OFFICE OF INSPECTOR GENERAL

*Catalyst for Improving the Environment*

## Evaluation Report

# Decline In EPA Particulate Matter Methods Development Activities May Hamper Timely Achievement of Program Goals

**Report No. 2003-P-00016**

**September 30, 2003**

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**Abbreviations**

| | |
|---|---|
| EPA | Environmental Protection Agency |
| FRM | Federal Reference Method |
| GAO | General Accounting Office |
| OAQPS | Office of Air Quality Planning and Standards |
| OIG | Office of Inspector General |
| ORD | Office of Research and Development |
| PM | Particulate Matter |
| STAPPA/ALAPCO | State and Territorial Air Pollution Program Administrators/ Association of Local Air Pollution Control Officials |
| TSP | Total Suspended Particulates |

**Cover photo:** Ambient air monitoring station in Wilmington, Delaware (obtained from Delaware Department of Natural Resources and Environmental Control web site).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

September 30, 2003

**MEMORANDUM**

SUBJECT: Decline in EPA Particulate Matter Methods Development Activities May Hamper Timely Achievement of Program Goals
Report No. 2003-P-00016

FROM: J. Rick Beusse /s/
Director for Program Evaluation, Air Quality Issues

TO: Jeffrey R. Holmstead
Assistant Administrator for Air and Radiation (6101A)

Dr. J. Paul Gilman
Assistant Administrator for Research and Development (8101R)

Attached is our final report regarding the Environmental Protection Agency (EPA) Particulate Matter methods development activities. This report contains findings regarding the decline in methods development activities and how this decline may hamper timely achievement of program goals. Also, the report contains corrective actions the Office of Inspector General (OIG) recommends. This report represents the opinion of the OIG and the findings contained in this report do not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established procedures.

EPA's Office of Air and Radiation provided us with a response on September 29, 2003, that consolidated its comments to the draft report with those from the Office of Research and Development (ORD). We included the Agency consolidated response in its entirety as Appendix B. Independent of the Agency's consolidated response, ORD officials requested that we include its own response as a separate attachment. Although we believe the Agency's official consolidated response adequately reflects ORD's position, ORD officials requested that we include the transmittal memorandum as an attachment to our final report (see Appendix D.)

**Action Required**

In accordance with EPA Directive 2750, as the action official, you are required to provide this office with a written response within 90 days of the final report date. Since this report deals primarily with Office of Air and Radiation's Particulate Matter Program, the Assistant Administrator of the Office of Air and Radiation was designated the primary action official.

As such, he should take the lead in coordinating the Agency's response. The response should address all recommendations. For the corrective actions planned but not completed by the response date, please describe the actions that are ongoing and provide a timetable for completion. If you disagree with a recommendation, please provide alternative actions addressing the findings reported. We appreciate the efforts of EPA officials and staff, as well as external stakeholders, in working with us to develop this report. For your convenience, this report will be available at http://www.epa.gov/oig/

If you or your staff have any questions regarding this report, please contact me at (919) 541-5747 or Patrick Milligan, Assignment Manager, at (215) 814-2326.

# Executive Summary

## Purpose

Particulate Matter (PM) is a complex mixture of harmful solid and liquid particles found in ambient (outdoor) air. $PM_{2.5}$ – the smallest of the two types of regulated airborne particles – represents "fine" particles that are less than or equal to 2.5 microns in diameter, or about 1/30th the thickness of a human hair. In addition to $PM_{2.5}$, the Environmental Protection Agency (EPA) also regulates $PM_{10}$ particles less than or equal to 10 microns in diameter. Exposure to excess levels of PM can result in respiratory and other health-related illnesses and, in some cases, premature death. EPA estimates that, annually, over 15,000 deaths in the United States may be attributable to PM exposure.

A fundamental component in ensuring reliable, valid, and complete PM measurements is "methods development" – the process of developing, evaluating, and validating the methods and associated instrumentation for measuring PM in ambient air. These measurements are the first step in identifying those areas of the country where people are exposed to unhealthy levels of airborne particulate matter. Accordingly, our objectives were to answer the following:

- Has EPA supported $PM_{2.5}$ methods development activities to the extent necessary to achieve the short- and long-term goals of the $PM_{2.5}$ program?

- Are increased methods development activities needed to ensure the timely, cost-effective achievement of PM program goals?

## Results in Brief

EPA has not supported $PM_{2.5}$ methods development activities to the extent necessary to fully achieve the short- and long-range goals of the $PM_{2.5}$ program in a timely manner. The Agency is about 18 months behind schedule in obtaining sufficient $PM_{2.5}$ monitoring data needed to determine areas with excess $PM_{2.5}$ levels, also known as making attainment designations, although EPA is planning to reduce the delay to about 9 months. Once areas have been identified, State and local agencies can develop emissions control strategies describing the specific actions to be taken to bring these areas into attainment with the health-based $PM_{2.5}$ standard. Thus, the delay in obtaining sufficient ambient air data is one of several contributing factors that could result in millions of individuals being exposed to excess levels of PM longer than planned. Increased methods development activities are needed to address current monitor limitations and ensure that an appropriate PM monitoring network is in place to best enable State and local agencies to develop plans to effectively reduce excess levels. Also, increased methods development activities will be needed to address future PM monitoring needs, including supporting homeland security and enabling areas to meet future PM standards, such as the new PM "coarse" standard being developed.

A significant reason for delays in achieving PM program goals was a gradual and largely unintended decline in EPA's methods development activities related to PM over the last decade. According to Agency officials, the key factors that contributed to the gradual decline in $PM_{2.5}$ methods development included the loss of technical expertise due to retirements, a shift in Office of Research and Development priorities, and the lack of a comprehensive methods development strategy to guard against unintended decreases in methods development support. As a result, methods development activities need to be increased to ensure the timely, cost-effective achievement of PM program goals.

EPA is aware of the problems with measuring PM, and many in the Agency have worked diligently to correct those problems. Still, these problems increased State, local, and tribal agency labor costs and resulted in data from many $PM_{2.5}$ monitoring sites being lost, delayed, or determined to be unusable. Consequently, as the Agency moves forward, these delays may impact EPA's progress in reducing human exposure to unhealthy levels of PM.

## Recommendations

We recommend that the Assistant Administrator for Air and Radiation, in collaboration with the Assistant Administrator for Research and Development, develop a comprehensive methods development strategy for the PM program. We are also making recommendations to improve the development of cost effective monitoring methods for the impending PM "coarse" standard, maximize opportunities to support and enhance EPA's homeland security efforts, address current technology limitations, re-evaluate the current $PM_{2.5}$ data quality requirements, and take needed human capital actions.

## Agency Comments and OIG Evaluation

EPA's Office of Air and Radiation provided us with a response that consolidated its comments to the draft report with those from ORD. Although the Agency had some disagreement with certain issues and underlying causes, it agreed to implement all of our recommendations. We included the Agency consolidated response in its entirety as Appendix B. However, EPA did not agree that the Agency had not supported $PM_{2.5}$ methods development activities to the extent necessary to achieve the short- and long-range goals of the $PM_{2.5}$ program. Nonetheless, our work with external stakeholders, particularly States tasked with implementing the monitoring network, suggested otherwise. EPA also provided several technical clarifications and comments. We have made changes in the report as a result of the Agency's consolidated response, as appropriate. Our evaluation of the Agency's consolidated response is in Appendix C.

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# Chapter 1
## Introduction

### Purpose

Particulate Matter (PM) is the complex mixture of harmful solid and liquid particles found in ambient (outdoor) air. $PM_{2.5}$ represents fine particles that are less than or equal to 2.5 microns in diameter. Exposure to unhealthy levels of $PM_{2.5}$ can result in respiratory and other health-related illnesses and, in some cases, premature death. The Environmental Protection Agency (EPA) estimates that 15,000 deaths in the U.S. may be attributable to PM exposure annually.[1] Reliable, valid, and complete measurements of PM are essential to developing control strategies and gauging the success of Federal, State, local, and industry activities designed to protect human health. A key component in ensuring reliable, valid, and complete PM measurements is "methods development," the process of developing, evaluating, and validating the methods and associated instrumentation for measuring PM. The ambient air measurements generated using these methods are the first step in identifying those areas of the country where people are exposed to unhealthy levels of airborne particulate matter. Once these areas have been identified, State and local agencies can develop emissions control strategies describing the specific actions that industry and others must take to bring areas into attainment with the health-based $PM_{2.5}$ standard. The objectives of our evaluation were to answer the following:

- Has the EPA supported $PM_{2.5}$ methods development activities to the extent necessary to achieve the short- and long-term goals of the $PM_{2.5}$ program?

- Are increased methods development activities needed to ensure the timely, cost-effective achievement of PM program goals?

### Background

#### *What Is Particulate Matter?*

PM includes acids, metals, gases, and other harmful airborne substances that can be breathed into the lungs. PM particles include elemental carbon (soot) from diesel engines and wood combustion; sulfate formed from sulfur dioxide emissions from power plants and industrial facilities; nitrates formed from nitrogen oxide emissions from power plants, automobiles, and other types of combustion sources; and dust from roads. Some particles are large or dark enough to be seen as soot or smoke;

[1] In 2002, the World Health Organization estimated that as many as 500,000 deaths may be attributable to PM exposure annually worldwide.

others are so small they can only be detected with an electron microscope. These particles vary significantly by location. Fine particles between one-half and 2 microns may travel thousands of miles, while larger particles – 10 microns in size or larger – may only travel 100 miles or less. Very large particles (100 microns) may only travel a few hundred meters. Distances for all sizes are strongly dependent on meteorology, such as wind speed.

Since the early 1970s, EPA has been concerned about the adverse effects of PM on human health and the environment. The first airborne particles to be regulated were Total Suspended Particulates (TSP), which included a broad range of large and small particles. Today, EPA no longer monitors for TSP, but instead regulates several smaller-sized particles. While the larger TSP particles are kept from the lung tissues by impaction in the nose, throat, and larynx, smaller particles can slip past those body defenses and penetrate deep into the lungs. EPA regulates two categories of these smaller airborne particles, as shown in Table 1.1.

**Table 1.1: Types of Regulated Particulate Matter**

| Type * | Description | Date Regulated |
| --- | --- | --- |
| $PM_{10}$ | Particles less than or equal to 10 microns in diameter (about one-seventh the diameter of a human hair). | 1987 |
| $PM_{2.5}$ | "Fine" particles, which are less than or equal to 2.5 microns in diameter (about 1/30th the diameter of a human hair). | 1997 |

* A new PM standard – $PM_c$ (known as "coarse") – is being considered by EPA to apply to the fraction of PM between 2.5 and 10 microns. EPA's current schedule should provide for a proposal of this standard in late 2004 and a final standard in late 2005.

The newer category – $PM_{2.5}$ – was established as a National Ambient Air Quality Standard in 1997 as a result of a growing body of scientific evidence indicating that these fine particles are most damaging to health since they can penetrate the lung tissues easier and deeper. When breathed, particulate matter can accumulate in the respiratory system. Fine particulate matter is associated with such adverse health effects as heart and lung disease and increased respiratory disease, and symptoms such as asthma, decreased lung function, and even premature death. Sensitive groups that appear to be at greatest risk include the elderly, individuals with cardiopulmonary disease, and children. Also, PM is a major cause of reduced visibility, and adversely impacts vegetation and ecosystems.

EPA's short-term goal for the PM program is to determine which areas exceed EPA's standards and by how much. Longer term PM goals include: (1) identifying and characterizing emissions sources[2]; (2) developing State, local, and tribal control strategies; (3) gauging the success of Federal, State, local, tribal, and

[2]When referring to emissions sources, unless otherwise stated, we are also referring to the larger category of sources such as mobile, industrial, etc.

industry activities to protect human health; and (4) aiding in the Nation's homeland security efforts by early detection of selected biological and chemical terrorist attacks.

## What Are the Uses of Ambient PM Air Monitoring Data?

Ambient air monitoring systems are a critical part of the nation's air program infrastructure. Methods for measuring PM in the air are used to both set and implement the standards. The United States spends over $200 million annually on ambient air monitoring. Moreover, industry spends billions to implement emission reduction strategies. Ambient air monitoring data provide an important means of determining emission reduction progress and whether our nation is achieving its environmental goals. Ambient air monitoring data from PM monitors are used to make major decisions by stakeholders, including scientists, researchers, lawmakers, and the public. Some of the key uses of ambient PM air monitoring data are depicted in Table 1.2.

**Table 1.2: Key Uses of Ambient PM Air Monitoring Data**

| | |
|---|---|
| , | Characterize air quality and the associated health and ecosystem impacts |
| , | Establish air quality standards |
| , | Identify areas exceeding the air quality standards |
| , | Identify pollution sources |
| , | Activate emergency control procedures that prevent or alleviate air pollution episodes |
| , | Develop emission reduction and control strategies |
| , | Review/evaluate State Implementation Plans for reducing PM levels |
| , | Track Agency progress in reducing PM levels |
| , | Assist research efforts by providing more information about:<br>• composition; interaction; and sources of PM;<br>C level of PM concentrations that are considered harmful (dose);<br>C length of time people are in contact with PM (exposure); and<br>C source-to-dose pathways and the critical routes of exposure. |
| , | Support the Agency's short- and long-term planning through the use of air quality models to project the impact on air quality from implementation of new regulations and controls. |
| , | Support the Air Quality Index, which presents daily information on many harmful pollutants. The Air Quality Index may be found in various media, such as *USA Today* and the *Weather Channel*. |
| , | Enable EPA to report its progress to Congress and the public, in accordance with the Government Performance and Results Act and EPA's Goal 1, "Clean Air." |

In 1999, the EPA convened a "National Monitoring Strategy Committee" of representatives from EPA and state, local, and tribal agencies to take an overall assessment of the nation's air monitoring networks and make recommendations for improving network design. They developed a National Monitoring Strategy to re-shape the monitoring program to accommodate both national and local needs, improve information flow to the public, and incorporate new technologies and measurements.

