4.5.2 of reference 4 in appendix A of this subpart.

(e) *Final assembly and inspection requirements.* Each sampler shall be tested after manufacture and before delivery to the final user. Each manufacturer shall document its post-manufacturing test procedures. As a minimum, each test shall consist of the following: Tests of the overall integrity of the sampler, including leak tests; calibration or verification of the calibration of the flow measurement device, barometric pressure sensor, and temperature sensors; and operation of the sampler with a filter in place over a period of at least 48 hours. The results of each test shall be suitably documented and shall be subject to review by an ISO-certified auditor.

(f) *Manufacturer's audit checklists.* Manufacturers shall require an ISO-certified auditor to sign and date a statement indicating that the auditor is aware of the appropriate manufacturing specifications contained in 40 CFR part 50, appendix L or O (as applicable), and the test or verification requirements in this subpart. Manufacturers shall also require an ISO-certified auditor to complete the checklists, shown in figures E–1 and E–2 of this subpart, which describe the manufacturer's ability to meet the requirements of the standard for both designation testing and product manufacture.

(1) *Designation testing checklist.* The completed statement and checklist as shown in figure E–1 of this subpart shall be submitted with the application for reference or equivalent method determination.

(2) *Product manufacturing checklist.* Manufacturers shall require an ISO-certified auditor to complete a Product Manufacturing Checklist (figure E–2 of this subpart), which evaluates the manufacturer on its ability to meet the requirements of the standard in maintaining quality control in the production of reference or equivalent devices. The completed checklist shall be submitted with the application for reference or equivalent method determination.

18. Section 53.52 is amended by revising paragraph (e)(1) to read as follows:

§ 53.52 Leak check test.

* * * * *

(e) *Test setup.* (1) The test sampler shall be set up for testing as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in its normal configuration for collecting PM samples, except that the sample air inlet shall be removed and the flow rate measurement adaptor shall be installed on the sampler's downtube.

* * * * *

19. Section 53.53 is amended by revising paragraph (e)(1) to read as follows:

§ 53.53 Test for flow rate accuracy, regulation, measurement accuracy, and cut-off.

* * * * *

(e) *Test setup.* (1) Setup of the sampler shall be as required in this paragraph (e) and otherwise as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in its normal configuration for collecting PM samples. A sample filter and (or) the device for creating an additional 55 mm Hg pressure drop shall be installed for the duration of these tests. The sampler's ambient temperature, ambient pressure, and flow rate measurement

systems shall all be calibrated per the sampler's operation or instruction manual within 7 days prior to this test.

* * * * *

20. Section 53.54 is amended by revising paragraph (d)(1) to read as follows:

§ 53.54 Test for proper sampler operation following power interruptions.

* * * * *

(d) *Test setup.* (1) Setup of the sampler shall be performed as required in this paragraph (d) and otherwise as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in its normal configuration for collecting PM samples. A sample filter and (or) the device for creating an additional 55 mm Hg pressure drop shall be installed for the duration of these tests. The sampler's ambient temperature, ambient pressure, and flow measurement systems shall all be calibrated per the sampler's operating manual within 7 days prior to this test.

* * * * *

21. Section 53.55 is amended as follows:

a. By revising paragraphs (a)(1) introductory text and (a)(2).

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

c. By revising paragraph (g)(5)(i).

§ 53.55 Test for effect of variations in power line voltage and ambient temperature.

(a) *Overview.* (1) This test procedure is a combined procedure to test various performance parameters under variations in power line voltage and ambient temperature. Tests shall be conducted in a temperature controlled environment over four 6-hour time periods during which reference temperature and flow rate measurements shall be made at intervals not to exceed 5 minutes. Specific parameters to be evaluated at line voltages of 105 and 125 volts and temperatures of − 20 °C and +40 °C are as follows:

* * * * *

(2) The performance parameters tested under this procedure, the corresponding minimum performance specifications, and the applicable test conditions are summarized in table E–1 of this subpart. Each performance parameter tested, as described or determined in the test procedure, must meet or exceed the associated performance specification given. The candidate sampler must meet all specifications for the associated $PM_{2.5}$ or $PM_{10\text{-}2.5}$ method (as applicable) to pass this test procedure.

* * * * *

(e) * * * (1) Setup of the sampler shall be performed as required in this paragraph (e) and otherwise as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in the temperature-controlled chamber in its normal configuration for collecting PM samples. A sample filter and (or) the device for creating an additional 55 mm Hg pressure drop shall be installed for the duration of these tests. The sampler's ambient temperature, ambient pressure, and flow measurement systems shall all be calibrated per the sampler's operating manual within 7 days prior to this test.

* * * * *

(g) * * *

(5) * * * (i) Calculate the absolute value of the difference between the mean ambient air temperature indicated by the test sampler and the mean ambient (chamber) air temperature measured with the ambient air temperature recorder as:

Equation 16

$$T_{diff} = \left| T_{ind,ave} - T_{ref,ave} \right|$$

Where:

$T_{ind,ave}$ = mean ambient air temperature indicated by the test sampler,°C; and

$T_{ref,ave}$ = mean ambient air temperature measured by the reference temperature instrument,°C.

* * * * *

22. Section 53.56 is amended by revising paragraphs (a)(2) and (e)(1) to read as follows:

§ 53.56 Test for effect of variations in ambient pressure.

(a) * * *

(2) The performance parameters tested under this procedure, the corresponding minimum performance specifications, and the applicable test conditions are summarized in table E–1 of this subpart. Each performance parameter tested, as described or determined in the test procedure, must meet or exceed the associated performance specification given. The candidate sampler must meet all specifications for the associated $PM_{2.5}$ or $PM_{10\text{-}2.5}$ method (as applicable) to pass this test procedure.

* * * * *

(e) * * * (1) Setup of the sampler shall be performed as required in this paragraph (e) and otherwise as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in the pressure-controlled chamber in its normal configuration for collecting PM samples. A sample filter and (or) the device for creating an additional 55 mm Hg pressure drop shall be installed for the duration of these tests. The sampler's ambient temperature, ambient pressure, and flow measurement systems shall all be calibrated per the sampler's operating manual within 7 days prior to this test.

* * * * *

23. Section 53.57 is amended by revising paragraphs (a), (b), and (e)(1) to read as follows:

§ 53.57 Test for filter temperature control during sampling and post-sampling periods.

(a) *Overview.* This test is intended to measure the candidate sampler's ability to prevent excessive overheating of the PM sample collection filter (or filters) under conditions of elevated solar insolation. The test evaluates radiative effects on filter temperature during a 4-hour period of active sampling as well as during a subsequent 4-hour non-sampling time period prior to filter retrieval. Tests shall be conducted in an environmental chamber which provides the proper radiant wavelengths and energies to adequately simulate the sun's radiant effects under clear conditions at sea level. For additional guidance on conducting solar radiative tests under controlled conditions, consult military standard specification 810–E (reference 6 in appendix A of this subpart). The performance parameters tested under this procedure, the corresponding minimum performance specifications, and the applicable test conditions are summarized in table E–1 of this subpart. Each performance parameter tested, as described or determined in the test procedure, must meet or exceed the associated performance specification to successfully pass this test.

(b) *Technical definition.* Filter temperature control during sampling is the ability of a sampler to maintain the temperature of the particulate matter sample filter within the specified deviation (5 °C) from ambient temperature during any active sampling period. Post-sampling temperature control is the ability of a sampler to maintain the temperature of the particulate matter sample filter within the specified deviation from ambient temperature during the period from the end of active sample collection by the sampler until the filter is retrieved from the sampler for laboratory analysis.

* * * * *

(e) * * * (1) Setup of the sampler shall be performed as required in this paragraph (e) and otherwise as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in the solar radiation environmental chamber in its normal configuration for collecting PM samples (with the inlet installed). The sampler's ambient and filter temperature measurement systems shall be calibrated per the sampler's operating manual within 7 days prior to this test. A sample filter shall be installed for the duration of this test. For sequential samplers, a sample filter shall also be installed in each available sequential channel or station intended for collection of a sequential sample (or at least 5 additional filters for magazine-type sequential samplers) as directed by the sampler's operation or instruction manual.

* * * * *

24. Section 53.58 is revised to read as follows:

§ 53.58 Operational field precision and blank test.

(a) *Overview.* This test is intended to determine the operational precision of the candidate sampler during a minimum of 10 days of field operation, using three collocated test samplers. Measurements of PM are made at a test site with all of the samplers and then compared to determine replicate precision. Candidate sequential samplers are also subject to a test for possible deposition of particulate matter on inactive filters during a period of storage in the sampler. This procedure is applicable to both reference and equivalent methods. In the case of equivalent methods, this test may be combined and conducted concurrently with the comparability test for equivalent methods (described in subpart C of this part), using three reference method samplers collocated with three candidate equivalent method samplers and meeting the applicable site and other requirements of subpart C of this part.

(b) *Technical definition.* (1) Field precision is defined as the standard deviation or relative standard deviation of a set of PM measurements obtained concurrently with three or more collocated samplers in actual ambient air field operation.

(2) Storage deposition is defined as the mass of material inadvertently deposited on a sample filter that is stored in a sequential sampler either prior to or subsequent to the active sample collection period.

(c) *Test site.* Any outdoor test site having $PM_{2.5}$ (or $PM_{10\text{-}2.5}$, as applicable) concentrations that are reasonably uniform over the test area and that meet the minimum level requirement of paragraph (g)(2) of this section is acceptable for this test.

(d) *Required facilities and equipment.* (1) An appropriate test site and suitable electrical power to accommodate three test samplers are required.

(2) Teflon sample filters, as specified in section 6 of 40 CFR part 50, appendix L, conditioned and preweighed as required by section 8 of 40 CFR part 50, appendix L, as needed for the test samples.

(e) *Test setup.* (1) Three identical test samplers shall be installed at the test site in their normal configuration for collecting PM samples in accordance with the instructions in the associated manual referred to in § 53.4(b)(3) and also in accordance with applicable supplemental guidance provided in reference 3 in appendix A of this subpart. The test samplers' inlet openings shall be located at the same height above ground and between 2 (1 for samplers with flow rates less than 200 L/min.) and 4 meters apart horizontally. The samplers shall be arranged or oriented in a manner that will minimize the spatial and wind directional effects on sample collection of one sampler on any other sampler.

(2) Each test sampler shall be successfully leak checked, calibrated, and set up for normal operation in accordance with the instruction manual and with any applicable supplemental guidance provided in reference 3 in appendix A of this subpart.

(f) *Test procedure.* (1) Install a conditioned, preweighed filter in each test sampler and otherwise prepare each sampler for normal sample collection. Set identical sample collection start and stop times for each sampler. For sequential samplers, install a conditioned, preweighed specified filter in each available channel or station intended for automatic sequential sample filter collection (or at least 5 additional filters for magazine-type sequential samplers), as directed by the sampler's operation or instruction manual. Since the inactive sequential channels are used for the storage deposition part of the test, they may not be used to collect the active PM test samples.

(2) Collect either a nominal 24-hour or 48-hour atmospheric PM sample simultaneously with each of the three test samplers.

(3) Following sample collection, retrieve the collected sample from each sampler. For sequential samplers, retrieve the additional stored (blank, unsampled) filters after at least 5 days (120 hours) storage in the sampler if the active samples are 24-hour samples, or after at least 10 days (240 hours) if the active samples are 48-hour samples.

(4) Determine the measured PM mass concentration for each sample in accordance with the applicable procedures prescribed for the candidate method in appendix L or appendix O, as applicable, of part 50 of this chapter, or in accordance with the associated manual referred to in § 53.4(b)(3) and supplemental guidance in reference 2 in appendix A of this subpart. For sequential samplers, also similarly determine the storage deposition as the net weight gain of each blank, unsampled filter after the 5-day (or 10-day) period of storage in the sampler.

(5) Repeat this procedure to obtain a total of 10 sets of any combination of (nominal) 24-hour or 48-hour PM measurements over 10 test periods. For sequential samplers, repeat the 5-day (or 10-day) storage test of additional blank filters once for a total of two sets of blank filters.

(g) *Calculations.* (1) Record the PM concentration for each test sampler for each test period as $C_{i,j}$, where i is the sampler number (i = 1,2,3) and j is the test period (j = 1,2, * * * 10).

(2)(i) For each test period, calculate and record the average of the three measured PM concentrations as $C_{ave,j}$ where j is the test period using equation 26 of this section:

Equation 26

$$C_{ave,j} = \frac{1}{3} \times \sum_{i=1}^{3} C_{i,j}$$

(ii) If $C_{ave,j} < 3\ \mu g/m^3$ for any test period, data from that test period are unacceptable, and an additional sample collection set must be obtained to replace the unacceptable data.

(3)(i) Calculate and record the precision for each of the 10 test periods, as the standard deviation, using equation 27 of this section:

Equation 27

$$P_j = \frac{\sum_{i=1}^{3} C_{i,j}^2 - \frac{1}{3}\left(\sum_{i=1}^{3} C_{i,j}\right)^2}{2}$$

(ii) For each of the 10 test periods, also calculate and record the precision as the relative standard deviation, in

percent, using equation 28 of this section:

Equation 28

$$RP_j = 100\% \times \frac{P_j}{C_{ave,j}}$$

(h) *Test results.* (1) The candidate method passes the precision test if either P_j or RP_j is less than or equal to the corresponding specification in table E–1 of this subpart for all 10 test periods.

(2) The candidate sequential sampler passes the blank filter storage deposition test if the average net storage deposition weight gain of each set of blank filters (total of the net weight gain of each blank filter divided by the number of filters in the set) from each test sampler (six sets in all) is less than 50 µg.

25. Section 53.59 is amended by revising paragraphs (a) and (b)(5) to read as follows:

§ 53.59 Aerosol transport test for Class I equivalent method samplers.

(a) *Overview.* This test is intended to verify adequate aerosol transport through any modified or air flow splitting components that may be used in a Class I candidate equivalent method sampler such as may be necessary to achieve sequential sampling capability. This test is applicable to all Class I candidate samplers in which the aerosol flow path (the flow path through which sample air passes upstream of sample collection filter) differs significantly from that specified for reference method samplers as specified in 40 CFR part 50, appendix L or appendix O, as applicable. The test requirements and performance specifications for this test are summarized in table E–1 of this subpart.

(b) * * *

(5) An added component is any physical part of the sampler which is different in some way from that specified for a reference method sampler in 40 CFR part 50, appendix L or appendix O, as applicable, such as a device or means to allow or cause the aerosol to be routed to one of several channels.

* * * * *

26. Table E–1 to subpart E is revised to read as follows:

TABLE E–1 TO SUBPART E.—SUMMARY OF TEST REQUIREMENTS FOR REFERENCE AND CLASS I EQUIVALENT METHODS FOR $PM_{2.5}$ AND $PM_{10-2.5}$

Subpart E procedure	Performance test	Performance specification	Test conditions	Part 50, Appendix L reference
§ 53.52 Sample leak check test	Sampler leak check facility	External leakage: 80 mL/min, max Internal leakage: 80 mL/min, max	Controlled leak flow rate of 80 mL/min	Sec. 7.4.6.
§ 53.53 Base flow rate test	Sample flow rate 1. Mean 2. Regulation 3. Meas accuracy 4. CV accuracy 5. Cut-off	1. 67.67 ±5% L/min 2. 2%, max 3. 2%, max 4. 0.3% max 5. Flow rate cut-off if flow rate deviates more than 10% from design flow rate for >60±30 seconds	(a) 6-hour normal operational test plus flow rate cut-off test (b) Norman conditions (c) Additional 55 mm Hg pressure drop to simulate loaded filter (d) Variable flow restrictions used for cut-off test	Sec. 7.4.1, Sec. 7.4.2, Sec. 7.4.3, Sec. 7.4.4, Sec. 7.4.5.
§ 53.54 Power interruption test	Sample flow rate: 1. Mean 2. Regulation 3. Meas. accuracy 4. CV accuracy 5. Occurrence time of power interruptions 6. Elapsed sample time 7. Sample volume	1. 16.67 ± 5% L/min 2. 2%, max 3. 2%, max 4. 0.3 max 5. ±2 min if >60 seconds 6. ±20 seconds 7. ±2%, max	(a) 6-hour normal operational test (b) Nominal conditions (c) Additional 55 mm Hg pressure drop to simulate loaded filter (d) 6 power interruptions of various durations	Sec. 7.4.1, Sec. 7.4.2, Sec. 7.4.3, Sec. 7.4.5, Sec. 7.4.12, Sec. 7.4.13, Sec. 7.4.15.4, Sec. 7.4.15.5.
§ 53.55 Temperature and line voltage test	Sample flow rate 1. Mean 2. Regulation 3. Meas. accuracy 4. CV accuracy 5. Temperature meas. accuracy 6. Proper operation	1. 16.67 ± 5% L/min 2. 2%, max 3. 2%, max 4. 0.3 max 5 2 °C	(a) 6-hour normal operational test (b) Normal conditions (c) Additional 55 mm Hg pressure drop to simulate loaded filter (d) Ambient temperature at −20 and +40 °C (e) Line voltage: 105 Vac to 125 Vac	Sec. 7.4.1, Sec. 7.4.2, Sec. 7.4.3, Sec. 7.4.5, Sec. 7.4.8, Sec. 7.4.15.1.
§ 53.56 Barometric pressure effect test	Sample flow rate 1. Mean 2. Regulation 3. Meas. accuracy 4. CV accuracy 5. Pressure meas. accuracy 6. Proper operation	1. 16.67 ± 5% L/min 2. 2%, max 3. 2%, max 4. 0.3% max 5. 10 mm Hg	(a) 6-hour normal operational test (b) Normal conditions (c) Additional 55 mm Hg pressure drop to simulate loaded filter (d) Barometer pressure at 600 and 800 mm Hg	Sec. 7.4.1, Sec. 7.4.2, Sec. 7.4.3, Sec. 7.4.5, Sec. 7.4.9.

TABLE E–1 TO SUBPART E.—SUMMARY OF TEST REQUIREMENTS FOR REFERENCE AND CLASS I EQUIVALENT METHODS FOR $PM_{2.5}$ AND $PM_{10-2.5}$—Continued

Subpart E procedure	Performance test	Performance specification	Test conditions	Part 50, Appendix L reference
§ 53.57 Filter temperature control test	1. Filter temp meas. accuracy 2. Ambient temp. meas. accuracy 3. Filter temp. control accuracy, sampling and non-sampling	1. 2 °C 2. 2 °C 3. Not more than 5 °C above ambient temp. for more than 30 min.	(a) 4-hour simulated solar radiation, sampling (b) 4-hour simulated solar radiation, non-sampling (c) Solar flux of 1000 ±50 W/m^2	Sec. 7.4.8, Sec. 7.4.10, Sec. 7.4.11.
§ 53.58 Field precision test	1 Measurement precision 2. Storage deposition test for sequential samplers	1. P_j <2 μg/m^3 or RP_j <5% 2. 50 μg max. average weight gain/blank filter	(a) 3 collocated samples at 1 site for at least 10 days; (b) $PM_{2.5}$ conc. > 3 μg/m^3 (c) 25- or 48-hour samples (d) 5- or 10-day storage period for inactive stored filters	Sec. 5.1, Sec. 7.4.5, Sec. 8, Sec. 9, Sec. 10.
The Following Requirement Is Applicable to Class I Candidate Equivalent Methods Only				
§ 53.59 Aerosol transport test	Aerosol transport	97%, min. for all channels	Determine aerosol transport through any new or modified components with respect to the reference method sampler before the filter for each channel.	

27. References (3) and (5) in appendix A to subpart E of part 53 are revised to read as follows:

Appendix A to Subpart E of Part 53—References

* * * * *

(3) Quality Assurance Guidance Document 2.12. Monitoring $PM_{2.5}$ in Ambient Air Using Designated Reference or Class I Equivalent Methods. U.S. EPA, National Exposure Research Laboratory, Research Triangle Park, NC, November 1998 or later edition. Currently available at *http://www.epa.gov/ttn/amtic/pmgainf.html*.

* * * * *

(5) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements. Revised March, 1995. EPA–600/R–94–038d. Available from National Technical Information Service, Springfield, VA 22161, (800–553–6847, *http://www.ntis.gov*). NTIS number PB95–199782INZ.

* * * * *

Subpart F—[Amended]

28. Section 53.60 is amended by revising paragraphs (b), (c), (d) introductory text, and (f)(4) to read as follows:

§ 53.60 General provisions.

* * * * *

(b) A candidate method described in an application for a reference or equivalent method determination submitted under § 53.4 shall be determined by the EPA to be a Class II candidate equivalent method on the basis of the definition of a Class II equivalent method given in § 53.1.

(c) Any sampler associated with a Class II candidate equivalent method (Class II sampler) must meet all applicable requirements for reference method samplers or Class I equivalent method samplers specified in subpart E of this part, as appropriate. Except as provided in § 53.3(a)(3), a Class II $PM_{2.5}$ sampler must meet the additional requirements as specified in paragraph (d) of this section.

(d) Except as provided in paragraphs (d)(1), (2), and (3) of this section, all Class II samplers are subject to the additional tests and performance requirements specified in § 53.62 (full wind tunnel test), § 53.65 (loading test), and § 53.66 (volatility test). Alternative tests and performance requirements, as described in paragraphs (d)(1), (2), and (3) of this section, are optionally available for certain Class II samplers which meet the requirements for reference method or Class I equivalent method samplers given in 40 CFR part 50, appendix L, and in subpart E of this part, except for specific deviations of the inlet, fractionator, or filter.

* * * * *

(f) * * *

(4) *Loading test*. The loading test is conducted to ensure that the performance of a candidate sampler is not significantly affected by the amount of particulate deposited on its interior surfaces between periodic cleanings. The candidate sampler is artificially loaded by sampling a test environment containing aerosolized, standard test dust. The duration of the loading phase is dependent on both the time between cleaning as specified by the candidate method and the aerosol mass concentration in the test environment. After loading, the candidate's performance must then be evaluated by § 53.62 (full wind tunnel evaluation), § 53.63 (wind tunnel inlet aspiration test), or § 53.64 (static fractionator test). If the results of the appropriate test meet the criteria presented in table F–1 of this subpart, then the candidate sampler passes the loading test under the condition that it be cleaned at least as often as the cleaning frequency proposed by the candidate method and that has been demonstrated to be acceptable by this test.

* * * * *

29. The section heading of § 53.61 is revised to read as follows.

§ 53.61 Test conditions.

* * * * *

30. Section 53.66 is amended by revising paragraph (e)(2)(iii) to read as follows:

§ 53.66 Test procedure: Volatility test.

* * * * *

(e) * * *

(2) * * *

(iii) Operate the candidate and the reference samplers such that they simultaneously sample the test aerosol for 2 hours for a candidate sampler operating at 16.7 L/min or higher, or proportionately longer for a candidate sampler operating at a lower flow rate.

* * * * *

31. Table F–1 to subpart F is revised to read as follows:

TABLE F–1 TO SUBPART F.—PERFORMANCE SPECIFICATIONS FOR $PM_{2.5}$ CLASS II EQUIVALENT SAMPLERS

Performance test	Specifications	Acceptance criteria
§ 53.62 Full Wind Tunnel Evaluation.	Solid VOAG produced aerosol at 2 km/hr and 24 km/hr	Dp_{50} = 2.5 μm ± 0.2 μm Numerical Analysis Results: 95% ≤R_c≤105%.
§ 53.63 Wind Tunnel Inlet Aspiration Test.	Liquid VOAG produced aerosol at 2 km/hr and 24 km/hr.	Relative Aspiration: 95% ≤A≤105%.
§ 53.64 Static Fractionator Test.	Evaluation of the fractionator under static conditions	Dp_{50} = 2.5 μm ± 0.2 μm Numerical Analysis Results: 95% ≤R_c≤105%.
§ 53.65 Loading Test	Loading of the clean candidate under laboratory conditions.	Acceptance criteria as specified in the post-loading evaluation test (§ 53.62, § 53.63, or § 53.64).
§ 53.66 Volatility Test	Polydisperse liquid aerosol producted by air nebulization of A.C.S. reagent grade glycerol, 99.5% minimum purity.	Regression Parameters Slope = 1 ± 0.1, Intercept = 0 ± 0.15 mg r ≥ 0.97.

32. In Figure E–1 to subpart F, the figure number ''E–1'' is revised to read ''F–1.''

PART 58—[AMENDED]

33. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7410, 7601(a), 7613, and 7619.

Subpart A—[Amended]

34. Sections 58.1, 58.2 and 58.3 are revised to read as follows:

§ 58.1 Definitions.

As used in this part, all terms not defined herein have the meaning given them in the Act.

Act means the Clean Air Act as amended (42 U.S.C. 7401, *et seq.*)

Additive and multiplicative bias means the linear regression intercept and slope of a linear plot fitted to corresponding candidate and reference method mean measurement data pairs.

Administrator means the Administrator of the Environmental Protection Agency (EPA) or his or her authorized representative.

Air Quality System (AQS) means EPA's computerized system for storing and reporting of information relating to ambient air quality data.

Approved regional method (ARM) means a continuous $PM_{2.5}$ method that has been approved specifically within a State or local air monitoring network for purposes of comparison to the NAAQS and to meet other monitoring objectives.

AQCR means air quality control region.

CO means carbon monoxide.

Combined statistical area (CSA) is defined by the U.S. Office of Management and Budget as a geographical area consisting of two or more adjacent Core Based Statistical Areas (CBSA) with employment interchange of at least 15 percent. Combination is automatic if the employment interchange is 25 percent and determined by local opinion if more than 15 but less than 25 percent (*http://www.census.gov/population/estimates/metro-city/List6.txt*).

Community monitoring zone (CMZ) means an optional averaging area with established, well defined boundaries, such as county or census block, within an MPA that has relatively uniform concentrations of annual $PM_{2.5}$ as defined by appendix N of part 50 of this chapter. Two or more community-oriented SLAMS monitors within a CMZ that meet certain requirements as set forth in appendix N of part 50 of this chapter may be averaged for making comparisons to the annual $PM_{2.5}$ NAAQS.

Core-based statistical area (CBSA) is defined by the U.S. Office of Management and Budget, as a statistical geographic entity consisting of the county or counties associated with at least one urbanized area/urban cluster of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration. Metropolitan and micropolitan statistical areas (MSA) are the two categories of CBSA (metropolitan areas have populations greater than 50,000; and micropolitan areas have populations between 10,000 and 50,000). In the case of very large cities where two or more CBSA are combined, these larger areas are referred to as combined statistical areas (*http://www.census.gov/population/estimates/metro-city/List1.txt*).

Corrected concentration pertains to the result of an accuracy or precision assessment test of an open path analyzer in which a high-concentration test or audit standard gas contained in a short test cell is inserted into the optical measurement beam of the instrument. When the pollutant concentration measured by the analyzer in such a test includes both the pollutant concentration in the test cell and the concentration in the atmosphere, the atmospheric pollutant concentration must be subtracted from the test measurement to obtain the corrected concentration test result. The corrected concentration is equal to the measured concentration minus the average of the atmospheric pollutant concentrations measured (without the test cell) immediately before and immediately after the test.

Design value means the calculated concentration according to the applicable appendix of part 50 of this chapter for the highest site in an attainment or nonattainment area.

EDO means environmental data operations.

Effective concentration pertains to testing an open path analyzer with a high-concentration calibration or audit standard gas contained in a short test cell inserted into the optical measurement beam of the instrument. Effective concentration is the equivalent ambient-level concentration that would produce the same spectral absorbance over the actual atmospheric monitoring path length as produced by the high-concentration gas in the short test cell. Quantitatively, effective concentration is equal to the actual concentration of the gas standard in the test cell multiplied by the ratio of the path length of the test cell to the actual atmospheric monitoring path length.

Equivalent method means a method of sampling and analyzing the ambient air

for an air pollutant that has been designated as an equivalent method in accordance with part 53 of this chapter; it does not include a method for which an equivalent method designation has been canceled in accordance with § 53.11 or § 53.16 of this chapter.

HNO_3 means nitric acid.

Local agency means any local government agency, other than the State agency, which is charged by a State with the responsibility for carrying out a portion of the plan.

Meteorological measurements means measurements of wind speed, wind direction, barometric pressure, temperature, relative humidity, solar radiation, ultraviolet radiation, and precipitation.

Metropolitan Statistical Area (MSA) means a CBSA associated with at least one urbanized area of at least 50,000 population. The central county plus adjacent counties with a high degree of integration comprise the area.

Monitor means an instrument, sampler, analyzer, or other device that measures or assists in the measurement of atmospheric air pollutants and which is acceptable for use in ambient air surveillance under the applicable provisions of appendix C to this part.

Monitoring agency means a State or local agency responsible for meeting the requirements of this part.

Monitoring organization means a State, local, or other monitoring organization responsible for operating a monitoring site for which the quality assurance regulations apply.

Monitoring path for an open path analyzer means the actual path in space between two geographical locations over which the pollutant concentration is measured and averaged.

Monitoring path length of an open path analyzer means the length of the monitoring path in the atmosphere over which the average pollutant concentration measurement (path-averaged concentration) is determined. See also, *optical measurement path length*.

Monitoring planning area (MPA) means a contiguous geographic area with established, well defined boundaries, such as a CBSA, county or State, having a common area that is used for planning monitoring locations for $PM_{2.5}$. An MPA may cross State boundaries, such as the Philadelphia PA-NJ MSA, and be further subdivided into community monitoring zones. MPA are generally oriented toward CBSA or CSA with populations greater than 200,000, but for convenience, those portions of a State that are not associated with CBSA can be considered as a single MPA.

NATTS means the national air toxics trends stations. This network provides hazardous air pollution ambient data.

NCore means the National Core multipollutant monitoring stations. Monitors at these sites are required to measure particles ($PM_{2.5}$, speciated $PM_{2.5}$, $PM_{10-2.5}$), O_3, SO_2, CO, nitrogen oxides ($NO/NO_2/NO_Y$), and basic meteorology.

Network means all stations of a given type or types.

NH_3 means ammonia.

NO_2 means nitrogen dioxide. NO means nitrogen oxide. NO_X means oxides of nitrogen and is defined as the sum of the concentrations of NO_2 and NO.

NO_y means the sum of all total reactive nitrogen oxides, including NO, NO_2, and other nitrogen oxides referred to as NO_Z.

O_3 means ozone.

Open path analyzer means an automated analytical method that measures the average atmospheric pollutant concentration in situ along one or more monitoring paths having a monitoring path length of 5 meters or more and that has been designated as a reference or equivalent method under the provisions of part 53 of this chapter.

Optical measurement path length means the actual length of the optical beam over which measurement of the pollutant is determined. The path-integrated pollutant concentration measured by the analyzer is divided by the optical measurement path length to determine the path-averaged concentration. Generally, the optical measurement path length is:

(1) Equal to the monitoring path length for a (bistatic) system having a transmitter and a receiver at opposite ends of the monitoring path;

(2) Equal to twice the monitoring path length for a (monostatic) system having a transmitter and receiver at one end of the monitoring path and a mirror or retroreflector at the other end; or

(3) Equal to some multiple of the monitoring path length for more complex systems having multiple passes of the measurement beam through the monitoring path.

PAMS means photochemical assessment monitoring stations.

Pb means lead.

Plan means a implementation plan approved or promulgated pursuant to section 110 of the Act.

$PM_{2.5}$ means particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers as measured by a reference method based on appendix L of part 50 of this chapter and designated in accordance with part 53 of this chapter, by an equivalent method designated in accordance with part 53 of this chapter, or by an approved regional method designated in accordance with appendix C to this part.

PM_{10} means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers as measured by a reference method based on appendix J of part 50 of this chapter and designated in accordance with part 53 of this chapter or by an equivalent method designated in accordance with part 53 of this chapter.

PM_{10C} means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers as measured by a reference method based on appendix O of part 50 of this chapter and designated in accordance with part 53 of this chapter or by an equivalent method designated in accordance with part 53 of this chapter.

$PM_{10-2.5}$ means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers and greater than a nominal 2.5 micrometers as measured by a reference method based on appendix O to part 50 of this chapter and designated in accordance with part 53 of this chapter or by an equivalent method designated in accordance with part 53 of this chapter.

Point analyzer means an automated analytical method that measures pollutant concentration in an ambient air sample extracted from the atmosphere at a specific inlet probe point and that has been designated as a reference or equivalent method in accordance with part 53 of this chapter.

Population-oriented monitoring (or sites) means residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day.

Primary quality assurance organization means a monitoring organization or other organization that is responsible for a set of stations that monitors the same pollutant and for which data quality assessments can be pooled. Each criteria pollutant sampler/monitor at a monitoring station in the SLAMS and SPM networks must be associated with one, and only one, primary quality assurance organization.

Probe means the actual inlet where an air sample is extracted from the atmosphere for delivery to a sampler or point analyzer for pollutant analysis.

PSD station means any station operated for the purpose of establishing the effect on air quality of the emissions from a proposed source for purposes of prevention of significant deterioration as required by § 51.24(n) of this chapter.

Reference method means a method of sampling and analyzing the ambient air for an air pollutant that is specified as a reference method in an appendix to part 50 of this chapter, or a method that has been designated as a reference method in accordance with this part; it does not include a method for which a reference method designation has been canceled in accordance with § 53.11 or § 53.16 of this chapter.

Regional Administrator means the Administrator of one of the ten EPA Regional Offices or his or her authorized representative.

Reporting organization means an entity, such as a State, local, or Tribal monitoring agency, that collects and reports air quality data to EPA.

Site means a geographic location. One or more stations may be at the same site.

SLAMS means State or local air monitoring stations. The SLAMS make up the ambient air quality monitoring sites that are primarily needed for NAAQS comparisons, but may serve other data purposes. SLAMS exclude special purpose monitor (SPM) stations and include NCore, PAMS, and all other State or locally operated stations that have not been designated as SPM stations.

SO_2 means sulfur dioxide.

Special purpose monitor (SPM) station means a monitor included in an agency's monitoring network that the agency has designated as a special purpose monitor station in its monitoring network plan and in the Air Quality System, and which the agency does not count when showing compliance with the minimum requirements of this subpart for the number and siting of monitors of various types.

State agency means the air pollution control agency primarily responsible for development and implementation of a plan under the Act.

State speciation site means a supplemental $PM_{2.5}$ speciation station that is not part of the speciation trends network.

Station means a single monitor, or a group of monitors with a shared objective, located at a particular site.

STN station means a $PM_{2.5}$ speciation station designated to be part of the speciation trends network. This network provides chemical species data of fine particulate.

Traceable means that a local standard has been compared and certified, either directly or via not more than one intermediate standard, to a National Institute of Standards and Technology (NIST)-certified primary standard such as a NIST-traceable Reference Material (NTRM) or a NIST-certified Gas Manufacturer's Internal Standard (GMIS).

TSP (total suspended particulates) means particulate matter as measured by the method described in appendix B of part 50 of this chapter.

Urbanized area means an area with a minimum residential population of at least 50,000 people and which generally includes core census block groups or blocks that have a population density of at least 1,000 people per square mile and surrounding census blocks that have an overall density of at least 500 people per square mile. The Census Bureau notes that under certain conditions, less densely settled territory may be part of each Urbanized Area.

VOC means volatile organic compounds.

§ 58.2 Purpose.

(a) This part contains requirements for measuring ambient air quality and for reporting ambient air quality data and related information. The monitoring criteria pertain to the following areas:

(1) Quality assurance procedures for monitor operation and data handling.

(2) Methodology used in monitoring stations.

(3) Operating schedule.

(4) Siting parameters for instruments or instrument probes.

(5) Minimum ambient air quality monitoring network requirements used to provide support to the State implementation plans (SIP), national air quality assessments, and policy decisions. These minimums are described as part of the network design requirements, including minimum numbers and placement of monitors of each type.

(6) Air quality data reporting, and requirements for the daily reporting of an index of ambient air quality.

(b) The requirements pertaining to provisions for an air quality surveillance system in the SIP are contained in this part.

(c) This part also acts to establish a national ambient air quality monitoring network for the purpose of providing timely air quality data upon which to base national assessments and policy decisions.

§ 58.3 Applicability

This part applies to:

(a) State air pollution control agencies.

(b) Any local air pollution control agency to which the State has delegated authority to operate a portion of the State's SLAMS network.

(c) Owners or operators of proposed sources.

Subpart B—Monitoring Network

35. The heading for subpart B is revised as set forth above.

36. Sections 58.10 through 58.14 are revised and §§ 58.15 and 58.16 are added to read as follows:

§ 58.10 Annual monitoring network plan and periodic network assessment.

(a)(1) Beginning July 1, 2007, the State, or where applicable local, agency shall adopt and submit to the Regional Administrator an annual monitoring network plan which shall provide for the establishment and maintenance of an air quality surveillance system that consists of a network of monitoring stations including Federal reference method (FRM), Federal equivalent method (FEM), and approved regional method (ARM) monitors that are part of SLAMS, NCore stations, STN stations, State speciation stations, SPM stations, and/or, in serious, severe and extreme ozone nonattainment areas, PAMS stations. The plan shall include a statement of purpose for each monitor and evidence that siting and operation of each monitor meets the requirements of appendices A, C, D, and E of this part, where applicable. The annual monitoring network plan must be made available for public inspection for at least 30 days prior to submission to EPA.

(2) Any annual monitoring network plan that proposes SLAMS network modifications including new monitoring sites is subject to the approval of the EPA Regional Administrator, who shall provide opportunity for public comment and shall approve or disapprove the plan and schedule within 120 days.

(3) $PM_{10-2.5}$ stations.

(i) The plan for establishing a network of $PM_{10-2.5}$ stations is due not later than January 1, 2008, as an addendum to the annual monitoring network plan required to be submitted July 1, 2007, unless the Regional Administrator extends this due date to July 1, 2008, in which case it shall be part of the annual monitoring network plan due by that date.

(ii) The plan shall provide for required $PM_{10-2.5}$ stations to be operational by January 1, 2009.

(iii) The plan shall identify whether each planned $PM_{10-2.5}$ station is suitable for comparison with the $PM_{10-2.5}$ NAAQS under the criteria of § 58.30(b), and shall include evidence for that identification including the information obtained and conclusions reached in each site-specific assessment.

(iv) Identification of existing and proposed sites as suitable for comparison against the 24-hour $PM_{10-2.5}$

NAAQS are subject to approval by the EPA Regional Administrator as part of the approval of the plan for the $PM_{10-2.5}$ monitoring network. Such approval will constitute a final action by EPA.

(4) The plan for establishing required NCore multipollutant stations is due July 1, 2009. The plan shall provide for all required stations to be operational by January 1, 2011.

(b) The annual monitoring network plan must contain cost information for the network and the following information for each existing and proposed site:

(1) The AQS site identification number.

(2) The location, including street address and geographical coordinates.

(3) The sampling and analysis method(s) for each measured parameter.

(4) The operating schedules for each monitor.

(5) Any proposals to remove or move a monitoring station within a period of 18 months following plan submittal.

(6) The monitoring objective and spatial scale of representativeness for each monitor as defined in appendix D to this part.

(7) The identification of any sites that are suitable and sites that are not suitable for comparison against the annual $PM_{2.5}$ NAAQS or 24-hour $PM_{10-2.5}$ NAAQS as described in § 58.30.

(8) Information supporting the basis for determining that $PM_{10-2.5}$ sites are either suitable or not suitable for comparison to the 24-hour $PM_{10-2.5}$ NAAQS as described in § 58.30(b).

(9) The MSA, CBSA, CSA or other area represented by the monitor.

(c) The annual monitoring network plan must consider the ability of existing and proposed sites to support air quality characterization for areas with relatively high populations of susceptible individuals (e.g., children with asthma), and, for any sites that are being proposed for discontinuance, the effect on data users other than the agency itself, such as nearby States and Tribes or health effects studies.

(d) The annual monitoring network plan must document how States and local agencies provide for the review of changes to a $PM_{2.5}$ monitoring network that impact the location of a violating $PM_{2.5}$ monitor or the creation/change to a community monitoring zone, including a description of the proposed use of spatial averaging for purposes of making comparisons to the annual $PM_{2.5}$ NAAQS as set forth in appendix N to part 50 of this chapter. The affected State or local agency must document the process for providing public hearings and include any comments received through the public notification process within their submitted plan.

(e) The State, or where applicable local, agency shall perform and submit to the EPA Regional Administrator an assessment of the air quality surveillance system every 5 years to determine, at a minimum, if the network meets the monitoring objectives defined in appendix D to this part, whether new sites are needed, whether existing sites are no longer needed and can be terminated, and whether new technologies are appropriate for incorporation into the ambient air monitoring network. For $PM_{2.5}$, the assessment also must identify needed changes to population-oriented sites. The State, or where applicable local, agency must submit a copy of this 5-year assessment, along with a revised annual network plan, to the Regional Administrator. The first assessment is due July 1, 2009. For $PM_{10-2.5}$, each assessment due on or after July 1, 2014 must identify needed changes to the identification of whether each site is suitable or unsuitable for comparison to the NAAQS under the criteria of § 58.30(b), based on changes in emissions sources affecting the site or better information about these sources.

(f) All proposed additions and discontinuations of monitors in annual monitoring network plans and periodic network assessments are subject to approval according to § 58.14.

§ 58.11 Network technical requirements.

(a) State and local governments shall follow the applicable quality assurance criteria contained in appendix A to this part when operating the SLAMS and SPM networks. The owner or operator of an existing or a proposed source shall follow the quality assurance criteria in appendix A to this part that apply to PSD monitoring when operating a PSD site.

(b) State and local governments must follow the criteria in appendix C to this part to determine acceptable monitoring methods or instruments for use in SLAMS networks. Appendix C criteria are optional at SPM stations.

(c) State and local governments must follow the network design criteria contained in appendix D to this part in designing and maintaining the SLAMS stations. The final network design and all changes in design are subject to approval of the Regional Administrator. NCore, STN, and PAMS network design and changes are also subject to approval of the Administrator. Changes in SPM stations do not require approvals, but a change in the designation of a monitoring site from SLAMS to SPM requires approval of the Regional Administrator.

(d) State and local governments must follow the criteria contained in appendix E to this part for siting monitor inlets, paths or probes at SLAMS stations. Appendix E adherence is optional for SPM stations that do not use appendix C methods.

§ 58.12 Operating schedules.

State and local governments shall collect ambient air quality data at any SLAMS station on the following operational schedules:

(a) For continuous analyzers, consecutive hourly averages must be collected except during:

(1) Periods of routine maintenance,

(2) Periods of instrument calibration, or

(3) Periods or monitoring seasons exempted by the Regional Administrator.

(b) For Pb and PM_{10} manual methods, at least one 24-hour sample must be collected every 6 days except during periods or seasons exempted by the Regional Administrator.

(c) For PAMS VOC samplers, samples must be collected as specified in section 5 of appendix D to this part. Area-specific PAMS operating schedules must be included as part of the PAMS network description and must be approved by the Regional Administrator.

(d) For manual $PM_{2.5}$ samplers:

(1) Manual $PM_{2.5}$ samplers at other SLAMS stations must operate on at least a 1-in-3 day schedule at sites without a collocated continuously operating $PM_{2.5}$ monitor. For SLAMS $PM_{2.5}$ sites with both manual and continuous $PM_{2.5}$ monitors operating, the $PM_{2.5}$ manual sampler may be operated with a 1-in-6 day sampling frequency under certain conditions. A monitoring agency may request approval for a reduction to 1-in-6 day $PM_{2.5}$ sampling at SLAMS stations or for seasonal sampling from the EPA Regional Administrator. The EPA Regional Administrator may grant sampling frequency reductions after consideration of the historical $PM_{2.5}$ data quality assessments, the location of current $PM_{2.5}$ design value sites, and their regulatory data needs. Sites that have design values that are within ±10 percent of the NAAQS; and sites where the 24-hour values exceed the NAAQS for a period of 3 years are required to maintain at least a 1-in-3 day sampling frequency.

(2) Manual $PM_{2.5}$ samplers at NCore stations and required regional background and regional transport sites must operate on at least a 1-in-3 day sampling frequency.

(3) Manual $PM_{2.5}$ speciation samplers at STN stations must operate on a 1-in-3 day sampling frequency.

(e) Manual $PM_{10-2.5}$ samplers at SLAMS stations must operate on a daily schedule at sites without a collocated continuously operating equivalent $PM_{10-2.5}$ method that has been designated in accordance with part 53 of this chapter.

§ 58.13 Monitoring network completion.

(a) The network of $PM_{10-2.5}$ sites must be physically established no later than January 1, 2009, and at that time, operating under all of the requirements of this part, including the requirements of appendices A, C, D, E, and G to this part.

(b) The network of NCore multipollutant sites must be physically established no later than January 1, 2011, and at that time, operating under all of the requirements of this part, including the requirements of appendices A, C, D, E, and G to this part.

§ 58.14 System modification.

(a) The State, or where appropriate local, agency shall develop and implement a plan and schedule to modify the ambient air quality monitoring network that complies with the findings of the network assessments required every 5 years by § 58.10(e). The State or local agency shall consult with the EPA Regional Administrator during the development of the schedule to modify the monitoring program, and shall make the plan and schedule available to the public for 30 days prior to submission to the EPA Regional Administrator. The final plan and schedule are subject to the approval of the EPA Regional Administrator, who shall provide opportunity for public comment and shall approve or disapprove the plan and schedule within 120 days.

(b) Nothing in this section shall preclude the State, or where appropriate local, agency from making modifications to the SLAMS network for reasons other than those resulting from the periodic network assessments. These modifications must be reviewed and approved by the Regional Administrator. Each monitoring network may make or be required to make changes between the 5-year assessment periods, including for example, site relocations or the addition of PAMS networks in bumped-up ozone nonattainment areas. These modifications must address changes invoked by a new census and changes due to changing air quality levels. The State, or where appropriate local, agency shall provide written communication describing the network changes to the Regional Administrator for review and approval as these changes are identified.

(c) State, or where appropriate, local agency requests for monitor station discontinuation, subject to the review of the Regional Administrator, will be approved if any of the following criteria are met. Other requests for discontinuation may also be approved on a case by case basis if discontinuance does not compromise data collection needed for implementation of a NAAQS.

(1) Any $PM_{2.5}$, O_3, CO, PM_{10}, SO_2, Pb, or NO_2 monitor which has shown attainment during the previous five years, that has a probability of less than 10 percent of exceeding 80 percent of the applicable NAAQS during the next three years based on the levels, trends, and variability observed in the past, and which is not specifically required by an attainment plan or maintenance plan.

(2) Any monitor for CO, PM_{10}, SO_2, or NO_2 which has consistently measured lower concentrations than another monitor for the same pollutant in the same county and same nonattainment area during the previous five years, and which is not specifically required by an attainment plan or maintenance plan, if control measures scheduled to be implemented or discontinued during the next five years would apply to the areas around both monitors and have similar effects on measured concentrations, such that the retained monitor would remain the higher reading of the two monitors being compared.

(3) For any pollutant, the highest reading monitor (which may be the only monitor) in a county (or portion of a county within a distinct nonattainment or maintenance area) provided the monitor has not measured violations of the applicable NAAQS in the previous five years, the MSA or CSA within which the county lies (if in any) would still meet requirements for the minimum number of monitors for the applicable pollutant if any, and the approved SIP provides for a specific, reproducible approach to representing the air quality of the affected county in the absence of actual monitoring data.

(4) A monitor which EPA has determined cannot be compared to the relevant NAAQS because of the siting of the monitor, in accordance with § 58.30.

(5) A monitor that is designed to measure concentrations upwind of an urban area for purposes of characterizing transport into the area and that has not recorded violations of the relevant NAAQS in the previous five years, if discontinuation of the monitor is tied to start-up of another station also characterizing transport.

§ 58.15 Annual air monitoring data certification.

(a) Beginning May 1, 2009, the State, or where appropriate local, agency shall submit to the EPA Regional Administrator an annual air monitoring data certification letter to certify data collected at all SLAMS and at all SPM stations that meet appendix C and appendix E criteria from January 1 to December 31 of the previous year. The senior air pollution control officer in each agency, or their designee, shall certify that the previous year of ambient concentration and quality assurance data are completely submitted to AQS and that the ambient concentration data are accurate to the best of her or his knowledge, taking into consideration the quality assurance findings.

(b) Along with each certification letter, the State shall submit to the Administrator (through the appropriate Regional Office) an annual summary report of all the ambient air quality data from all monitoring stations designated as SLAMS. The State also shall submit an annual summary to the appropriate Regional Administrator of all the ambient air quality monitoring data from all FRM, FEM, and ARM at SPM stations that are described in the State's current monitoring network description. The annual report(s) shall be submitted for data collected from January 1 to December 31 of the previous year. The annual summary report(s) must contain all information and data required by the State's approved plan and be submitted by July 1 of each year, unless an approved alternative date is included in the plan. The annual summary serves as the record of the specific data that is the object of the certification letter.

§ 58.16 Data submittal.

(a) The State, or where appropriate, local agency, shall report to the Administrator, via AQS all ambient air quality data and associated quality assurance data for SO_2, CO, O_3, NO_2, NO, NO_Y, Pb, PM_{10}, $PM_{2.5}$ mass concentration, for filter-based $PM_{2.5}$ FRM/FEM (field blank mass, sampler-generated average daily temperature, sampler-generated average daily pressure), chemically speciated $PM_{2.5}$ mass concentration data, $PM_{10-2.5}$ (mass concentration and chemically speciated data), meteorological data from NCore and PAMS sites, and metadata records and information specified by the AQS Data Coding Manual (*http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm*). Such air quality data and

information must be submitted directly to the AQS via electronic transmission on the specified quarterly schedule described in paragraph (b) of this section.

(b) The specific quarterly reporting periods are January 1–March 31, April 1–June 30, July 1–September 30, and October 1–December 31. The data and information reported for each reporting period must contain all data and information gathered during the reporting period, and be received in the AQS within 90 days after the end of the quarterly reporting period. For example, the data for the reporting period January 1–March 31 are due on or before June 30 of that year.

(c) Air quality data submitted for each reporting period must be edited, validated, and entered into the AQS (within the time limits specified in paragraph (b) of this section) pursuant to appropriate AQS procedures. The procedures for editing and validating data are described in the AQS Data Coding Manual and in each monitoring agency's quality assurance project plan.

(d) The State shall report VOC and if collected, carbonyl, NH_3, and HNO_3 data, from PAMS sites to AQS within 6 months following the end of each quarterly reporting period listed in paragraph (b) of this section.

(e) The State shall also submit any portion or all of the SLAMS and SPM data to the appropriate Regional Administrator upon request.

Subpart C—Special Purpose Monitors

37. The heading for subpart C is revised as set forth above.

38. Section 58.20 is revised to read as follows:

§ 58.20 Special purpose monitors (SPM).

(a) An SPM is defined as any monitor included in an agency's monitoring network that the agency has designated as a special purpose monitor in its annual monitoring network plan and in AQS, and which the agency does not count when showing compliance with the minimum requirements of this subpart for the number and siting of monitors of various types. Any SPM operated by an air monitoring agency must be included in the periodic assessments and annual monitoring network plan required by § 58.10. The plan shall include a statement of purpose for each SPM monitor and a evidence that siting and operation of each monitor meets the requirements of appendix A where applicable. The monitoring agency may designate a monitor as an SPM after January 1, 2007 only if it is a new monitor not previously included in the monitoring plan.

(b) Any SPM data collected by an air monitoring agency using a Federal reference method (FRM), Federal equivalent method (FEM), or approved regional method (ARM) must meet the requirements of § 58.11, § 58.12, and appendices A and C to this part. Compliance with appendix E to this part is optional but encouraged except when the monitoring agency's data objectives are inconsistent with those requirements. Data collected at an SPM meeting these requirements must be submitted to AQS according to the requirements of § 58.16. The monitoring agency must also submit to AQS an indication of whether the monitor meets the requirements of appendix E to this part.

(c) All data from an SPM using an FRM, FEM, or ARM which has operated for more than 24 months is eligible for comparison to the relevant NAAQS, subject to the conditions of § 58.30, unless the air monitoring agency demonstrates in the documentation required in paragraph (a) of this section that the data from a particular period does not meet the requirements in paragraph (b) of this section.

(d) If an SPM using an FRM, FEM, or ARM is discontinued within 24 months of start-up, the Administrator will not use data from the SPM for NAAQS violation determinations for the $PM_{2.5}$, $PM_{10\text{-}2.5}$, ozone, or the annual PM_{10} NAAQS.

(e) If an SPM using an FRM, FEM, or ARM is discontinued within 24 months of start-up, the Administrator will not use data from the SPM for NAAQS violation determinations for purposes of designating an area as nonattainment, for the CO, SO_2, NO_2, Pb, or 24-hour PM_{10} NAAQS. Such data are eligible for use in determinations of whether a nonattainment area has attained one of these NAAQS.

(f) Prior approval from EPA is not required for discontinuance of an SPM.

39. Sections 58.21 through 58.28 are removed.

Subpart D—Comparability of Ambient Data to NAAQS

40. The heading for subpart D is revised as set forth above.

41. Section 58.30 is revised to read as follows:

§ 58.30 Special considerations for data comparisons to the NAAQS.

(a) *Comparability of $PM_{2.5}$* data. (1) There are two forms of the $PM_{2.5}$ NAAQS described in part 50 of this chapter. The $PM_{2.5}$ monitoring site characteristics (see appendix D, section 4.7.1) impact how the resulting $PM_{2.5}$ data can be compared to the annual $PM_{2.5}$ NAAQS form. $PM_{2.5}$ data that are representative, not of areawide but rather, of relatively unique population-oriented microscale, or localized hot spot, or unique population-oriented middle-scale impact sites are only eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS. For example, if the $PM_{2.5}$ monitoring site is adjacent to a unique dominating local $PM_{2.5}$ source or can be shown to have average 24-hour concentrations representative of a smaller than neighborhood spatial scale, then data from a monitor at the site would only be eligible for comparison to the 24-hour $PM_{2.5}$ NAAQS.

(2) There are cases where certain population-oriented, microscale or middle scale $PM_{2.5}$ monitoring sites are determined by the Regional Administrator to collectively identify a larger region of localized high ambient $PM_{2.5}$ concentrations. In those cases, data from these population-oriented sites would be eligible for comparison to the annual $PM_{2.5}$ NAAQS.

(b) *Comparability of $PM_{10\text{-}2.5}$ data.* To be eligible (or suitable) for comparison to the $PM_{10\text{-}2.5}$ NAAQS, $PM_{10\text{-}2.5}$ data must be from a monitoring site that meets all five of the following conditions.

(1) The site must be within the boundaries of an urbanized area as defined by the U.S. Bureau of the Census which has a population of at least 100,000 persons.

(2) The site must be in a census block group with a population density of 500 or more persons per square mile. Alternatively, the site may be in a census block group with a lower population density if the block group is part of an enclave that is not more than five square miles in land area.

(3) The site must be population-oriented.

(4) The site may not be in source-influenced microenvironments (such as a microscale or localized hot spot site) not eligible for comparison to the annual $PM_{2.5}$ NAAQS under the conditions of paragraph (a) of this section. For example, if the $PM_{10\text{-}2.5}$ monitoring site is located on the fenceline of a dominating local $PM_{10\text{-}2.5}$ source, then data from a monitor at the site would not be eligible for comparison to the 24-hour $PM_{10\text{-}2.5}$ NAAQS.

(5) $PM_{10\text{-}2.5}$ concentrations at the site must be dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and must not be dominated by rural windblown dust and soils and PM generated by

agricultural and mining sources, as determined by the State (and approved by the Regional Administrator) in a site-specific assessment. The site-specific assessment shall consider the types and sizes of sources that may impact the site, the impact of meteorological conditions on site-source relationships, verification that the site is not exposed to windblown rural dust and soil or emissions from agriculture and mining to such an extent that those sources would dominate the mix of $PM_{10-2.5}$ sampled at that site, and other factors necessary for completing the assessment.

42. Sections 58.31 through 58.36 are removed.

Subpart E—[Removed and Reserved]

43. Subpart E of part 58 is removed and reserved.

Subpart F—[Amended]

44. Section 58.50 is revised to read as follows:

§ 58.50 Index reporting.

(a) The State or where applicable, local agency shall report to the general public on a daily basis through prominent notice an air quality index that complies with the requirements of appendix G to this part.

(b) Reporting is required for all individual MSA with a population exceeding 350,000.

(c) The population of a MSA for purposes of index reporting is the most recent decennial U.S. census population.

Subpart G—[Amended]

45. Sections 58.60 and 58.61 are revised to read as follows:

§ 58.60 Federal monitoring.

The Administrator may locate and operate an ambient air monitoring site if the State or local agency fails to locate, or schedule to be located, during the initial network design process, or as a result of the 5-year network assessments required within § 58.10, a SLAMS station at a site which is necessary in the judgement of the Regional Administrator to meet the objectives defined in appendix D to this part.

§ 58.61 Monitoring other pollutants.

The Administrator may promulgate criteria similar to that referenced in subpart B of this part for monitoring a pollutant for which an NAAQS does not exist. Such an action would be taken whenever the Administrator determines that a nationwide monitoring program is necessary to monitor such a pollutant.

49. Appendix A to part 58 is revised to read as follows:

Appendix A to Part 58—Quality Assurance Requirements for SLAMS, NCore, and PSD Air Monitoring

1. General Information.
2. Quality System Requirements.
3. Measurement Quality Check Requirements.
4. Calculations for Data Quality Assessments.
5. Reporting Requirements.
6. References.

