Board of Scientific Counselors

Office of Research and Development
United States Environmental Protection Agency

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Particulate Matter and Ozone Research Program Review

Report of the Subcommittee on
Particulate Matter and Ozone Research

April 14, 2005
Revised August 11, 2005

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REPORT OF THE
BOARD OF SCIENTIFIC COUNSELORS

PARTICULATE MATTER AND OZONE RESEARCH PROGRAM REVIEW

Office of Research and Development
U.S. Environmental Protection Agency

APRIL 14, 2005
REVISED AUGUST 11, 2005

SUBCOMMITTEE ON PARTICULATE MATTER AND OZONE RESEARCH

Dr. Rogene Henderson (Chair)—Lovelace Respiratory Research Institute
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Dr. Brian Lamb—Washington State University
Dr. Michael Lipsett—California Department of Health Services
Dr. Peipei Ping—UCLA School of Medicine
Dr. Charles Rodes—Research Triangle Institute
Dr. Christian Seigneur—Atmospheric and Environmental Research, Inc.

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EXECUTIVE SUMMARY

Overall Goals, Charge, and Structure of the Review

The National Academy of Sciences (NAS) has recommended independent expert review for evaluating federal research programs. The U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD) is committed to independent expert review of its environmental research programs for objective evaluation of research at the program level to establish "best practices" in federal research program design, management, and evaluation and to assist the Agency in preparing performance and accountability reports to Congress under the Government Performance and Results Act (GPRA) of 1993.

The Board of Scientific Counselors (BOSC) Executive Committee agreed in September 2004, to undertake four program reviews: Human Health Research Program, Drinking Water Research Program, Ecological Research Program, and Particulate Matter and Ozone (PM & O_3) Research Program. The BOSC formed a Subcommittee of experts (see Appendix A) to conduct a program review of ORD's PM & O_3 Research Program. This Subcommittee was charged with reviewing ORD's PM & O_3 Research Program and providing a report to the BOSC Executive Committee.

This review differs from previous Multi-Year Plan (MYP) reviews in that it included a retrospective, as well as a prospective evaluation, examining progress made to date and the future direction of the EPA research in this program. The program review is intended to provide guidance that will help ORD to: (1) assess the progress and direction of the PM & O_3 Research Program; (2) plan, implement, and strengthen the program; (3) evaluate research investment decisions over the next 5 years; (4) compare the program with any programs designed to achieve similar outcomes in other parts of EPA and in other federal agencies; (5) prepare EPA's performance and accountability reports to Congress under GPRA; and (6) consider options for the reporting of outcomes as defined by the Office of Management and Budget (OMB) Program Assessment Rating Tool (PART) review process.

The objective of the PM & O_3 Research Program review was to review the relevance, quality, performance, scientific leadership, and resources of the program. The Subcommittee responded to a series of questions organized into four broad charges that were framed to solicit comments on the program's: (1) design and leadership; (2) quality of science; (3) relevance; and (4) demonstrated program outcomes (see the charge questions to the Subcommittee in Appendix B). The Subcommittee chose to organize the review and report around the four charge questions.

Following an initial administrative conference call, the Subcommittee met in March by conference call to discuss the proposed charge questions and scope of work. The Subcommittee members were sent background information on the program, including copies of the integrated posters to be presented at the face-to-face meeting, which was to be held March 30-31, 2005, in Research Triangle Park (RTP), North Carolina. The Chair of the Subcommittee assigned specific charge questions to each member and asked them to prepare preliminary comments prior to the face-to-face meeting. During the meeting in RTP, EPA researchers and air program

managers, as well as university faculty whose research has been supported by ORD, presented information to the Subcommittee about PM and ozone research and linkages to the regulatory and non-regulatory programs of the EPA Office of Air and Radiation (OAR), the program's principal client. During the meeting, the Subcommittee members revised the preliminary review comments they had prepared before the meeting, and a conference call was convened on April 12, 2005, to complete the draft review report. The Subcommittee members agreed to forward the draft with recommended edits to the Air National Program Director (NPD) and to the BOSC Executive Committee for review at its June 2-3, 2005, meeting. A key issue for the Subcommittee at the outset of the face-to-face meeting was to reach a clear understanding of the difference between a research "output" and an "outcome" within the context of this review. The insights described and commentary provided in this report are based on the technical content and organizational structure of the EPA PM & O_3 Research Program. Detailed resource allocations by research program area were not provided to the Subcommittee. The Subcommittee concluded that although such information might have provided some useful insights in selected areas, it was not required to address the charge questions posed to the BOSC by EPA.

Background for the Particulate Matter & Ozone Research Program

EPA provided the Subcommittee with voluminous materials related to the charge questions. The Subcommittee reviewed the background material for the PM & O_3 Research Program and extracted the following highlights to provide a context for the remainder of the report.

Over the last decade, a wealth of studies has underscored anthropogenic air pollution—notably PM and ozone—as environmental factors that can adversely impact human health and welfare, despite clear evidence that overall air quality has improved.[1] OMB has estimated an annual savings of $101 to $119 billion in hospitalizations and emergency room visits, lost workdays, and premature deaths averted between 1992 and 2002 that can be attributed to air pollution regulations, especially those that resulted in decreased PM.[2] To further increase these benefits, the EPA PM & O_3 program is focused on reducing the uncertainties regarding the source-associated attributes of PM responsible for these impacts and the biological factors that underlie susceptibility to them so that even more cost-effective strategies for environmental regulation and control can be developed.

In 1997, EPA promulgated new national ambient air quality standards (NAAQS) for fine particles ($PM_{2.5}$), based primarily on time-series studies of morbidity and mortality and on two long-term cohort mortality studies. At that time, however, there were many uncertainties regarding, for example, the relationship of fixed-site monitors and actual human exposures, the biological plausibility of the responses to ambient PM, and, assuming a causal relationship between PM exposures and the various adverse health outcomes, which PM constituents were most likely responsible for these effects. These uncertainties prompted Congress to augment the President's recommended EPA budget of $27.8 million in 1998 with a supplement of $22.4

[1] These data are summarized in the recently released NCEA Air Quality Criteria Documents for PM (10/29/04 – http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=87903) and Ozone and Related Photochemical Air Pollutants (01/31/05 - http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=114523). Trends in air quality and emissions can be found on the OAQPS Web Site at http://www.epa.gov/air/oaqps/cleanair.html.

[2] http://www.whitehouse.gov/omb/inforeg/2003_cost-ben_final_rpt.pdf.

million per year and an additional $18.0 million in Fiscal Year (FY) 1999. These additional resources became part of the base PM Research Program and have been included in the Agency's budget requests since that time. The charge to EPA was to accelerate investigations of the role of PM in air pollution-associated health outcomes, and to implement health risk reductions via scientifically defensible regulatory actions. President Clinton emphasized the national scope of the issue when he stated, "The EPA, in partnership with other federal agencies, will develop a greatly expanded coordinated interagency PM research program. The program will contribute to expanding the science associated with PM health effects, as well as developing improved monitoring methods and cost-effective mitigation strategies." To assist in this national effort, Congress mandated the formation of a committee of air pollution experts via the NAS National Research Council (NRC). This NRC Committee met initially to define the scope of the issue and to compile the pressing research needs to advance the science and support the regulatory agenda.[3] The Committee met periodically through 2004, completing a series of four documents delineating the PM research needs in health, and, beginning with the second report, aspects of air quality management. This series of documents also provided, most recently in Volume IV published in April 2004,[4] ongoing assessments of progress, both scientific and administrative, in reducing the uncertainties associated with the relationships of PM and adverse health outcomes, as well as recommendations regarding the direction and implementation of the program.

Following the release of another related NRC report in 2004 entitled *Air Quality Management in the United States*,[5] the Clean Air Act Advisory Committee (CAAAC)—established in 1990 to periodically address issues more specific to air quality—formed a work group to develop recommendations for improvements to air quality management. This Air Quality Management (AQM) Work Group is comprised of representatives from EPA, state and local agencies, tribes, industry, and environmental and research organizations. The charge to the AQM Work Group was to evaluate the NRC AQM findings and develop its own recommendations for consideration by the CAAAC.

Nearly 7 years of intensive research activity have taken place since the initial NRC Research Priorities Report, yielding significant advances in the understanding of PM. In February 2004, ORD released *Particulate Matter Research Program: Five Years of Progress*,[6] which summarized the achievements of EPA's research program in advancing the understanding of both health/exposure and air quality issues. The report, although aimed at the knowledgeable public, is the most comprehensive account of the progress in the PM Research Program through early 2003. The Report summarized the advances in the PM Research Program over the last several years into three broad areas: (1) the credibility and extent of PM-associated health effects and the complex roles of PM attributes and human host factors that contribute to the health outcomes; (2) the factors determining public and individual exposures, including characterization of the sources and atmospheric processes needed to aid implementation of the

[3] http://www4.nas.edu/cp.nsf/Projects+_by+_PIN/BEST-K-98-02-A?OpenDocument.

[4] http://books.nap.edu/catalog/10957.html.

[5] http://www.nap.edu/catalog/10728.html.

[6] http://www.epa.gov/pmresearch/pm_research_accomplishments.

NAAQS; and (3) the development and improvement of "tools" and state-of-the-art technologies needed by the regions, states, and tribes to implement the NAAQS to achieve EPA's Strategic Air Quality Goal (i.e., *"Protect and improve the air so it is healthy to breathe and risks to human health and the environment are reduced."*).[7]

Overarching Conclusions and Recommendations

The Subcommittee was generally pleased with the content and progress of the PM dimensions of ORD's PM & O_3 Research Program. Based on the review, it was clear that the large group of investigators, both within and outside EPA, worked diligently together to present the program in an integrated and readily comprehensible manner that facilitated the job of the reviewers. The following statements summarize the Subcommittee's conclusions and recommendations.

CONCLUSIONS

1. The Subcommittee finds that the PM & O_3 Program directly addresses NRC (and OMB) concerns in terms of the Agency's long-term goals, the plans to meet these goals, and the ways to measure progress toward these goals. The ORD PM & O_3 Research Program has resulted in significant reductions in scientific uncertainty in critical areas, especially the distribution and dosimetry of inhaled fine and ultrafine particles, the relationship of ambient, fixed-site PM monitoring to real-world human exposures, the identification of susceptible subpopulations, the identification of biologically plausible mechanisms of PM toxicity (including cardiovascular effects), the validity of PM epidemiological studies, including in particular confounding and misclassification of exposure, as well as improved emissions monitoring and air quality modeling.

2. The Subcommittee finds that the outputs produced by research to support these reductions in uncertainty have provided a sound basis for subsequent improvements in public health (outcomes). The current ORD PM program provides a balanced blend of research outputs targeted at uncertainty reduction and outcome-directed research to assist OAR in protecting public health. The Subcommittee considers that this blend of output- and outcome-directed research is critical to the long-term success and relevance of the program.

3. The Subcommittee finds that the PART process for evaluating the useful outcomes of the activities of governmental agencies is difficult to apply in evaluating scientific research. The purpose of the EPA research effort is to reduce the uncertainties associated with setting regulations to protect public health and the environment. This type of focused, applied research is not usually funded by the National Institutes of Health, and proprietary research conducted by industry is not available for public use. The metric of success for the ORD research effort is the extent to which the outputs of the research are used by the regulatory offices to set appropriate regulations for protection of public health and the environment (outcome).

[7] EPA Strategic Plan: http://www.epa.gov/ocfo/plan/2003sp.pdf.

4. The Subcommittee finds that the strategic decision to terminate ozone-related health research undercuts part of ORD'S first long-term goal (i.e., *"In 2012, reduced uncertainties in the air pollution sciences will lead to more effective and efficient PM and ozone standard setting and air quality management during each regulatory cycle to minimize adverse risks to human health and the environment"*). The Subcommittee identified two areas of concern if the ozone-related research is curtailed: (1) continuing uncertainty around health effects and the association with increased mortality, and (2) uncertainties around unresolved issues regarding sources of ground-level ozone.

5. The Subcommittee finds a high degree of integration in the conduct of intramural and extramural research across the various laboratories, centers, and scientific disciplines.

6. The Subcommittee finds that ORD has been responsive to the needs of its primary client, OAR, and to its other stakeholders, particularly the EPA Regions and the states. The stakeholders have multiple opportunities for involvement in ORD's assessment and prioritization of research needs.

7. The Subcommittee finds the overall science being conducted by the ORD PM & O_3 Research Program in both intramural and extramural research laboratories to be of high quality as indicated by: (a) scholarship and scientific publications; (b) credentials of participating investigators; (c) integrative and outcome-oriented program design; and (d) building of a knowledge and information database.

8. The Subcommittee finds that the funding for extramural research is based on a highly competitive, merit-based process. The process for intramural funding is not as transparent but is based on the recommendations of the Air Research Coordination Team (RCT), which includes the Air NPD, high-level representatives of ORD's laboratories and the extramural research program, a regional representative, senior scientists from OAR, and others.