### *What Is Methods Development?*

Because EPA has not yet developed a comprehensive definition of which activities comprise methods development, we identified key PM methods development activities through discussions with more than 50 internal and external stakeholders. According to these stakeholders, methods development is an integrated system for meeting the information and data needs of the many users of ambient air monitoring data. In particular, "methods development" is the process of developing, evaluating, and validating the methods and associated instrumentation for reliable, valid, and complete measurements of PM in ambient air. To achieve environmental data needs, the methods development process requires considerable time and highly-developed expertise since it includes: research and development; testing and analysis; operational demonstration to identify and validate state-of-the-art air sampling and measuring technologies; measurement against standards; and development of monitoring instrumentation. These activities are a key component for each type of PM regulated.

After the particular method and associated durable instrumentation is developed, it should be field tested (validated) to ensure it (1) meets specifications, (2) successfully operates under real world conditions, and (3) generates quality data that will meet the users' needs. Regarding the latter activity, EPA requires that environmental data meet the Agency's data quality objectives, wherein data must meet certain precision, accuracy, completeness, representativeness, and comparability parameters before users can make reliable decisions from the data. Ideally, the newly developed method should also collect and analyze data in the most cost-effective manner, taking into consideration life cycle costs such as operation and maintenance expenses.

### *What Is the Primary Monitor Used to Measure $PM_{2.5}$?*

The filter-based mass-only monitor is the Federal Reference Method (FRM) that EPA designated for use in measuring $PM_{2.5}$. When the $PM_{2.5}$ regulation was issued in 1997, it essentially prescribed the size particle that would be measured, the instrumentation that must be used, how the monitor must be operated, and the data quality objectives. State and local agencies must use this FRM method when gathering data to determine whether an area is in attainment of the $PM_{2.5}$ standard. Agency officials indicated that the development of a filter-based FRM was consistent with their scientific understanding of PM, the available technology, and the stringent requirements for methods performance that must be met to achieve the required health protection.

By drawing air across a teflon filter at a pre-determined flow rate, filter-based mass-only monitors collect $PM_{2.5}$ particles over a 24-hour period. Before each filter is placed in the monitor, the State or local agency must weigh it. Then, after 24 hours in the monitoring device, the exposed filter is taken to a laboratory, conditioned to account for humidity and other factors, and weighed again. The difference in the before and after weight of a filter represents the amount of $PM_{2.5}$

mass that gathered on the filter, and is an estimate of the amount of fine particulate matter that a person would breathe in a 24-hour period. According to the 2002 database provided by the Office of Air and Radiation's Office of Air Quality Planning and Standards (OAQPS), of the 2,033 $PM_{2.5}$ monitors nationwide, 1,616 were FRM filter-based mass-only monitors. The FRM filter monitors are used to identify those areas of the country where people are exposed to unhealthy levels of airborne particulate matter, and determine the extent that such levels exceed the $PM_{2.5}$ standard. The remaining monitors are used to help ascertain the source and composition of the harmful airborne PM.

### *How Many People Live in Areas That Exceed the $PM_{2.5}$ Standard?*

Although data limitations have slowed EPA progress in making non-attainment designations to date, the Agency has developed preliminary estimates of the designations for the United States. As shown in Table 1.3 below, as of January 2003, EPA estimated that at least one-third of the Nation's population lived in areas that would eventually be classified as exceeding the $PM_{2.5}$ standard.

**Table 1.3: EPA's Preliminary Estimates of $PM_{2.5}$ Designation Status**

| Designation Status | Estimated Population Affected | Estimated Percent of Population |
|---|---|---|
| Attainment | 56,000,000 | 20% |
| Non-attainment | 101,000,000 | 35% |
| Incomplete Data (status not yet determined) | 79,000,000 | 28% |
| Unclassified (no monitors; attainment assumed) | 49,000,000 | 17% |
| **Total** | **285,000,000** | **100%** |

## Scope and Methodology

To assess whether EPA has supported method development activities to the extent necessary to achieve the goals of the PM program, we reviewed numerous reports. We also discussed the PM program with more than 50 key stakeholders, from EPA, selected States and local agencies, equipment manufacturers, key industry organizations, key health and environmental organizations, and academics. Additionally, we observed a PM ambient air monitoring station that included various types of monitors, and also visited a laboratory responsible for analyzing $PM_{2.5}$ filters. We conducted this evaluation in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States. Additional details on our scope and methodology are in Appendix A. Our fieldwork was conducted from November 2002 to May 2003.

# Chapter 2
## Declining Methods Development Support Hampers Timely Achievement of Program Goals

EPA is about 18 months[3] behind schedule in obtaining sufficient $PM_{2.5}$ monitoring data needed to determine areas with excess $PM_{2.5}$ levels, also known as making attainment designations. However, EPA plans to make final designations by the end of 2004 which would reduce the delay from 18 months to about 9 months. State and local agencies encountered trouble operating about one-third of their monitors as they endeavored to obtain data on $PM_{2.5}$ levels in their areas. A significant reason for the problems encountered was a gradual and largely unintended decline in EPA's methods development activities related to PM over the last decade. EPA has been aware of the problems with measuring PM, and many in the Agency have worked diligently to correct those problems. Still, these problems increased State, local, and tribal agency labor costs and resulted in data from many $PM_{2.5}$ monitoring sites being lost, delayed, or determined to be unusable. Consequently, as the Agency moves forward, these delays may impact EPA's progress in reducing human exposure to unhealthy levels of PM.

## Unmet Data Needs Hampered Efforts

### *Identification of $PM_{2.5}$ Non-attainment Areas Delayed*

State and local agencies were to begin collecting 3 years of $PM_{2.5}$ air monitoring data in January 1999, with 3 years of data available by January 2002. Based on the data, areas were to be designated in either "attainment" or "non-attainment." An area is considered non-attainment if the $PM_{2.5}$ levels exceed the $PM_{2.5}$ standard.[4] Areas in non-attainment must comply with Federal regulations designed to protect public health and the environment, including the development and implementation of emissions control strategies to reduce emissions of fine particulate matter. Such efforts are costly and often take years to achieve program goals. EPA estimates compliance with $PM_{2.5}$ emissions control strategies will cost industry $37 billion annually by 2010. Therefore, the completeness, accuracy, and reliability of ambient monitoring data are critical.

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[3] Section 107 of the 1990 Clean Air Act required States to designate attainment upon promulgation of the $PM_{2.5}$ National Ambient Air Quality Standard. Recognizing the monitoring network first needed to be deployed to collect sufficient data, the 1998 Transportation Equity Act for the 21st Century allowed the States 3 years, until September 2001, to gather the data. However, a complete set of data was not available until July 2003.

[4] The $PM_{2.5}$ standard requires that the annual arithmetic mean be less than or equal to 15 micrograms per cubic meter of ambient air, and that the 98th percentile readings for peak concentrations over a 24-hour period be less than 65 micrograms per cubic meter of ambient air.

Because the FRM monitors were deployed between 1998 and 2000, the 3 years of data were staggered. Initially, EPA planned to make the first designations in 2002 and the last in 2005. However, EPA now does not plan to make the first designations until December 2004, as much as 18 months behind schedule. Consequently, the dates for when States in non-attainment would be required to submit State Implementation Plans detailing their control strategies, as well as when they would expect to be in an attainment status, were also delayed, as shown in Table 2-1.

**Table 2.1: Implementation of $PM_{2.5}$ National Ambient Air Quality Standard and Related Designation Process**

| Activity | Clean Air Act Required Dates | Current Estimated Dates |
|---|---|---|
| EPA Issues $PM_{2.5}$ National Ambient Air Quality Standard | 1997 | 1997 |
| 3 Years of $PM_{2.5}$ Data Available For Attainment Designations | 2001 | 2003 |
| EPA Designates $PM_{2.5}$ Non-attainment Areas | 2002 | 2004 |
| States Submit $PM_{2.5}$ Control Strategies | 2005 | 2007 |
| States Have Up to 5 Years To Meet $PM_{2.5}$ Standards (5-Year Extension Possible) | 2007-2012 | 2009-2014 |

## *Difficulties Encountered in Putting Monitoring Network in Place*

EPA experienced difficulty in implementing the $PM_{2.5}$ monitoring network, resulting in incomplete, missing, or inaccurate data. For example, from 1999 to 2001, equipment malfunction and start-up problems contributed to 439 of 1,202, or 37 percent, of the $PM_{2.5}$ monitoring sites failing to operate in one or more of the required 12 quarters (3 years). However, EPA officials believe that the issues and problems encountered by the States were not atypical for the deployment of a large network of new monitors across the country.

Public concern over the health effects of $PM_{2.5}$ sparked presidential and congressional directives to accelerate the $PM_{2.5}$ ambient air monitoring network implementation. As a result, EPA officials acknowledged that they hurried to implement the $PM_{2.5}$ filter-based mass-only monitoring network at a time when the Agency had experienced a decline in resources devoted to methods development activities, as well as a decline in methods expertise. Consequently, EPA did not fully develop several key aspects of planning, implementing, and maintaining the $PM_{2.5}$ network, resulting in: (1) limited $PM_{2.5}$ ambient air monitor options; (2) lack of sufficient field testing; and (3) monitors that were not properly installed, maintained, and operated.

**Limited $PM_{2.5}$ Ambient Air Monitor Options.** State officials told us that they had little involvement in the design and development of the $PM_{2.5}$ ambient air monitors that they were expected to use to implement the $PM_{2.5}$ network. They believed they should have been continually involved through the design, development, and selection of the new $PM_{2.5}$ method. Largely because of the decline in EPA's resources and expertise for developing new methods, filter-based mass-only monitors were the only viable option when ambient air monitoring implementation began in 1998. According to States, monitor manufacturers, and academics we contacted, had EPA invested more in methods development, the Agency would have had more choices regarding the types of monitors to deploy and more knowledge about how the $PM_{2.5}$ network should be configured.

Throughout most of the 1990s, ORD had been primarily responsible for developing the $PM_{2.5}$ standard and the associated monitoring methods. However, OAQPS was undergoing an effort to update and improve its ambient air data quality objectives at the same time that ORD was developing the $PM_{2.5}$ standard, yet the two offices did not coordinate their efforts. As a result of the tight timeframes and inadequate coordination, OAQPS officials said that the $PM_{2.5}$ standard imposed by EPA's FRM standard may have been too stringent in relation to the quality of data needed, and that this effectively precluded continuous $PM_{2.5}$ monitoring methods as a possible option for meeting the FRM equivalency determinations. OAQPS and ORD are re-evaluating the data quality objectives for $PM_{2.5}$. Such a modification could result in allowing certain $PM_{2.5}$ continuous methods to demonstrate that they meet the $PM_{2.5}$ data quality objectives and could be used in lieu of filter monitors. This would provide EPA with more flexibility in implementing its monitoring program and provide a wider array of more useful data.

**Lack of Sufficient Field Testing.** When a new monitoring method is developed, field testing is a vital step in ensuring that the monitor performs adequately under varied operating conditions before the network is fully deployed. EPA and monitor manufacturers indicated time constraints forced EPA to purchase and deploy filter-based mass-only $PM_{2.5}$ monitors without full and adequate field testing under real-world conditions. Consequently, malfunctions occurred that resulted in a loss of data. For example, monitors were only field tested in warm conditions, and some monitors malfunctioned in cold climates. A General Accounting Office (GAO) report[5] and our discussions with EPA personnel indicated insufficient field testing resulted in the following types of problems with one-third of the filter-based mass-only $PM_{2.5}$ monitors:

- Oil freezing and water condensation causing monitor malfunctions.
- Filter cassettes jamming in cold weather.
- Improper sealing on monitor access doors allowing dust into the monitor and contaminating the filter.

[5]GAO Report: Air Pollution - EPA's Actions to Resolve Concerns With the Fine Particulate Monitoring Program (August 1999, GAO/RCED-99-215).

- Monitor cooling fans pulling in dust-containing coarse material and other unwanted particles.
- New readings overwriting prior ones due to software malfunction.

Our discussions with over 50 stakeholders, including ambient air monitor manufacturers, environmental groups, industry associations, State and local agency officials, and EPA, suggested that a principal underlying reason such problems occurred related largely to the lack of continued investment in methods development activities by EPA.