1. *General Information.*

This appendix specifies the minimum quality system requirements applicable to SLAMS air monitoring data and PSD data submitted to EPA. In this section, NCore stations and SPM stations (using FRM, FEM, or ARM methods) are considered a subset of the SLAMS network. Monitoring organizations are encouraged to develop and maintain quality systems more extensive than the required minimums. The permit-granting authority for PSD may require more frequent or more stringent requirements. Monitoring organizations may, based on their quality objectives, be required to develop and maintain quality systems beyond the required minimum. Additional guidance for the requirements reflected in this appendix can be found in the ''Quality Assurance Handbook for Air Pollution Measurement Systems'', volume II, part 1 (see reference 10 of this appendix) and at a national level in references 1, 2, and 3 of this appendix.

1.1 Similarities and Differences Between SLAMS and PSD Monitoring. In most cases, the quality assurance requirements for SLAMS and PSD are the same. Table A–1 of this appendix summarizes the major similarities and differences of the requirements for SLAMS and PSD. Both programs require:

(a) The development, documentation, and implementation of an approved quality system;

(b) The assessment of data quality;

(c) The use of reference, equivalent, or approved methods (optional for SPM);

(d) The use of calibration standards traceable to NIST or other primary standard;

(e) Performance evaluations and systems.

1.1.1 The monitoring and quality assurance responsibilities for SLAMS are with the State or local agency, hereafter called the monitoring organization, whereas for PSD they are with the owner/operator seeking the permit. The monitoring duration for SLAMS is indefinite, whereas for PSD the duration is usually 12 months. Whereas the reporting period for precision and accuracy data is on an annual or calendar quarter basis for SLAMS, it is on a continuing sampler quarter basis for PSD—since the monitoring may not commence at the beginning of a calendar quarter.

1.1.2 The performance evaluations for PSD must be conducted by personnel different from those who perform routine span checks and calibrations, whereas for SLAMS, it is the preferred but not the required condition. For PSD, the evaluation rate is 100 percent of the sites per reporting quarter whereas for SLAMS it is 25 percent of the sites or instruments quarterly. Note that monitoring for sulfur dioxide (SO_2) and nitrogen dioxide (NO_2) for PSD must be done with automated analyzers—the manual bubbler methods are not permitted.

1.1.3 The requirements for precision assessment for the automated methods are the same for both SLAMS and PSD. However, for manual methods, only one collocated site is required for PSD.

1.1.4 The precision, accuracy and bias data for PSD are reported separately for each sampler (site), whereas for SLAMS, the report may be by sampler (site) or primary quality assurance organization, depending on the pollutant. SLAMS data are required to be reported to the AQS, PSD data are required to be reported to the permit-granting authority. Requirements in this appendix, with the exception to the differences discussed in this section, and in Table A–1 of this appendix will be expected to be followed by both SLAMS and PSD networks unless directly specified in a particular section.

1.2 Measurement Uncertainty. Measurement uncertainty is a term used to describe deviations from a true concentration or estimate that are related to the measurement process and not to spatial or temporal population attributes of the air being measured. Monitoring organizations must develop quality assurance project plans (QAPP) which describe how the organization intends to control measurement uncertainty to an appropriate level in order to achieve the data quality objectives. Data quality indicators associated with measurement uncertainty include:

(a) Precision. A measurement of mutual agreement among individual measurements of the same property usually under prescribed similar conditions, expressed generally in terms of the standard deviation.

(b) Bias. The systematic or persistent distortion of a measurement process which causes errors in one direction.

(c) Accuracy. The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (imprecision) and systematic error (bias) components which are due to sampling and analytical operations.

(d) Completeness. A measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions.

(e) Detectability. The low critical range value of a characteristic that a method specific procedure can reliably discern.

1.3 Measurement Quality Checks. The SLAMS measurement quality checks described in sections 3.2 and 3.3 of this appendix shall be reported to AQS and are included in the data required for certification. The PSD network is required to implement the measurement quality checks and submit this information quarterly along with assessment information to the permit-granting authority.

1.4 Assessments and Reports. Periodic assessments and documentation of data quality are required to be reported to EPA or to the permit granting authority (PSD). To

provide national uniformity in this assessment and reporting of data quality for all networks, specific assessment and reporting procedures are prescribed in detail in sections 3, 4, and 5 of this appendix. On the other hand, the selection and extent of the quality assurance and quality control activities used by a monitoring organization depend on a number of local factors such as field and laboratory conditions, the objectives for monitoring, the level of data quality needed, the expertise of assigned personnel, the cost of control procedures, pollutant concentration levels, etc. Therefore, quality system requirements in section 2 of this appendix are specified in general terms to allow each monitoring organization to develop a quality system that is most efficient and effective for its own circumstances while achieving the data quality objectives required for the SLAMS sites.

2. *Quality System Requirements.*

A quality system is the means by which an organization manages the quality of the monitoring information it produces in a systematic, organized manner. It provides a framework for planning, implementing, assessing and reporting work performed by an organization and for carrying out required quality assurance and quality control activities.

2.1 Quality Management Plans and Quality Assurance Project Plans. All monitoring organizations must develop a quality system that is described and approved in quality management plans (QMP) and quality assurance project plans (QAPP) to ensure that the monitoring results:

(a) Meet a well-defined need, use, or purpose;

(b) Provide data of adequate quality for the intended monitoring objectives;

(c) Satisfy stakeholder expectations;

(d) Comply with applicable standards specifications;

(e) Comply with statutory (and other) requirements of society; and

(f) Reflect consideration of cost and economics.

2.1.1 The QMP describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, assessing and reporting activities involving environmental data operations (EDO). The QMP must be suitably documented in accordance with EPA requirements (reference 2 of this appendix), and approved by the appropriate Regional Administrator, or Regional Administrator's designee. The quality system will be reviewed during the systems audits described in section 2.5 of this appendix. Organizations that implement long-term monitoring programs with EPA funds should have a separate QMP document. Smaller organizations or organizations that do infrequent work with EPA funds may combine the QMP with the QAPP based on negotiations with the funding agency. Additional guidance on this process can be found in reference 10 of this appendix. Approval of the recipient's QMP by the appropriate Regional Administrator, or the Regional Administrator's designee, may allow delegation of the authority to review and approve QAPP to the recipient, based on adequacy of quality assurance procedures described and documented in the QMP. The QAPP will be reviewed by EPA during systems audits or circumstances related to data quality.

2.1.2 The QAPP is a formal document describing, in sufficient detail, the quality system that must be implemented to ensure that the results of work performed will satisfy the stated objectives. The quality assurance policy of the EPA requires every EDO to have written and approved QAPP prior to the start of the EDO. It is the responsibility of the monitoring organization to adhere to this policy. The QAPP must be suitably documented in accordance with EPA requirements (reference 3 of this appendix).

2.1.3 The monitoring organizations' quality system must have adequate resources both in personnel and funding to plan, implement, assess and report on the achievement of the requirements of this appendix and its approved QAPP.

2.2 Independence of Quality Assurance. The monitoring organization must provide for a quality assurance management function; that aspect of the overall management system of the organization that determines and implements the quality policy defined in a monitoring organization's QMP. Quality management includes strategic planning, allocation of resources and other systematic planning activities (e.g. planning, implementation, assessing and reporting) pertaining to the quality system. The quality assurance management function must have sufficient technical expertise and management authority to conduct independent oversight and assure the implementation of the organization's quality system relative to the Ambient Air Quality Monitoring Program and should be organizationally independent of environmental data generation activities.

2.3 Data Quality Performance Requirements.

2.3.1 Data Quality Objectives. Data quality objectives (DQO) or the results of other systematic planning processes are statements that define the appropriate type of data to collect and specify the tolerable levels of potential decision errors that will be used as a basis for establishing the quality and quantity of data needed to support the objectives of the SLAMS stations. DQO will be developed by EPA to support the primary SLAMS objectives for each criteria pollutant. As they are developed they will be added to the regulation. DQO or the results of other systematic planning processes for PSD or other monitoring will be the responsibility of the monitoring organizations. The quality of the conclusions made from data interpretation can be affected by population uncertainty (spatial or temporal uncertainty) and measurement uncertainty (uncertainty associated with collecting, analyzing, reducing and reporting concentration data). This appendix focuses on assessing and controlling measurement uncertainty.

2.3.1.1 Measurement Uncertainty for Automated and Manual $PM_{2.5}$ Methods. The goal for acceptable measurement uncertainty is defined as 10 percent coefficient of variation (CV) for total precision and ± 10 percent for total bias.

2.3.1.2 Measurement Uncertainty for Automated Ozone Methods. The goal for acceptable measurement uncertainty is defined for precision as an upper 90 percent confidence limit for the coefficient variation (CV) of 7 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 7 percent.

2.3.1.3 Measurement Uncertainty for $PM_{10\text{-}2.5}$ Methods. The goal for acceptable measurement uncertainty is defined for precision as an upper 90 percent confidence limit for the coefficient variation (CV) of 15 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

2.4 National Performance Evaluation Programs. Monitoring plans or QAPP shall provide for the implementation of a program of independent and adequate audits of all monitors providing data for SLAMS and PSD including the provision of adequate resources for such audit programs. A monitoring plan (or QAPP) which provides for monitoring organization participation in EPA's National Performance Audit Program (NPAP) and the PM Performance Evaluation Program (PEP) program and which indicates the consent of the monitoring organization for EPA to apply an appropriate portion of the grant funds, which EPA would otherwise award to the monitoring organization for monitoring activities, will be deemed by EPA to meet this requirement. For clarification and to participate, monitoring organizations should contact either the appropriate EPA Regional Quality Assurance (QA) Coordinator at the appropriate EPA Regional Office location, or the NPEP Coordinator, Emissions Monitoring and Analysis Division (D205–02), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

2.5 Technical Systems Audit Program. Technical systems audits of each ambient air monitoring organization shall be conducted at least every 3 years by the appropriate EPA Regional Office and reported to the AQS. Systems audit programs are described in reference 10 of this appendix. For further instructions, monitoring organizations should contact the appropriate EPA Regional QA Coordinator.

2.6 Gaseous and Flow Rate Audit Standards.

2.6.1 Gaseous pollutant concentration standards (permeation devices or cylinders of compressed gas) used to obtain test concentrations for carbon monoxide (CO), sulfur dioxide (SO_2), nitrogen oxide (NO), and nitrogen dioxide (NO_2) must be traceable to either a National Institute of Standards and Technology (NIST) Traceable Reference Material (NTRM) or a NIST-certified Gas Manufacturer's Internal Standard (GMIS), certified in accordance with one of the procedures given in reference 4 of this appendix. Vendors advertizing certification with the procedures provided in reference 4 of this appendix and distributing gasses as ''EPA Protocol Gas'' must participate in the EPA Protocol Gas Verification Program or not use ''EPA'' in any form of advertizing.

2.6.2 Test concentrations for ozone (O_3) must be obtained in accordance with the

ultra violet photometric calibration procedure specified in appendix D to part 50 of this chapter, or by means of a certified O_3 transfer standard. Consult references 7 and 8 of this appendix for guidance on primary and transfer standards for O_3.

2.6.3 Flow rate measurements must be made by a flow measuring instrument that is traceable to an authoritative volume or other applicable standard. Guidance for certifying some types of flowmeters is provided in reference 10 of this appendix.

2.7 Primary Requirements and Guidance. Requirements and guidance documents for developing the quality system are contained in references 1 through 10 of this appendix, which also contain many suggested procedures, checks, and control specifications. Reference 10 of this appendix describes specific guidance for the development of a quality system for SLAMS. Many specific quality control checks and specifications for methods are included in the respective reference methods described in part 50 of this chapter or in the respective equivalent method descriptions available from EPA (reference 6 of this appendix). Similarly, quality control procedures related to specifically designated reference and equivalent method analyzers are contained in the respective operation or instruction manuals associated with those analyzers.

3. *Measurement Quality Check Requirements.*

This section provides the requirements for performing the measurement quality checks that can be used to assess data quality and with the exception of the flow rate verifications (sections 3.2.3 and 3.3.2 of this appendix) are required to be submitted to the AQS within the same time frame requirements as routine data. Section 3.2 of this appendix describes checks of automated or continuous instruments while section 3.3 describe checks associated with manual sampling instruments. Other quality control samples are identified in the various references described earlier and can be used to control certain aspects of the measurement system.

3.1 Primary Quality Assurance Organization. Estimates of data quality will be calculated on the basis of single monitors, and primary quality assurance organizations. A primary quality assurance organization is defined as a monitoring organization or other organization that is responsible for a set of stations that monitors the same pollutant and for which data quality assessments can be pooled. Each criteria pollutant sampler/monitor at a monitoring station in the SLAMS network must be associated with one, and only one, primary quality assurance organization.

3.1.1 Each primary quality assurance organization shall be defined such that measurement uncertainty among all stations in the organization can be expected to be reasonably homogeneous, as a result of common factors. Common factors that should be considered by monitoring organizations in defining primary quality assurance organizations include:

(a) Operation by a common team of field operators according to a common set of procedures;

(b) Use of a common QAPP or standard operating procedures;

(c) Common calibration facilities and standards;

(d) Oversight by a common quality assurance organization; and

(e) Support by a common management, laboratory or headquarters.

3.1.2 Primary quality assurance organizations are not necessarily related to the organization reporting data to the AQS. Monitoring organizations having difficulty in defining the primary quality assurance organizations or in assigning specific sites to primary quality assurance organizations should consult with the appropriate EPA Regional Office. All definitions of primary quality assurance organizations shall be subject to final approval by the appropriate EPA Regional Office during scheduled network reviews or systems audits.

3.1.3 Assessment results shall be reported as specified in section 5 of this appendix.

3.2 Measurement Quality Checks of Automated Methods. Table A–2 of this appendix provides a summary of the types and frequency of the measurement quality checks that will be described in this section.

3.2.1 One-Point Quality Control Check for SO_2, NO_2, O_3, and CO. A one-point quality control (QC) check must be performed at least once every 2 weeks on each automated analyzer used to measure SO_2, NO_2, O_3 and CO. The frequency of QC checks may be reduced based upon review, assessment and approval of the EPA Regional Administrator. However, with the advent of automated calibration systems more frequent checking is encouraged. See Reference 10 of this appendix for guidance on the review procedure. The QC check is made by challenging the analyzer with a QC check gas of known concentration (effective concentration for open path analyzers) between 0.01 and 0.10 parts per million (ppm) for SO_2, NO_2, and O_3, and between 1 and 10 ppm for CO analyzers. The ranges allow for appropriate check gas selection for SLAMS sites that may be sampling for different objectives, i.e., trace gas monitoring vs. comparison to National Ambient Air Quality Standards (NAAQS). It is suggested that the QC check gas concentration selected should be related to the routine concentrations normally measured at sites within the monitoring network in order to appropriately reflect the precision and bias at these routine concentration ranges. To check the precision and bias of SLAMS analyzers operating at ranges either above or below the levels identified, use check gases of appropriate concentrations as approved by the appropriate EPA Regional Administrator or their designee. The standards from which check concentrations are obtained must meet the specifications of section 2.6 of this appendix.

3.2.1.1 Except for certain CO analyzers described below, point analyzers must operate in their normal sampling mode during the QC check, and the test atmosphere must pass through all filters, scrubbers, conditioners and other components used during normal ambient sampling and as much of the ambient air inlet system as is practicable. If permitted by the associated operation or instruction manual, a CO point analyzer may be temporarily modified during the QC check to reduce vent or purge flows, or the test atmosphere may enter the analyzer at a point other than the normal sample inlet, provided that the analyzer's response is not likely to be altered by these deviations from the normal operational mode. If a QC check is made in conjunction with a zero or span adjustment, it must be made prior to such zero or span adjustments.

3.2.1.2 Open path analyzers are tested by inserting a test cell containing a QC check gas concentration into the optical measurement beam of the instrument. If possible, the normally used transmitter, receiver, and as appropriate, reflecting devices should be used during the test and the normal monitoring configuration of the instrument should be altered as little as possible to accommodate the test cell for the test. However, if permitted by the associated operation or instruction manual, an alternate local light source or an alternate optical path that does not include the normal atmospheric monitoring path may be used. The actual concentration of the QC check gas in the test cell must be selected to produce an effective concentration in the range specified earlier in this section. Generally, the QC test concentration measurement will be the sum of the atmospheric pollutant concentration and the QC test concentration. If so, the result must be corrected to remove the atmospheric concentration contribution. The corrected concentration is obtained by subtracting the average of the atmospheric concentrations measured by the open path instrument under test immediately before and immediately after the QC test from the QC check gas concentration measurement. If the difference between these before and after measurements is greater than 20 percent of the effective concentration of the test gas, discard the test result and repeat the test. If possible, open path analyzers should be tested during periods when the atmospheric pollutant concentrations are relatively low and steady.

3.2.1.3 Report the audit concentration (effective concentration for open path analyzers) of the QC gas and the corresponding measured concentration (corrected concentration, if applicable, for open path analyzers) indicated by the analyzer. The percent differences between these concentrations are used to assess the precision and bias of the monitoring data as described in sections 4.1.2 (precision) and 4.1.3 (bias) of this appendix.

3.2.2 Performance evaluation for SO_2, NO_2, O_3, or CO. Each calendar quarter (during which analyzers are operated), evaluate at least 25 percent of the SLAMS analyzers that monitor for SO_2, NO_2, O_3, or CO such that each analyzer is evaluated at least once per year. If there are fewer than four analyzers for a pollutant within a primary quality assurance organization, it is suggested to randomly evaluate one or more analyzers so that at least one analyzer for that pollutant is evaluated each calendar quarter. Where possible, EPA strongly encourages more frequent evaluations, up to a frequency of once per quarter for each SLAMS analyzer. It is also suggested that the evaluation be

conducted by a trained experienced technician other than the routine site operator.

3.2.2.1 (a) The evaluation is made by challenging the analyzer with audit gas standard of known concentration (effective concentration for open path analyzers) from at least three consecutive ranges that are applicable to the analyzer being evaluated:

Audit level	Concentration range, ppm			
	O_3	SO_2	NO_2	CO
1	0.02–0.05	0.0003–0.005	0.0002–0.002	0.08–0.10
2	0.06–0.10	0.006–0.01	0.003–0.005	0.50–1.00
3	0.11–0.20	0.02–0.10	0.006–0.10	1.50–4.00
4	0.21–0.30	0.11–0.40	0.11–0.30	5–15
5	0.31–0.90	0.41–0.90	0.31–0.60	20–50

(b) An additional 4th range is encouraged for those monitors that have the potential for exceeding the concentration ranges described by the initial three selected.

3.2.2.2(a) NO_2 audit gas for chemiluminescence-type NO_2 analyzers must also contain at least 0.08 ppm NO. NO concentrations substantially higher than 0.08 ppm, as may occur when using some gas phase titration (GPT) techniques, may lead to evaluation errors in chemiluminescence analyzers due to inevitable minor NO–NO_X channel imbalance. Such errors may be atypical of routine monitoring errors to the extent that such NO concentrations exceed typical ambient NO concentrations at the site. These errors may be minimized by modifying the GPT technique to lower the NO concentrations remaining in the NO_2 audit gas to levels closer to typical ambient NO concentrations at the site.

(b) To evaluate SLAMS analyzers operating on ranges higher than 0 to 1.0 ppm for SO_2, NO_2, and O_3 or 0 to 50 ppm for CO, use audit gases of appropriately higher concentration as approved by the appropriate EPA Regional Administrator or the Administrators's designee.

3.2.2.3 The standards from which audit gas test concentrations are obtained must meet the specifications of section 2.6 of this appendix. The gas standards and equipment used for evaluations must not be the same as the standards and equipment used for calibration or calibration span adjustments. For SLAMS sites, the auditor should not be the operator or analyst who conducts the routine monitoring, calibration, and analysis. For PSD sites the auditor must not be the operator or analyst who conducts the routine monitoring, calibration, and analysis.

3.2.2.4 For point analyzers, the evaluation shall be carried out by allowing the analyzer to analyze the audit gas test atmosphere in its normal sampling mode such that the test atmosphere passes through all filters, scrubbers, conditioners, and other sample inlet components used during normal ambient sampling and as much of the ambient air inlet system as is practicable. The exception provided in section 3.2.1 of this appendix for certain CO analyzers does not apply for evaluations.

3.2.2.5 Open path analyzers are evaluated by inserting a test cell containing the various audit gas concentrations into the optical measurement beam of the instrument. If possible, the normally used transmitter, receiver, and, as appropriate, reflecting devices should be used during the evaluation, and the normal monitoring configuration of the instrument should be modified as little as possible to accommodate the test cell for the evaluation. However, if permitted by the associated operation or instruction manual, an alternate local light source or an alternate optical path that does not include the normal atmospheric monitoring path may be used. The actual concentrations of the audit gas in the test cell must be selected to produce effective concentrations in the evaluation level ranges specified in this section of this appendix. Generally, each evaluation concentration measurement result will be the sum of the atmospheric pollutant concentration and the evaluation test concentration. If so, the result must be corrected to remove the atmospheric concentration contribution. The corrected concentration is obtained by subtracting the average of the atmospheric concentrations measured by the open path instrument under test immediately before and immediately after the evaluation test (or preferably before and after each evaluation concentration level) from the evaluation concentration measurement. If the difference between the before and after measurements is greater than 20 percent of the effective concentration of the test gas standard, discard the test result for that concentration level and repeat the test for that level. If possible, open path analyzers should be evaluated during periods when the atmospheric pollutant concentrations are relatively low and steady. Also, the monitoring path length must be reverified to within ±3 percent to validate the evaluation, since the monitoring path length is critical to the determination of the effective concentration.

3.2.2.6 Report both the evaluation concentrations (effective concentrations for open path analyzers) of the audit gases and the corresponding measured concentration (corrected concentrations, if applicable, for open path analyzers) indicated or produced by the analyzer being tested. The percent differences between these concentrations are used to assess the quality of the monitoring data as described in section 4.1.4 of this appendix.

3.2.3 Flow Rate Verification for Particulate Matter. A one-point flow rate verification check must be performed at least once every month on each automated analyzer used to measure PM_{10}, $PM_{10\text{-}2.5}$ and $PM_{2.5}$. The verification is made by checking the operational flow rate of the analyzer. If the verification is made in conjunction with a flow rate adjustment, it must be made prior to such flow rate adjustment. Randomization of the flow rate verification with respect to time of day, day of week, and routine service and adjustments is encouraged where possible. For the standard procedure, use a flow rate transfer standard certified in accordance with section 2.6 of this appendix to check the analyzer's normal flow rate. Care should be used in selecting and using the flow rate measurement device such that it does not alter the normal operating flow rate of the analyzer. Report the flow rate of the transfer standard and the corresponding flow rate measured (indicated) by the analyzer. The percent differences between the audit and measured flow rates are used to assess the bias of the monitoring data as described in section 4.2.2 of this appendix (using flow rates in lieu of concentrations).

3.2.4 Semi-Annual Flow Rate Audit for Particulate Matter. Every 6 months, audit the flow rate of the PM_{10}, $PM_{10\text{-}2.5}$ and $PM_{2.5}$ particulate analyzers. Where possible, EPA strongly encourages more frequent auditing. It is also suggested that the audit be conducted by a trained experienced technician other than the routine site operator. The audit is made by measuring the analyzer's normal operating flow rate using a flow rate transfer standard certified in accordance with section 2.6 of this appendix. The flow rate standard used for auditing must not be the same flow rate standard used to calibrate the analyzer. However, both the calibration standard and the audit standard may be referenced to the same primary flow rate or volume standard. Great care must be used in auditing the flow rate to be certain that the flow measurement device does not alter the normal operating flow rate of the analyzer. Report the audit flow rate of the transfer standard and the corresponding flow rate measured (indicated) by the analyzer. The percent differences between these flow rates are used to validate the one-point flow rate verification checks used to estimate bias as described in section 4.2.3 of this appendix.

3.2.5 Collocated Procedures for $PM_{10\text{-}2.5}$ and $PM_{2.5}$. For each pair of collocated monitors, designate one sampler as the primary monitor whose concentrations will be used to report air quality for the site, and designate the other as the audit monitor.

3.2.5.1 Each EPA designated Federal reference method (FRM) or Federal equivalent method (FEM) within a primary quality assurance organization must:

(a) Have 15 percent of the monitors collocated (values of .5 and greater round up); and

(b) Have at least 1 collocated monitor (if the total number of monitors is less than 3).

The first collocated monitor must be a designated FRM monitor.

3.2.5.2 In addition, monitors selected for collocation must also meet the following requirements:

(a) A primary monitor designated as an EPA FRM shall be collocated with an audit monitor having the same EPA FRM method designation.

(b) For each primary monitor designated as an EPA FEM, 50 percent of the monitors designated for collocation shall be collocated with an audit monitor having the same method designation and 50 percent of the monitors shall be collocated with an FRM audit monitor. If the primary quality assurance organization only has one FEM monitor it shall be collocated with an FRM audit monitor. If there are an odd number of collocated monitors required, the additional monitor shall be an FRM audit monitor. An example of this procedure is found in Table A–3 of this appendix.

3.2.5.3 The collocated monitors should be deployed according to the following protocol:

(a) 80 percent of the collocated audit monitors should be deployed at sites with annual average or daily concentrations estimated to be within ± 20 percent of the applicable NAAQS and the remainder at what the monitoring organizations designate as high value sites;

(b) If an organization has no sites with annual average or daily concentrations within ± 20 percent of the annual NAAQS (or 24-hour NAAQS if that is affecting the area), 60 percent of the collocated audit monitors should be deployed at those sites with the annual mean concentrations (or 24-hour NAAQS if that is affecting the area) among the highest 25 percent for all sites in the network.

3.2.5.4 In determining the number of collocated sites required for $PM_{2.5}$, monitoring networks for visibility assessments should not be treated independently from networks for particulate matter, as the separate networks may share one or more common samplers. However, for Class I visibility areas, EPA will accept visibility aerosol mass measurement instead of a $PM_{2.5}$ measurement if the latter measurement is unavailable. Any $PM_{2.5}$ monitoring site which does not have a monitor which is an EPA FRM or FEM is not required to be included in the number of sites which are used to determine the number of collocated monitors.

3.2.5.5 For each PSD monitoring network, one site must be collocated. A site with the predicted highest 24-hour pollutant concentration must be selected.

3.2.5.6 The two collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference. Calibration, sampling, and analysis must be the same for both collocated samplers and the same as for all other samplers in the network.

3.2.5.7 Sample the collocated audit monitor for SLAMS sites on a 12-day schedule; sample PSD sites on a 6-day schedule or every third day for PSD daily monitors. If a primary quality assurance organization has only one collocated monitor, higher sampling frequencies than the 12-day schedule may be needed in order to produce ~25 valid sample pairs a year. Report the measurements from both primary and collocated audit monitors at each collocated sampling site. The calculations for evaluating precision between the two collocated monitors are described in section 4.3.1 of this appendix.

3.2.6 Performance Evaluation Procedures for $PM_{10-2.5}$ and $PM_{2.5}$. (a) The performance evaluation is an independent assessment used to estimate total measurement system bias. These evaluations will be performed under the PM Performance Evaluation Program (PEP) (section 2.4 of this appendix) or a comparable program. Performance evaluations will be performed on the SLAMS monitors annually within each primary quality assurance organization. For primary quality assurance organizations with less than or equal to five monitoring sites, five valid performance evaluation audits must be collected and reported each year. For primary quality assurance organizations with greater than five monitoring sites, eight valid performance evaluation audits must be collected and reported each year. A valid performance evaluation audit means that both the primary monitor and PEP audit concentrations are valid and above 3 $\mu g/m^3$. Additionally, each year, every designated FRM or FEM within a primary quality assurance organization must:

(1) Have each method designation evaluated each year; and,

(2) Have all FRM or FEM samplers subject to an PEP audit at least once every six years; which equates to approximately 15 percent of the monitoring sites audited each year.

(b) Additional information concerning the Performance Evaluation Program is contained in reference 10 of this appendix. The calculations for evaluating bias between the primary monitor and the performance evaluation monitor for $PM_{2.5}$ are described in section 4.3.2 of this appendix. The calculations for evaluating bias between the primary monitor(s) and the performance evaluation monitors for $PM_{10-2.5}$ are described in section 4.1.3 of this appendix.

3.3 Measurement Quality Checks of Manual Methods. Table A–2 of this appendix provides a summary of the types and frequency of the measurement quality checks that will be described in this section.

3.3.1 Collocated Procedures for PM_{10}. For each network of manual PM_{10} methods, select 15 percent (or at least one) of the monitoring sites within the primary quality assurance organization for collocated sampling. For purposes of precision assessment, networks for measuring total suspended particulate (TSP) and PM_{10} shall be considered separately from one another. PM_{10} and TSP sites having annual mean particulate matter concentrations among the highest 25 percent of the annual mean concentrations for all the sites in the network must be selected or, if such sites are impractical, alternative sites approved by the EPA Regional Administrator may be selected.

3.3.1.1 In determining the number of collocated sites required for PM_{10}, monitoring networks for lead (Pb) should be treated independently from networks for particulate matter (PM), even though the separate networks may share one or more common samplers. However, a single pair of samplers collocated at a common-sampler monitoring site that meets the requirements for both a collocated Pb site and a collocated PM site may serve as a collocated site for both networks.

3.3.1.2 The two collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference. Calibration, sampling, analysis and verification/validation procedures must be the same for both collocated samplers and the same as for all other samplers in the network.

3.3.1.3 For each pair of collocated samplers, designate one sampler as the primary sampler whose samples will be used to report air quality for the site, and designate the other as the audit sampler. Sample SLAMS sites on a 12-day schedule; sample PSD sites on a 6-day schedule or every third day for PSD daily samplers. If a primary quality assurance organization has only one collocated monitor, higher sampling frequencies than the 12-day schedule may be needed in order to produce 25 valid sample pairs a year. Report the measurements from both samplers at each collocated sampling site. The calculations for evaluating precision between the two collocated samplers are described in section 4.2.1 of this appendix.

3.3.2 Flow Rate Verification for Particulate Matter. Follow the same procedure as described in section 3.2.3 of this appendix for $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$ and TSP instruments. The percent differences between the audit and measured flow rates are used to assess the bias of the monitoring data as described in section 4.2.2 of this appendix.

3.3.3 Semi-Annual Flow Rate Audit for Particulate Matter. Follow the same procedure as described in section 3.2.4 of this appendix for $PM_{2.5}$, PM_{10}, $PM_{10-2.5}$ and TSP instruments. The percent differences between these flow rates are used to validate the one-point flow rate verification checks used to estimate bias as described in section 4.2.3 of this appendix. Great care must be used in auditing high-volume particulate matter samplers having flow regulators because the introduction of resistance plates in the audit flow standard device can cause abnormal flow patterns at the point of flow sensing. For this reason, the flow audit standard should be used with a normal filter in place and without resistance plates in auditing flow-regulated high-volume samplers, or other steps should be taken to assure that flow patterns are not perturbed at the point of flow sensing.

3.3.4 Pb Methods.

3.3.4.1 Annual Flow Rate. For the Pb Reference Method (40 CFR part 50, appendix G), the flow rates of the high-volume Pb samplers shall be verified and audited using the same procedures described in sections 3.3.2 and 3.3.3 of this appendix.

3.3.4.2 Pb Strips. Each calendar quarter or sampling quarter (PSD), audit the Pb

Reference Method analytical procedure using glass fiber filter strips containing a known quantity of Pb. These audit sample strips are prepared by depositing a Pb solution on unexposed glass fiber filter strips of dimensions 1.9 centimeters (cm) by 20.3 cm (3/4 inch by 8 inch) and allowing them to dry thoroughly. The audit samples must be prepared using batches of reagents different from those used to calibrate the Pb analytical equipment being audited. Prepare audit samples in the following concentration ranges:

Range	Pb concentration, µg/strip	Equivalent ambient Pb concentration, µg/m³ [1]
1	100–300	0.5–1.5
2	400–1000	3.0–5.0

[1] Equivalent ambient Pb concentration in µg/m³ is based on sampling at 1.7 m³/min for 24 hours on a 20.3 cm x 25.4 cm (8 inch x 10 inch) glass fiber filter.

(a) Audit samples must be extracted using the same extraction procedure used for exposed filters.

(b) Analyze three audit samples in each of the two ranges each quarter samples are analyzed. The audit sample analyses shall be distributed as much as possible over the entire calendar quarter.

(c) Report the audit concentrations (in µg Pb/strip) and the corresponding measured concentrations (in µg Pb/strip) using AQS unit code 077. The relative percent differences between the concentrations are used to calculate analytical accuracy as described in section 4.4.2 of this appendix.

(d) The audits of an equivalent Pb method are conducted and assessed in the same manner as for the reference method. The flow auditing device and Pb analysis audit samples must be compatible with the specific requirements of the equivalent method.

3.3.5 Collocated Procedures for $PM_{10\text{-}2.5}$ and $PM_{2.5}$. Follow the same procedure as described in section 3.2.5 of this appendix.

3.3.6 Performance Evaluation Procedures for $PM_{10\text{-}2.5}$ and $PM_{2.5}$. Follow the same procedure as described in section 3.2.6 of this appendix.

4. *Calculations for Data Quality Assessment.*

(a) Calculations of measurement uncertainty are carried out by EPA according to the following procedures. Primary quality assurance organizations should report the data for all appropriate measurement quality checks as specified in this appendix even though they may elect to perform some or all of the calculations in this section on their own.

(b) The EPA will provide annual assessments of data quality aggregated by site and primary quality assurance organization for SO_2, NO_2, O_3 and CO and by primary quality assurance organization for PM_{10}, $PM_{2.5}$, $PM_{10\text{-}2.5}$ and Pb.

(c) At low concentrations, agreement between the measurements of collocated samplers, expressed as relative percent difference or percent difference, may be relatively poor. For this reason, collocated measurement pairs are selected for use in the precision and bias calculations only when both measurements are equal to or above the following limits:

(1) TSP: 20 µg/m³.

(2) Pb: 0.15 µg/m³.

(3) PM_{10} (Hi-Vol): 15 µg/m³.

(4) PM_{10} (Lo-Vol): 3 µg/m³.

(5) $PM_{10\text{-}2.5}$ and $PM_{2.5}$: 3 µg/m³.

4.1 Statistics for the Assessment of QC Checks for SO_2, NO_2, O_3 and CO.

4.1.1 Percent Difference. All measurement quality checks start with a comparison of an audit concentration or value (flowrate) to the concentration/value measured by the analyzer and use percent difference as the comparison statistic as described in equation 1 of this section. For each single point check, calculate the percent difference, d_i, as follows:

Equation 1

$$d_i = \frac{meas - audit}{audit} \cdot 100$$

where, *meas* is the concentration indicated by the monitoring organization's instrument and *audit* is the audit concentration of the standard used in the QC check being measured.

4.1.2 Precision Estimate. The precision estimate is used to assess the one-point QC checks for SO_2, NO_2, O_3, or CO described in section 3.2.1 of this appendix. The precision estimator is the coefficient of variation upper bound and is calculated using equation 2 of this section:

Equation 2

$$CV = \sqrt{\frac{n \cdot \sum_{i=1}^{n} d_i^2 - \left(\sum_{i=1}^{n} d_i\right)^2}{n(n-1)}} \cdot \sqrt{\frac{n-1}{X^2_{0.1,n-1}}}$$

where, $X_{0.1,n-1}$ is the 10th percentile of a chi-squared distribution with n–1 degrees of freedom.

4.1.3 Bias Estimate. The bias estimate is calculated using the one-point QC checks for SO_2, NO_2, O_3, or CO described in section 3.2.1 of this appendix and the performance evaluation program for $PM_{10\text{-}2.5}$ described in section 3.2.6 of this appendix. The bias estimator is an upper bound on the mean absolute value of the percent differences as described in equation 3 of this section:

Equation 3

$$|bias| = AB + t_{0.95,n-1} \cdot \frac{AS}{\sqrt{n}}$$

where, *n* is the number of single point checks being aggregated; $t_{0.95,n-1}$ is the 95th quantile of a t-distribution with n-1 degrees of freedom; the quantity *AB* is the mean of the absolute values of the d_i's and is calculated using equation 4 of this section:

Equation 4

$$AB = \frac{1}{n} \cdot \sum_{i=1}^{n} |d_i|$$

and the quantity *AS* is the standard deviation of the absolute value of the d_i's and is calculated using equation 5 of this section:

Equation 5

$$AS = \sqrt{\frac{n \cdot \sum_{i=1}^{n} |d_i|^2 - \left(\sum_{i=1}^{n} |d_i|\right)^2}{n(n-1)}}$$

4.1.3.1 Assigning a sign (positive/negative) to the bias estimate. Since the bias statistic as calculated in equation 3 of this appendix uses absolute values, it does not have a tendency (negative or positive bias) associated with it. A sign will be designated by rank ordering the percent differences of the QC check samples from a given site for a particular assessment interval.

4.1.3.2 Calculate the 25th and 75th percentiles of the percent differences for each site. The absolute bias upper bound should be flagged as positive if both percentiles are positive and negative if both percentiles are negative. The absolute bias upper bound would not be flagged if the 25th and 75th percentiles are of different signs.

4.1.4 Validation of Bias Using Performance Evaluations. The annual performance evaluations for SO_2, NO_2, O_3, or CO described in section 3.2.2 of this appendix are used to verify the results obtained from the one-point QC checks and to validate those results across a range of concentration levels. To quantify this annually at the site level and at the 3-year

primary quality assurance organization level, probability limits will be calculated from the one-point QC checks using equations 6 and 7 of this appendix:

Equation 6

$$\text{Upper probability limit} = m + 1.96 \cdot S$$

Equation 7

$$\text{Lower probability limit} = m + 1.96 \cdot S$$

Where, *m* is the mean (equation 8 of this appendix):

Equation 8

$$m = \frac{1}{k}\sum_{i=1}^{k} d_i$$

where, *k* is the total number of one point QC checks for the interval being evaluated and *S* is the standard deviation of the percent differences (equation 9 of this appendix) as follows:

Equation 9

$$S = \sqrt{\frac{k \cdot \sum_{i=1}^{k} d_i^2 - \left(\sum_{i=1}^{k} d_i\right)^2}{k(k-1)}}$$

4.1.5 Percent Difference. Percent differences for the performance evaluations, calculated using equation 1 of this appendix can be compared to the probability intervals for the respective site or at the primary quality assurance organization level. Ninety-five percent of the individual percent differences (all audit concentration levels) for the performance evaluations should be captured within the probability intervals for the primary quality assurance organization.

4.2 Statistics for the Assessment of PM_{10}.

4.2.1 Precision Estimate from Collocated Samplers. Precision is estimated via duplicate measurements from collocated samplers of the same type. It is recommended that the precision be aggregated at the primary quality assurance organization level quarterly, annually, and at the 3-year level. The data pair would only be considered valid if both concentrations are greater than the minimum values specified in section 4(c) of this appendix. For each collocated data pair, calculate the relative percent difference, d_i, using equation 10 of this appendix:

Equation 10

$$d_i = \frac{X_i - Y_i}{(X_i + Y_i)/2} \cdot 100$$

where, X_i is the concentration from the primary sampler and Y_i is the concentration value from the audit sampler. The coefficient of variation upper bound is calculated using the equation 11 of this appendix:

Equation 11

$$CV = \sqrt{\frac{n \cdot \sum_{i=1}^{n} d_i^2 - \left(\sum_{i=1}^{n} d_i\right)^2}{2n(n-1)}} \cdot \sqrt{\frac{n-1}{X^2_{0.1,n-1}}}$$

where, *n* is the number of valid data pairs being aggregated, and $X_{0.1,n-1}$ is the 10th percentile of a chi-squared distribution with n–1 degrees of freedom. The factor of 2 in the denominator adjusts for the fact that each d_i is calculated from two values with error.

4.2.2 Bias Estimate Using One-Point Flow Rate Verifications. For each one-point flow rate verification described in sections 3.2.3 and 3.3.2 of this appendix, calculate the percent difference in volume using equation 1 of this appendix where *meas* is the value indicated by the sampler's volume measurement and *audit* is the actual volume indicated by the auditing flow meter. The absolute volume bias upper bound is then calculated using equation 3, where *n* is the number of flow rate audits being aggregated; $t_{0.95,n-1}$ is the 95th quantile of a t-distribution with n–1 degrees of freedom, the quantity *AB* is the mean of the absolute values of the d_i's and is calculated using equation 4 of this appendix, and the quantity *AS* in equation 3 of this appendix is the standard deviation of the absolute values of the d_i's and is calculated using equation 5 of this appendix.

4.2.3 Assessment Semi-Annual Flow Rate Audits. The flow rate audits described in sections 3.2.4 and 3.3.3 of this appendix are used to assess the results obtained from the one-point flow rate verifications and to provide an estimate of flow rate acceptability. For each flow rate audit, calculate the percent difference in volume using equation 1 of this appendix where *meas* is the value indicated by the sampler's volume measurement and *audit* is the actual volume indicated by the auditing flow meter. To quantify this annually and at the 3-year primary quality assurance organization level, probability limits are calculated from the percent differences using equations 6 and 7 of this appendix where *m* is the mean described in equation 8 of this appendix and *k* is the total number of one-point flow rate verifications for the year and *S* is the standard deviation of the percent differences as described in equation 9 of this appendix.

4.2.4 Percent Difference. Percent differences for the annual flow rate audit concentration, calculated using equation 1 of this appendix, can be compared to the probability intervals for the one-point flow rate verifications for the respective primary quality assurance organization. Ninety-five percent of the individual percent differences (all audit concentration levels) for the performance evaluations should be captured within the probability intervals for primary quality assurance organization.

4.3 Statistics for the Assessment of $PM_{2.5}$ and $PM_{10-2.5}$.

4.3.1 Precision Estimate. Precision for collocated instruments for $PM_{2.5}$ and $PM_{10-2.5}$ may be estimated where both the primary and collocated instruments are the same method designation and when the method designations are not similar. Follow the procedure described in section 4.2.1 of this appendix. In addition, one may want to perform an estimate bias when the primary monitor is an FEM and the collocated monitor is an FRM. Follow the procedure described in section 4.1.3 of this appendix in order to provide an estimate of bias using the collocated data.

4.3.2 Bias Estimate. Follow the procedure described in section 4.1.3 of this appendix for the bias estimate of $PM_{10-2.5}$. The $PM_{2.5}$ bias estimate is calculated using the paired routine and the PEP monitor data described in section 3.2.6 of this appendix. Calculate the percent difference, d_i, using equation 1 of this appendix, where *meas* is the measured concentration from agency's primary monitor and *audit* is the concentration from the PEP monitor. The data pair would only be considered valid if both concentrations are greater than the minimum values specified in section 4(c) of this appendix. Estimates of bias are presented for various levels of aggregation, sometimes aggregating over time, sometimes aggregating over samplers, and sometimes aggregating over both time and samplers. These various levels of aggregation are achieved using the same basic statistic.

4.3.2.1 This statistic averages the individual biases described in equation 1 of this appendix to the desired level of aggregation using equation 12 of this appendix:

Equation 12

$$D = \frac{1}{n_j} \times \sum_{i=1}^{n_j} d_i$$

where, n_j is the number of pairs and d_1, d_2, . . ., d_{nj} are the biases for each of the pairs to be averaged.

4.3.2.2 Confidence intervals can be constructed for these average bias estimates in equation 12 of this appendix using equations 13 and 14 of this appendix:

Equation 13

$$\text{Lower 90\% Confidence Interval} = D - t_{0.95,df} \times \frac{s}{\sqrt{n_j}}$$

Equation 14

$$\text{Upper 90\% Confidence Interval} = D - t_{0.95,df} \times \frac{s}{\sqrt{n_j}}$$

Where, $t_{0.95,df}$ is the 95th quantile of a t-distribution with degrees of freedom $df = n_j - 1$ and *s* is an estimate of the variability of the average bias calculated using equation 15 of this appendix:

Equation 15

$$s = \sqrt{\frac{\sum_{i=1}^{n_j} (d_i - D)^2}{n_j - 1}}$$

4.4 Statistics for the Assessment of Pb.

4.4.1 Precision Estimate. Follow the same procedures as described for PM_{10} in section 4.2.1 of this appendix using the data from the collocated instruments. The data pair would only be considered valid if both concentrations are greater than the minimum values specified in section 4(c) of this appendix.

4.4.2 Bias Estimate. In order to estimate bias, the information from the flow rate audits and the Pb strip audits needs to be combined as described below. To be consistent with the formulas for the gases, the recommended procedures are to work with relative errors of the lead measurements. The relative error in the concentration is related to the relative error in the volume and the relative error in the mass measurements using equation 16 of this appendix:

Equation 16

$$\text{rel. error} = \frac{(\text{measured concentration} - \text{audit concentration})}{\text{audit concentration}} = \left(\frac{1}{1 = \text{rel. error}}\right)(\text{rel. mass error} - \text{rel. volume error})$$

As with the gases, an upper bound for the absolute bias is desired. Using equation 16 above, the absolute value of the relative (concentration) error is bounded by equation 17 of this appendix:

Equation 17

$$|\text{rel. error}| \le \frac{|\text{relative mass error}| + |\text{relative volume error}|}{1 - |\text{relative volume error}|}$$

The quality indicator data collected are then used to bound each part of equation 17 separately.

4.4.2.1 Flow rate calculations. For each flow rate audit, calculate the percent difference in volume by equation 1 of this appendix where *meas* is the value indicated by the sampler's volume measurement and *audit* is the actual volume indicated by the auditing flow meter. The absolute volume bias upper bound is then calculated using equation 3 of this appendix where *n* is the number of flow rate audits being aggregated; $t_{0.95,n-1}$ is the 95th quantile of a t-distribution with $n - 1$ degrees of freedom; the quantity *AB* is the mean of the absolute values of the d_i's and is calculated using equation 4, and the quantity *AS* in equation 3 of this appendix is the standard deviation of the absolute values of the d_i's and is calculated using equation 5 of this appendix.

4.4.2.2 Lead strip calculations. Similarly for each lead strip audit, calculate the percent difference in mass by equation 1 where *meas* is the value indicated by the mass measurement and *audit* is the actual lead mass on the audit strip. The absolute mass bias upper bound is then calculated using equation 3 of this appendix where *n* is the number of lead strip audits being aggregated; $t_{0.95,n-1}$ is the 95th quantile of a t-distribution with n-1 degrees of freedom; the quantity *AB* is the mean of the absolute values of the d_i's and is calculated using equation 4 of this appendix and the quantity *AS* in equation 3 of this appendix is the standard deviation of the absolute values of the d_i's and is calculated using equation 5 of this appendix.

4.4.2.3 Final bias calculation. Finally, the absolute bias upper bound is given by combining the absolute bias estimates of the flow rate and Pb strips using equation 18 of this appendix:

Equation 18

$$|\text{bias}| = \frac{|\text{mass bias}| + |\text{vol. bias}|}{100 - |\text{vol. bias}|} \cdot 100$$

where, the numerator and denominator have been multiplied by 100 since everything is expressed as a percentage.

4.5 Time Period for Audits. The statistics in this section assume that the mass and flow rate audits represent the same time period. Since the two types of audits are not performed at the same time, the audits need to be grouped by common time periods. Consequently, the absolute bias estimates should be done on annual and 3-year levels. The flow rate audits are site-specific, so the absolute bias upper bound estimate can be done and treated as a site-level statistic.

5. *Reporting Requirements.*

5.1 SLAMS Reporting Requirements. For each pollutant, prepare a list of all monitoring sites and their AQS site identification codes in each primary quality assurance organization and submit the list to the appropriate EPA Regional Office, with a copy to AQS. Whenever there is a change in this list of monitoring sites in a primary quality assurance organization, report this change to the EPA Regional Office and to AQS.

5.1.1 Quarterly Reports. For each quarter, each primary quality assurance organization shall report to AQS directly (or via the appropriate EPA Regional Office for organizations not direct users of AQS) the results of all valid measurement quality checks it has carried out during the quarter. The quarterly reports must be submitted consistent with the data reporting requirements specified for air quality data as set forth in § 58.16. EPA strongly encourages early submission of the quality assurance data in order to assist the monitoring organizations control and evaluate the quality of the ambient air data.

5.1.2 Annual Reports.

5.1.2.1 When the monitoring organization has certified their data for the calendar year, EPA will calculate and report the measurement uncertainty for the entire calendar year. These limits will then be associated with the data submitted in the annual report required by § 58.15.

5.1.2.2 Each primary quality assurance organization shall submit, along with its annual report, a listing by pollutant of all monitoring sites in the primary quality assurance organization.

5.2 PSD Reporting Requirements. At the end of each sampling quarter, the organization must report the appropriate statistical assessments in section 4 of this appendix for the pollutants measured. All data used to calculate reported estimates of precision and bias including span checks, collocated sampler and audit results must be made available to the permit granting authority upon request.

6.0 References.

(1) American National Standard—Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs. ANSI/ASQC E4–2004. February 2004. Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

(2) EPA Requirements for Quality Management Plans. EPA QA/R–2. EPA/240/B–01/002. March 2001. Office of Environmental Information, Washington DC 20460. *http://www.epa.gov/quality/qs-docs/r2-final.pdf.*

(3) EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations. EPA QA/R–5. EPA/240/B–01/003. March 2001. Office of Environmental Information, Washington DC 20460. *http://www.epa.gov/quality/qs-docs/r5-final.pdf.*

(4) EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards. EPA–600/R–97/121. September 1997. Available from U.S. Environmental Protection Agency, ORD Publications Office, Center for Environmental Research Information (CERI), 26 W. Martin Luther King Drive, Cincinnati, OH 45268.

(5) Guidance for the Data Quality Objectives Process. EPA QA/G–4. EPA/600/R–96/055. August 2000. Office of Environmental Information, Washington DC 20460. *http://www.epa.gov/quality/qs-docs/g4-final.pdf.*

(6) List of Designated Reference and Equivalent Methods. Available from U.S. Environmental Protection Agency, National Exposure Research Laboratory, Human Exposure and Atmospheric Sciences Division, MD–D205–03, Research Triangle Park, NC 27711. *http://www.epa.gov/ttn/amtic/criteria.html.*

(7) McElroy, F.F. Transfer Standards for the Calibration of Ambient Air Monitoring Analyzers for Ozone. EPA–600/4–79–056. U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, September, 1979. *http://www.epa.gov/ttn/amtic/cpreldoc.html.*

(8) Paur, R.J. and F.F. McElroy. Technical Assistance Document for the Calibration of Ambient Ozone Monitors. EPA–600/4–79–057. U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, September, 1979. *http://www.epa.gov/ttn/amtic/cpreldoc.html.*

(9) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume 1—A Field Guide to Environmental Quality Assurance. EPA–600/R–94/038a. April 1994. Available from U.S. Environmental Protection Agency, ORD Publications Office, Center for Environmental Research Information (CERI), 26 W. Martin Luther King Drive, Cincinnati, OH 45268. *http://www.epa.gov/ttn/amtic/qabook.html.*

(10) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II: Part 1—Ambient Air Quality Monitoring Program Quality System Development. EPA–454/R–98–004. *http://www.epa.gov/ttn/amtic/qabook.html.*

TABLE A–1 OF APPENDIX A TO PART 58.—DIFFERENCE AND SIMILARITIES BETWEEN SLAMS AND PSD REQUIREMENTS

Topic	SLAMS	PSD
Requirements	1. The development, documentation, and implementation of an approved quality system. 2. The assessment of data quality. 3. The use of reference, equivalent, or approved methods. 4. The use of calibration standards traceable to NIST or other primary standard. 5. The participation in EPA performance evaluations and the permission for EPA to conduct system audits.	
Monitoring and QA Responsibility.	State/local agency via the "primary quality assurance organization".	Source owner/operator.
Monitoring Duration	Indefinitely	Usually up to 12 months.
Annual Performance Evaluation (PE).	Standards and equipment different from those used for spanning, calibration, and verifications. Prefer different personnel.	Personnel, standards and equipment different from those used for spanning, calibration, and verifications.
PE audit rate:		
—Automated	100% per year	100% per quarter.
—Manual	Varies depending on pollutant. See Table A–2 of this appendix.	100% per quarter.
Precision Assessment:		
—Automated	One-point QC check biweekly but data quality dependent	One point QC check biweekly.

TABLE A–1 OF APPENDIX A TO PART 58.—DIFFERENCE AND SIMILARITIES BETWEEN SLAMS AND PSD REQUIREMENTS—Continued

Topic	SLAMS	PSD
—Manual	Varies depending on pollutant. See Table A–2 of this appendix.	One site: 1 every 6 days or every third day for daily monitoring (TSP and Pb).
Reporting:		
—Automated	By site—EPA performs calculations annually	By site—source owner/operator performs calculations each sampling quarter.
—Manual	By reporting organization—EPA performs calculations annually.	By site—source owner/operator performs calculations each sampling quarter.

TABLE A–2 OF APPENDIX A TO PART 58.—MINIMUM DATA ASSESSMENT REQUIREMENTS FOR SLAMS SITES

Method	Assessment method	Coverage	Minimum frequency	Parameters reported
Automated Methods				
1-Point QC: for SO_2, NO_2, O_3, CO.	Response check at concentration 0.01–0.1 ppm SO_2, NO_2, O_3, and 1–10 ppm CO.	Each analyzer	Once per 2 weeks.	Audit concentration [1] and measured concentration [2].
Performance Evaluation for SO_2, NO_2, O_3, CO.	See section 3.2.2 of this appendix.	Each analyzer	Once per year	Audit concentration [1] and measured concentration [2] for each level.
Flow rate verification PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$.	Check of sampler flow rate	Each sampler	Once every month.	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$.	Check of sampler flow rate using independent standard.	Each sampler	Once every 6 months.	Audit flow rate and measured flow rate indicated by the sampler.
Collocated Sampling $PM_{2.5}$, $PM_{10-2.5}$.	Collocated samplers	15%	Every twelve days.	Primary sampler concentration and duplicate sampler concentration.
Performance Evaluation $PM_{2.5}$, $PM_{10-2.5}$.	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤5 sites. 2. 8 valid audits for primary QA orgs, with >5 sites. 3. All samplers in 6 years.	over all 4 quarters.	Primary sampler concentration and performance evaluation sampler concentration.
Manual Methods				
Collocated Sampling PM_{10}, TSP, $PM_{10-2.5}$, $PM_{2.5}$,.	Collocated samplers	15%	Every 12 days, TSP—every 6 days.	Primary sampler concentration and duplicate sampler concentration.
Flow rate verification PM_{10}, TSP, $PM_{10-2.5}$ $PM_{2.5}$.	Check of sampler flow rate	Each sampler	Once every month.	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM_{10}, TSP, $PM_{10-2.5}$ $PM_{2.5}$.	Check of sampler flow rate using independent standard.	Each sampler, all locations	Once every 6 months.	Audit flow rate and measured flow rate indicated by the sampler.
Manual Methods Lead.	1. Check of sample flow rate as for TSP. 2. Check of analytical system with Pb audit strips.	1. Each sampler 2. Analytical system	1. Include with TSP. 2. Each quarter	1. Same as for TSP. 2. Actual concentration and measured (indicated) concentration of audit samples (μg Pb/strip).
Performance Evaluation $PM_{2.5}$, $PM_{10-2.5}$.	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤5 sites.. 2. 8 valid audits for primary QA orgs, with ≥5 sites. 3. All samplers in 6 years.	Over all 4 quarters.	Primary sampler concentration and performance evaluation sampler concentration.

[1] Effective concentration for open path analyzers.
[2] Corrected concentration, if applicable, for open path analyzers.

TABLE A–3 TO APPENDIX A OF PART 58.—SUMMARY OF $PM_{2.5}$ OR $PM_{10-2.5}$. NUMBER AND TYPE OF COLLOCATION (15% COLLOCATION REQUIREMENT) NEEDED AS AN EXAMPLE OF A PRIMARY QUALITY ASSURANCE ORGANIZATION THAT HAS 54 MONITORS AND PROCURED FRMS AND THREE OTHER EQUIVALENT METHOD TYPES

Primary sampler method designation	Total number of monitors	Total number collocated	Number of collocated FRM	Number of collocated monitors of same method designation as primary
FRM	20	3	3	N/A
FEM (A)	20	3	2	1
FEM (C)	2	1	1	0
FEM (D)	12	2	1	1

50. Appendix C is revised to read as follows:

Appendix C to Part 58—Ambient Air Quality Monitoring Methodology

1.0 Purpose.
2.0 SLAMS Ambient Air Monitoring Stations.
3.0 NCore Ambient Air Monitoring Stations.
4.0 Photochemical Assessment Monitoring Stations (PAMS).
5.0 Particulate Matter Episode Monitoring.
6.0 References.

1.0 Purpose.

This appendix specifies the criteria pollutant monitoring methods (manual methods or automated analyzers) which must be used in the State and local air monitoring stations (SLAMS) and the National Core (NCore) stations that are a subset of SLAMS.

2.0 *SLAMS Ambient Air Monitoring Network.*

2.1 Except as otherwise provided in this appendix, a criteria pollutant monitoring method used for making NAAQS decisions at a SLAMS site must be a reference or equivalent method as defined in § 50.1 of this chapter.

2.2 Through December 31, 2012, data produced from any PM_{10} method approved under part 53 of this chapter may be used in lieu of a required $PM_{10-2.5}$ monitor to determine attainment of the $PM_{10-2.5}$ NAAQS according to the following stipulations.

2.2.1 At any sites proposed for monitoring in lieu of $PM_{10-2.5}$ monitoring, the 98th percentile value for the most recent complete calendar year of PM_{10} monitoring data must be less than the $PM_{10-2.5}$ NAAQS, based on a sample frequency of at least 1 in 3 sample days, and reported at local conditions of temperature and pressure.