9. The Subcommittee concludes that the recent appointment of a permanent director for the Air Research Program is a step forward to improve the overall management of the program.

10. The Subcommittee finds that intra- and interagency communications are excellent. Communication of research results is sufficient and is done through regional, national, and international presentations at scientific conferences and workshops, through publications in peer-reviewed journals, through the EPA Web Site, and through press releases.

RECOMMENDATIONS

1. The Subcommittee recommends that ORD maintain a periodic, formalized process for assessing its primary stakeholders' perceptions of and satisfaction with its role in the source-to-health outcome process. Such an assessment should provide information needed for the PART review. As stated in the conclusions, the metric of success for the program is the extent to which the outputs of the research are used by the regulatory offices to set appropriate regulations for protection of public health and the environment.

2. The Subcommittee recommends that the two long-term goals read as follows:

   (a) By 2012, reduced uncertainties in the air pollution sciences will lead to more effective and efficient PM and ozone standard setting and air quality management during each regulatory cycle to minimize adverse risks to human health and the environment.

   (b) By 2015, reduced uncertainty in the integrated linkages of pollutant sources to health outcomes will ensure that ORD clients target air pollutant strategies most effectively and efficiently to best protect human health and the environment.

3. The Subcommittee recommends structuring the performance of the second long-term goal around two to three hypothesis-driven pilot studies that would demonstrate the source-to-health outcome concept and should provide a reasonable metric to measure the success of the program, both from a science and policy perspective. The Subcommittee recommends the use of an expert panel or workshop to review the pilot studies and to follow their progress on a regular basis. The staff should work with the expert panel or workshop participants to define a baseline of the major current uncertainties for each program component on which future research efforts should be focused. Then the expert panels can assess the reduction of or alterations in uncertainties at regular intervals.

4. Recognizing that EPA faces serious research resource constraints, the Subcommittee nevertheless recommends that ORD reconsider the decision to completely disinvest in ozone research. Continuing research is required for effective ozone standard setting to protect public health and for improved air quality management in regard to sources of ground-level ozone.

5. The Subcommittee reinforces the NRC recommendation that includes the establishment of multi-agency goals and measures of success in meeting national goals, preparation of an MYP for PM/O_3 that incorporates input from other federal agencies, as well as states and private organizations, defines the roles of individual agencies, provides for input from nonfederal organizations into the federal planning process, and expands communication of the planning process to the public. These remain worthwhile recommendations and areas where ORD can assume a leadership role.

6. The Subcommittee recommends that the PM & O_3 Research Program maintain the strong balance between intramural and extramural research that has resulted in the productive program they have today. If funding is reduced, that balance still should be maintained.

7. The Subcommittee recommends that funding decisions for any active intramural project undergo review by the Air RCT.

8. The Subcommittee recommends that the MYP include a discussion indicating how the goals set out by the NRC flow into the crosscutting research issues and how these are embodied under the two long-term goals. If this discussion is in the Research Strategy for the program, the MYP needs to be organized to make obvious the connection between the research and the NRC goals.

9. The Subcommittee recommends that funding be set aside for anticipatory research needs, and that steps be taken by ORD to identify and highlight key anticipatory research needs to inform longer term research and to ensure that current and out-year funded levels of research will be consistent with potential long-term regulatory needs.

The remainder of the report is the more detailed review of the ORD PM & O_3 Research Program organized according to the four charge questions.

CHARGE QUESTION 1: PROGRAM DESIGN AND DEMONSTRATED LEADERSHIP

Does the new draft PM & O_3 MYP structure reflect the identified science needs of the program and show integration and leveraging of human and fiscal resources?

The science needs of the PM & O_3 Research Program largely have been identified and refined through the NRC review process, culminating in the NRC Volume IV report. The NRC has identified several research priorities for the program. In the most recent report, five crosscutting issues across the research priorities were identified: (1) an increasing number of adverse health outcomes associated with PM and the related susceptible subpopulations; (2) particle toxicity in relation to different particle characteristics and emission-source types; (3) increasing emphasis on exposure-dose-response relationships; (4) considering PM health effects within the broader context of other pollutants in the ambient air; and (5) designing PM research programs to inform most effectively the setting and implementation of the PM NAAQS. At the same time and in line with crosscutting issue 4, EPA and the science community have begun to crystallize the concept of "one atmosphere" when dealing with multiple pollutants; this is particularly true in terms of the close correlation between O_3 and PM precursor emissions and chemistry. Finally, the recent assessment of the EPA PM Program using the OMB PART analysis highlighted the need for identified research targets and associated measures of success in achieving these targets. Together, the 10 research priorities, the 5 crosscutting research issues, recognition of the value of the one atmosphere concept, and the need to develop clear targets and associated measures provide the foundation for the PM & O_3 MYP. The research priorities and crosscutting issues form the science needs that must be addressed in the MYP, whereas the one atmosphere approach and the need for program assessment require the integration and leveraging of human and fiscal resources.

Is the PM & O_3 MYP structure strategic by design, implementation, and review?

The structure of the MYP is designed to address two long-term goals (LTGs):

LTG 1: In 2012, reduced uncertainties in the air pollution sciences will lead to more effective and efficient PM and ozone standard setting and air quality management during each regulatory cycle to minimize adverse risks to human health and the environment.[8]

[8] The Subcommittee has suggested changes in the wording for LTG 1 as follows: By 2012, enhance understanding in the air pollution sciences and reduce associated uncertainties leading to more effective and efficient PM and ozone standard setting and air quality management during each regulatory cycle to minimize adverse risks to human health and the environment.

LTG 2: By 2015, reduced uncertainty in the integrated linkages of pollutant sources to health outcomes will ensure that ORD clients target air pollutant strategies most effectively and efficiently to best protect human health and the environment.[9]

The research needed to address LTG 1 provides the sound, specific science required to develop NAAQS for PM and ozone and also the proven tools and support required for implementation of NAAQS. An important aspect of this LTG is the need to communicate PM & O_3 research results to EPA clients to ensure that results are properly interpreted and tools are used effectively to implement NAAQS.

LTG 2 encompasses a shift in approach in proposing to link health outcomes with pollutant source attributes. Because LTG 2 explicitly links emissions with health impacts, it inherently requires integration across disciplines within the EPA research community. These two LTGs explicitly address the science needs identified by the NRC review process, and require that EPA adopt full integration of research activities across disciplines and throughout both the intramural and extramural research programs. Thus, the MYP provides a strategic plan to address science needs and integration of the resources required to achieve results. The LTGs within the MYP also provide the targets and a basis for measuring progress toward those goals as highlighted by the recent PART analysis. The Subcommittee would suggest that the identified measures to track progress in meeting LTG 2 might be better served by identifying two to three hypotheses-driven pilot studies that would demonstrate the source-to-health outcome concept. These proposed studies should consider source-health outcome relationships that likely will have the largest return on demonstrating cost-effective strategies for improving public health.

Does the PM & O_3 MYP structure provide a reasonable "roadmap" of the program, demonstrating a well thought-out plan, identifying critical paths, clear goals, priorities, and schedules?

There are specific measures of success that accompany each LTG. These provide the roadmap for the PM & O_3 Research Program. Under LTG 1, research results must be provided that: (1) establish concentration-effect relationships showing that lower doses of PM lead to lower health impacts; (2) show steady improvement in the quality of predictions from and a reduction of uncertainty in atmospheric models for both PM and ozone; and (3) document that real-world emission reductions lead to improved air quality and reductions in adverse health outcomes. Progress toward these goals requires results that will be measured in terms of periodic reviews of the program and through compilations of EPA peer-reviewed literature. Under LTG 2, results are needed to show: (1) coherence across disciplines that attribute health impacts to sources; and (2) these source-health linkages lead to cost-effective strategies for improving public health. LTG 2 also specifically requires the full integration across the sciences, including the regulatory process, to provide a built-in feedback between science results and regulatory action. The

[9] The Subcommittee has suggested changes in the wording for LTG 2 as follows: By 2015, demonstrate the integrated linkages of pollutant sources to health outcomes and reduce their associated uncertainties to ensure that ORD clients target air pollutant strategies most effectively and efficiently to best protect human health and the environment.

outcome will be an ability to create flexible and cost-effective strategies for protection of public health. As suggested above, structuring LTG 2 performance around hypothesis-driven pilot studies that would demonstrate the source-to-health outcome concept should provide a reasonable metric to measure the success of the program from both a science and policy perspective.

The overall timeline for the MYP is fixed by the NAAQS review and revision process, which specifies the next NAAQS revision cycle begins in FY 2012. Within this timeframe, the MYP will establish intermediate Annual Performance Goals (APGs) and associated Annual Performance Measures (APMs). Beyond an example of these short-term goals, the draft MYP does not appear to include a complete set of APGs and APMs. These will need to be provided in the final MYP.

In the overall structure of the MYP and as part of this review, the Subcommittee has reviewed the original 10 research priorities identified in the initial NRC PM review, 5 crosscutting research issues identified by the NRC Volume IV report, 2 LTGs that form the center piece of the MYP, and, finally, 3 EPA themes within which research results are presented for review. These latter themes include: (1) Health and Exposure; (2) Air Quality; and (3) Source-to-Health Outcomes. It would be useful in the MYP to have a clear delineation among these different ways of addressing the research needs and corresponding research plans. How do the original 10 research priorities flow into the 5 crosscutting themes? How are these embodied in the two LTGs, and how are these addressed in an integrated way within the three EPA research themes? It also would be useful to show the linkage between development of integrated teams (via the existing laboratories, centers, and extramural projects) and the LTGs.

Is the extramural program adequately integrated into the program MYP and goals?

The extramural program includes PM Centers, PM Supersites, and other projects funded via the Science To Achieve Results (STAR) grants program. These are critical pieces in the overall research program because they provide intensive regional efforts across the country, which are yielding important new data regarding PM (and ozone) air quality data and health impacts, and, thus, the beginnings of linked emissions-health outcomes. The extramural program represents a significant fraction of PM and ozone funding by EPA, and there are close ties via relevance reviews and project reports reviewed by EPA staff. STAR grant requests are developed through a process that specifically addresses EPA research needs. Thus, there appears to be adequate integration of the extramural program within the MYP.

Does the PM & O_3 MYP structure reflect an "outcome" orientation that provides measures demonstrating the true impact on public health and the environment?

It seems clear that the LTGs have been written specifically to address the need for an "outcome" orientation. The measures of success that accompany each LTG, as described above, are aimed at documenting how public health is affected by changes in regulation of PM and O_3 and at understanding the mechanisms by which these changes occur. Further details regarding short-term goals are needed.

Is the ORD PM & O_3 Research Program responsive to the recommendations of the NRC in terms of products and outputs? Are the near- and long-term visions of the program consistent with the NRC-noted "challenges for the future"?

The PM & O_3 MYP appears to address directly NRC (and OMB) concerns in terms of the LTGs, the plan to meet these goals, and the ways to measure progress toward these goals. In turn, the MYP also addresses the near- and long-term visions in a manner consistent with the NRC crosscutting research issues. To a large extent, this effort to be responsive is embodied in the source-attribute-health outcome concept that underlies the LTGs. By adopting this source-to-health outcome concept, it is necessary to have emissions and air quality scientists working closely with health outcome investigators. This moves EPA toward integration of efforts across disciplines, and it is necessary to develop and apply tools—measurement, modeling, and health impact methods—to move beyond PM mass toward PM biochemical properties. The source-to-health outcome concept will require the development of innovative proximity measurement techniques and demonstration studies to evaluate source apportionment modeling approaches. In addition, the adoption of the one atmosphere concept that ties PM with ozone as a foundation for research will have common threads with air toxics and hazardous air pollutants, which also will have linkages with the source-to-health outcome paradigm.

Is ORD sufficiently coordinating research across categories of the risk assessment paradigm (source, exposure, health, assessment, and management)?

As noted in the MYP, each ORD laboratory is focused on one aspect related to the risk assessment paradigm. With the growing emphasis on source-to-health outcome, however, close coordination of efforts between various laboratories is essential. Examples of this coordination, as noted by EPA, include collaborative work between the National Health and Environmental Effects Research Laboratory (NHEERL) and the National Exposure Research Laboratory (NERL) for the study of PM effects on highway patrol troopers and collaborative work between NHEERL and the National Risk Management Research Laboratory (NRMRL) to study health effects of various combustion sources. In addition, the development of the MYP inherently includes input from the laboratories, as well as from the ORD administration so there is feedback in research planning among all of the participants.

Is the work within the ORD laboratories and centers integrated to maximize resource investment?

As noted above, there is coordination of research among the laboratories and centers, and the MYP outlines LTGs that require an integrated effort by each specialty area. It is more difficult, however, to judge the degree of integration that currently exists and the degree of integration that is targeted. It would be helpful in this regard to develop measures of integration and measures of success that such integration produces. Documenting the contributions to key findings by different disciplines and the mix of disciplines represented by co-authors on peer-reviewed papers might help measure the success of these integration efforts.