**Monitors Not Properly Installed, Maintained, and Operated.** To maximize data quality and minimize post-deployment ambient air monitoring costs, written standard operating procedures need to be developed prior to monitor deployment. Due to limited resources and time constraints, EPA did not provide written standard operating procedures to State and local agencies prior to $PM_{2.5}$ monitor deployment. According to State and local agency officials contacted, such guidance would have helped ensure consistency in the operation of the monitors, provided direction on repairing mechanical malfunctions, and more fully explained how to handle filters before and after sampling. Because EPA did not prepare such procedures, many States developed their own, which resulted in inconsistencies in the data collected. Due to insufficient training and support from EPA, State and local officials said they struggled with the installation, operation, and maintenance of the new monitors, particularly at the outset. For example, they noted that:

- Insufficient troubleshooting instructions resulted in monitors needing to be shipped back to the manufacturer rather than be repaired on-site.
- EPA did not initially provide funding for spare parts and monitors.
- States had difficulty establishing weighing facilities to handle the massive influx of filters to be analyzed.

Operating in a reactive mode, EPA and State and local agencies corrected implementation problems as they arose. According to Agency officials, the deployment of the network was extremely challenging and EPA could not predict in advance the issues that arose. They also said that, taking into consideration the magnitude of the effort and the time frames allowed, they believe their deployment of the $PM_{2.5}$ network was quite successful. Still, the problems encountered increased State and local agency labor costs and resulted in data from many $PM_{2.5}$ monitoring sites being lost, delayed, or determined to be unusable.

## Several Factors Contributed to Decline in Methods Development

EPA's reduction in methods development activities was a gradual process that began in the early 1990s before the current $PM_{2.5}$ standard was implemented. Although most of the reduction was largely unintended, some was knowingly carried out. For example, the 1996 *Exit Strategy*[6] written by ORD and OAQPS described ORD's plans to provide less support to OAQPS in areas such as routine technical support to sustain the network and quality assurance/quality control work, activities that were related to methods development. However, there was general consensus among the many stakeholders we contacted that PM methods development warrants increased attention by EPA, not less. According to Agency officials, key factors that contributed to the gradual decline in $PM_{2.5}$ methods development included the loss of technical expertise due to retirements, a shift in ORD priorities, and the lack of a comprehensive methods development strategy. Details follow.

### *Attrition Resulted In Loss of In-House Expertise*

Agency officials said the loss of expertise has been occurring for years and will likely continue. Many current EPA employees began their careers when EPA was founded in 1970 and have reached retirement eligibility. EPA's problem of recruiting and retaining first-rate scientists was recently discussed in a January 2003 report by GAO, *Major Management Challenges and Program Risks*. ORD has recognized the loss of expertise and its impact on methods development activities, and has initiated efforts to overcome it. For example, ORD recently hired a national PM methods expert; has developed a hiring strategy with plans to double the methods development staff (from approximately four to eight individuals); and has implemented a Post Doctorate Program aimed at attracting and retaining young, qualified staff. However, we believe more needs to be done under a formal process. GAO's Human Capital guide, *"Human Capital: A Self-Assessment Checklist for Agency Leaders"* (GAO/OGC-00-14G), September 2000, provides guidance that could help EPA managers improve their human capital systems, including hiring, retention, and succession planning.

### *ORD Priorities Shifted to Other PM Research*

Many stakeholders described how ORD personnel moved toward research and away from the routine tasks associated with sustaining the air monitoring network and developing new methods. In 1997, ORD found that airborne fine particulate matter was much more of a health hazard than previously thought, and ORD's priorities shifted to conducting more fine particulate matter research, partly at the expense of methods development. Agency officials said that a decline in expertise also contributed to the decision to shift focus because it became increasingly challenging to carry out existing duties with the continual loss of expertise. Another cause for ORD's shift to more traditional research activities, at the unintended expense of the Agency's methods development efforts, were the results of the National Research Council's

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[6]November 1996, NERL/ORD Exit Strategy - Quality Assurance Support To OAQPS/OAR (Document is a description of decreased quality assurance support provided by ORD to OAQPS).

independent assessment of EPA's fine particulate matter research efforts. The Council made 10 recommendations emphasizing the need for more and better research on PM health effects as they relate to risk, dose, and exposure to fine particulate matter. Also, as part of performing this needed research, the Council cited the need for increased methods development activities by EPA to develop new and improved monitoring instrumentation. However, the Council's more resounding message, as interpreted by EPA officials, was the need to increase $PM_{2.5}$ research to better understand the relationship between fine particulate matter exposure and human health.

### *Comprehensive Methods Development Strategy Lacking*

EPA does not have a system or process that clearly defines the essential activities that comprise PM methods development, nor is there an explicit mechanism for determining whether these activities are performed at a sufficient level. A comprehensive methods development strategy would ensure that methods activities are clearly defined and tracked, increase the likelihood that needed activities are properly funded, and guard against unintended decreases. Although there was no comprehensive methods development strategy, we were able to identify through extensive interviews and research some of EPA's key methods development, shown in Table 2.2.

**Table 2.2: Key Methods Development Activities**

| Activities |
|---|
| , Pro-actively Researching New Monitoring Techniques and Instrumentation |
| , Identifying Users of the Data and Assessing Their Needs |
| , Developing Standards and Associated Methods |
| , Designing Instrumentation and Sampling Protocols |
| , Field Testing/Validating Instrumentation |
| , Modifying Methods, Instrumentation, and Sampling Protocols |
| , Configuring Network |
| , Deploying and Installing Instruments |
| , Operating, Maintaining, and Supporting the Network |
| , Re-assessing Networks and Seeking Improvement |

Both OAQPS and ORD officials agree that the activities listed above are vital to successfully supporting the Agency's PM monitoring program, and acknowledge that there were unintended reductions in the support for these activities that adversely impacted the $PM_{2.5}$ program. We also noted that EPA's methods development activities for PM were not tracked as a separate budget line item, which may have contributed to the decline in its emphasis. We believe such tracking is needed to adequately monitor the program. Further, even though there have been budget increases for PM research since

1997, ORD and OAQPS confirmed that the additional funding did not go toward methods development. The Government Performance and Results Act of 1993 intended for Federal programs to link resources to activities that produce results, and the Office of Inspector General and others have identified EPA's difficulty in linking mission to management as a key management challenge.[7]

## Conclusions

Methods development activities are a fundamental component in EPA's efforts to ensure that $PM_{2.5}$ ambient monitors produce reliable, valid, and complete data on environmental conditions. We found that a significant reason that problems occurred in operating many of the $PM_{2.5}$ monitors was due to the Agency's unintended reductions in the support for PM methods development activities. EPA has worked diligently to correct problems, and the Agency expects to have sufficient data to make non-attainment designations by December 2004. However, EPA needs new and different $PM_{2.5}$ monitors to meet its goals. To achieve better results from these future $PM_{2.5}$ air monitoring efforts and other PM program goals, the Agency should develop a comprehensive strategy that would ensure that methods development activities are clearly defined and tracked, and properly funded.

## Recommendations

We recommend that the Assistant Administrator for Air and Radiation, in collaboration with the Assistant Administrator for Research and Development:

2-1. Develop a comprehensive PM methods development strategy that:

(a) identifies the methods development activities critical to meeting the Agency's short- and long-term PM program goals;
(b) ensures that these PM methods activities are clearly defined, tracked, and appropriately funded;
(c) defines the roles and responsibilities of the EPA offices responsible for conducting PM methods development activities; and
(d) guards against any unintended decrease in PM methods activities, including the impact of lost program expertise through retirement or career transition.

2-2. Use the EPA data quality objectives process to re-evaluate the $PM_{2.5}$ program's data quality objectives and the associated $PM_{2.5}$ ambient air

[7]EPA's Progress in Using the Government Performance and Results Act to Manage for Results [EPA-OIG 2001-B-000001], June 13, 2001; Audit of EPA's Fiscal 2000 Financial Statements [EPA-OIG 2001-1-00107], February 28, 2001. EPA - Major Management Challenges and Program Risks [GAO-01-257], January 2001.

monitoring methods requirements, and ensure that both are appropriate to achieve the short- and long-term goals of the program.

We also recommend that the Assistant Administrator for Research and Development:

2-3. Include in the ongoing revisions to ORD's Human Capital Strategy explicit measures to minimize the impact of losing PM methods development expertise, and that ORD use GAO's Human Capital guide, "Human Capital: A Self-Assessment Checklist for Agency Leaders," to help managers improve their human capital systems, particularly for hiring, retention, and succession planning.

## Agency Comments and OIG Evaluation

EPA made detailed comments to our draft report and, where appropriate, we made revisions. The Agency generally agreed with the recommendations in this chapter. With respect to Recommendation 2-1, the Agency supported the recommendation to develop a comprehensive methods development strategy, but commented that a strategy that focuses on $PM_{2.5}$ is too narrow. We agree, and are now recommending that EPA develop a comprehensive particulate matter strategy. The Agency's consolidated response and our evaluation of that consolidated response are in Appendices B and C, respectively.

# Chapter 3
## Limitations of Existing PM Monitors Need To Be Addressed By Increasing Methods Development Activities

EPA has not ensured that an appropriate monitoring network is in place to best enable States and local agencies to develop plans to effectively reduce excess levels of PM. Increased methods development activities will be needed to address future PM monitoring needs, such as supporting homeland security and enabling areas to meet future PM standards. For example, EPA is preparing to develop a new PM coarse ($PM_C$) standard in 2004, and EPA is working with the Department of Homeland Security to develop a continuous ambient air monitoring method capable of identifying a biological or chemical attack. Manufacturers and others told us that EPA will need to increase its support of PM methods development activities, improve its efforts to involve external stakeholders early in the methods development process, and do more to enhance the development of alternative PM monitors if earlier problems experienced in the $PM_{2.5}$ program are to be avoided as the Agency mobilizes to meet these other PM program goals.

### Use of Other Monitor Types Should Be Considered

Each type of PM monitor serves a valuable purpose, including the filter-based mass-only monitor used as the approved FRM $PM_{2.5}$ standard to protect public health. However, Agency officials said that all of the types of PM monitors need improvement. Many of the stakeholders we contacted said EPA needs to work with industry/manufacturers to improve the present limitations of PM monitors in three areas – monitor capability, data collection frequency, and cost. Using the Clean Air Scientific Advisory Committee process would provide the appropriate framework for such a government-industry partnership, ensuring that such activities are transparent to all interested and affected parties, and that such parties have an opportunity to provide input into the process.

Filter-based mass-only monitors are the primary type of monitors being used to measure PM, but many of the stakeholders we contacted said two other types of PM monitors show promise, although they also have limitations. Both types – continuous mass monitors and speciation monitors – are available and have been used to develop certain types of PM data for specific applications. A general description of each is in Table 3.1.

**Table 3.1: Two Alternate Types of PM Monitors**

| Type | Description |
|---|---|
| **Continuous Mass Monitors** | Unlike the filter monitor, which measures the weight of a filter after a 24-hour period and compares it to its weight prior to sampling, a continuous mass monitor analyzes and records the *concentration* of the particulate matter that pass through the sampling chamber, and then mathematically calculates the mass of the particulate matter. No filter handling is involved, nor is there a need for subsequent laboratory analysis. These monitors can record PM data as frequently as every 5 minutes, but usually do so in 1-hour increments. Different continuous monitors may use different analytical techniques, depending on what is being measured. For example, to analyze for sulfates a flame ionization analytical technique may be used, while for nitrates a chemiluminescence analytical technique may be used. |
| **Speciation Monitors** | Speciation monitors identify the *make-up* of the particulate matter, which is necessary to trace the sources of pollution and to better understand health effects of the particulate matter. These monitors generally use several different inlet tubes and several different filters (nylon, teflon, quartz) to collect suspected harmful components of the PM mixture, such as acids, metals, or organic carbon. The filters are analyzed in a laboratory using many of the same analytical techniques discussed above. Speciation data are critical to determining the toxicity of the particulate matter and developing pollution abatement strategies. Most chemical speciation monitors are filter-based, but EPA is experimenting with continuous speciation instruments. |

Table 3.2 below illustrates some of the strengths and limitations of the basic PM monitor types currently in use. [Note: Check mark (**T**) indicates monitor strengths; no check mark indicates a monitor limitation.]

**Table 3.2: Strengths and Limitations of Basic Types of PM Monitors**

| Attribute | Filter-Based Mass | Continuous Mass | Filter-Based Speciation[1] | Continuous Speciation[2] |
|---|---|---|---|---|
| Used for Designations | **T** | Potential | | |
| Least Expensive Capital Cost | **T** | | | |
| Minimal Operational/Life Cycle Costs | | | | **T** |
| Identifies pollution source and PM composition | | | **T** | **T** |
| Real time data | | **T** | | **T** |
| Filter can be stored (historical record) | **T** | | **T** | |
| Supports mapping/modeling | Minimal | **T** | **T** | **T** |
| Supports health research | Minimal | **T** | **T** | **T** |
| Identifies PM levels during day | | **T** | | **T** |
| Air Quality Index | | **T** | | |

1/ Filter-based speciation monitors measure PM constituents by weight in a specified period of time.
2/ Continuous speciation monitors measure PM constituents by concentration at continual specified intervals.