2.2.2 PM_{10} data used in lieu of required $PM_{10-2.5}$ monitoring must be based on a daily sampling frequency.

2.2.3 During any calendar year of sampling in lieu of a required $PM_{10-2.5}$ sampler, if more than seven 24-hour average PM_{10} concentrations exceed the numerical value of the $PM_{10-2.5}$ NAAQS, as reported at local conditions of temperature and pressure, the State must deploy a Federal reference method (FRM) or Federal equivalent method (FEM) $PM_{10-2.5}$ monitor within a 1-year period.

2.3 Any manual method or analyzer purchased prior to cancellation of its reference or equivalent method designation under § 53.11 or § 53.16 of this chapter may be used at a SLAMS site following cancellation for a reasonable period of time to be determined by the Administrator.

2.4 Approval of Non-designated Continuous $PM_{2.5}$ Methods as Approved Regional Methods (ARM) Operated Within a Network of Sites. A method for $PM_{2.5}$ that has not been designated as an FRM or FEM as defined in § 50.1 of this chapter may be approved as an approved regional method (ARM) for purposes of section 2.1 of this appendix at a particular site or network of sites under the following stipulations.

2.4.1 The candidate ARM must be demonstrated to meet the requirements for $PM_{2.5}$ Class III equivalent methods as defined in subpart C of part 53 of this chapter. Specifically the requirements for precision, correlation, and additive and multiplicative bias apply. For purposes of this section 2.4, the following requirements shall apply:

2.4.1.1 The candidate ARM shall be tested at the site(s) in which it is intended to be used. For a network of sites operated by one reporting agency, the testing shall occur at a subset of sites to include one site in each MSA/CSA, up to the first 2 highest population MSA/CSA and at least one rural area or Micropolitan Statistical Area site. If the candidate ARM for a network is already approved for purposes of this section in another agency's network, subsequent testing shall minimally occur at one site in a MSA/CSA and one rural area or Micropolitan Statistical Area. There shall be no requirement for tests at any other sites.

2.4.1.2 For purposes of this section, a full year of testing may begin and end in any season, so long as all seasons are covered.

2.4.1.3 No PM_{10} samplers shall be required for the test, as determination of the $PM_{2.5}/PM_{10}$ ratio at the test site shall not be required.

2.4.1.4 The test specification for $PM_{2.5}$ Class III equivalent method precision defined in subpart C of part 53 of this chapter applies; however, there is no specific requirement that collocated continuous monitors be operated for purposes of generating a statistic for coefficient of variation (CV). To provide an estimate of precision that meets the requirement identified in subpart C of part 53 of this chapter, agencies may cite peer-reviewed published data or data in AQS that can be presented demonstrating the candidate ARM operated will produce data that meets the specification for precision of Class III $PM_{2.5}$ methods.

2.4.1.5 A minimum of 90 valid sample pairs per site for the year with no less than 20 valid sample pairs per season must be generated for use in demonstrating that additive bias, multiplicative bias and correlation meet the comparability requirements specified in subpart C of part 53 of this chapter. A valid sample pair may be generated with as little as one valid FRM and one valid candidate ARM measurement per day.

2.4.1.6 For purposes of determining bias, FRM data with concentrations less than 3 micrograms per cubic meter $\mu g/m^3$) may be excluded. Exclusion of data does not result in failure of sample completeness specified in this section.

2.4.2 The monitoring agency wishing to use an ARM must develop and implement appropriate quality assurance procedures for the method. Additionally, the following procedures are required for the method:

2.4.2.1 The ARM must be consistently operated throughout the network. Exceptions to a consistent operation must be approved according to section 2.8 of this appendix;

2.4.2.2 The ARM must be operated on an hourly sampling frequency capable of providing data suitable for aggregation into daily 24-hour average measurements;

2.4.2.3 The ARM must use an inlet and separation device, as needed, that are already approved in either the reference method identified in appendix L to part 50 of this chapter or under part 53 of this chapter as approved for use on a $PM_{2.5}$ reference or equivalent method. The only exceptions to this requirement are those methods that by their inherent measurement principle may not need an inlet or separation device that segregates the aerosol; and

2.4.2.4 The ARM must be capable of providing for flow audits, unless by its inherent measurement principle, measured flow is not required. These flow audits are to be performed on the frequency identified in appendix A to this part.

2.4.3 The monitoring agency wishing to use the method must develop and implement appropriate procedures for assessing and reporting the precision and accuracy of the method comparable to the procedures set forth in appendix A of this part for designated reference and equivalent methods.

2.4.4 Assessments of data quality shall follow the same frequencies and calculations

as required under section 3 of appendix A to this part with the following exceptions:

2.4.4.1 Collocation of ARM with FRM/FEM samplers must be maintained at a minimum of 30 percent of the SLAMS sites with a minimum of 1 per network;

2.4.4.2 All collocated FRM/FEM samplers must maintain a sample frequency of at least 1 in 6 sample days;

2.4.4.3 Collocated FRM/FEM samplers shall be located at the design value site, with the required FRM/FEM samplers deployed among the largest MSA/CSA in the network, until all required FRM/FEM are deployed; and

2.4.4.4 Data from collocated FRM/FEM are to be substituted for any calendar quarter that an ARM method has incomplete data.

2.4.4.5 Collocation with an ARM under this part for purposes of determining the coefficient of variation of the method shall be conducted at a minimum of 7.5 percent of the sites with a minimum of 1 per network. This is consistent with the requirements in appendix A to this part for one-half of the required collocation of FRM/FEM (15 percent) to be collocated with the same method.

2.4.4.6 Assessments of bias with an independent audit of the total measurement system shall be conducted with the same frequency as an FEM as identified in appendix A to this part.

2.4.5 Request for approval of a candidate ARM, that is not already approved in another agency's network under this section, must meet the general submittal requirements of section 2.7 of this appendix. Requests for approval under this section when an ARM is already approved in another agency's network are to be submitted to the EPA Regional Administrator. Requests for approval under section 2.4 of this appendix must include the following requirements:

2.4.5.1 A clear and unique description of the site(s) at which the candidate ARM will be used and tested, and a description of the nature or character of the site and the particulate matter that is expected to occur there.

2.4.5.2 A detailed description of the method and the nature of the sampler or analyzer upon which it is based.

2.4.5.3 A brief statement of the reason or rationale for requesting the approval.

2.4.5.4 A detailed description of the quality assurance procedures that have been developed and that will be implemented for the method.

2.4.5.5 A detailed description of the procedures for assessing the precision and accuracy of the method that will be implemented for reporting to AQS.

2.4.5.6 Test results from the comparability tests as required in section 2.4.1 through 2.4.1.4 of this appendix.

2.4.5.7 Such further supplemental information as may be necessary or helpful to support the required statements and test results.

2.4.6 Within 120 days after receiving a request for approval of the use of an ARM at a particular site or network of sites under section 2.4 of this appendix, the Administrator will approve or disapprove the method by letter to the person or agency requesting such approval. When appropriate for methods that are already approved in another SLAMS network, the EPA Regional Administrator has approval/disapproval authority. In either instance, additional information may be requested to assist with the decision.

2.5 [Reserved]

2.6 Use of Methods With Higher, Nonconforming Ranges in Certain Geographical Areas.

2.6.1 [Reserved]

2.6.2 An analyzer may be used (indefinitely) on a range which extends to concentrations higher than two times the upper limit specified in table B–1 of part 53 of this chapter if:

2.6.2.1 The analyzer has more than one selectable range and has been designated as a reference or equivalent method on at least one of its ranges, or has been approved for use under section 2.5 (which applies to analyzers purchased before February 18, 1975);

2.6.2.2 The pollutant intended to be measured with the analyzer is likely to occur in concentrations more than two times the upper range limit specified in table B–1 of part 53 of this chapter in the geographical area in which use of the analyzer is proposed; and

2.6.2.3 The Administrator determines that the resolution of the range or ranges for which approval is sought is adequate for its intended use. For purposes of this section (2.6), ''resolution'' means the ability of the analyzer to detect small changes in concentration.

2.6.3 Requests for approval under section 2.6.2 of this appendix must meet the submittal requirements of section 2.7. Except as provided in section 2.7.3 of this appendix, each request must contain the information specified in section 2.7.2 in addition to the following:

2.6.3.1 The range or ranges proposed to be used;

2.6.3.2 Test data, records, calculations, and test results as specified in section 2.7.2.2 of this appendix for each range proposed to be used;

2.6.3.3 An identification and description of the geographical area in which use of the analyzer is proposed;

2.6.3.4 Data or other information demonstrating that the pollutant intended to be measured with the analyzer is likely to occur in concentrations more than two times the upper range limit specified in table B–1 of part 53 of this chapter in the geographical area in which use of the analyzer is proposed; and

2.6.3.5 Test data or other information demonstrating the resolution of each proposed range that is broader than that permitted by section 2.5 of this appendix.

2.6.4 Any person who has obtained approval of a request under this section (2.6.2) shall assure that the analyzer for which approval was obtained is used only in the geographical area identified in the request and only while operated in the range or ranges specified in the request.

2.7 Requests for Approval; Withdrawal of Approval.

2.7.1 Requests for approval under sections 2.4, 2.6.2, or 2.8 of this appendix must be submitted to: Director, National Exposure Research Laboratory, (MD–D205–03), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. For ARM that are already approved in another agency's network, subsequent requests for approval under section 2.4 are to be submitted to the applicable EPA Regional Administrator.

2.7.2 Except as provided in section 2.7.3 of this appendix, each request must contain:

2.7.2.1 A statement identifying the analyzer (*e.g.*, by serial number) and the method of which the analyzer is representative (*e.g.*, by manufacturer and model number); and 2.7.2.2 Test data, records, calculations, and test results for the analyzer (or the method of which the analyzer is representative) as specified in subpart B, subpart C, or both (as applicable) of part 53 of this chapter.

2.7.3 A request may concern more than one analyzer or geographical area and may incorporate by reference any data or other information known to EPA from one or more of the following:

2.7.3.1 An application for a reference or equivalent method determination submitted to EPA for the method of which the analyzer is representative, or testing conducted by the applicant or by EPA in connection with such an application;

2.7.3.2 Testing of the method of which the analyzer is representative at the initiative of the Administrator under § 53.7 of this chapter; or

2.7.3.3 A previous or concurrent request for approval submitted to EPA under this section (2.7).

2.7.4 To the extent that such incorporation by reference provides data or information required by this section (2.7) or by sections 2.4, 2.5, or 2.6 of this appendix, independent data or duplicative information need not be submitted.

2.7.5 After receiving a request under this section (2.7), the Administrator may request such additional testing or information or conduct such tests as may be necessary in his judgment for a decision on the request.

2.7.6 If the Administrator determines, on the basis of any available information, that any of the determinations or statements on which approval of a request under this section was based are invalid or no longer valid, or that the requirements of section 2.4, 2.5, or 2.6, as applicable, have not been met, he/she may withdraw the approval after affording the person who obtained the approval an opportunity to submit information and arguments opposing such action.

2.8 Modifications of Methods by Users.

2.8.1 Except as otherwise provided in this section, no reference method, equivalent method, or ARM may be used in a SLAMS network if it has been modified in a manner that could significantly alter the performance characteristics of the method without prior approval by the Administrator. For purposes of this section, ''alternative method'' means an analyzer, the use of which has been approved under section 2.4, 2.5, or 2.6 of this appendix or some combination thereof.

2.8.2 Requests for approval under this section (2.8) must meet the submittal

requirements of sections 2.7.1 and 2.7.2.1 of this appendix.

2.8.3 Each request submitted under this section (2.8) must include:

2.8.3.1 A description, in such detail as may be appropriate, of the desired modification;

2.8.3.2 A brief statement of the purpose(s) of the modification, including any reasons for considering it necessary or advantageous;

2.8.3.3 A brief statement of belief concerning the extent to which the modification will or may affect the performance characteristics of the method; and

2.8.3.4 Such further information as may be necessary to explain and support the statements required by sections 2.8.3.2 and 2.8.3.3.

2.8.4 The Administrator will approve or disapprove the modification by letter to the person or agency requesting such approval within 75 days after receiving a request for approval under this section and any further information that the applicant may be asked to provide.

2.8.5 A temporary modification that could alter the performance characteristics of a reference, equivalent, or ARM may be made without prior approval under this section if the method is not functioning or is malfunctioning, provided that parts necessary for repair in accordance with the applicable operation manual cannot be obtained within 45 days. Unless such temporary modification is later approved under section 2.8.4 of this appendix, the temporarily modified method shall be repaired in accordance with the applicable operation manual as quickly as practicable but in no event later than 4 months after the temporary modification was made, unless an extension of time is granted by the Administrator. Unless and until the temporary modification is approved, air quality data obtained with the method as temporarily modified must be clearly identified as such when submitted in accordance with § 58.16 and must be accompanied by a report containing the information specified in section 2.8.3 of this appendix. A request that the Administrator approve a temporary modification may be submitted in accordance with sections 2.8.1 through 2.8.4 of this appendix. In such cases the request will be considered as if a request for prior approval had been made.

2.9 Use of IMPROVE Samplers at a SLAMS Site. ''IMPROVE'' samplers may be used in SLAMS for monitoring of regional background and regional transport concentrations of fine particulate matter. The IMPROVE samplers were developed for use in the Interagency Monitoring of Protected Visual Environments (IMPROVE) network to characterize all of the major components and many trace constituents of the particulate matter that impair visibility in Federal Class I Areas. Descriptions of the IMPROVE samplers and the data they collect are available in references 4, 5, and 6 of this appendix.

3.0 *NCore Ambient Air Monitoring Stations.*

3.1 Methods employed in NCore multipollutant sites used to measure SO_2, CO, NO_2, O_3, $PM_{2.5}$, or $PM_{10\text{-}2.5}$ must be reference or equivalent methods as defined in § 50.1 of this chapter, or an ARM as defined in section 2.4 of this appendix, for any monitors intended for comparison with applicable NAAQS.

3.2 If alternative SO_2, CO, NO_2, O_3, $PM_{2.5}$, or $PM_{10\text{-}2.5}$ monitoring methodologies are proposed for monitors not intended for NAAQS comparison, such techniques must be detailed in the network description required by § 58.10 and subsequently approved by the Administrator.

4.0 *Photochemical Assessment Monitoring Stations (PAMS).*

4.1 Methods used for O_3 monitoring at PAMS must be automated reference or equivalent methods as defined in § 50.1 of this chapter.

4.2 Methods used for NO, NO_2 and NO_X monitoring at PAMS should be automated reference or equivalent methods as defined for NO_2 in § 50.1 of this chapter. If alternative NO, NO_2 or NO_X monitoring methodologies are proposed, such techniques must be detailed in the network description required by § 58.10 and subsequently approved by the Administrator.

4.3 Methods for meteorological measurements and speciated VOC monitoring are included in the guidance provided in references 2 and 3 of this appendix. If alternative VOC monitoring methodology (including the use of new or innovative technologies), which is not included in the guidance, is proposed, it must be detailed in the network description required by § 58.10 and subsequently approved by the Administrator.

5.0 *Particulate Matter Episode Monitoring.*

5.1 For short-term measurements of PM_{10} during air pollution episodes (see § 51.152 of this chapter) the measurement method must be:

5.1.1 Either the ''Staggered PM_{10}'' method or the ''PM_{10} Sampling Over Short Sampling Times'' method, both of which are based on the reference method for PM_{10} and are described in reference 1: or

5.1.2 Any other method for measuring PM_{10}:

5.1.2.1 Which has a measurement range or ranges appropriate to accurately measure air pollution episode concentration of PM_{10},

5.1.2.2 Which has a sample period appropriate for short-term PM_{10} measurements, and 5.1.2.3 For which a quantitative relationship to a reference or equivalent method for PM_{10} has been established at the use site. Procedures for establishing a quantitative site-specific relationship are contained in reference 1.

5.2 PM_{10} methods other than the reference method are not covered under the quality assessment requirements of appendix A to this part. Therefore, States must develop and implement their own quality assessment procedures for those methods allowed under this section 4. These quality assessment procedures should be similar or analogous to those described in section 3 of appendix A to this part for the PM_{10} reference method.

6.0 *References.*

1. Pelton, D. J. Guideline for Particulate Episode Monitoring Methods, GEOMET Technologies, Inc., Rockville, MD. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Contract No. 68–02–3584. EPA 450/4–83–005. February 1983.

2. Technical Assistance Document For Sampling and Analysis of Ozone Precursors. Atmospheric Research and Exposure Assessment Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711. EPA 600/8–91–215. October 1991.

3. Quality Assurance Handbook for Air Pollution Measurement Systems: Volume IV. Meteorological Measurements. Atmospheric Research and Exposure Assessment Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711. EPA 600/4–90–0003. August 1989.

4. Eldred, R.A., Cahill, T.A., Wilkenson, L.K., *et al.*, Measurements of fine particles and their chemical components in the IMPROVE/NPS networks, in Transactions of the International Specialty Conference on Visibility and Fine Particles, Air and Waste Management Association: Pittsburgh, PA, 1990; pp 187–196.

5. Sisler, J.F., Huffman, D., and Latimer, D.A.; Spatial and temporal patterns and the chemical composition of the haze in the United States: An analysis of data from the IMPROVE network, 1988–1991, ISSN No. 0737–5253–26, National Park Service, Ft. Collins, CO, 1993.

6. Eldred, R.A., Cahill, T.A., Pitchford, M., and Malm, W.C.; IMPROVE—a new remote area particulate monitoring system for visibility studies, Proceedings of the 81st Annual Meeting of the Air Pollution Control Association, Dallas, Paper 88–54.3, 1988.

51. Appendix D to part 58 is revised to read as follows:

Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring

1. Monitoring Objectives and Spatial Scales.
2. General Monitoring Requirements.
3. Design Criteria for NCore Sites.
4. Pollutant-Specific Design Criteria for SLAMS Sites.
5. Design Criteria for Photochemical Assessment Monitoring Stations (PAMS).
6. References.

1. *Monitoring Objectives and Spatial Scales.*

The purpose of this appendix is to describe monitoring objectives and general criteria to be applied in establishing the required SLAMS ambient air quality monitoring stations and for choosing general locations for additional monitoring sites. This appendix also describes specific requirements for the number and location of FRM, FEM, and ARM sites for specific pollutants, NCore multipollutant sites, $PM_{10\text{-}2.5}$ mass sites, chemically-speciated $PM_{10\text{-}2.5}$ sites, continuous $PM_{2.5}$ mass sites, chemically-speciated $PM_{2.5}$ sites, and O_3 precursor measurements sites (PAMS). These criteria will be used by EPA in evaluating the adequacy of the air pollutant monitoring networks.

1.1 Monitoring Objectives. The ambient air monitoring networks must be designed to

meet three basic monitoring objectives. These basic objectives are listed below. The appearance of any one objective in the order of this list is not based upon a prioritized scheme. Each objective is important and must be considered individually.

(a) Provide air pollution data to the general public in a timely manner. Data can be presented to the public in a number of attractive ways including through air quality maps, newspapers, Internet sites, and as part of weather forecasts and public advisories.

(b) Support compliance with ambient air quality standards and emissions strategy development. Data from FRM, FEM, and ARM monitors will be used for comparing an area's air pollution levels against the National Ambient Air Quality Standards (NAAQS). Data from monitors of various types can be used in the development of attainment and maintenance plans. SLAMS, and especially NCore station data, will be used to evaluate the regional air quality models used in developing emission strategies, and to track trends in air pollution abatement control measures' impact on improving air quality. In monitoring locations near major air pollution sources, source-oriented monitoring data can provide insight into how well industrial sources are controlling their pollutant emissions.

(c) Support for air pollution research studies. Air pollution data from the NCore network can be used to supplement data collected by researchers working on health effects assessments and atmospheric processes, or for monitoring methods development work.

1.1.1 In order to support the air quality management work indicated in the three basic air monitoring objectives, a network must be designed with a variety of types of monitoring sites. Monitoring sites must be capable of informing managers about many things including the peak air pollution levels, typical levels in populated areas, air pollution transported into and outside of a city or region, and air pollution levels near specific sources. To summarize some of these sites, here is a listing of six general site types:

(a) Sites located to determine the highest concentrations expected to occur in the area covered by the network.

(b) Sites located to measure typical concentrations in areas of high population density.

(c) Sites located to determine the impact of significant sources or source categories on air quality.

(d) Sites located to determine general background concentration levels.

(e) Sites located to determine the extent of Regional pollutant transport among populated areas; and in support of secondary standards.

(f) Sites located to measure air pollution impacts on visibility, vegetation damage, or other welfare-based impacts.

1.1.2 This appendix contains criteria for the basic air monitoring requirements. The total number of monitoring sites that will serve the variety of data needs will be substantially higher than these minimum requirements provide. The optimum size of a particular network involves trade-offs among data needs and available resources. This regulation intends to provide for national air monitoring needs, and to lend support for the flexibility necessary to meet data collection needs of area air quality managers. EPA, State, and local agencies will periodically collaborate on network design issues through the network assessment process outlined in § 58.10.

1.1.3 This appendix focuses on the relationship between monitoring objectives, site types, and the geographic location of monitoring sites. Included are a rationale and set of general criteria for identifying candidate site locations in terms of physical characteristics which most closely match a specific monitoring objective. The criteria for more specifically locating the monitoring site, including spacing from roadways and vertical and horizontal probe and path placement, are described in appendix E to this part.

1.2 Spatial Scales. (a) To clarify the nature of the link between general monitoring objectives, site types, and the physical location of a particular monitor, the concept of spatial scale of representativeness is defined. The goal in locating monitors is to correctly match the spatial scale represented by the sample of monitored air with the spatial scale most appropriate for the monitoring site type, air pollutant to be measured, and the monitoring objective.

(b) Thus, spatial scale of representativeness is described in terms of the physical dimensions of the air parcel nearest to a monitoring site throughout which actual pollutant concentrations are reasonably similar. The scales of representativeness of most interest for the monitoring site types described above are as follows:

(1) *Microscale*—defines the concentrations in air volumes associated with area dimensions ranging from several meters up to about 100 meters.

(2) *Middle scale*—defines the concentration typical of areas up to several city blocks in size with dimensions ranging from about 100 meters to 0.5 kilometer.

(3) *Neighborhood scale*—defines concentrations within some extended area of the city that has relatively uniform land use with dimensions in the 0.5 to 4.0 kilometers range. The neighborhood and urban scales listed below have the potential to overlap in applications that concern secondarily formed or homogeneously distributed air pollutants.

(4) *Urban scale*—defines concentrations within an area of city-like dimensions, on the order of 4 to 50 kilometers. Within a city, the geographic placement of sources may result in there being no single site that can be said to represent air quality on an urban scale.

(5) *Regional scale*—defines usually a rural area of reasonably homogeneous geography without large sources, and extends from tens to hundreds of kilometers.

(6) *National and global scales*—these measurement scales represent concentrations characterizing the nation and the globe as a whole.

(c) Proper siting of a monitor requires specification of the monitoring objective, the types of sites necessary to meet the objective, and then the desired spatial scale of representativeness. For example, consider the case where the objective is to determine NAAQS compliance by understanding the maximum ozone concentrations for an area. Such areas would most likely be located downwind of a metropolitan area, quite likely in a suburban residential area where children and other susceptible individuals are likely to be outdoors. Sites located in these areas are most likely to represent an urban scale of measurement. In this example, physical location was determined by considering ozone precursor emission patterns, public activity, and meteorological characteristics affecting ozone formation and dispersion. Thus, spatial scale of representativeness was not used in the selection process but was a result of site location.

(d) In some cases, the physical location of a site is determined from joint consideration of both the basic monitoring objective and the type of monitoring site desired, or required by this appendix. For example, to determine $PM_{2.5}$ concentrations which are typical over a geographic area having relatively high $PM_{2.5}$ concentrations, a neighborhood scale site is more appropriate. Such a site would likely be located in a residential or commercial area having a high overall $PM_{2.5}$ emission density but not in the immediate vicinity of any single dominant source. Note that in this example, the desired scale of representativeness was an important factor in determining the physical location of the monitoring site.

(e) In either case, classification of the monitor by its type and spatial scale of representativeness is necessary and will aid in interpretation of the monitoring data for a particular monitoring objective (*e.g.*, public reporting, NAAQS compliance, or research support).

(f) Table D–1 of this appendix illustrates the relationship between the various site types that can be used to support the three basic monitoring objectives, and the scales of representativeness that are generally most appropriate for that type of site.

TABLE D–1 OF APPENDIX D TO PART 58.—RELATIONSHIP BETWEEN SITE TYPES AND SCALES OF REPRESENTATIVENESS

Site type	Appropriate siting scales
1. Highest concentration	Micro, middle, neighborhood (*sometimes* urban or regional for secondarily formed pollutants).
2. Population oriented	Neighborhood, urban.
3. Source impact	Micro, middle, neighborhood.

TABLE D–1 OF APPENDIX D TO PART 58.—RELATIONSHIP BETWEEN SITE TYPES AND SCALES OF REPRESENTATIVENESS—Continued

Site type	Appropriate siting scales
4. General/background & regional transport	Urban, regional.
5. Welfare-related impacts	Urban, regional.

2. *General Monitoring Requirements.*

(a) The National ambient air monitoring system includes several types of monitoring stations, each targeting a key data collection need and each varying in technical sophistication.

(b) Research grade sites are platforms for scientific studies, either involved with health or welfare impacts, measurement methods development, or other atmospheric studies. These sites may be collaborative efforts between regulatory agencies and researchers with specific scientific objectives for each. Data from these sites might be collected with both traditional and experimental techniques, and data collection might involve specific laboratory analyses not common in routine measurement programs. The research grade sites are not required by regulation; however, they are mentioned here due to their important role in supporting the air quality management program.

(c) The NCore multipollutant sites are sites that measure multiple pollutants in order to provide support to integrated air quality management data needs. NCore sites include urban scale measurements in general, in a selection of metropolitan areas and a limited number of more rural locations. Continuous monitoring methods are to be used at the NCore sites when available for a pollutant to be measured, as it is important to have data collected over common time periods for integrated analyses. NCore multipollutant sites are intended to be long-term sites useful for a variety of applications including air quality trends analyses, model evaluation, and tracking metropolitan area statistics. As such, the NCore sites should be placed away from direct emission sources that could substantially impact the ability to detect area-wide concentrations. NCore sites will also supplement other SLAMS sites in reporting to the public in major metropolitan areas. It is not the intent of the NCore sites to monitor in every area where the NAAQS are violated, rather they provide only a subset of the total monitoring effort necessary to accomplish air quality management goals. The total number of monitoring sites that will serve the variety of national, State, and local governmental needs will be substantially higher than these NCore requirements. The Administrator must approve the NCore sites.

(d) Monitoring sites designated as SLAMS sites, but not as NCore sites, are intended to address specific air quality management interests, and as such, are frequently single-pollutant measurement sites. The EPA Regional Administrator must approve the SLAMS sites.

(e) This appendix uses the statistical-based definitions for metropolitan areas provided by the Office of Management and Budget and the Census Bureau. These areas are referred to as metropolitan statistical areas (MSA), micropolitan statistical areas, core-based statistical areas (CBSA), and combined statistical areas (CSA). A CBSA associated with at least one urbanized area of at least 50,000 population is termed a Metropolitan Statistical Area. A CBSA associated with at least one urbanized cluster of at least 10,000 population is termed a Micropolitan Statistical Area. CSA consist of two or more adjacent CBSA. In this appendix, the term MSA is used to refer to a Metropolitan Statistical Area. By definition, both MSA and CSA have a high degree of integration; however, many such areas cross State or other political boundaries. MSA and CSA may also cross more than one air shed. EPA recognizes that State or local agencies must consider MSA/CSA boundaries and their own political boundaries and geographical characteristics in designing their air monitoring networks. EPA recognizes that there may be situations where the EPA Regional Administrator and the affected State or local agencies may need to augment or to divide the overall MSA/CSA monitoring responsibilities and requirements among these various agencies to achieve an effective network design. Full monitoring requirements apply separately to each affected State or local agency in the absence of an agreement between the affected agencies and the EPA Regional Administrator.

3. *Design Criteria for NCore Sites.*

(a) Each State is required to operate one NCore site. States may delegate this requirement to a local agency. States with many MSA often also have multiple air sheds with unique characteristics and, often, elevated air pollution. These States include, at a minimum, California, Florida, Illinois, Michigan, New York, North Carolina, Ohio, Pennsylvania, and Texas. These States are required to identify one to two additional NCore sites in order to account for their unique situations. Any State or local agency can propose additional candidate NCore sites or modifications to these requirements for approval by the Administrator. The NCore locations should be leveraged with other multipollutant air monitoring sites including PAMS sites, NATTS sites, CASTNET sites, and STN sites. Site leveraging includes using the same monitoring platform and equipment to meet the objectives of the variety of programs where possible and advantageous.

(b) The NCore sites must measure, at a minimum, $PM_{2.5}$ particle mass using continuous and integrated/filter-based samplers, speciated $PM_{2.5}$, $PM_{10\text{-}2.5}$ particle mass using continuous samplers, O_3, SO_2, CO, NO/NO_Y wind speed, wind direction, relative humidity, and ambient temperature. EPA recognizes that, in some cases, the physical location of the NCore site may not be suitable for representative meteorological measurements due to the site's physical surroundings. It is also possible that nearby meteorological measurements may be able to fulfill this data need. In these cases, the requirement for meteorological monitoring can be waived by the Administrator.

(c) In addition to the continuous measurements listed above, 10 of the NCore locations (either at the same sites or elsewhere within the MSA/CSA boundary) must also measure lead (Pb). These ten Pb sites are included within the NCore networks because they are intended to be long-term in operation, and not impacted directly from a single lead source. These locations for Pb monitoring must be located in the most populated MSA/CSA in each of the 10 EPA Regions. Alternatively, it is also acceptable to use the Pb concentration data provided at urban air toxics sites. In approving any substitutions, the Administrator must consider whether these alternative sites are suitable for collecting long-term lead trends data for the broader area.

4. *Pollutant-Specific Design Criteria for SLAMS Sites.*

4.1 Ozone (O_3) Design Criteria. (a) State, and where appropriate, local Agencies must operate O_3 sites for various locations depending upon area size (in terms of population and geographic characteristics) and typical peak concentrations (expressed in percentages above, below, or near the O_3 NAAQS). Specific SLAMS O_3 site minimum requirements are included in Table D–2 of this appendix. Typically, most of these required ozone sites will be SLAMS. The NCore sites are expected to compliment the O_3 data collection that takes place at SLAMS sites, and both types of sites can be used to meet the network minimum requirements. The total number of O_3 sites needed to support the basic monitoring objectives of public data reporting, air quality mapping, compliance, and understanding O_3-related atmospheric processes will include more sites than these minimum numbers required in Table D–2 of this appendix. The EPA Regional Administrator and the responsible State or local air monitoring agency must work together to design and/or maintain the most appropriate O_3 network to service the variety of data needs in an area.

TABLE D–2 OF APPENDIX D TO PART 58.—SLAMS MINIMUM O_3 MONITORING REQUIREMENTS

MSA or CSA population [3, 5]	Most recent 3-year design value concentrations >115% of any O_3 NAAQS [1]	Most recent 3-year design value concentrations ±15% of any O_3 NAAQS [1]	Most recent 3-year design value concentrations <85% of any O_3 NAAQS [1, 2]
>10 million	3	4	2
4–10 million	2	3	1
1–4 million	2	2	1
350,000–1 million	2	2	1
200,000–350,000	1	1	0
50,000–<200,000 [4]	1	1	0

[1] The ozone (O_3) National Ambient Air Quality Standards (NAAQS) levels and forms are defined in 40 CFR part 50.
[2] These minimum monitoring requirements apply in the absence of a design value.
[3] Minimum monitoring requirements apply to the Combined statistical area (CSA) as a whole, if applicable.
[4] Metropolitan statistical areas (MSA) must contain an urbanized area of 50,000 or more population.
[5] Population based on latest available census figures.

(b) At least one O_3 site in each MSA/CSA's O_3 network must be designed to record the maximum concentration for that particular metropolitan area. More than one maximum concentration site may be necessary in some areas. Table D–2 of this appendix does not account for the full breadth of additional factors that would be considered in designing a complete ozone monitoring program for an area. Some of these additional factors include geographic size, population density, complexity of terrain and meteorology, adjacent ozone monitoring programs, air pollution transport from neighboring areas, and measured air quality in comparison to all forms of the O_3 NAAQS (*i.e.*, 8-hour and 1-hour forms). Networks must be designed to account for all of these area characteristics. Network designs must be re-examined in periodic network assessments. Deviations from the above O_3 requirements are allowed if approved by the EPA Regional Administrator.

(c) The appropriate spatial scales for ozone sites are neighborhood, urban, and regional. Since ozone requires appreciable formation time, the mixing of reactants and products occurs over large volumes of air, and this reduces the importance of monitoring small scale spatial variability.

(1) *Neighborhood scale*—Measurements in this category represent conditions throughout some reasonably homogeneous urban subregion, with dimensions of a few kilometers. Homogeneity refers to pollutant concentrations. Neighborhood scale data will provide valuable information for developing, testing, and revising concepts and models that describe urban/regional concentration patterns. These data will be useful to the understanding and definition of processes that take periods of hours to occur and hence involve considerable mixing and transport. Under stagnation conditions, a site located in the neighborhood scale may also experience peak concentration levels within a metropolitan area.

(2) *Urban scale*—Measurement in this scale will be used to estimate concentrations over large portions of an urban area with dimensions of several kilometers to 50 or more kilometers. Such measurements will be used for determining trends, and designing area-wide control strategies. The urban scale sites would also be used to measure high concentrations downwind of the area having the highest precursor emissions.

(3) *Regional scale*—This scale of measurement will be used to typify concentrations over large portions of a metropolitan area and even larger areas with dimensions of as much as hundreds of kilometers. Such measurements will be useful for assessing the ozone that is transported to and from a metropolitan area, as well as background concentrations. In some situations, particularly when considering very large metropolitan areas with complex source mixtures, regional scale sites can be the maximum concentration location.

(d) EPA's technical guidance documents on ozone monitoring network design should be used to evaluate the adequacy of each existing O_3 monitor, to relocate an existing site, or to locate any new O_3 sites.

(e) For locating a neighborhood scale site to measure typical city concentrations, a reasonably homogeneous geographical area near the center of the region should be selected which is also removed from the influence of major NO_X sources. For an urban scale site to measure the high concentration areas, the emission inventories should be used to define the extent of the area of important nonmethane hydrocarbons and NO_X emissions. The meteorological conditions that occur during periods of maximum photochemical activity should be determined. These periods can be identified by examining the meteorological conditions that occur on the highest ozone air quality days. Trajectory analyses, an evaluation of wind and emission patterns on high ozone days, can also be useful in evaluating an ozone monitoring network. In areas without any previous ozone air quality measurements, meteorological and ozone precursor emissions information would be useful.

(f) Once the meteorological and air quality data are reviewed, the prospective maximum concentration monitor site should be selected in a direction from the city that is most likely to observe the highest ozone concentrations, more specifically, downwind during periods of photochemical activity. In many cases, these maximum concentration ozone sites will be located 10 to 30 miles or more downwind from the urban area where maximum ozone precursor emissions originate. The downwind direction and appropriate distance should be determined from historical meteorological data collected on days which show the potential for producing high ozone levels. Monitoring agencies are to consult with their EPA Regional Office when considering siting a maximum ozone concentration site.

(g) In locating a neighborhood scale site which is to measure high concentrations, the same procedures used for the urban scale are followed except that the site should be located closer to the areas bordering on the center city or slightly further downwind in an area of high density population.

(h) For regional scale background monitoring sites, similar meteorological analysis as for the maximum concentration sites may also inform the decisions for locating regional scale sites. Regional scale sites may be located to provide data on ozone transport between cities, as background sites, or for other data collection purposes. Consideration of both area characteristics, such as meteorology, and the data collection objectives, such as transport, must be jointly considered for a regional scale site to be useful.

(i) Since ozone levels decrease significantly in the colder parts of the year in many areas, ozone is required to be monitored at SLAMS monitoring sites only during the ''ozone season'' as designated in the AQS files on a State-by-State basis and described below in Table D–3 of this appendix. Deviations from the ozone monitoring season must be approved by the EPA Regional Administrator, documented within the annual monitoring network plan, and updated in AQS. Information on how to analyze ozone data to support a change to the ozone season in support of the 8-hour standard for a specific State can be found in reference 8 to this appendix.

TABLE D–3 TO APPENDIX D OF PART 58.—OZONE MONITORING SEASON BY STATE

State	Begin month	End month
Alabama	March	October.
Alaska	April	October.
Arizona	January	December.
Arkansas	March	November.
California	January	December.
Colorado	March	September.
Connecticut	April	September.
Delaware	April	October.
District of Columbia	April	October.
Florida	March	October.
Georgia	March	October.
Hawaii	January	December.
Idaho	May	September.
Illinois	April	October.
Indiana	April	September.
Iowa	April	October.
Kansas	April	October.
Kentucky	March	October.
Louisiana AQCR 019,022	March	October.
Louisiana AQCR 106	January	December.
Maine	April	September.
Maryland	April	October.
Massachusetts	April	September.
Michigan	April	September.
Minnesota	April	October.
Mississippi	March	October.
Missouri	April	October.
Montana	June	September.
Nebraska	April	October.
Nevada	January	December.
New Hampshire	April	September.
New Jersey	April	October.
New Mexico	January	December.
New York	April	October.
North Carolina	April	October.
North Dakota	May	September.
Ohio	April	October.
Oklahoma	March	November.
Oregon	May	September.
Pennsylvania	April	October.
Puerto Rico	January	December.
Rhode Island	April	September.
South Carolina	April	October.
South Dakota	June	September.
Tennessee	March	October.
Texas AQCR 106,153, 213, 214, 216	January	December.
Texas AQCR 022, 210, 211, 212, 215, 217, 218	March	October.
Utah	May	September.
Vermont	April	September.
Virginia	April	October.
Washington	May	September.
West Virginia	April	October.
Wisconsin	April 15	October 15.
Wyoming	April	October.
American Samoa	January	December.
Guam	January	December.
Virgin Islands	January	December.

4.2 Carbon Monoxide (CO) Design Criteria. (a) There are no minimum requirements for the number of CO monitoring sites. Continued operation of existing SLAMS CO sites using FRM or FEM methods is required until discontinuation is approved by the EPA Regional Administrator. Where SLAMS CO monitoring is required, at least one site must be a maximum concentration site for that area under investigation.

(b) Microscale and middle scale measurements are useful site classifications for SLAMS sites since most people have the potential for exposure on these scales. Carbon monoxide maxima occur primarily in areas near major roadways and intersections with high traffic density and often poor atmospheric ventilation.

(1) *Microscale*—This scale applies when air quality measurements are to be used to represent distributions within street canyons, over sidewalks, and near major roadways. In the case with carbon monoxide, microscale measurements in one location can often be considered as representative of other similar locations in a city.

(2) *Middle scale*—Middle scale measurements are intended to represent areas with dimensions from 100 meters to 0.5 kilometer. In certain cases, middle scale measurements may apply to areas that have a total length of several kilometers, such as ''line'' emission source areas. This type of emission sources areas would include air quality along a commercially developed

street or shopping plaza, freeway corridors, parking lots and feeder streets.

(c) After the spatial scale and type of site has been determined to meet the monitoring objective for each location, the technical guidance in reference 2 of this appendix should be used to evaluate the adequacy of each existing CO site and must be used to relocate an existing site or to locate any new sites.

4.3 Nitrogen Dioxide (NO_2) Design Criteria. (a) There are no minimum requirements for the number of NO_2 monitoring sites. Continued operation of existing SLAMS NO_2 sites using FRM or FEM methods is required until discontinuation is approved by the EPA Regional Administrator. Where SLAMS NO_2 monitoring is required, at least one NO_2 site in the area must be located to measure the maximum concentration of NO_2.

(b) NO/NO_Y measurements are included within the NCore multipollutant site requirements and the PAMS program. These NO/NO_Y measurements will produce conservative estimates for NO_2 that can be used to track continued compliance with the NO_2 NAAQS. NO/NO_Y monitors are used at these sites because it is important to collect data on total reactive nitrogen species for understanding ozone photochemistry.

4.4 Sulfur Dioxide (SO_2) Design Criteria. (a) There are no minimum requirements for the number of SO_2 monitoring sites. Continued operation of existing SLAMS SO_2 sites using FRM or FEM methods is required until discontinuation is approved by the EPA Regional Administrator. Where SLAMS SO_2 monitoring is required, at least one of the SLAMS SO_2 sites must be a maximum concentration site for that specific area.

(b) The appropriate spatial scales for SO_2 SLAMS monitoring are the microscale, middle, and possibly neighborhood scales. The multi-pollutant NCore sites can provide for metropolitan area trends analyses and general control strategy progress tracking. Other SLAMS sites are expected to provide data that are useful in specific compliance actions, for maintenance plan agreements, or for measuring near specific stationary sources of SO_2.

(1) *Micro and middle scale*—Some data uses associated with microscale and middle scale measurements for SO_2 include assessing the effects of control strategies to reduce concentrations (especially for the 3-hour and 24-hour averaging times) and monitoring air pollution episodes.

(2) *Neighborhood scale*—This scale applies where there is a need to collect air quality data as part of an ongoing SO_2 stationary source impact investigation. Typical locations might include suburban areas adjacent to SO_2 stationary sources for example, or for determining background concentrations as part of these studies of population responses to exposure to SO_2.

(c) Technical guidance in reference 1 of this appendix should be used to evaluate the adequacy of each existing SO_2 site, to relocate an existing site, or to locate new sites.

4.5 Lead (Pb) Design Criteria. (a) State, and where appropriate, local agencies are required to conduct Pb monitoring for all areas where Pb levels have been shown or are expected to be of concern over the most recent 2 years. As a minimum, there must be two SLAMS sites in any area where Pb concentrations currently exceed or have exceeded the Pb NAAQS in the most recent 2 years, and at least one of these two required sites must be a maximum concentration site. Where the Pb air quality violations are widespread or the emissions density, topography, or population locations are complex and varied, the EPA Regional Administrator may require more than two Pb ambient air monitoring sites.

(b) The most important spatial scales to effectively characterize the emissions from point sources are the micro, middle, and neighborhood scales.

(1) *Microscale*—This scale would typify areas in close proximity to lead point sources. Emissions from point sources such as primary and secondary lead smelters, and primary copper smelters may under fumigation conditions likewise result in high ground level concentrations at the microscale. In the latter case, the microscale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Data collected at microscale sites provide information for evaluating and developing ''hot-spot'' control measures.

(2) *Middle scale*—This scale generally represents Pb air quality levels in areas up to several city blocks in size with dimensions on the order of approximately 100 meters to 500 meters. The middle scale may for example, include schools and playgrounds in center city areas which are close to major Pb point sources. Pb monitors in such areas are desirable because of the higher sensitivity of children to exposures of elevated Pb concentrations (reference 3 of this appendix). Emissions from point sources frequently impact on areas at which single sites may be located to measure concentrations representing middle spatial scales.

(3) *Neighborhood scale*—The neighborhood scale would characterize air quality conditions throughout some relatively uniform land use areas with dimensions in the 0.5 to 4.0 kilometer range. Sites of this scale would provide monitoring data in areas representing conditions where children live and play. Monitoring in such areas is important since this segment of the population is more susceptible to the effects of Pb. Where a neighborhood site is located away from immediate Pb sources, the site may be very useful in representing typical air quality values for a larger residential area, and therefore suitable for population exposure and trends analyses.

(c) Technical guidance is found in references 4 and 5 of this appendix. These documents provide additional guidance on locating sites to meet specific urban area monitoring objectives and should be used in locating new sites or evaluating the adequacy of existing sites.

4.6 Particulate Matter (PM_{10}) Design Criteria. (a) There are no minimum requirements for the number of PM_{10} monitoring sites. In areas where the PM_{10} NAAQS has not been revoked, continued operation of existing SLAMS PM_{10} sites using FRM or FEM methods is required until discontinuation is approved by the EPA Regional Administrator. In areas for where the PM_{10} NAAQS has been revoked, there is no requirement for continued operation of existing sites.

(b) The most important spatial scales to effectively characterize the emissions of PM_{10} from both mobile and stationary sources are the middle scales and neighborhood scales. For purposes of establishing monitoring sites to represent large homogenous areas other than the above scales of representativeness and to characterize regional transport, urban or regional scale sites would also be needed.

(1) *Microscale*—This scale would typify areas such as downtown street canyons, traffic corridors, and fence line stationary source monitoring locations where the general public could be exposed to maximum PM_{10} concentrations. Microscale particulate matter sites should be located near inhabited buildings or locations where the general public can be expected to be exposed to the concentration measured. Emissions from stationary sources such as primary and secondary smelters, power plants, and other large industrial processes may, under certain plume conditions, likewise result in high ground level concentrations at the microscale. In the latter case, the microscale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Data collected at microscale sites provide information for evaluating and developing hot spot control measures.

(2) *Middle scale*—Much of the short-term public exposure to coarse fraction particles (PM_{10}) is on this scale and on the neighborhood scale. People moving through downtown areas or living near major roadways or stationary sources, may encounter particulate pollution that would be adequately characterized by measurements of this spatial scale. Middle scale PM_{10} measurements can be appropriate for the evaluation of possible short-term exposure public health effects. In many situations, monitoring sites that are representative of micro-scale or middle-scale impacts are not unique and are representative of many similar situations. This can occur along traffic corridors or other locations in a residential district. In this case, one location is representative of a neighborhood of small scale sites and is appropriate for evaluation of long-term or chronic effects. This scale also includes the characteristic concentrations for other areas with dimensions of a few hundred meters such as the parking lot and feeder streets associated with shopping centers, stadia, and office buildings. In the case of PM_{10}, unpaved or seldomly swept parking lots associated with these sources could be an important source in addition to the vehicular emissions themselves.

(3) *Neighborhood scale*—Measurements in this category represent conditions throughout some reasonably homogeneous urban subregion with dimensions of a few kilometers and of generally more regular shape than the middle scale. Homogeneity refers to the particulate matter concentrations, as well as the land use and

land surface characteristics. In some cases, a location carefully chosen to provide neighborhood scale data would represent not only the immediate neighborhood but also neighborhoods of the same type in other parts of the city. Neighborhood scale PM_{10} sites provide information about trends and compliance with standards because they often represent conditions in areas where people commonly live and work for extended periods. Neighborhood scale data could provide valuable information for developing, testing, and revising models that describe the larger-scale concentration patterns, especially those models relying on spatially smoothed emission fields for inputs. The neighborhood scale measurements could also be used for neighborhood comparisons within or between cities.

(4) *Urban scale*—This class of measurement would be made to characterize the particulate matter concentration over an entire metropolitan or rural area ranging in size from 4 to 50 kilometers. Such measurements would be useful for assessing trends in area-wide air quality, and hence, the effectiveness of large scale air pollution control strategies.

(5) *Regional scale*—These measurements would characterize conditions over areas with dimensions of as much as hundreds of kilometers. As noted earlier, using representative conditions for an area implies some degree of homogeneity in that area. For this reason, regional scale measurements would be most applicable to sparsely populated areas. Data characteristics of this scale would provide information about larger scale processes of particulate matter emissions, losses and transport.

4.7 Fine Particulate Matter ($PM_{2.5}$) Design Criteria.

4.7.1 General Requirements. (a) State, and where applicable local, agencies must operate the minimum number of required $PM_{2.5}$ SLAMS sites listed in Table D–4 of this appendix. The NCore sites are expected to complement the $PM_{2.5}$ data collection that takes place at non-NCore SLAMS sites, and both types of sites can be used to meet the minimum $PM_{2.5}$ network requirements. Deviations from these $PM_{2.5}$ monitoring requirements must be approved by the EPA Regional Administrator.

TABLE D–4 OF APPENDIX D TO PART 58.—$PM_{2.5}$ MINIMUM MONITORING REQUIREMENTS

MSA or CSA population [3, 5]	Most recent 3-year design value ≥115% of any $PM_{2.5}$ NAAQS [1]	Most recent 3-year design value ±15% of $PM_{2.5}$ NAAQS [1]	Most recent 3-year design value ≤85% of any $PM_{2.5}$ NAAQS [1 2]
> 1,000,000	2	3	2
500,000–1,000,000	1	2	1
250,000–500,000	1	1	0
100,000–250,000	1	1	0
50,000–<100,000 [4]	1	1	0

[1] The $PM_{2.5}$ National Ambient Air Quality Standards (NAAQS) levels and forms are defined in 40 CFR part 50.
[2] These minimum monitoring requirements apply in the absence of a design value.
[3] Minimum monitoring requirements apply to the Combined statistical area (CSA) as a whole, where applicable.
[4] Metropolitan statistical areas (MSA) must contain an urbanized area of 50,000 or more population.
[5] Population based on latest available census figures.

(b) The technical guidance in references 6 and 7 of this appendix should be used for siting $PM_{2.5}$ monitors.

(c) The most important spatial scale to effectively characterize the emissions of particulate matter from both mobile and stationary sources is the neighborhood scale for $PM_{2.5}$. For purposes of establishing monitoring sites to represent large homogenous areas other than the above scales of representativeness and to characterize regional transport, urban or regional scale sites would also be needed. Most $PM_{2.5}$ monitoring in urban areas should be representative of a neighborhood scale.

(1) *Microscale*—This scale would typify areas such as downtown street canyons and traffic corridors where the general public would be exposed to maximum concentrations from mobile sources. In some circumstances, the microscale is appropriate for particulate sites; community-oriented SLAMS sites measured at the microscale level should, however, be limited to urban sites that are representative of long-term human exposure and of many such microenvironments in the area. In general, microscale particulate matter sites should be located near inhabited buildings or locations where the general public can be expected to be exposed to the concentration measured. Emissions from stationary sources such as primary and secondary smelters, power plants, and other large industrial processes may, under certain plume conditions, likewise result in high ground level concentrations at the microscale. In the latter case, the microscale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Data collected at microscale sites provide information for evaluating and developing hot spot control measures. Unless these sites are indicative of population-oriented monitoring, they may be more appropriately classified as special purpose monitors (SPMs). Microscale $PM_{2.5}$ sites would be excluded from comparison with the annual $PM_{2.5}$ NAAQS in accordance with § 58.30(a)(1).

(2) *Middle scale*—People moving through downtown areas, or living near major roadways, encounter particle concentrations that would be adequately characterized by this spatial scale. Thus, measurements of this type would be appropriate for the evaluation of possible short-term exposure public health effects of particulate matter pollution. In many situations, monitoring sites that are representative of microscale or middle-scale impacts are not unique and are representative of many similar situations. This can occur along traffic corridors or other locations in a residential district. In this case, one location is representative of a number of small scale sites and is appropriate for evaluation of long-term or chronic effects. This scale also includes the characteristic concentrations for other areas with dimensions of a few hundred meters such as the parking lot and feeder streets associated with shopping centers, stadia, and office buildings.

(3) *Neighborhood scale*—Measurements in this category would represent conditions throughout some reasonably homogeneous urban subregion with dimensions of a few kilometers and of generally more regular shape than the middle scale. Homogeneity refers to the particulate matter concentrations, as well as the land use and land surface characteristics. Much of the $PM_{2.5}$ exposures are expected to be associated with this scale of measurement. In some cases, a location carefully chosen to provide neighborhood scale data would represent the immediate neighborhood as well as neighborhoods of the same type in other parts of the city. $PM_{2.5}$ sites of this kind provide good information about trends and compliance with standards because they often represent conditions in areas where people commonly live and work for periods comparable to those specified in the NAAQS. In general, most $PM_{2.5}$ monitoring in urban areas should have this scale.

(4) *Urban scale*—This class of measurement would be used to characterize the particulate matter concentration over an entire metropolitan or rural area ranging in size from 4 to 50 kilometers. Such measurements would be useful for assessing trends in area-wide air quality, and hence, the effectiveness of large scale air pollution control strategies. Community-oriented $PM_{2.5}$ sites may have this scale.

(5) *Regional scale*—These measurements would characterize conditions over areas with dimensions of as much as hundreds of kilometers. As noted earlier, using representative conditions for an area implies some degree of homogeneity in that area. For

this reason, regional scale measurements would be most applicable to sparsely populated areas. Data characteristics of this scale would provide information about larger scale processes of particulate matter emissions, losses and transport. $PM_{2.5}$ transport contributes to elevated particulate concentrations and may affect multiple urban and State entities with large populations such as in the eastern United States. Development of effective pollution control strategies requires an understanding at regional geographical scales of the emission sources and atmospheric processes that are responsible for elevated $PM_{2.5}$ levels and may also be associated with elevated ozone and regional haze.

4.7.2 Requirement for Continuous $PM_{2.5}$ Monitoring. State, or where appropriate, local agencies must operate continuous fine particulate analyzers at one-half (round up) of the minimum required sites listed in Table D–4 of this appendix. State and local air monitoring agencies must use methodologies and quality assurance/quality control (QA/QC) procedures approved by the EPA Regional Administrator for these sites.

4.7.3 Requirement for $PM_{2.5}$ Background and Transport Sites. Each State shall install and operate at least one $PM_{2.5}$ site to monitor for regional background and at least one $PM_{2.5}$ site to monitor regional transport. These monitoring sites may be at community-oriented sites and this requirement may be satisfied by a corresponding monitor in an area having similar air quality in another State. State and local air monitoring agencies must use methodologies and QA/QC procedures approved by the EPA Regional Administrator for these sites. Methods used at these sites may include non-federal reference method samplers such as IMPROVE or continuous $PM_{2.5}$ monitors.

4.7.4 $PM_{2.5}$ Chemical Speciation Site Requirements. Each State shall continue to conduct chemical speciation monitoring and analyses at sites designated to be part of the $PM_{2.5}$ Speciation Trends Network (STN). The selection and modification of these STN sites must be approved by the Administrator. The $PM_{2.5}$ chemical speciation urban trends sites shall include analysis for elements, selected anions and cations, and carbon. Samples must be collected using the monitoring methods and the sampling schedules approved by the Administrator. Chemical speciation is encouraged at additional sites where the chemically resolved data would be useful in developing State implementation plans and supporting atmospheric or health effects related studies.

4.7.5 Special Network Considerations Required When Using $PM_{2.5}$ Spatial Averaging Approaches. (a) The $PM_{2.5}$ NAAQS, specified in 40 CFR 50, provides State and local air monitoring agencies with an option for spatially averaging $PM_{2.5}$ air quality data. More specifically, two or more community-oriented (*i.e.*, sites in populated areas) $PM_{2.5}$ monitors may be averaged for comparison with the annual $PM_{2.5}$ NAAQS. This averaging approach is directly related to epidemiological studies used as the basis for the $PM_{2.5}$ annual NAAQS. Spatial averaging does not apply to comparisons with the daily $PM_{2.5}$ NAAQS.

(b) State and local agencies must carefully consider their approach for $PM_{2.5}$ network design when they intend to spatially average the data for compliance purposes. These State and local air monitoring agencies must define the area over which they intend to average $PM_{2.5}$ air quality concentrations. This area is defined as a Community Monitoring Zone (CMZ), which characterizes an area of relatively similar annual average air quality. State and local agencies can define a CMZ in a number of ways, including as part or all of a metropolitan area. These CMZ must be defined within a State or local agencies network description, as required in § 58.10 of this part and approved by the EPA Regional Administrator. When more than one CMZ is described within an agency's network design plan, CMZs must not overlap in their geographical coverage. The criteria that must be used for evaluating the acceptability of spatial averaging are defined in Appendix N of 40 CFR Part 50.

4.8 Coarse Particulate Matter ($PM_{10-2.5}$) Design Criteria.

4.8.1 General Monitoring Requirements. (a) Consistent with the indicator for the proposed $PM_{10-2.5}$ NAAQS, required $PM_{10-2.5}$ monitoring will address areas where the mix of $PM_{10-2.5}$ is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and will not address areas where it is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources.

(b) State, and where applicable, local Agencies must operate, at a minimum, the number of required $PM_{10-2.5}$ SLAMS sites listed in Table D–5 of this appendix. The minimum requirements of Table D–5 apply only to MSAs that contain all or part of an urbanized area with a population of at least 100,000 persons. NCore sites are expected to complement the $PM_{10-2.5}$ data collection that takes place at SLAMS Sites. Data from urban NCore sites can be used to meet minimum $PM_{10-2.5}$ network requirements if those sites meet the NAAQS comparability criteria in § 58.30(b). Modifications from the $PM_{10-2.5}$ monitoring requirements must be approved by the Regional Administrator.

TABLE D–5 OF APPENDIX D TO PART 58.—$PM_{10-2.5}$ MINIMUM MONITORING REQUIREMENTS

MSA population [1, 5]	Most recent 3-year design value [2] ≥80% of $PM_{10-2.5}$ NAAQS [3]	Most recent 3-year design value 50%–80% of $PM_{10-2.5}$ NAAQS [3 4]	Most recent 3-year design value <50% of $PM_{10-2.5}$ NAAQS [3]
>5,000,000	5	3	2
1,000,000–<5,000,000	4	2	1
500,000–<1,000,000	3	1	0
100,000–<500,000	2	1	0

[1] Metropolitan Statistical Area (MSA) as defined by the Office of Management of Budget. The minimum requirements of this table apply only to MSAs that contain all or part of an urbanized area with a population of at least 100,000 persons. Multiple MSA in a Combined statistical area (CSA) are separately subject to these requirements based on their population and design value.

[2] A database of estimated $PM_{10-2.5}$ design values will be provided by EPA until the network is fully deployed for three years. States may propose alternate estimates for EPA Regional Administrator approval.

[3] The $PM_{10-2.5}$ National Ambient Air Quality Standards (NAAQS) levels and forms are defined in part 50 of this chapter.

[4] These minimum monitoring requirements apply in the absence of a design value.

[5] Population based on latest available census figures.