Is EPA ORD providing evident and appropriate science leadership and program management?

The responsiveness of the PM & O_3 Research Program to NRC recommendations, the development of appropriate LTGs, integration of research across EPA laboratories, and the overall structure of the MYP are all indications of successful program management. Science leadership comes from the role EPA has assumed as the lead federal agency on PM issues, as well as from the quality of the science that has evolved in the EPA PM & O_3 Research Program. Key steps that will continue to provide science leadership have been the adoption of the one atmosphere approach and the incorporation of the emission source-to-health outcome paradigm. These are guiding concepts for moving the research program ahead.

Are there changes or refinements in management or science leadership that are needed to improve the Program?

The NRC Volume IV report noted that there have been frequent personnel changes of the NPD and that more stability in this position would improve overall program management. As noted by EPA, a permanent director has recently been appointed, which should improve overall management stability. EPA also notes that there is close coordination between ORD and OAR; this coordination will be critical in meeting the MYP LTGs as they relate to responsiveness between science and regulatory action. The NRC also recommended implementation of modern computer-based management tools to help track short- and long-term goals, resources, and integration of efforts. The Air NPD reports that ORD has established a PM Research Web Page[10] as a portal to the PM research information available from each ORD laboratory and center. The link to ORD's National Center for Environmental Research (NCER) Web Site provides access to project abstracts, progress and final reports, and publication listings for all PM research grants; however, EPA is only in the initial stages of implementing the NRC recommendation to develop this resource into a single repository that includes a comprehensive, easily accessible database of all ongoing research projects. ORD reportedly plans to develop a multipurpose PM & O_3 Web site that will be built on information access starting with the latest NCER listing of PM and ozone publications, inclusive of reference citation and an abstract for each. This database will be maintained in a commonly available commercial bibliographic scheme that can be easily downloaded and used by the science community. Similarly, updated project descriptions and linkages to other relevant Web sites (e.g., EPA, PM Centers, and other federal agencies, etc.) also will be available.

Is the EPA ORD sufficiently communicating its results to its clients and the broader scientific community?

The NRC recommended implementation of methods to focus on communication of research needs from OAR and research results from ORD; EPA responded to this recommendation and noted that working groups were formed to address specific issues. In addition, an executive steering committee composed of the three Laboratory Directors and the Director of OAR's Office of Air Quality Planning and Standards was formed. ORD also employs a variety of methods to maintain communication with the EPA regions and other OAR offices. These

[10] http://www.epa.gov/pmresearch.

include annual briefings, assignment of an ORD liaison to each region, and regular electronic conferences.

Communication with the broader scientific community occurs through the peer-reviewed literature, via presentations by EPA scientists at national and international scientific conferences, and via EPA Web sites. Scientific results also are communicated to the public via the Web and through press releases and public documents.

What can be done to improve communication and access to information by regulatory and science communities?

The NRC recommended development of a PM (and ozone) database that is searchable via the Web. EPA plans to implement this database, but it does not yet exist. This kind of database, encompassing all of the crosscutting research issues, would promote greater exchange of scientific knowledge between EPA and the broader community, and it also would promote greater integration of knowledge across disciplines both within and outside the Agency. Within the air quality community, there has been an effort to promote the Community Multiscale Air Quality (CMAQ) system as a community model through ready availability of the code and updates, annual workshops, and limited support for a center of CMAQ activities. This effort is a good example of how EPA can communicate results and, in turn, take advantage of independent work in the broader community.

Are there important interagency or extramural collaborations that should and can be improved to advance the Agency's research agenda?

To what extent has EPA established and utilized other agencies (inside and outside the government) in advancing the Agency's research agenda? Is the interaction and leadership role of EPA ORD with other federal agencies through the Committee on Environment and Natural Resources (CENR) effectively providing national coordination?

The cross-Agency Particulate Matter Work Group, co-chaired by EPA and the National Institute of Environmental Health Sciences (NIEHS), has tasks to: (1) integrate health, exposure, ecology, atmospheric process, and source characterization research pertaining to PM matter; (2) coordinate efforts among U.S. federal agencies and, as feasible, the private sector; and (3) address the highest research priorities first to inform public policy choices for standard setting and air quality management. Through periodic meetings and a coordinated response to the NRC recommendations and other reports, it appears that this group, with leadership from ORD, is an effective way to promote a unified federal research response to PM (and ozone). The NRC reviewed the situation with respect to a coordinated federal PM research agenda and offered several recommendations. These included establishing multi-agency goals and measures of success in meeting national goals, preparing an MYP for PM that incorporates other federal agencies, as well as states and private organizations, defining the roles of individual agencies, obtaining input from nonfederal organizations into the federal planning process, and expanding communication of the planning process to the public. These remain worthwhile recommendations and areas where ORD can assume a leadership role.

CHARGE QUESTION 2: SCIENCE QUALITY

Is the science being conducted by EPA ORD research laboratories and centers of recognized high quality and appropriate to the perceived needs?

The Subcommittee review of the research program finds the overall science being conducted by the EPA ORD intramural research laboratories to be high quality; the scientific investigative activities contracted to individual research laboratories as well as the PM Centers in various regions of the nation also are recognized as high quality. These evaluations are formulated on the basis of supporting evidence as represented in the following four categories: (1) scholarship and scientific publications; (2) credentials of participating investigators; (3) integrative and outcome-oriented program design; and (4) building a knowledge base and information database.

The scholarship and scientific publications have demonstrated their high quality. More than 1,100 publications between 1998 and February 2005 address various key issues in PM research and document high productivity and scholarly activity. These publications received a high number of citations (e.g., more than 320 manuscripts are among the top 10 percent being cited—and the overall average citations of all manuscripts is 10 times higher than the average for the entire environmental literature), documenting a strong impact in the scientific community and society on PM-related issues. In the most recent iteration of the PM Staff Paper (January 2005), approximately 40 percent of the post-1998 citations involve work conducted under the intramural PM & O_3 Research Program, according to OAR staff.

The high quality of the science is demonstrated by the credentials of the participating investigators. Review of the biographic sketches of the participating investigators finds that participating scientists in both the intramural program and the extramural programs possess excellent to outstanding scientific credentials. Evidence of their individual scholarly achievements includes excellent to outstanding track records, leadership roles in particular scientific subjects, and knowledgeable presentations at program review (poster sessions). The diversity and the collection of the investigator expertise serve to enhance the overall quality of the science. Multiple participating investigators are national- or world-known scholars with expertise and specialty in an array of scientific disciplines and communities. The credentials of the participating investigators served to assure a high scientific quality; however, members of the Subcommittee expressed the opinion that future BOSC reviews would benefit from more detailed information on how projects were actually executed, particularly, identification of all key investigators, whether EPA staff, partner agencies, or researchers under contract.

High quality is demonstrated in the integrated and outcome-oriented program design. This is evidenced by a comprehensive design of an outcome-based research program with a well-qualified and effective management team; scientific approaches that integrate multiple models and utilize validated approaches with the appropriate mix of state-of-the-art technologies; scientific goals that link emission sources to health effects; and publications in the scientific literature, active Web sites, program calls/conferences, and communication programs. ORD

promotes communication of its science and strives to enhance the distribution of its information database.

High quality is demonstrated in building a knowledge base in PM and its related information database. The building of the scientific knowledge base and the collection of its related information database have served to define what was largely unknown. This knowledge base and information database have served to identify and characterize the toxic source (physical and chemical characteristics and the temporal profile and distributions of PM, e.g., roadways as mobile sources and associated PM distributions along the freeway) and its related health effects. Thus, these scientific accomplishments have effectively reduced uncertainties in understanding the adverse toxicity of PM exposure and informed the regulatory process, contributing to improving health outcomes. Scientific discoveries are made in defining and quantifying the toxicity of PM, which served to build a knowledge base that previously did not exist. The knowledge base and information database are used to build air pollution models to analyze and predict exposure outcomes and associated health effects. Scientific progress made in the PM Research Program established biological plausibility, linking health effects to components toward sources. The knowledge base and information database are used to educate the public (e.g., white papers by the American Heart Association formulated on the knowledge base provided by EPA PM research), to facilitate prevention, and to minimize disease occurrence (e.g., myocardial infarction), linking scientific discoveries to improve human health. The scientific progress made has advanced significantly our understanding pertaining to how PM contributes to the pathogenesis of various disease phenotypes, documenting that the adverse effects of PM are multifaceted in nature and, therefore, providing novel information for potential therapeutic regimens. Several projects and centers have attempted to establish potential genomic, proteomic, and physiological biomarkers/parameters to assess the sensitivity and susceptibility on population subsets to PM exposure. These investigations have the potential to aid the identification, monitoring, and regulation of air pollution exposure to humans. They have profound implications in serving the EPA goals to improve human health.

The Subcommittee review of the research program finds that the overall science being conducted by the ORD laboratories and centers is targeted to address the perceived needs. These evaluations are formulated on the basis of supporting evidence as represented below.

Three specific themes are organized to comprehensively address the perceived needs. The theme on *Health and Exposure* research addresses the following specific questions:

1. What are the PM components responsible for its adverse effects?
2. Who is susceptible to the adverse effects of PM?
3. How does PM cause adverse health effects?
4. What are the effects of long-term exposure to PM?

The theme on *Air Quality Management* addresses targeted issues, such as:

1. What is the atmospheric characterization of PM and its co-pollutants; its mass, composition, and variability?
2. What are the sources of PM and co-pollutants and precursors?
3. What are the processes that govern PM (and co-pollutants)?

Through research topics and program management, this theme tackles important scientific and regulatory issues of PM with respect to atmospheric environment, exposure impacts, and regulatory policies.

The theme on *Source-to-Health Outcome* recognizes that health outcomes are linked to sources by a continuum of interconnected biological, chemical, and physical behaviors. It supports research projects to facilitate a greater degree of integration across disciplines and to improve our understanding of the overall impact of PM. Insights provided by studies in this theme characterized multisource or single-source effects (e.g., Utah Valley), clues to toxic attributes, ambient particles in controlled exposures, distribution of pollutants, and air quality models to track PM from specific sources; delineated the effects of complex mixtures; and ultimately supported decision making.

NRC research priorities are implemented for PM research to meet the perceived needs. Program management and the planning process set research priorities to facilitate the implementation of NRC priorities. The program review process assures the directions and quality of the science projects.

There is integration of the LTGs to address the perceived needs. The LTGs are established to reduce uncertainty in exposure and health effects and to serve the perceived needs. The LTGs are organized to link and integrate source-to-health outcome with more efficient strategies.

Is program integration across laboratories, centers, and science discipline making full advantage of research opportunities?

The Subcommittee finds that there is high integration across the various laboratories, centers, and scientific disciplines. This is evidenced in the information presented below.

Program integration ensures synergistic interactions. There is a strong interaction, coordination, and synergism among various laboratories and centers, as is evidenced in the oral presentations, poster presentations, and documents provided to the Subcommittee. It also is apparent that the management of these projects includes planning and procedures that ensure vibrant scientific communications (such as conference calls, investigator meetings at various locations, and the active management of Web site information).

Resource and information sharing maximize research opportunities. With limited resources, the program design has aimed at leveraging resources wherever and whenever possible to maximize the research opportunities. A large portfolio on these issues is funded through the global priority ($30 million over the past 4 or 5 years). Investigators at various laboratories and centers are encouraged to share resources. It is clear from the poster presentations that multiple laboratories have shared specimens, samples, technologies, scientific discoveries, and an information database. The global view of ORD has integrated tightly, and this has transpired in the research program across both the intramural laboratories and the extramural centers. The scientific information sharing process has stimulated research development and discoveries among different centers and laboratories.

Does the program ensure high-quality research through competitive, merit-based funding? If funds are not competitively awarded, what process does the program use to allocate funds? Does this process ensure that quality is maintained?

The extramural programs are funded through Requests for Applications (RFAs), which undergo the normal competitive, merit-based review processes. Investigators across the nation are encouraged to apply to these grants, and the review process has ensured high-quality research that is targeted to NRC priorities.

The funding priorities for the intramural programs are set according to NRC and ORD research priorities for PM, but the exact criteria are less transparent than those for the extramural grants. Based on the high productivity and high quality of science that is coming out of these programs, however, it is clear that the funding process is highly directed and prioritized, and the decisions made were appropriate. The Subcommittee was informed at the meeting that each intramural laboratory distributes the resources differently. Principal investigators (PIs) are invited to provide proposals, and they are encouraged to be interactive among different laboratories. In general, the funds are distributed internally based on the demonstrated ability to deliver the products, the productivity, and the credentials of the PI.