All current PM monitors, including the $PM_{2.5}$ FRM mass-only monitors, have a limitation related to volatility (evaporation) for nitrates and some organics. When temperatures rise, the nitrate or organic portion of the particulate matter may volatilize, thus understating the amount of $PM_{2.5}$ in the air. Monitors that rely on filters require that filters be refrigerated after collection to avoid some of this, but in high nitrate areas, volatilization still occurs. For continuous monitors, the instruments actually heat the sample to remove moisture from the particulate matter for a more reliable, valid, and complete measurement; however, this heating process causes some degree of volatilization. While volatilization may never be entirely eliminated, attempts are being made to minimize the impact of this process on continuous measurements.

It should be noted that cost plays a factor in determining which PM monitors to use. As shown in Table 3.3, capital costs of $PM_{2.5}$ monitors can range from \$11,000 to \$85,000, and annual operating costs from \$8,000 to \$53,000.

**Table 3.3: Cost to Purchase and Operate $PM_{2.5}$ PM Monitors**

| Monitor Type | Estimated Costs | |
|---|---|---|
| | Capital | Annual Operation and Maintenance |
| Filter-Based Speciation | \$20,000 | \$53,000 |
| Filter-Based Mass | \$11,000 - \$14,000 | \$20,000 - \$35,000 |
| Continuous Speciation (nitrate, sulfate, and carbon) | \$85,000 | \$20,000 |
| Continuous Mass | \$20,000 | \$8,000 |

The filter-based mass-only equipment has the lowest initial cost but requires more operation and maintenance resources because it is labor intensive (collection and analysis) and requires frequent material replacement (a new filter every 24 hours).

### *Advanced Monitors Are Needed to Effectively Reduce PM Levels*

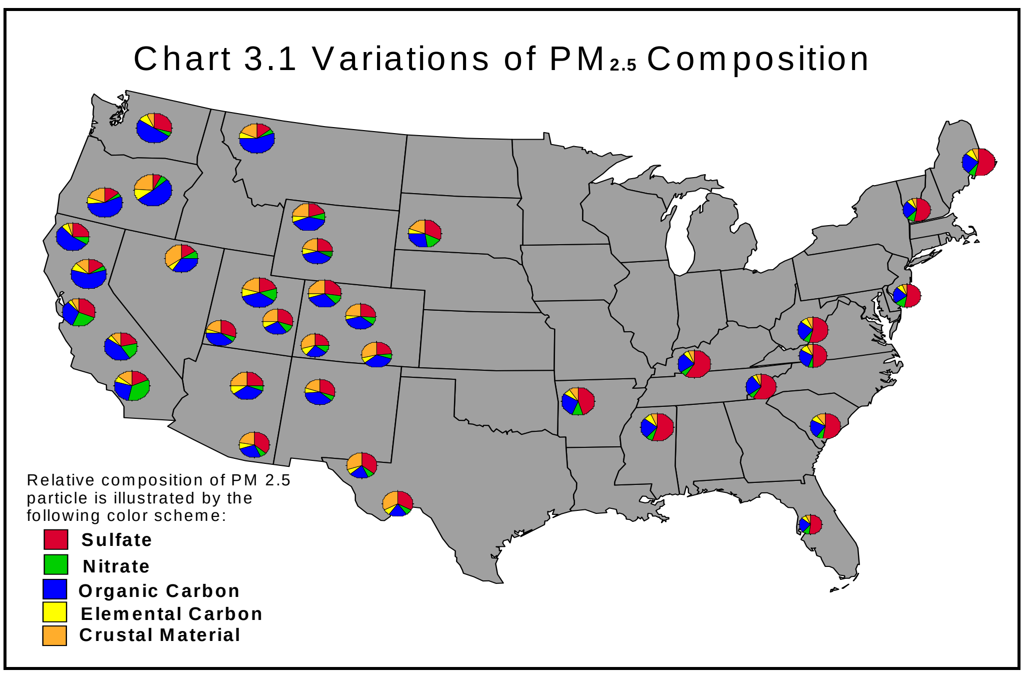
EPA recognizes the need for other types of monitors if it is to achieve its PM program goals. For example, according to ORD's September 2001 Draft Multi-year Plan for Particulate Matter Research:

> *Methodology must be developed for continuous and more accurate measurements of PM mass and components such as nitrates, metals, and organic and elemental carbons. This methodology will then be applied to specific PM characteristics which toxicology studies indicate may be responsible for adverse health effects.*

Monitor manufacturers and State and EPA officials that we contacted agreed that existing monitors need to be modified and new monitors created if EPA is to meet the other needs for PM data. Many also believed continuous mass and continuous speciation monitors are among the most promising near-term technologies, although Agency officials stated that much more research is needed. OAQPS' National Monitoring Strategy recommends the replacement of 50 percent of $PM_{2.5}$ filter-based monitors with continuously operating ones, and notes network assessments should be used to determine whether goals and objectives are being met in the most efficient way. EPA will need to ensure that all PM methods fully address data needs for both short- and long-term goals of all PM programs and that, prior to implementation, the proposed methods are peer reviewed.

Also, although the filter-based mass-only monitoring network is close to obtaining the required 3 years of data for achieving the short-term goal of making attainment designations, the network will need to include the capacity to determine particulate matter origin and composition on a national, regional, and local basis to effectively measure its progress in achieving longer term goals. To determine where pollution is coming from, States must identify the sources of $PM_{2.5}$ and the extent to which each source contributes to the overall levels. Currently, over 93 percent (1,891 of 2,033) of EPA's $PM_{2.5}$ ambient air monitoring network consists of monitors that only measure particulate matter mass, with less than 7 percent (142[8] of 2,033) obtaining data on particulate matter composition and origin. In its $PM_{2.5}$ Implementation Plan, EPA said 300 speciation monitors – more than double the number presently deployed – would be needed to obtain data on the composition and origin of $PM_{2.5}$.

Generally, $PM_{2.5}$ consists of five substances: sulfate, nitrate, organic carbon, elemental carbon, and crustal material. However, the composition of a particulate matter differs in various parts of the country. For example, particulate matter in the eastern half of the country is comprised mainly of sulfate, while particulate matter in the northwest consists primarily of organic carbon. Therefore, it is important for States to know the specific composition of $PM_{2.5}$ in its area so that it can take the most appropriate corrective actions. Particulate matter composition also influences the type of monitor needed. Chart 3.1 shows how the composition of $PM_{2.5}$ particles varies across the continental United States.




Source - OIG-developed chart based on data obtained from
*EPA's 1999 National Air Quality and Emissions Trends Report.*

[8]The 142 speciation monitors are based on information provided by OAQPS in January 2003.

After an area is designated non-attainment, States will develop and submit for EPA approval their State Implementation Plans describing the actions that will be taken to bring areas into attainment with the $PM_{2.5}$ standard. Among other things, the State's Implementation Plan should: (1) identify the $PM_{2.5}$ sources and the levels contributed by each source; (2) develop, implement, and enforce new controls on the $PM_{2.5}$ sources targeted; and (3) determine the level of reductions needed to bring an area into attainment within required milestones.

Volume 1 of a four-volume National Research Council Report recommended that EPA first identify the particular components of PM and conduct studies to understand human exposure and health effects of PM. EPA's response to this report is essentially embodied in ORD's Multi-Year Plan for PM which described the goals and targets of the PM program. Volume 3 of the National Research Council report calls for EPA to increase its methods development activities to better understand particulate matter composition and its impact on health. The Council stated that EPA's filter-based mass-only monitors provide limited data and are not sufficient to address this increased need for health effects data. Four of the Council's 10 recommendations cited the need for more and improved speciation data to better understand the composition of the particulate matter and to what extent the public is at risk. EPA officials noted that while ORD was redirecting some internal resources to respond to the National Research Council report, overall EPA investment in methods work was being augmented by the Supersites Program. One of the objectives of this program is to develop and test measurement methods.

### *New Monitors Needed for $PM_c$ Program Efforts*

ORD and OAQPS are considering the need for a $PM_C$ "coarse" standard for particulate matter between 2.5 microns and 10 microns in diameter. EPA's schedule provides for a proposal in late 2004 and a final standard in late 2005. EPA plans for the $PM_C$ standard and the associated ambient air monitors to replace the current $PM_{10}$ standard and associated monitors. Manufacturers told us EPA will need to increase its support of PM methods development activities, improve its efforts to involve them and other external stakeholders early in the methods development process, and do more to foster the development of alternative PM monitors. EPA will also need to ensure that the methods fully address data needs for both the short- and long-term goals of the $PM_C$ program and that, prior to implementation, the proposed methods are peer reviewed.

EPA officials said there are numerous instruments capable of measuring $PM_C$, and ORD is conducting field test studies on these instruments. There are numerous viewpoints on which monitoring method should be defined as the FRM for $PM_C$. Some officials believe that existing monitors can be modified, while others believe a new monitor must be developed to measure coarse exclusively. Further, some believe a monitor must be developed to measure $PM_{2.5}$ and $PM_C$ simultaneously. Some officials believe a mass weight standard like $PM_{2.5}$ should be used to identify *how much* coarse particulate matter is in the air, while others believe EPA should regulate by composition, to identify *what* the toxic components are. To avoid some of the problems encountered while implementing the $PM_{2.5}$ standard, EPA, State, and local agencies, and monitor manufacturers agree that the Agency needs to take a more proactive approach to developing and implementing the $PM_c$ standard.

### *Support of Homeland Security Also Requires Increased Efforts*

The terrorist attacks of September 11, 2001, and the subsequent anthrax releases expanded EPA's mission, to include working with other Federal agencies in protecting our country against the environmental and health consequences of terrorist acts. Details of EPA's homeland security responsibilities are described in EPA's September 2002 *Strategic Plan for Homeland Security*. One of EPA's primary roles will be providing technical expertise to identify the threat of biological, chemical, radiological, and other terrorist attacks, as well as responding to and recovering from such attacks. EPA's expanded homeland security responsibilities further demonstrate the need for increased activity in PM methods development.

One of the homeland security goals is for EPA to work closely with other Federal and State agencies to identify useful information already available. Under air protection, a key source of information will be the data collected from the Agency's existing ambient air monitoring network. EPA is responsible for ensuring that its existing monitoring expertise, standards, capabilities, and data are appropriately integrated into the Agency's efforts to detect terrorist threats. The Agency is also to make historic data available to determine trends and background levels that will aid in establishing baselines for detection. Monitoring data may also provide a means of detecting anomalies in the ambient air that would indicate further analysis is warranted. The existing ambient air monitoring network will be valuable because there already exists an infrastructure of monitoring platforms, electricity, and land. In addition, EPA has an established working relationship with State and local agencies that should expedite efforts to develop a monitoring network for homeland security purposes.

OAQPS officials said their goal is to develop a continuous ambient air monitoring method that would result in real-time information for identifying a biological or chemical attack. This network, in combination with other Agency activities, would aid in tracking any plume of contamination and help to minimize exposure risks. Agency officials said that the PM network, designed to detect and measure various size particles found in the air, may aid in efforts to detect and measure bio-agents. For example, anthrax spores, which typically range in size from 2 to 6 microns, are potentially within the range of particles that EPA measures with its PM monitors. However, the current network does not provide data timely enough to readily detect terrorist attacks, and speciation data takes longer to obtain.

EPA is currently evaluating many types of PM monitors and exploring potential options for how monitors can help with homeland security efforts. In the event of a national incident, EPA is the lead agency responsible for decontaminating affected areas and determining when it is safe to return. To do so, EPA needs to enhance the deployable component of its emergency response air monitoring efforts to quickly transport mobile/non-stationary monitors to contaminated areas.

## Conclusions

Monitor manufacturers, State, and EPA officials we contacted said that existing monitors need to be modified and new monitors created if EPA is to meet the other needs for PM data, such as the Agency's expanded homeland security responsibilities since September 11. Presently, the Agency's monitors do not provide information timely enough to readily detect terrorist attacks. However, because of the costs associated with developing new monitoring methods and the associated instrumentation, manufacturers said EPA will have to take a greater leadership role in the development of such monitors, including methods development. As EPA moves to develop monitors for addressing longer-term data needs, insufficient attention to methods development activities not only presents a risk that there will be lost or unusable data and increased operating costs, but also a risk that industry will be faced with unnecessary or overly stringent compliance costs. With billions of dollars in estimated annual costs of compliance to industry, EPA should ensure that the Agency's data quality objectives process is strictly followed in establishing the $PM_c$ FRM for the PM coarse standard, keeping in mind that methods that are too stringent impose unnecessary costs and methods that are too lenient and jeopardize data quality.

## Recommendations

We recommend that the Assistant Administrator for Air and Radiation, in collaboration with the Assistant Administrator for Research and Development:

3-1. Establish a government-industry partnership that facilitates an objective assessment of PM measurement issues that need to be addressed to improve PM ambient monitoring capability and data collection frequency at less cost, and that provides for transparency and openness to the public.

3-2. Enhance the development of cost-effective methods for addressing $PM_C$ program goals by:

- (a) ensuring that the shortcomings of the $PM_{2.5}$ implementation process will not be repeated;
- (b) using the EPA data quality objectives process to develop the $PM_C$ standard planned for 2004 and the associated ambient air monitoring requirements, and ensuring that both are appropriate to achieve the short- and long-term goals of the $PM_C$ program;
- (c) ensuring sufficient stakeholder involvement in developing the most promising and cost effective monitors for addressing $PM_C$ program goals; and

(d) ensuring that the proposed methods are externally peer reviewed prior to implementation.