(c) Middle and neighborhood scale measurements are the most important station classifications for $PM_{10-2.5}$ to assess the variation in coarse particle concentrations that would be expected across populated areas that are in proximity to large emissions sources. Sites that represent larger spatial scales would characterize concentrations in the suburban, highly populated areas of larger MSA's that are more distant from the zones of most concentrated industrial activity.

(1) *Microscale*—This scale would typify relatively small areas immediately adjacent to: Industrial sources; locations experiencing ongoing construction, redevelopment, and soil disturbance; and heavily traveled roadways. Data collected at microscale stations would characterize exposure over areas of limited spatial extent and population exposure, and may provide information useful for evaluating and developing source-oriented control measures. Microscale sites would be excluded from comparison with the NAAQS in accordance with § 58.30(b)(4), and may be more appropriately classified as SPMs.

(2) *Middle scale*—People living or working near major roadways or industrial districts encounter particle concentrations that would

be adequately characterized by this spatial scale. Thus, measurements of this type would be appropriate for the evaluation of public health effects of coarse particle exposure. Monitors located in populated areas that are nearly adjacent to large industrial point sources of coarse particles provide suitable locations for assessing maximum population exposure levels and identifying areas of potentially poor air quality. Similarly, monitors located in populated areas that border dense networks of heavily-traveled traffic are appropriate for assessing the impacts of resuspended road dust. This scale also includes the characteristic concentrations for other areas with dimensions of a few hundred meters such as school grounds and parks that are nearly adjacent to major roadways and industrial point sources, locations exhibiting mixed residential and commercial development, and downtown areas featuring office buildings, shopping centers, and stadiums.

(3) *Neighborhood scale*—Measurements in this category would represent conditions throughout some reasonably homogeneous urban subregion with dimensions of a few kilometers and of generally more regular shape than the middle scale. Homogeneity refers to the particulate matter concentrations, as well as the land use and land surface characteristics. This category includes suburban neighborhoods dominated by residences that are somewhat distant from major roadways and industrial districts but still impacted by urban sources, and areas of diverse land use where residences are interspersed with commercial and industrial neighborhoods. In some cases, a location carefully chosen to provide neighborhood scale data would represent the immediate neighborhood as well as neighborhoods of the same type in other parts of the city. The comparison of data from middle scale and neighborhood scale sites would provide valuable information for determining the variation of $PM_{10-2.5}$ levels across urban areas and assessing the spatial extent of elevated concentrations caused by major industrial point sources and heavily traveled roadways. Neighborhood scale sites would provide concentration data that are relevant to informing a large segment of the population of their exposure levels on a given day.

4.8.2 $PM_{10-2.5}$ Specific Siting Requirements.

4.8.2.1 A minimum of 50 percent of the $PM_{10-2.5}$ sites required in Table D–5 of this appendix must characterize middle scale-sized areas (values of 0.5 monitors and greater round up). Middle-scale sites must be situated in areas of expected maximum concentration among sites eligible for comparison to the NAAQS.

4.8.2.2 For those areas with monitoring requirements greater than one required monitor, at least one of the required monitors must be at a population-oriented site in a neighborhood scale-sized area that is highly populated and which may be somewhat further away from emission sources than the required middle-scale sites, subject to the requirement that the site must meet the comparability criteria in § 58.30(b). Among such sites, the State should select a site characterized by a large number of people subject to exposure; typically, this population number would be higher than the population at middle-scale sites expected to record maximum concentrations.

4.8.2.3 For MSA's with a requirement for four or five monitors, the siting of the remaining unspecified monitor is left to the discretion of the State or local monitoring agency, subject to the requirement that the site must meet the comparability criteria in § 58.30(b). This site could be placed in middle-scale or neighborhood scale locations similar to those that would be eligible as monitoring sites for the other required monitors. A State may also choose to place the site in a location that is somewhat more distant from downtown areas, main industrial source regions, or areas of highest traffic density, such as in a suburban residential community.

4.8.3 $PM_{10-2.5}$ Chemical Speciation Site Requirements. One chemical speciation monitoring site is required in each MSA with total population over 500,000 people that also has an estimated $PM_{10-2.5}$ design value greater than 80% of the NAAQS. These sites will gather data in areas that have a higher probability of exceeding the proposed NAAQS and also have larger exposed populations at risk, and will support the characterization of coarse particles concentrations that control the attainment/nonattainment status of the area. Samples must be collected using monitoring methods and the sampling schedules approved by the EPA Regional Administrator. Chemical speciation is encouraged at additional sites to support development of State implementation plans and atmospheric or health effects related studies. These additional locations may include STN, NCore, CASTNET, and IMPROVE sites to provide coverage of sources typical of urban core locations, suburban regions typified by predominantly residential districts, and less densely-settled rural locations that may be characterized by naturally occurring geologic materials. The selection and modification of $PM_{10-2.5}$ chemical speciation sites must be approved by the EPA Regional Administrator.

4.9 Filter Archive Requirements for $PM_{2.5}$, PM_{10}, and $PM_{10-2.5}$. Air pollution control agencies shall archive $PM_{2.5}$, PM_{10}, and $PM_{10-2.5}$ filters from all SLAMS sites for 1 year after collection. These filters shall be made available during the course of that year for supplemental analyses at the request of EPA or to provide information to State and local agencies on $PM_{2.5}$ composition. Other Federal Agencies may request access to filters for purposes of supporting air quality management or community health—such as biological assay—through the applicable EPA Regional Administrator. The filters shall be archived according to procedures approved by the Administrator. EPA recommends that particulate matter filters be archived for longer periods, especially for key sites in making NAAQS related decisions or for supporting health-related air pollution studies.

5. *Network Design for Photochemical Assessment Monitoring Stations (PAMS).*

The PAMS program provides more comprehensive data on O_3 air pollution in areas classified as serious, severe, or extreme nonattainment for ozone than would otherwise be achieved through the NCore and SLAMS sites. More specifically, the PAMS program includes measurements for ozone, oxides of nitrogen, volatile organic compounds, and meteorology.

5.1 PAMS Monitoring Objectives. PAMS design criteria are site specific. Concurrent measurements of O_3, oxides of nitrogen, speciated VOC, CO, and meteorology are obtained at PAMS sites. Design criteria for the PAMS network are based on locations relative to O_3 precursor source areas and predominant wind directions associated with high O_3 events. Specific monitoring objectives are associated with each location. The overall design should enable characterization of precursor emission sources within the area, transport of O_3 and its precursors, and the photochemical processes related to O_3 nonattainment. Specific objectives that must be addressed include assessing ambient trends in O_3, oxides of nitrogen, VOC species, and determining spatial and diurnal variability of O_3, oxides of nitrogen, and VOC species. Specific monitoring objectives associated with each of these sites may result in four distinct site types. Detailed guidance for the locating of these sites may be found in reference 9 of this appendix.

(a) Type 1 sites are established to characterize upwind background and transported O_3 and its precursor concentrations entering the area and will identify those areas which are subjected to transport.

(b) Type 2 sites are established to monitor the magnitude and type of precursor emissions in the area where maximum precursor emissions are expected to impact and are suited for the monitoring of urban air toxic pollutants.

(c) Type 3 sites are intended to monitor maximum O_3 concentrations occurring downwind from the area of maximum precursor emissions.

(d) Type 4 sites are established to characterize the downwind transported O_3 and its precursor concentrations exiting the area and will identify those areas which are potentially contributing to overwhelming transport in other areas.

5.2 Monitoring Period. PAMS precursor monitoring must be conducted annually throughout the months of June, July and August (as a minimum) when peak O_3 values are expected in each area. Alternate precursor monitoring periods may be submitted for approval to the Administrator as a part of the annual monitoring network plan required by § 58.10.

5.3 Minimum Monitoring Network Requirements. A Type 2 site is required for each area. Overall, only two sites are required for each area, providing all chemical measurements are made. For example, if a design includes two Type 2 sites, then a third site will be necessary to capture the NO_y measurement. The minimum required number and type of monitoring sites and sampling requirements are listed in Table D–6 of this appendix. Any alternative plans may be put in place in lieu of these requirements, if approved by the Administrator.

TABLE D–6 OF APPENDIX D TO PART 58.—MINIMUM REQUIRED PAMS MONITORING LOCATIONS AND FREQUENCIES

Measurement	Where required	Sampling frequency (all daily except for upper air meteorology)[1]
Speciated VOC[2]	Two sites per area, one of which must be a Type 2 site	During the PAMS monitoring period: (1) Hourly auto GC, or (2) Eight 3-hour canisters, or (3) 1 morning and 1 afternoon canister with a 3-hour or less averaging time plus Continuous Total Non-methane Hydrocarbon measurement.
Carbonyl Sampling	Type 2 site in areas classified as serious or above for the 8-hour ozone standard.	3-hour samples every day during the PAMS monitoring period.
NO_X	All Type 2 sites	Hourly during the ozone monitoring season.[3]
NO_Y	One site per area at the Type 3 or Type 1 site	Hourly during the ozone monitoring season.
CO (ppb level)	One site per area at a Type 2 site	Hourly during the ozone monitoring season.
Ozone	All sites	Hourly during the ozone monitoring season.
Surface met	All sites	Hourly during the ozone monitoring season.
Upper air meteorology	One representative location within PAMS area	Sampling frequency must be approved as part of the PAMS Network Description described in 40 CFR 58.41.

[1] Daily or with an approved alternative plan.
[2] Speciated VOC is defined in the ''Technical Assistance Document for Sampling and Analysis of Ozone Precursors'', EPA/600–R–98/161, September 1998.
[3] Approved ozone monitoring season as stipulated in 40 CFR part 58, Table D–3 of this appendix.

5.4 Transition Period. A transition period is allowed for phasing in the operation of newly required PAMS programs (due generally to reclassification of an area into serious, severe, or extreme nonattainment for ozone). Following the date of redesignation or reclassification of any existing O_3 nonattainment area to serious, severe, or extreme, or the designation of a new area and classification to serious, severe, or extreme O_3 nonattainment, a State is allowed one year to develop plans for its PAMS implementation strategy. Subsequently, a minimum of one Type 2 site must be operating by the first month of the following approved PAMS season. Operation of the remaining site(s) must, at a minimum, be phased in at the rate of one site per year during subsequent years as outlined in the approved PAMS network description provided by the State.

6. *References.*

1. Ball, R.J. and G. E. Anderson. Optimum Site Exposure Criteria for SO_2 Monitoring. The Center for the Environment and Man, Inc., Hartford, CT. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Publication No. EPA–450/3–77–013. April 1977.

2. Ludwig, F.F., J.H.S. Kealoha, and E. Shelar. Selecting Sites for Carbon Monoxide Monitoring. Stanford Research Institute, Menlo Park, CA. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Publication No. EPA–450/3–75–077, September 1975.

3. Air Quality Criteria for Lead. Office of Research and Development, U.S. Environmental Protection Agency, Washington, DC. EPA Publication No. 600/8–89–049F. August 1990. (NTIS document numbers PB87–142378 and PB91–138420.)

4. Optimum Site Exposure Criteria for Lead Monitoring. PEDCo Environmental, Inc. Cincinnati, OH. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Contract No. 68–02–3013. May 1981.

5. Guidance for Conducting Ambient Air Monitoring for Lead Around Point Sources. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA–454/R–92–009. May 1997.

6. Koch, R.C. and H.E. Rector. Optimum Network Design and Site Exposure Criteria for Particulate Matter. GEOMET Technologies, Inc., Rockville, MD. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Contract No. 68–02–3584. EPA 450/4–87–009. May 1987.

7. Watson *et al.* Guidance for Network Design and Optimum Site Exposure for $PM_{2.5}$ and PM_{10}. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA–454/R–99–022, December 1997.

8. Guideline for Selecting and Modifying the Ozone Monitoring Season Based on an 8-Hour Ozone Standard. Prepared for U.S. Environmental Protection Agency, RTP, NC. EPA–454/R–98–001, June 1998.

9. Photochemical Assessment Monitoring Stations Implementation Manual. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA–454/B–93–051. March 1994.

52. Appendix E to part 58 is revised to read as follows:

Appendix E to Part 58—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

1. Introduction.
2. Horizontal and Vertical Placement.
3. Spacing from Minor Sources.
4. Spacing From Obstructions.
5. Spacing From Trees.
6. Spacing From Roadways.
7. Cumulative Interferences on a Monitoring Path.
8. Maximum Monitoring Path Length.
9. Probe Material and Pollutant Sample Residence Time.
10. Waiver Provisions.
11. Summary.
12. References.

1. *Introduction.*

(a) This appendix contains specific location criteria applicable to SLAMS, NCore, and PAMS ambient air quality monitoring probes, inlets, and optical paths after the general location has been selected based on the monitoring objectives and spatial scale of representation discussed in appendix D to this part. Adherence to these siting criteria is necessary to ensure the uniform collection of compatible and comparable air quality data.

(b) The probe and monitoring path siting criteria discussed in this appendix must be followed to the maximum extent possible. It is recognized that there may be situations where some deviation from the siting criteria may be necessary. In any such case, the reasons must be thoroughly documented in a written request for a waiver that describes how and why the proposed siting deviates from the criteria. This documentation should help to avoid later questions about the validity of the resulting monitoring data. Conditions under which the EPA would consider an application for waiver from these siting criteria are discussed in section 11 of this appendix.

(c) The pollutant-specific probe and monitoring path siting criteria generally apply to all spatial scales except where noted otherwise. Specific siting criteria that are phrased with a ''must'' are defined as requirements and exceptions must be approved through the waiver provisions. However, siting criteria that are phrased with a ''should'' are defined as goals to meet for consistency but are not requirements.

2. *Horizontal and Vertical Placement.*

The probe or at least 80 percent of the monitoring path must be located between 2 and 15 meters above ground level for all ozone, sulfur dioxide and nitrogen dioxide monitoring sites, and for neighborhood scale Pb, PM_{10}, $PM_{10\text{-}2.5}$, $PM_{2.5}$, and carbon monoxide sites. Middle scale $PM_{10\text{-}2.5}$ sites are required to have sampler inlets between 2 and 7 meters above ground level. Microscale Pb, PM_{10}, and $PM_{2.5}$ sites are required to have sampler inlets between 2 and 7 meters above ground level. The inlet

probes for microscale carbon monoxide monitors that are being used to measure concentrations near roadways must be 3±½ meters above ground level. The probe or at least 90 percent of the monitoring path must be at least 1 meter vertically or horizontally away from any supporting structure, walls, parapets, penthouses, etc., and away from dusty or dirty areas. If the probe or a significant portion of the monitoring path is located near the side of a building, then it should be located on the windward side of the building relative to the prevailing wind direction during the season of highest concentration potential for the pollutant being measured.

3. *Spacing from Minor Sources.*

(a) It is important to understand the monitoring objective for a particular location in order to interpret this particular requirement. Local minor sources of a primary pollutant, such as SO_2, lead, or particles, can cause high concentrations of that particular pollutant at a monitoring site. If the objective for that monitoring site is to investigate these local primary pollutant emissions, then the site is likely to be properly located nearby. This type of monitoring site would in all likelihood be a microscale type of monitoring site. If a monitoring site is to be used to determine air quality over a much larger area, such as a neighborhood or city, a monitoring agency should avoid placing a monitor probe, path, or inlet near local, minor sources. The plume from the local minor sources should not be allowed to inappropriately impact the air quality data collected at a site. Particulate matter sites should not be located in an unpaved area unless there is vegetative ground cover year round, so that the impact of wind blown dusts will be kept to a minimum.

(b) Similarly, local sources of nitric oxide (NO) and ozone-reactive hydrocarbons can have a scavenging effect causing unrepresentatively low concentrations of O_3 in the vicinity of probes and monitoring paths for O_3. To minimize these potential interferences, the probe or at least 90 percent of the monitoring path must be away from furnace or incineration flues or other minor sources of SO_2 or NO. The separation distance should take into account the heights of the flues, type of waste or fuel burned, and the sulfur content of the fuel.

4. *Spacing From Obstructions.*

(a) Buildings and other obstacles may possibly scavenge SO_2, O_3, or NO_2, and can act to restrict airflow for any pollutant. To avoid this interference, the probe, inlet, or at least 90 percent of the monitoring path must have unrestricted airflow and be located away from obstacles. The distance from the obstacle to the probe, inlet, or monitoring path must be at least twice the height that the obstacle protrudes above the probe, inlet, or monitoring path. An exception to this requirement can be made for measurements taken in street canyons or at source-oriented sites where buildings and other structures are unavoidable.

(b) Generally, a probe or monitoring path located near or along a vertical wall is undesirable because air moving along the wall may be subject to possible removal mechanisms. A probe, inlet, or monitoring path must have unrestricted airflow in an arc of at least 180 degrees. This arc must include the predominant wind direction for the season of greatest pollutant concentration potential. For particle sampling, a minimum of 2 meters of separation from walls, parapets, and structures is required for rooftop site placement.

(c) Special consideration must be devoted to the use of open path analyzers due to their inherent potential sensitivity to certain types of interferences, or optical obstructions. A monitoring path must be clear of all trees, brush, buildings, plumes, dust, or other optical obstructions, including potential obstructions that may move due to wind, human activity, growth of vegetation, etc. Temporary optical obstructions, such as rain, particles, fog, or snow, should be considered when siting an open path analyzer. Any of these temporary obstructions that are of sufficient density to obscure the light beam will affect the ability of the open path analyzer to continuously measure pollutant concentrations. Transient, but significant obscuration of especially longer measurement paths could occur as a result of certain meteorological conditions (e.g., heavy fog, rain, snow) and/or aerosol levels that are of a sufficient density to prevent the open path analyzer's light transmission. If certain compensating measures are not otherwise implemented at the onset of monitoring (e.g., shorter path lengths, higher light source intensity), data recovery during periods of greatest primary pollutant potential could be compromised. For instance, if heavy fog or high particulate levels are coincident with periods of projected NAAQS-threatening pollutant potential, the representativeness of the resulting data record in reflecting maximum pollutant concentrations may be substantially impaired despite the fact that the site may otherwise exhibit an acceptable, even exceedingly high overall valid data capture rate.

5. *Spacing From Trees.*

(a) Trees can provide surfaces for SO_2, O_3, or NO_2 adsorption or reactions, and surfaces for particle deposition. Trees can also act as obstructions in cases where they are located between the air pollutant sources or source areas and the monitoring site, and where the trees are of a sufficient height and leaf canopy density to interfere with the normal airflow around the probe, inlet, or monitoring path. To reduce this possible interference/obstruction, the probe, inlet, or at least 90 percent of the monitoring path must be at least 10 meters or further from the drip line of trees.

(b) The scavenging effect of trees is greater for O_3 than for other criteria pollutants. Monitoring agencies must take steps to consider the impact of trees on ozone monitoring sites and take steps to avoid this problem.

(c) For microscale sites of any air pollutant, no trees or shrubs should be located between the probe and the source under investigation, such as a roadway or a stationary source.

6. *Spacing From Roadways.*

6.1 Spacing for Ozone and Oxide of Nitrogen Probes and Monitoring Paths. In siting an O_3 analyzer, it is important to minimize destructive interferences from sources of NO, since NO readily reacts with O_3. In siting NO_2 analyzers for neighborhood and urban scale monitoring, it is important to minimize interferences from automotive sources. Table E–1 of this appendix provides the required minimum separation distances between a roadway and a probe or, where applicable, at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A sampling site having a point analyzer probe located closer to a roadway than allowed by the Table E–1 requirements should be classified as middle scale rather than neighborhood or urban scale, since the measurements from such a site would more closely represent the middle scale. If an open path analyzer is used at a site, the monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For those situations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, one must consider the entire segment of the monitoring path in the area of potential atmospheric interference from automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and the minimum separation distance, as determined from Table E–1 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

TABLE E–1 TO APPENDIX E OF PART 58.—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND PROBES OR MONITORING PATHS FOR MONITORING NEIGHBORHOOD AND URBAN SCALE OZONE (O_3) AND OXIDES OF NITROGEN (NO, NO_2, NO_X, NO_Y)

Roadway average daily traffic, vehicles per day	Minimum distance[1] (meters)
≤1,000	10
10,000	20
15,000	30
20,000	40
40,000	60
70,000	100
110,000	250

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

6.2 Spacing for Carbon monoxide Probes and Monitoring Paths. (a) Street canyon and traffic corridor sites (microscale) are intended to provide a measurement of the influence of the immediate source on the pollution exposure of the population. In order to provide some reasonable consistency and comparability in the air quality data from microscale sites, a minimum distance of 2 meters and a maximum distance of 10 meters from the edge of the nearest traffic lane must be maintained for these CO monitoring inlet probes. This should give consistency to the

data, yet still allow flexibility of finding suitable locations.

(b) Street canyon/corridor (microscale) inlet probes must be located at least 10 meters from an intersection and preferably at a midblock location. Midblock locations are preferable to intersection locations because intersections represent a much smaller portion of downtown space than do the streets between them. Pedestrian exposure is probably also greater in street canyon/corridors than at intersections.

(c) In determining the minimum separation between a neighborhood scale monitoring site and a specific roadway, the presumption is made that measurements should not be substantially influenced by any one roadway. Computations were made to determine the separation distance, and Table E–2 of this appendix provides the required minimum separation distance between roadways and a probe or 90 percent of a monitoring path. Probes or monitoring paths that are located closer to roads than this criterion allows should not be classified as a neighborhood scale, since the measurements from such a site would closely represent the middle scale. Therefore, sites not meeting this criterion should be classified as middle scale.

TABLE E–2 TO APPENDIX E OF PART 58.—MINIMUM SEPARATION DISTANCE BETWEEN ROADWAYS AND PROBES OR MONITORING PATHS FOR MONITORING NEIGHBORHOOD SCALE CARBON MONOXIDE

Roadway average daily traffic, vehicles per day	Minimum distance [1] (meters)
≤10,000	10
15,000	25
20,000	45
30,000	80
40,000	115
50,000	135
≥60,000	150

[1] Distance from the edge of the nearest traffic lane. The distance for intermediate traffic counts should be interpolated from the table values based on the actual traffic count.

6.3 Spacing for Particulate Matter ($PM_{2.5}$, PM_{10}, Pb) Inlets. (a) Since emissions associated with the operation of motor vehicles contribute to urban area particulate matter ambient levels, spacing from roadway criteria are necessary for ensuring national consistency in PM sampler siting.

(b) The intent is to locate localized hot-spot sites in areas of highest concentrations whether it be from mobile or multiple stationary sources. If the area is primarily affected by mobile sources and the maximum concentration area(s) is judged to be a traffic corridor or street canyon location, then the monitors should be located near roadways with the highest traffic volume and at separation distances most likely to produce the highest concentrations. For the microscale traffic corridor site, the location must be between 5 and 15 meters from the major roadway. For the microscale street canyon site the location must be between 2 and 10 meters from the roadway. For the middle scale site, a range of acceptable distances from the roadway is shown in figure E–1 of this appendix. This figure also includes separation distances between a roadway and neighborhood or larger scale sites by default. Any site, 2 to 15 meters high, and further back than the middle scale requirements will generally be neighborhood, urban or regional scale. For example, according to Figure E–1 of this appendix, if a PM sampler is primarily influenced by roadway emissions and that sampler is set back 10 meters from a 30,000 ADT (average daily traffic) road, the site should be classified as microscale, if the sampler height is between 2 and 7 meters. If the sampler height is between 7 and 15 meters, the site should be classified as middle scale. If the sample is 20 meters from the same road, it will be classified as middle scale; if 40 meters, neighborhood scale; and if 110 meters, an urban scale.

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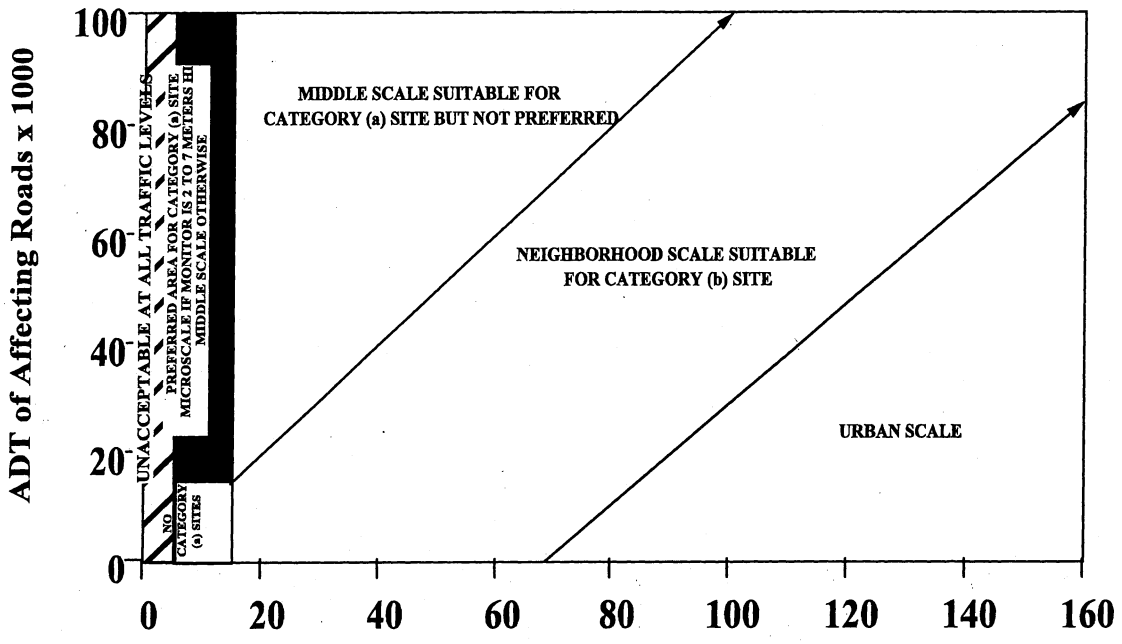

Figure E-1. Distance of PM samplers to nearest traffic lane (meters)

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7. *Cumulative Interferences on a Monitoring Path.*

(This paragraph applies only to open path analyzers.) The cumulative length or portion of a monitoring path that is affected by minor sources, trees, or roadways must not exceed 10 percent of the total monitoring path length.

8. *Maximum Monitoring Path Length.*

(This paragraph applies only to open path analyzers.) The monitoring path length must not exceed 1 kilometer for analyzers in neighborhood, urban, or regional scale. For middle scale monitoring sites, the monitoring path length must not exceed 300 meters. In areas subject to frequent periods of dust, fog, rain, or snow, consideration should be given to a shortened monitoring path length to minimize loss of monitoring data due to these temporary optical obstructions. For

certain ambient air monitoring scenarios using open path analyzers, shorter path lengths may be needed in order to ensure that the monitoring site meets the objectives and spatial scales defined in appendix D to this part. The Regional Administrator may require shorter path lengths, as needed on an individual basis, to ensure that the SLAMS sites meet the appendix D requirements. Likewise, the Administrator may specify the maximum path length used at NCore monitoring sites.

9. *Probe Material and Pollutant Sample Residence Time.*

For the reactive gases, SO_2, NO_2, and O_3, special probe material must be used for point analyzers. (a) Studies [20–24] have been conducted to determine the suitability of materials such as polypropylene, polyethylene, polyvinyl chloride, Tygon®, aluminum, brass, stainless steel, copper, Pyrex® glass and Teflon® for use as intake sampling lines. Of the above materials, only Pyrex® glass and Teflon® have been found to be acceptable for use as intake sampling lines for all the reactive gaseous pollutants. Furthermore, the EPA[25] has specified borosilicate glass or FEP Teflon® as the only acceptable probe materials for delivering test atmospheres in the determination of reference or equivalent methods. Therefore, borosilicate glass, FEP Teflon®, or their equivalent must be used for existing and new NCore monitors.

(b) For volatile organic compound (VOC) monitoring at PAMS, FEP Teflon® is unacceptable as the probe material because of VOC adsorption and desorption reactions on the FEP Teflon®. Borosilicate glass, stainless steel, or its equivalent are the acceptable probe materials for VOC and carbonyl sampling. Care must be taken to ensure that the sample residence time is kept to 20 seconds or less.

(c) No matter how nonreactive the sampling probe material is initially, after a period of use reactive particulate matter is deposited on the probe walls. Therefore, the time it takes the gas to transfer from the probe inlet to the sampling device is also critical. Ozone in the presence of nitrogen oxide (NO) will show significant losses even in the most inert probe material when the residence time exceeds 20 seconds.[26] Other studies [27–28] indicate that a 10-second or less residence time is easily achievable. Therefore, sampling probes for reactive gas monitors at NCore must have a sample residence time less than 20 seconds.

10. *Waiver Provisions.*

Most sampling probes or monitors can be located so that they meet the requirements of this appendix. New sites with rare exceptions, can be located within the limits of this appendix. However, some existing sites may not meet these requirements and yet still produce useful data for some purposes. EPA will consider a written request from the State agency to waive one or more siting criteria for some monitoring sites providing that the State can adequately demonstrate the need (purpose) for monitoring or establishing a monitoring site at that location.

10.1 For establishing a new site, a waiver may be granted only if both of the following criteria are met:

10.1.1 The site can be demonstrated to be as representative of the monitoring area as it would be if the siting criteria were being met.

10.1.2 The monitor or probe cannot reasonably be located so as to meet the siting criteria because of physical constraints (e.g., inability to locate the required type of site the necessary distance from roadways or obstructions).

10.2 However, for an existing site, a waiver may be granted if either of the criteria in sections 10.1.1 and 10.1.2 of this appendix are met.

10.3 Cost benefits, historical trends, and other factors may be used to add support to the criteria in sections 10.1.1 and 10.1.2 of this appendix, however, they in themselves, will not be acceptable reasons for granting a waiver. Written requests for waivers must be submitted to the Regional Administrator.

11. *Summary.*

Table E–4 of this appendix presents a summary of the general requirements for probe and monitoring path siting criteria with respect to distances and heights. It is apparent from Table E–4 that different elevation distances above the ground are shown for the various pollutants. The discussion in this appendix for each of the pollutants describes reasons for elevating the monitor, probe, or monitoring path. The differences in the specified range of heights are based on the vertical concentration gradients. For CO, the gradients in the vertical direction are very large for the microscale, so a small range of heights are used. The upper limit of 15 meters is specified for consistency between pollutants and to allow the use of a single manifold or monitoring path for monitoring more than one pollutant.

TABLE E–4 OF APPENDIX E TO PART 58.—SUMMARY OF PROBE AND MONITORING PATH SITING CRITERIA

Pollutant	Scale (maximum monitoring path length, meters)	Height from ground to probe, inlet or 80% of monitoring path[1]	Horizontal and vertical distance supporting structures[2] to probe, inlet or 90% of monitoring path[1] (meters)	Distance from trees to probe, inlet or 90% of monitoring path[1] (meters)	Distance from roadways to probe, inlet or monitoring path[1] (meters)
SO_2 [3, 4, 5, 6]	Middle (300 m) Neighborhood Urban, and Regional (1 km).	2–15	>1	>10	N/A.
CO[4, 5, 7]	Micro, middle (300 m), Neighborhood (1 km).	3±½: 2–15	> 1	> 10	2–10; see Table E–2 of this appendix for middle and neighborhood scales.
NO_2, O_3[3, 4, 5]	Middle (300 m) Neighborhood, Urban, and Regional (1 km).	2–15	> 1	> 10	See Table E–1 of this appendix for all scales.
Ozone precursors (for PAMS)[3, 4, 5].	Neighborhood and Urban (1 km).	2–15	> 1	> 10	See Table E–4 of this appendix for all scales.
PM, Pb[3, 4, 5, 6, 8]	Micro: Middle, Neighborhood, Urban and Regional.	2–7 (micro); 2–7 (middle $PM_{10-2.5}$); 2–15 (all other scales).	> 2 (all scales, horizontal distance only).	> 10 (all scales)	2–10 (micro); see Figure E–1 of this appendix for all other scales.

N/A—Not applicable.

[1] Monitoring path for open path analyzers is applicable only to middle or neighborhood scale CO monitoring and all applicable scales for monitoring SO_2, O_3 precursors, and NO_2.

[2] When probe is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.

[3] Should be >20 meters from the dripline of tree(s) and must be 10 meters from the dripline when the tree(s) act as an obstruction.

[4] Distance from sampler, probe, or 90% of monitoring path to obstacle, such as a building, must be at least twice the height the obstacle protrudes above the sampler, probe, or monitoring path. Sites not meeting this criterion may be classified as middle scale (see text).

[5] Must have unrestricted airflow 270 degrees around the probe or sampler; 180 degrees if the probe is on the side of a building.

[6] The probe, sampler, or monitoring path should be away from minor sources, such as furnace or incineration flues. The separation distance is dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fuel (sulfur, ash, or lead content). This criterion is designed to avoid undue influences from minor sources.

[7] For microscale CO monitoring sites, the probe must be >10 meters from a street intersection and preferably at a midblock location.

[8] Collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference.

12. *References.*

1. Bryan, R.J., R.J. Gordon, and H. Menck. Comparison of High Volume Air Filter Samples at Varying Distances from Los Angeles Freeway. University of Southern California, School of Medicine, Los Angeles, CA. (Presented at 66th Annual Meeting of Air Pollution Control Association. Chicago, IL., June 24–28, 1973. APCA 73–158.)

2. Teer, E.H. Atmospheric Lead Concentration Above an Urban Street. Master of Science Thesis, Washington University, St. Louis, MO. January 1971.

3. Bradway, R.M., F.A. Record, and W.E. Belanger. Monitoring and Modeling of Resuspended Roadway Dust Near Urban Arterials. GCA Technology Division, Bedford, MA. (Presented at 1978 Annual Meeting of Transportation Research Board, Washington, DC. January 1978.)

4. Pace, T.G., W.P. Freas, and E.M. Afify. Quantification of Relationship Between Monitor Height and Measured Particulate Levels in Seven U.S. Urban Areas. U.S. Environmental Protection Agency, Research Triangle Park, NC. (Presented at 70th Annual Meeting of Air Pollution Control Association, Toronto, Canada, June 20–24, 1977. APCA 77–13.4.)

5. Harrison, P.R. Considerations for Siting Air Quality Monitors in Urban Areas. City of Chicago, Department of Environmental Control, Chicago, IL. (Presented at 66th Annual Meeting of Air Pollution Control Association, Chicago, IL., June 24–28, 1973. APCA 73–161.)

6. Study of Suspended Particulate Measurements at Varying Heights Above Ground. Texas State Department of Health, Air Control Section, Austin, TX. 1970. p. 7.

7. Rodes, C.E. and G.F. Evans. Summary of LACS Integrated Pollutant Data. In: Los Angeles Catalyst Study Symposium. U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Publication No. EPA–600/4–77–034. June 1977.

8. Lynn, D.A. *et. al.* National Assessment of the Urban Particulate Problem: Volume 1, National Assessment. GCA Technology Division, Bedford, MA. U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Publication No. EPA–450/3–75–024. June 1976.

9. Pace, T.G. Impact of Vehicle-Related Particulates on TSP Concentrations and Rationale for Siting Hi-Vols in the Vicinity of Roadways. OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, NC. April 1978.

10. Ludwig, F.L., J.H. Kealoha, and E. Shelar. Selecting Sites for Monitoring Total Suspended Particulates. Stanford Research Institute, Menlo Park, CA. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Publication No. EPA–450/3–77–018. June 1977, revised December 1977.

11. Ball, R.J. and G.E. Anderson. Optimum Site Exposure Criteria for SO_2 Monitoring. The Center for the Environment and Man, Inc., Hartford, CT. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Publication No. EPA–450/3–77–013. April 1977.

12. Ludwig, F.L. and J.H.S. Kealoha. Selecting Sites for Carbon Monoxide Monitoring. Stanford Research Institute, Menlo Park, CA. Prepared for U.S. Environmental Protection Agency, Research Park, NC. EPA Publication No. EPA–450/3–75–077. September 1975.

13. Ludwig, F.L. and E. Shelar. Site Selection for the Monitoring of Photochemical Air Pollutants. Stanford Research Institute, Menlo Park, CA. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Publication No. EPA–450/3–78–013. April 1978.

14. Lead Analysis for Kansas City and Cincinnati, PEDCo Environmental, Inc., Cincinnati, OH. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Contract No. 66–02–2515, June 1977.

15. Barltrap, D. and C. D. Strelow. Westway Nursery Testing Project. Report to the Greater London Council. August 1976.

16. Daines, R.H., H. Moto, and D. M. Chilko. Atmospheric Lead: Its Relationship to Traffic Volume and Proximity to Highways. Environ. Sci. and Technol., 4:318, 1970.

17. Johnson, D.E., *et al.* Epidemiologic Study of the Effects of Automobile Traffic on Blood Lead Levels, Southwest Research Institute, Houston, TX. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA–600/1–78–055, August 1978.

18. Air Quality Criteria for Lead. Office of Research and Development, U.S. Environmental Protection Agency, Washington, DC EPA–600/8–83–028 aF–dF, 1986, and supplements EPA–600/8–89/049F, August 1990. (NTIS document numbers PB87–142378 and PB91–138420.)

19. Lyman, D.R. The Atmospheric Diffusion of Carbon monoxide and Lead from an Expressway, Ph.D. Dissertation, University of Cincinnati, Cincinnati, OH. 1972.

20. Wechter, S.G. Preparation of Stable Pollutant Gas Standards Using Treated Aluminum Cylinders. ASTM STP. 598:40–54, 1976.

21. Wohlers, H.C., H. Newstein and D. Daunis. Carbon Monoxide and Sulfur Dioxide Adsorption On and Description From Glass, Plastic and Metal Tubings. J. Air Poll. Con. Assoc. 17:753, 1976.

22. Elfers, L.A. Field Operating Guide for Automated Air Monitoring Equipment. U.S. NTIS. p. 202, 249, 1971.

23. Hughes, E.E. Development of Standard Reference Material for Air Quality Measurement. ISA Transactions, 14:281–291, 1975.

24. Altshuller, A.D. and A.G. Wartburg. The Interaction of Ozone with Plastic and Metallic Materials in a Dynamic Flow System. Intern. Jour. Air and Water Poll., 4:70–78, 1961.

25. Code of Federal Regulations. Title 40 part 53.22, July 1976.

26. Butcher, S.S. and R.E. Ruff. Effect of Inlet Residence Time on Analysis of Atmospheric Nitrogen Oxides and Ozone, Anal. Chem., 43:1890, 1971.

27. Slowik, A.A. and E.B. Sansone. Diffusion Losses of Sulfur Dioxide in Sampling Manifolds. J. Air. Poll. Con. Assoc., 24:245, 1974.

28. Yamada, V.M. and R.J. Charlson. Proper Sizing of the Sampling Inlet Line for a Continuous Air Monitoring Station. Environ. Sci. and Technol., 3:483, 1969.

29. Koch, R.C. and H.E. Rector. Optimum Network Design and Site Exposure Criteria for Particulate Matter, GEOMET Technologies, Inc., Rockville, MD. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA Contract No. 68–02–3584. EPA 450/4–87–009. May 1987.

30. Burton, R.M. and J.C. Suggs. Philadelphia Roadway Study. Environmental Monitoring Systems Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, N.C. EPA–600/4–84–070 September 1984.

31. Technical Assistance Document For Sampling and Analysis of Ozone Precursors. Atmospheric Research and Exposure Assessment Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711. EPA 600/8–91–215. October 1991.

32. Quality Assurance Handbook for Air Pollution Measurement Systems: Volume IV. Meteorological Measurements. Atmospheric Research and Exposure Assessment Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711. EPA 600/4–90–0003. August 1989.

33. On-Site Meteorological Program Guidance for Regulatory Modeling Applications. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711. EPA 450/4–87–013. June 1987.

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Part IV

Environmental Protection Agency

40 CFR Part 86

Emission Durability Procedures and Component Durability Procedures for New Light-Duty Vehicles, Light-Duty Trucks and Heavy-Duty Vehicles; Final Rule and Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 86

[FRL–8019–2]

RIN 2060–AK76

Emission Durability Procedures for New Light-Duty Vehicles, Light-Duty Trucks and Heavy-Duty Vehicles

AGENCY: Environmental Protection Agency.

ACTION: Final Rule.

SUMMARY: This final rulemaking contains procedures to be used by manufacturers of light-duty vehicles, light-duty trucks, and some heavy-duty vehicles to demonstrate, for purposes of emission certification, that new motor vehicles will comply with EPA emission standards throughout their useful lives. Today's action defines procedures to be used by manufacturers to demonstrate the expected rate of deterioration of the emission levels of their vehicles.

DATES: This rule is effective February 16, 2006. The information collection requirements of this rule have been approved by OMB and are effective February 16, 2006.

ADDRESSES: EPA has established a docket for this action under Docket ID No. OAR–2002–0079. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Air Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The 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 Public Reading Room is (202) 566–1744.

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SUPPLEMENTARY INFORMATION:

I. Background
A. Overview of certification process, CAP 2000 history
B. Durability demonstration process history
1. Durability demonstration methods used prior to the CAP 2000 regulations
2. Emission durability procedures under CAP 2000
C. Ethyl petition to reconsider CAP 2000 rules
D. Judicial review of the CAP 2000 rules
E. Applicability of the NPRM preamble discussion
F. Supplemental notice regarding component durability
II. Summary and Analysis of Comments
A. The Durability Objective
B. Evaluation of the certification durability procedures based on in-use emissions data
C. Standard whole vehicle durability procedure
1. Standard Road Cycle (SRC)
2. Vehicle ballasting on SRC mileage accumulation
3. Calculating the DF from mileage accumulation of 75% of full useful life mileage
4. Testing required for DF calculation
5. Use of an engine dynamometer to recreate the aging on the SRC
D. Standard Bench Aging Procedure
E. Catalyst time-at-temperature data measurement
F. Customized/Alternative durability procedures
1. Equivalency factors and alternative road cycles
2. Bench durability aging
3. Approval of customized/alternative durability procedures
4. Experimentally determining a customized R-factor
5. Alternative bench aging cycle content
G. Component Durability
H. Minor modifications to approved durability procedures
I. Required notification to EPA that an approved durability procedure will be used for a particular durability group
J. Public Availability of the equivalency factor and supporting data
K. Carryover
L. Evaporative Durability Procedures
M. Starting model year for the rule
N. Special provisions for new manufacturers
O. Delete incorrect reference to intermediate useful life standards for the evaporative and refueling durability objective
III. What is EPA promulgating today?
A. Standard whole vehicle exhaust durability procedure
B. Standard bench aging exhaust durability procedure
1. The Standard Bench Cycle (SBC)
2. The Bench Aging Time (BAT) calculation
3. The effective reference temperature for the SBC
C. Customization of the standard procedures
1. Customization of the Standard Road Cycle
2. Customization of the standard bench procedures
3. Replication by outside parties
D. Using In-Use Verification Program (IUVP) data to improve durability predictions
E. Evaporative and refueling durability
F. Effective date and carryover of existing durability data
G. Miscellaneous regulatory amendments and corrections
IV. What are the economic and environmental impacts?
A. Economic impacts
1. Comparison to CAP 2000 economic impacts
2. Economic impact of today's final rule
B. Environmental impacts
V. What are the Statutory and Executive Order Reviews for this Rule?
A. Executive Order 128866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132 (Federalism)
F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
G. Executive Order 13045: Children's Health Protection
H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer Advancement Act
J. Congressional Review Act

I. Background

A. Overview of certification process, CAP 2000 history

Before a manufacturer may introduce a new motor vehicle into commerce, the manufacturer must obtain an EPA certificate of conformity indicating compliance with all applicable emission standards over the vehicle's useful life period. The useful life for cars and light trucks is currently 100,000 miles or 10 years, whichever occurs first; for heavy light trucks, medium duty passenger vehicles (MDPV) and complete heavy duty vehicles the useful life period is 120,000 miles or 11 years, whichever occurs first. [Section 202(d) of the Clean Air Act and 40 CFR 86.1805–04]

To receive a certificate, the manufacturer submits an application to EPA containing various information specified in the regulations, including emissions test data. EPA reviews the submitted information as well as any other relevant information, and issues a Certificate upon a determination that the manufacturer has demonstrated that its new motor vehicle will meet the requirements of the Clean Air Act (Act) and the regulations. [40 CFR 86.1848–01] A certificate of conformity is effective for only one model year;

therefore, new vehicle certification must occur annually.

EPA's regulations detail the process motor vehicle manufacturers must follow to obtain EPA emissions certification. In 2000, EPA issued a comprehensive update to the certification regulations for light-duty vehicles and light-duty trucks.[1] These certification regulations are known as ''CAP [Compliance Assurance Program] 2000''.[2] They include detailed procedures on the selection of vehicles for testing and testing procedure, specifications on the information that must be submitted to EPA, and other requirements pertaining to reporting and testing.

Issuance of a certificate is based on a determination by EPA that the vehicles at issue will conform with the applicable emissions standards. Compliance with the emissions standards requires that the vehicles meet the standards for the specified useful life period. A determination of compliance, therefore, must be based on an evaluation of both the performance of the vehicles' emissions control system when new, as well as performance over the entire time period of the vehicles' useful life.[3]

The process of predicting how and to what degree a vehicle's emission levels will change over its useful life period [emissions deterioration] as well as the robustness of the vehicle's emission-related components [component durability] is known as an emission durability demonstration.[4] Today's final rule specifies the methods that manufacturers must use to determine emissions deterioration for the purpose of certification.

Over the years, EPA has promulgated regulations prescribing several different emissions durability demonstration methods to fulfill EPA's need to determine compliance with emission standards over the vehicle's full useful life. The following is a short summary of this prior regulatory history, to put today's final rule in context.

B. Durability Demonstration Process History

1. Durability Demonstration Methods Used Prior to the CAP 2000 Regulations

Prior to CAP 2000, EPA's regulations (ref. 40 CFR Part 86) specified the method to demonstrate a vehicle's emission durability. The method used a whole vehicle mileage accumulation cycle, commonly referred to as the Approved Mileage Accumulation (AMA) cycle. It required manufacturers to accumulate mileage on a pre-production vehicle, known as a durability data vehicle (DDV), by driving it over the prescribed AMA driving cycle for the full useful life mileage.[5] This was to simulate the real-world aging of the vehicle's emissions control systems over the useful life.

The DDV was tested in a laboratory for emissions at periodic intervals during AMA mileage accumulation, and a linear regression of the test data was performed to calculate a multiplicative deterioration factor (DF) for each exhaust constituent. Then, low mileage vehicles more representative of those intended to go into production (referred to as ''emission data vehicles,'' or EDVs) were emission-tested. The emission results from these tests were multiplied by the DFs[6] to project the emissions levels at full useful life (referred to as the ''certification levels''). The certification levels had to be at or below the applicable emission standards in order to obtain a certificate of conformity.

EPA was concerned about the ability of any fixed cycle—including the AMA cycle—to produce emission durability data that accurately predicted in-use deterioration for all vehicles. EPA had particular concerns that the AMA did not represent current driving patterns and did not appropriately age current design vehicles. In addition, manufacturers have long identified the durability process based on mileage accumulation using the AMA cycle as very costly and requiring extensive lead time for completion. As a result, EPA came to believe that the AMA had become outdated[7].

The AMA cycle was developed before vehicles were equipped with catalytic converters. It contains a substantial portion of low speed driving, designed to address concerns about engine deposits. While engine deposits were a major source of emissions deterioration in pre-catalyst vehicles, the advent of catalytic converters, better fuel control, and the use of unleaded fuel shifted the causes of deterioration from low speed driving to driving modes which include higher speed/load regimes that cause elevated catalyst temperatures. The AMA driving cycle does not adequately focus on these higher catalyst temperature driving modes. It also contains numerous driving modes which do not significantly contribute to deterioration. This makes the process longer but adds little benefit in predicting emission deterioration.

In response to these concerns, EPA began a voluntary emission durability program in the 1994 model year for light-duty vehicles. This program allowed manufacturers to develop their own procedures to evaluate durability and deterioration subject to prior Agency approval.[8] EPA's approval criteria required the manufacturer to demonstrate that the durability procedures would cover a significant majority of in-use vehicle's emission deterioration.[9] One additional condition for approval was that the manufacturer conduct or fund an in-use test program to evaluate the effectiveness of its predictions. The initial program was referred to as revised durability program

[1] Separate certification regulations exist for heavy-duty highway vehicles and engines, which refer to the light-duty certification procedures. Today's final rule will apply to those subsets for heavy-duty vehicles which use the same certification procedures as light-duty trucks. for convenience, the term ''vehicle'' or ''motor vehicle'' will be used in this preamble to mean those light-duty and heavy-duty motor vehicles subject to these regulations.

[2] 63 FR 39654 (July 23, 1998).

[3] Since a certificate must be issued before the new vehicles may be introduced into commerce, the emissions testing and other relevant data and information used to support an application for a certificate are usually developed on pre-production prototypes.

[4] The durability demonstration program consists of two elements: emission deterioration and component durability. Emission deterioration prediction is a process of predicting to what degree emissions will increase during the vehicles useful life. The deterioration factor (DF) is a measure of deterioration. Component durability is a demonstration that the emission control components will not break and will continue to operate as described in the Application for Certification during the minimum maintenance interval proscribed in 40 CFR 1834–01. The component durability demonstration is conducted by the manufacturer using good engineering judgement.

[5] At the time this durability procedure was effective, the useful life mileage for light-duty vehicles was 100,000 miles. Refer to 40 CFR 86.1805–04 for current useful life mileage values.

[6] A multiplicative DF is calculated by performing a least-squares regression of the emission versus mileage data for each exhaust emission constituent and dividing the emission level at full useful life (historically, 100,000 miles) by the emission level at the 4,000 mile point.

[7] Reference: 63 FR 39653, 39659 (July 23, 1998) (CAP 2000 NPRM).

[8] EPA approved three types of emission durability programs under these procedures: whole vehicle, full mileage, whole vehicle, accelerated mileage; and bench aging procedures which involved thermal aging of the catalyst-plus-oxygen-sensor system.

[9] Reference EPA Guidance Letter No. CD–94–13, ''Alternative Durability Guidance for MY94 through MY98'', dated July 29, 1994. This letter explained that as-received, un-screened in-use data should be compared to vehicles run on the alternative durability program (ASADP). A ''significant majority'' of the in-use data should be covered by the durability program. We defined the acceptance ceriteria in that letter as follows: ''EPA does not require ASADPs to meet a specific minimum severity level (or confidence level) because different methods may be used to estimate the degree of severity. * * * However, an ASADP would be acceptable to EPA if EPA believes that it were designed to match the in-use deterioration of 90–95 percent of vehicles in the engine family.''

I (RDP I). It was an interim program scheduled to expire after the 1995 model year and was intended to serve as a bridge to an anticipated complete revision to the durability process. The provisions of RDP I were extended in a series of regulatory actions.[10] Ultimately, the Agency instituted a comprehensive revision to the durability process as part of the CAP 2000 rulemaking.

For evaporative and refueling emissions deterioration, EPA allowed manufacturers to develop their own process to either bench age components or do whole vehicle aging, also subject to Agency review and approval. The evaporative and refueling deterioration factor is required to be additive.[11]

2. Emission Durability Procedures Under CAP 2000

The CAP 2000 rulemaking was a comprehensive update to the entire light-duty vehicle certification process. One part of this involved the manufacturer's required demonstration of emission durability. The Agency eliminated the requirement for the use of AMA for new durability demonstrations. In CAP 2000, the Agency replaced the AMA-based durability program with a durability process similar to the optional RDP–I program. Each manufacturer, except small volume manufacturers, was required to develop an emission durability process which would accurately predict the in-use deterioration of the vehicles they produce. The manufacturer had the flexibility to design an efficient program that met that objective.

The manufacturer's plan was then reviewed by EPA for approval.[12] Approval from the Agency required a demonstration that the durability process was designed to generate DFs representative of in-use deterioration. This demonstration was more than simply matching the average in-use deterioration with DFs. Manufacturers needed to demonstrate to EPA's satisfaction that their durability process would result in the same or more deterioration than is reflected by the in-use data for a significant majority of their vehicles. Manufacturers were required to provide evidence that their durability process resulted in predicted emission deterioration that were equal to or more severe than the deterioration rates experienced by a significant majority (approximately 90%) of candidate in-use vehicles.[13] Furthermore, this demonstration was required to cover the breadth of the vehicles covered by the durability procedure.

This evaluation concerning coverage of a significant majority of the in-use data was usually made independently on several potential worst-case vehicles which bound the envelope of vehicles covered by the durability procedure. Manufacturers typically demonstrated that emission deterioration predicted by their durability program would cover approximately 90 percent of the in-use population using one (or more) of the following sources of data: in-use emission tests, in-use driving characteristics, or in-use catalyst temperature measurements. At that time EPA had not developed a specific required method to make this demonstration.

Two major types of durability processes emerged from the CAP 2000 experience: whole vehicle and bench aging processes.

The whole vehicle aging procedures involve driving vehicles on a track or dynamometer on an aggressive driving cycle of the manufacturer's design. In general, the speed, acceleration rates, and/or vehicle load are significantly increased compared to the AMA cycle or normal in-use driving patterns. The vehicle can be driven either for full useful-life mileage, or, for a higher stress cycle, the vehicle can be driven for a reduced number of miles (e.g., 1 mile on the high speed cycle equals 2 miles in use). In either case, the vehicle is tested periodically and a DF is calculated.

The bench aging procedures involve the removal of critical emission components, such as the catalyst and oxygen sensor, and the accelerated aging of those components on an engine dynamometer bench.[14] During the bench aging process important engine/catalyst parameters are controlled to assure proper aging. Usually, elevated catalyst temperatures are maintained while fuel is controlled to include lean, rich, and stoichiometric control. Through a series of tests, manufacturers determine the amount of time needed to bench-age a catalyst so it is aged to the equivalent of 100,000 miles. In some cases the manufacturer developed the amount of aging time using catalyst temperature data measured on a road cycle. In other cases, the manufacturer developed the aging time through a trial and error process. Typical bench aging periods are 100–300 hours, although these can vary from manufacturer to manufacturer. Sources of deterioration other than thermal aging can be accounted for by aging the catalyst for an additional amount of time.

The CAP 2000 regulations allow manufacturers to choose from three different methods to demonstrate emissions durability. Manufacturers could calculate additive DFs, multiplicative DFs, or test EDVs with aged hardware[15] installed on them.

Regardless of whether manufacturers used whole vehicle or bench aging durability procedures, CAP 2000 also required the manufacturer to later collect emission data on candidate in-use vehicles selected under the provisions of the in-use verification program (IUVP).[16] Among other uses of the data, the IUVP data must be used by the manufacturer to check on and improve its durability program. The data also is available to assist the Agency to target vehicle testing for its recall program. The Agency may intercede[17] when the in-use data

[10] Ref. 59 FR 36368 (July 19, 1994), 62 FR 11082 (March 11, 1997) 62 FR 11138 (March 11, 1997) and 62 FR 44872 (August 22, 1997).

[11] An additive DF is calculated by performing a least-squares regression of the emission versus mileage data for each exhaust emission constituent and subtracting the 4,000-mile emission level from the full useful life emission level (historically, 100,000 miles). The DF is then used with emission data from the emission data vehicle to demonstrate compliance with the standards for the purpose of certification. The sum of the emissions from the EDV plus the additive DF is referred to as the certification level and must be less than or equal to the emission standard to receive a certificate of conformity.

[12] The CAP 2000 regulations ''grand-fathered'' procedures which had been already approved under the RDP provisions. Consequently, these grand fathered procedures were not approved again under the CAP 2000 provisions. [63 FR.39661]

[13] Candidate in-use vehicles are vehicles selected under the provisions of the in-use verification program (IUVP). This includes mileage restrictions, procurement requirements, and screening requirements designed to eliminate only tampered, mis-used or unsafe vehicles. [reference: 40 CFR 86.1845–01 and 40 CFR 86.1845.04]

[14] An engine dynamometer bench generally consists of an engine dynanometer, a ''slave'' engine, and required controllers and sensors to achieve the desired operation of the engine on the dynanometer.

[15] Under this alternative, emission components aged to the equivalent of full useful life would be installed on EDVs. The test data from the EDV would then serve to establish the certification level and show compliance with the full useful life emission standards.

[16] Reference: 40 CFR 86.1845–01 and 40 CFR 86.1845–04.

[17] The Agency may withdraw approval for a durability process if the Administrator determines, based on IUVP or other data, that the durability process does not accurately predict emission levels or compliance with the standards. [Ref. 40 CFR 86.1923–01(h)]. In addition, where the average in-use verification data for a test group (or several test groups) exceeds 1.3 times the applicable emission standard and at least 50% of the test vehicles fail the standard in use, manufacturers are required to supply additional ''recall quality'' in-use data. [Ref. 40 CFR 86.1846–01].

indicate the durability process underestimates in-use emission levels.

The CAP 2000 regulations did not change the previous procedures used to obtain DFs for evaporative/refueling families.

C. Ethyl Petition To Reconsider the CAP 2000 Rules

On August 17, 1999, Ethyl Corporation petitioned EPA to reconsider the CAP 2000 regulations. EPA requested public comment on the petition, 64 FR 60401 (November 5, 1999 and 64 FR 70665 (December 17, 1999), and received comments from various interested parties. After consideration of the petition and of all comments, EPA denied the petition for reconsideration. 66 FR 45777 (August 30, 2001).

Ethyl Corporation also petitioned the Agency to reconsider the final rule entitled ''Emissions Control, Air Pollution From 2004 and Later Model Year Heavy-Duty Highway Engines and Vehicles; Light-Duty On-Board Diagnostics Requirements, Revision; Final Rule,'' 65 FR 59896–59978 (referred to here as the ''Heavy Duty Rule''). After consideration of the petition and all of the comments, EPA denied the petition for reconsideration. 66 FR 45777 (August 30, 2001).