CHARGE QUESTION 3: RELEVANCE

The OMB PART criteria for relevance are articulated as follows:

"RELEVANCE" refers to the contextual framework for the identification of priority research questions related to EPA's regulatory mission and is related to the following questions:

- ✧ Is there an overall conceptual framework with clear goals and priorities?
- ✧ Is the program based on Agency priorities and does it include input from potential users of the research outputs?
- ✧ Is the core research relevant to problem-driven areas of high priority to the Agency?
- ✧ Does the program leverage its efforts with federal and other laboratories to study high-impact environmental questions?"

The charge questions presented below were posed to the Subcommittee by EPA to address the issue of relevance.

Does the PM & O_3 MYP structure and Research Program clearly reflect its focus and the rationale behind its research direction and out-year emphasis?

The BOSC Subcommittee finds that the research directions and rationales for the PM components of the MYP are clearly articulated both in EPA documents, such as the 2003 PM MYP, and in a variety of assessments undertaken by external organizations, most notably the NRC. Congress and EPA requested guidance on PM research from the latter institution, which established a blue-ribbon Committee on Research Priorities for Airborne Particulate Matter in 1998. The NRC committee was charged with formulating a research agenda and with periodically monitoring progress in reducing the uncertainties in the evidence used as the basis for setting the NAAQS for PM. The NRC has undertaken extensive reviews of prior and ongoing research and has issued four reports, most recently in 2004. Initially, the NRC proposed 10 areas of emphasis, focusing mainly on issues related to health research, but, in subsequent reports, added 2 additional topic areas to its research portfolio, specifically atmospheric measurements and methods and source-to-health outcome assessments. An overarching focus for all of these issues was conducting research that would reduce the inherent level of uncertainty in each area. In the opinion of the BOSC Subcommittee, the NRC research recommendations have formed a central intellectual core around which much of the ORD PM Research Program has been structured. Within the compass of the Subcommittee's review, all of EPA's PM research projects, both intramural and extramural, have been designed to answer questions or develop methods within the broad categories recommended by the NRC.

The most recent NRC assessment of research progress on PM indicates substantial progress in some areas and less in others. The NRC recognized that investigations in certain areas would

have to be addressed serially, which is reflected in part in the sequencing of EPA's intermediate- and longer term research objectives. For other topics, the NRC intimated that it would have liked to see greater progress. The Subcommittee, however, finds that, viewed *in toto*, the EPA PM Research Program has resulted in dramatic reductions in scientific uncertainty in critical areas, especially (among many others) the relationship of ambient (outdoor), fixed-site PM monitoring to real-world human exposures; the identification of susceptible subpopulations; the identification of biologically plausible mechanisms of PM toxicity (including cardiovascular effects); and the validity of PM epidemiological studies, critically examining the potential effects of confounding by co-pollutants and misclassification of exposure. The Agency's current research agenda will build on these achievements and help strengthen the basis for the PM standards' protection of public health.

The Subcommittee finds that the outputs produced by the research to support these reductions in uncertainty have provided a sound basis for subsequent improvements in public health (outcomes) in the out-years estimated in the most recent (2005) PM Staff Paper to result from revising the PM NAAQS. The current ORD PM program appears to provide an exceptional blend of research outputs targeted at uncertainty reduction and outcome-directed research to assist OAR in protecting public health. The Subcommittee considers this blend of output- and outcome-directed research critical to the long-term success and relevance of the program.

In contrast to EPA's strong commitment to multidimensional PM-related research, there is little rationale adduced by EPA for the decision to end health-related research on ozone. In epidemiological studies examining the relationship of PM with various health outcomes, the potential confounding influence of ozone must be considered; however, this is not an optimal strategy to investigate ozone's effects. Although it is clear that exposures to ambient PM impart significant risks to public health at and below the levels of the current ambient air quality standards, similar considerations also may apply to ozone. During the 1980s and early 1990s, ORD researchers demonstrated that controlled, multi-hour ozone exposures of exercising adults resulted in lung inflammation, airway hyperreactivity, reduced lung function, and respiratory symptoms, even at the lowest concentration tested (0.08 ppm).[11] The federal ambient air quality standard for ozone of 0.08 ppm, averaged over 8 hours, provides little, if any, margin of safety against these and possibly other effects. Moreover, recent epidemiological studies suggest that ozone exposure is, like PM, associated with increased daily mortality.[12]

Although the importance of continued research emphasis on PM is clear, the strategic decision to terminate ozone-associated health research effectively undercuts part of ORD's LTG 1: "In 2012, reduced uncertainties in the air pollution sciences will lead to more effective and efficient PM and ozone standard setting and air quality management during each regulatory cycle to minimize adverse risks to human health and the environment." The extent to which ozone is associated with increased mortality or other health effects (e.g., new cases of asthma[13]) represents an area of scientific uncertainty that impinges on the health-protectiveness of the existing ozone NAAQS. These concerns are echoed in the most recent formal peer review of

[11] Horstman, et al., 1990 ; Devlin, et al., 1991; McDonnell, et al., 1991.

[12] See, e.g., Bell, et al., 2004.

[13] See McConnell, et al., 2002.

ORD's NERL (September 30 - October 2, 2003): "There are concerns about the yet unresolved issues regarding sources of ground-level ozone, the ability to adequately model its formation and fate, and to fully understand its effects on human health. It is hoped that research on knowledge gaps regarding ground-level ozone can be funded adequately so that important control policy questions can be answered." Therefore, absent a renewed commitment to ozone health research, the ozone component of LTG 1 is not adequately addressed in the PM & O_3 MYP. Recognizing that EPA faces serious research resource constraints, the Subcommittee nevertheless recommends that ORD reconsider the decision to completely disinvest in ozone health research.[14]

Although a stated commitment (in the material provided to the Subcommittee by ORD) has been made to fund several key research efforts to completion within the PM & O_3 plan (notably the Multi-Ethnic Study of Atherosclerosis-Air Study and the PM Centers), similar guarantees for funding out-years of other long-term programs do not appear to exist. EPA staff described an internal review process to make focused program reductions, when necessary, but this process was not transparent to the Subcommittee. The Subcommittee recommends that decisions to significantly reduce funding for any activated intramural project within the PM & O_3 Program should undergo a review by the Air RCT. This would take full advantage of the integrated oversight and review mechanism already in place to guide the PM & O_3 Program. Such structured review is considered critical to ensure long-term funding accountability, especially when resource reductions are unavoidable or new scientific findings warrant project redirection or reprioritization.

Are the potential public benefits in terms of public health protection and pollution abatement clearly articulated?

The Clean Air Act directs EPA to set ambient air quality standards with an adequate margin of safety "that are requisite to protect public health." This legislative mandate represents the ultimate authority and rationale for EPA's research program, which is intended to provide the scientific support for such standards. Epidemiological research described in the most recent (2004) Air Quality Criteria Document (AQCD) has convincingly demonstrated that ambient PM exposures are linked with increased risks of premature mortality, hospital admissions and emergency room visits for both cardiovascular and pulmonary disease, asthma attacks, missed

[14] Bell ML, McDermott A, Zeger SL, Samet JM, Dominici F. Ozone and short-term mortality in 95 U.S. urban communities, 1987-2000. *JAMA* 2004;292(19):2372-2378.
Devlin RB, McDonnell WF, Mann R, Becker S, House DE, Schreinemachers D, Koren HS. Exposure of humans to ambient levels of ozone for 6.6 hours causes cellular and biochemical changes in the lung. *Am J Respir Cell Mol Biol* 1991;4(1):72-81.
Horstman DH, Folinsbee LJ, Ives PJ, Abdul-Salaam S, McDonnell WF. Ozone concentration and pulmonary response relationships for 6.6-hour exposures with five hours of moderate exercise to 0.08, 0.10, and 0.12 ppm. *Am Rev Respir Dis* 1990;142(5):1158-1163.
McConnell R, Berhane K, Gilliland F, London SJ, Islam T, Gauderman WJ, Avol E, Margolis HG, Peters JM. Asthma in exercising children exposed to ozone: a cohort study. *Lancet* 2002;359(9304):386-391.
McDonnell WF, Kehrl HR, Abdul-Salaam S, Ives PJ, Folinsbee LJ, Devlin RB, O'Neil JJ, Horstman DH. Respiratory response of humans exposed to low levels of ozone for 6.6 hours. *Arch Environ Health* 1991;46(3):145-150.
National Research Council. Committee on Research Priorities for Airborne Particulate Matter. Washington, DC, National Academy of Sciences, 2004, 240 pp.

school and work days, long-term effects on children's lung growth and development, and other adverse effects. Studies of the associations of both long- and short-term exposures to ambient PM indicate that the risks of adverse effects increase with increased levels of exposure. This evidence is presented in encyclopedic detail in the AQCD produced by ORD and applied in the Staff Paper, which is compiled by OAR with extensive input from ORD scientists.

The logical corollary to the increase in health risks associated with increased ambient PM is that sustained decreases in pollutant concentrations would result in significant improvements in public health. ORD is intent on increasing research to ascertain the extent to which improvements in air quality result in improvements in public health, an area that has been dubbed "accountability research." At first blush, this would seem to be a relatively straightforward enterprise; however, such research is actually quite difficult to undertake in a scripted manner in the absence of abrupt changes in pollution. Nevertheless, there have been a few "natural experiments" that have corroborated the notion that reductions in air pollution result in observable decreases in adverse health events. One dramatic example involved the Utah Valley, where respiratory hospital admissions decreased substantially during a steel mill closure in the mid-1980s, increasing again when the mill reopened (Pope, 1989). Recent ORD research provided biological support for this epidemiological finding in a toxicological investigation of the pro-inflammatory effects of PM collected in the Utah Valley both when the mill was operating and when it was not.[15] Similarly, after coal distribution was banned in 1990 in Dublin, Ireland, nontraumatic mortality, including respiratory and cardiovascular deaths, dropped substantially within the next few years, coincident with the decrease in coal combustion emissions.[16] New, as-yet-unpublished analyses of mortality in the Harvard Six Cities study also indicate that there is markedly less PM-associated mortality in cities where there have been substantial reductions in ambient PM.

Until additional accountability research is undertaken, however, the public health benefits of pollution control will have to be based on estimates derived from existing epidemiological studies. Such benefits are enormous. In 2003, OMB produced a report estimating that air pollution regulations resulted in an annual savings of $101 to $119 billion from 1992 to 2002, due to avoidance of premature deaths, hospitalizations, emergency room visits, and lost workdays.[17]

An additional public benefit resulting from ORD research has been the provision of tools to the general public, health care providers, and certain institutions (e.g., schools) to raise awareness of pollution-associated health effects and to allow for nonregulatory, individual actions to reduce

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[15] Dye JA, Lehmann JR, McGee JK, Winsett DW, Ledbetter AD, Everitt JI, Ghio AJ, Costa DL. Acute pulmonary toxicity of particulate matter filter extracts in rats: coherence with epidemiologic studies in Utah Valley residents. *Environ Health Perspect* 2001;109(Suppl 3):395-403.

[16] Clancy L, Goodman P, Sinclair H, Dockery DW. Effect of air-pollution control on death rates in Dublin, Ireland: an intervention study. *Lancet* 2002;360(9341):1210-1214.
Goodman PG, Dockery DW, Clancy L. Cause-specific mortality and the extended effects of particulate pollution and temperature exposure. *Environ Health Perspect* 2004;112(2):179-185.

[17] See Table 2, p. 8 of OMB report.
Pope CA III. Respiratory disease associated with community air pollution and a steel mill, Utah Valley. *Am J Public Health* 1989;79(5):623-628.

personal exposures to ozone and PM. ORD staff members have worked in collaboration with their primary client, OAR, to develop a nationally uniform air quality index (AQI), which is transmitted via local media and on the Web so that potentially susceptible populations can alter their activities to reduce exposures, depending on local air quality. The utility of the AQI has been critically dependent on ORD's continually improving air quality modeling efforts, which are used to predict local pollutant concentrations, facilitating the transmission of relevant information in a timely manner. Other OAR tools developed with ORD assistance include educational materials for health care providers, such as downloadable pollutant fact sheets, a Web-based course on air pollution and health, and a medical office poster for patient education.

During the face-to-face meeting, Dr. Mark Utell clearly illustrated the dramatic strides the PM Research Program has made in the past decade in convincing clinicians of the adverse impacts of minute quantities of air pollutants. He noted that neither cardiologists nor cardiovascular physiologists seriously linked cardiac mortality and morbidity with air pollution in 1999. By 2004, however, the American Heart Association issued a formal statement acknowledging the linkage.[18] This change in thinking was accomplished in only 5 years, clearly indicating the strength and relevance of the science, as well as the effectiveness of the mechanisms used to convey the messages to the medical community, particularly through publication in high-caliber medical journals.

Has the PM & O_3 Research Program effectively engaged stakeholders in its assessment processes and provided useful information and tools in a timely manner?