3-3. Maximize opportunities for utilizing current and newly developed monitors to support and enhance EPA's Homeland Security efforts.

## Agency Comments and OIG Evaluation

EPA made detailed comments to our draft report and, where appropriate, we made revisions. The Agency generally agreed with the recommendations in this chapter. With respect to Recommendation 3-1, the Agency did not agree that using the Federal Advisory Committee Act would be the best approach to establishing a government-industry partnership. EPA believed that using the Clean Air Scientific Advisory Committee process would be a suitable alternative. We agree that our draft recommendation would have unnecessarily restricted EPA's options for improving PM monitoring methods, and we have modified our recommendation to reflect this. The Agency's consolidated response and our evaluation of that response are in Appendices B and C, respectively.

# Details on Scope and Methodology

To assess whether EPA has supported methods development activities to the extent necessary to achieve the short- and long-term goals of the $PM_{2.5}$ program, we reviewed numerous reports about the goals, objectives, and needs of the $PM_{2.5}$ program, including the EPA's *National Ambient Air Monitoring Strategy*; the National Research Council's *Research Priorities for Airborne Particulate Matter Volumes I, II, and III;* EPA's *Third External Review of Air Quality Criteria for PM*, and EPA's *1996 Exit Strategy*, written by the ORD and OAQPS. We also reviewed a prior GAO report, *EPA's Actions to Resolve Concerns With the Fine Particulate Monitoring Program* (GAO/RCED-99-215), March 1999. This GAO report addressed problems encountered by State and local agencies when deploying the $PM_{2.5}$ filter-based mass-only monitoring network.

Additionally, to understand how various PM monitors are operated and maintained, and how and what type of information is collected, we observed a PM ambient air monitoring station in Wilmington, Delaware, equipped with several types of PM monitors, including one or more of the following: (a) TSP monitor, (b) $PM_{10}$ filter-based monitor, (c) $PM_{2.5}$ filter-based mass-only monitor, (d) $PM_{2.5}$ continuous mass monitor, and (e) $PM_{2.5}$ speciation filter-based mass monitor. To understand the $PM_{2.5}$ laboratory and analytical processes, we observed a Philadelphia, Pennsylvania, Department of Health laboratory responsible for analyzing $PM_{2.5}$ filters.

To gain an understanding of the $PM_{2.5}$ monitoring network and the role methods development plays, we conducted interviews with 51 stakeholders. The following table provides information on interviews conducted, and details on each type of stakeholder follow.

| | Interviewees | No. |
|---|---|---|
| **Internal Interviews** | ORD | 9 |
| | OAQPS | 7 |
| | EPA Regional Offices | 7 |
| **External Interviews** | State and Local Air Protection Agencies | 9 |
| | Air Monitor Manufacturers | 6 |
| | Health/Environmental Groups | 3 |
| | Industrial Groups | 3 |
| | Academia | 3 |
| | Air Associations | 2 |
| | Other Federal Agencies | 2 |
| **Total** | | 51 |

The manufacturers of the monitoring equipment are key players in the monitoring program. Therefore, we contacted the four main vendors that provided EPA with monitors for the $PM_{2.5}$ program, and two additional smaller vendors for their viewpoints. The six manufacturers were:

- BGI, Inc.
- Met One, Inc.
- Rupprecht & Patashnik Co., Inc.
- Thermo Andersen, Inc.

- Tisch Environmental, Inc.
- URG, Inc.

We interviewed representatives from three health/environmental groups that have been actively involved in the PM program:

- American Lung Association, which funds scientific research on lung diseases.
- Resources for the Future, which performs research related to improving air quality.
- Natural Resources Defense Council, which works to strengthen and enforce the Clean Air Act.

We interviewed representatives from three key industrial organizations groups that have been actively involved in the PM program and will likely have constituent members that may be economically impacted by PM attainment designations:

- American Chemistry Council, which represents leading companies in the chemistry industry.
- American Petroleum Institute, which is doing research on PM.
- National Association of Manufacturers, the nation's largest industrial trade association.

Because academia is in the forefront of exploratory research in the area of air monitoring instrumentation, we interviewed scientists from three universities involved in PM research:

- University of Delaware
- University of Maryland
- University of Southern California.

We interviewed the Chairman of the Clean Air Science Advisory Committee subcommittee on fine particulate matter; representatives from the State and Territorial Air Pollution Program Administrators/ Association of Local Air Pollution Control Officials (STAPPA/ALAPCO); and the Lake Michigan Air Directors Consortium. We also interviewed personnel at the Department of Energy and the National Oceanic and Atmospheric Administration.

As the implementers of the $PM_{2.5}$ network, State and local air pollution control agencies are critical to the success of the network. We used a structured interview to discuss with these groups the issues and challenges associated with the PM network. We interviewed officials from a total of eight State agencies and one local agency, as well as their corresponding EPA region, to obtain their input and views of the PM air monitoring network. We did not evaluate any of the State or local ambient air monitoring programs' performance as part of these interviews. A table of the State and local agencies and their corresponding regions follows.

| | Agency | Region |
|---|---|---|
| **State** | New York Department of Environmental Conservation | 2 |
| | Pennsylvania Department of Environmental Protection | 3 |
| | South Carolina Department of Health and Environmental Control | 4 |
| | Mississippi Department of Environmental Quality | 4 |
| | Illinois Environmental Protection Agency | 5 |
| | Ohio Environmental Protection Agency | 5 |
| | Texas Commission on Environmental Quality | 6 |
| | California Air Resources Board | 9 |
| **Local** | Puget Sound Clean Air Agency (in Washington State) | 10 |

We solicited input from OAQPS, Region 3, STAPPA/ALAPCO, and States regarding the State and local agencies we should contact, but we independently made our selection after giving careful consideration to the input received. We considered the following items (listed in order of importance) when selecting the nine organizations:

- **Number of people estimated to be living in counties expected to be in non-attainment for $PM_{2.5}$.** The six larger States selected had 53 of the 179 counties (30 percent) expected to be in non-attainment for $PM_{2.5}$. Those 53 counties had an exposed population of 52 million, which represents 63 percent of the country's exposed population.

- **Number of PM monitors in each State: filter-based mass-only, continuous, and speciation.** We looked for States with the largest and more mature networks, taking into account those agencies monitoring the air quality with various types of instruments. The six larger States that we selected operated 27 percent of the filter-based mass-only $PM_{2.5}$ network, 35 percent of the continuous mass monitors, and 27 percent of the speciation monitors.

- **Levels of $PM_{2.5}$ concentrations detected from filter-based mass-only monitors.** We reviewed the 1999 levels of PM nationwide from the filter-based mass-only monitors. States with higher concentrations were considered.

- **Levels of $PM_{2.5}$ emissions reported to EPA.** We reviewed the States' emissions inventories, and considered those areas with higher emissions. Six of the States we selected reported a total of 203,000 tons of emissions in 1999. This represents 30 percent of the 673,000 tons of emissions nationwide.

- **Coverage of various EPA Regions.** For the 9 State and local agencies selected, 7 of the 10 EPA regions were represented.

- **Representation of various parts of the United States.** In order to account for varying geographical and meteorological conditions, we covered six geographic areas of the country: Northeast, North Central, Northwest, Southeast, South Central, and Southwest.

- **PM Constituents.** We identified the five main components of $PM_{2.5}$ (sulfate, nitrate, organic carbon, elemental carbon, and crustal material). The States selected support adequate representation of the various PM constituents.

- **Recommendations of State selections by OAQPS, Region 3, STAPPA/ALAPCO, and States.** An OAQPS official suggested we consider talking to one or two States with smaller networks and less resources. They explained that the "big" States usually have large budgets and more staff to handle new requirements imposed upon them. Our sample includes two such "smaller" States: Mississippi and South Carolina.

We selected California, Illinois, Ohio, Pennsylvania, New York, and Texas on the basis that they were ranked highest in exposed population, size of monitor network, highest $PM_{2.5}$ concentrations, and $PM_{2.5}$ emissions. In addition, these States provided a diverse representation for EPA regional coverage, geographic sections of the country, and variety of PM constituents.

Mississippi, a smaller State, provides representation in Region 4 and the Southeast. Additionally Mississippi was ranked toward the middle in exposed population, network size, and emissions. South Carolina was average in population, monitor network size, and emission levels, and was fairly high in $PM_{2.5}$ concentration level. Thus, it represents a smaller State with a mature network and a fairly significant $PM_{2.5}$ problem.

We initially were planning to contact Washington State because it had the fourth largest monitoring network, and it provided us with Northwest representation, where PM is mainly composed of organic carbon. STAPPA/ALAPCO said that some local agencies are quite advanced in their approaches to $PM_{2.5}$ monitoring, and may offer "richness in perspective." The Puget Sound Clean Air Agency was selected as an active Agency in Washington's air monitoring program.

Detailed information on the States selected is highlighted in the following table.

## Details on Attainment/Nonattainment Estimates, Monitor Types, and Particulate Matter Composition

***(Note: these attainment and non attainment figures are based on preliminary January 2003 EPA estimates and should not be considered the Agency's final position.)***