D. Judicial Review of the CAP 2000 Rules

Ethyl Corporation petitioned for review of the CAP 2000 rulemaking, claiming among other things that the CAP 2000 durability provisions were unlawful as EPA had not promulgated methods and procedures for making tests by regulation as required by § 206. [*Ethyl Corp.* v. *EPA*, 306 F.3d 1144 (DC Cir. Oct. 22, 2002).]

In an opinion issued on October 22, 2002, the Court found that the CAP 2000 regulations did not satisfy the requirements of section 206(d) of the CAA to establish methods and procedures for making tests through regulation.

The Court recognized that there was an important distinction between an EPA regulation that established general or vaguely articulated test procedures, with more specific details provided in a later proceeding, and a regulation which failed to establish any test procedures at all and only adopted procedures for the later development of tests. The former situation would receive deferential judicial review under the applicable case law. The latter case, however, would fail to meet the requirements of section 206(d). The Court held that the CAP 2000 regulations fell into this latter group, and were improper because EPA itself failed to establish any test procedures at all in the regulation, vaguely articulated or not. EPA's regulation provided only for the manufacturer to develop its own test procedure and submit it for later EPA approval. This was inconsistent with the scope of section 206(d), [*Ethyl* at 1149–50.]

The Court also said that ''nothing in our opinion requires that EPA use only a 'one-size-fits-all' test method. All that is required is that it establish its procedures, no matter how variegated, 'by regulation.' '' [*Ethyl* at 1150.]

Since the issue before the Court was the legality of EPA's adoption of the CAP 2000 durability provisions, EPA believes the court's vacature of ''the CAP 2000 program'' is limited to vacating the CAP 2000 durability provisions.

The Court also remanded the case to EPA with instructions to establish test methods and procedures by regulation. Today's final rule is the result of the court's decision, and is limited to emission durability procedures.

E. Applicability of the NPRM Preamble Discussion

Unless otherwise indicated below, the discussion presented in the preamble to the notice of proposed rulemaking published at 69 FR 17532 is applicable to this final rule.

F. Supplemental Notice Regarding Component Durability

The Agency received a comment from Afton Chemical Corporation (''Afton,'' formerly known as Ethyl suggesting that EPA did not address the component durability portion of the emission durability process and should establish a procedure for determining component durability. After the Court decision which remanded EPA to write new regulations regarding emissions durability, EPA discussed with the Petitioner and automotive manufacturers the ramifications of that decision. To aid in these discussions, EPA provided a draft ''mark-up'' version of the CAP 2000 regulations, showing via stricken text exactly which regulations we believed had been vacated.[18] We did not strike out the regulatory language regarding component durability. At that time, neither the petitioner nor the automotive manufacturers spoke out in opposition to this. We did not propose new procedures for component durability and proceeded with the proposed durability regulation, which retained the ''good engineering judgment'' language for component durability.[19] Today's final rule includes only procedures for the emission deterioration portion of the durability process, because our understanding was that component durability was not at issue. However, Afton's comments are significant enough, that we believe it is appropriate to take the opportunity for further comment on component durability regulations. We believe it is appropriate, given the need for notice and comment for all interested parties, that we treat component durability in a separate action. Therefore, in addition to today's final rule, EPA is also today publishing a separate Supplemental Notice of Proposed Rulemaking requesting comments on a proposal which addresses component durability. Today's final rule has not revised the regulatory language for component durability.

II. Summary and Analysis of Comments

EPA received comments from the automotive makers Ford, Volkswagen and Cummins, two automotive trade associations on behalf of their member automotive companies, the Afton Chemical Corporation (formerly know as the Ethyl Corporation), and one comment from a private citizen.

The comments have been grouped together by subject matter. The following discussion presents the summary of EPA's proposal, of the comments received on that proposal, and EPA's response to those comments.

A. The Durability Objective

Summary of proposed rule. The proposed rules included a provision that defined the durability objective [Ref 40 CFR 86.1823–08(a)] as follows: ''The durability program must predict an expected in-use emission deterioration rate and emission level that effectively represents a significant majority (approximately 90 percent) of the distribution of emission levels and deterioration in actual use over the full and intermediate useful life of candidate in-use vehicles[20] of each vehicle design which uses the durability program.''

Summary of Comments. The Alliance and AIAM commented that the phrase ''approximately 90 percent'' could

[18] A copy of the strike-out version of CAP 2000 language is included in the Docket to this regulation.

[19] Ref. 69 FR 17533 ''EPA is not proposing to change the existing regulations for determining emission-related component durability''.

[20] Candidate in-use vehicles are vehicles selected under provisions of the in-use verification program (IUVP). This includes mileage restrictions, procurement requirements, and screening requirements designed to eliminate only tampered, mis-used or unsafe vehicles. [Reference: 40 CFR 86.1845–01 and 40 CFR 86.1845–04]

effectively increase the stringency of the standards by ignoring whether vehicles are passing the standards in-use and focusing on the probability distribution that in-use emissions exceed the emission levels projected at certification. This represents a substantial and unnecessary departure from the CAP 2000 rules. Instead, the rules should be in line with the ''significant majority'' goal espoused in CAP 2000 and the RDP guidance letter (CD–94–13, July 29, 1994).

In response to a request by EPA to clarify their comments, the Alliance stated that they were concerned that the proposed provision in the regulations themselves which defined ''significant majority'' to mean ''approximately 90 percent'' could be interpreted to establish an inflexible percentage criterion and eliminate EPA's discretion to consider other factors when evaluating the effectiveness of a manufacturer's durability program taken as a whole.

Response to Comments. The purpose of the durability program is to provide EPA with reasonable assurance that vehicles covered by a certificate of conformity will, in actual use, comply with the applicable emission standards over their full useful life. As discussed in the proposal, production variability or other reasons can lead to differences in actual emission levels among vehicles of the same nominal design.

In the CAP 2000 rulemaking, EPA required that a durability program adequately predict emission deterioration for a significant majority of candidate in-use vehicles. In the CAP 2000 program, EPA had typically considered ''significant majority'' to mean approximately 90 percent coverage of the distribution of in-use deterioration. This concept was discussed in the preamble to the CAP 2000 rule [21]; however, EPA had not set a strict numerical criteria in the CAP 2000 regulations.

It was not the EPA's intention to establish in this rule a single rigid method or an inflexible numerical criteria to evaluate the durability objective. EPA understands the Alliance's concerns that the proposed language might lend itself to a more rigid interpretation that may limit EPA discretion and/or impose unintended burdens on manufacturers. Consequently, EPA has removed the parenthetical phrase ''approximately 90 percent'' from the finalized durability objective language in the regulations.

By making this change we are not relaxing the requirement. The manufacturer must still demonstrate that a customized/alternative durability procedure is expected to effectively represent a significant majority of the distribution of emission deterioration in actual use to obtain EPA approval to use the procedure for certification. EPA and the manufacturers will still review IUVP data and/or other data to determine if the durability objective was achieved in use and whether it is appropriate to continue to use that durability process for future certification requests. EPA will consider a variety of different evidence and/or analyses that the durability objective has been or is expected to be achieved. However, a demonstration that approximately 90 percent of the distribution of in-use emission deterioration or emission levels is effectively represented by the durability procedure will continue to be a satisfactory showing for this purpose.

The following section discusses how the durability objective will be used to evaluate certification durability procedures based on in-use emission data.

B. Evaluation of the Certification Durability Procedures Based on In-Use Emissions Data

Summary of Proposal. Manufacturers must use information gathered from the IUVP, as well as other sources of in-use emissions data, to periodically review whether the durability procedure it employs achieves the durability objective. EPA may require a manufacturer to perform an analysis to evaluate its durability procedure. EPA may withdraw approval of a durability procedure, or require modifications to the procedure, if the Agency determines that the durability objective is not being achieved by the durability procedure. [Ref. 86.1823–08 (i) and (j)]

Summary of Comments. The Alliance and AIAM stated that they had concerns that a number of variables could affect IUVP emission data (including in-use fuel characteristics, mal-maintenance, testing variability, small sample size, random recruitment and as-received testing (rather than testing properly maintained and used vehicles)) and that these variables could affect the accuracy of decisions made using IUVP data. They stated that these concerns ''were already addressed in the CAP 2000 rulemaking in an appropriate fashion''.

To illustrate their concern, the Alliance and AIAM provided this example: All in-use vehicles can be well below the applicable standards, but the durability procedure could be deemed deficient under the proposed rule merely because in-use emissions exceed the emission levels projected at certification.

The Alliance and AIAM also suggested that ''If the IUVP data show that a manufacturer meets emissions standards in use (because, for example, the manufacturer certified with a sufficient compliance margin, known as ''headroom''), then the Agency should not be concerned and should not make decisions based on the accuracy of the certification emission deterioration seen in isolation.''

In response to a request by EPA to clarify their comments, the Alliance stated that the new provision could be interpreted to require changes in their durability programs even when a significant majority of candidate in-use vehicles comply with emission standards. They believed that the proposed rule could, therefore, effectively tighten the applicable emission standards.

Ford commented that: (1) The proposal effectively increases the stringency of the standards. (2) The focus of this criteria appear to change from the strawman which compared the IUVP emission results to the standard and the highest certification level of all certification and running change tests. (3) Applying the 90 percent criteria [significant majority] criteria to IUVP data (''as received vehicles'') rather than ''properly maintained and used'' vehicles [the quality of data used to order recalls] further increase the stringency. (4) The proposed requirement forces change and cost increases to methods where 100% of the IUVP data meet applicable standards. (5) Reviewing the rate of deterioration is inconsistent with the use of certifying with aged components (rather than calculating a deterioration factor).

The Alliance and AIAM also commented Review of durability processes should only be required when the in-use confirmatory test criteria are triggered.

Response to Comments. EPA did not propose, nor are we finalizing, any changes to the IUVP testing program promulgated in the CAP 2000 rulemaking. As discussed in the proposal, EPA does not believe these provisions were vacated by the Court's decision and they remain effective without any further action required by the Agency.

The provisions for using IUVP emissions data and/or other information to evaluate a durability procedure and for the Administrator to reject the use of a durability procedure based on such an evaluation were also contained in the CAP 2000 rules. The CAP 2000 rule established the requirement to reject a

[21] Ref. CAP 2000 NPRM preamble 63 FR 39661.

durability procedure when ''the durability process has not been shown to effectively predict emission levels *or compliance with the standards* in use on candidate vehicles'' using this data. This requirement is practically equivalent to the ''not achieving the durability objective'' language in the proposal. As long as in-use vehicle data is below the standards, the durability procedure would be considered acceptable, even if the in-use emissions exceed the emission levels projected at certification. However, if it was found that the in-use emissions were significantly higher than the projected certification levels, we may decide to review the durability procedure to determine why the in-use emission results are so far off from the projected certification results in order to improve the procedure being used.

We disagree with the comment that the comparison of IUVP emission data to the durability objective in the proposal is a new requirement (not contained in the CAP 2000 rules) that increases the stringency of the standards. As discussed in the last paragraph, the basis for the evaluation of a durability program in CAP 2000 was ''candidate in-use vehicle'' which are defined to be vehicles eligible for selection by the IUVP program. Clearly, comparing actual IUVP emission data to the durability objective is precisely what was intended by this requirement. *Consequently, this requirement is not new and therefore does not increase stringency of the standards.* Ford is confusing the ''well maintained and used'' quality of data requirement that applies to ordered recalls with the process of evaluating the effectiveness of a durability process for certification. As discussed in the CAP 2000 rule, EPA does not intend to order recalls of vehicles using unscreened IUVP data. EPA did not propose, nor are we finalizing, any provision that would change the process of ordering recalls of non-complying vehicles by using unscreened IUVP data.

We continue to believe it is necessary to re-evaluate a manufacturer's durability process using actual in-use emission, data such as IUVP data, when that information becomes available. It is only through such review that we can be assured that the predictions made at the time of certification are actually valid in use. When that data indicate that the durability process does not achieve the durability objective in actual use, then the Agency may decide to withdraw approval for the durability procedure or require modification to the procedure for future certification purposes. Again, such remedial action is necessary for the Agency to assure an effective certification program. It would be reckless for the Agency to allow the continued use of a unmodified durability process for future certification once it has been shown to be ineffective in actual use for similar vehicles.

We disagree with the suggestion that review of the durability procedures should only occur when the in use confirmatory program (IUCP) *triggers*[22] are activated. The confirmatory test criteria are considered to be a screening criteria that identifies the very worst cases only for automatic reconsideration. EPA expects that there will be cases where the durability procedures are not working satisfactorily for a particular test group that are not identified by these criteria. Furthermore, reviewing in-use data in large groups allows the Agency to determine if there is an underlying trend that a durability process is not satisfactorily achieving the durability objective. In those cases, EPA is naturally and justifiably concerned about the accuracy of the durability process. These reviews conducted on a case-by-case basis are necessary for the Agency to assure an effective certification program.

EPA has retained the proposed provision to eliminate unrepresentative in-use data when making this determination.

EPA has not established a single required method to perform an analysis to evaluate the effectiveness of the durability process using in-use emission data. The Agency will consider all information and analyses presented by the manufacturer submitted within the 60-day period specified in the regulations before reaching a final decision to withdraw approval for a durability procedure. Although there is no specified procedure for this evaluation, there are several observations which are applicable to this process.

Calculating deterioration rates only from in-use emission results conducted at various vehicle mileage points on randomly procured vehicles within a test group can be misleading. It is well known that individual vehicle configurations within a test group or durability group will have different levels of absolute emissions. Since the IUVP uses random procurement, it is possible that the lower emission vehicles would be tested at low mileage and the higher emission vehicles would be tested at high mileage. This situation would lead to a exaggeratedly high calculated deterioration rate. This, in turn, could lead to the false determination that the durability process does not meet the durability objective. Comparing individual in-use emission levels to the certification levels or the applicable emission standards will result in more accurate evaluations of the in-use data and is recommended for that reason.

It is better to make overall decisions about the effectiveness of a durability procedure using the largest possible data set of comparable vehicles. Consequently, EPA recommends performing analyses on a broad group of comparable vehicles rather than on single test groups or other small data sets. Comparable vehicles complying with different standards may be combined into the same analysis if the emission levels are standardized by the ratio of the emission standards.

We agree with the Alliance and AIAM that the Agency should not make decisions based on the accuracy of the certification emission deterioration seen in isolation. Compliance margin should also be considered in the analysis.

The proposed and finalized rules discuss ''*effectively* representing a significant majority'' (emphasis added). The word ''effectively'' in this context is intended to allow the use of compliance margin (also called ''headroom'') to expand the predictive coverage of a durability program. As stated previously, the purpose of the durability program is to provide EPA with reasonable assurance that vehicles covered by a certificate of conformity will, in actual use, comply with the applicable emission standards over their full useful life.

This purpose may be accomplished by employing a durability process that directly predicts emission levels that represent a significant majority of the distribution of emission levels in actual use. Alternatively, the durability process may under-predict emission levels, but when coupled with the compliance margin, a significant majority of the vehicles comply with the emission standards in actual use. Providing that the same amount of compliance margin is used in future certification requests, it is reasonable to conclude that such a durability process when coupled with this level of compliance margin *effectively* represents a significant majority of the distribution of emission levels in actual use.

For example: if after removing unrepresentative data only 70 percent of

[22] Mean In-Use Verification Program (IUVP) emissions for a test group exceed threshold of 1.3 times the certification emission standard and at least 50% of test vehicles for that test group fail for the same pollutant.

the emission data was less than or equal to the predicted value (the certification level determined at certification time), then one could conclude that the predictive accuracy of the durability process was approximately 70% which would not constitute a ''significant majority''. If, however, when compliance margin is taken into account, 95% of the vehicles comply with the applicable emission standards, it could be safely concluded that a significant majority of vehicles are *effectively* represented by the durability procedure. Such an analysis would be performed separately for each applicable emission constituent and associated emission standard.

Based on the preceding description of how the ''effectively represent'' criteria may be implemented, we disagree with the Alliance, AIAM, and Ford that the proposed requirements will result in the Agency withdrawing approving for a durability process when all the IUVP data is complying with the applicable standards.

Lastly, we do not see an inconsistency, as a comment suggests, in comparing IUVP emission data to the durability objective when the manufacturer elects to certify using aged components rather than calculate a deterioration factor. EPA is allowing flexibility in the method for the manufacturer to conduct this analysis. EPA does not require (nor do we recommend, as discussed above) comparing certification DFs to DFs calculated from IUVP data. EPA's preferred method for the analysis involves comparing IUVP emission results to certification levels and standards; all of this data is available to manufacturers electing to certify with aged components rather than calculating a certification DF.

In summary, the Agency is retaining the proposed requirement to require manufacturers to evaluate the durability procedures using in-use emission data generated on candidate vehicles (such as IUVP data) and the authority for EPA to withdraw approval of the durability procedure if the durability objective was not achieved in actual use on comparable vehicles. The Agency did not propose, nor are we finalizing, a specific required method to evaluate certification durability procedures based on in-use emissions data. However, a demonstration that approximately 90 percent of the distribution of in-use emission results (considering each emission constituent separately) comply with the applicable standard will be a satisfactory showing that the durability objective has been achieved.

C. Standard Whole Vehicle Durability Procedure

1. Standard Road Cycle (SRC)

Summary of Proposal. The standard whole vehicle durability procedure consists of mileage accumulation on a durability vehicle following the standard road cycle (SRC). The SRC was defined in the proposal in Appendix V of part 86.

Summary of Comments. The Alliance and AIAM commented that the proposed standard road cycle is effective at meeting the Agency's intent.

Response to Comments. Having received no adverse comments on the proposal, EPA is finalizing the SRC as proposed.

2. Vehicle Ballasting on SRC Mileage Accumulation

Summary of Proposal. The proposed rules required that during mileage accumulation ''the durability data vehicle (DDV) must be ballasted to a minimum of the loaded vehicle weight for light-duty vehicles and a minimum of the ALVW for all other vehicles'' [Ref 86.1823–08(c)(1)(iii)].

Summary of Comments. The Alliance and AIAM suggested that EPA should harmonize the vehicle weight requirements for truck DDVs with the current emission testing requirements for emission data vehicles (EDV).

Response to Comments. The proposal required heavier payload for truck mileage accumulation because trucks are designed to carry loads in addition to transporting the occupants of the vehicle. In our review of manufacturer vehicle design and durability processes, we found that trucks have special design and durability requirements acknowledging their load carrying capability. We also believe that trucks carry loads in actual use some fraction of the time.

The standard whole vehicle durability program is designed to achieve the durability objective. The durability objective requires the durability program to represent a significant majority of the distribution of emission levels and deterioration experienced in actual use on those vehicles. To reach this goal of significant majority coverage, EPA believes that it is necessary to address heavier vehicle loads that occur in trucks some fraction of the time. The adjusted loaded vehicle weight (ALVW) loading requirement requires ballasting with half the payload rather than 300 pounds (the loaded vehicle weight which is applicable to light duty vehicle mileage accumulation in the proposal).

The amount of ballasting for mileage accumulation should not be confused with the vehicle weight basis for conducting emission testing. EPA did not propose, nor are we finalizing, any change to the weight basis for emission testing, including testing that may be performed on the DDV to calculate a deterioration factor (DF).

Although EPA continues to believe it is necessary to ballast most trucks to ALVW to assure that the durability objective is achieved, this requirement may to too severe for some light light-duty trucks.[23] These lighter trucks are much more frequently used only for passenger transportation and more rarely used to transport significant payloads. Consequently, EPA is changing this provision in the final rule to require ballasting during mileage accumulation to a minimum of the loaded vehicle weight to apply to both light-duty vehicles and light light-duty trucks. We are retaining the provision to ballast all other vehicles to a minimum of the ALVW.

3. Calculating the DF From Mileage Accumulation of 75% of Full Useful Life Mileage

Summary of Proposal. The description of the proposed standard whole-vehicle durability procedure contained a provision [Ref. 86.1823–08(c)(2)] that would require mileage accumulation of at least 75% of the full useful life mileage. If the mileage accumulation was less than 100% of the useful life mileage this provision would require the DF to be based on the upper 80 percent statistical confidence limit calculated from the emission data.

Summary of Comments. The Alliance and AIAM commented that projecting a full-useful life DF from data generated over 75% percent of the useful life is sufficient without adding the proposed 80% confidence factor. The proposed requirement is more stringent than the original CAP 2000 and Tier 1 requirement for projecting DFs. Projected full useful life emissions should use mean values rather than 80% statistical point.

Response to Comments. We disagree. EPA promulgated the provision to allow reduced (75% rather than 100% useful life) mileage accumulation in the CAP 2000 and Tier 1 rules to address the concern of the excessive time necessary to complete full mileage accumulation with the AMA cycle. The excessive time concern has been addressed in the proposal by the SRC which is a

[23] Light light-duty trucks are trucks that are rated through 6000 pounds GVWR. This includes truck classes LDT1 and LDT2.

substantially faster[24] cycle than the AMA cycle. For that reason, EPA had considered eliminating the provision to allow less than full useful life mileage accumulation altogether. Although the provision has been rarely used in the past, EPA thought it would be worthwhile to retain it in the standard whole-vehicle durability procedure providing that the reduced mileage accumulation did not adversely affect the quality of the projected DF.

It is a basic statistical principle to apply a confidence factor when performing projections from a limited data set. The confidence factor addresses the added uncertainty inherent in not generating actual data for the last 25% of the mileage accumulation. The one-sided 80 percent limit is a loose requirement; it is not uncommon in projections to apply a confidence factor of 90% or higher. Running less than the full useful life mileage accumulation is voluntary.

The need for this confidence factor is heightened now that Tier 2 has extended useful life to a maximum of 150K miles. The idea of allowing the 150,000 mile useful life as an option in Tier 2 [and thereby avoiding compliance with the intermediate useful life standards] is predicated on the assumption that the added emission data between 120,000 and 150,000 miles would improve our statistical confidence that the vehicles comply with full useful life standards. If we now (as suggested in this comment) allow manufacturers to project emission compliance without considering statistical confidence when only 75% of useful life mileage is run, then 150,000 durability could be demonstrated by running only 112,500 miles. Running 75 percent of the 150,000 miles [112,500 miles] is actually less breadth of data than the normal 120,000 miles and reduces our compliance confidence rather than enhancing it.

Consequently, for the reasons discussed above, EPA is adopting its proposal to require the use of the upper 80 percent one-sided statistical confidence limit when less than full mileage accumulation is conducted using the standard whole-vehicle durability procedure.

4. Testing Required for DF Calculation

Summary of Proposal. If a manufacturer elects to calculate a DF, then it must conduct at least one FTP emission test at each of five different mileage points selected using good engineering judgement. The required testing must include testing at 5,000 miles and the highest mileage point run during mileage accumulation. Additional testing may be conducted. [Ref. 40 CFR 86.1823–08(c)(3)]

Summary of Comments. Manufacturers should be allowed to choose the number of tests for DF testing on the SRC, rather than the Agency mandating the use of five (or more) tests at different mileage points as proposed.

Response to Comments. The reason for specifying a minimum number and distribution of test points to be used in calculating a deterioration factor is to assure a minimum level of confidence in the result of the calculation. It is possible that the same level of confidence could be achieved with multiple tests conducted at a fewer number of discrete mileage points.

Since the intention of this requirement was to provide a minimum level of confidence in the DF, another plan that results in at least as much confidence would equally achieve this goal. To allow greater flexibility in deterioration testing plans, we are adding a provision in the final rule that would allow other testing plans providing the manufacturer determines, using good engineering judgement, that the alternative plan would result in equivalent or superior DF confidence interval.

To justify such an alternative testing plan, the manufacturer would need to document that the alternative testing intervals result in a DF confidence interval equal to or better than the confidence interval using the testing plan specified in the regulations [one test at 5,000 miles, one test at full useful life mileage, and three equally spaced tests between 5,000 miles and the full useful life mileage].

5. Use of an Engine Dynamometer To Recreate the Aging on the SRC

Summary of Proposal. The proposal did not specifically address what type of dynamometer could be used for mileage accumulation on the SRC. The proposed regulation simply specified use of a mileage accumulation dynamometer.

Summary of Comments. Cummins commented that vehicle mileage accumulation on the SRC could be effectively duplicated on an engine dynamometer by aging the complete engine and emission control system in an appropriate manner. They suggested that EPA allow the use of an engine dynamometer as an option for whole vehicle aging.

Response to Comments. EPA agrees with Cummins that it is possible to replicate the aging that occurs on the SRC by installing a complete engine and emission control system on an engine dynamometer and appropriately controlling the engine load and other parameters during service accumulation. Although, this option was not prohibited in the proposal, EPA decided to clarify the language and specifically allow service accumulation on a engine dynamometer as an option method to conduct aging following the SRC.

D. Standard Bench Aging Procedure

Summary of Proposal. The standard bench aging procedure requires installation of the catalyst-plus-oxygen-sensor system on a catalyst aging bench. Aging on the bench is conducted by following the standard bench cycle (SBC) for the period of time calculated from the bench aging time (BAT) equation. The BAT equation requires, as input, catalyst time-at-temperature data measured on the SRC. This procedure was not applicable to diesel vehicles.

Summary of Comments. The Alliance and AIAM commented that they believe that the standard bench cycle incorporates appropriate elements to provide an effective procedure to bench age exhaust emission hardware.

Volkswagen commented that the proposed prohibition of bench aging procedure for use on diesel vehicles is inappropriate. The Agency should allow manufacturers the opportunity to propose an appropriate bench aging procedure for diesel vehicles which EPA would approve on a case-by-case basis.

Cummins acknowledged that there is not an effective established procedure currently available for bench aging of diesel vehicles. However, they encouraged the Agency to provide some mechanism in the final rule that could allow approval of a bench aging procedure for diesels on a case-by-case basis at a later time without the need for further rulemaking.

Response to Comments. Volkswagen's and Cummins suggestion that EPA allow a manufacturer to propose a bench aging durability procedure applicable to diesel vehicles without the Agency promulgating any description of the framework of the bench aging durability procedure for diesel vehicles in the regulations do not fulfill the Court's mandate. Nor does it fulfill the Clean Air Act requirement to establish methods and procedures for making

[24] The fastest allowable AMA cycle (with a top speed of 70 MPH) has an average speed of 30.72 MPH while the SRC has an average speed of 46.26 MPH. The time necessary to complete 120,000 miles on the SRC [2594 run-hours] is less than time necessary on the AMA to complete 75% of the miles [90,000 miles take 2930 run-hours].

tests through regulation [Ref. CAA section 206 (d)].

None of the comments take issue with EPA's conclusion that the proposed bench aging procedures cannot be effectively used for diesel-fueled vehicles. The proposed bench aging procedures are designed to age the vehicle's catalyst-oxygen-sensor system as well as to replicate the total aging that occurs in use. Diesel vehicles to not employ catalyst technology as the principle emission control strategy, consequently the proposed bench aging procedure will not be effective for diesels. The comments did not suggest a bench aging procedure that was effective for diesel vehicles. In fact, Cummins acknowledged that there is not an effective established procedure currently available for bench aging of diesel vehicles.

Consequently, EPA is retaining the proposed exclusion of diesel-fueled vehicles from employing the bench aging procedures finalized in these regulations. At a later date, EPA may choose to propose regulations providing bench aging procedures applicable to diesel-fueled vehicles. In the meantime, diesel-fueled vehicles must use the whole vehicle exhaust durability provisions.

E. Catalyst Time-at-Temperature Data Measurement

Summary of Proposal. EPA proposed that catalyst temperature must be measured at the highest temperature location in the hottest catalyst on the DDV. Catalyst temperature must be measured at a rate of one hertz (one measurement per second).

Summary of Comments. The Alliance and AIAM commented that the measurement rate of catalyst temperature of 1 hertz should be changed to allow manufacturers to determine the appropriate rate. EPA should not dictate the location of catalyst temperature measurements. Determining the worst-case location is not practical.

Response to Comments. Both of these measurement procedures only apply to the standard bench procedure and its elements. Manufacturers may use other procedures if using a customized/alternative process that does not use the EPA standard BAT equation, the standard aging bench design (as discussed in Appendix VIII) or EPA's standard method to experimentally determine a customized R-factor for the BAT equation (as discussed in Appendix IX).

Because the measured temperature is the basis for calculating aging time or determining that the appropriate amount of aging has actually occurred on the aging bench, it is important to carefully specify where to measure the temperature. Temperatures can vary by over 100 °C between various locations in a catalyst. In developing the BAT equation, EPA developed the equation based on measuring the maximum temperature in the catalyst. EPA has been receiving catalyst temperature data from manufacturers for many years which was measured at the hottest point in the catalyst to support carryover requests or to evaluate durability procedure approvals under RDP–I or CAP 2000. Typically, manufacturers have selected measure along the central axis of the catalyst about one inch back of the front face. This history indicates to the Agency that determination of the hottest location in the catalyst is practical.

In Appendix VIII, EPA proposes that the measurement of catalyst temperature may be either at the highest temperature location or another location (providing the temperature is adjusted by a linear transform to represent the temperature measured at the hottest catalyst location). To address the practicality of actual measurement, EPA has modified the regulation language to correspond to the appendix.

The temperature measured in a catalyst also can change quickly over time during the SBC. When EPA was developing the standard bench cycle we used time-at-temperature data recorded at a one hertz rate. The temperature measured in adjacent seconds frequently is different in these data sets. Consequently, EPA concluded that one hertz was the minimum acceptable frequency rate acceptable for this purpose. Faster measurement would be acceptable, because it would allow for more accurate measurement of the changing catalyst temperature. To allow faster measurement, EPA has changed the regulation from the proposal to specify that one hertz is a minimum frequency.

F. Customized/Alternative Durability Procedures

Summary of Proposal. Several of the comments received to the proposal discuss provisions that apply to different aspects of the customized/alternative durability procedures. As background for the discussion of these general comments, the following paragraphs summarize the provisions that were proposed for customized/alternative road cycles, calculation and use the equivalency factor, and customized/alternative bench aging durability procedures.

Customized/Alternative Road Cycles. The Agency proposed that a customized or alternative road cycle could be used for certification if approved by the Administrator. The approval criteria require that the manufacturer demonstrate that whole vehicle mileage accumulation on the alternative/customized road cycle is expected to achieve the durability objective in actual use for the full range of vehicles to be covered by the procedure.

The equivalency factor. The manufacturer must calculate an equivalency factor that equates the alternative or customized road cycle to the SRC run for full useful life mileage. The equivalency factor is used to determine how much in-use data the manufacturer must present in the analysis that the durability objective is expected to be achieved. The equivalency factor would also be made available to outside parties for their use to recreate aging conducted by the manufacturer during certification. For example, if the equivalency factor is 90% then the durability aging conducted by the manufacturer can be replicated by running the SRC for 90% of the useful life mileage or by bench aging using the SBC for the time calculated from the BAT equation using time-at-temperature data run on the SRC based on 90% of the useful life mileage.

Customized/Alternative Bench Aging Durability Procedures. The Agency proposed that a customized or alternative bench aging procedure could be used for certification if approved by the Administrator. The proposal discussed seven types of customization allowable for the bench aging procedures and presented the criteria for their approval to the Agency. Specifically the Agency could approve the following customization to the standard bench aging durability procedure:

- Use a different lower-control temperature on the SBC providing the BAT equation was used to calculate the appropriate aging time.
- Use an customized R-factor in EPA's BAT equation providing that it is determined experimentally using the manufacturer's actual catalyst design.
- Use an customized A-factor in EPA's BAT equation, to ensure that the modified durability process will achieve the durability objective.
- Conduct bench aging using fuel with additional compounds that may lead to catalyst poisoning, such as phosphorus, sulfur or lead, rather than the standard fuel.
- Use an approved customized/alternative road cycle (rather than the

SRC) to develop catalyst temperature histograms for use in the BAT equation.

- Use a different bench cycle than the SBC with prior EPA approval.
- Use a different method than the standard BAT equation to calculate bench aging time with prior EPA approval.

1. Equivalency Factors and Alternative Road Cycles

Summary of Comments. The Alliance and AIAM commented that it is pivotal that manufacturers be able to customize the standardized durability procedures. They support the equivalency factor approach because it provides the means for third parties to use the SRC to effectively replicate the aging effects produced by any manufacturer's durability protocols without requiring manufacturers to disclose proprietary engineering data and analysis. The equivalency factor, as proposed, also allows these customized/alternative procedures to be linked to the standard procedures. They do not object to the publication of the equivalency factors, themselves, but they comment that release of the underlying proprietary information is not required and is contrary to the Freedom of Information Act requirements.

Afton (formerly known as Ethyl) commented that EPA must use appropriate rulemaking procedures which meet the requirements of section 307(d) of the CAA to adopt alternative road cycles rather than using the equivalency factor and the approval process discussed in the proposal. They acknowledge that the equivalency factor may provide a constructive means to attempt to balance the competing objectives of maintaining the secrecy of individualized certification test procedures, on the one hand, and disclosing to the public the test procedures on which the government relies to issue certification decisions, on the other. However, they state that the equivalency factor does not alter the Agency's obligation to promulgate alternative test procedures by regulation and include underlying data upon which the alternative test procedure is based. Consequently they believe that the proposed provision to allow the Agency to approve alternative road cycles does not meet the CAA requirements nor does it comply with the Court's mandate in *Ethyl Corp.* v. *EPA.*

Response to Comments. We disagree with Afton's comments that the proposed regulations, which allow the Agency to approve alternative road cycles, do not meet the CAA requirements and do not comply with the Court's mandate in *Ethyl Corp.* v. *EPA.* The Court stated ''nothing in our opinion requires that EPA use only a ''one-size-fits-all'' test method. All that is required is that it establish its procedures, no matter how variegated, ''by regulation.'' That is what we have done in this rulemaking.

We have established procedures that define the SRC as the standard whole-vehicle durability process. We have also described procedures to use a customized/alternative road cycle that is tied to a comparison of that cycle to the SRC and a demonstration that the cycle achieves the durability objective. In particular, the customized road cycle is the SRC run for a different distance. The actual distance run on a customized road cycle is the basis of the equivalency factor which EPA does not believe is confidential business information (CBI). The Agency plans to provide the equivalency factors to any interested party and post a listing on its Web site for public use.

In the case of alternative cycles (cycles which use a different speed-versus-time trace than the SRC), we have also proposed (and are finalizing) durability procedures using those cycles. We have proposed procedures that specify the amount and type of data necessary for approval of such a cycle. We have proposed procedures that specify the approval method used by the Agency for approving the cycle. We have proposed procedures (the equivalency factor) to equate a customized cycle to the SRC. We have determined that the equivalency factor may be publically released. Furthermore, we have determined that if an outside party ran a vehicle on the SRC for the distance specified by the equivalency factor, the resulting deterioration would be equivalent to the manufacturer's durability showing using the customized road cycle. We have also proposed procedures that specify how to use the customized road cycle for calculating deterioration factors and/or conducting aged component testing. Lastly, we have proposed procedures for determining compliance using this data.

In summary, in addition to the SRC, we have proposed and are finalizing, many details on the durability procedure for the use of customized road cycles. We believe we have clearly articulated a durability procedure (i.e., the SRC) by regulation fulfilling the mandate of the Court. We have also used our discretion in electing to describe most, but not all details, of the alternative road cycle durability process in the regulations. (See *American Trucking Associations* v. *Department of Transportation,* 166 F.3d 374 (DC Cir. 1999) and *New Mexico* v. *EPA,* 114 F.3d 290 (DC Cir. 1997). Agencies are entitled to broad deference in picking the suitable level of detail to specify in the regulations.)

For the above reasons, EPA is finalizing the provision to allow alternative road cycles approved by the Administrator as proposed.

2. Bench Durability Aging

Summary of Comments. Afton expresses concern that whether and how new systems perform in the field can directly impact operation of the catalyst in ways that may not be captured by thermal aging. They specifically cite the lack of aging of certain engine and fuel system components. They expressed concern that the analysis presented in EPA's draft technical support document (TSD) for the CAP 2000 proposal, which shows little engine-out deterioration, may be dated. Their concern is based on the fact that the analysis does not include vehicles using certain new technology devices and strategies which may, at some future time, begin to appear in production but which are not used in general production vehicles at this time.

The Alliance and AIAM commented that the bench aging procedures incorporate appropriate elements to provide an effective method to bench age exhaust emission hardware.

Response to Comments. We do not share Afton's concern that the proposed bench aging procedures may not be sufficiently accurate for certification purposes. The bench aging procedures are designed to effectively replicate the aging that occurs during in-use operation.

As discussed in the preamble to the proposed rule, the bench aging procedures are required to be adjusted to duplicate the full emission deterioration that occurs in-use by thermally aging the catalyst. This may result in over-aging the catalyst to account for emission deterioration that occurs from other sources. The amount of over-aging may be large or small. The proposed BAT equation includes a term (the A-factor) which is used for this purpose. EPA has set the initial value of A as 1.1 based on the low expected engine-out deterioration identified in the TSD. However, if for any cause (including unexpected emission control deterioration of components not aged on the aging bench, or based on the future technology that Afton mentions in their comments), the bench aging durability does not achieve the durability objective, EPA has proposed a requirement that manufacturers change

the A factor to ensure that the durability goal is appropriately achieved by the bench aging process. Furthermore, EPA has proposed requirements that the manufacturer must periodically review their durability process to assure that the durability object is achieved in actual use. To facilitate this review, EPA requires manufacturers to provide IUVP emission data that must be used in this evaluation process. Lastly, EPA can require the manufacturer to change their durability process if the Administrator determines that the durability goal is not being achieved in actual use. Consequently, any risk that the bench aging process may not achieve the durability goal is controlled by this feedback process using IUVP emission data.

For the above reasons, EPA is finalizing the standard bench aging durability procedures as proposed.

3. Approval of Customized/Alternative Durability Procedures

Summary of Comments. The Alliance and AIAM made a series of comments to ''eliminate unnecessary and excessive administrative burden''. Specifically they suggested:

Manufacturers should be allowed to self-approve a customized/alternative durability road cycle if they can show it is more severe than the SRC.

Manufacturers should not be required to submit data from 20 in-use vehicles to obtain approval, rather the manufacturer should review in-use data as it becomes available.

The proposal requires the approval of a customized bench aging cycle even when the aging time is determined using the BAT equation. They suggest that this additional approval step is unnecessary and unjustified.

EPA should eliminate all requirements for pre-approval and re-authorization of existing durability protocols absent in-use data which does not meet the existing requirements.

Response to Comments. We disagree that the approval requirements of the proposal are either unnecessary or excessively burdensome. EPA must determine to its satisfaction that a potential customized/alternative durability process is expected to achieve the durability goal in use. Most of the durability procedures approved prior to the vacature of CAP 2000 rules were significantly changed based on the Agency's review and comment during the Agency's initial review. Although we now expect that most manufacturers have the skill necessary to design an appropriate customized/alternative process, we still believe that an initial review and approval by the Agency is still warranted.

The proposal only requires an initial approval of the customized/alternative durability process. Once a process is approved, the manufacturer must determine, using good engineering judgement, whether to apply the procedure to future durability groups.

The proposal does contain provisions to require less in-use data for EPA approval when the customized/alternative cycle is shown to be significantly more severe than the SRC. We expect that approval of more severe cycles than the SRC to be granted, but the question still remains whether the customized/alternative cycle is severe enough to achieve the durability objective in use for the vehicles involved. Consequently, approval of a more severe customized/alternative cycle is not automatic.

In the proposal, the amount of in-use emission data required for approval is varied depending whether the cycle is more or less severe than or approximately equivalent to the SRC. The amount of data required reflects the data necessary for the Agency to reach a valid conclusion to approve a cycle. As previously discussed, more severe cycles are rewarded in the approval process by a reduction in the amount of required data.

The proposal requires approval of an alternative bench aging cycle because the distribution of air/fuel ratios and temperature is important to assure that adequate aging occurs. As discussed in the preamble to the proposed rule, a manufacturer must develop a new R factor if they change the bench aging cycle. Our standard R-factor applies only to the standard bench cycle (SBC). The determination of a customized R-factor is necessary because the same temperature exposure will result in a different amount of emission deterioration if the bench aging cycle is changed. The use of the standard BAT equation [with a different R-factor] provides no added assurance that the bench aging cycle will effectively replicate the emission deterioration that occurs on the associated road cycle as suggested in the comment. Consequently, EPA is finalizing the requirement to obtain Agency approval for alternative bench cycles.

The proposed requirements are different than the CAP 2000 requirements, although the durability objective has not changed. Pertinent facts may have changed since the approval (under the CAP 2000 rules) of a particular durability procedure including production designs and the existence of more in-use data available for review. Although, the Agency expects that most of the durability processes that were approved prior to the court's vacature of the CAP 2000 rules will meet the requirements of this rule, we find no compelling case to make any blanket determination. Reviewing each durability process according to the new requirements on its own merits is an appropriate course of action for the Agency. Therefore, EPA is retaining and finalizing the proposed requirement that all customized/alternative durability procedures must be approved under the new rules (including all procedures used before the vacature of the CAP 2000 rules).

4. Experimentally Determining a Customized R-Factor

Summary of the Proposal. EPA proposed that a manufacturer may determine an customized R-factor for use in the BAT equation. This would allow the BAT equation to be customized to better predict the required amount of bench aging necessary for a particular catalyst design. EPA proposed a standard experimental method for determining a customized R-factor in Appendix IX to the rule. EPA also proposed that other experimental techniques may be used if approved by the Administrator. To obtain approval the manufacturer must demonstrate that the calculated bench aging results in the same (or larger) amount of emission deterioration as the associated approved road cycle.

Summary of Comments. The Alliance and AIAM commented that EPA's standard method for experimentally determining a R-factor [in Appendix IX] is overly restrictive and significantly increases the stringency of determining an R-factor.

Ford commented that the approval procedure for using alternative techniques to experimentally determine the R-factor for the BAT equation should be based on accomplishing the durability objective rather than a comparison to the associated road cycle (the criteria in the proposal).

Ford suggested an alternative standardized method to experimentally determine the R-factor that they felt would be more accurate and easier to implement. Their proposal (a detailed description is in the docket) suggested that emissions rather than catalyst efficiency be measured and that the emission deterioration projected from a least-squares regression of the emission versus time data be calculated directly from the experimental data rather than the two step process proposed by EPA.

Response to Comments. EPA agrees that the standard method for

experimentally determining an R-factor supplied by Ford in their comments would be appropriate to use for that purpose. We also anticipate that it would be easier to generate the emission data required in Ford's alternative procedure than the conversion efficiency required in the proposed standard R-Factor determination procedure. Also this alternative approach eliminates one step compared to the proposed process. For those reasons, we have modified the Appendix in the final rule to allow this procedure.

It should also be noted that other techniques, beyond the standard procedure outlined in Appendix IX to part 86, may be used as allowed in 40 CFR 1823–08(e)(2)(iii). Ford recommended that we take a step back from the proposed approval criteria which require ''that the calculated bench aging time results in the same (or larger) amount of emission deterioration as the associated approved road cycle.'' They recommended that we require instead that the manufacturer should demonstrate that the use of the R-factor would achieve the durability objective. One concern was that the proposed text seemed to require the existence of a customized/alternative road cycle because this would be the only cycle that was ''approved'', the SRC could be used without a specific Agency approval.

It was not our intention to require that a manufacturer have an approved customized/alternative road cycle to determine an R-factor by an alternative method (rather than the standard method in Appendix IX to Part 86). Manufacturer may also use an alternative method to calculate an R-Factor when using the SRC as the associated road cycle to measure catalyst time-at-temperature data necessary to calculate aging time. It is our intention however, that a manufacturer must generate catalyst time-at-temperature data on either the SRC or an approved customized/alternative road cycle. Furthermore, that an alternative method will only be approved if it results in the same (or more) aging as that associated cycle.

We believe that the approval criteria suggested by Ford (achieving the durability objective) will be functionally the same as the proposed criteria to replicate the aging seen on the associated road cycle but potentially less burdensome. For an alternative bench cycle to be approved the manufacturer must demonstrate that it achieves the durability objective. However, in the case where a manufacturer is using the SRC, it may not have the necessary in-use emission data to demonstrate that durability objective is being achieved. For these reasons, we continue to believe that the proposed requirement is a less burdensome and equally effective requirement as Ford's proposal. In today's final regulation text we have clarified that the road cycle used for comparison may be either the SRC or an approved customized/alternative cycle. Otherwise, we have finalized the alternative R-factor methodology approval criteria as proposed.

5. Alternative Bench Aging Cycle Content

Summary of Proposal. EPA did not propose any limitations on the content of an alternative bench aging cycle. EPA did propose that to obtain approval for such an alternative bench cycle the manufacturer must demonstrate that bench aging with the new bench cycle provides the same or larger amount of emission deterioration as the associated road cycle.

Summary of Comments. The Alliance suggested that we clarify which provisions (in the proposed section 86.1823–08(e)(2)) pertain to manufacturers bench cycle and which provisions pertain to the EPA standard bench cycle.

Response to Comments. EPA did not propose, nor are we finalizing, any limitations on the content of an alternative bench aging cycle. The alternative cycle may (among other differences) be of different length, have a different proportion of Air/Fuel ratios, different temperatures, different amounts of secondary air injection, and/or use no secondary air injection at all. However, whatever the content, the manufacturer must demonstrate that the alternative bench aging cycle works effectively by reproducing (or alternatively overstating) the aging that occurs on the associated road cycle which was used to measure the time-at-temperature data used to calculate the aging time on the aging bench.

G. Component Durability

Summary of Proposal. The proposal retains the CAP 2000 requirement that manufacturers use good engineering judgement to determine that all exhaust-related components are designed to operate properly for the useful life of the vehicles in actual use.

Summary of Comments. Afton argued that EPA did not meet the requirements of the Act or the Court's mandate in *Ethyl Corp.* v. *EPA,* by not proposing test methods or procedures for assessing the durability of emission control system components, either separately for components, or for all the components operating together as an integrated system.

In response to this comment, the Alliance and AIAM stated that there is no need to implement additional ''component'' durability test methods and procedures because the SRC re-establishes the requisite threshold level of stringency for the components as well as the system as a whole. They also claim that the Court did not impose any obligation on EPA to establish a whole new regime of component durability tests.

Response to Comments. While EPA believes that Afton has raised an important issue, the NPRM did not contemplate any revisions to the component durability regulations. Therefore, EPA believes that before taking any final action on component durability, it is appropriate to open this issue to further comment. Therefore, concurrent with today's final rule, EPA is publishing a Supplemental Notice of Rulemaking (SNPRM) that addresses component durability. The SNPRM will seek comment on several options that EPA is considering for addressing component durability during the vehicle emissions certification process. After a formal comment period, EPA will consider any further comments received and issue a final rule.

H. Minor Modifications to Approved Durability Procedures

Summary of Proposal. The proposal contained a provision [ref. 86.1823 h)(1)] that allowed a manufacturer to modify an approved durability procedure by increasing or decreasing the number of miles run on an approved road cycle to represent full or intermediate useful life emissions deterioration or by changing the A-Factor in the BAT equation for a bench aging, using good engineering judgment, to ensure that the modified procedure will achieve the durability objective.

Summary of Comments. The Alliance and AIAM commented that EPA should restore the CAP 2000 provision that allowed manufacturers to make minor modifications (using good engineering judgement) to an approved durability procedure without the need to obtain a new approval from EPA.

Response to Comments. The proposal listed only certain changes that the manufacturer could make to an approved durability procedure using good engineering judgement without obtaining approval by the Administrator. Those changes were increasing or decreasing the number of miles run on an approved road cycle or changing the A-Factor in the BAT

equation. At that time, these were the only changes that the Agency envisioned that could be applied to the standard EPA durability procedures without considering the changes to constitute a customization of the standard procedures that would require Agency approval. We also proposed that these same changes could be made to customized/alternative durability procedures without requiring Agency approval.

We agree that allowing some level of minor adjustments or changes to an approved customized/alternative manufacturer durability process would also be appropriate if the changes were limited in scope and made using good engineering judgement to assure that the modified durability procedures would achieve the durability objective. We believe that the level of adjustments allowed under CAP 2000 continue to be appropriate in the new durability regulations. In the vacated CAP 2000 durability regulations we stated: (1) Such modifications will be limited to incorporating additional data into the original algorithms of the approved durability process and (2) if a manufacturer wishes to change the algorithms used to determine the aging characteristics of the durability process, these changes will be considered a new durability process and will require advance approval by the Administrator. Therefore, we have modified the final regulation language to include a provision for manufacturers to make these minor changes, using good engineering judgement, without obtaining new approval from the Agency.

I. Required Notification to EPA That an Approved Durability Procedure Will Be Used for a Particular Durability Group

Summary of Proposal. The manufacturer must notify the Administrator of its determination to use an approved (or modified) durability procedure on particular test groups and durability groups prior to emission data vehicle testing for the affected test groups (notification at an annual preview meeting scheduled before the manufacturer begins certification activities for the model year is preferred).

Summary of Comments. The Alliance and AIAM commented that the timing of the notification (prior to emission data vehicle testing) is too early in the certification process. They suggested that notification in the Application for Certification should be sufficient and is preferable to them.

Response to Comments. The purpose of this requirement is to provide the Agency the necessary information about the manufacturers durability demonstration plans early enough in the certification process to be useful to the Agency. In particular, if the Agency wished to question the manufacturers judgement to apply a durability procedure to a particular durability group, it would be more efficient to raise this issue earlier in the certification process. Consequently, the Agency suggested that the notification occurs in the annual preview meeting which is typically scheduled before a manufacturer begins certification activity for a model year.

As discussed in the current good engineering judgement provisions [ref. 40 CFR 86.1851–01 which is not being modified in today's final action] the Administrator may reject a manufacturers decision, even after certification is granted, if it is not based on good engineering judgement. Consequently, EPA agrees that notification at the time of the Application for Certification would provide the opportunity for sufficient oversight for the Agency. The risk to the manufacturer is that any questions regarding the good engineering decision basis of the manufacturers decision to apply a durability procedure to a certain durability group will come late in the process (or even after certification was granted). The good engineering judgement provisions in the current rule provide sufficient tools for the Agency to address these concerns in that time period. We still suggest that the best time for the notification is at the preview meeting to avoid last minute questions in the certification process. Nevertheless, we are changing the final regulation language to require the notification prior to or concurrently with the Application for Certification.

J. Public Availability of the Equivalency Factor and Supporting Data

Summary of Proposal. EPA proposed methods to calculate the equivalency factor. EPA also stated the opinion in the proposal that the equivalency factor was not confidential business information (CBI) and it may be released to the public. EPA also announced its plan to post the equivalency factors on the Agency's Web site.

Summary of Comments. The Alliance agreed with the proposal that the equivalency factor is not confidential and may be released to the public. However, they stated that manufacturers should not be compelled to disclose to the public any of their underlying data or other proprietary information used to develop their durability process.

The Alliance and AIAM also commented that EPA should not require extensive engineering reports justifying equivalency factors unless there is in-use or other data suggesting that the manufacturer's cycle does not achieve the durability objective.

They also commented that manufacturers should only be required to supply equivalency factors for processes that are used in the future (after the effective date of the proposed rules).

Afton commented that the Court's mandate *Ethyl Corp.* v. *EPA,* applies to all certification decisions made since the effective date of the mandate. Specifically, they disagreed with the Alliance and AIAM comment that equivalency factor need only be supplied for new durability procedures approved under the proposed rules and need not be reported for existing durability processes that were used after the vacature of the CAP 2000 rules as well as aging processes that were approved by EPA prior to the vacature.

Response to Comments. EPA continues to believe that the equivalency factor is not confidential business information and may be released to the public. EPA renews its intention to post the equivalency factors on the Agency's Web site for public use.

We are not making any other determinations (beyond the equivalency factor) regarding whether other information submitted by a manufacturer is or is not confidential business information. These decisions to release other information will be made on a case-by-case basis using the existing regulations [Ref. 40 CFR part 2].

We agree with Afton that the Court's mandate applies to all certification decisions made after the effective date of the mandate. However, once the Court's mandate became effective, EPA ceased requiring durability showings as a prerequisite to issuing a certificate of conformity. The basis for granting certification after the vacature of the CAP 2000 rule was EPA reliance on a statement made by the manufacturer using good engineering judgement that the vehicles in question will comply with the applicable standards for their full useful life. This statement was typically placed in the Application for Certification and has not generally been viewed by manufacturers as confidential business information. There are no approved durability procedures between the effective date of the Court's mandate and the effective date and model year of today's final rules. Consequently, there are no equivalency factors nor any supporting data that can be made

available by the manufacturers that apply to certification during that period.

K. Carryover

Summary of Proposal. EPA did not propose any changes to the carryover provisions in the current regulations (ref. 40 CFR 86.1839–01). These provisions allow manufacturers to use durability data that was previously generated and used to support certification provided that the data ''represent a worst case or equivalent rate of deterioration''.

EPA proposed that the manufacturer may not, however, continue to use CAP 2000 durability processes to generate new data starting with the effective date of the new regulations. When the proposed rule becomes effective, manufacturers must use durability procedures that have been approved under the new rules to generate new durability demonstrations.

Summary of Comments. The Alliance and AIAM commented that, in addition to allowing carry over of existing durability data prior to CAP 2000 vacature, manufacturers should also be allowed to use existing durability data employed after vacature from previously approved processes conforming with good engineering judgment.

They also suggested that manufacturers should be allowed to carry over aging data generated after the vacature of the CAP 2000 rules providing that these data were compiled using aged component processes approved by EPA prior to the vacature.

Lastly, they commented that manufacturers should be allowed to continue to use aging processes approved by EPA prior to the vacature to age components on future data fleet vehicles.

Response to Comments. EPA did not propose any change to the carryover provisions. After the effective date of the new regulations, if a manufacturer can meet these requirements, it may use existing durability data (i.e., DFs or aged hardware). This would apply to any data that exists prior to the effective date of the today's regulation which is compiled using a durability procedure that was approved prior to the vacature of the CAP 2000 rules. All new data generated after the effective date of today's rulemaking must meet all the applicable requirements including the requirement that it was generated using an approved durability procedure.

L. Evaporative Durability Procedures

Summary of Proposal. The proposal contained provisions for conducting evaporative durability using either a (1) whole vehicle demonstration using the SRC or another approved road cycle or a (2) bench aging demonstration using procedures contained in the regulations or (3) a combination of whole vehicle and bench procedures.

Summary of Comments. The Alliance and AIAM commented that the Court's ruling dealt exclusively with tailpipe emissions and did not compel EPA to revisit evaporative durability.

They also commented that separate durability demonstration for each evaporative family should be allowed via carryover using good engineering judgment.

They also commented that EPA's right to revoke use of evaporative durability based on IUVP is not in keeping with CAP 2000, which said that EPA would use the data primarily for modeling purposes. They are concerned that the sample size is too small and would force manufacturers to ensure that IUVP evaporative emission test vehicles match the emission level of certification test vehicles. Non-fuel related emissions can not be represented in the certification durability process.

Response to Comments. We disagree that the Court's decision regarding durability was limited to exhaust emission deterioration. Consequently, we proposed (and are finalizing) exhaust, evaporative, and refueling durability procedures.

As discussed previously, the carryover procedures of the current regulations (ref. 40 CFR 86.1839–01) are not changed on the proposal. These provisions allow manufacturers to use durability data that was previously generated and used to support certification provided that the data ''represent a worst case or equivalent rate of deterioration''. Consequently, existing evaporative durability data and results may be carried-over providing they meet these requirements.

We agree that the IUVP sample size (one test per test group) is too small to make this decision on an individual test group basis. However, EPA intends to review in-use evaporative data and evaluate the effectiveness of the durability process to achieve the durability objective when a reasonable amount of data does exist for this purpose. This expanded data set could include data from another source or it may consist of data combined from several related test groups or from several years of IUVP data. If the expanded data set indicates a problem, EPA believes it is appropriate to invoke this provision to re-evaluate the manufacturer's evaporative durability procedure. Furthermore, if the Agency ultimately concludes that there is sufficient data and that the data indicate that the durability objective is not achieved, EPA believes it is appropriate to require modifications to the durability procedure in the same method used for exhaust emission deterioration. It would not be acceptable to continue to use an evaporative durability process that was demonstrated to not achieve the durability objective; EPA relies on the accuracy of this data to make appropriate decisions to grant certification. Consequently, we are finalizing these provisions as proposed with the acknowledgment that a sufficient body of data must exist to make this determination with appropriate confidence.

M. Starting Model Year for the Rule

Summary of Proposal. EPA proposed that the rules would apply to 2006 model year vehicles certified after the effective date of the regulations.

Summary of Comments. The Alliance and AIAM commented that the proposed effective date of 2006 model year (MY) should be changed to 2008 MY, or later if final rule published after August 2004. They stated that manufacturers are already doing durability testing on 2006 models, and developmental work is already underway for early introduction 2007 models.

Volkswagen commented that the effective date of 2006 MY is unworkable, but they do not propose an alternative date.

Ford commented that the effective date for the regulation should be changed to 2009 MY if component durability issues are addressed in a single rulemaking and 2008 MY if the emission deterioration provisions are finalized separately.

The Alliance and AIAM suggest that we add a provision allowing early opt-in at the manufacturer's discretion.

Response to Comments. We agree that 2006 is no longer possible given the current timing for publication of the final rule. Because publication of the FRM has taken longer than expected, and manufacturers are now certifying 2006 model year vehicles and already performing durability testing for 2007 models, we are delaying the implementation of the rule to become effective beginning with the 2008 MY.

N. Special Provisions for New Manufacturers

Summary of Proposal. EPA did not propose any special procedures for new manufacturers to obtain approval of a customized/alternative durability procedure. However, the standard procedures may be employed by these

manufacturers without generating any in-use emission data. Also, the Agency did not change the special certification procedures that apply to small volume manufacturers (ref. 40 CFR 86.1838–01).