ORD's primary client for the PM & O_3 Research Program outputs within EPA is OAR, which is responsible for periodically reviewing and, if necessary, revising the NAAQS. In general, the Subcommittee believes the primary clients and stakeholders for the PM & O_3 Research Program (i.e., OAR and the EPA regions) have multiple opportunities for involvement in ORD's assessment of research needs and direction (see response to Charge Question 4) and that ORD has provided useful information to these groups. ORD staff and programs play critical roles in assisting OAR to fulfill its mission. First and foremost, ORD's National Center for Environmental Assessment and other scientific staff develop AQCDs, encyclopedic compilations of relevant scientific results with multiple OAR applications, specifically: (1) providing the scientific foundations for air quality standards and other regulations; (2) identifying important gaps to be addressed in future research; (3) providing input into assessments of the benefits of air quality regulations; and (4) serving as a resource for the development of OAR's public outreach and education efforts, such as the AQI or posters for health care professionals. OAR staff members synthesize the materials presented in the AQCD to formulate policy-relevant recommendations for the NAAQS. ORD scientists also provide technical peer review and consultation in the development of both the staff paper and the NAAQS.
Regarding the utility of the information developed for OAR, the Subcommittee believes that the compass of research sponsored by or conducted intramurally under the auspices of the PM

[18] Brook RD, Franklin B, Cascio W, Hong Y, Howard G, Lipsett M, Luepker R, Mittleman M, Samet J, Smith SC Jr, Tager I. Air pollution and cardiovascular disease: a statement for healthcare professionals from the Expert Panel on Population and Prevention Science of the American Heart Association. *Circulation* 2004;109(21):2655-2671.

Program since 1997, has been extremely important in reducing major scientific uncertainties related to the PM NAAQS. For example, in 1997 the scientific database regarding the biological plausibility of serious human toxicity from ambient PM exposures was quite thin. In contrast, caused in large part by research sponsored by or conducted intramurally by ORD, there is a substantial body of evidence supporting biological plausibility, including major contributions on potential mechanisms such as oxidative stress and inflammation (Froines and Ghio posters), cellular signal transduction (Samet poster), perturbations of hemostasis and cardiac autonomic balance (Cascio poster), alterations of vascular function (Frampton and Dreher posters), focal hyperdeposition of particles in individuals with preexisting lung disease (Kim poster), and ultrafine particle uptake and reactivity (Froines and Oberdörster posters). Most of this work was undertaken directly by ORD scientists or by investigators funded by NCER, notably the Southern California and the Rochester PM Centers. In its intramural research, ORD scientists have provided many of the important reports utilized by OAR in developing Staff Papers. In the most recent iteration of the PM Staff Paper (January 2005), approximately 40 percent of the post-1998 citations involve work undertaken by the intramural PM Research Program, according to OAR staff.

A number of other research projects highlighted during the Subcommittee Meeting illustrated forward-looking efforts to examine source-to-health outcome relationships among the general population and among those with the high exposures, including both healthy and compromised individuals. In the Detroit Exposure and Aerosol Research Study, subjects within the Detroit metropolitan area have been selected in part based on their residential proximity to localized sources (Vette poster). Other ORD studies examine the impact of high-level experimental exposures to mobile source emissions among both healthy adults (the Car-related Occupational PM and Air Toxics Exposure to Patrolmen Study) and potentially compromised older subjects (the St. Louis bus study; Suh poster). The Baldauf poster described mobile source emission characterizations, allowing for the examination of a wide range of source strengths and exposure proximity. The latter posters illustrate the relevance of the development of science within ORD that will inform OAR's future regulatory processes. The Subcommittee supports the development of research characterizing the intersection of the most exposed with the most susceptible subpopulations as important components in evaluating the potential health benefits of different regulatory scenarios.

Throughout the research planning process in ORD, there are frequent opportunities for OAR and the other principal EPA internal clients (the regions) to provide input. The Air RCT, which plays a pivotal role in all research planning for the air programs, includes a regional representative and senior scientists from OAR. The RCT holds weekly teleconferences; another weekly conference call is dedicated specifically to PM-related research. The regional representative receives input from the various regions and from the states regarding their needs for implementation-related research, such as improvements to CMAQ modeling. In addition, ORD representatives attend annual meetings of the regional offices, both to provide information about the current state of relevant research and to elicit input from the Regions on their needs. In addition, representatives of the NCER STAR program go to the regional offices to present information on STAR research and to receive regional feedback. Thus, there are many opportunities for ORD's primary stakeholders to provide input to research planning.

With respect to research intended to assist states and tribes with implementation of standards, the Subcommittee believes that EPA has made substantial progress in recent years. Standing

committees have been established to provide formal outreach to states and tribes to help assess and address the needs of both of the latter groups with respect to measurement technology, emissions inventories, and air quality modeling. For instance, EPA staff and extramural grantees have been developing measurement technologies for coarse particles, including quality assurance/quality control protocols, which will be needed at the local level to implement any future coarse particle standard.

Some Subcommittee members voiced concerns, however, that EPA has not undertaken sufficient anticipatory research for coarse particles, as it has been clear for nearly 5 years that an NAAQS for $PM_{10-2.5}$ would be required by the courts. Moreover, the poster by Vanderpool highlighted Subcommittee concerns that some aspects of the $PM_{10-2.5}$ research within ORD and the potential monitoring network deployment by OAR should be revisited. Specifically, the apparent absence of siting criteria for $PM_{10-2.5}$ monitors and very limited funding to deploy significant numbers of samplers may seriously affect the representativeness of any data collected. $PM_{10-2.5}$ is known to be much more spatially variable in metropolitan areas. The influences of factors such as proximity to localized sources (e.g., roadway dust resuspension), ground cloud concentrations by height, bluff body biases from nearby obstructions, and so forth, need to be considered. Otherwise, the data produced could seriously be biased. Having an insufficient number of $PM_{10-2.5}$ samplers to characterize these potential spatial biases also could produce databases lacking the robustness needed to support epidemiological studies or other outcome assessments. The organizational integration between ORD and OAR in the PM & O_3 Research Program that was demonstrated to the Subcommittee should, in principle, facilitate addressing technical issues such as these, which require blending research and regulatory requirements to meet multiple objectives in the most technically sound and cost-effective manner.

In addition to its pursuit of policy- and implementation-relevant research objectives, ORD has continued to pursue other long-range anticipatory research components to answer questions not considered necessary for its primary client's near-term programmatic needs. With input from OAR and other stakeholders, ORD supports research that could play important roles in out-year Staff Papers. Examples include research on source and exposure characterization, dosimetry, and health effects of ultrafine particles (UFPs). Recent findings now clearly demonstrate that UFP can generate significant oxidative stress relative to either $PM_{2.5}$ or $PM_{10-2.5}$ and can produce adverse responses both in the lung and at distal sites (Oberdörster and Froines posters). Ambient concentrations of UFP are markedly elevated on and near roadways (Suh and Sioutas posters) and may explain some of the adverse respiratory and other effects associated with residences near heavily trafficked streets. As with coarse particles, however, some Subcommittee members expressed concern that the timing and magnitude of ORD research funding may not have been commensurate with the apparent toxicity of or the breadth of population exposures to UFP.

Overall, the Subcommittee finds that ORD has been responsive to the needs of its primary client, OAR, and to its secondary stakeholders, particularly the Regions and the states. ORD staff members and officials regularly interact with these and other stakeholders and make conscientious and frequently productive efforts to meet their needs.

During the Subcommittee's review, it transpired that there is no institutionalized formal mechanism for ORD to assess stakeholders' perceptions of its performance. Such a mechanism could be a useful means for ORD to help gauge its progress in providing relevant information

and tools to its clients. Therefore, the Subcommittee recommends that ORD consider establishing a periodic formalized process for assessing its primary stakeholders' perceptions of and satisfaction with its efforts.

Has the program begun to establish a process for using the results of assessments, along with stakeholder feedback, to identify key research gaps and to update the programs' research agenda?

Since the inception of the enhanced PM & O_3 Research Program in 1998, ORD has incorporated the recommendations of the NRC Committee on Research Priorities for Airborne Particulate Matter into its research planning process. These general recommendations have formed the core of the PM research effort in ORD and are clearly reflected in the PM MYP (2003). These research directions have been supplemented by the Fine Particle Assessment of NARSTO[19], which focused mainly on issues related to standards implementation, and those of the Clean Air Act Advisory Committee. In general, the Subcommittee recognizes that ORD seriously considers the research recommendations of these independent expert panels.

Two of the ORD laboratories (NHEERL and NERL) have institutionalized periodic formal peer review processes to address not only the technical quality of their scientific programs, but also their relevance to EPA needs. Excerpts from the most recent peer review of NHEERL provided to the Subcommittee indicate strong support for the Human Studies Division's (HSD) research on PM components, susceptibility, and mechanisms (e.g., "HSD scientists have a proven track record of identifying major scientific uncertainties and then designing and carrying out appropriate research approaches to address them"), balanced with recommendations for improvements.

Although NCER has not established formal periodic reviews of its programs, the NRC conducted an assessment of the STAR program in 2002-2003, including an evaluation of NCER's PM research.[20] The NRC review committee provided a highly favorable assessment of the STAR program's research scope, process, and relevance to EPA's mission, indicating at the same time, however, that the STAR program was still too young to assess in terms of its programmatic impact. In addition, EPA's Science Advisory Board evaluated NCER's PM Center program in 2002,[21] likewise providing positive, complimentary feedback on this program, along with guidance for future directions, which EPA has incorporated into its research planning. The RFAs issued by NCER are developed with iterative input from the RCTs, and are intended to complement EPA's intramural research program. Proposals submitted in response to NCER RFAs are rigorously reviewed by independent scientists; those proposals receiving favorable assessments then are evaluated by ORD's Programmatic Review Panel (including representation from OAR and the Regions, as well as ORD), which makes funding recommendations based on,

[19] Formerly an acronym for the North American Research Strategy for Tropospheric Ozone, the term NARSTO has become simply a wordmark signifying a tri-national (U.S., Canada, and Mexico), public-private partnership dealing with multiple features of tropospheric pollution, including ozone and suspended PM.

[20] http://books.nap.edu/catalog/10701.html.

[21] http://www.epa.gov/sab/pdf/ec02008.pdf.

among other things, relevance to EPA's mission and the addition of balance to the existing research portfolio.

One of the primary venues for the identification of research gaps has been the cyclic development of AQCDs by ORD and the Staff Paper by OAR. This process affords numerous opportunities for the identification of important research gaps by both ORD scientists and those associated with OAR and other stakeholders. The process of compiling an assessment of research illuminates not only what is known, but also what is still unknown. One result of the Staff Paper development is to identify important research gaps; for instance, Section 5.5 of the most recent PM Staff Paper (January 2005) is entitled "Summary of Key Uncertainties and Research Recommendations Related to Setting Primary PM Standards," and includes seven high-priority areas for PM research prior to the next cycle of review. Development of the AQCD and the Staff Paper are very public processes, during which there are multiple occasions for input from OAR and other stakeholders with respect to the identification of research needs. Toward the end of the AQCD/Staff Paper process, EPA holds workshops to provide input into the Research Needs Document, with OAR as the lead office. This Research Needs Document is incorporated into all aspects of the Air RCT's planning processes. Thus, OAR plays a large role in determining that the allocation of research funding is relevant to its programmatic needs.

Although the results of research endeavors may reduce important scientific uncertainties, they may raise additional previously unrecognized questions. As discussed in the Subcommittee's response to the previous charge question, recent research on UFP deposition and clearance indicated that such tiny particles can cross the lung surface into the bloodstream to be transported to other organs, elevating the importance of their potential toxicity. Although this finding narrowed one aspect of uncertainty about a potential mechanism by which particles in the lung could cause systemic effects (i.e., could particles act directly on distant organs?), it also raised questions about whether such particles also could cross another tissue barrier to go directly into the brain (via the olfactory nerve). Toxicological experiments recently undertaken at the University of Rochester PM Center, funded by ORD, have demonstrated that such translocation of particles into the brain does indeed occur, resulting in inflammation in the area of deposition. This in turn creates additional uncertainties (e.g., can exposure to PM cause chronic, low-level neurological inflammation, resulting in brain damage and dementia?). Thus, although research can lay to rest some uncertainties, it also can generate new and often highly relevant questions. The absence of funding to permit followup on promising lines of research undermines the strength of the PM & O_3 Research Program, which is at a stage of discovery that would likely yield important new understanding from opportunities to expand research in key areas. The Subcommittee finds that, were such funds set aside for anticipatory research projects, the PM & O_3 Research Program would effectively employ them.

Both the AQCD and the Staff Paper are reviewed by the Clean Air Scientific Advisory Committee (CASAC), which generally includes not only academic experts, but also at least one representative each from industry, public health organizations, and the states. The CASAC provides advice to the EPA Administrator and essentially has *de facto* authority with respect to the quality and relevance of the science contained in both documents. Given CASAC's institutional prominence and the high visibility of it reviews, ORD must address that committee's concerns regarding research needs. Although other stakeholders are afforded opportunities at CASAC meetings to voice their opinions regarding the quality of the science in the AQCD and Staff Paper, this does not appear to represent an optimal setting to identify research gaps that

EPA incorporates into its planning process. A more appropriate public forum would be the workshops sponsored by OAR during the development of the Research Needs Document.