| States (ordered by Non Attainment[1] population) | Population in Non Attainment | Populations in Attainment | Population not Monitored | Total State Population | Percentage in Non Attainment | Monitor Types | | | | Primary Composition of PM 2.5 Particulate Matter |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Continuous | Filter-Based | Speciation | Grand Total | |
| ***CALIFORNIA*** [2] | ***21,959,496*** | ***10,991,378*** | ***920,774*** | ***33,871,648*** | ***64.83%*** | ***4*** | ***127*** | ***9*** | ***140*** | ***Organic Carbon, Nitrate, Sulfate*** |
| ***ILLINOIS*** | ***7,573,425*** | ***2,541,000*** | ***2,304,868*** | ***12,419,293*** | ***60.98%*** | ***3*** | ***52*** | ***1*** | ***56*** | ***Organic Carbon, Sulfate, Crustal Material*** |
| ***OHIO*** | ***6,886,794*** | ***332,071*** | ***4,134,275*** | ***11,353,140*** | ***60.66%*** | ***9*** | ***55*** | ***13*** | ***77*** | ***Sulfate, Organic Carbon*** |
| ***PENNSYLVANIA*** | ***5,470,027*** | ***3,682,085*** | ***3,128,942*** | ***12,281,054*** | ***44.54%*** | ***12*** | ***57*** | ***6*** | ***75*** | ***Sulfate, Organic Carbon*** |
| ***NEW YORK*** | ***5,335,171*** | ***10,602,169*** | ***3,039,117*** | ***18,976,457*** | ***28.11%*** | ***27*** | ***58*** | ***9*** | ***94*** | ***Sulfate, Organic Carbon*** |
| ***TEXAS*** | ***4,695,849*** | ***9,901,776*** | ***6,254,195*** | ***20,851,820*** | ***22.52%*** | ***40*** | ***89*** | | ***129*** | ***Sulfate, Organic Carbon, Crustal Material*** |
| GEORGIA | 4,503,857 | 92,115 | 3,590,481 | 8,186,453 | 55.02% | | 44 | | 44 | Sulfate, Organic Carbon |
| NORTH CAROLINA | 3,543,051 | 1,280,006 | 3,226,256 | 8,049,313 | 44.02% | 7 | 51 | 8 | 66 | Sulfate, Organic Carbon |
| MARYLAND | 2,696,617 | 1,309,805 | 1,290,064 | 5,296,486 | 50.91% | | 23 | 1 | 24 | Sulfate, Organic Carbon |
| TENNESSEE | 2,647,536 | 435,623 | 2,606,124 | 5,689,283 | 46.54% | 1 | 36 | 4 | 41 | Sulfate, Organic Carbon |
| ALABAMA | 2,508,058 | 193,653 | 1,745,389 | 4,447,100 | 56.40% | 1 | 29 | 6 | 36 | Sulfate, Organic Carbon |
| INDIANA | 2,266,858 | 1,194,203 | 2,619,424 | 6,080,485 | 37.28% | 3 | 50 | 2 | 55 | Organic Carbon, Sulfate, Crustal Material |
| MICHIGAN | 2,084,543 | 5,288,118 | 2,565,783 | 9,938,444 | 20.97% | 7 | 36 | 6 | 49 | Organic Carbon, Sulfate, Crustal Material |
| NEW JERSEY | 1,925,149 | 4,573,812 | 1,915,389 | 8,414,350 | 22.88% | 15 | 25 | 5 | 45 | Sulfate, Organic Carbon |
| KENTUCKY | 1,780,088 | 262,542 | 1,999,139 | 4,041,769 | 44.04% | | 31 | 10 | 41 | Organic Carbon, Sulfate, Crustal Material |
| ***SOUTH CAROLINA*** | ***1,538,177*** | ***1,211,820*** | ***1,262,015*** | ***4,012,012*** | ***38.34%*** | ***6*** | ***30*** | ***4*** | ***40*** | ***Sulfate, Organic Carbon*** |
| CONNECTICUT | 824,008 | 1,998,838 | 582,719 | 3,405,565 | 24.20% | 3 | 17 | | 20 | Sulfate, Organic Carbon |
| MASSACHUSETTS | 689,807 | 5,341,018 | 318,272 | 6,349,097 | 10.86% | 4 | 31 | | 35 | Sulfate, Organic Carbon |
| WEST VIRGINIA | 658,406 | 305,717 | 844,221 | 1,808,344 | 36.41% | | 19 | | 19 | Sulfate, Organic Carbon |
| DISTRICT OF COLUMBIA | 572,059 | 0 | - | 572,059 | 100.00% | | 6 | | 6 | Sulfate, Organic Carbon |
| ARKANSAS | 536,339 | 805,886 | 1,331,175 | 2,673,400 | 20.06% | | 49 | 3 | 52 | Sulfate, Organic Carbon |
| ***MISSISSIPPI*** | ***528,109*** | ***863,930*** | ***1,452,619*** | ***2,844,658*** | ***18.56%*** | ***4*** | ***17*** | ***2*** | ***23*** | ***Sulfate, Organic Carbon*** |
| DELAWARE | 500,265 | 283,335 | - | 783,600 | 63.84% | 2 | 11 | 2 | 15 | Sulfate, Organic Carbon |
| MISSOURI | 390,554 | 2,928,474 | 2,276,183 | 5,595,211 | 6.98% | 1 | 28 | 5 | 34 | Organic Carbon, Sulfate, Crustal Material |
| LOUISIANA | 300,345 | 2,580,061 | 1,588,570 | 4,468,976 | 6.72% | 5 | 28 | | 33 | Organic Carbon, Crustal Material |
| VIRGINIA | 112,278 | 3,354,344 | 3,611,893 | 7,078,515 | 1.59% | | 20 | 3 | 23 | Sulfate, Organic Carbon |
| IDAHO | 98,453 | 851,417 | 344,083 | 1,293,953 | 7.61% | 13 | 30 | 1 | 44 | Organic Carbon, Sulfate |
| UTAH | 90,354 | 1,877,321 | 265,494 | 2,233,169 | 4.05% | | 29 | 3 | 32 | Organic Carbon, Sulfate, Crustal Material |
| IOWA | 60,296 | 1,392,704 | 1,473,324 | 2,926,324 | 2.06% | 31 | 18 | 3 | 52 | Organic Carbon, Sulfate, Crustal Material |
| PUERTO RICO | 52,393 | 1,244,915 | 2,511,302 | 3,808,610 | 1.38% | 2 | 10 | 1 | 13 | NA |
| ARIZONA | 51,335 | 4,419,413 | 659,884 | 5,130,632 | 1.00% | | 21 | 2 | 23 | Sulfate, Organic Carbon |
| WYOMING | 35,804 | 126,418 | 331,560 | 493,782 | 7.25% | | 7 | | 7 | Organic Carbon, Sulfate, Crustal Material |
| MINNESOTA | 31,671 | 3,182,639 | 1,705,169 | 4,919,479 | 0.64% | 2 | 58 | 4 | 64 | Organic Carbon, Sulfate, Crustal Material |
| NEW MEXICO | 29,979 | 1,212,256 | 576,811 | 1,819,046 | 1.65% | 11 | 21 | | 32 | Organic Carbon, Sulfate |
| WISCONSIN | 19,680 | 3,179,563 | 2,164,432 | 5,363,675 | 0.37% | 4 | 36 | 6 | 46 | Organic Carbon, Sulfate, Crustal Material |
| MONTANA | 18,837 | 620,322 | 263,036 | 902,195 | 2.09% | | 19 | 2 | 21 | Organic Carbon, Sulfate |
| NORTH DAKOTA | 5,737 | 295,331 | 341,132 | 642,200 | 0.89% | 4 | 14 | 3 | 21 | Organic Carbon, Sulfate, Crustal Material |
| KANSAS | 3,319 | 1,267,224 | 1,417,875 | 2,688,418 | 0.12% | 10 | 17 | 1 | 28 | Organic Carbon, Crustal Material |
| ***WASHINGTON*** | ***0*** | ***5,103,104*** | ***791,017*** | ***5,894,121*** | ***0.00%*** | ***29*** | ***53*** | ***1*** | ***83*** | ***Organic Carbon, Sulfate*** |
| FLORIDA | 0 | 12,872,487 | 3,109,891 | 15,982,378 | 0.00% | 7 | 33 | 3 | 43 | Sulfate, Organic Carbon |
| OREGON | 0 | 2,508,440 | 912,959 | 3,421,399 | 0.00% | | 41 | 1 | 42 | Organic Carbon, Sulfate |
| COLORADO | 0 | 3,222,385 | 1,078,876 | 4,301,261 | 0.00% | 1 | 31 | 5 | 37 | Organic Carbon, Crustal Material |
| OKLAHOMA | 0 | 2,069,031 | 1,381,623 | 3,450,654 | 0.00% | | 32 | 2 | 34 | Organic Carbon, Crustal Material |
| SOUTH DAKOTA | 0 | 327,709 | 427,135 | 754,844 | 0.00% | 1 | 21 | 1 | 23 | Sulfate, Organic Carbon |
| NEBRASKA | 0 | 1,022,563 | 688,700 | 1,711,263 | 0.00% | | 20 | 1 | 21 | Organic Carbon, Sulfate, Crustal Material |
| NEW HAMPSHIRE | 0 | 998,144 | 237,642 | 1,235,786 | 0.00% | 1 | 20 | | 21 | Sulfate, Organic Carbon |
| MAINE | 0 | 1,038,282 | 236,641 | 1,274,923 | 0.00% | 3 | 17 | | 20 | Sulfate, Organic Carbon |
| ALASKA | 0 | 453,777 | 173,155 | 626,932 | 0.00% | | 13 | 1 | 14 | NA |
| NEVADA | 0 | 1,756,510 | 241,747 | 1,998,257 | 0.00% | | 10 | 1 | 11 | Organic Carbon, Nitrate, Sulfate |
| RHODE ISLAND | 0 | 912,238 | 136,081 | 1,048,319 | 0.00% | | 11 | | 11 | Sulfate, Organic Carbon |
| VERMONT | 0 | 305,004 | 303,823 | 608,827 | 0.00% | 2 | 8 | 1 | 11 | Sulfate, Organic Carbon |
| HAWAII | 0 | 1,004,250 | 207,287 | 1,211,537 | 0.00% | | 7 | | 7 | NA |

[1] Attainment and Non Attainment figures are based on recent EPA estimates.

[2] States reviewed are indicated in shaded boxes and are also bolded

# *Consolidated EPA Response to Draft Report*

September 26, 2003

**MEMORANDUM**

**SUBJECT:** Response to the Draft Evaluation Report: Decline in EPA Particulate Matter Methods Development Activities May Hamper Timely Achievement of Program Goals, Assignment No. 2002-000355

**FROM:** Jeffrey R. Holmstead /s/
Assistant Administrator for Air and Radiation (6101A)

**TO:** J. Rick Beusse
Director for Program Evaluation, Air Quality Issues
Office of Inspector General

Thank you for providing us with the opportunity to respond to the draft report from the Office of Inspector General (OIG). We have discussed the draft report with the Office of Research and Development (ORD) and share many of the same concerns.

The Office of Air and Radiation (OAR) and the ORD agree with the OIG authors' statement that air monitoring methods development is key to supporting the Agency's regulatory agenda and science needs. Both offices support the OIG recommendation to work jointly to establish a methods development program plan. In developing a plan, EPA will need to balance near-term method needs associated with the 1997 National Ambient Air Quality Standard (NAAQS) for fine particles ($PM_{2.5}$) and long-term methods research to support health and exposure studies and future NAAQS.

There appears to be a general misunderstanding throughout the report that three years of $PM_{2.5}$ data using the Federal Reference Method (FRM) are unavailable and that this lack of data has delayed the designation of $PM_{2.5}$ nonattainment areas by two years. This is simply not true and we cannot concur with that conclusion. We believe that the delays incurred in designating nonattainment areas and beginning implementation of this important standard are due to a number of factors, including the time it took to settle the litigation over the standard, but not to the time necessary to deploy the network.

See Appendix C Note 1

$PM_{2.5}$ is a new pollutant for which a new FRM had to be established. The schedule for deploying the new network was extremely ambitious and was, in fact, directed by the President. The Congress subsequently codified the schedule into law. Moreover, as we believed that the health consequences of this pollutant were significant, we sought and obtained full funding from the Congress for state deployment of the network.

States deployed the $PM_{2.5}$ FRM network over two years, 1998 and 1999. Three years of data are now available and on a schedule that is consistent with Congress'

See Appendix C Note 1

expectation and the 40 CFR 58 monitoring regulation published in 1997. The OAR has already published draft $PM_{2.5}$ design values, and we expect to have the states' recommendations on nonattainment designations by mid-February 2004. As a result, we believe the underlying premise of the report that "EPA has not supported $PM_{2.5}$ methods development activities to the extent necessary to achieve the short- and long-range goals of the $PM_{2.5}$ program" is not accurate.

The draft OIG report does not describe particulate matter methods development in the context of the outcome-oriented design for EPA's particulate matter research program in the *Particulate Matter Research Program Multi-year Plan*. This design – established with participation by ORD clients – describes the research needed to achieve short-term outcomes, respond to recommendations by the National Research Council Committee on Research Priorities for Airborne Particulate Matter, and help EPA achieve its strategic goals and objectives. As the *Scope and Methodology* sections of the draft OIG report do not mention the *Particulate Matter Research Program Multi-year Plan,* we believe that this important design context was not considered when the OIG prepared its observations, findings, and results-in-brief.

See Appendix C Note 2

The draft report asserts that EPA provided limited monitoring options for the FRM supporting the 1997 NAAQS. We believe the development of a filter-based FRM was consistent with our scientific understanding of PM, the technology available at the time, and the stringent requirements for method performance that must be met to achieve the required public health protection. The FRM promulgated as part of the 1997 NAAQS was reviewed by the Clean Air Scientific Advisory Committee (CASAC) and underwent public comment along with the NAAQS. EPA considered comments from both of these reviews in the final decision to promulgate the FRM for $PM_{2.5}$. We believe that our work should be evaluated in light of the scientific understanding that existed at that time, not with current scientific understanding. We have attached a scientific and historical perspective to place the work in the proper context (Attachment A).

See Appendix C Note 3

The OAR and ORD agree there were a number of technical obstacles encountered with the initial $PM_{2.5}$ network deployment that lasted into 1999. These obstacles stemmed from many sources, including methods development, equipment vendor support, states' ability to hire and retain staff, and the compressed time schedule EPA dictated in deploying the network. However, we believe that the issues and problems encountered were not atypical for the deployment of a large network of new technology monitors across the entire country. Both the ORD and OAR recognized that problems and issues in deploying such a large network were likely and worked extremely hard to address this issues that arose during implementation of the new monitoring network. Nonetheless, the OAR and ORD did learn many lessons that will be useful in developing and managing our future monitoring programs.

See Appendix C Note 4

With consideration given to these concerns, we do support the spirit of the recommendations for forward looking methods development research. We concur with all but one of the recommendations contained within the draft report. We do not concur with the use the Federal Advisory Committee Act (FACA) to establish a government-industry partnership (Recommendation 3-1). We believe that the CASAC – established under the FACA – provides a better alternative. Although we concur with the

See Appendix C Note 5

recommendations to develop a PM methods development strategy (Recommendation 2-1) and to maximize opportunities to enhance Homeland Security efforts (Recommendation 3-3), we have comments regarding their implementation. The comments are included in the attachment to this memorandum

I am including more detailed information on specific recommendations, clarifications, and suggested improvements (Attachment B). Please contact Dr. Richard Scheffe (919-541-4650) of OAR or Tim Watkins (919-541-5114) of ORD if you have any additional questions.

Attachment

cc: Lee Byrd, OAQPS/EMAD
Tom Coda, OAQPS/PRRMS
Gary Foley, NERL
Paul Gilman, ORD
Tim Hanley, OAQPS/EMAD
Mike Jones, OAQPS/EMAD
Joe Paisie, OAQPS/AQSSD
Rich Scheffe, OAQPS/EMAD
Peter Tsirigotis, OAQPS/EMAD
Tim Watkins, NERL
Lydia Wegman, OAQPS/AQSSD

**Scientific and Historical Perspective**

The 1997 PM NAAQS included a new standard for fine particles, or $PM_{2.5}$, based upon scientific evidence that demonstrated an association between ambient $PM_{2.5}$ levels and observed health effects. However, questions and concerns remained regarding the true public health significance and credibility of the effects of ambient PM. These concerns led to an increase the in the budget for the EPA PM research program and the formation of the NRC committee on Research Priorities for Airborne Particulate Matter.

See Appendix C Note 2

In their 1998 report, the NRC developed a broad source-to-exposure-to-response framework for evaluating PM issues. The original research portfolio suggested by the NRC included research to provide insight on how people are exposed to PM and its components and the mechanisms by which these exposures lead to adverse health outcomes. To accomplish this, EPA would first need to identify the particular components of PM that were leading to adverse outcomes. EPA would then conduct studies to understand actual human exposures to these components and to relate these exposures to health effects observed in the real world. Subsequently, the NRC identified the need to develop methods for measuring PM components to support these exposure and health studies.