Summary of Comments. The Alliance and AIAM commented that new manufacturers should not have to rely on IUVP data for feedback purposes since they supply little or no IUVP data. They suggested that the rule should have clear provisions for new manufacturers.

Response to Comments. New manufacturers may use the standard durability procedures without submitting in-use data or obtaining EPA approval. We believe that these standard procedures provide a reasonable method for new manufacturers to supply the required durability data without the need to compile in-use emission data. However, if a new manufacturer did wish to obtain approval for a customized/alternative durability road cycle, EPA would accept appropriate data from another manufacturer's comparable in-use vehicles to demonstrate the effectiveness of their durability procedures to achieve the durability objective.

O. Delete Incorrect Reference to Intermediate Useful Life Standards for the Evaporative and Refueling Durability Objective

Response to Comment. We made the appropriate correction in the final regulations.

P. Comments From a Private Citizen

Summary of Comments. One citizen submitted comments that touched upon various topics, many of which were not germain to the proposed rule. In general, the consumer believed that the proposal was ''too friendly'' to manufacturers. The commenter requested that the public should always be invited to all meetings EPA has with manufacturers to assure that no ''secret dealings'' are taking place.

EPA response. Some of the comments touched on issues that have been addressed elsewhere in this section. We disagree that the proposal was ''too friendly'' to manufacturers. Emissions durability requirements impose a significant burden on manufacturers, and the provisions to allow for alternatives does not lessen the responsibility placed upon manufacturers to perform the required emission durability demonstration. We also disagree that all meetings with manufacturers should be open to the public. The discussions at these meetings center around individual manufacturers' business plans and are forward-looking in nature. Revealing these plans publicly would compromise the competitive automotive market. However, by informing the public of what sort of information is exchanged in these meetings, we believe we have provided the public with enough assurance that no ''deals'' are being made.

III. What Is EPA Promulgating Today?

Today's final rule includes two well-defined test methods for determining the exhaust emissions durability of vehicles from which manufacturers may choose: the standard whole vehicle aging process and the standard bench aging process. It also includes well-defined criteria allowing EPA to approve customization of or alternatives to these test methods, based upon a demonstration to EPA of the level of stringency needed to meet the durability objective, and the level of stringency demonstrated for the SCR and the customization or alternative.

A. Standard Whole Vehicle Exhaust Durability Procedure

EPA is promulgating a standard road cycle (SRC) which is targeted to effectively cover a significant majority of the distribution of exhaust emission deterioration rates that occur on candidate in-use vehicles. The SRC is fuel-neutral. It applies to all vehicles, regardless of fuel used. The SRC consists of seven laps of 3.7 miles each. The average speed on the SRC is 46.3 mph, the maximum cruise speed is 75 mph, and the acceleration rates range from light to hard accelerations. Most accelerations are moderate and there are no wide-open-throttle accelerations. The SRC contains 24 fuel-cut decelerations. The deceleration rates range from coast-down (no brake force applied) to moderate.

EPA is promulgating a standard whole vehicle durability procedure which consists of running a vehicle (the durability data vehicle (DDV)) on the SRC for the full useful life mileage of the vehicle. We are also finalizing rules that manufacturers may terminate mileage accumulation at 75% of full useful life and project DFs based upon the upper 80% statistical confidence limit.

The weight of the vehicle during SRC mileage accumulation is proposed to be the loaded vehicle weight (curb plus 300 pounds) for light-duty vehicles and light light-duty trucks. The weight basis for SRC mileage accumulation is the adjusted loaded vehicle weight ((curb + gross vehicle weight)/2) for all other vehicles covered by this rule. The fuel used on the SRC is proposed to be representative of commercially available gasoline (with a provision that extra poisoning may be added, such as phosphorus, sulfur or lead).

EPA is retaining the CAP 2000 options of determining emission compliance levels by either (1) calculating deterioration factors (DF) and applying the DF to the emission data vehicle (EDV) emission results or (2) testing the EDV with emission control components aged using the SRC and installed prior to testing. If DF's are to be calculated, emission testing would be conducted at periodic intervals during milage accumulation.

B. Standard Bench Aging Exhaust Durability Procedure

Bench aging is a different way to achieve the same emission deterioration as whole-vehicle aging using a road cycle. EPA is promulgating a standard bench aging procedure that uses a bench aging time (BAT) equation and the standard bench cycle (SBC) to reproduce emission deterioration from a road cycle. EPA's standard bench procedure specifies that the SRC be used to generate the catalyst temperature histogram needed to determine bench aging time. Because the standard bench aging procedure relies on increasing catalyst thermal aging to account for all sources of emission deterioration, this procedure is not applicable to diesel fueled vehicles or vehicles which do not use a catalyst as the principal after-treatment emission control device.

The standard bench aging durability procedure has been designed to reproduce the exhaust emission deterioration that occurs on the standard whole vehicle durability procedure. The standard bench aging procedure is as follows:

a. Catalyst temperature data is measured at a minimum rate of one hertz (one measurement per second) during at least two replicates of the standard road cycle (SRC). The temperature results are tabulated into a histogram with temperature bins of no larger than 25 °C.

b. The effective reference temperature of the standard bench cycle (SBC), described below, is determined for the catalyst system and the aging bench which is to be used for the bench aging.

c. The bench aging time is calculated using the bench aging time (BAT) equation, described below, using the effective reference temperature of the SBC and the catalyst temperature histogram measured on the SRC.

d. The exhaust system (including the catalyst and oxygen sensors) is installed on the aging bench. The aging bench

follows the SBC for the amount of time calculated from the BAT equation.

e. Catalyst temperatures and A/F ratios are measured during the bench aging process to assure that the proper amount of aging has actually occurred. Aging on the bench is extended if the aging targets are not properly achieved.

1. The Standard Bench Cycle (SBC)

EPA is promulgating a standard bench cycle (SBC) which contains a mix of rich, lean and stoichiometric A/F ratios designed to achieve appropriate emission deterioration on the aging bench when operated for the period of time calculated from the BAT equation.

The standard bench cycle consists of a 60-second cycle which is defined based on the A/F ratio of the engine (which is part of the aging bench) and the amount of secondary air injection (shop air which is added to the exhaust stream in front of the first catalyst).

2. The Bench-Aging Time (BAT) Calculation

EPA is promulgating a bench aging time (BAT) equation to calculate the appropriate length of time to age a catalyst system on an aging bench to yield equivalent emission deterioration as running a vehicle on the associated road cycle. The standard bench aging durability procedure uses catalyst temperatures measured on the SRC to calculate the bench aging time necessary to reproduce the thermal exposure seen on the SRC. As discussed in the NPRM preamble, the BAT equation is based on the Arrehenius equation which relates chemical reaction rates with temperature.

3. The Effective Reference Temperature for the SBC

The BAT equation uses a single temperature value called the effective reference temperature to represent the entire temperature-history experienced during the SBC on the catalyst aging bench. The effective reference temperature will be calculated using catalyst temperature histogram data measured in the catalyst on the aging bench following the SBC. The BAT equation would then be used to calculate the effective reference temperature by iterative changes to the reference temperature (T_r) until the calculated aging time equaled the actual time representing in the catalyst temperature histogram. The resulting temperature is the effective reference temperature for the SBC.

C. Customization of the Standard Procedures

1. Customization of the Standard Road Cycle

EPA has established criteria to obtain approval for a customized/alternative road cycle that require the manufacturer to demonstrate that the objective of the durability program will be achieved for the breadth of the vehicles which are covered by the cycle. Approval of a customized/alternative road cycle requires a thorough analysis of whether the cycle will achieve the durability program objective using in-use emissions data, including a demonstration of the relative stringency of the SRC and the manufacturer's program.

To make the initial demonstration necessary for the Agency to approve a customized/alternative cycle, EPA is requiring that the manufacturer supply high mileage in-use emission data on applicable candidate in-use vehicles. The vehicles would be randomly procured from actual customer use, generally with an age of 4 to 5 years and with a minimum of approximately 50,000 miles. They would cover the breadth of the vehicles that the manufacturer intends to certify using the customized/alternative cycle. Vehicles would be procured and FTP tested as received under the provisions of the IUVP program (ref: 40 CFR 86.1845–04). Manufacturers could use previously generated in-use data from the CAP 2000 high mileage IUVP program or the fourth-year-of-service RDP ''reality check'' in-use program as well as other sources of in-use emissions data for this purpose. EPA will also consider additional emissions data or analyses that the manufacturer may choose to provide, including data from vehicles which have been screened for proper maintenance and use.

The amount of in-use emission data required for this analysis is based on whether the customized/alternative cycle is more or less severe than the SRC. In most cases, EPA will accept a minimum of 20 candidate in-use vehicles. There is less risk of underestimating actual in-use emission levels when the customized/alternative cycle is more severe than the SRC. However, if the customized/alternative cycle is significantly more severe than the SRC, EPA may accept less data. Conversely, if the customized/alternative cycle is significantly less severe than the SRC, EPA may require more data up to a maximum of 30 vehicles.

EPA will also consider the equivalency factor of the customized/alternative cycle when evaluating the cycle for approval.

Once the durability process is approved, the manufacturer must determine, using good engineering judgement, whether to apply the durability procedure to a particular test group. The manufacturer may make modifications to an approved customized/alternative road cycle and apply them to a test group to ensure that the modified process will effectively achieve the durability objective for future candidate in-use vehicles. The manufacturer would be required to identify such changes in its certification application and explain the basis for the changes. Manufacturers must use good engineering judgement in making these decisions. Significant, major, or fundamental changes to a customized/alternative cycle would be considered new cycles and would require advance approval by EPA.

2. Customization of Standard Bench Procedures

The manufacturers are allowed, subject to Agency approval, a limited degree of customization of the standard bench procedures. However, in all cases EPA is requiring that alternative bench aging procedures be based upon measured vehicle performance (such as catalyst temperature) on an approved road cycle.

Specifically EPA is allowing customization of any or all of the following parameters when the accompanying conditions for approval are met:

a. The lower control temperature on the SBC may be modified without prior EPA approval provided that the high control temperature is set 90 °C (± 10 °C) above the lower control temperature and an approved BAT equation is used to calculate bench aging time.

b. The R-factor used in EPA's BAT equation may be determined experimentally using EPA's standard procedures (specified in the appendix to the regulations) without prior EPA approval. Other experimental techniques to calculate the R-factor require advance EPA approval. To obtain approval, the manufacturer must demonstrate that the calculated bench aging time results in the same (or larger) amount of emission deterioration as the associated road cycle.

c. The A-factor used in EPA's BAT equation may be modified, using good engineering judgement without prior EPA approval, to ensure that the modified durability process will achieve the durability objective (discussed previously).

d. Bench-aging may be conducted using fuel with additional poisons (such as phosphorus, sulfur and lead) without prior EPA approval. Using fuel with additional poisons is worst case for emissions deterioration. Normally a manufacturer using fuel with additional poisons will either calculate a new R-factor or A-factor to assure that the durability objective is properly achieved.

e. An approved alternative road cycle or customized SRC may be used to develop catalyst temperature histograms for use in the BAT equation without additional EPA approval beyond the original approval necessary to use the road cycle for mileage accumulation.

f. A different bench cycle may be used during bench aging with prior EPA approval. To obtain approval the manufacturer must demonstrate that bench aging with the new bench cycle provides the same (or larger) amount of emission deterioration as the associated road cycle.

g. A different method to calculate bench aging time may be used with prior EPA approval. To obtain approval the manufacturer must demonstrate that bench aging for the time calculated by the alternative method results in the same (or larger) amount of emission deterioration as the associated road cycle.

3. Reproducibility by Outside Parties

EPA is finalizing the provision that an alternative road cycle must be designed to achieve the durability objective. As part of this evaluation, EPA is requiring that all alternative road cycles are equated to the SRC by means of an equivalency factor that determines the amount of SRC-driving that results in the same emission deterioration as the alternative cycle. EPA is requiring that every alternative bench aging procedure be based upon measured vehicle performance on an approved road cycle. Lastly, EPA is requiring that any alternative bench cycle be designed to result in the same levels of emission deterioration as the road cycle upon which it was based.

An important element of the regulation is that, regardless of whether a manufacturer uses the EPA standard procedures or customized procedures, any interested party will be able to use the equivalency factor to reproduce the amount of emission deterioration produced by any manufacturer's customized/alternative durability process used during vehicle certification. Any alternative road or bench procedure is equated to a given number of miles on the SRC.

To reproduce the deterioration generated by a customized/alternative road cycle, standard bench procedure, or alternative bench procedure, an outside party may run a vehicle using the SRC for the number of miles indicated by the equivalency factor.

Similarly, an outside party will be able to perform bench aging using the SBC. The aging time may be calculated using the BAT equation and measured catalyst temperature on the SRC (with full-useful-life-mileage adjusted by the equivalency factor).

D. Using IUVP Data To Improve Durability Predictions

Manufacturers are required to review their durability program and prepare an analysis for EPA evaluation when: (1) The IUVP emission levels exceed the applicable certification emission standard 50% or more of the test vehicles and (2) the average emission level is at least 1.3 times the applicable emission standard. These criteria would be evaluated independently for all applicable FTP emission constituents. Each constituent should be considered separately in this analysis.

The Agency may, from time to time, require manufacturers to analyze available IUVP data, or other information, when it indicates that the durability objective is not being achieved for some portion of the fleet of vehicles covered by a durability procedure. This provision would apply whether or not the screening criteria are exceeded.

As in the CAP 2000 program, EPA may withdraw approval of a durability program or require its modification if it determines that the program does not meet the objectives for a durability program. The Agency will give the manufacturer a preliminary notice at least 60 days prior to rendering a final decision to withdraw approval for or require modifications to a durability procedure. During this period the manufacturer may submit technical discussion, statistical analyses, additional data, or other information that is relevant to the decision. This may include an analysis to determine whether factors other than the durability program, such as part defects, are the source of the problem. The Administrator will consider all information submitted by the deadline before reaching a final decision. A final decision to withdraw approval or require modification to a durability procedure would apply to future applications for certification and to the portion of the manufacturer's product line (or the entire product line) that the Administrator determines to be affected.

If the manufacturer was using the standard road cycle or standard bench cycle, EPA will require the manufacturer to adjust the durability process so it would achieve the durability objective. The Agency will allow two options in this situation: (1) Increasing future DFs by the average percent-difference between certification levels and IUVP data, or (2) increasing the whole vehicle miles driven or catalyst aging time by the average percent-difference between certification levels and IUVP data. Additionally the manufacturer may obtain approval for a new alternative durability process that has been demonstrated to meet the durability objective. If the data set used in the analysis contains less than 20 pieces of data, the Administrator may reduce the degree of adjustment required to account for uncertainty in the data.

E. Evaporative and Refueling Durability

EPA is finalizing provisions that require manufacturers determine the evaporative/refueling deterioration using either whole vehicle durability or bench aging methods or a combination of the two methods.

Whole Vehicle Evaporative/Refueling Durability. Manufacturers may conduct evaporative and/or refueling durability program by running the DDV on the SRC or an approved alternative road cycle and conducting the applicable test at each testing point. Manufacturers may combine exhaust and evaporative/refueling whole vehicle durability demonstrations.

Bench-Aging Evaporative/Refueling Durability. Manufacturers may use bench procedures designed, using good engineering judgement, to evaluate the following potential causes of evaporative emission deterioration and achieve the durability objective:

(1) Cycling of canister loading due to diurnal and refueling events,

(2) Use of various commercially available fuels, including the Tier 2 requirement to include alcohol fuel;

(3) Vibration of components;

(4) Deterioration of hoses, etc. due to environmental conditions; and

(5) Deterioration of fuel cap due to wear.

Manufacturers will determine evaporative and refueling DFs using good engineering judgement without the need for prior EPA approval.

F. Compliance Date and Carryover of Existing Durability Data

Manufacturers must meet the requirements of today's action beginning with the 2008 model year.

EPA is not making any changes to the carryover provisions in the current regulations (ref. 40 CFR 86.1839–01). These provisions allow manufacturers to use durability data that was previously generated and used to support certification provided that the data ''represent a worst case or equivalent rate of deterioration''. Beginning in the 2008 model year, if a manufacturer can meet these requirements, it may use existing durability data (i.e., DFs or aged hardware) to support certification.

The manufacturer may not, however, continue to use CAP 2000 durability processes to generate new data starting with the 2008 model year. When the proposed rule becomes effective in the 2008 model year, manufacturers must use durability procedures that have been approved under the new rules to generate new durability demonstrations.

G. Miscellaneous Regulatory Amendments and Corrections

1. With the addition of the new durability regulations (sections 86.1823–08, 86.1824–08, and 86.1825–08), the regulatory references in a number of other sections of subpart S of part 86 have been updated accordingly.

2. Section 1864 of subpart S is being moved to section 1801. This section describes the applicability of subpart S to heavy-duty vehicles, and is more appropriately located in the Applicability section of the regulations.

3. An outdated address in section 1817–05 has been corrected.

4. A typographical error in section 1830–01(c) has been corrected.

5. Two corrections are being made to section 86.1806–05, on-board diagnostics. First, in a previous regulatory action, this section was amended to add provisions for diesel vehicles and HDVs and MDPVs. In doing this, an inadvertent error was made in paragraph (a)(3). The provision allowing compliance with 86.004–17, in lieu of 1806–05, should be limited to apply only to MDPVs and HDVs. The language has been revised accordingly. Second, in the original CAP 2000 regulation, there is an incorrect reference to section 86.094–17(e) and (f). The correct reference is 1806–05(e) and (f).

IV. What Are the Economic and Environmental Impacts?

A. Economic Impacts

1. Comparison to CAP 2000 Economic Impacts

In considering the economic and environmental impacts of today's proposal, we used the CAP 2000 regulations as a comparison benchmark. In those regulations, EPA estimated that there would be an average annual net savings to the automotive industry of about $55 million. The analysis performed to reach that conclusion was part of the record for the CAP 2000 regulation, and was not contested.

In today's final rulemaking, one of our goals was to retain those savings. In the CAP 2000 cost analysis, about half of the total estimated annual savings was attributed to the durability component of the regulations. The elements of CAP 2000 durability which provided the most significant savings are:

a. *Reduced number of durability data vehicles (DDVs)*. The creation of the ''durability group'' under CAP 2000 allowed manufacturers to significantly reduce the number of required durability demonstrations. The savings that are claimed in the CAP 2000 rule resulting from the ''durability group'' provision come from requiring physically fewer DDVs, fewer durability tests, and less reporting (e.g. instead of having to report 912 durability tests, there would only be 620 tests). The ''durability group'' concept was not part of the *Ethyl* v. *EPA* litigation, nor was it mentioned in the Court's opinion on this case. Thus EPA is not modifying the ''durability group'' regulations in today's final rule.

In fact, it is possible that today's final rule could actually slightly reduce some costs to the industry, in that manufacturers using one of the EPA-prescribed durability processes (either whole-vehicle or bench) would no longer have to provide a description of their durability process (which was required under CAP 2000, and would continue to be required for manufacturers using customized procedures under today's final rule).

b. *Reduced burden-hours per DDV*. In addition to fewer DDVs, in the CAP 2000 rulemaking, EPA also slightly reduced the estimated number of burden-hours required per DDV. As above, this element was not affected by the Court mandate, and is not impacted by today's final rule.

2. Economic Impact of Today's Rule

Today's final rule prescribes two methods for determining the emission deterioration of vehicles over their useful life periods—the whole-vehicle procedure or the bench-aging procedure. Details of how to perform these procedures are prescribed in the proposed regulations. Because these procedures are similar in nature to those approved by EPA under the CAP 2000 regulations, the added burden for manufacturers utilizing them will be minimal.[25] The costs involved with either of these processes (equipment costs, vehicle costs, testing costs, labor costs, etc.) are fairly fixed. Manufacturers using one of the prescribed methods will not be required to make major changes to or add any new equipment, test any additional vehicles with any additional frequency, or to increase the amount of labor. We expect that manufacturers who, under the old CAP 2000 regulations, used a bench-aging (or whole-vehicle) process will continue to use a bench-aging (or whole-vehicle) process—the only difference is that now that process is codified.

The final regulations also include the option for manufacturers to use customized or alternative procedures, with EPA approval. The approval requires the manufacturer to submit an analysis of about 20 in-use emission tests. Most manufacturers will be able to utilize in-use data and analyses that they have previously collected from other sources (such as the CAP 2000 in-use verification data). Some manufacturers may need to augment this data by running a few additional tests, but this would be a small, one-time cost. EPA estimates that this small added cost is more than offset by the fact that once approved, manufacturers will be able to use their durability programs without the need to make any changes to those programs.

As discussed above, EPA is issuing a separate Supplemental Notice of Proposed Rulemaking which addresses component durability. Any costs associated with that proposal will be addressed in that notice.

B. Environmental Impacts

In the CAP 2000 rule, no quantifiable environmental benefits were projected. Intangible benefits were possible due to the In-Use Verification Program (IUVP) element of the CAP 2000 rule—manufacturers would be able to use the in-use data from this program to identify and fix in-use compliance problems and to make improvements upon their certification durability processes. This intangible benefit is not changed in today's final rule—the in-use verification program is not affected by the Court mandate, and no changes to this program are being proposed. EPA is modifying an existing CAP 2000 provision whereby manufacturers utilize the IUVP data to assess the ability of the durability program to

[25] Added burden will be in the form of the one-time reprogramming of automated driving or bench-aging devices with the new driving/aging cycle, and other minor equipment adjustments.

predict in-use compliance. The modification includes more explicit instructions as to what the manufacturer is required to assess and when corrective action is required (see section III C.). This proposed provision will have the effect of improving the predictive qualities of the durability process, but again, with intangible environmental benefits.

VI. What Are the Statutory and Executive Order Reviews for This Proposed Rule?

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735 October 4, 1993), EPA must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of this Executive Order. The Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or 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;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, OMB has notified EPA that it considers this a ''significant regulatory action'' within the meaning of the Executive Order. OMB has waived review of this action.

B. Paperwork Reduction Act

This action does not impose any new information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations (64 FR 23906) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0104, EPA ICR number 0783.44. A copy of the OMB approved Information Collection Requests (ICR) may be obtained from Susan Auby, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW., Washington, DC 20460 or by calling (202) 566–1672.

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.

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.

C. Regulatory Flexibility Analysis

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administrations' regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities. A small business that manufacturers automobiles has a NAIC code of 336111. Based on Small Business Administration size standards, a small business for this NAIC code is defined as a manufacturer having less than 1000 employees. The requirements are only applicable to manufacturers of motor vehicles, a group which does not contain a substantial number of small entities. Out of a total of approximately 80 automotive manufacturers subject to today's proposal, EPA estimates that approximately 15–20 of these could be classified as small entities based on SBA size standards. EPA's CAP 2000 compliance regulations include numerous regulatory relief provisions for such small entities. Those provisions remain in effect and are not impacted by today's final rule.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory action on state, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and proposed rules with ''Federal mandates'' that may result in expenditures by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. Before promulgation an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the proposed rule an explanation why that alternative was not adopted.

Before we establish any regulatory requirement that may significantly or uniquely affect small governments, including tribal governments, we must develop, under section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of our regulatory proposals with significant federal intergovernmental mandates. The plan must also provide for informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA believes this final rule contains no Federal mandates for state, local, or tribal governments. Nor does this rule have federal mandates that may result in the expenditures of $100 million or more in any year by the private sector as defined by the provisions of Title II

of the UMRA. Nothing in the final rule would significantly or uniquely affect small governments.

E. Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), 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 will impose no direct compliance costs on states. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 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.'' ''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 final rule does not have tribal implications. It 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. The requirements of this action impact private sector businesses, particularly the automotive and engine manufacturing industries. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Children's Health Protection

Executive Order 13045: ''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 E.O. 13045 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 rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This final rule is not subject to E.O. 13045 because it is based on technology performance and not on health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

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) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, 12(d) (15 U.S.C. 272), directs the EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standard bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rule does not involve consideration of any new technical standards. The durability test procedures that EPA is adopting are unique and have not been previously published in the public domain.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as amended 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 Congress and the comptroller General of the United States. We 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).

List of Subjects in 40 CFR Part 86

Environmental protection, Air pollution control, Motor vehicle pollution, Confidential business information, Reporting and recordkeeping requirements.

Dated: December 29, 2005.

Stephen Johnson,

Administrator.

■ For the reasons set forth in the preamble, The Environmental Protection Agency title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 86—CONTROL OF EMISSIONS FROM NEW AND IN-USE HIGHWAY VEHICLES AND ENGINES

■ 1. The authority citation for part 86 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart S—General Compliance Provisions for Control of Air Pollution From New and In-Use Light-Duty Vehicles, Light-Duty Trucks, and Complete Otto-Cycle Heavy-Duty Vehicles

■ 2. Amend § 86.1803–01 by adding a new definition in alphabetical order, to read as follows:

§ 86.1803–01 Definitions.

* * * * *

Secondary air injection means a system whereby air (not ingested by the engine) is introduced into the exhaust system in front of a catalyst.

* * * * *

■ 3. Amend § 86.1804–01 by adding new acronyms in alphabetical order, to read as follows:

§ 86.1804–01 Acronyms and abbreviations.

* * * * *

A/F—Air/Fuel

* * * * *

BAT—Bench-Aging Time

* * * * *

SBC—Standard Bench Cycle

* * * * *

SRC—Standard Road Cycle

* * * * *

■ 4. Amend § 86.1817–05 by revising paragraph (i)(3)(i) to read as follows:

§ 86.1817–05 Complete heavy-duty vehicle averaging, trading, and banking program.

* * * * *

(i) * * *

(3) * * *

(i) These reports shall be submitted within 90 days of the end of the model year to: Director, Certification and Compliance Division, U.S. Environmental Protection Agency, Mail Code 6405J, 1200 Pennsylvania Ave., NW., 20460.

* * * * *

■ 5. Add a new § 86.1823–08 subpart S to read as follows:

§ 86.1823–08 Durability demonstration procedures for exhaust emissions.

This section applies to all 2008 and later model year vehicles which meet the applicability provisions of § 86.1801. Optionally, a manufacturer may elect to use this section for earlier model year vehicles which meet the applicability provisions of § 86.1801. Eligible small volume manufacturers or small volume test groups may optionally meet the requirements of §§ 86.1838–01 and 86.1826–01 in lieu of the requirements of this section. A separate durability demonstration is required for each durability group.

(a) *Durability program objective.* The durability program must predict an expected in-use emission deterioration rate and emission level that effectively represents a significant majority of the distribution of emission levels and deterioration in actual use over the full and intermediate useful life of candidate in-use vehicles of each vehicle design which uses the durability program.

(b) *Required durability demonstration.* Manufacturers must conduct a durability demonstration for each durability group using a procedure specified in either paragraph (c), (d), or (e) of this section.

(c) *Standard whole-vehicle durability procedure.* This procedure consists of conducting mileage accumulation and periodic testing on the durability data vehicle, selected under the provisions of § 86.1822 described as follows:

(1) Mileage accumulation must be conducted using the standard road cycle (SRC). The SRC is described in Appendix V of this part.

(i) Mileage accumulation on the SRC may be conducted on a track or on a chassis mileage accumulation dynamometer. Alternatively, the entire engine and emission control system may be aged on an engine dynamometer using methods that will replicate the aging that occurs on the road for that vehicle following the SRC.

(ii) The fuel used for mileage accumulation must comply with the mileage accumulation fuel provisions of § 86.113 for the applicable fuel type (e.g., gasoline or diesel fuel).

(iii) The DDV must be ballasted to a minimum of the loaded vehicle weight for light-duty vehicles and light light-duty trucks and a minimum of the ALVW for all other vehicles.

(iv) The mileage accumulation dynamometer must be setup as follows:

(A) The simulated test weight will be the equivalent test weight specified in § 86.129 using a weight basis of the loaded vehicle weight for light-duty vehicles and ALVW for all other vehicles.

(B) The road force simulation will be determined according to the provisions of § 86.129.

(C) The manufacturer will control the vehicle, engine, and/or dynamometer as appropriate to follow the SRC using good engineering judgement.

(2) Mileage accumulation must be conducted for at least 75% of the applicable full useful life mileage period specified in § 86.1805. If the mileage accumulation is less than 100% of the full useful life mileage, then the DF calculated according to the procedures of paragraph (f)(1)(ii) of this section must be based upon a line projected to the full-useful life mileage using the upper 80 percent statistical confidence limit calculated from the emission data.

(3) If a manufacturer elects to calculate a DF pursuant to paragraph (f)(1) of this section, then it must conduct at least one FTP emission test at each of five different mileage points selected using good engineering judgement. Additional testing may be conducted by the manufacturer using good engineering judgement. The required testing must include testing at 5,000 miles and at the highest mileage point run during mileage accumulation (e.g. the full useful life mileage). Different testing plans may be used providing that the manufacturer determines, using good engineering judgement, that the alternative plan would result in an equivalent or superior level of confidence in the accuracy of the DF calculation compared to the testing plan specified in this paragraph.

(d) *Standard bench-aging durability procedure.* This procedure is not applicable to diesel fueled vehicles or vehicles which do not use a catalyst as the principle after-treatment emission control device. This procedure requires installation of the catalyst-plus-oxygen-sensor system on a catalyst aging bench. Aging on the bench is conducted by following the standard bench cycle (SBC) for the period of time calculated from the bench aging time (BAT) equation. The BAT equation requires, as input, catalyst time-at-temperature data measured on the SRC.

(1) *Standard bench cycle (SBC).* Standard catalyst bench aging is conducted following the SBC

(i) The SBC must be run for the period of time calculated from the BAT equation.

(ii) The SBC is described in Appendix VII to Part 86.

(2) *Catalyst time-at-temperature data*

(i) Catalyst temperature must be measured during at least two full cycles of the SRC.

(ii) Catalyst temperature must be measured at the highest temperature location in the hottest catalyst on the DDV. Alternatively, the temperature may be measured at another location providing that it is adjusted to represent the temperature measured at the hottest location using good engineering judgement.

(iii) Catalyst temperature must be measured at a minimum rate of one hertz (one measurement per second).

(iv) The measured catalyst temperature results must be tabulated into a histogram with temperature bins of no larger than 25° C.

(3) *Bench-aging time.* Bench aging time is calculated using the bench aging time (BAT) equation as follows:

t_e for a temperature bin = $t_h\ e^{((R/Tr)-(R/Tv))}$

Total t_e = Sum of t_e over all the temperature bins

Bench-Aging Time = A (Total t_e)

Where:

A = 1.1 This value adjusts the catalyst aging time to account for deterioration from sources other than thermal aging of the catalyst.

R = Catalyst thermal reactivity coefficient. For the SBC, R=17500 for Tier 2 vehicles and R=18500 for all other vehicles.

t_h = The time (in hours) measured within the prescribed temperature bin of the vehicle's catalyst temperature histogram adjusted to a full useful life basis e.g., if the histogram represented 400 miles, and full useful life was 100,000 miles; all histogram time entries would be multiplied by 250 (100000/400).

Total t_e = The equivalent time (in hours) to age the catalyst at the temperature of T_r on the catalyst aging bench using the catalyst aging cycle to produce the

same amount of deterioration experienced by the catalyst due to thermal deactivation over the vehicle's full useful life.

t_e for a bin = The equivalent time (in hours) to age the catalyst at the temperature of T_r on the catalyst aging bench using the catalyst aging cycle to produce the same amount of deterioration experienced by the catalyst due to thermal deactivation at the temperature bin of T_v over the vehicle's full useful life.

T_r = The effective reference temperature (in °K) of the catalyst on the catalyst bench run on the bench aging cycle. The effective temperature is the constant temperature that would result in the same amount of aging as the various temperatures experienced during the bench aging cycle.

T_v = The mid-point temperature (in °K) of the temperature bin of the vehicle on-road catalyst temperature histogram.

(4) *Effective reference temperature on the SBC.* The effective reference temperature of the standard bench cycle (SBC) is determined for the actual catalyst system design and actual aging bench which will be used using the following procedures:

(i) Measure time-at-temperature data in the catalyst system on the catalyst aging bench following the SBC.

(A) Catalyst temperature must be measured at the highest temperature location of the hottest catalyst in the system. Alternatively, the temperature may be measured at another location providing that it is adjusted to represent the temperature measured at the hottest location using good engineering judgement.

(B) Catalyst temperature must be measured at a minimum rate of one hertz (one measurement per second) during at least 20 minutes of bench aging.

(C) The measured catalyst temperature results must be tabulated into a histogram with temperature bins of no larger than 10° C.

(ii) The BAT equation must be used to calculate the effective reference temperature by iterative changes to the reference temperature (T_r) until the calculated aging time equals the actual time represented in the catalyst temperature histogram. The resulting temperature is the effective reference temperature on the SBC for that catalyst system and aging bench.

(5) *Catalyst Aging Bench.* The manufacturer must design, using good engineering judgement, a catalyst aging bench that follows the SBC and delivers the appropriate exhaust flow, exhaust constituents, and exhaust temperature to the face of the catalyst.

(i) A manufacturer may use the criteria and equipment discussed in Appendix VIII to part 86 to develop its catalyst aging bench without prior Agency approval. The manufacturer may use another design that results in equivalent or superior results with advance Agency approval.

(ii) All bench aging equipment and procedures must record appropriate information (such as measured A/F ratios and time-at-temperature in the catalyst) to assure that sufficient aging has actually occurred.

(6) *Required Testing.* If a manufacturer is electing to calculate a DF (as discussed in paragraph (f)(1) of this section), then it must conduct at least two FTP emissions tests on the DDV before bench aging of emission control hardware and at least two FTP emission tests on the DDV after the bench-aged emission hardware is re-installed. Additional testing may be conducted by the manufacturer using good engineering judgement.

(e) *Additional durability procedures*—(1) Whole vehicle durability procedures. A manufacturer may use either a customized SRC or an alternative road cycle for the required durability demonstration, with prior EPA approval.

(i) *Customized SRC.* A customized SRC is the SRC run for a different number of miles and/or using a different mileage accumulation fuel with higher levels of certain compounds that may lead to catalyst poisoning, such as phosphorus, sulfur and lead, than specified in paragraph (c)(1)(ii) of this section.

(ii) *Alternative Road Cycle.* An alternative cycle is a whole vehicle mileage accumulation cycle that uses a different speed-versus-time trace than the SRC, conducted for either the full useful life mileage or for less than full useful life mileage. An alternative road cycle may also include the use of fuel with higher levels of certain compounds that may lead to catalyst poisoning, such as phosphorus, sulfur and lead, than specified in paragraph (c)(1)(ii) of this section.

(iii) *Approval Criteria.* The manufacturer must obtain approval from EPA prior to using a customized/alternative road cycle. EPA may approve a customized/alternative cycle when the manufacturer demonstrates that the cycle is expected to achieve the durability program objective of paragraph (a) of this section for the breadth of vehicles using the customized/alternative cycle. To obtain approval the manufacturer must submit all the following information and perform all the following analyses:

(A) The manufacturer must supply in-use FTP emission data on past model year vehicles which are applicable to the vehicle designs it intends to cover with the customized/alternative cycle.

(*1*) The amount of in-use emission data required to demonstrate the effectiveness of a customized/alternative cycle in meeting the durability objective is based on whether the customized/alternative cycle is more or less severe than the SRC. In most cases, EPA will accept a minimum of 20 candidate in-use vehicles tested as-received on the FTP cycle. If the customized/alternative cycle is significantly more severe than the SRC, EPA may accept less data. Conversely, if the customized/alternative cycle is significantly less severe than the SRC, EPA may require more data, up to a maximum of 30 vehicles.

(*2*) This data set must consist of randomly procured vehicles from actual customer use. The vehicles selected for procurement must cover the breadth of the vehicles that the manufacturer intends to certify using the customized/alternative cycle. Vehicles should be procured and FTP tested in as-received condition under the guidelines of the high mileage IUVP program (ref: 40 CFR 86.1845–04).

(*3*) Manufacturers may use previously generated in-use data from the CAP 2000 IUVP or the RDP ''reality check'' in-use program as well as other sources of in-use emissions data for approval under this section.

(*4*) Manufacturers must remove unrepresentative data from the data set using good engineering judgement. The manufacturer must provide EPA with the data removed from the analysis and a justification for the removal of that data.

(*5*) Manufacturers may supply additional in-use data.

(B) The manufacturer must submit an analysis which includes a comparison of the relative stringency of the customized/alternative cycle to the SRC and a calculated equivalency factor for the cycle.

(*1*) The equivalency factor may be determined by an evaluation of the SRC and the customized/alternative cycle using catalyst time-at-temperature data from both cycles and the BAT equation to calculate the required bench aging time of each cycle. The equivalency factor is the ratio of the aging time on the SRC divided by the aging time on the alternative cycle.

(*2*) If emissions data is available from the SRC, as well as time-at-temperature data, then that emissions information

may be included in the evaluation of the relative stringency of the two cycles and the development of the equivalency factor.

(*3*) A separate equivalency factor may be determined for each test group, or test groups may be combined together (using good engineering judgement) to calculate a single equivalency factor.

(C) The manufacturer must submit an analysis which evaluates whether the durability objective will be achieved for the vehicle designs which will be certified using the customized/alternative cycle. The analysis must address of the following elements:

(*1*) How the durability objective has been achieved using the data submitted in paragraph (e)(1)(iii)(A) of this section.

(*2*) How the durability objective will be achieved for the vehicle designs which will be covered by the customized/alternative cycle. This analysis should consider the emissions deterioration impact of the design differences between the vehicles included in the data set required in (e)(1)(iii)(A) of this section and the vehicle designs that the manufacturer intends to certify using the customized/alternative cycle.

(2) *Bench-aging durability procedures.* A manufacturer may use a customized or alternative bench aging durability procedure for a required durability demonstration, if approved as described in paragraphs (e)(2)(i) through (vii) of this section. A customized/alternative bench aging procedure must use vehicle performance data (such as catalyst temperature) measured on an approved road cycle as part of the algorithm to calculate bench aging time. The manufacturer must obtain approval from the Agency prior to using a customized bench durability procedure.

(i) The lower control temperature on the SBC may be modified without prior EPA approval provided that the high control temperature is set 90 °C above the lower control temperature and an approved BAT equation is used to calculate bench aging time.

(ii) The R-factor used in EPA's BAT equation may be determined experimentally using EPA's standard procedures (specified in Appendix IX of this part) without prior EPA approval. Other experimental techniques to calculate the R-factor require advance EPA approval. To obtain approval, the manufacturer must demonstrate that the calculated bench aging time results in the same (or larger) amount of emission deterioration as the associated road cycle.

(iii) The A-factor used in EPA's BAT equation may be modified, using good engineering judgement without prior EPA approval, to ensure that the modified durability process will achieve the durability objective of paragraph (a) of this section.

(iv) Bench aging may be conducted using fuel with additional compounds that may lead to catalyst poisoning, such as phosphorus, sulfur or lead, without prior EPA approval. A manufacturer using fuel with these additional compounds may either calculate a new R-factor or A-factor to assure that the durability objective of paragraph (a) of this section is properly achieved regardless of the use of worst-case fuel, in which case the approval criteria for those changes would apply.

(v) An approved customized/alternative road cycle may be used to develop catalyst temperature histograms for use in the BAT equation without additional EPA approval beyond the original approval necessary to use that cycle for mileage accumulation.

(vi) A different bench cycle than the SBC may be used during bench aging with prior EPA approval. To obtain approval the manufacturer must demonstrate that bench aging for the appropriate time on the new bench cycle provides the same or larger amount of emission deterioration as the associated road cycle.

(vii) A different method to calculate bench aging time may be used with prior EPA approval. To obtain approval the manufacturer must demonstrate that bench aging for the time calculated by the alternative method results in the same or larger amount of emission deterioration as the associated road cycle.

(f) *Use of deterioration program to determine compliance with the standard.* A manufacturer may select from two methods for using the results of the deterioration program to determine compliance with the applicable emission standards. Either a deterioration factor (DF) is calculated and applied to the emission data vehicle (EDV) emission results or aged components are installed on the EDV prior to emission testing.

(1) *Deterioration factors.*

(i) Deterioration factors are calculated using all FTP emission test data generated during the durability testing program except as noted:

(A) Multiple tests at a given mileage point are averaged together unless the same number of tests are conducted at each mileage point.

(B) Before and after maintenance test results are averaged together.

(C) Zero-mile test results are excluded from the calculation.

(D) Total hydrocarbon (THC) test points beyond the 50,000-mile (useful life) test point are excluded from the intermediate useful life deterioration factor calculation.

(E) A procedure may be employed to identify and remove from the DF calculation those test results determined to be statistical outliers providing that the outlier procedure is consistently applied to all vehicles and data points and is approved in advance by the Administrator.

(ii) The deterioration factor must be based on a linear regression, or another regression technique approved in advance by the Administrator. The deterioration must be a multiplicative or additive factor. Separate factors will be calculated for each regulated emission constituent and for the full and intermediate useful life periods as applicable. Separate DF's are calculated for each durability group except as provided in § 86.1839.

(A) A multiplicative DF will be calculated by taking the ratio of the full or intermediate useful life mileage level, as appropriate (rounded to four decimal places), divided by the stabilized mileage (reference § 86.1831–01(c), e.g., 4000-mile) level (rounded to four decimal places) from the regression analysis. The result must be rounded to three-decimal places of accuracy. The rounding required in this paragraph must be conducted in accordance with § 86.1837. Calculated DF values of less than one must be changed to one for the purposes of this paragraph.

(B) An additive DF will be calculated to be the difference between the full or intermediate useful life mileage level (as appropriate) minus the stabilized mileage (reference § 86.1831–01(c), *e.g.* 4000-mile) level from the regression analysis. The full useful life regressed emission value, the stabilized mileage regressed emission value, and the DF result must be rounded to the same precision and using the same procedures as the raw emission results according to the provisions of § 86.1837–01. Calculated DF values of less than zero must be changed to zero for the purposes of this paragraph.

(iii) The DF calculated by these procedures will be used for determining full and intermediate useful life compliance with FTP exhaust emission standards, SFTP exhaust emission standards, and cold CO emission standards. At the manufacturer's option and using procedures approved by the Administrator, a separate DF may be calculated exclusively using cold CO test data to determine compliance with cold CO emission standards. Also at the manufacturer's option and using procedures approved by the Administrator, a separate DF may be

calculated exclusively using US06 and/or air conditioning (SC03) test data to determine compliance with the SFTP emission standards.

(2) *Installation of aged components on emission data vehicles.* For full and intermediate useful life compliance determination, the manufacturer may elect to install aged components on an EDV prior to emission testing rather than applying a deterioration factor. Different sets of components may be aged for full and intermediate useful life periods. Components must be aged using an approved durability procedure that complies with paragraph (b) of this section. The list of components to be aged and subsequently installed on the EDV must selected using good engineering judgement.

(g) *Emission component durability.* [Reserved] For guidance see 40 CFR 86.1823–01(e).

(h) *Application of the durability procedure to future durability groups.* The manufacturer may apply a durability procedure approved under paragraphs (c), (d) or (e) of this section to a durability group, including durability groups in future model years, if the durability process will achieve the objective of paragraph (a) of this section for that durability group. The manufacturer must use good engineering judgment in determining the applicability of an approved durability procedure to a durability group.

(1) Modifications to a durability procedure.

(i) Standard durability procedures. The manufacturer may modify a standard durability procedure (allowed in paragraphs (c) or (d) of this section) by increasing or decreasing the number of miles run on the SRC to represent full or intermediate useful life emissions deterioration or by changing the A-Factor in the BAT equation for a bench aging, using good engineering judgment, to ensure that the modified procedure will achieve the objective of paragraph (a) of this section for that durability group.

(ii) Customized/Alternative durability procedures. The manufacturer may modify an alternative/customized durability procedure approved under the provisions of paragraph (e) of this section, using good engineering judgment, for the purposes of ensuring that the modified procedure will achieve the objective of paragraph (a) of this section for that durability group.

(2) The manufacturer must notify the Administrator of its determination to use an approved (or modified) durability procedure on particular test groups and durability groups prior to, or concurrently with, its submission of the Application for Certification for the affected test groups (notification at an annual preview meeting scheduled before the manufacturer begins certification activities for the model year is preferred).

(3) Prior to certification, the Administrator may reject the manufacturer's determination in paragraph (h) of this section to apply an approved or modified durability procedure for a durability group or test group if:

(i) It is not made using good engineering judgment,

(ii) It fails to properly consider data collected under the provisions of §§ 86.1845–04, 86.1846–01, and 86.1847–01 or other information, or

(iii) The Administrator determines that the durability procedure has not been shown to achieve the objective of paragraph (a) of this section for particular test groups which the manufacturer plans to cover with the durability procedure.

(i) *Evaluation of the certification durability procedures based on in-use emissions data.*

(1) Manufacturers must use the information gathered from the IUVP, as well as other sources of in-use emissions data, to periodically review whether the durability procedure it employs achieves the objective specified in paragraph (a) of this section.

(2) Required analysis of a manufacturer's approved durability procedures.

(i) In addition to any periodic reviews under paragraph (i)(1) of this section, a manufacturer must conduct a review of whether the durability procedure it employs achieves the durability objective specified in paragraph (a) of this section when the criteria for additional testing specified in § 86.1846 (b) are activated.

(ii) These criteria are evaluated independently for all applicable FTP emission constituents.

(iii) This analysis must be performed for each test group certified by the manufacturer.

(iv) These procedures apply to the EPA standard durability procedures discussed in paragraphs (c) and (d) of this section as well as durability procedures approved under paragraph (e) of this section, including modifications under paragraph (h) of this section.

(v) The analysis must be submitted to EPA no later than 60 days after the submission of the IUVP data report specified in § 86.1847(f).

(3) EPA may require a manufacturer to perform an analysis as described in paragraph (i)(2) of this section if EPA is concerned that the manufacturer's durability procedure may not achieve the durability objective of paragraph (a) of this section.

(j) If, based on the analysis required in paragraph (i) of this section and/or any other information, EPA determines that the durability procedure does not achieve the durability objective of paragraph (a) of this section, EPA may withdraw approval to use the durability procedure or condition approval on modifications to the durability procedure. Such withdrawal or conditional approval will apply to future applications for certification and to the portion of the manufacturer's product line (or the entire product line) that the Administrator determines to be affected. Prior to such a withdrawal the Administrator will give the manufacturer a preliminary notice at least 60 days prior to the final decision. During this period, the manufacturer may submit technical discussion, statistical analyses, additional data, or other information which is relevant to the decision. The Administrator will consider all information submitted by the deadline before reaching a final decision.

(k) If EPA withdraws approval, under the provisions of paragraph (j) of this section, for a durability procedure approved under the provisions of paragraphs (c) and/or (d) of this section, the following procedures apply:

(1) The manufacturer must select one of the following options for future applications for certification for the applicable portion of the manufacturers product-line affect by the Agency's decision:

(i) Increase future DFs calculated using the applicable durability process by the average percent-difference between certification levels and IUVP data; or

(ii) Increase the miles driven on the SRC or the aging time calculated by the BAT equation by the average percent-difference between certification levels and IUVP data, or

(iii) The manufacturer may obtain approval for a new customized durability process, as allowed in paragraph (e) of this section, that has been demonstrated to meet the durability objective.

(2) If EPA's decision to withdraw approval under the provisions of paragraph (j) of this section is based on fewer than 20 tests, the Administrator may require a smaller adjustment than specified in paragraph (k)(1)(i) or (ii) of this section.

(l) Any manufacturer may request a hearing on the Administrator's

withdrawal of approval in paragraphs (j) or (k) of this section. The request must be in writing and must include a statement specifying the manufacturer's objections to the Administrator's determinations, and data in support of such objection. If, after review of the request and supporting data, the Administrator finds that the request raises a substantial factual issue, she/he must provide the manufacturer a hearing in accordance with § 86.1853–01 with respect to such issue.

■ 6. Add § 86.1824–08 to subpart S to read as follows:

§ 86.1824–08 Durability demonstration procedures for evaporative emissions.

This section applies to gasoline-, methanol-, liquefied petroleum gas-, and natural gas-fueled 2008 and later model year vehicles which meet the applicability provisions of § 86.1801. Optionally, a manufacturer may elect to use this section for earlier model year gasoline-, methanol-, liquefied petroleum gas-, and natural gas-fueled vehicles which meet the applicability provisions of § 86.1801. Eligible small volume manufacturers or small volume test groups may optionally meet the requirements of §§ 86.1838–01 and 86.1826–01 in lieu of the requirements of this section. A separate durability demonstration is required for each evaporative/refueling family.

(a) *Durability program objective.* The durability program must predict an expected in-use emission deterioration rate and emission level that effectively represents a significant majority of the distribution of emission levels and deterioration in actual use over the full useful life of candidate in-use vehicles of each vehicle design which uses the durability program.

(b) *Required durability demonstration.* Manufacturers must conduct a durability demonstration which satisfies the provisions of either paragraph (c), (d), or (e) of this section.

(c) *Whole vehicle evaporative durability demonstration.*

(1) Mileage accumulation must be conducted using the SRC or any road cycle approved under the provisions of § 86.1823(e)(1).

(2) Mileage accumulation must be conducted for either:

(i) The applicable full useful life mileage period specified in § 86.1805, or

(ii) At least 75 percent of the full useful life mileage. In which case, the manufacturer must calculate a df calculated according to the procedures of paragraph (f)(1)(ii) of this section, except that the DF must be based upon a line projected to the full-useful life mileage using the upper 80 percent statistical confidence limit calculated from the emission data.

(3) The manufacturer must conduct at least one evaporative emission test at each of the five different mileage points selected using good engineering judgement. The required testing must include testing at 5,000 miles and at the highest mileage point run during mileage accumulation (e.g. the full useful life mileage). Additional testing may be conducted by the manufacturer using good engineering judgement. The manufacturer may select to run either the 2-day and/or 3-day evaporative test at each test point using good engineering judgement.

(d) *Bench aging evaporative durability procedures.* Manufacturers may use bench procedures designed, using good engineering judgement, to evaluate the emission deterioration of evaporative control systems. Manufacturers may base the bench procedure on an evaluation the following potential causes of evaporative emission deterioration:

(1) Cycling of canister loading due to diurnal and refueling events,

(2) Use of various commercially available fuels, including the Tier 2 requirement to include alcohol fuel;

(3) Vibration of components;

(4) Deterioration of hoses, etc. due to environmental conditions; and

(5) Deterioration of fuel cap due to wear.

(e) *Combined whole-vehicle and bench-aging programs.* Manufacturers may combine the results of whole vehicle aging and bench aging procedures using good engineering judgement.

(f) *Fuel requirements.*

(1) For gasoline fueled vehicles certified to meet the evaporative emission standards set forth in § 86.1811–04(e)(1), any mileage accumulation method for evaporative emissions must employ gasoline fuel for the entire mileage accumulation period which contains ethanol in, at least, the highest concentration permissible in gasoline under federal law and that is commercially available in any state in the United States. Unless otherwise approved by the Administrator, the manufacturer must determine the appropriate ethanol concentration by selecting the highest legal concentration commercially available during the calendar year before the one in which the manufacturer begins its mileage accumulation. The manufacturer must also provide information acceptable to the Administrator to indicate that the mileage accumulation method is of sufficient design, duration and severity to stabilize the permeability of all non-metallic fuel and evaporative system components to the mileage accumulation fuel constituents.

(2) For flexible-fueled, dual-fueled, multi-fueled, ethanol-fueled and methanol-fueled vehicles certified to meet the evaporative emission standards set forth in § 86.1811–04(e)(1), any mileage accumulation method must employ fuel for the entire mileage accumulation period which the vehicle is designed to use and which the Administrator determines will have the greatest impact upon the permeability of evaporative and fuel system components. The manufacturer must also provide information acceptable to the Administrator to indicate that the mileage accumulation method is of sufficient design, duration and severity to stabilize the permeability of all non-metallic fuel and evaporative system components to mileage accumulation fuel constituents.

(3) A manufacturer may use other methods, based upon good engineering judgment, to meet the requirements of paragraphs (f)(1) and (2) of this section, as applicable. These methods must be approved in advance by the Administrator and meet the objectives of paragraphs (f)(1) and (2) of this section, as applicable: to provide assurance that the permeability of all non-metallic fuel and evaporative system components will not lead to evaporative emission standard exceedance under sustained exposure to commercially available alcohol-containing fuels for the useful life of the vehicle.

(g) *Calculation of a deterioration factor.* The manufacturer must calculate a deterioration factor which is applied to the evaporative emission results of the emission data vehicles. The deterioration factor must be based on a linear regression, or an other regression technique approved in advance by the Administrator. The DF will be calculated to be the difference between the full life mileage evaporative level minus the stabilized mileage (e.g., 4000 − mile) evaporative level from the regression analysis. The full useful life regressed emission value, the stabilized mileage regressed emission value, and the DF result must be rounded to the same precision and using the same procedures as the raw emission results according to the provisions of § 86.1837–01. Calculated DF values of less than zero must be changed to zero for the purposes of this paragraph.

(h) *Emission component durability.* [Reserved] For guidance see 40 CFR 86.1824–01(d).

(i) If EPA determines based on IUVP data or other information that the

durability procedure does not achieve the durability objective of paragraph (a) of this section, EPA may withdraw approval to use the durability procedure or condition approval on modifications to the durability procedure. Such withdrawal or conditional approval will apply to future applications for certification and to the portion of the manufacturer's product line (or the entire product line) that the Administrator determines to be affected. Prior to such a withdrawal the Administrator will give the manufacturer a preliminary notice at least 60 days prior to the final decision. During this period, the manufacturer may submit technical discussion, statistical analyses, additional data, or other information which is relevant to the decision. The Administrator will consider all information submitted by the deadline before reaching a final decision.

(j) Any manufacturer may request a hearing on the Administrator's withdrawal of approval in paragraph (i) of this section. The request must be in writing and must include a statement specifying the manufacturer's objections to the Administrator's determinations, and data in support of such objection. If, after review of the request and supporting data, the Administrator finds that the request raises a substantial factual issue, she/he must provide the manufacturer a hearing in accordance with § 86.1853–01 with respect to such issue.

■ 7. Add a new § 86.1825–08 to Subpart S to read as follows:

§ 86.1825–08 Durability demonstration procedures for refueling emissions.

This section applies to 2008 and later model year light-duty vehicles, light-duty trucks, and heavy-duty vehicles which are certified under light-duty rules as allowed under the provisions of § 86.1801–01(c)(1) which are subject to refueling loss emission compliance. Optionally, a manufacturer may elect to use this section for earlier model year light-duty vehicles, light-duty trucks, and heavy-duty vehicles which are certified under light-duty rules as allowed under the provisions of § 86.1801–01(c)(1) which are subject to refueling loss emission compliance. Refer to the provisions of §§ 86.1811, 86.1812, 86.1813, 86.1814, and 86.1815 to determine applicability of the refueling standards to different classes of vehicles for various model years. Diesel fuel vehicles may qualify for an exemption to the requirements of this section under the provisions of § 86.1810.

(a) *Durability program objective.* The durability program must predict an expected in-use emission deterioration rate and emission level that effectively represents a significant majority of the distribution of emission levels and deterioration in actual use over the full useful life of candidate in-use vehicles of each vehicle design which uses the durability program.

(b) *Required durability demonstration.* Manufacturers must conduct a durability demonstration which satisfies the provisions of either paragraph (c), (d), or (e) of this section.

(c) *Whole vehicle refueling durability demonstration.* The following procedures must be used when conducting a whole vehicle durability demonstration:

(1) Mileage accumulation must be conducted using the SRC or a road cycle approved under the provisions of § 86.1823(e)(1).

(2) Mileage accumulation must be conducted for either:

(i) The applicable full useful life mileage period specified in § 86.1805, or

(ii) At least 75 percent of the full useful life mileage. In which case, the manufacturer must calculate a df calculated according to the procedures of paragraph (f)(1)(ii) of this section, except that the DF must be based upon a line projected to the full-useful life mileage using the upper 80 percent statistical confidence limit calculated from the emission data.

(3) The manufacturer must conduct at least one refueling emission test at each of the five different mileage points selected using good engineering judgement. The required testing must include testing at 5,000 miles and at the highest mileage point run during mileage accumulation (e.g. the full useful life mileage). Additional testing may be conducted by the manufacturer using good engineering judgement.

(d) *Bench aging refueling durability procedures.* Manufacturers may use bench procedures designed, using good engineering judgement, to evaluate the emission deterioration of evaporative/refueling control systems. Manufacturers may base the bench procedure on an evaluation the following potential causes of evaporative/refueling emission deterioration:

(1) Cycling of canister loading due to diurnal and refueling events;

(2) Use of various commercially available fuels, including the Tier 2 requirement to include alcohol fuel;

(3) Vibration of components;

(4) Deterioration of hoses, etc. due to environmental conditions; and

(5) Deterioration of fuel cap due to wear.

(e) *Combined whole-vehicle and bench-aging programs.* Manufacturers may combine the results of whole vehicle aging and bench aging procedures using good engineering judgement.

(f) [Reserved]

(g) *Calculation of a deterioration factor.* The manufacturer must calculate a deterioration factor which is applied to the evaporative emission results of the emission data vehicles. The deterioration factor must be based on a linear regression, or an other regression technique approved in advance by the Administrator. The DF will be calculated to be the difference between the full life mileage evaporative level minus the stabilized mileage (e.g., 4000-mile) evaporative level from the regression analysis. The full useful life regressed emission value, the stabilized mileage regressed emission value, and the DF result must be rounded to the same precision and using the same procedures as the raw emission results according to the provisions of § 86.1837–01. Calculated DF values of less than zero must be changed to zero for the purposes of this paragraph.