An additional avenue by which ORD identifies research needs is through interactions and collaborations with other organizations that fund research on air pollution, including federal agencies, the Health Effects Institute (HEI), and industry institutes. Along with NIEHS, EPA co-chairs the Particulate Matter Workgroup of the interagency CENR that comprises 22 federal agency representatives, including several of the National Institutes of Health, the Centers for Disease Control and Prevention, the Department of Energy, the Department of Transportation, and the Department of Defense, among others. This CENR workgroup meets bimonthly with the goals of integrating and prioritizing PM-related research and coordinating their efforts to eliminate duplication. One recent outgrowth of this collaboration was the issuance of a joint EPA-NIEHS RFA soliciting research proposals to examine the role of PM in cardiovascular disease. The explosion of recent research suggesting major health impacts of traffic emissions has created an area of common concern to many of the CENR participants that may result in cross-agency partnerships to examine traffic-related exposures and health effects.

The HEI owes its existence to funding provided by ORD, OAR, and industry. A joint OAR-ORD committee coordinates research priorities with HEI, which has funded several major efforts that have complemented EPA's PM research, including the National Morbidity, Mortality, and Air Pollution Study of the largest metropolitan areas in the United States, as well as detailed re-analyses of the two large longitudinal epidemiological studies that serve as the principal foundation of the annual average PM NAAQS.

ORD also has, on occasion, worked jointly with industry funders on specific research projects, such as the extension of the Atlanta Supersite research into the Aerosol Research and Inhalation Epidemiology Study, which is largely supported by the Electric Power Research Institute. ORD also has partnered with HEI and the Coordinating Research Council on the Advanced Collaborative Emissions Study, which was originally proposed by the Engine Manufacturers Association to measure emissions and examine potential health effects of new diesel engines designed to meet on-road heavy-duty emissions standards. Though somewhat opportunistic, these examples indicate ORD's willingness to leverage its scarce resources by investing with the private sector in pursuit of research objectives of mutual interest. Such partnering appears easily facilitated through existing linkages to organizations such as HEI and NARSTO and can potentially provide significant leveraging of available PM & O_3 resources. Neither the criteria by which such projects are selected nor the process of prioritization of these efforts relative to other research needs, however, was obvious to the Subcommittee.

CHARGE QUESTION 4: DEMONSTRATED OUTCOMES

The two LTGs of ORD's PM & O_3 Research Program were introduced under Charge Question 1. These LTGs are qualitative, and there must be quantitative goals/measures to assess progress and success.

As discussed under Charge Question 1: Program Design and Demonstrated Leadership, some minor changes in the wording of the two LTGs identified in the MYP for the PM & O_3 Research Program have been suggested and, most importantly, the Subcommittee proposes consideration of a hypothesis-driven approach in tracking and quantifying progress in LTG 2. The linking of health outcomes to sources entails unraveling the complex interactions and contributions of primary and secondary pollutants to human exposure and demonstration of the overall toxicity of source-specific components. The Subcommittee believes that demonstration of the viability of the source-to-health outcome concept would be best served through well-designed hypothesis-driven pilot studies.

The following questions raised in the "Charge to the BOSC Subcommittee" are aimed at assessing whether EPA has developed quantitative goals/measures and how well EPA is doing with respect to those goals/measures.

Does the program have a limited number of specific long-term performance measures that focus on outcomes and meaningfully reflect the purpose of the program?

The program has defined several specific long-term performance measures that adequately focus on outcomes and that are consistent with the purpose of the ORD program. EPA provided examples of possible measures to the BOSC Subcommittee on page 11 of Section 2 – Multi-Year Plan Development. Those measures are listed below in italics for each LTG. Many of those measures are, at this point, qualitative rather than quantitative. EPA acknowledges that "[t]he measures require a degree of quantification." We provide below some guidance to quantify those measures so that progress made by the program can be assessed.

LTG 1

By 2012, enhance understanding in the air pollution sciences and reduce associated uncertainties leading to more effective and efficient PM and ozone standard setting and air quality management during each regulatory cycle to minimize adverse risks to human health and the environment.

ORD publications in AQCD will exceed 20 percent. This is a reasonable measure because the AQCDs for ozone and PM provide a comprehensive review of the state-of-the-science. Another additional measure could be added; for example, 20 percent of citations in the air quality, exposure, and health effect literature will correspond to ORD-sponsored publications. Such measures (20 percent) seem realistic based on the current level of high-quality research sponsored by ORD.

Atmospheric models will show incremental improvements in predicting real-world ambient PM and ozone levels—every 2 years an improved model will be formally released and adopted for field use. This measure as currently stated is too vague. The term "improved" should be quantified because improvements can range from minor to significant. The performance of CMAQ has improved significantly over the past few years because of improvements in model formulation and inputs (emissions). The performance of CMAQ (and other similar air quality models), however, is still poor for PM components because of our limited understanding of atmospheric processes (e.g., formation of secondary organic aerosols from volatile organic compounds [VOCs]) and uncertainties in model inputs (mostly meteorology and emissions). The CMAQ update cycle, as proposed, will provide a steady stream of "new and better" chemical kinetic modules, but unless the essential model inputs also improve (especially 3-D meteorology and emissions), state, local government, and tribal entities may construct State Implementation Plans that do not reflect the best information. The Subcommittee recommends that an independent expert panel be responsible to define the current uncertainties associated with the modeling of ozone and PM ambient air concentrations. Those uncertainties could be characterized according to a ranking similar to that used in the NARSTO report for PM air quality modeling. To better track progress, five uncertainty categories could be used: very high, high, moderate, low, and very low. Then, the expert panel would evaluate progress made for each of the areas under consideration according to a realistic schedule (e.g., every 2 years).

Real-world reductions yield less health impacts (accountability. This is an important measure. Some examples of progress made over the past several years were provided by EPA using results from the Harvard Six Cities study (evolution of annual average PM concentrations and mortality relative risk). EPA should propose some quantification of this measure along the same lines. EPA also should consider quantifying the health benefits. Research into improved methodologies for estimating health benefits may be needed in that regard.

The accumulated peer-reviewed literature in the air pollution sciences will be compiled and interpreted about every 5 years for review in AQCD. This is a valuable measure of the use of ORD's sponsored research for the development of NAAQS. The schedule is consistent with that for the AQCD (although some delays will typically be associated with CASAC review for the preparation of the final versions of the AQCD).

At 3-4 year intervals, ad hoc *expert review panels assess progress on the NRC Topic Areas or through the use of "expert elicitation"-like approaches*. This measure is important as it provides outside expert judgment on EPA ORD's progress toward the stated LTG 1. One of the expert review panels should address the improvements made in the air quality model CMAQ (see recommendation above). The Subcommittee recommends that, in addition to the NRC topic areas, those *ad hoc* expert review panels also address the eight NARSTO "policy questions." To facilitate the evaluation of progress, a baseline of the current uncertainties should first be established for each component of the program. The expert panels then can assess the uncertainties at regular intervals and measure progress accordingly. The frequency of the reviews should be selected to correspond to the pace of anticipated progress in the various components of the program (i.e., it should be about 2 years for the evaluation of improvement in CMAQ).

LTG 2

By 2015, demonstrate the integrated linkages of pollutant sources to health outcomes and reduce their associated uncertainties to ensure that ORD clients target air pollutant strategies most effectively and efficiently to best protect human health and the environment.

Multi-city approaches show coherence across disciplines attributing health impacts to hazardous components/sources—a hierarchy of source risk will be established (10 percent per year). Coherence across disciplines is an important point. The Utah Valley smelter study (poster presented by Alice Dye) is one example of how coherence among different disciplines can provide an answer to a real-world air pollution problem. The EPA goal of one city per year seems reasonable.

Actions lead to most cost-effective strategies for improving public health. This cost-effectiveness measure is very valuable as the costs associated with the control of air pollution can be significant. EPA needs to develop a methodology to clarify how this cost-effectiveness will be quantified. There needs to be recognition that cost-benefit analyses can be biased as control costs are frequently overestimated and health benefits are underestimated.

At regular and frequent intervals, ad hoc *expert review panels assess progress on the source-to-health outcome*. The *ad hoc* expert review panels will play a similar role as for LTG 1. The Subcommittee recommends that the frequency of the reviews be less than 5 years (e.g., 3 to 4 years) to provide for a minimum of three reviews through 2015 and to ensure a continuous evaluation of progress toward LTG 2.

The program will fully integrate from the sciences to the regulatory process to create flexible and cost-effective approaches to protecting the public from air pollution. The use of hypotheses (e.g., "primary PM causes health effects") was proposed above as an effective way to measure progress toward LTG 2. The Subcommittee recommends that the hypotheses proposed by EPA should first be reviewed by an expert panel. EPA then may revise some hypotheses based on comments received from the panel. Then, the expert panel will review progress on the work conducted to address those hypotheses every 5 years. At the time of those reviews, some hypotheses may be confirmed, whereas others may not. New hypotheses then may be proposed based on new available information. This approach will provide the flexibility needed for the integrated source-to-health outcome process by allowing ORD to adjust its hypotheses (and the related research) at regular intervals.

Has the program made significant progress in the conduct of the planned research and in answering the key science questions related to public health and pollution abatement?

Key science questions include the questions raised by the NRC Committee that focus mostly, but not exclusively, on health effects and the questions raised by the NARSTO Assessment that focus mostly on the emissions/PM concentrations relationships (the NARSTO questions are actually called "policy questions," but they are technical questions meant to address policy

issues). One question is similar in the NRC and NARSTO lists (relationship between emissions and PM concentrations) that would give a list of 17 questions. NARSTO also raises the key question: "How can we measure progress?" that relates to this entire section.

Based on the review of the work accomplished by ORD's program (as presented in the oral presentations and the corresponding posters), the Subcommittee concluded that significant progress has been made in the various areas of the research program.

Although the PM program has made significant strides in addressing some of the key health issues, there remains much that needs to be done. As with any well-designed research program, new and unexpected questions have arisen from the findings of research completed to date. Based on the funded projects and their timelines, the program seems to have some flexibility to follow promising new leads when identified.

Since the late 1990s, EPA's research program has focused on PM. Recently, EPA staff has recognized that there are still significant questions remaining with reference to the public health impacts of ozone. Consequently, the PM research program has been expanded to include ozone. The return to investigation of ozone impacts is welcome and overdue.

In many cases, the questions and data gaps with reference to ozone readily fit into the same topics as those that have guided the PM Research Program. Since the beginning of the emphasis on PM research, only a few studies have included ozone, and much remains to be done in planning an effective ozone research plan to move forward. There does not, however, appear to be a developed plan for ozone health research, at least based on the materials presented for review.

The following charge questions in the "Charge to the BOSC Subcommittee" are broken down into sub-questions.

Does the program have ambitious targets and timeframes for long-term goals?

Has the program made adequate progress in meeting its long-term goals?

Several independent reviews (e.g., Fourth NRC report) have stated that EPA was making significant progress. The Subcommittee review of the posters also suggests that EPA is making significant progress.

Are there baselines and appropriate targets and timeframes for long-term measures?

Baselines need to be established for the various areas of the programs. The Subcommittee recommends that expert panels define the current levels of uncertainties in the various areas of the program. Those uncertainties would constitute the baselines. The NARSTO Assessment report provides a suitable listing of the current state-of-the-science for the air quality portion that can be used to provide the baselines for the emissions/ambient concentration component. Perhaps the NRC report can provide baselines for the health and exposure components. EPA then can define quantitative targets with associated timeframes to reduce the uncertainties. For

example, what uncertainties are associated with organic PM? The expert panels then would review progress with respect to the baselines and those targets.

Have the research products been consistent with the program's goals and supportive of client needs?

The overall answer is "yes." There are, however, some areas where ORD work products have been lagging behind the needs of the community because of a lack of resources. One example is the development of emission inventories for biogenic VOCs that are PM precursors. Although EPA has conducted some excellent research work to characterize emissions of biogenic VOCs from vegetation, the incorporation of the resulting information into practical tools (such as the emission models) is slow. Although the biogenic emission inventory system, BEIS3, now includes monoterpene speciation, it took several years before it became available and it still does not include sesquiterpenes. This problem is caused in part by a lack of resources (i.e., not enough full-time equivalents) but possibly also in part to insufficient planning across disciplines. The Subcommittee recommends that adequate resources be assigned to the timely transfer of fundamental research products to practical tools that can be used for air quality management.

Are the research program findings incorporated into regulation and standards, published in the peer-reviewed literature, or do they otherwise demonstrate superior scientific quality?

The overall answer is "yes." The ORD-sponsored research includes some scientific products of high quality (see answer to Charge Question 2).