See Appendix C Note 2

Since the issuance of the 1998 NRC report, we have learned much about PM, but we have not identified a particular component that is solely responsible for observed adverse health outcomes. We now believe that most PM components are likely to have a toxic effect and we also are focusing on particular sources of PM as potential risk drivers. As a result, our PM methods research needs to provide the measurement techniques necessary to support investigations relating to components and sources of PM. If future research studies justify a change in the format of the PM NAAQS, the methods used in those studies could be developed as a revised FRM. The challenge faced by the ORD is to find an appropriate balance between supporting nearer-term needs associated with the 1997 NAAQS and longer-term research to provide the scientific basis for future NAAQS and, given its role in supporting both of these needs, our PM methods research program lies at the center of this challenge.

See Appendix C Note 2

**Detailed Comments on the Office of Inspector General's Draft Evaluation Report: Decline in EPA Particulate Matter Methods Development Activities May Hamper Timely Achievement of Program Goals, Assignment No. 2002-000355**

Comments are provided in three categories: (1) responses to recommendations contained within the report, (2) clarification on a number of misunderstandings that have arisen from the very complex nature of this area, and (3) specific suggestions to improve the report.

**Responses to Recommendations**

In general, OAR and ORD agree with the recommendations contained within the draft report, with the possible exception of using the Federal Advisory Committee Act (FACA) to establish a government-industry partnership. Below are our comments on the recommendations:

See Appendix C Note 6

- *Recommendation 2-1:* OAR and ORD support the recommendation to work jointly to develop a comprehensive methods development strategy. However, we feel that a strategy that focuses only on $PM_{2.5}$ is too narrow. The EPA is preparing for a potential PM coarse FRM and also needs to address longer term methods development, such as identifying specific components of PM for evaluation with health associations. The health associations are part of the methods development work identified in the guidance set forth by the NRC in their 1998 report. The NRC report recognized that individuals develop adverse health responses to PM in the air that they breathe (exposure). It also shows that understanding exposure provides a critical link between regulatory monitoring and health outcomes. PM is a complex mixture of particles of different sizes and compositions that will effect both its toxicity and relationships between sources, ambient concentrations, and actual human exposures. As EPA moves forward with future PM standards development activities, we need to be able to measure PM mass, species, or components in the ambient air, link these measurements to sources and actual exposure, and relate the exposure to health effects. As a result, a comprehensive PM methods development strategy must address all measurements needed to understand the entire source-to-exposure-to-effect continuum, including measurement methods for various PM size fractions, PM composition, PM precursors, and tracers for PM sources. Furthermore, as part of an overall strategy, activities to develop FRMs that are used to determine compliance with the future standards should reflect the relationship between ambient measurements and exposures.

- *Recommendation 2-2:* OAR and ORD support the use of Data Quality Objectives (DQO) to ensure important decisions with data are made with an acceptable amount of uncertainty. The OAR and ORD are actively engaged in a DQO process to define acceptable criteria for candidate equivalent $PM_{2.5}$ monitoring methods.

- *Recommendation 2-3:* OAR and ORD agree with the recommendation for ORD to maintain personnel in the area of PM methods development as part of a strategic hiring plan.

- *Recommendation 3-1:* OAR and ORD believe that, for formal review of PM measurement method issues, using the CASAC provides a better alternative to establishing a new government-industry partnership. CASAC has a functional subcommittee working on particle monitoring and is expected to continue meeting as EPA considers possible changes to the PM networks. The current process of involving the CASAC provides an unbiased opinion for methods development issues. The EPA can continue to informally communicate with other external stakeholders to ensure that their needs and issues are addressed.

See Appendix C Note 5

- *Recommendation 3-2:* OAR and ORD have learned many valuable lessons in developing and implementing the FRM for $PM_{2.5}$, which are being applied in developing the FRM for $PM_{10-2.5}$. We have tried to improve our approach to methods development while participating in the PM Supersites program (see below)

- and in evaluating methods for the speciation networks. Insights from this draft report will allow us to develop a better PM methods development program that is an integral part of our other PM program.

<u>Clarifications</u>

- There is a general misunderstanding throughout the report that three years of $PM_{2.5}$ FRM data are unavailable, or at least unavailable for designation purposes. This is simply untrue. The $PM_{2.5}$ FRM network was deployed over two years, 1998 and 1999. Three years of data from the initially deployed monitors were available on July 1, 2002 (for the years 1999, 2000, 2001) and from all sites on July 1, 2003 (for the years 2000, 2001, 2002). This July 1 schedule is consistent with the 40 CFR 58 monitoring regulation published in 1997.

See Appendix C Note 1

- The goal of EPA's air program is to protect public health and the environment and, for criteria pollutants, NAAQS are set based on a comprehensive scientific understanding of the exposures and adverse health and environmental effects associated with elevated levels measured at ambient monitoring sites. These NAAQS are implemented by the states and tribes using tools and data provided in large part by EPA. Methods for measuring PM in air are used to both set and implement the standards. This is an important distinction and one that is blurred throughout the report.

See Appendix C Note 7

- The FRM is the primary tool for implementing the NAAQS. FRMs are the basis for the standard and are used to determine regulatory compliance. Much of the discussion in the report, and the title itself, is directed at the development of the FRM for measuring $PM_{2.5}$. This method was developed from 1994 to 1998 to determine compliance with the $PM_{2.5}$ NAAQS set in 1997. The development of a filter-based FRM was consistent with our scientific understanding of PM, the available technology, and the stringent requirements for

See Appendix C Note 3

method performance that must be met to achieve the required public health protection. In our judgement, it was not feasible to develop a continuous measurement method that would meet all of the performance requirements for all areas of the country in the time frame that was needed for implementation monitoring. Finally, the epidemiological studies upon which the 1997 NAAQS was founded used filter-based methods to measure PM mass. To use some other surrogate of mass would have been inconsistent with the state of knowledge at that time. So, although there are now concerns voiced over the resources required to run a filter-based method, it is important to point out that when we developed the FRM for $PM_{2.5}$, we placed a premium on ensuring public health protection in a timely and scientifically rigorous manner.

- The EPA has not proposed a new PM NAAQS since the existing NAAQS was issued in 1997. The report authors make several references to a proposed "coarse" particle standard within the draft report. The EPA is currently reviewing the PM standards and is considering the need for a coarse particle standard; however, it is premature to describe this as a proposed standard. The EPA's current schedule should provide for a proposal in late 2004 and a final standard in late 2005. The ORD, OAR, and the state and local agencies are working together to identify and field test a variety of candidate coarse particle methods, including both filter-based and continuous devices.

See Appendix C
Note 8

- The ORD conducts research that provides the scientific underpinning of our regulations with an overall goal of protecting public health. In the PM area, methods development is but one research component that provides inputs to both developing and implementing the standards. As an important example, the 1997 $PM_{2.5}$ standard was developed based on epidemiological studies that found relatively consistent but poorly understood associations between ambient PM concentrations and various adverse health effects. These studies raised two important questions: (1) could PM at ambient levels actually be responsible for the adverse health outcomes and (2) could ambient monitors be used to represent exposure to PM mass. These were critical questions associated with the NAAQS. In 1998, these questions were given a higher priority than methods development in areas not associated with the FRM as mandated by Congress, the President, and the NRC. The ORD is striving for a balanced program that develops the methods, data, and the models for both implementing the current standard, and developing future standards. In the next three years, ORD has placed an emphasis on developing the tools that can be used by states in implementing the NAAQS. In the future, we will emphasize research that supports setting future NAAQS and balance our activities in methods development, ambient and exposure measurement studies, source apportionment, health studies, and atmospheric and human exposure modeling to address the agency's most critical data gaps.

See Appendix C
Note 9

- The EPA has taken the NRC recommendations very seriously and worked very hard to develop a PM research program that was responsive to both the spirit and intent of all of the recommendations. The third chapter of the initial NRC report recommended research to develop new personal and ambient monitoring methods for measuring particle species and sizes. The methods research

See Appendix C
Note 2

identified by the NRC, which supports health and exposure research studies, was and continues to be, a focal point of the ORD PM methods research program. However, it was not until the third NRC report that methods research was explicitly acknowledged as a technical support activity to the overall PM research program.

- It is important to note the role of the PM Supersites program in the EPA PM methods program. As ORD responded to the recommendations in the NRC report, the EPA PM Supersites Program was being planned and implemented by OAR and ORD. An important objective of the Supersites program is to develop and test measurement methodologies. So, while ORD was redirecting some internal resources to respond to the NRC, overall EPA investment in methods work was being augmented by the PM Supersites program. Significant strides in methods development have occurred through the PM Supersites Program, which will be winding down by the end of 2004, including testing and inter-comparisons of continuous and speciation methods. As more PM Supersites data become available and are analyzed, EPA will be in a position to use the results to improve its activities relating to PM methods development.

See Appendix C Note 10

Suggestions:

- Page 1, Background, paragraph 1, line 1-5. The authors list a number of sources but miss many important sources (e.g., diesel for elemental carbon). We suggest they limit this discussion to the composition and major components, then state these components are from both natural and anthropogenic sources, including combustion of fossil fuels and modern material, secondary pollutants (e.g., sulfates and nitrates) from combustion sources, and, for example, organic carbon, which is a relatively major constituent everywhere, virtually all the time, and is emitted directly into the air (primary) or formed in the air from gas phase precursor species (secondary), both from a variety of combustion and other sources.

See Appendix C Note 11

- Page 2, paragraph 1, line 4. Rather than say "Some particles may travel.." and "while others remain within …," we suggest being more specific about particle size and distance. Fine particles about 0.5 – 2 um in size may travel thousands of miles… while larger particles, 10 um in size, may only travel on the order of up to 100 miles, and very large particles 100 um in size may only travel a few hundred meters, distances for all sizes are strongly dependent on meteorology, such as wind speed.

See Appendix C Note 12

- Page 4, top. Measurement against standards is an important missing component that should be mentioned. For PM, this is an extremely difficult task, but one that ORD in conjunction with NIST and others are beginning to make progress.

See Appendix C Note 13

- Page 4, paragraph 4, line 1. Only Teflon filters are used within the $PM_{2.5}$ FRM network. The nylon and quartz filters are used for chemical speciation analyses.

See Appendix C Note 14

- Page 4, paragraph 4, line 7, measure. A more accurate word would be 'estimate.' The mass measured on the filter is not a measure of the fine particles that a person would breathe, it is, however, 'an estimate.'

See Appendix C Note 15

- Page 9, paragraph 3. Several items are identified as causes for data gaps from the $PM_{2.5}$ network. Oil freezing in the WINS impactors, water condensation, and the mentioned software malfunctions did not result in $PM_{2.5}$ concentration data loss. While these are issues of concern, they did not lead to data loss. The WINS impactor oil crystallization issue was researched by the ORD and found to be a non-issue for data quality. The software malfunction was due to a manufacturer defect that did not prevent mass data from being collected.

See Appendix C Note 16

- Page 10, 3rd bullet. Note that EPA funded 52 filter weighing laboratories in FY 1998, one for each State, Puerto Rico, and D.C. In 1999, an additional 14 more filter weighing laboratories were funded for local air monitoring agencies. Additionally, there are several commercial laboratories available for this function. Although EPA does recognize the difficulty of establishing laboratories for filter weighing, EPA does not believe that these difficulties were due to a lack of timely funding.

See Appendix C Note 17

- Page 16, Tables 3.1 and 3.2; Pages 18 and 19. In several locations, the draft report states that the chemical speciation monitoring data will be used to identify a "source." To prevent the misinterpretation of this statement, EPA advises the authors to state that the data will identify "source categories," for example, mobile sources, industrial sources, etc., that cause elevated particulate matter levels.

See Appendix C Note 18

- Page 16 and 17, Tables 3.2 and 3.3. The draft report discusses the chemical speciation network size and cost in its Chapter 3. A few corrections are needed here. In experimenting with the continuous speciation analyzers, EPA has realized that the annual operation and maintenance costs for these devices can be as expensive as for filter based methods. As a result, EPA suggests deleting the checkmark in Table 3.2 that suggests that these samplers have "minimal operational/life cycle costs." Additionally, in Table 3.3, the initial capital cost for a set of continuous instruments (nitrate, sulfate, and carbon) is $85,000 rather than $20,000.

See Appendix C Note 19

- Page 17, last paragraph. Comment regarding continuous speciation methods is among the most promising near-term technologies. The Supersites Program has been examining many continuous methods for mass and species. Although three years ago we believed several of these were very promising, results from the Supersites Program often suggest that we do not know what these monitors are actually measuring and much more research is needed in this area as well as a better understanding of their operational effectiveness.

See Appendix C Note 20

- Page 18, paragraph 1, line 11. There are currently more than 350 rural and urban chemical speciation sites providing data to EPA. The report indicates that only 142 are operating.

See Appendix C Note 21

- Page 18, paragraph 2, line 2. "However, the composition of a particle differs…" Change 'a particle' to 'particulate matter.' The same for several other locations in this paragraph -- change particle to particulate matter.