(h) *Emission component durability.* [Reserved] For guidance see 40 CFR 86.1845–01 (e).

(i) If EPA determines based on IUVP data or other information that the durability procedure does not achieve the durability objective of paragraph (a) of this section, EPA may withdraw approval to use the durability procedure or condition approval on modifications to the durability procedure. Such withdrawal or conditional approval will apply to future applications for certification and to the portion of the manufacturer's product line (or the entire product line) that the Administrator determines to be affected. Prior to such a withdrawal the Administrator will give the manufacturer a preliminary notice at least 60 days prior to the final decision. During this period, the manufacturer may submit technical discussion, statistical analyses, additional data, or other information which is relevant to the decision. The Administrator will consider all information submitted by the deadline before reaching a final decision.

(j) Any manufacturer may request a hearing on the Administrator's withdrawal of approval in paragraph (i) of this section. The request must be in writing and must include a statement specifying the manufacturer's objections to the Administrator's determinations, and data in support of such objection.

If, after review of the request and supporting data, the Administrator finds that the request raises a substantial factual issue, she/he must provide the manufacturer a hearing in accordance with § 86.1853–01 with respect to such issue.

■ 8. Amend § 86.1826–01 by revising paragraphs (a) and (b)(3)(iv) to read as follows:

§ 86.1826–01 Assigned deterioration factors for small volume manufacturers and small volume test groups.

(a) *Applicability.* This program is an option available to small volume manufacturers certified under the small volume manufacturer provisions of § 86.1838–01(b)(1) and small volume test groups certified under the small volume test group provisions of § 86.1838–01(b)(2). Manufacturers may elect to use these procedures in lieu of the requirements of §§ 86.1823, 86.1824, and 86.1825 of this subpart.

(b) * * *

(3) * * *

(iv) The manufacturer must develop either deterioration factors or aged components to use on EDV testing by generating durability data in accordance with §§ 86.1823, 86.1824, and/or 86.1825 on a minimum of 25 percent of the manufacturer's projected sales (based on durability groups) that is equipped with unproven emission control systems.

* * * * *

■ 9. Amend § 86.1829–01 by revising paragraphs (a)(3) and (d)(1) to read as follows:

§ 86.1829–01 Durability and emission testing requirements; waivers.

(a) * * *

(3) The DDV shall be tested and accumulate service mileage according to the provisions of §§ 86.1831–01, 86.1823, 86.1824 and 86.1825. Small volume manufacturers and small volume test groups may optionally meet the requirements of § 86.1838–01.

* * * * *

(d)(1) Beginning in the 2004 model year, the exhaust emissions must be measured from all LDV/T exhaust emission data vehicles tested in accordance with the federal Highway Fuel Economy Test (HWFET; 40 CFR part 600, subpart B). The oxides of nitrogen emissions measured during such tests must represent the full useful life emissions in accordance with § 86.1823–08(f) and subsequent model year provisions. Those results are then rounded and compared with the applicable emission standard in § 86.1811–04. All data obtained from the testing required under this paragraph (d) must be reported in accordance with the procedures for reporting other exhaust emission data required under this subpart.

* * * * *

■ 10. Amend § 86.1830–01 by revising paragraphs (b)(1), (b)(2), (c)(1), (c)(2), (c)(3) and (c)(4) to read as follows:

§ 86.1830–01 Acceptance of vehicles for emission testing.

* * * * *

(b) Special provisions for durability data vehicles. (1) For DDV's, the mileage at all test points shall be within 250 miles of the scheduled mileage point as required under § 86.1823–08(c)(3). Manufacturers may exceed the 250 mile upper limit if there are logistical reasons for the deviation and the manufacturer determines that the deviation will not affect the representativeness of the durability demonstration.

(2) For DDV's aged using the standard or a customized/alternative whole-vehicle cycle, all emission-related hardware and software must be installed and operational during all mileage accumulation after the 5000-mile test point.

* * * * *

(c) *Special provisions for emission data vehicles.* (1) All EDV's shall have at least the minimum number of miles accumulated to achieve stabilized emission results according to the provisions of § 86.1831–01(c).

(2) Within a durability group, the manufacturer may alter any emission data vehicle (or other vehicles such as current or previous model year emission data vehicles, running change vehicles, fuel economy data vehicles, and development vehicles) in lieu of building a new test vehicle providing that the modification will not impact the representativeness of the vehicle's test results. Manufacturers shall use good engineering judgment in making such determinations. Development vehicles which were used to develop the calibration selected for emission data testing may not be used as the EDV for that configuration. Vehicles from outside the durability group may be altered with advance approval of the Administrator.

(3) Components used to reconfigure EDV's under the provisions of paragraph (c)(2) of this section must be appropriately aged if necessary to achieve representative emission results. Manufacturers must determine the need for component aging and the type and amount of aging required using good engineering judgment.

(4) Bench-aged hardware may be installed on an EDV for emission testing as a method of determining certification levels (projected emission levels at full or intermediate useful life) using bench aging procedures under the provisions of § 86.1823.

■ 11. Amend § 86.1831–01 by revising paragraphs (a)(1) and (b)(1) to read as follows:

§ 86.1831–01 Mileage accumulation requirements for test vehicles.

(a) *Durability Data Vehicles.* (1) The manufacturer must accumulate mileage on DDV's using the procedures in § 86.1823.

(b) * * *

(1) The standard method of mileage accumulation for emission data vehicles and running change vehicles is mileage accumulation using either the Standard Road Cycle specified in Appendix V to this part or the Durability Driving Schedule specified in Appendix IV to this part.

* * * * *

■ 12. Amend § 86.1838–01 by revising paragraph (c)(1) to read as follows:

§ 86.1838–01 Small volume manufacturers certification procedures.

* * * * *

(c) * * *

(1) Durability demonstration. Use the provisions of § 86.1826–01 rather than the requirements of §§ 86.1823, 86.1824, and/or 86.1825.

* * * * *

■ 13. Amend § 86.1839–01 by revising paragraph (b) to read as follows:

§ 86.1839–01 Carryover of certification data.

* * * * *

(b) In lieu of using newly aged hardware on an EDV as allowed under the provisions of § 86.1823–08(f)(2), a manufacturer may use similar hardware aged for an EDV previously submitted, provided that the manufacturer determines that the previously aged hardware represents a worst case or equivalent rate of deterioration for all applicable emission constituents for durability demonstration.

■ 14. Amend § 86.1841–01 by revising paragraphs (a)(1) introductory text and (a)(2) and removing and reserving paragraph (a)(3) to read as follows:

§ 86.1841–01 Compliance with emission standards for the purpose of certification.

(a) * * *

(1) If the durability demonstration procedure used by the manufacturer under the provisions of §§ 86.1823, 86.1824, or 86.1825 requires a DF to be calculated, the DF shall be applied to the official test results determined in § 86.1835–01(c) for each regulated

emission constituent and for full and intermediate useful life, as appropriate, using the following procedures:

* * * * *

(2) If the durability demonstration procedure used by the manufacturer under the provisions of §§ 86.1823, 86.1824, or 86.1825, as applicable, requires testing of the EDV with aged emission components, the official results of that testing determined under the provisions of § 86.1835–01(c) shall be rounded to the same level of precision as the standard for each regulated constituent at full and intermediate useful life, as appropriate. This rounded emission value is the certification level for that emission constituent at that useful life mileage.

(3) [Reserved]

* * * * *

■ 15. Amend § 86.1844–01 by revising paragraph (d)(4) to read as follows:

§ 86.1844–01 Information requirements: Application for certification and submittal of information upon request.

* * * * *

(d) * * *

(4) Durability information.

(i) A description of the durability method used to establish useful life durability, including exhaust and evaporative/refueling emission deterioration factors as required in §§ 86.1823, 86.1824 and 86.1825 when applicable.

(ii) The equivalency factor required to be calculated in § 1823–06(e)(iii)(B), when applicable.

* * * * *

■ 16. Add Appendices V, VII, VIII, and IX to part 86 to read as follows:

Appendix V to Part 86—The Standard Road Cycle (SRC)

1. The standard road cycle (SRC) is a mileage accumulation cycle that may be used for any vehicle which is covered by the applicability provisions of § 86.1801. The vehicle may be run on a track or on a mileage accumulation dynamometer.

2. The cycle consists of 7 laps of a 3.7 mile course. The length of the lap may be changed to accommodate the length of the service-accumulation track.

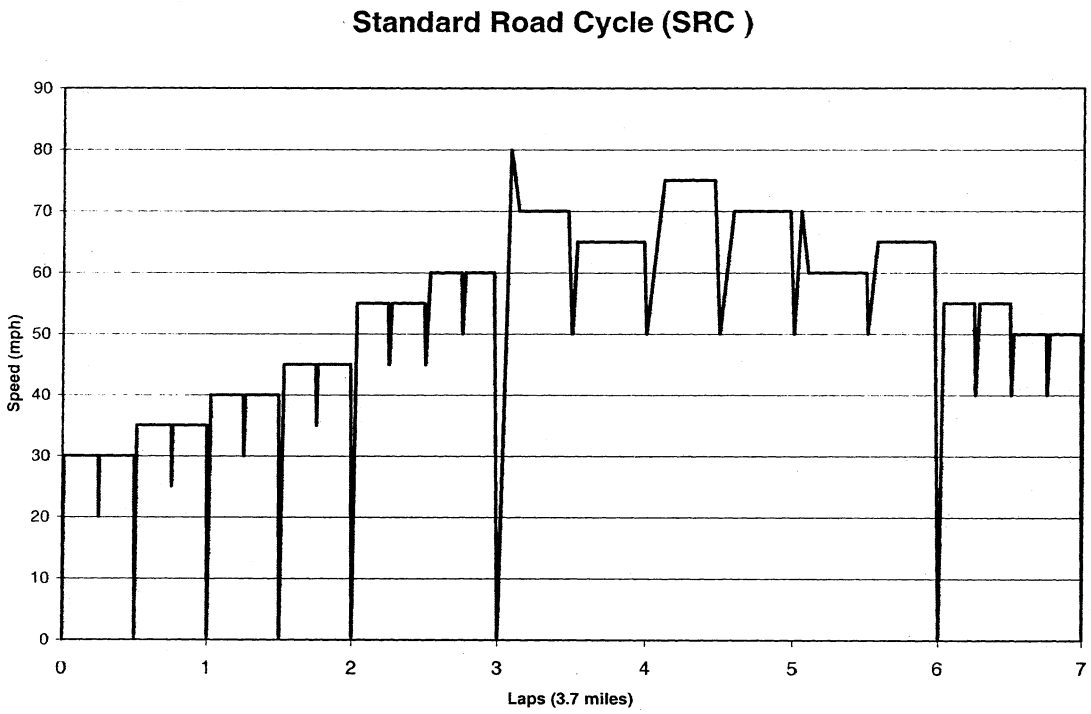
DESCRIPTION OF THE SRC

Lap	Description	Typical accel rate (MPH/s)
1	(start engine) Idle 10 sec	0
1	Mod accel to 30 MPH	4
1	Cruise at 30 MPH for ¼ lap	0
1	Mod. decel to 20 MPH	−5
1	Mod accel to 30 MPH	4
1	Cruise at 30 MPH for ¼ lap	0
1	Mod. decel to stop	−5
1	Idle 5 sec	0
1	Mod accel to 35 MPH	4
1	Cruise at 35 MPH for ¼ lap	0
1	Mod. decel to 25 MPH	−5
1	Mod accel to 35 MPH	4
1	Cruise at 35 MPH for ¼ lap	0
1	Mod. decel to stop	−5
2	Idle 10 sec	0
2	Mod accel to 40 MPH	3
2	Cruise at 40 MPH for ¼ lap	0
2	Mod. decel to 30 MPH	−5
2	Mod accel to 40 MPH	3
2	Cruise at 40 MPH for ¼ lap	0
2	Mod. decel to stop	−5
2	Idle 5 sec	0
2	Mod accel to 45 MPH	3
2	Cruise at 45 MPH for ¼ lap	0
2	Mod. decel to 35 MPH	−5
2	Mod accel to 45 MPH	3
2	Cruise at 45 MPH for ¼, lap	0
2	Mod. decel to stop	−5
3	Idle 10 sec	0
3	Hard accel to 55 MPH	4
3	Cruise at 55 MPH for ¼ lap	0
3	Mod. decel to 45 MPH	−5
3	Mod accel to 55 MPH	2
3	Cruise at 55 MPH for ¼ lap	0
3	Mod. decel to 45 MPH	−5
3	Mod accel to 60 MPH	2
3	Cruise at 60 MPH for ¼ lap	0
3	Mod. decel to 50 MPH	−5
3	Mod. accel to 60 MPH	2
3	Cruise at 60 MPH for ¼ lap	0
3	Mod. decel to stop	−4
4	Idle 10 sec	0
4	Hard accel to 80 MPH	3
4	Coastdown to 70 MPH	−1
4	Cruise at 70 MPH for ½ Lap	0
4	Mod. decel to 50 MPH	−3

DESCRIPTION OF THE SRC—Continued

Lap	Description	Typical accel rate (MPH/s)
4	Mod accel to 65 MPH	2
4	Cruise at 65 MPH for ½ lap	0
4	Mod. decel to 50 MPH	−3
5	Mod accel to 75 MPH	1
5	Cruise at 75 MPH for ½ lap	0
5	Mod. decel to 50 MPH	−3
5	Lt. accel to 70 MPH	1
5	Cruise at 70 MPH for ½ lap	0
5	Mod. decel 50 MPH	−3
6	Mod accel to 70 MPH	2
6	Coastdown to 60 MPH	−1
6	Cruise at 60 MPH for ½ lap	0
6	Mod. decel to 50 MPH	−4
6	Mod. accel to 65 MPH	1
6	Cruise at 65 MPH for ½ lap	0
6	Mod. decel to stop	−4
7	Idle 45 sec	0
7	Hard accel to 55 MPH	4
7	Cruise at 55 MPH for ¼ lap	0
7	Mod. decel to 40 MPH	−5
7	Mod. accel to 55 MPH	2
7	Cruise at 55 MPH for ¼ lap	0
7	Mod. decel to 40 MPH	−5
7	Mod. accel to 50 MPH	2
7	Cruise at 50 MPH for ¼ lap	0
7	Mod. decel to 40 MPH	−5
7	Mod. accel to 50 MPH	2
7	Cruise at 50 MPH for ¼ lap	0
7	Mod. decel to stop	−5

The standard road cycle is represented graphically in the following figure:



* * * * *

Appendix VII to Part 86—Standard Bench Cycle (SBC)

1. The standard bench aging durability procedures [Ref. § 86.1823–08(d)] consist of aging a catalyst-oxygen-sensor system on an aging bench which follows the standard bench cycle (SBC) described in this appendix.

2. The SBC requires use of an aging bench with an engine as the source of feed gas for the catalyst.

3. The SBC is a 60-second cycle which is repeated as necessary on the aging bench to conduct aging for the required period of time. The SBC is defined based on the catalyst temperature, engine air/fuel (A/F) ratio, and the amount of secondary air injection which is added in front of the first catalyst.

Catalyst Temperature Control

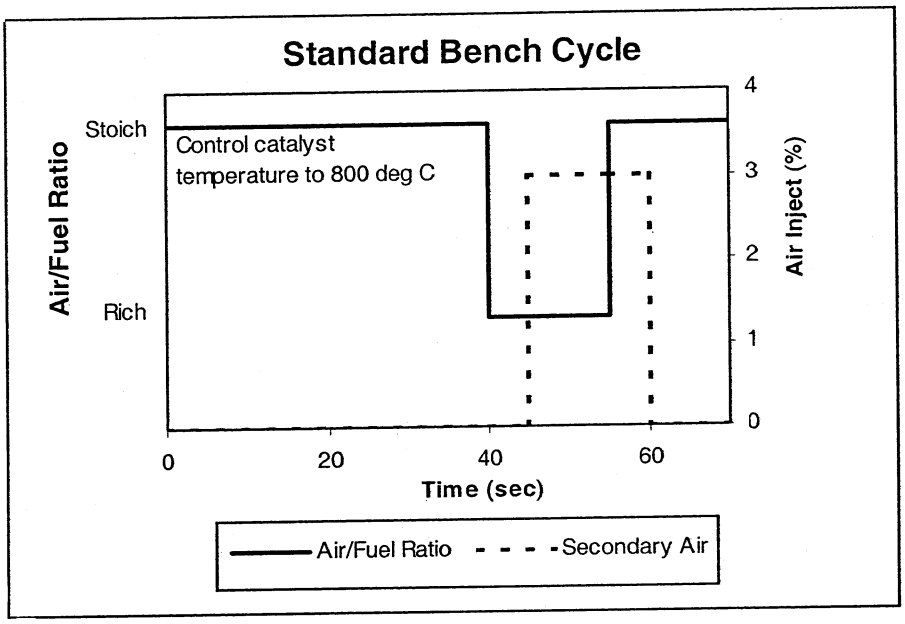
1. Catalyst temperature shall be measured in the catalyst bed at the location where the highest temperature occurs in the hottest catalyst. Alternatively, the feed gas temperature may be measured and converted to catalyst bed temperature using a linear transform calculated from correlation data collected on the catalyst design and aging bench to be used in the aging process.

2. Control the catalyst temperature at stoichiometric operation (01 to 40 seconds on the cycle) to a minimum of 800 °C (± 10 °C) by selecting the appropriate Engine speed, load, and spark timing for the engine. Control the maximum catalyst temperature that occurs during the cycle to 890 °C (± 10 °C) by selecting the appropriate A/F ratio of the engine during the ''rich'' phase described in the table below.

3. If a low control temperature other than 800 °C is utilized, the high control temperature shall be 90 °C higher than the low control temperature.

STANDARD BENCH CYCLE (SBC)

Time (seconds)	Engine air/fuel ratio	Secondary air injection
01–40	14.7 (stoichiometric, with load, spark timing, and engine speed controlled to achieve a minimum catalyst temperature of 800 °C).	None
41–45	''Rich'' (A/F ratio selected to achieve a maximum catalyst temperature over the entire cycle of 890 °C, or 90° higher than low control temperature).	None
46–55	''Rich'' (A/F ratio selected to achieve a maximum catalyst temperature over the entire cycle of 890 °C, or 90° higher than low control temperature).	3% (± 0.1%)
56—60	14.7 (stoichiometric, same load, spark timing, and engine speed as used in the 01–40 sec period of the cycle).	3% (± 0.1%)



Appendix VIII to Part 86—Aging Bench Equipment and Procedures

This appendix provides specifications for standard aging bench equipment and aging procedures which may be used to conduct bench aging durability under the provisions of § 86.1823–08.

1. Aging Bench Configuration

The aging bench must provide the appropriate exhaust flow rate, temperature, air-fuel ratio, exhaust constituents and secondary air injection at the inlet face of the catalyst.

a. The EPA standard aging bench consists of an engine, engine controller, and engine dynamometer. Other configurations may be acceptable (*e.g.* whole vehicle on a dynamometer, or a burner that provides the correct exhaust conditions), as long as the catalyst inlet conditions and control features specified in this appendix are met.

b. A single aging bench may have the exhaust flow split into several streams providing that each exhaust stream meets the requirements of this appendix. If the bench has more than one exhaust stream, multiple catalyst systems may be aged simultaneously.

2. Fuel and Oil

The fuel used by the engine shall comply with the mileage accumulation fuel provisions of § 86.113 for the applicable fuel type (*e.g.*, gasoline or diesel fuel). The oil used in the engine shall be representative of commercial oils and selected using good engineering judgement.

3. Exhaust System Installation

a. The entire catalyst(s)-plus-oxygen-sensor(s) system, together with all exhaust piping which connects these components, [the ''catalyst system''] will be installed on the bench. For engines with multiple exhaust streams (such as some V6 and V8 engines), each bank of the exhaust system will be installed separately on the bench.

b. For exhaust systems that contain multiple in-line catalysts, the entire catalyst system including all catalysts, all oxygen sensors and the associated exhaust piping will be installed as a unit for aging. Alternatively, each individual catalyst may be separately aged for the appropriate period of time.

4. Temperature Measurement

Catalyst temperature shall be measured using a thermocouple placed in the catalyst bed at the location where the highest temperature occurs in the hottest catalyst (typically this occurs approximately one-inch behind the front face of the first catalyst at its longitudinal axis). Alternatively, the feed gas temperature just before the catalyst inlet face may be measured and converted to catalyst bed temperature using a linear transform calculated from correlation data collected on the catalyst design and aging bench to be used in the aging process. The catalyst temperature must be stored digitally at the speed of 1 hertz (one measurement per second).

5. Air/Fuel Measurement

Provisions must be made for the measurement of the air/fuel (A/F) ratio (such as a wide-range oxygen sensor) as close as possible to the catalyst inlet and outlet flanges. The information from these sensors must be stored digitally at the speed of 1 hertz (one measurement per second).

6. Exhaust Flow Balance

Provisions must be made to assure that the proper amount of exhaust (measured in grams/second at stoichiometry, with a tolerance of ±5 grams/second) flows through each catalyst system that is being aged on the bench. The proper flow rate is determined based upon the exhaust flow that would occur in the original vehicle's engine at the steady state engine speed and load selected for the bench aging in paragraph (7).

7. Setup

a. The engine speed, load, and spark timing are selected to achieve a catalyst bed temperature of 800 °C (± 10 °C) at steady-state stoichiometric operation.

b. The air injection system is set to provide the necessary air flow to produce 3.0% oxygen (± 0.1%) in the steady-state stoichiometric exhaust stream just in front of the first catalyst. A typical reading at the upstream A/F measurement point (required in paragraph 5) is lambda 1.16 (which is approximately 3% oxygen).

c. With the air injection on, set the ''Rich'' A/F ratio to produce a catalyst bed temperature of 890 °C (± 10 °C). A typical A/F value for this step is lambda 0.94 (approximately 2% CO).

8. Aging Cycle

The standard bench aging procedures use the standard bench cycle (SBC) which is described in Appendix VII to Part 86. The SBC is repeated until the amount of aging calculated from the bench aging time (BAT) equation [ref. § 86.1823–08 (d)(3)] is achieved.

9. Quality Assurance

a. The temperatures and A/F ratio information that is required to be measured in paragraphs (4) and (5) shall be reviewed periodically (at least every 50 hours) during aging. Necessary adjustments shall be made to assure that the SBC is being appropriately followed throughout the aging process.

b. After the aging has been completed, the catalyst time-at-temperature collected during the aging process shall be tabulated into a histogram with temperature bins of no larger than 10 °C. The BAT equation and the calculated effective reference temperature for the aging cycle [ref. § 86.1823–08(d)] will be used to determine if the appropriate amount of thermal aging of the catalyst has in fact occurred. Bench aging will be extended if the thermal effect of the calculated aging time is not at least 95% of the target thermal aging.

10. Startup and Shutdown

Care should be taken to assure that the maximum catalyst temperature for rapid deterioration (*e.g.*, 1050 °C) does not occur during startup or shutdown. Special low temperature startup and shutdown procedures may be used to alleviate this concern.

Appendix IX to Part 86—Experimentally Determining the R-Factor for Bench Aging Durability Procedures

The R-Factor is the catalyst thermal reactivity coefficient used in the bench aging time (BAT) equation [Ref. § 86.1826–08(d)(3)]. Manufacturers may determine the value of R experimentally using the following procedures.

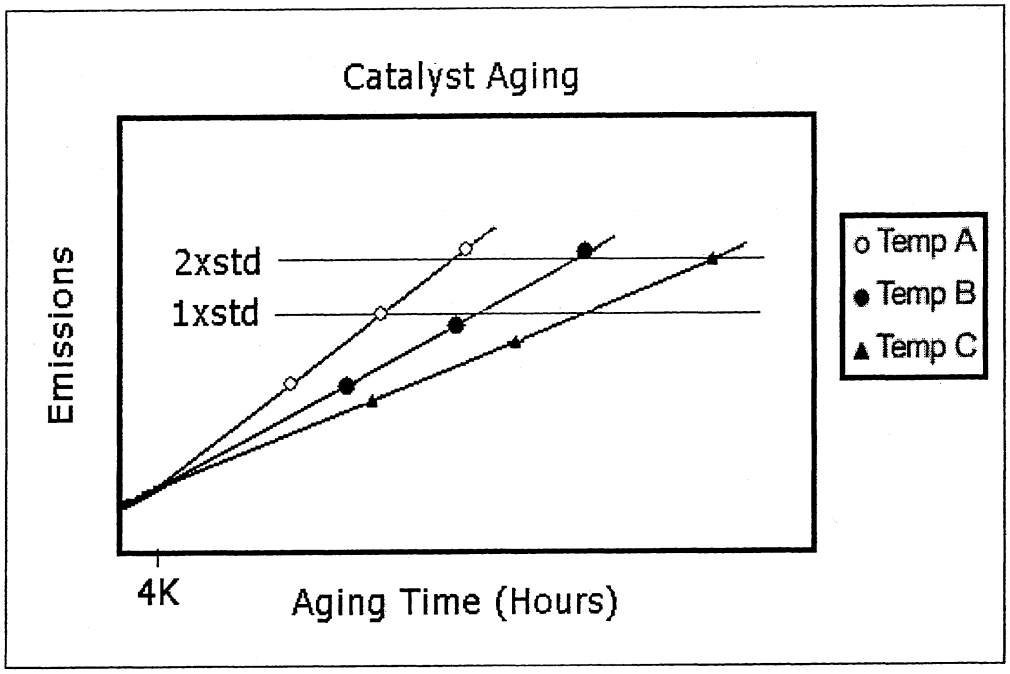
1. Using the applicable bench cycle and aging bench hardware, age several catalysts (minimum of 3 of the same catalyst design) at different control temperatures between the normal operating temperature and the damage limit temperature. Measure emissions (or catalyst inefficiency (1-catalyst efficiency)) for each constituent. Assure that the final testing yields data between one- and two-times the standard.

2. Estimate the value of R and calculate the effective reference temperature (T_r) for the bench aging cycle for each control temperature according to the procedure described in § 86.1826–08(d)(4).

3. Plot emissions (or catalyst inefficiency) versus aging time for each catalyst. Calculate the least-squared best-fit line through the data. For the data set to be useful for this purpose the data should have an approximately common intercept between 0 and 4000 miles. See the following graph for an example.

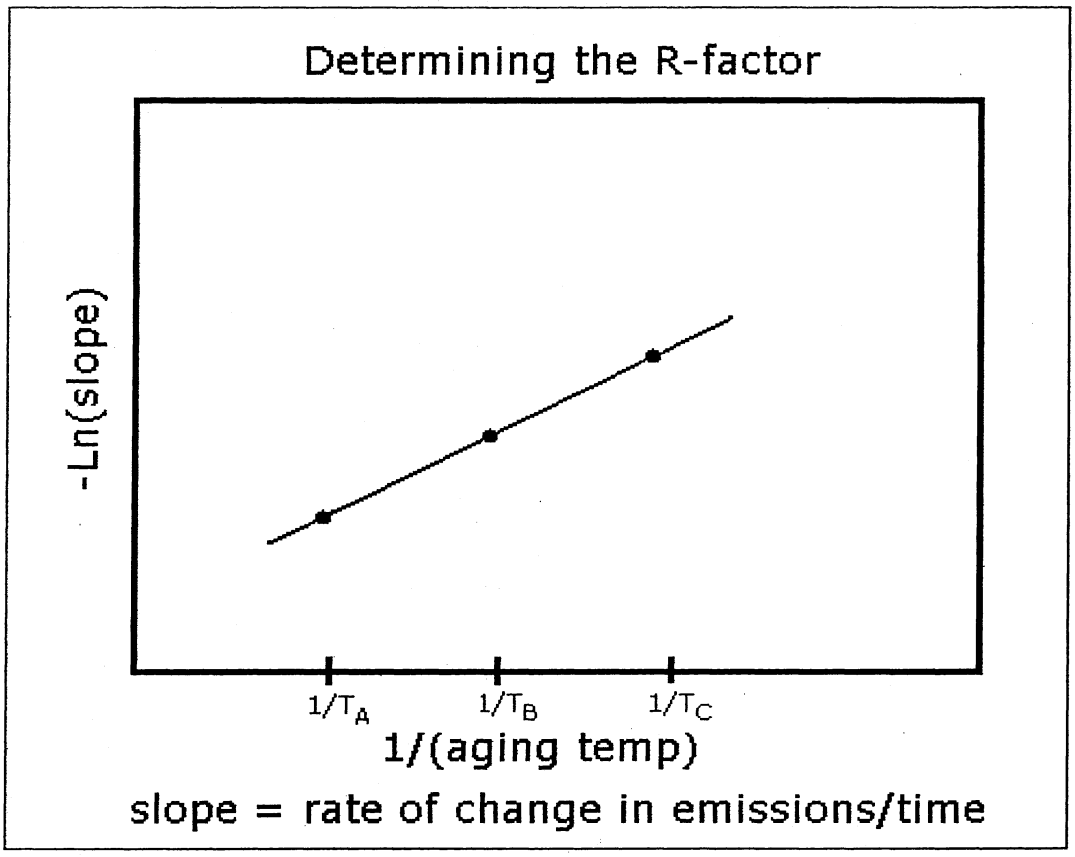
4. Calculate the slope of the best-fit line for each aging temperature.

5. Plot the natural log (ln) of the slope of each best-fit line (determined in step 4) along the vertical axis, versus the inverse of aging temperature (1/(aging temperature, deg K)) along the horizontal axis, Calculate the least-squared best-fit lines through the data. The slope of the line is the R-factor. See the following graph for an example.



6. Compare the R-factor to the initial value that was used in Step 2. If the calculated R-factor differs from the initial value by more than 5%, choose a new R-factor that is between the initial and calculated values, then repeat Steps 2–6 to derive a new R-factor. Repeat this process until the calculated R-factor is within 5% of the initially assumed R-factor.

7. Compare the R-factor determined separately for each constituent. Use the lowest R-factor (worst case) for the BAT equation.



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BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 86

[FRL–8019–1]

RIN 2060–AN01

Component Durability Procedures for New Light-Duty Vehicles, Light-Duty Trucks and Heavy-Duty Vehicles

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplemental Notice of Proposed Rulemaking.

SUMMARY: On April 2, 2004 (69 FR 17531), EPA issued a notice of proposed rulemaking (NPRM) to propose procedures to be used by manufacturers of light-duty vehicles, light-duty trucks and heavy-duty vehicles to demonstrate, for purposes of emission certification, that new motor vehicles will comply with EPA emissions standards throughout their useful lives. The NPRM proposed emissions certification durability procedures to be used by manufacturers to demonstrate the expected rate of deterioration of the emission levels of their vehicles. The Agency received several comments concerning the component durability portion of the durability process. Options for addressing component durability were not discussed in the April 2004 proposal, and EPA believes it is appropriate to address component durability in a supplemental proposal. Therefore, EPA is issuing this action to request comments on three options for addressing component durability during the vehicle emissions certification process.

DATES: Written comments on this SNPRM must be submitted on or before February 16, 2006. A public hearing will be held on February 1, 2006. Requests to present oral testimony must be received on or before January 27, 2006. If EPA receives no requests to present oral testimony by this date, the hearing will be canceled.

ADDRESSES: *Comments:* Comments may be submitted by mail to: Air Docket, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OAR–2002–0079. Comments may also be submitted electronically, by facsimile, or through hand delivery/courier. For more information submitting comments and on the comment procedure and public hearings, follow the detailed instructions as provided in Section XI, ''Public Participation'' section. We must receive them by the date indicated under **DATES** above. Paper copies of written comments (in duplicate if possible) should also be sent to the general contact person listed below.

Docket: EPA's Air Docket makes materials related to this rulemaking available for review in Public Docket No. A–2002–0079 at the following address: U.S. Environmental Protection Agency (EPA), Air Docket (6102), Room M–1500 (on the ground floor in Waterside Mall), 401 M Street, SW., Washington, DC 20460 between 8 a.m. to 5:30 p.m., Monday through Friday, except on government holidays. You can reach the Air Docket by telephone at (202) 260–7548, and by facsimile (202) 260–4400. We may charge a reasonable fee for copying docket materials, as provided in 40 CFR part 2.

FOR FURTHER INFORMATION CONTACT: Holly Pugliese, U.S. EPA, National Vehicle and Fuels Emission Laboratory, 2000 Traverwood, Ann Arbor, MI 48105; Telephone (734) 214–4288; FAX: (734) 214–4053; e-mail: pugliese.holly@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Why is this Action being taken?
II. History of EPA's Component Durability Requirements
III. What comments has EPA received on component durability?
IV. What are the differences between component durability and emissions durability?
V. Statutory Authority
VI. How has EPA evaluated component durability in the past in deciding to issue a certificate?
VII. Is EPA required to use testing to evaluate component durability?
VIII. What options are being considered by EPA?
IX. Request for Comments
X. What are the environmental and economic impacts?
XI. What are the opportunities for public participation?
A. Copies of This Proposal and Other Related Information
B. Submitting Comments on This Proposal
C. Public Hearing
XII. What are the Administrative Requirements for this Proposed Rule?
A. EO 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Children's Health Protection
H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer Advancement Act

I. Why is this Action being taken?

The demonstration of light-duty vehicle emission durability for purposes of certification consists of two elements: Emission deterioration and component durability. On April 2, 2004, EPA published an NPRM that proposed durability procedures to be used by manufacturers to demonstrate the expected rate of deterioration of the emission levels of their vehicles. The proposal did not make any changes to component durability procedures. It carried over the component durability requirements from the updated certification regulations for light-duty vehicles and light-duty trucks published in 1999 known as ''CAP 2000'' (Compliance Assurance Program). EPA received several comments on the NPRM pertaining to component durability.

Because of the complex nature of the comments, we determined that the issue of component durability warranted further consideration and discussion. EPA intends to proceed with finalization of the emission deterioration procedures discussed in the NPRM, but will consider issues regarding component durability in this supplemental proposal.

II. History of EPA's Component Durability Requirements

A. Pre-1994 Component Durability

Prior to 1994, EPA's regulations (ref. 40 CFR part 86) specified the method to demonstrate a vehicle's emission durability. The method used a whole vehicle mileage accumulation cycle, commonly referred to as the Approved Mileage Accumulation (AMA) cycle.[1] It required manufacturers to accumulate mileage on a pre-production vehicle, known as a durability data vehicle (DDV), by driving it over the prescribed AMA driving cycle for the full useful life mileage.[2] This was to simulate the real-world aging of the vehicle's emissions control systems and components over the useful life. The AMA whole vehicle mileage accumulation was used to develop evidence to demonstrate both component durability and emission deterioration. Component durability is a demonstration that all emission-related components are designed to operate properly for the full useful life of the vehicles in actual use. Successful

[1] Ref. 40 CFR Part 86 Appendix IV.

[2] Useful life is the period of use (mileage) or time during which an emission standard applies to light-duty vehicles and light-duty trucks. For most light-duty vehicles and light-duty trucks, the useful life requirement is 120,000 miles or 10 years, which ever comes first (86.1805–01 and 86.1805–04).

completion of the required whole vehicle useful life mileage accumulation without the need to replace or adjust those components (beyond that allowed by regulation) provided evidence that those components could be considered durable and would operate properly for the full useful life. Separate or additional evidence of component durability was not developed.

B. Revised Durability Program (RDP) and Component Durability

EPA's first separate component durability demonstration requirements came with the promulgation of the revised durability program (RDP) [3]. Under these provisions (which took effect in 1994), manufacturers were given options for demonstrating emission deterioration. One option allowed rapid bench-aging techniques instead of mileage accumulation on a whole vehicle to conduct emission deterioration evaluation. In the preamble to the proposed RDP rule, EPA stated that ''accumulation of mileage by the DDVs provides valuable information on the physical durability of individual emission-related components, because these components are exercised during the operation of the DDV.'' [57 FR 18545, April 30, 1992.] EPA went on to propose conditions under which it would issue a certificate of conformity for manufacturers using the rapid aging techniques. One of these conditions was that ''the manufacturer provides data that shows to the satisfaction of the Administrator that all emission-related components are designed to properly operate for the useful life of the vehicles in actual use (or such minimum intervals, as specified in allowable scheduled maintenance regulations).'' ''[Id. at 18548]'' EPA adopted this condition in its final RDP rule. The regulations required that manufacturers using the rapid aging option were required to ''provide reliability data that shows to the Administrator's satisfaction that all emission-related components are designed to operate properly for the durability useful life of the vehicles in actual use (or such shorter intervals as permitted in section § 86.094–25).'' [40 CFR 86.094–13(e)(7)(ii)].

When implementing the RDP regulations, EPA issued a guidance letter which provided further instructions to manufacturers on the process to obtain EPA approval to use alternate durability processes.[4] The guidance addressed component durability by stating that ''[F]or each ASADP [Alternate Service Accumulation Durability Process, also known as ''RDP''] engine family, the manufacturer should submit a plan to demonstrate component durability for that engine family. Sources of data for component durability are defect reports, bench testing of components, and other similar data.'' In meeting these requirements, many manufacturers demonstrated to us their own extensive validation process to ensure the durability of the components used in production vehicles.[5] It was clear that the scope of this validation work far exceeded in rigorousness the durability demonstration requirement of running a single pre-production prototype vehicle on a driving cycle for the full useful life mileage. Thus, the manufacturer component validation processes added significant assurance of component durability, and in fact is the primary source of such assurance.

C. CAP 2000 Regulations and Component Durability

The CAP 2000 rulemaking (applicable beginning with the 2001 model year), was a comprehensive update to the entire light-duty vehicle certification process. A major part of this involved the manufacturer's required demonstration of emission durability. The Agency eliminated the use of the AMA cycle as the default mileage accumulation cycle. In CAP 2000, the Agency replaced the AMA-based durability program with a durability process similar to the optional Revised Durability Program (RDP). Each manufacturer, except small manufacturers, was required to develop an emission durability process which would accurately predict in-use deterioration of the vehicles they produce. The manufacturer had the flexibility to design an efficient program that met that objective.

The manufacturer's plan was then reviewed by EPA for approval. Many manufacturers continued using the processes previously approved under the RDP program. Approval from the Agency for purposes of CAP 2000 required a demonstration that the emission deterioration process was designed to generate emission deterioration factors (DFs) representative of in-use deterioration. This demonstration was more than simply matching average in-use deterioration with DFs. Manufacturers needed to demonstrate to EPA's satisfaction that their durability process would result in the same or more emissions deterioration than is reflected by the in-use data for a significant majority of their vehicles. If, in the course of EPA's review, we found that certain aspects of a manufacturer's plan were inadequate, we would make recommendations to the manufacturer as to how to improve their plan and the manufacturer would make the appropriate modifications. Upon the conclusion of our extensive review, we would approve the plan.

EPA also adopted a component durability provision applicable to all vehicles that required manufacturers to ''use good engineering judgment to determine that all emission-related components are designed to operate properly for the full useful life of the vehicles in actual use.'' [6] While the manufacturer did not need to submit the underlying engineering evaluation with its certification application, EPA reserved the right to evaluate the basis underlying this engineering determination. 40 CFR 86.1823–01(e), 86.1824–01(d), 86.1825–01(e), 86.1826–01(c).

This component durability requirement was based on our experience under RDP, in which we obtained significant information about manufacturers' internal component validation processes. In general, information from defect reports, in-use testing, and in-use on-board diagnostics (OBD) data indicated that problems usually occurred at the production stage or later.[7] EPA was confident that

[3] Ref. 59 FR 36368 (July 18, 1994), 62 FR 11082 (March 11, 1997), 62 FR 11138 (March 11, 1997) and 62 FR 44872 (August 22, 1997).

[4] CD–94–13 July 24, 1994.

[5] Emission related parts and systems are evaluated for durability by manufacturers during the vehicle and emission control system development process. Evaluations can take several forms including mileage accumulation, engineering evaluations, validation testing, and computer simulations. Manufacturers use these processes to develop performance and design specifications that are supplied to part vendors and/or used during their own manufacturing processes. During production of these parts, manufacturers evaluate random samples of parts to assure compliance with design specifications. The supplier who designs the emission components for the vehicle manufacturer perform extensive product validation testing to ensure that the component design is durable before it is ever used on the vehicle.

[6] Ref. 40 CFR 18.1823–01(e) and EPA Guidance Letter No. CD–94–13, ''Alternative Durability Guidance for MY94 through MY98'', dated July 29, 1994.

[7] The On-Board Diagnostic (OBD) systems regulations (40 CFR 86.1808–01) require the on-board computer to monitor most emission control components and illuminate a dashboard light when the components fail or operate improperly. The defect reporting regulations (40 CFR 86.1903) require manufacturers to report occurrences of a significant number of defective emission control components to the Agency. The recall provisions (40 CFR 85 Subpart S) allow EPA to order recalls when properly maintained and used vehicles fail to comply with the applicable regulations promulgated under section 202 of the Clean Air Act. All of these are important means for

manufacturers would continue using their component validation processes and other component-related information for component durability as a basis to develop the good engineering judgement that was required. The CAP 2000 regulations include a provision allowing EPA to review and evaluate the basis for a manufacturer's engineering judgment decision, when appropriate.

III. What comments has EPA received on component durability?

Comments related to component durability were submitted to the EPA Docket A–2002–0079 during the comment period for the proposed emissions deterioration rule being finalized in a separate action today. These comments are summarized below. In today's SNPRM, EPA is seeking comments in addition to those already submitted.

The comments were submitted by the Afton Corporation (Afton, formerly Ethyl Corporation) and jointly by the Alliance of Automobile Manufacturers (Alliance and the Association of International Automobile Manufacturers (AIAM).

Afton comments (May 17):

• Based on recent events pointing to an emission component failure allegedly caused by one of Afton's products and Afton's investigation of emission-related component defect reports from recent model years, Afton questions whether an exclusive focus on thermal aging of the catalytic converter and oxygen sensor provides an adequate means to ensure proper vehicle operation in the field.

• EPA has failed to propose test methods and procedures for assessing the durability of emission control system components as required under Section 206 of the CAA as ordered by the Court in *Ethyl Corp.* v. *EPA.* EPA has clearly recognized that certification requires ''testing of emission system component durability''. CAP 2000 regulations require manufacturers to provide a description of the procedures used to establish durability *and* exhaust * * * deterioration factors; indicating that component durability is a necessary part of certification.

• EPA's component durability requirements of good engineering judgment allow EPA and manufacturers to agree on the methods and procedures for testing component durability on a case-by-case basis is in violation of CAA Section 206(d), thus falling on the Court's ''forbidden side of the line''.

• EPA has instead proposed that manufacturers continue to develop test methods and procedures for component durability on a case-by-case basis, without rulemaking.

• EPA should focus on emission control components as a system, rather than as individual components. How the system performs as a whole in the field cannot be captured by thermal aging of the catalytic converter.

• Evidence that components are failing in use is found in the defect reports submitted by manufacturers, showing that millions of vehicles are affected by defects, but very few are recalled.

• Component durability must include insurance (1) the durability of each component, (2) the durability of the entire emission control system operated in an integrated manner and (3) any deterioration in an otherwise durable system of components will not cause emissions to exceed the useful life standards.

• A catalyst cannot be ''overaged'' to mimic component defects when such defect would cause an emission failure, because this would preclude certification.

• EPA provided no factual basis in the docket supporting its presumption that all components will be durable. Defect reports submitted by manufacturers indicate otherwise.

• Congress intended certification to include assurance of component durability. By limiting the warranty period Congress was recognizing that other elements of the regulatory program would protect the consumer, citing H.R. Rep. No. 101–490 at 308 (1990).

Alliance/AIAM comments (June 17):

• CAA provisions are clear that Congress' concern was the ability of vehicles to comply with standards over useful life. Durability NPRM complies with this by implementing SRC as a baseline stringency for demonstrating emission control system durability, similar to how the AMA had done prior to CAP 2000. System durability is a function of the durability of its components.

• Nothing in CAA purports to require separate durability tests for each and every component of a system.

• Contrary to Afton contention, component durability has never been done as a separate analysis of each individual component, nor does the law require it to be handled in such a manner.

• No need to establish separate procedures since the SRC provides requisite stringency level for components as well as system as a whole.

• Court did not cite 86.1823(e) in its opinion.

• 1823(e) goes beyond CAA testing requirements in requiring manufacturers to make a qualitative evaluation of component durability.

• Afton's use of defect reports as evidence of widespread ineffectiveness of component durability is flagrant misinterpretation of the reports. These reports summarize manufacturing problems, installation of incorrect components, or components not functioning as intended. No amount of durability testing on design intent systems would uncover such issues. The defect reporting threshold of 25 known occurrences is not necessarily indicative of systematic problem, exceedance of standards or even an emissions increase.

• Best way to address impact of fuel additives on component durability is through the regulations under CAA 211 for fuel additives

• EPA regulations have never imposed requirements that manufacturers conduct tests to evaluate component durability.

• Component-by-component durability testing not feasible for certification.

Afton Response comments (Aug 5):

• Agrees with industry claim that SRC sets the threshold stringency for emission control system as a whole and supports that EPA clarify this.

• Disagrees that EPA has never imposed a test requirement for component durability. Prior to RDP, AMA useful life driving was the test. With RDP, the requirement was for mfrs. to demonstrate full-life durability for all emission related components. CAP 2000 clearly contains a requirement for component durability testing.

• Agree with mfr that durability of a system is a function of the durability of its components and confirms concerns about merit of relying exclusively on thermal aging of cat and O_2 sensor. Not clear how bench aging cat is sufficient to assess the many other components of a system.

IV. What are the differences between component durability and emissions deterioration?

For the purpose of emission certification, EPA evaluates component durability to determine whether emission control system components are designed to operate properly for the full useful life in actual use. More specifically, component durability is a

identifying and repairing or replacing failed emission components in use. However, they also serve the important function of alerting manufacturers and the Agency of potential design or manufacturing problems that need to be addressed and resolved so that they are prevented in future model years.

demonstration that the emission control components will not break and will continue to operate as described in the Application for Certification during the minimum maintenance interval prescribed in 40 CFR 86.1834–01. The factors that can effect emissions control components fall into three general categories: In-use exposure, design flaws and production factors. In-use exposure is the expected normal wear and tear resulting from exposure to the elements and the vehicle's operating environment. Design flaws result in the unintentional failure of a component as a result of a poor design. Production factors consist of manufacturing problems and installation problems (e.g., installation of incorrect parts or improper installation of correct parts on the assembly line). The assurance needed at the time of emission certification is that the components are designed to operate properly for the full useful life in actual use. The certification process, because it occurs pre-production, cannot predict problems that may occur during the manufacturing or installation of emission components. EPA has other mechanisms in place (such as defect reporting and other in-use programs) which help to identify and correct manufacturing or installation problems. The component durability process is designed to provide EPA with adequate information to make the required pre-production certification decision.

In contrast to component durability, EPA's emission deterioration procedures, finalized in a separate action are designed to provide a quantitative prediction of how the emissions of a vehicle will deteriorate over time. The deterioration factor (DF) is a measure of the deterioration. Successful completion of the emission deterioration combined with adequate demonstration of component durability informs EPA that vehicles are likely to comply with emission standards for their useful life. Although some of the emission components may not actually be installed on the vehicle during the required emissions deterioration testing during a bench aging procedure (which ages only the catalytic converter and oxygen sensor), the results of this procedure (e.g. the deterioration factors) are applied to an entire vehicle, including any and all emission control components and systems that will be used.

V. Statutory Authority

Section 206(a)(1) of the Clean Air Act states that the Administrator shall test, or require to be tested in such a manner as he deems appropriate, any new motor vehicle or new motor vehicle engine submitted by a manufacturer to determine whether such vehicle or engine conforms with the emission standard regulations. 42 U.S.C. 7521(a)(1). Section 206(d) states that the Administrator shall by regulation establish methods and procedures for making tests under this section. 42 U.S.C. 7525(d). If such a vehicle conforms with the regulations prescribing establishing emissions standards, the Administrator shall issue a certificate of conformity. 42 U.S.C. 7525(a). The statute also requires that the vehicle conform to the standard for its useful life. 42 U.S.C. 7521(a)(1).

VI. How has EPA evaluated component durability in the past in deciding to issue a certificate under CAA section 206?

Issuance of a certificate of conformity is based on EPA determining whether the vehicle or group of vehicles will conform to the applicable emissions standards over the applicable useful life period. EPA has traditionally evaluated two forms of durability in making this pre-production determination—emissions deterioration and component durability. For many years EPA relied on the whole vehicle mileage accumulation process, used to evaluate emissions deterioration, to also evaluate component durability. When EPA later allowed a manufacturer to accelerate aging of a vehicle under RDP, EPA required submission of reliability data showing that all emission related components were designed to operate properly for the useful life of the vehicles in actual use. See 40 CFR 86.094–13(e)(7)(ii). Under CAP 2000, EPA required the manufacturer to determine, using good engineering judgement, that all emission-related components are designed to operate properly for the full useful life of the vehicle in actual use. While the manufacturer did not need to submit the underlying engineering evaluation with its certification application, EPA reserved the right to evaluate the basis underlying this engineering determination. 40 CFR 86.1823–01(e), 86.1824–01(d), 86.1825–01(e), 86.1826–01(c).

EPA continues to believe that the durability demonstration for purposes of certification should consist of two elements: emission deterioration and component durability.[8] Therefore, EPA will evaluate component durability at the certification stage as part of ensuring that a new motor vehicle will meet the emissions standards for its useful life.

VII. Is EPA required to use testing to evaluate component durability?

Section 206(a)(1) clearly requires that EPA either conduct or require manufacturers to conduct testing as part of the certification process. At the same time, this section does not preclude EPA from also relying on information other than that derived from testing. This provision provides significant discretion to EPA to determine the appropriate mix of information from required testing and information from other sources for use in determining whether a vehicle or group of vehicles will be expected to comply with the emissions standards for their useful lives.

In this case, EPA is clearly requiring a significant amount of emissions durability testing to be performed for purposes of certification. The required testing is focused on obtaining information useful to determine emissions deterioration. EPA believes that the kind of emissions durability testing required by EPA will provide information that is highly useful in determining how the emissions performance of the emissions control system can be expected to deteriorate over the useful life of the vehicle. The issue in this proposal concerns whether additional or different durability testing should also be required to obtain information to evaluate component durability, or whether it is appropriate to require manufacturers to develop information concerning component durability in a manner other than requiring testing of component durability. EPA believes that CAA section 206(a)(1), which limits required testing to testing ''in such manner as [the Administrator] deems appropriate,'' provides discretion in these circumstances on whether and how EPA requires testing to obtain information to evaluate component durability as part of the certification process. 42 U.S.C. 7521(a)(1).

EPA recognizes that there are various ways that information can be obtained on component durability for purposes of pre-production certification. One method that EPA has used in the past involves requiring whole vehicle mileage accumulation to test component durability, as was done under the AMA program. However whole vehicle mileage accumulation provides only a limited kind of information on component durability, basically a simple pass-fail test that is not very probative of component durability. Another method that EPA has used in the past involves requiring the

[8] 69 FR 17532 (April 2, 2004).

manufacturer to conduct an engineering analysis to evaluate component durability for the entire emissions control system. This allows the evaluation of a wide variety of different types of information, including information ranging from real world in-use experience to performance information on a supplier's products and the supplier's quality control practices and can include computer modeling of design performance. Actual physical testing of a product or system may make up only a small part and perhaps no part at all of the information used to perform such an engineering evaluation. EPA believes that in many ways that kind of engineering evaluation, tailored to the parts and systems at issue, can provide a more in-depth and comprehensive evaluation and result in a better real world prediction of in-use durability than a simple pass-fail type of test using whole vehicle mileage accumulation on a pre-production prototype vehicle.

Given the potential benefit for in-use emissions control in using such an engineering evaluation approach, EPA believes it is reasonable and within the discretion provided by section 206(a)(1) to consider an option requiring a manufacturer to conduct such an engineering evaluation of component durability, and not require the manufacturer to perform a specified test for component durability. This engineering evaluation would then be combined with the results of testing performed to evaluate emissions deterioration, as well as any other relevant information, in making the conformity determination required for issuance of a certificate. Under this engineering evaluation option, EPA would not specify a test procedure under section 206(d) for component durability, as EPA is not requiring component durability testing. EPA believes the requirement of section 206(d) only applies where EPA requires testing to be conducted under section 206(a)(1), as it does for evaluation of emissions deterioration.

EPA is also considering requiring manufacturers to conduct a limited amount of whole vehicle aging to test component durability. Both options are discussed in more detail below.

VIII. What options are being considered by EPA?

EPA is today proposing three options to address component durability. Based upon further comments received, EPA intends to finalize one of these options.

A. Retain the Good Engineering Judgement Determination on Component Durability

In this option, EPA would retain the approach taken in the component durability regulations contained in the original CAP 2000 regulations (40 CFR 86.1823–01(e), 86.1824–01(d), 86.1825–01(e), and 86.1826–01(c)). Under CAP 2000, EPA required the manufacturer to determine, using good engineering judgement, that all emission-related components are designed to operate properly for the full useful life of the vehicle in actual use. While the manufacturer did not need to submit the underlying engineering evaluation with its certification application, EPA reserved the right to evaluate the basis underlying this engineering determination (40 CFR 86.1844(g)(1)).

EPA's experience indicates that the basis for past determinations of component durability good engineering judgement came from a wide variety of sources. In some cases, the determination has been based on accelerated customer fleet vehicles or other durability mileage data, component bench testing, engineering analysis data, computer modeling data, purchase agreements, component specifications, or other information. However, it was never based on testing alone. Even though the basis for the good engineering judgement may include reliance on a limited amount of testing, in general, the preponderance of the data is derived from sources other than testing.

EPA's requirement to make the good engineering judgement determination does not constitute a requirement to do testing. Under this option, EPA would not specify what information manufacturers must rely on as a basis for making the good engineering judgement determination. Even though some of the information may be a result of some testing, EPA does not consider this a requirement to conduct testing, since testing is not required as a basis for the good engineering judgement statement and typically is, at most, a limited part of the engineering determination. Because testing is not required, EPA is not required to ''establish methods and procedures for making tests by regulation,'' and section 206(d) does not apply. 42 U.S.C. 7525(d).

B. Good Engineering Judgement Determination Combined With Whole Vehicle Testing for Worst-Case Vehicle Configuration

This option would require manufacturers to continue to make the good engineering judgement determination, as discussed above in option A, but would also require manufacturers to conduct a limited amount of whole vehicle aging. This option would include the requirement to perform full useful life mileage accumulation, using either the EPA Standard Road Cycle (included in final rulemaking issued concurrently with this SNPRM), or a modified or alternative cycle approved by EPA. In this option EPA would allow any whole mileage accumulation cycle which EPA has approved for emission deterioration to be used for demonstrating component durability.

The vehicle's OBD system is designed to monitor most emission control components and report faults by illuminating malfunction indicator light (MIL). Consequently, EPA is proposing that the OBD light will be used to detect emission control component failures during mileage accumulation. The manufacturer must record any OBD MIL illumination during the course of the mileage accumulation and also record readiness codes and active fault codes on the OBD system proceeding and following each FTP test conducted. As a further demonstration of component durability, EPA is proposing that the vehicle demonstrate compliance with all applicable FTP standards following mileage accumulation.

The same vehicle used for the component durability demonstration could also be used for emission deterioration purposes for either exhaust or evaporative emissions. Under this option, manufacturers would choose a vehicle expected to be ''worst case'' for emission component durability. Manufacturers would be allowed to apply the component durability demonstration from that vehicle to other vehicles across other test groups having components similar enough that the vehicle tested would be reasonably considered worst case (known as ''carry across''). EPA would also permit manufacturers to ''carry over'' a component durability demonstration from a previous model year to subsequent model years, when appropriate. Although EPA does not view it as essential, some limited whole-vehicle testing in addition to good engineering judgement determination would provide a limited amount of additional component durability information using the entire vehicle emission control system operated in an integrated manner. This information would enhance the data received from the good engineering requirements that already come from a wide variety of sources. EPA would continue to

augment its evaluation of component durability with an assessment of the information from the defect reports, IUVP data, recall data, etc.

We are limiting the whole-vehicle testing to a ''worst case'' configuration rather than requiring it for all durability groups [9] to limit the additional durability test burden to manufacturers, recognizing that EPA believes the whole vehicle aging provides only a limited benefit on top of that obtained from good engineering judgement determinations. One of the benefits of allowing bench-aging in evaluating emissions deterioration is that emission deterioration testing can be done much quicker than with whole-vehicle testing. Whole vehicle testing can take up to four months to complete, whereas bench aging can be completed within several weeks. The CAP 2000 rulemaking and the emissions deterioration regulations issues separately from this notice, provide highly valuable information on emission deterioration in a manner that minimizes the testing burden on manufacturers. Requiring whole-vehicle testing for all durability groups would effectively defeat this aspect of CAP 2000 for many manufacturers, since those manufacturers that use bench aging would also be required to perform whole-vehicle testing, dramatically increasing their testing burden and it would provide only limited additional benefit in evaluating component durability.

Because most of the emission control technologies and components used by manufacturers are very similar in design and function among their different vehicle models, we are confident that whole-vehicle test data from a ''worst case'' component durability vehicle in conjunction with the information from the manufacturer's good engineering assessment will be sufficient for EPA to make a determination as to whether a manufacturer's durability plan is acceptable. Since the emission control components are similar in design and function, one of the most significant differences between vehicle models is the location of the components on the vehicle. The worst case vehicle may likely be the vehicle that has ''packaging'' constraints where some components have to be located on the vehicle in placements that may make them more susceptible to damage, wear, or failure.