Results from EPA-funded research are normally published in the peer-reviewed literature. It contributes significantly to NAAQS reviews, review of AAQS in California, and to air quality standards abroad as well.

Do independent evaluations of sufficient scope and quality indicate that the program is effective and is achieving results?

It appears that there are several mechanisms in place for independent evaluations of ORD's research (pp. 19-21 of Response Question 3). Those evaluations seem to focus on the overall quality and quantity of the results, the major uncertainties and scientific gaps, and future directions. Independent detailed technical reviews could be set up for specific work products; for example, independent review of a biostatistical analysis of epidemiological data (such a review was done a few years ago for the Harvard Six Cities and American Cancer Society data), independent review of the CMAQ computer code, and so on. Such reviews would be expensive and would have to be selected carefully.

Does the program demonstrate improved efficiencies and cost effectiveness in achieving program goals each year?

The program demonstrates an effective use of research funding to advance the state-of-the-science with real-world benefits in terms of material that is used by OAR to develop air quality standards and manage air quality.

Do EPA-ORD and program leadership make adjustments in the program's science and emphasis to meet the evolving science and research needs?

EPA-ORD has shown some flexibility in adjusting to the changes resulting from new standards (switch in emphasis from ozone to PM) and from new scientific results (addition of cardiovascular PM risk). The review by expert panels of research conducted to address hypotheses (see above) at regular intervals will provide the opportunity for EPA to adjust its program's science and emphasis based on the results of the research and comments received from the expert panel. It also will provide the opportunity to the expert panel to assess EPA's flexibility.

Is the program appropriately structured to allow for flexibility in direction and emphasis?

The program offers some flexibility to adjust to the needs of ORD's clients. Examples include the switch of health science from ozone to PM, the new focus on UFP and coarse particles, the new interest in cardiovascular health effects of PM, and the increased interest in source-to-health outcomes.

APPENDIX A: CHARGE QUESTIONS

Charge for the BOSC Subcommittee on Particulate Matter and Ozone Research

1.0 Objective

The objective of this review is to evaluate the relevance, quality, performance, as well as the scientific and managerial leadership of Office of Research and Development's (ORD) Particulate Matter and Ozone (PM & O_3) Research Program. The Subcommittee's evaluation and recommendations will provide guidance to ORD to help:

- ✧ Plan, implement, and strengthen the Program;
- ✧ Make research investment decisions over the next 5 years;
- ✧ Refine the integration of the ORD Program with those of other federal agencies;
- ✧ Prepare EPA's performance and accountability reports to Congress under the Government Performance and Results Act; and
- ✧ Respond to evaluations of federal research such as those conducted by the Office of Management and Budget (OMB highlights the value of recommendations from independent expert panels in guidance to federal agencies[1,2]).

2.0 Background Information

Independent expert review is used extensively in industry, federal agencies, congressional committees, and academia. The National Academy of Sciences (NAS) has recommended this approach for evaluating federal research programs.[3]

Because of the nature of research, it is not possible to measure the creation of new knowledge as it develops, or the pace at which research progresses or scientific breakthroughs occur. Demonstrating research contributions to outcomes is very challenging[4] when federal agencies conduct research to support regulatory decisions, and then rely on third parties,[5] such as state environmental agencies, to enforce the regulations and demonstrate environmental improvements. Typically, many years may be required for practical research applications to be developed, and decades may be required for some research outcomes to be achieved.

Most of EPA's environmental research programs investigate complex environmental problems and processes—combining use-inspired basic research[6,7] with applied research and integrating several scientific disciplines across a conceptual framework[8] that links research to environmental decisions or environmental outcomes. In multidisciplinary research programs such as these, progress toward outcomes cannot be measured by outputs created in a single year. Rather,

research progress occurs over several years as research teams explore hypotheses with individual studies, interpret research findings, and then develop hypotheses for future studies.

In designing and managing its research programs, ORD emphasizes the importance of identifying priority research questions to guide the research. Similarly, ORD recommends that its programs develop a small number of performance goals that serve as indicators of progress. Short-term outcomes are accomplished when research is applied by specific clients to strengthen environmental decisions or regulations. These decisions and resulting actions (e.g., the reduction of contaminant emissions or the reduction of uncertainties in risk assessment) ultimately contribute to improved environmental quality and health.

In a comprehensive evaluation of science and research at EPA, the National Research Council (NRC) recommended[9] that the Agency substantially increase its efforts to explain the significance of its research products and to assist clients inside and outside the Agency in applying them. In response to this recommendation, ORD has engaged science advisors from client organizations to serve as members of its research program teams. These teams help identify research contributions with significant decision-making value and help plan for their transfer and application.

For EPA's environmental research programs, periodic retrospective analysis at intervals of 4 or 5 years is needed to characterize research progress, to identify when clients are applying research to strengthen environmental decisions, and to evaluate client feedback about the research. Conducting program evaluation at this interval enables assessment of research progress, the scientific quality and decision-making value of the research, and whether research progress has resulted in short-term outcomes for specific clients.

In 1998, Congress augmented the budget for PM-related research and mandated the establishment of an NRC Committee to assess the research needs for PM. The NRC Committee since has published four reports of *Research Priorities for Airborne Particulate Matter*, with Volume IV published in October 2004.[10] The four volumes have provided guidance to the PM & O_3 Research Program in the form of an initial 10 (and eventually 12) priority research areas (needs). In these same reports, the NRC has submitted peer-expert evaluations of the Agency's PM & O_3 Research Program that identify its strengths, productivity, and shortcomings, as well as challenges for the future. Since 1998, ORD has aligned its research program with the NRC priorities, evolving the relative emphases on these priorities with the development of the science, client needs, and frequent peer reviews of all or selected parts of the program.

It is essential to appreciate that the ORD PM Program comprises an intramural research program in health and implementation, as well as an extramural (grant funded) program that is complimentary and integrated by design to meet the needs of its client, the Office of Air and Radiation. In completing the final report (Volume IV), the NRC provided its assessment of the PM & O_3 Research Program and its accomplishments and delineated a series of challenges for the years ahead. These challenges were provided in the presentation of the Committee Chair, Dr. Jonathan Samet of Johns Hopkins University, to ORD at the completion of Volume IV. The charge to the NRC Committee reviewing the PM Program now is complete, and the formal Committee will cease to exist; however, it is expected that *ad hoc* committees will be convened at points in the future to revisit the program priorities and directions.

Beginning in 1997, ORD gradually redirected its long-standing Ozone Research Program, initially focused on health and ecology, to allow for the growth and emphasis in health research in PM. Agency-supported ozone-specific research in these areas currently is minimal. More recently, an analogous adjustment has occurred in the implementation program as well. In the latter case, the atmospheric science research in ozone and PM were merged in research of atmospheric processes and modeling, as they are inextricably linked in the air environment. With the disinvestment in the ozone-specific research and its emergence in a more integrated form within the PM Program efforts in atmospheric chemistry and co-pollutant health research, these two largely independent research programs have been fully merged, which is evidenced by plans to revise the Multi-Year Plans (MYP) for PM and Ozone into a merged, single MYP.

In 2003, the PM Program underwent review by OMB using a novel approach to assess program success. This approach used the Program Assessment Rating Tool (PART) that, in brief, focused on: (1) the relevance of the PM Program to its clients; (2) the clarity and specificity of its long-term goals and resultant outcomes that could be linked explicitly with measurable improvements in health and the environment; (3) research progress and performance; and (4) the resource management that ensures high-quality research. Overall, the PM Program scored well in this process, except in the areas designated in focus (2) requiring demonstrated measurable outcomes in public health and the environment. As the PM and Ozone Programs have been merged and enter a second PART review, the intent is to use this BOSC assessment of the program's new structure, its management and leadership, as well as its scientific achievements and directions to guide preparations for the PART review, which will be conducted in spring/summer 2004.

3.0 Draft Charge Questions for ORD's Particulate Matter & Ozone Research Program

The following charge questions will help evaluate the relevance, quality, performance, as well as management and scientific leadership of ORD's PM & O_3 Research Program:

1. <u>Program Design and Demonstrated Leadership</u>

- ✧ Does the new draft PM & O_3 MYP structure reflect the identified science needs of the program and show integration and leveraging of human and fiscal resources?
  - Is the PM & O_3 MYP structure strategic by design, implementation, and review?
  - Does the PM & O_3 MYP structure provide a reasonable "road-map" of the program demonstrating a well thought-out plan and identifying critical paths, clear goals, priorities, and schedules?
  - Is the extramural program adequately integrated into the program MYP and goals?
  - Does the PM & O_3 MYP structure reflect an "outcome" orientation that provides measures demonstrating the true impact on public health and the environment?
  - Is the ORD PM & O_3 Program responsive to the recommendations of the NRC in terms of products and outputs?
  - Are the near and long-term visions of the program consistent with the NRC-noted "challenges for the future"?

- ✧ Is ORD sufficiently coordinating research across categories of the risk assessment paradigm (source, exposure, health, assessment, and management)?
  - Is the work within laboratories and centers integrated to maximize resource investment?

- ✧ Is EPA-ORD providing evident and appropriate science leadership and program management?
  - Are there changes or refinements in management or science leadership that are needed to improve the program?

- ✧ Is EPA-ORD sufficiently communicating its results to its clients and the broader scientific community?
  - What can be done to improve communication and access to information by regulatory and science communities?

- ✧ Are there important interagency or extramural collaborations that should and can be improved to advance the Agency's research agenda?
  - To what extent has EPA established and utilized other organizations (inside and outside governments) in advancing the Agency's research agenda?
  - Is the interaction and leadership role of EPA-ORD with other federal agencies through the Committee on Environment and Natural Resources effectively providing national coordination?

2. <u>Science Quality</u>

- ✧ Is the research being conducted by EPA-ORD laboratories and centers of recognized high quality and appropriate to the perceived needs?

- ✧ Is program integration across laboratories, centers, and science disciplines making full advantage of research opportunities?

- ✧ Does the program ensure high-quality research through competitive, merit-based funding? If funds are not competitively awarded, what process does the program use to allocate funds? Does this process ensure that quality is maintained?

3. <u>Relevance</u>

- ✧ Does the PM & O_3 MYP structure and Research Program clearly reflect its focus and the rationale behind its research direction and out-year emphasis?

- ✧ Are the potential public benefits in terms of public health protection and pollution abatement clearly articulated?

- ✧ Has the PM & O_3 Research Program effectively engaged stakeholders in its assessment processes and provided useful information and tools in a timely manner?
- ✧ Has the program begun to establish a process for using the results of assessments, along with stakeholder feedback, to identify key research gaps and to update the program's research agenda?

4. Demonstrated Outcomes

- ✧ Does the program have a limited number of specific long-term performance measures that focus on outcomes and meaningfully reflect the purpose of the program?

- ✧ Has the program made significant progress in the conduct of the planned research and in answering the key science questions related to public health and pollution abatement?

- ✧ Does the program have ambitious targets and timeframes for long-term measures?
  - Has the program made adequate progress in meeting its long-term goals?
  - Are there baselines and appropriate targets for the program's annual measures?
  - Have the program's research products been consistent with the program's goals and supportive of client needs?
  - Are the research program's findings incorporated into regulations and standards, published in the peer-reviewed literature, or do they otherwise demonstrate superior scientific quality?

- ✧ Do independent evaluations of sufficient scope and quality indicate that the program is effective and is achieving results?
  - Does the program demonstrate improved efficiencies and cost effectiveness in achieving program goals each year?

- ✧ Do EPA-ORD and program leadership make adjustments in the program's science and emphasis to meet the evolving science and research needs?
  - Is the program appropriately structured to allow for flexibility in direction and emphasis?

4.0 Potential BOSC Approach for Program Review

- ✧ Hold conference call(s) in the month preceding a face-to-face meeting.
  - ▸ Goal: Familiarize the Subcommittee with review objectives, introduce review materials, and make assignments for the face-to-face meeting.
    1. The Designated Federal Officer distributes background materials and documents requested by the Subcommittee 4 weeks in advance of the first conference call.
    2. ORD presents background materials to the Subcommittee during the first call for initial orientation.
    3. The Subcommittee reviews and comments on the charge.
    4. The Subcommittee asks clarifying questions about the program under review.
    5. The Subcommittee Chair makes review and writing assignments to Subcommittee members in advance of the face-to-face meeting.

- ✧ Hold a 2 to 3 day face-to-face meeting for the program review at a location where a critical mass of ORD scientists is located.
  - ▸ Goal: A draft Subcommittee report is available for circulation and comment at the end of the face-to-face meeting that thoroughly addresses all charge questions.
    1. The first segment of the meeting: ORD presentations and poster sessions, Subcommittee questions and discussion, identification of issues for further resolution.

2. The second segment of the meeting: the Subcommittee discusses prepared written assignments in context of presentations and discussion, identifies and agrees to areas for change, elaboration, or other adjustment of the text as necessary.
3. The third segment of the meeting: the Subcommittee revises written assignments and assembles them into a draft report.