See Appendix C Note 22

- Page 20. The OAR and ORD believe there are areas of the ambient monitoring network that can be leveraged for supporting of EPA's homeland security goals while maintaining their primary function to support NAAQS implementation. However, careful attention needs to be paid in not over-selling the leveraging that can be done in these areas. The EPA has been working with the Department of Homeland Security (DHS) and other federal agencies to establish the existing biological sensing network (BioWatch). In many cases, the BioWatch network uses or supplements existing ambient monitoring network infrastructure, such as sample platform locations, access to electrical power, and field staff to operate the network. The EPA is also in regular contact with the homeland security researchers involved with the ongoing methods development work. The DHS and the Los Alamos and Lawrence Livermore National Laboratories are investing significant resources in developing methods for identifying biological and chemical agents. Developing methods that detect biological agents requires live biological agent testing, an understanding of terrorist threat scenarios, and other factors that cannot be pursued by EPA acting alone. The components of the ambient monitoring network used for NAAQS should not be used for homeland security, except in the most high priority situation. As an example, PM filters could not be used for both air pollution program and homeland security purposes because the biological agent analyses must be performed immediately and will destroy the filter. As well, the ambient network has been established for neighborhood to regional scale analyses, while tracking a plume for a toxic release at local scales would require a different network of monitors. There also would be questions about the usefulness of the ambient filters, based on the amount of material collected and subsequent analyses for biological and chemical agents. Except for continuous monitors, the ambient network mostly operates on a 1-in-3 or 1-in-6 day schedule, leaving large temporal gaps for homeland security information. Finally, most ambient continuous near real-time methods are only for the major components of mass (sulfate, nitrate, ammonium, OC, and EC). Continuous real-time methods do not yet exist nor are they in place in the network for potentially toxic biologically active or chemical toxins. The authors would have to drift significantly from the evaluation's scope in order to make the report better reflect the complexity of this cooperation between EPA and various Federal agencies.

See Appendix C Note 23

# OIG Evaluation of EPA Response to Draft Report

**Note 1 -** We agree that the Agency's description of timeframes is consistent with 40 CFR 58. However, the 1998 Transportation Equity Act for the 21st Century allowed the States 3 years, until September 2001, to gather the data. However, a complete set of data was not available until July 2003. We have added a footnote for clarification. Also, we have modified the wording in our report to recognize that the decline in methods development activities was one of several contributing factors that jeopardizes EPA's ability to fully achieve the short- and long-range goals of the $PM_{2.5}$ program in a timely manner. Nonetheless, our work indicated that the decline in methods development was a key contributing factor, and our report continues to reflect that position.

**Note 2** - We agree and have modified the report to clarify the distinction between National Research Council's recommendations in its Volume 1 report and the National Research Council's Volume 3 report. We did review the PM Research Program Multi-year Plan, as indicated on page 17 of the draft report. It should be noted that the documents in the Scope and Methodology section of our report were not meant to be all inclusive. Instead, we list some of the key documents used to develop the facts and issues presented in our report. However, we have modified our report to present a more balanced view of the longer-term research needs of the overall PM research program, as outlined in the National Research Council's report.

**Note 3 -** We agree that filter-based mass-only monitors were the viable option when ambient air monitoring implementation began in 1998, and have added further emphasis to highlight this point. However, having a vigorous methods development program will potentially result in more monitor options becoming available as EPA moves forward with its PM monitoring network.

**Note 4 -** We agree that the deployment of the $PM_{2.5}$ monitoring network was extremely challenging and that problems encountered by States were typical of a large network. We have modified the report to reflect this.

**Note 5 -** We agree that our recommendation should not restrict EPA to using a particular process, such as the Federal Advisory Committee Act, to accomplish the goals and objectives of the PM program. We agree that the Clean Air Scientific Advisory Committee process is a suitable alternative, and have modified our recommendation to reflect this.

**Note 6 -** We agree that a methods development strategy that only focuses on $PM_{2.5}$ may be too narrow. We have modified our recommendation for EPA to develop a comprehensive PM strategy.

**Note 7 -** We agree that methods for measuring PM in air are used to both set and implement the standards, and have modified our report to reflect this.

**Note 8 -** We have modified our report to reflect EPA's current estimate for the schedule of proposing and finalizing a coarse standard.

**Note 9** - We agree with the importance for ORD to strive for a balanced program that develops the methods, data, and models for both implementing the current standard and developing future standards. However, as part of achieving this balanced program, both OAQPS and ORD officials have acknowledged that PM methods development warrants increased attention by EPA.

**Note 10 -** We agree that the PM Supersites program is important in the overall EPA PM methods program, and have modified our report accordingly.

**Note 11** - We agree that the Agency's definition of the sources of PM is more complete. However, we believe our definition is more appropriate for the non-scientific readers of this report.

**Note 12** - We have modified our report regarding PM travel as it relates to the size of the particle.

**Note 13 -** We have modified the report to reflect that monitoring is also a form of measurement against the standards.

**Note 14** - We have modified the report to reflect that only teflon filters are used within the $PM_{2.5}$ FRM network.

**Note 15 -** We have modified the report to reflect that the $PM_{2.5}$ data is not a measurement but instead is an estimate of the fine particulate matter that a person would breathe.

**Note 16** - We agree that data gaps were eventually filled; however, our work found that the monitor malfunctions did result in a loss of data.

**Note 17** - We have modified our report to reflect that while there were difficulties with establishing laboratories for filter weighing, EPA does not believe these issues were due to a lack of funding.

**Note 18 -** We have added a footnote to clarify that, when referring to emissions sources, unless otherwise stated, we are also referring to the larger category of sources, such as mobile, industrial, etc.

**Note 19 -** We changed the original EPA estimate of $20,000 (provided to us by Agency staff during our field work) to reflect the Agency's most recent estimate of $85,000 for a set of continuous instruments (nitrate, sulfate, carbon).

**Note 20 -** Based on our discussions with EPA and State officials, we still maintain that continuous mass and continuous speciation monitors are among the most promising near-term technologies. However we have added that EPA officials also believe that much more research is needed.

**Note 21 -** We agree that there are 350 rural and urban chemical speciation sites, which include IMPROVE and Speciation Trends Network monitors. However, our number of 142 speciation monitors is based on information provided by OAQPS in January 2003.

**Note 22 -** Where appropriate, we have changed the terminology from "a particle" to "particulate matter."

**Note 23** - We agree with the Agency that the ambient monitoring network can be leveraged to support EPA's homeland security goals while maintaining its primary function to support National Ambient Air Quality Standard implementation. We have clarified that EPA must work closely with other Federal agencies to accomplish this effort.

# *ORD Response to Draft Report*

***Note: We did not include ORD's attachments to its response because they were the same as the attachments in EPA's consolidated response.***

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**

September 26, 2003

OFFICE OF
RESEARCH AND DEVELOPMENT

**MEMORANDUM**

**SUBJECT:** ORD Response to the Inspector General's Draft Report "Decline in EPA Particulate Matter Methods Development May Hamper Timely Achievement of Program Goals"

**FROM:** Paul Gilman ***/s/ Paul Gilman***
Assistant Administrator (8101R)

**TO:** J. Rick Beusse
Director for Program Evaluation, Air Quality Issues
Office of Inspector General

Introduction

The purpose of this memorandum is to provide you with the Office of Research and Development's (ORD) response to the Office of Inspector General's (OIG) draft report "Decline in EPA Particulate Matter Methods Development May Hamper Timely Achievement of Program Goals." We do not concur with the findings of this report, and the underlying premise that a decline in EPA's methods development activities has led to delays in achieving particulate matter (PM) program goals. This memorandum outlines our concerns with the findings, presents our response to the report recommendations, and provides a scientific and historical perspective of the EPA PM research program that must be appreciated to place this draft OIG report in the proper context. We have also included an attachment that provides more detailed comments on the draft report.

Response to Findings and Recommendations

We do not concur with the overall findings in this draft report. Specifically, we do not agree with the statement, "EPA has not supported $PM_{2.5}$ methods development activities to the extent necessary to achieve the short- and long-range goals of the $PM_{2.5}$ program." The draft OIG report focuses on the short-term issue of deployment of the $PM_{2.5}$ monitoring network in response to the 1997 National Ambient Air Quality Standard (NAAQS), but does not present a balanced view of the longer-term research needs of the overall PM research program as outlined by the National Research Council's (NRC) Committee on Research Priorities for Airborne Particulate Matter. In addition, the report indicates that reduced emphasis on PM methods activities has led to delays in obtaining data to make compliance determinations and, therefore, led to "millions of individuals being exposed to excess levels of PM." This conclusion is false. The $PM_{2.5}$ Federal Reference Method (FRM) was developed in time for promulgation of the 1997 PM NAAQS. In addition, EPA has met the schedule for obtaining data to make compliance determinations using the FRM that was contained in the monitoring regulation that supported the 1997 NAAQS. As a result, concluding that a decline in EPA PM methods development activities led to excess exposures across the country is not appropriate.

The draft OIG report does not describe PM methods development in the context of the outcome-oriented design for EPA's PM research program documented in the *Particulate Matter Research Program Multi-year Plan*. This design–established with participation by our clients–describes the research needed to achieve short-term outcomes, responds to recommendations by the National Research Council Committee on Research Priorities for Airborne Particulate Matter, and helps EPA achieve its strategic goals and objectives. The *Scope and Methodology* sections of the draft OIG report do not mention the *Particulate Matter Research Program Multi-year Plan*, indicating that this important design context was not considered when the OIG prepared its observations, findings, and results-in-brief.

This draft report also indicates that a decline in EPA methods development activities led to difficulties encountered by states in deploying the $PM_{2.5}$ ambient monitoring network caused by limited monitoring options, insufficient field testing, and insufficient technical assistance and guidance. We do not agree. We believe that the issues and problems encountered by the states were not atypical for the deployment of a large network of new monitors across the entire country. Both ORD and OAR recognized that problems and issues in deploying such a large network were likely and worked extremely hard to address these issues as they arose during implementation of the new monitoring network. Senior managers from both organizations met monthly to address issues and provide necessary and timely resources to remedy problems brought to their attention. Overall, the deployment of the $PM_{2.5}$ monitoring network was extremely challenging and EPA could not predict issues that ultimately arose. However, we were prepared to address the issues that were raised, and were successful in resolving them.

Another assertion identified in the draft report is that EPA provided limited monitoring options for the FRM supporting the 1997 NAAQS. We believe the development of a filter-based FRM was consistent with our scientific understanding of PM, the available technology, and the stringent requirements for method performance that must be met to achieve the required public health protection. It is also important to note that the FRM, promulgated as part of the 1997 NAAQS, was reviewed by the Clean Air Scientific Advisory Committee (CASAC) and underwent public comment along with the NAAQS.

EPA considered comments from both of these reviews in its final decision to promulgate the FRM for $PM_{2.5}$.

Additionally, the recommendations in this draft report do not follow from the premise and findings discussed above. We support the spirit of the recommendations for forward looking methods development research, and concur with all but one of the recommendations. The one exception is the recommendation to use the Federal Advisory Committee Act (FACA) to establish a government-industry partnership (Recommendation 3-1). In addition, while we concur with the recommendations to develop a PM methods development strategy (Recommendation 2-1) and to maximize opportunities to enhance Homeland Security efforts (Recommendation 3-3), we have comments regarding their implementation. Our detailed comments on the recommendations contained in this draft report are included in the attachment to this memorandum.

Scientific and Historical Perspective

The 1997 PM NAAQS included a new standard for fine particles, or $PM_{2.5}$, based upon scientific evidence that demonstrated an association between ambient $PM_{2.5}$ levels and observed health effects. However, questions and concerns remained regarding the true public health significance and credibility of the effects of ambient PM. These concerns led to an increase in the budget for the EPA PM research program and the formation of the NRC committee on Research Priorities for Airborne Particulate Matter.

In their 1998 report, the NRC developed a broad source-to-exposure-to-response framework for evaluating PM issues. The original research portfolio suggested by the NRC included research to provide insight on how people are exposed to PM and its components and the mechanisms by which these exposures lead to adverse health outcomes. To accomplish this, EPA would first need to identify the particular components of PM that were leading to adverse outcomes. EPA would then conduct studies to understand actual human exposures to these components and to relate these exposures to health effects observed in the real world. Subsequently, the NRC identified the need to develop methods for measuring PM components to support these exposure and health studies.

Since the issuance of the 1998 NRC report, we have learned much about PM, but we have not identified a particular component that is solely responsible for observed adverse health outcomes. We now believe that most PM components are likely to have a toxic effect and we are also focusing on particular sources of PM as potential risk drivers. As a result, our PM methods research needs to provide the measurement techniques necessary to support investigations relating to components and sources of PM. If future research studies justify a change in the format of the PM NAAQS, the methods used in those studies could be developed as a revised FRM. The challenge that we face in ORD is to seek an appropriate balance between supporting nearer-term needs associated with the 1997 NAAQS and longer-term research to provide the scientific basis for future NAAQS and, given its role in supporting both of these needs, our PM methods research program lies at the center of this challenge.

Conclusion

As indicated above, ORD does not agree with the findings of this draft report. We do not accept the underlying premise that a decline in EPA methods development activities has led to delay in achieving EPA PM program goals. We also believe that this draft report has not adequately captured the scientific and historical perspective of the EPA PM research program, which must be understood to place this report in the proper context.

If you have any questions you would like to bring to my attention, please call me on (202) 564-6620.

Attachment

cc: Henry L. Longest II
William Farland
Gary Foley
Jeffrey Holmstead
Rob Brenner
Jerry Kurtzwig

Appendix E

# Distribution

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