C. Good Engineering Judgement Determination Combined With Whole Vehicle Testing for Vehicle Configurations With New Types of Components or Technology

This option would be identical to option B above except that instead of testing the ''worst case'' vehicle, the manufacturer would only test a vehicle when a new type of component or a new technology was being introduced. A new type of component or technology would be defined as a component or technology that has not been previously used in production by that manufacturer. [10] A manufacturer would have to get approval from EPA before determining whether a component would be considered new. New components or technologies not yet used on production vehicles but that have been used on prototype or development vehicles would be subject to the whole-vehicle mileage accumulation and testing.

Requiring whole-vehicle testing for new types of technology would limit the testing to the vehicles where typically less is known about component durability. The information provided from the good engineering assessment would be used generally to assess component durability and this option would require additional information on component durability from whole-vehicle testing for technologies or components that are new to a manufacturer, where they typically have less data or information to evaluate component durability.

IX. Request for Comments

EPA requests comments on each of these proposed options, in terms of their technical and legal merits. In particular, comments are requested on the following topics:

- The burden of Options B and C on regulated entities, including supporting data for those conclusions, where possible.
- The extent to which Options B and C provide any additional environmental benefit over Option A.
- Whether whole-vehicle mileage accumulation and related emissions testing provides an adequate demonstration of component durability, and what other options exist for demonstrating component durability prior to certification.
- Any comment which augment those already submitted to the Docket for this rulemaking.
- Whether the options are consistent with section 206 of the CAA.

X. What are the environmental and economic impacts?

A. Environmental Impacts

No quantifiable environmental impacts are anticipated by this proposed rule. Having appropriate procedures to address component durability in the certification process helps to ensure that the benefits already claimed in the regulations promulgating those standards are more likely to be realized. However, even absent this proposal, there are other requirements in place which help to ensure that manufacturers make durable emissions components: customer satisfaction, In-Use Verification Program (IUVP), and, EPA recall authority among others.

B. Economic Impacts

Under option A, there would be no economic impact. Manufacturers would be allowed to continue using their good engineering judgment to determine component durability. For options B and C there would be some economic impact. Some manufacturers use whole-vehicle testing exclusively. For those manufacturers, there would be no need to perform any additional whole-vehicle testing for component durability purposes. Other manufacturers use a combination of whole-vehicle testing and bench testing. These manufacturers could choose to test their ''worst case'' vehicle or any new type of emission control components or technologies as part of their already existing whole-vehicle test program. Thus, there would be no additional testing costs for them.

For those manufacturers who perform bench testing exclusively, there would be some economic impact. For option B, we would only require a manufacturer to perform whole-vehicle testing for the ''worst case'' vehicle configuration. Therefore, our cost estimate for option B is based on testing a single vehicle. We believe this same logic would apply for option C where a manufacturer is only required to perform whole-vehicle testing for new types of emission control components or technologies. We feel that for option C, a manufacturer would only be required to test a single vehicle as well. Our estimate of total annual cost of whole-vehicle testing for component durability is based on a single vehicle tested over the Standard Road Cycle for a useful life of 120,000 miles with periodic FTP emission tests. We estimated two FTP tests for the

[9] Manufacturers divide their motor vehicles into groups called ''durability groups'' which include vehicles which are likely to exhibit similar exhaust emission deterioration over their useful lives, based on those characteristics of current-technology vehicles that most significantly affect the deterioration of emission control over time. Durability groups are based on engine type, fuel type, fuel system, catalyst construction, type of precious metals used in the catalyst, and relative engine/catalyst size and loading rates.

[10] An example of a new type of component or technology would be a manufacturer switching from vacuum-based EGR to electronic EGR.

minimum estimate and six FTP tests for the maximum estimate with costs ranging from $800 to $1,200 per FTP test. We did not include any Supplemental Federal Test Procedure (SFTP) tests.

Table X. B–1 presents the total annual cost for industry to perform whole-vehicle testing on a ''worst case'' vehicle or a vehicle equipped with a new type of emission control component or technology. We did not include any small volume manufacturers in our estimate. For a more conservative estimate, we included all manufacturers regardless of whether they currently perform whole-vehicle testing for emission deterioration. The estimated annual cost for industry to perform whole-vehicle testing would range from $3,750,600 to $5,401,200.

TABLE X.—B–1.—ESTIMATED ANNUAL COST TO INDUSTRY FOR WHOLE-VEHICLE TESTING

Minimum cost	Maximum cost
$3,750,600	$5,401,200

As can be seen in Table X. B–2, the estimated annual cost per manufacturer to perform whole-vehicle testing on a ''worst case'' vehicle or a vehicle equipped with a new type of emission control component or technology would range from $178,600 to $257,200.[11]

TABLE X.—B–2.—ESTIMATED ANNUAL COST PER MANUFACTURER FOR WHOLE-VEHICLE TESTING

Minimum cost	Maximum cost
$178,600	$257,200

EPA has requested comment on the potential burden associated with the options it considered to require a minimum amount of whole-vehicle mileage accumulation. (See Sec. IV. above).

[11] These numbers were derived from the CAP 2000 rulemaking and can be found in the Support Document on the EPA Web site at *http://www.epa.gov/otaq*. We choose to use the more conservative 1999 dollar estimates, since the Producer Price Index (PPI) for 2004 actually decreased from the 1999 index value. The index used can be found on the U.S. Department of Labor Web site at *http://www.data.bls.gov*. Series Id: PCU336110336110.

XI. What are the opportunities for public participation?

A. Copies of This Proposal and Other Related Information

1. Docket

EPA has established an official public docket for this action under Docket ID No. OAR–2002–0079. 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 by referencing Docket No. OAR–2002–0079 at the EPA Air Docket Section, (see **ADDRESSES** section above). You may submit comments electronically, by mail, or through hand delivery/courier as described below. To ensure proper receipt by EPA, identify the appropriate docket identification 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 Section V.B.3 Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

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. Once in the system, select ''search,'' then key in the appropriate docket identification 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. 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 in 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.

B. Submitting Comments on This Proposal

You may submit comments electronically, by mail, by facsimile, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification 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.

1. Electronically

If you submit an electronic comment, 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.

a. 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. To access EPA's electronic public docket from the EPA Internet Home Page, select ''Information Sources,'' ''Dockets,'' and ''EPA Dockets.'' Once in the system, select ''Quick Search,'' and then key in Docket ID No. OAR–2002–0079. 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.

b. E-mail

Comments may be sent by electronic mail to hormes.linda@epa.gov, Attention Docket ID No. OAR–2002–0079. 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.

c. Disk or CD ROM

You may submit comments on a disk or CD ROM that you mail to the mailing address identified in section 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: Air Docket, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. OAR–2002–0079.

3. By Hand Delivery or Courier

Deliver your comments to: EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC., Attention Docket ID No. OAR–2002–0079. Such deliveries are only accepted during the Docket's normal hours of operation from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

4. By Facsimile

Fax your comments to: (202) 566–1741, Attention Docket ID. No. OAR–2002–0079.

5. Submitting Comments With Proprietary Information

Commenters who wish to submit proprietary information for consideration should clearly separate such information from other comments by (1) labeling proprietary information ''Confidential Business Information'' and (2) sending proprietary information directly to the contact person listed (see **FOR FURTHER INFORMATION CONTACT**) and not to the public docket. This helps insure that proprietary information is not inadvertently placed in the docket. If a commenter wants EPA to use a submission labeled as confidential business information as part of the basis for the final rule, then a non-confidential version of the document, which summarizes the key data or information, should be sent to the docket.

Information covered by a claim of confidentiality will be disclosed by EPA only to the extent allowed and by the procedures set forth in 40 CFR Part 2. If no claim of confidentiality accompanies the submission when it is received by EPA, the submission may be made available to the public without notifying the commenters.

C. Public Hearing

Anyone wishing to present testimony about this proposal at the public hearing (see **DATES**) should notify the general contact person (see **FOR FURTHER INFORMATION CONTACT**) no later than five days prior to the day of the hearing. The contact person should be given an estimate of the time required for the presentation of testimony and notification of any need for audio/visual equipment. Testimony will be scheduled on a first come, first serve basis. A sign-up sheet will be available at the registration table the morning of the hearing for scheduling those who have not notified the contact earlier. This testimony will be scheduled on a first come, first serve basis to follow the previously scheduled testimony.

EPA requests that approximately 50 copies of the statement or material to be presented be brought to the hearing for distribution to the audience. In addition, EPA would find it helpful to receive an advanced copy of any statement or material to be presented at the hearing at least one week before the scheduled hearing date. This is to give EPA staff adequate time to review such material before the hearing. Such advanced copies should be submitted to the contact person listed.

The official records of the hearing will be kept open for 30 days following the hearing to allow submission of rebuttal and supplementary testimony. All such submissions should be directed to the Air Docket Section, Docket No. OAR–2002–0079 (see **ADDRESSES**). The hearing will be conducted informally, and technical rules of evidence will not apply. A written transcript of the hearing will be placed in the above docket for review. Anyone desiring to purchase a copy of the transcript should make individual arrangements with the court reporter recording the proceedings.

XII. What Are the Administrative Requirements for This Proposed Rule?

A. E.O. 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735 October 4, 1993), EPA must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of this Executive Order. The Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or 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;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

EPA has determined that this proposed rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Paperwork Reduction Act

Today's action proposes three different options under consideration for component durability testing. If option A is finalized, this action would not impose any new information collection burden. However, if options B or C were finalized, new information collection requirements would be imposed. The information collection requirements for options B or C in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 783.49.

The information being collected is to be used by EPA to ensure that new light-duty vehicles and light-duty trucks comply with applicable emissions standards through certification requirements including whole-vehicle testing for emission component durability assurance.

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 88 hours per response, with collection required annually. The estimated number of respondents is 21. The total annual cost of the program is estimated to be $3,750,600 per year and includes no annualized capital costs, $101,640 in operating and maintenance costs, at a total of 1,848 hours per year.

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.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number. Submit any comments related to the ICR for this proposed rule to EPA and OMB. See ''Addresses'' section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after January 17, 2006, a comment to OMB is best assured of having its full effect if OMB receives it by February 16, 2006. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act 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.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that manufactures automobiles as defined by NAIC code 336111. Based on Small Business Administration size standards, a small business for this NAIC code is defined as a manufacturer having less than 1000 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The requirements are only applicable to manufacturers of motor vehicles, a group which does not contain a substantial number of small entities. Out of a total of approximately 80 automotive manufacturers subject to today's proposal, EPA estimates that approximately 15–20 of these could be classified as small entities based on SBA size standards. EPA's CAP 2000 compliance regulations include numerous regulatory relief provisions for such small entities. Those provisions remain in effect and are not impacted by today's proposal. Thus, we have determined that small entities will not experience any economic impact as a result of this proposal. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory action on state, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and proposed rules with ''Federal mandates'' that may result in expenditures by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. Before promulgation an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the proposed rule an explanation why that alternative was not adopted.

Before we establish any regulatory requirement that may significantly or uniquely affect small governments, including tribal governments, we must develop, under section 203 of the UMRA, a small government agency

plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of our regulatory proposals with significant federal intergovernmental mandates. The plan must also provide for informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA believes this proposed rule contains no federal mandates for state, local, or tribal governments. Nor does this rule have federal mandates that may result in the expenditures of $100 million or more in any year by the private sector as defined by the provisions of Title II of the UMRA. Nothing in the proposed rule would significantly or uniquely affect small governments.

E. Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), 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 proposed rule will impose no direct compliance costs on states. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 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.'' ''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 proposed rule does not have tribal implications. It 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. The requirements proposed by this action impact private sector businesses, particularly the automotive and engine manufacturing industries. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Children's Health Protection

Executive Order 13045: ''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 E.O. 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 rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This final rule is not subject to E.O. 13045 because it is based on technology performance and not on health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

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) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, 12(d) (15 U.S.C. 272), directs the EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standard bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rule does not involve consideration of any new technical standards. The durability test procedures that EPA is proposing are unique and have not been previously published in the public domain.

List of Subjects in 40 CFR Part 86

Environmental protection, Air pollution control, Motor vehicle pollution, Confidential business information, Reporting and recordkeeping requirements.

Dated: December 29, 2005.

Stephen L. Johnson,

Administrator.

For the reasons set out in the preamble, part 86 of title 40 of the Code of Federal Regulations is proposed to be amended as follows:

Draft Regulatory Language for Option A

PART 86—CONTROL OF EMISSIONS FROM NEW AND IN-USE HIGHWAY VEHICLES AND ENGINES

1. The authority citation for part 86 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart S—General Compliance Provisions for Control of Air Pollution From New and In-use Light-duty Vehicles, Light-duty Trucks, and Complete Otto-cycle Heavy-duty Vehicles

2. Amend § 86.1823–08 to revise paragraph (g) to read as follows:

§ 86.1823–08 Durability demonstration procedures for exhaust emissions.

* * * * *

(g) *Emission component durability.* The manufacturer shall use good engineering judgment to determine that all emission-related components are designed to operate properly for the full useful life of the vehicles in actual use.

* * * * *

3. Amend § 86.1824–08 to revise paragraph (h) to read as follows:

§ 86.1824–08 Durability demonstration procedures for evaporative emissions.

* * * * *

(h) *Emission component durability.* The manufacturer shall use good engineering judgment to determine that all evaporative emission-related components are designed to operate properly for the full useful life of the vehicles in actual use.

* * * * *

4. Amend § 86.1825–08 to revise paragraph (h) to read as follows:

§ 86.1825–08 Durability demonstration procedures for refueling emissions.

* * * * *

(h) *Emission component durability.* The manufacturer shall use good engineering judgment to determine that all emission-related components are designed to operate properly for the full useful life of the vehicles in actual use.

* * * * *

5. Amend § 86.1826–01 to revise paragraph (c) to read as follows:

§ 86.1826–01 Assigned deterioration factors for small volume manufacturers and small volume test groups.

* * * * *

(c) *Emission component durability.* The manufacturer shall use good engineering judgment to determine that all emission-related components are designed to operate properly for the full useful life of the vehicles in actual use.

Draft Regulatory Language for Option B

6. Amend § 86.1823–08 to revise paragraph (g) to read as follows:

§ 86.1823–08 Durability demonstration procedures for exhaust emissions.

* * * * *

(g) *Emission component durability.* Manufacturers must determine that all exhaust emission-related components are designed to operate properly for the full useful life of the vehicles in actual use. The manufacturer must demonstrate emission component durability using the following procedures.

(1) The manufacturer must determine using good engineering judgement the vehicle (or vehicles) that are worst case for component durability. In making this determination the manufacturer must evaluate their entire product line. For the vehicles that will be represented, the manufacturer must consider at a minimum all the following information:

(i) The past in-use history of component durability for the emission related parts;

(ii) The effect of the vehicle environment (temperature, flow rate, exhaust constituents, vibration, exposure to elements etc.) on the durability of the part;

(iii) How sensitive in-use emission compliance is to the potential failure of a particular part; and

(iv) If the design of the part is new (without proven in-use component durability and emission compliance).

(2) For the vehicle (or vehicles) identified as worst case in paragraph (g)(1) of this section, the manufacturer must conduct full useful life mileage accumulation on a whole vehicle with all emission control hardware installed and operating. The mileage accumulation procedure used must meet the requirements of either paragraph (c) or paragraph (e) (1) of this section. The mileage accumulation must be conducted either on the road or on a vehicle dynamometer; it may not be conducted on an engine dynamometer for this purpose.

(3) The manufacturer must conduct at least one FTP test following completion of full useful life mileage accumulation. Up to three FTP tests may be conducted. If more than one test is conducted the emission results are averaged. Prior to conducting the testing the manufacturer must assure that all OBD readiness codes are set (completed). Up to 100 miles of off-cycle mileage accumulation may be conducted to achieve the completion of all OBD monitoring.

(4) The manufacturer must record any OBD illumination during the course of the mileage accumulation and must record readiness codes and active fault codes on the OBD system preceding and following each test conducted under the provisions of paragraph (g)(3) of this section.

(5) If the OBD light becomes illuminated during the course of mileage accumulation, the manufacturer must investigate the cause of the OBD illumination and record the active fault code that caused illumination of the light.

(6) To demonstrate acceptable component durability:

(i) The test results (or the average of multiple test results) must comply with all applicable emission standards; and

(ii) The OBD system must not set any valid active fault codes that pertain to emission related parts or systems during the course of mileage accumulation, including before and after testing.

* * * * *

7. Amend § 86.1824–08 to revise paragraph (h) to read as follows:

§ 86.1824–08 Durability demonstration procedures for evaporative emissions.

* * * * *

(h) *Emission component durability.* Manufacturers must determine that all evaporative emission-related components are designed to operate properly for the full useful life of the vehicles in actual use. The manufacturer must demonstrate emission component durability using the following procedures.

(1) The manufacturer must determine using good engineering judgement the vehicle (or vehicles) that are worst case for component durability. In making this determination the manufacturer must evaluate their entire product line. For the vehicles that will be represented, the manufacturer must consider at a minimum all the following information:

(i) The past in-use history of component durability for the emission related parts;

(ii) The effect of the vehicle environment (temperature, flow rate, exhaust constituents, vibration, exposure to elements etc.) on the durability of the part;

(iii) How sensitive in-use emission compliance is to the potential failure of a particular part; and

(iv) If the design of the part is new (without proven in-use component durability and emission compliance).

(2) For the vehicle (or vehicles) identified as worst case in paragraph (g)(1) of this section, the manufacturer must conduct full useful life mileage accumulation on a whole vehicle with all emission control hardware installed and operating. The mileage accumulation procedure used must meet the requirements of either paragraph (c) or paragraph (e)(1) of this section. The mileage accumulation must be conducted either on the road or on a vehicle dynamometer; it may not be conducted on an engine dynamometer for this purpose.

(3) The manufacturer must conduct at least one evaporative 2-day test following completion of full useful life mileage accumulation. Up to three tests may be conducted. If more than one test is conducted the emission results are averaged. Prior to conducting the testing the manufacturer must assure that all OBD readiness codes are set (completed). Up to 100 miles of off-cycle mileage accumulation may be conducted to achieve the completion of all OBD monitoring.

(4) The manufacturer must record any OBD illumination during the course of the mileage accumulation and must record readiness codes and active fault codes on the OBD system preceding and following each test conducted under the provisions of paragraph (g)(3) of this section.

(5) If the OBD light becomes illuminated during the course of mileage accumulation, the manufacturer must investigate the cause of the OBD illumination and record the active fault code that caused illumination of the light.

(6) To demonstrate acceptable component durability:

(i) The test results (or the average of multiple test results) must comply with all applicable emission standards; and

(ii) The OBD system must not set any valid active fault codes that pertain to emission related parts or systems during the course of mileage accumulation, including before and after testing.

* * * * *

8. Amend § 86.1825–08 to revise paragraph (h) to read as follows:

§ 86.1825–08 Durability demonstration procedures for refueling emissions.

* * * * *

(h) *Emission component durability.* Manufacturers must determine that all refueling emission-related components are designed to operate properly for the full useful life of the vehicles in actual use. The manufacturer must demonstrate component durability using the following procedures.

(1) The manufacturer must determine using good engineering judgement the vehicle (or vehicles) that are worst case for refueling component durability. In making this determination the manufacturer must evaluate their entire product line. For the vehicles that will be represented, the manufacturer must consider at a minimum all the following information:

(i) The past in-use history of component durability for the emission related parts;

(ii) The effect of the vehicle environment (temperature, flow rate, exhaust constituents, vibration, exposure to elements etc.) on the durability of the part;

(iii) How sensitive in-use emission compliance is to the potential failure of a particular part; and

(iv) If the design of the part is new (without proven in-use component durability and emission compliance).

(2) For the vehicle (or vehicles) identified as worst case in paragraph (g)(1)of this section, the manufacturer must conduct full useful life mileage accumulation on a whole vehicle with all emission control hardware installed and operating. The mileage accumulation procedure used must meet the requirements of either paragraph (c) or paragraph (e)(1) of this section. The mileage accumulation must be conducted either on the road or on a vehicle dynamometer; it may not be conducted on an engine dynamometer for this purpose.

(3) The manufacturer must conduct at least one refueling test following completion of full useful life mileage accumulation. Up to three tests may be conducted. If more than one test is conducted the emission results are averaged. Prior to conducting the testing the manufacturer must assure that all OBD readiness codes are set (completed). Up to 100 miles of off-cycle mileage accumulation may be conducted to achieve the completion of all OBD monitoring.

(4) The manufacturer must record any OBD illumination during the course of the mileage accumulation and must record readiness codes and active fault codes on the OBD system preceding and following each test conducted under the provisions of paragraph (g)(3) of this section.

(5) If the OBD light becomes illuminated during the course of mileage accumulation, the manufacturer must investigate the cause of the OBD illumination and record the active fault code that caused illumination of the light.

(6) To demonstrate acceptable component durability:

(i) The test results (or the average of multiple test results) must comply with all applicable emission standards; and

(ii) The OBD system must not set any valid active fault codes that pertain to emission related parts or systems during the course of mileage accumulation, including before and after testing.

* * * * *

Draft Regulatory Language for Option C

9. Amend § 86.1823–08 to revise paragraph (g) to read as follows:

§ 86.1823–08 Durability demonstration procedures for exhaust emissions.

* * * * *

(g) *Emission component durability.* Manufacturers must determine that all exhaust emission-related components are designed to operate properly for the full useful life of the vehicles in actual use. The manufacturer must demonstrate emission component durability using the following procedures.

(1) The manufacturer must determine using good engineering judgement the vehicle (or vehicles) that use a new component or technology for component durability. In making this determination the manufacturer must evaluate their entire product line. For the vehicles that will be represented, the manufacturer must consider at a minimum all the following information:

(i) If the design of the part is new (without proven in-use component durability and emission compliance);

(ii) The effect of the vehicle environment (temperature, flow rate, exhaust constituents, vibration, exposure to elements etc.) on the durability of the part; and

(iii) How sensitive in-use emission compliance is to the potential failure of a particular part.

(2) For the vehicle (or vehicles) identified as worst case in paragraph (g)(1)of this section, the manufacturer must conduct full useful life mileage accumulation on a whole vehicle with all emission control hardware installed and operating. The mileage accumulation procedure used must meet the requirements of either paragraph (c) or paragraph (e)(1) of this section. The mileage accumulation must be conducted either on the road or on a vehicle dynamometer; it may not be conducted on an engine dynamometer for this purpose.

(3) The manufacturer must conduct at least one FTP test following completion of full useful life mileage accumulation. Up to three FTP tests may be conducted. If more than one test is conducted the emission results are averaged. Prior to conducting the testing the manufacturer must assure that all OBD readiness codes are set (completed). Up to 100 miles of off-cycle mileage accumulation may be conducted to achieve the completion of all OBD monitoring.

(4) The manufacturer must record any OBD illumination during the course of the mileage accumulation and must record readiness codes and active fault codes on the OBD system preceding and following each test conducted under the provisions of paragraph (g)(3) of this section.

(5) If the OBD light becomes illuminated during the course of mileage accumulation, the manufacturer must investigate the cause of the OBD illumination and record the active fault code that caused illumination of the light.

(6) To demonstrate acceptable component durability:

(i) The test results (or the average of multiple test results) must comply with all applicable emission standards; and

(ii) The OBD system must not set any valid active fault codes that pertain to emission related parts or systems during the course of mileage accumulation, including before and after testing.

* * * * *

10. Amend § 86.1824–08 to revise paragraph (h) to read as follows:

§ 86.1824–08 Durability demonstration procedures for evaporative emissions.

* * * * *

(h) *Emission component durability.* Manufacturers must determine that all evaporative emission-related components are designed to operate properly for the full useful life of the vehicles in actual use. The manufacturer must demonstrate emission component durability using the following procedures.

(1) The manufacturer must determine using good engineering judgement the vehicle (or vehicles) that use a new component or technology for component durability. In making this determination the manufacturer must evaluate their entire product line. For the vehicles that will be represented, the manufacturer must consider at a minimum all the following information:

(i) If the design of the part is new (without proven in-use component durability and emission compliance);

(ii) The effect of the vehicle environment (temperature, flow rate, exhaust constituents, vibration, exposure to elements etc.) on the durability of the part; and

(iii) How sensitive in-use emission compliance is to the potential failure of a particular part.

(2) For the vehicle (or vehicles) identified as worst case in paragraph (g)(1) of this section, the manufacturer must conduct full useful life mileage accumulation on a whole vehicle with all emission control hardware installed and operating. The mileage accumulation procedure used must meet the requirements of either paragraph (c) or paragraph (e) (1) of this section. The mileage accumulation must be conducted either on the road or on a vehicle dynamometer; it may not be conducted on an engine dynamometer for this purpose.

(3) The manufacturer must conduct at least one evaporative 2-day test following completion of full useful life mileage accumulation. Up to three tests may be conducted. If more than one test is conducted the emission results are averaged. Prior to conducting the testing the manufacturer must assure that all OBD readiness codes are set (completed). Up to 100 miles of off-cycle mileage accumulation may be conducted to achieve the completion of all OBD monitoring.

(4) The manufacturer must record any OBD illumination during the course of the mileage accumulation and must record readiness codes and active fault codes on the OBD system preceding and following each test conducted under the provisions of paragraph (g)(3) of this section.

(5) If the OBD light becomes illuminated during the course of mileage accumulation, the manufacturer must investigate the cause of the OBD illumination and record the active fault code that caused illumination of the light.

(6) To demonstrate acceptable component durability:

(i) The test results (or the average of multiple test results) must comply with all applicable emission standards; and

(ii) The OBD system must not set any valid active fault codes that pertain to emission related parts or systems during the course of mileage accumulation, including before and after testing.

* * * * *

11. Amend § 86.1825–08 to revise paragraph (e) to read as follows:

§ 86.1825–08 Durability demonstration procedures for refueling emissions.

* * * * *

(e) *Emission component durability.* Manufacturers must determine that all refueling emission-related components are designed to operate properly for the full useful life of the vehicles in actual use. The manufacturer must demonstrate component durability using the following procedures.

(1) The manufacturer must determine using good engineering judgement the vehicle (or vehicles) that use a new component or technology for component durability. In making this determination the manufacturer must evaluate their entire product line. For the vehicles that will be represented, the manufacturer must consider at a minimum all the following information:

(i) If the design of the part is new (without proven in-use component durability and emission compliance);

(ii) The effect of the vehicle environment (temperature, flow rate, exhaust constituents, vibration, exposure to elements etc.) on the durability of the part; and

(iii) How sensitive in-use emission compliance is to the potential failure of a particular part.

(2) For the vehicle (or vehicles) identified as worst case in paragraph (g)(1)of this section, the manufacturer must conduct full useful life mileage accumulation on a whole vehicle with all emission control hardware installed and operating. The mileage accumulation procedure used must meet the requirements of either paragraph (c) or paragraph (e) (1) of this section. The mileage accumulation must be conducted either on the road or on a vehicle dynamometer; it may not be conducted on an engine dynamometer for this purpose.

(3) The manufacturer must conduct at least one refueling test following completion of full useful life mileage accumulation. Up to three tests may be conducted. If more than one test is conducted the emission results are averaged. Prior to conducting the testing the manufacturer must assure that all OBD readiness codes are set (completed). Up to 100 miles of off-cycle mileage accumulation may be conducted to achieve the completion of all OBD monitoring.

(4) The manufacturer must record any OBD illumination during the course of the mileage accumulation and must record readiness codes and active fault codes on the OBD system preceding and following each test conducted under the provisions of paragraph (g)(3) of this section.

(5) If the OBD light becomes illuminated during the course of mileage accumulation, the manufacturer must investigate the cause of the OBD illumination and record the active fault code that caused illumination of the light.

(6) To demonstrate acceptable component durability:

(i) The test results (or the average of multiple test results) must comply with all applicable emission standards; and

(ii) The OBD system must not set any valid active fault codes that pertain to emission related parts or systems during the course of mileage accumulation, including before and after testing.

* * * * *

[FR Doc. 06–73 Filed 1–13–06; 8:45 am]

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Federal Register

Vol. 71, No. 10

Tuesday, January 17, 2006

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FEDERAL REGISTER PAGES AND DATE, JANUARY

1–230 3
231–536 4
537–872 5
873–1388 6
1389–1472 9
1473–1682 10
1683–1914 11
1915–2134 12
2135–2452 13
2453–2856 17

CFR PARTS AFFECTED DURING JANUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
6867 (See: Notice of January 10, 2006) 2133
7757 (See: Notice of January 10, 2006) 2133
Administrative Orders:
Memorandums:
Memorandum of December 15, 2005 1467
Presidential Determinations:
No. 2006–6 of December 22, 2005 1469
No. 2006–7 of December 30, 2005 871
No. 2006–8 of December 30, 2005 1471
Notices:
Notice of January 6, 2006 1681
Notice of January 10, 2006 2133

5 CFR

1650 1389
Proposed Rules:
1651 1984

7 CFR

226 1
400 2135
930 1915
946 1919
982 1921
Proposed Rules:
56 2168
70 2168
319 1700
1000 545
1001 545
1005 545
1006 545
1007 545
1030 545
1032 545
1033 545
1124 545
1126 545
1131 545

9 CFR

317 1683
381 1683
391 2135
590 2135
592 2135
Proposed Rules:
77 1985
318 2483
381 2483
392 1988
439 2483

10 CFR

35 1926
Proposed Rules:
20 29
30 ..... 29, 275
31 ..... 29, 275
32 ..... 29, 275
33 29
35 29
150 275

12 CFR

205 ..... 1473, 1638
Proposed Rules:
Ch. I 287
Ch. II 287
Ch. III 287
Ch. V 287
611 1704

14 CFR

11 1483
21 534
23 ..... 537, 1926, 2143
25 1485
36 530
39 ..... 231, 873, 1390, 1930, 1935, 1937, 1939, 1941, 1947, 1949, 1951, 2453, 2455
71 ..... 537, 2145
73 2146
97 ..... 1393, 1686
121 ..... 534, 1666, 1688
135 534
Proposed Rules:
39 ..... 291, 293, 295, 297, 299, 1718, 2491
71 ..... 552, 889, 1397, 1398

15 CFR

930 788

17 CFR

36 1953
37 1953
38 1953
39 1953
40 1953
242 232
Proposed Rules:
4 1463

18 CFR

2 1348
33 1348
Proposed Rules:
35 303

370 303

19 CFR

101 2457

20 CFR

404 2312

21 CFR

210 2458
510 ....875, 2147
520 875
522 1689
558 ....5, 1689
803 1488
Proposed Rules:
56 2493
210 2494
310 2309
866 1399

23 CFR

Proposed Rules:
1313 29

24 CFR

401 2112
402 2112
Proposed Rules:
401 2126
402 2126
1000 2176

25 CFR

243 2426

26 CFR

1 ....6, 11, 1971, 2462
20 2147
31 11
602 6
Proposed Rules:
1 2496
31 46
301 ....2497, 2498

27 CFR

Proposed Rules:
9 1500

28 CFR

16 16
105 1690

29 CFR

2520 1904
4022 2147
4044 ....2147, 2148
Proposed Rules:
2700 553
2704 553
2705 553

30 CFR

946 1488

31 CFR

103 496
215 2149
501 1971
Proposed Rules:
103 516
501 1994

32 CFR

199 1695

33 CFR

117 ....1494, 2151
165 ....538, 2152
Proposed Rules:
117 2176

36 CFR

223 ....522, 523
1011 2109
Proposed Rules:
219 307

37 CFR

Proposed Rules:
1 ....48, 61
2 2498

38 CFR

17 2464
21 1496

39 CFR

111 1976
3001 2464

40 CFR

9 ....388, 654
16 232
35 17
52 ....19, 21, 24, 241, 244, 541, 1463, 1696
60 2472
61 2472
63 1378
81 ....24, 541
86 2810
141 ....388, 654
142 ....388, 654
Proposed Rules:
50 2620
51 69
52 ....85, 569, 577, 890, 892, 1994, 1996, 2177
53 2710
58 2710
60 2509
61 2509
63 ....1386, 1403
86 2843
122 894
180 901
745 1588
1604 309

41 CFR

301–10 876

42 CFR

419 2617

46 CFR

10 2154

47 CFR

1 2167
73 ....245, 246, 247, 877
Proposed Rules:
54 1721
73 ....312, 313

48 CFR

Ch. 1 ....198, 228, 864, 866
1 200
2 ....208, 211
4 208
5 ....219, 220
6 219
7 ....208, 211
8 221
9 ....219, 227
11 ....211, 227
12 ....211, 219, 220
14 219
16 211
17 219
19 ....220, 221
22 ....219, 864
25 ....219, 221, 223, 224, 227, 864
27 227
34 227
37 211
38 227
39 ....211, 227
42 ....200, 221
43 227
44 225
46 ....200, 227
47 200
48 227
50 227
52 ....200, 208, 219, 221, 224, 225, 226, 227, 864
53 200
2401 2432
2402 2432
2406 2432
2408 2432
2409 2432
2411 2432
2413 2432
2415 2432
2416 2432
2419 2432
2422 2432
2426 2432
2432 2432
2437 2432
2442 2432
2446 2432
2448 2432
2452 2432
Proposed Rules:
Ch. 8 2342
2404 2444
2408 2444
2415 2444
2437 2444
2439 2444
2452 2444
9903 313

49 CFR

219 1498
571 877
Proposed Rules:
192 1504

50 CFR

223 834
224 834
229 1980
299 247
600 27
635 ....273, 1395
648 1982
679 1698
Proposed Rules:
17 315
660 ....1998, 2510
679 386

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 JANUARY 17, 2006

ENVIRONMENTAL PROTECTION AGENCY

Hazardous waste program authorizations:

Massachusetts; published 11-18-05

FEDERAL COMMUNICATIONS COMMISSION

Radio stations; table of assignments:

Maryland and Virginia; published 12-21-05

HOMELAND SECURITY DEPARTMENT

Coast Guard

Maritime security:

Dangerous cargo definition change and electronic notification of arrival submission options; published 12-16-05

INTERIOR DEPARTMENT

Minerals Management Service

Outer Continental Shelf; oil, gas, and sulphur operations:

Ultra-deep well drilling; suspension of operations; published 12-16-05

JUSTICE DEPARTMENT

Drug Enforcement Administration

Anabolic Steroid Control Act of 2004; implementation; published 12-16-05

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

American Champion Aircraft Corp.; published 1-9-06

BAE Systems (Operations) Ltd.; published 12-13-05

Dassault; published 12-13-05

Frakes Aviation; published 1-12-06

Rolls-Royce plc; published 12-13-05

TREASURY DEPARTMENT

Internal Revenue Service

Income taxes:

Partnerships; treatment of controlled foreign corporation's distributive share of partnership income; guidance under subpart F; published 1-17-06

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Animal and Plant Health Inspection Service

Exportation and importation of animals and animal products:

Bovine Spongiform encephalopathy; minimal-risk regions and importation of commodities; comments due by 1-27-06; published 11-28-05 [FR 05-23334]

AGRICULTURE DEPARTMENT

Food Safety and Inspection Service

Meat and poultry inspection:

Poultry product exportation to United States; eligible countries; addition—

China; comments due by 1-23-06; published 11-23-05 [FR 05-23123]

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:

Caribbean, Gulf, and South Atlantic fisheries—

Gulf of Mexico shrimp; comments due by 1-23-06; published 11-23-05 [FR 05-23203]

ENVIRONMENTAL PROTECTION AGENCY

Air pollutants, hazardous; national emission standards:

Miscellaneous organic chemical manufacturing; comments due by 1-24-06; published 12-8-05 [FR 05-23666]

Air quality implementation plans; approval and promulgation; various States:

Alabama; comments due by 1-27-06; published 12-28-05 [FR 05-24473]

Tennessee; comments due by 1-26-06; published 12-27-05 [FR 05-24415]

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Tralkoxydim; comments due by 1-23-06; published 11-23-05 [FR 05-23106]

FEDERAL COMMUNICATIONS COMMISSION

Emergency Alert System; digital communications technology coverage; comments due by 1-24-06; published 11-25-05 [FR 05-23270]

HEALTH AND HUMAN SERVICES DEPARTMENT

Food and Drug Administration

Animal drugs, feeds, and related products:

Minor uses or minor species; new drugs designation; comments due by 1-27-06; published 12-28-05 [FR 05-24512]

HEALTH AND HUMAN SERVICES DEPARTMENT

Administrative requirements:

Health Insurance Portability and Accountability Act; implementation—

Electronic health care claims attachments; comments due by 1-23-06; published 11-22-05 [FR 05-23077]

Medicare and medicaid:

Health Insurance Portability and Accountability Act; implementation—

Electronic health care claims attachments; standards; comments due by 1-23-06; published 9-23-05 [FR 05-18927]

HEALTH AND HUMAN SERVICES DEPARTMENT

Health Resources and Services Administration

Health resources development:

Organ Procurement and Transplantation Network—

Intestines; comments due by 1-23-06; published 11-23-05 [FR 05-23149]

HOMELAND SECURITY DEPARTMENT

Coast Guard

Drawbridge operations:

New Jersey; comments due by 1-23-06; published 11-22-05 [FR 05-23028]

INTERIOR DEPARTMENT

Land Management Bureau

Land resource management:

Public land recreation permits; comments due by 1-23-06; published 11-22-05 [FR 05-23113]

LABOR DEPARTMENT

Labor-Management Standards Office

Standards of conduct:

Labor organization officer and employee reports; comments due by 1-26-06; published 10-24-05 [FR 05-21274]

NUCLEAR REGULATORY COMMISSION

Plants and materials; physical protection:

Design basis threat; comments due by 1-23-06; published 11-7-05 [FR 05-22200]

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

Boeing; comments due by 1-23-06; published 11-23-05 [FR 05-23156]

Gulfstream; comments due by 1-23-06; published 12-9-05 [FR 05-23832]

Lycoming Engines; comments due by 1-26-06; published 12-27-05 [FR E5-07815]

Raytheon; comments due by 1-23-06; published 11-22-05 [FR 05-23055]

Airworthiness standards:

Transport category airplanes—

Seat belt attachment fittings on passenger seats; unreliable design; policy statement; comments due by 1-27-06; published 12-28-05 [FR 05-24501]

Class D airspace; comments due by 1-25-06; published 10-31-05 [FR 05-21585]

Class E airspace; comments due by 1-27-06; published 1-5-06 [FR 06-00080]

Colored Federal airways; comments due by 1-23-06; published 12-8-05 [FR 05-23759]

Offshore airspace areas; comments due by 1-23-06; published 12-8-05 [FR 05-23757]

TRANSPORTATION DEPARTMENT

Federal Transit Administration

Buy America requirements; definitions and waiver procedures amendments; comments due by 1-27-06; published 11-28-05 [FR 05-23323]

TRANSPORTATION DEPARTMENT

Pipeline and Hazardous Materials Safety Administration

Pipeline safety:

Gas gathering line definition; safety standards for onshore lines; public meeting; comments due by 1-26-06; published 1-10-06 [FR 06-00224]

TREASURY DEPARTMENT

Internal Revenue Service

Income taxes:

Partner's distributive share; comments due by 1-25-06; published 11-18-05 [FR 05-22281]

VETERANS AFFAIRS DEPARTMENT

Servicemembers' and veterans' group life insurance:

Traumatic injury protection; comments due by 1-23-06; published 12-22-05 [FR 05-24390]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

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H.R. 4340/P.L. 109–169

United States-Bahrain Free Trade Agreement Implementation Act (Jan. 11, 2006; 119 Stat. 3581)

Last List January 12, 2006

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Title	Stock Number	Price	Revision Date
1	(869–056–00001–4)	5.00	Jan. 1, 2005
2	(869–056–00002–2)	5.00	Jan. 1, 2005
3 (2003 Compilation and Parts 100 and 101)	(869–056–00003–1)	35.00	[1] Jan. 1, 2005
4	(869–056–00004–9)	10.00	[4] Jan. 1, 2005
5 Parts:			
1–699	(869–056–00005–7)	60.00	Jan. 1, 2005
700–1199	(869–056–00006–5)	50.00	Jan. 1, 2005
1200–End	(869–056–00007–3)	61.00	Jan. 1, 2005
6	(869–056–00008–1)	10.50	Jan. 1, 2005
7 Parts:			
1–26	(869–056–00009–0)	44.00	Jan. 1, 2005
27–52	(869–056–00010–3)	49.00	Jan. 1, 2005
53–209	(869–056–00011–1)	37.00	Jan. 1, 2005
210–299	(869–056–00012–0)	62.00	Jan. 1, 2005
300–399	(869–056–00013–8)	46.00	Jan. 1, 2005
400–699	(869–056–00014–6)	42.00	Jan. 1, 2005
700–899	(869–056–00015–4)	43.00	Jan. 1, 2005
900–999	(869–056–00016–2)	60.00	Jan. 1, 2005
1000–1199	(869–056–00017–1)	22.00	Jan. 1, 2005
1200–1599	(869–056–00018–9)	61.00	Jan. 1, 2005
1600–1899	(869–056–00019–7)	64.00	Jan. 1, 2005
1900–1939	(869–056–00020–1)	31.00	Jan. 1, 2005
1940–1949	(869–056–00021–9)	50.00	Jan. 1, 2005
1950–1999	(869–056–00022–7)	46.00	Jan. 1, 2005
2000–End	(869–056–00023–5)	50.00	Jan. 1, 2005
8	(869–056–00024–3)	63.00	Jan. 1, 2005
9 Parts:			
1–199	(869–056–00025–1)	61.00	Jan. 1, 2005
200–End	(869–056–00026–0)	58.00	Jan. 1, 2005
10 Parts:			
1–50	(869–056–00027–8)	61.00	Jan. 1, 2005
51–199	(869–056–00028–6)	58.00	Jan. 1, 2005
200–499	(869–056–00029–4)	46.00	Jan. 1, 2005
500–End	(869–056–00030–8)	62.00	Jan. 1, 2005
11	(869–056–00031–6)	41.00	Jan. 1, 2005
12 Parts:			
1–199	(869–056–00032–4)	34.00	Jan. 1, 2005
200–219	(869–056–00033–2)	37.00	Jan. 1, 2005
220–299	(869–056–00034–1)	61.00	Jan. 1, 2005
300–499	(869–056–00035–9)	47.00	Jan. 1, 2005
500–599	(869–056–00036–7)	39.00	Jan. 1, 2005
600–899	(869–056–00037–5)	56.00	Jan. 1, 2005
900–End	(869–056–00038–3)	50.00	Jan. 1, 2005
13	(869–056–00039–1)	55.00	Jan. 1, 2005
14 Parts:			
1–59	(869–056–00040–5)	63.00	Jan. 1, 2005
60–139	(869–056–00041–3)	61.00	Jan. 1, 2005
140–199	(869–056–00042–1)	30.00	Jan. 1, 2005
200–1199	(869–056–00043–0)	50.00	Jan. 1, 2005
1200–End	(869–056–00044–8)	45.00	Jan. 1, 2005
15 Parts:			
0–299	(869–056–00045–6)	40.00	Jan. 1, 2005
300–799	(869–056–00046–4)	60.00	Jan. 1, 2005
800–End	(869–056–00047–2)	42.00	Jan. 1, 2005
16 Parts:			
0–999	(869–056–00048–1)	50.00	Jan. 1, 2005
1000–End	(869–056–00049–9)	60.00	Jan. 1, 2005
17 Parts:			
1–199	(869–056–00051–1)	50.00	Apr. 1, 2005
200–239	(869–056–00052–9)	58.00	Apr. 1, 2005
240–End	(869–056–00053–7)	62.00	Apr. 1, 2005
18 Parts:			
1–399	(869–056–00054–5)	62.00	Apr. 1, 2005
400–End	(869–056–00055–3)	26.00	[6] Apr. 1, 2005
19 Parts:			
1–140	(869–056–00056–1)	61.00	Apr. 1, 2005
141–199	(869–056–00057–0)	58.00	Apr. 1, 2005
200–End	(869–056–00058–8)	31.00	Apr. 1, 2005
20 Parts:			
1–399	(869–056–00059–6)	50.00	Apr. 1, 2005
400–499	(869–056–00060–0)	64.00	Apr. 1, 2005
500–End	(869–056–00061–8)	63.00	Apr. 1, 2005
21 Parts:			
1–99	(869–056–00062–6)	42.00	Apr. 1, 2005
100–169	(869–056–00063–4)	49.00	Apr. 1, 2005
170–199	(869–056–00064–2)	50.00	Apr. 1, 2005
200–299	(869–056–00065–1)	17.00	Apr. 1, 2005
300–499	(869–056–00066–9)	31.00	Apr. 1, 2005
500–599	(869–056–00067–7)	47.00	Apr. 1, 2005
600–799	(869–056–00068–5)	15.00	Apr. 1, 2005
800–1299	(869–056–00069–3)	58.00	Apr. 1, 2005
1300–End	(869–056–00070–7)	24.00	Apr. 1, 2005
22 Parts:			
1–299	(869–056–00071–5)	63.00	Apr. 1, 2005
300–End	(869–056–00072–3)	45.00	Apr. 1, 2005
23	(869–056–00073–1)	45.00	Apr. 1, 2005
24 Parts:			
0–199	(869–056–00074–0)	60.00	Apr. 1, 2005
200–499	(869–056–00074–0)	50.00	Apr. 1, 2005
500–699	(869–056–00076–6)	30.00	Apr. 1, 2005
700–1699	(869–056–00077–4)	61.00	Apr. 1, 2005
1700–End	(869–056–00078–2)	30.00	Apr. 1, 2005
25	(869–056–00079–1)	63.00	Apr. 1, 2005
26 Parts:			
§§ 1.0–1–1.60	(869–056–00080–4)	49.00	Apr. 1, 2005
§§ 1.61–1.169	(869–056–00081–2)	63.00	Apr. 1, 2005
§§ 1.170–1.300	(869–056–00082–1)	60.00	Apr. 1, 2005
§§ 1.301–1.400	(869–056–00083–9)	46.00	Apr. 1, 2005
§§ 1.401–1.440	(869–056–00084–7)	62.00	Apr. 1, 2005
§§ 1.441–1.500	(869–056–00085–5)	57.00	Apr. 1, 2005
§§ 1.501–1.640	(869–056–00086–3)	49.00	Apr. 1, 2005
§§ 1.641–1.850	(869–056–00087–1)	60.00	Apr. 1, 2005
§§ 1.851–1.907	(869–056–00088–0)	61.00	Apr. 1, 2005
§§ 1.908–1.1000	(869–056–00089–8)	60.00	Apr. 1, 2005
§§ 1.1001–1.1400	(869–056–00090–1)	61.00	Apr. 1, 2005
§§ 1.1401–1.1550	(869–056–00091–0)	55.00	Apr. 1, 2005
§§ 1.1551–End	(869–056–00092–8)	55.00	Apr. 1, 2005
2–29	(869–056–00093–6)	60.00	Apr. 1, 2005
30–39	(869–056–00094–4)	41.00	Apr. 1, 2005
40–49	(869–056–00095–2)	28.00	Apr. 1, 2005
50–299	(869–056–00096–1)	41.00	Apr. 1, 2005

Title	Stock Number	Price	Revision Date
300–499	(869–056–00097–9)	61.00	Apr. 1, 2005
500–599	(869–056–00098–7)	12.00	[5]Apr. 1, 2005
600–End	(869–056–00099–5)	17.00	Apr. 1, 2005
27 Parts:			
1–199	(869–056–00100–2)	64.00	Apr. 1, 2005
200–End	(869–056–00101–1)	21.00	Apr. 1, 2005
28 Parts:			
0–42	(869–056–00102–9)	61.00	July 1, 2005
43–End	(869–056–00103–7)	60.00	July 1, 2005
29 Parts:			
0–99	(869–056–00104–5)	50.00	July 1, 2005
100–499	(869–056–00105–3)	23.00	July 1, 2005
500–899	(869–056–00106–1)	61.00	July 1, 2005
900–1899	(869–056–00107–0)	36.00	[7]July 1, 2005
1900–1910 (§§ 1900 to 1910.999)	(869–056–00108–8)	61.00	July 1, 2005
1910 (§§ 1910.1000 to end)	(869–056–00109–6)	58.00	July 1, 2005
1911–1925	(869–056–00110–0)	30.00	July 1, 2005
1926	(869–056–00111–8)	50.00	July 1, 2005
1927–End	(869–056–00112–6)	62.00	July 1, 2005
30 Parts:			
1–199	(869–056–00113–4)	57.00	July 1, 2005
200–699	(869–056–00114–2)	50.00	July 1, 2005
700–End	(869–056–00115–1)	58.00	July 1, 2005
31 Parts:			
0–199	(869–056–00116–9)	41.00	July 1, 2005
200–499	(869–056–00117–7)	33.00	July 1, 2005
500–End	(869–056–00118–5)	33.00	July 1, 2005
32 Parts:			
1–39, Vol. I		15.00	[2] July 1, 1984
1–39, Vol. II		19.00	[2] July 1, 1984
1–39, Vol. III		18.00	[2] July 1, 1984
1–190	(869–056–00119–3)	61.00	July 1, 2005
191–399	(869–056–00120–7)	63.00	July 1, 2005
400–629	(869–056–00121–5)	50.00	July 1, 2005
630–699	(869–056–00122–3)	37.00	July 1, 2005
700–799	(869–056–00123–1)	46.00	July 1, 2005
800–End	(869–056–00124–0)	47.00	July 1, 2005
33 Parts:			
1–124	(869–056–00125–8)	57.00	July 1, 2005
125–199	(869–056–00126–6)	61.00	July 1, 2005
200–End	(869–056–00127–4)	57.00	July 1, 2005
34 Parts:			
1–299	(869–056–00128–2)	50.00	July 1, 2005
300–399	(869–056–00129–1)	40.00	[7]July 1, 2005
400–End & 35	(869–056–00130–4)	61.00	July 1, 2005
36 Parts:			
1–199	(869–056–00131–2)	37.00	July 1, 2005
200–299	(869–056–00132–1)	37.00	July 1, 2005
300–End	(869–056–00133–9)	61.00	July 1, 2005
37	(869–056–00134–7)	58.00	July 1, 2005
38 Parts:			
0–17	(869–056–00135–5)	60.00	July 1, 2005
18–End	(869–056–00136–3)	62.00	July 1, 2005
39	(869–056–00139–1)	42.00	July 1, 2005
40 Parts:			
1–49	(869–056–00138–0)	60.00	July 1, 2005
50–51	(869–056–00139–8)	45.00	July 1, 2005
52 (52.01–52.1018)	(869–056–00140–1)	60.00	July 1, 2005
52 (52.1019–End)	(869–056–00141–0)	61.00	July 1, 2005
53–59	(869–056–00142–8)	31.00	July 1, 2005
60 (60.1–End)	(869–056–00143–6)	58.00	July 1, 2005
60 (Apps)	(869–056–00144–4)	57.00	July 1, 2005
61–62	(869–056–00145–2)	45.00	July 1, 2005
63 (63.1–63.599)	(869–056–00146–1)	58.00	July 1, 2005
63 (63.600–63.1199)	(869–056–00147–9)	50.00	July 1, 2005
63 (63.1200–63.1439)	(869–056–00148–7)	50.00	July 1, 2005
63 (63.1440–63.6175)	(869–056–00149–5)	32.00	July 1, 2005
63 (63.6580–63.8830)	(869–056–00150–9)	32.00	July 1, 2005
63 (63.8980–End)	(869–056–00151–7)	35.00	[7]July 1, 2005
64–71	(869–056–00152–5)	29.00	July 1, 2005
72–80	(869–056–00153–5)	62.00	July 1, 2005
81–85	(869–056–00154–1)	60.00	July 1, 2005
86 (86.1–86.599–99)	(869–056–00155–0)	58.00	July 1, 2005
86 (86.600–1–End)	(869–056–00156–8)	50.00	July 1, 2005
87–99	(869–056–00157–6)	60.00	July 1, 2005
100–135	(869–056–00158–4)	45.00	July 1, 2005
136–149	(869–056–00159–2)	61.00	July 1, 2005
150–189	(869–056–00160–6)	50.00	July 1, 2005
190–259	(869–056–00161–4)	39.00	July 1, 2005
260–265	(869–056–00162–2)	50.00	July 1, 2005
266–299	(869–056–00163–1)	50.00	July 1, 2005
300–399	(869–056–00164–9)	42.00	July 1, 2005
400–424	(869–056–00165–7)	56.00	[8]July 1, 2005
425–699	(869–056–00166–5)	61.00	July 1, 2005
700–789	(869–056–00167–3)	61.00	July 1, 2005
790–End	(869–056–00168–1)	61.00	July 1, 2005
41 Chapters:			
1, 1–1 to 1–10		13.00	[3] July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
3–6		14.00	[3] July 1, 1984
7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
10–17		9.50	[3] July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3] July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3] July 1, 1984
18, Vol. III, Parts 20–52		13.00	[3] July 1, 1984
19–100		13.00	[3] July 1, 1984
1–100	(869–056–00169–0)	24.00	July 1, 2005
101	(869–056–00170–3)	21.00	July 1, 2005
102–200	(869–056–00171–1)	56.00	July 1, 2005
201–End	(869–056–00172–0)	24.00	July 1, 2005
42 Parts:			
1–399	(869–056–00173–8)	61.00	Oct. 1, 2005
400–429	(869–056–00174–6)	63.00	Oct. 1, 2005
430–End	(869–056–00175–4)	64.00	Oct. 1, 2005
43 Parts:			
1–999	(869–056–00176–2)	56.00	Oct. 1, 2005
1000–end	(869–052–00175–9)	62.00	Oct. 1, 2004
44	(869–056–00178–9)	50.00	Oct. 1, 2005
45 Parts:			
1–199	(869–056–00179–7)	60.00	Oct. 1, 2005
200–499	(869–056–00180–1)	34.00	Oct. 1, 2005
500–1199	(869–056–00171–9)	56.00	Oct. 1, 2005
1200–End	(869–056–00182–7)	61.00	Oct. 1, 2005
46 Parts:			
1–40	(869–056–00183–5)	46.00	Oct. 1, 2005
41–69	(869–056–00184–3)	39.00	[9]Oct. 1, 2005
70–89	(869–056–00185–1)	14.00	[9]Oct. 1, 2005
90–139	(869–056–00186–0)	44.00	Oct. 1, 2005
140–155	(869–056–00187–8)	25.00	Oct. 1, 2005
156–165	(869–056–00188–6)	34.00	[9]Oct. 1, 2005
166–199	(869–056–00189–4)	46.00	Oct. 1, 2005
200–499	(869–056–00190–8)	40.00	Oct. 1, 2005
500–End	(869–056–00191–6)	25.00	Oct. 1, 2005
47 Parts:			
0–19	(869–056–00192–4)	61.00	Oct. 1, 2005
20–39	(869–056–00193–2)	46.00	Oct. 1, 2005
40–69	(869–056–00194–1)	40.00	Oct. 1, 2005
70–79	(869–052–00193–8)	63.00	Oct. 1, 2004
80–End	(869–056–00196–7)	61.00	Oct. 1, 2005
48 Chapters:			
1 (Parts 1–51)	(869–056–00197–5)	63.00	Oct. 1, 2005
1 (Parts 52–99)	(869–056–00198–3)	49.00	Oct. 1, 2005
2 (Parts 201–299)	(869–056–00199–1)	50.00	Oct. 1, 2005
3–6	(869–056–00200–9)	34.00	Oct. 1, 2005
7–14	(869–056–00201–7)	56.00	Oct. 1, 2005
15–28	(869–056–00202–5)	47.00	Oct. 1, 2005

Title	Stock Number	Price	Revision Date
29–End	(869–056–00203–3)	47.00	Oct. 1, 2005
49 Parts:			
1–99	(869–056–00204–1)	60.00	Oct. 1, 2005
100–185	(869–052–00203–8)	63.00	Oct. 1, 2004
186–199	(869–056–00206–8)	23.00	Oct. 1, 2005
200–299	(869–056–00207–6)	32.00	Oct. 1, 2005
300–399	(869–056–00208–4)	32.00	Oct. 1, 2005
400–599	(869–056–00209–2)	64.00	Oct. 1, 2005
600–999	(869–056–00210–6)	19.00	Oct. 1, 2005
1000–1199	(869–056–00211–4)	28.00	Oct. 1, 2005
1200–End	(869–056–00212–2)	34.00	Oct. 1, 2005
50 Parts:			
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17.1–17.95	(869–052–00211–9)	64.00	Oct. 1, 2004
17.96–17.99(h)	(869–056–00215–7)	61.00	Oct. 1, 2005
17.99(i)–end and 17.100–end	(869–056–00217–3)	47.00	Oct. 1, 2005
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200–599	(869–056–00218–1)	45.00	Oct. 1, 2005
600–End	(869–052–00216–0)	62.00	Oct. 1, 2004
CFR Index and Findings Aids	(869–056–00050–2)	62.00	Jan. 1, 2005
Complete 2006 CFR set		1,398.00	2006
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Complete set (one-time mailing)		325.00	2004

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 2004, through January 1, 2005. The CFR volume issued as of January 1, 2004 should be retained.

[5] No amendments to this volume were promulgated during the period April 1, 2000, through April 1, 2005. The CFR volume issued as of April 1, 2000 should be retained.

[6] No amendments to this volume were promulgated during the period April 1, 2004, through April 1, 2005. The CFR volume issued as of April 1, 2004 should be retained.

[7] No amendments to this volume were promulgated during the period July 1, 2004, through July 1, 2005. The CFR volume issued as of July 1, 2004 should be retained.

[8] No amendments to this volume were promulgated during the period July 1, 2004, through July 1, 2005. The CFR volume issued as of July 1, 2003 should be retained.

[9] No amendments to this volume were promulgated during the period October 1, 2004, through October 1, 2005. The CFR volume issued as of October 1, 2004 should be retained.