- ✧ As necessary, hold one to two conference calls to complete the draft report in the month following the face-to-face meeting.
  - ▸ Goal: A report approved by the Subcommittee is available for BOSC Executive Committee discussion/approval at the May 2005 BOSC Executive Committee meeting, with a final draft completed within 30 days following the meeting.

5.0 References

1 Budget Data Request 04-31. Executive Office of the President, Office of Management and Budget. March 22, 2004. "Completing the Program Assessment Rating Tool (PART) for the FY06 Review Process," pp. 50-56.

2 Memorandum for the Heads of Executive Departments and Agencies. Executive Office of the President, Office of Management and Budget. June 5, 2003. "FY 2005 Interagency Research and Development Priorities," pp. 5-10.

3 *Evaluating Federal Research Under the Government Performance and Results Act*, National Research Council, Washington, DC, 1999.

4 The House Science Subcommittee. Letter to Dr. Bruce Alberts, President of the National Academy of Sciences, from F. James Sensenbrenner, Jr. and George E. Brown. October 23, 1997.

5 *The Government Performance and Results Act: 1997 Government-wide Implementation Will Be Uneven*. U.S. General Accounting Office (GAO/GGD), Washington, DC, 1997.

6 *Building a Foundation for Sound Environmental Decisions*, National Research Council, Washington, DC, 1997.

7 "Renewing the Compact between Science and Government," Stokes DE, in *1995 Forum Proceedings, Vannevar Bush II—Science for the 21st Century*. Sigma Xi, Research Triangle Park, NC, 1995, pp. 15-32.

8 Risk Assessment in the Federal Government: Managing the Process, National Research Council, Washington, DC, 1983.

9 *Strengthening Science at the U.S. Environmental Protection Agency*, National Research Council, Washington, DC, 2000, p. 141.

10 National Research Council of the National Academies: *Research Priorities for Airborne Particulate Matter IV*, The National Academies Press, Washington, DC, 2004 (http://www.nap.edu; Volume IV - http://www.nap.edu/books/0309091993/html/).

Note: A PDF file of the OSTP/OMB Research and Development Investment Criteria was included with the Charge.

APPENDIX B: BIOGRAPHICAL SKETCHES OF THE SUBCOMMITTEE MEMBERS

Rogene Henderson, Ph.D.

Dr. Henderson is Director of the Lovelace Respiratory Symposium at the Lovelace Respiratory Research Institute (LRRI), and Clinical Professor at the University of New Mexico's College of Pharmacy. She is a National Associate of the National Academy of Sciences (NAS), and has participated on NAS committees and EPA's Science Advisory Board. Her research interests include: biochemistry of the lung; mechanisms by which pulmonary inflammation leads to repair or chronic disease; pharmacokinetics of inhaled xenobiotics; and chemical-specific biomarkers of chemical exposure. Dr. Henderson has studied the use of biological markers of exposure and effects to link environmental exposure to induced disease. LRRI is an independent research institution focused on respiratory health, funded by government agencies, industry associations, private companies, health advocacy groups, and private donors.

Juarine Stewart, Ph.D.

Dr. Stewart is the interim Dean of the School of Computer, Mathematical, and Natural Sciences at Morgan State University in Baltimore, Maryland. She received her Ph.D. in Biomedical Sciences from the Oak Ridge Graduate School of Biomedical Sciences, University of Tennessee at Knoxville, in 1978. She was a post-doctoral fellow in Biochemistry at the Department of Chemistry at Clark Atlanta University, Atlanta, Georgia, from 1979 to 1981. She has conducted research and published on the subject of complex sphingolipids at the enzyme activity, protein, and mRNA levels. Dr. Stewart has served in many professional capacities and presently is a member of the Visiting Committee, Commission on Colleges, Southern Association of Colleges and Schools; and Chair of the Department of Defense Review Committee for Historically Black Colleges and Universities Prostate Cancer Program. Prior to her position at Morgan State, Dr. Stewart was a Professor in the Department of Biological Sciences at Clark Atlanta University.

Bart E. Croes, P.E.

Mr. Croes is the Chief of the Research Division of the California Air Resources Board. He received his M.S. in Chemical Engineering from the University of California at Santa Barbara, and is licensed by the State of California as a Professional Engineer (P.E.). His responsibilities for the Research Division include: setting California ambient air quality standards for particulate matter, ozone, and nitrogen dioxide; assessing personal exposure and indoor air quality for homes, schools, and in vehicles; incorporating health impacts, cost/benefit analysis, and model of the California economy into the Diesel Risk Reduction Program and other major state regulations; managing a research portfolio with $5 to 10 million in new projects each year; and developing a 10-year strategic research plan, annual research plans, and research plan for vulnerable populations. Other recent research related activity includes: serving as a consultant for projects in Canada (reactivity of alternative fuels), Mexico

(air quality modeling), Germany (emission inventory reconciliation, hydrocarbon reactivity), The Netherlands (emission inventory reconciliation, field study design), China (monitoring network design, forecasting, modeling), and Thailand (reformulated fuels); serving as a Program Manager for the $6 million 1997 Southern California Ozone Study (SCOS97)-North American Research Strategy for Tropospheric Ozone (NARSTO) and the $1 million SCOS97-NARSTO Aerosol Program and Radiation Study (comprehensive efforts to better understand the processes involved in the formation of high ozone and PM concentrations in southern California); guided development of hydrocarbon reactivity scale for California's Low Emission Vehicle/ Clean Fuel regulations; planned modeling and analysis of the $14 million Southern California Air Quality Study in Los Angeles and designed the data management process; and developed modeling guidelines for New Source Review to include impacts of secondarily formed particles on PM_{10} and sulfate standards. His other professional services include: invited participant to EPA's workshops to set national policy for modeling in PM_{10} State Implementation Plans; member of Ambient Air Monitoring and Methods Subcommittee of the Clean Air Scientific Advisory Committee (CASAC), 2004-present; member of the Clean Air Technical Advisory Group of the American Lung Association of California (ALAC), 2004-present; member of the South Coast Air Quality Management District (SCAQMD) Asthma Consortium Advisory Committee, 2003-present; member of the SCAQMD Research Advisory Committee, 2002-present; Public Sector Co-Chair for NARSTO, 2002-2004; member of the Haagen-Smit Symposium Steering Committee, 2001-present; member of the California EPA-Resources Agency–University of California at Davis Memorandum of Understanding Joint Steering Committee, 2000-present; member of NARSTO Executive Assembly, 2000-present; member of National Research Council Committee on Research Priorities for Airborne Particulate Matter, 1998-2004.

Kenneth Demerjian, Ph.D.

Dr. Demerjian is the Director of the Atmospheric Sciences Research Center at the Albany State University of New York. He received his Ph.D. from The Ohio State University in Physical Chemistry in 1973 and an M.S. in Physical Chemistry in 1970. Dr. Demerjian's research interests include: chemical kinetics and mechanistic pathways of elementary atmospheric reactions and the development of reaction mechanisms of polluted and clean atmospheres; instrumentation development and measurement of atmospheric trace gases and particulate matter; development and evaluation of air quality forecast models and diagnostic analysis of atmospheric processes within air quality modeling systems; experimental and theoretical studies of actinic solar flux and atmospheric photolytic rate constants; sources and evaluation of uncertainty in theoretical models of atmospheric processes, air quality, and pollutant exposures; and the articulation and effective use of scientific uncertainty in the decision-making process. His awards include the EPA Bronze Medal for Commendable service, and his professional service includes: Health Effects Institute Research Committee; CASAC National Ambient Air Monitoring Strategy Subcommittee; Executive Committee, Board on Oceans and Atmosphere of the National

Association of State Universities and Land Grant Colleges; University Corporation of Atmospheric Research Members' Nominating Committee; National Research Council (NRC) Committee on Atmospheric Chemistry, Co-Chair, Synthesis Team-NARSTO, 1996 to 2000; Coordinating Committee for the Atmospheric Chemistry and Environmental Education in Global Change, 1994 to 1999; Chairman, Peer Review Panel – NO_x/VOC Science Program, Environment Canada, 1993; NRC/NAS Committee on Tropospheric Ozone Formation and Measurement, 1989 to 1991; International Joint Commission Air Quality Advisory Board/Expert Group on Monitoring, 1987 to 1991; Desert Research Institute National Science Advisory Committee, 1988 to 1992; Office of Technology Assessment, and U.S. Congress Advisory Panel on the Assessment of New Clean Air Act Issues, 1987 to 1989. He has published widely and recent invited lectures include: United Nations Economic Commission for Europe EMEP Workshop on Particulate Matter Measurement and Modeling sponsored by the U.S. EPA and Environment Canada, New Orleans, LA, April 19-23, 2004; EPA Carbonaceous PM: The State of the Science (CPM II), Carbonaceous $PM_{2.5}$: Lessons [Being] Learned from the New York Supersite, April 11-12; and Health Effects Institute, 2003 Annual Conference, Committee on Health Impact of Regulations to Improve Air Quality, "What Is Accountability?", Boulder, CO, May 4-6, 2003.

Brian Lamb, Ph.D.

Dr. Lamb is the Boeing Distinguished Professor of Environmental Engineering at Idaho State University. He received his Ph.D. in Chemistry in 1978 from the California Institute of Technology. Dr. Lamb has been involved in atmospheric pollutant transport and dispersion studies for more than 20 years. This has involved a combination of atmospheric tracer field studies and the development, evaluation, and application of a variety of air quality models. Currently, Dr. Lamb is directing the development of a real-time urban air quality forecast system for the Puget Sound region of Seattle, as well as a project to demonstrate the application of the EPA Community Multi-Scale Air Quality model to the Pacific Northwest for regional haze. This has involved development of detailed emission inventories, incorporation of prognostic meteorological modeling, and evaluation of model performance using an array of available monitoring data. Dr. Lamb also has directed the development of a regional windblown dust air quality model for the Columbia Plateau region of eastern Washington. In related work, Dr. Lamb has developed atmospheric tracer instrumentation—portable syringe samplers and real-time continuous tracer analyzers—that have been widely used at Washington State University (WSU) and by others to probe the nature of pollutant transport and dispersion over scales ranging from a few meters to hundreds of kilometers. Dr. Lamb helped to pioneer the use of numerical 3-D turbulence models applied to flow near buildings, and he was responsible for the development of one of the first plume models designed to yield concentration fluctuation statistics related to the instantaneous behavior of a plume. Dr. Lamb also is involved in research concerning biogenic trace gas emissions and their role in atmospheric chemistry. The EPA Biogenic Emission Inventory System was originally developed under his direction at WSU. Ongoing work includes isoprene flux measurements in northern Michigan as part

of the National Science Foundation PROPHET program, measurement of terpene emissions at an old growth Douglas fir forest using the Wind River Crane Research Facility as part of the Department of Energy's (DOE) terrestrial carbon exchange research, and development of a revised biogenic emission inventory in the Pacific Northwest. These studies involve the application of eddy flux, relaxed eddy accumulation, ambient sampling, and leaf/needle cuvette measurement methods.

Michael Lipsett, M.D., J.D. Dr. Lipsett is the Chief of the Exposure Assessment Section in the Environmental Health Investigations Branch of the California Department of Health Services. He is licensed to practice medicine and law in California and Board Certified in Public Health and General Preventive Medicine. Dr. Lipsett received his J.D. from the University of California at Berkeley in 1976, and his M.D. from the University of California at San Diego in 1980. Current and recent research includes: childhood asthma prevalence and risk factors at the border funded by the Centers for Disease Control and Prevention; air pollution and cardiovascular disease in the California Teachers Study, funded by the California Air Resources Board; the relationship of ambient particulate matter to heart rate variability and cardiac arrhythmias in a population of elderly adults with coronary artery disease, supported by EPA; and the Center for the Health Assessment of Mothers and Children of Salinas. He has an academic appointment as Associate Clinical Professor in the University of California at San Francisco Department of Epidemiology and Biostatistics. His awards include: Gold Superior Achievement Award (in recognition of exceptional contribution and service to state government), Air Resources Board, 2002; Clean Air Award, ALAC, 1998; Clean Air ENVY (Environmental) Award, American Lung Association, San Francisco/San Mateo, 1996; and Phi Beta Kappa, 1971. Dr. Lipsett is a reviewer for numerous professional journals, including: *Environmental Health Perspectives*, *Environmental Research*, *Journal of Exposure Analysis and Environmental Epidemiology*, *American Journal of Epidemiology*, *Epidemiology*, *New England Journal of Medicine*, *American Journal of Respiratory and Critical Care Medicine*, *Inhalation Toxicology*, *Israel Journal of Medical Sciences*, *International Journal of Occupational and Environmental Medicine*, *Journal of Environmental Medicine*, and *Thorax*. Additionally, he was a reviewer for the National Science and Technology Council, Executive Office of the President of the United States, "Interagency Assessment of Potential Health Risks Associated with Oxygenated Gasoline," in 1996; and for the U.S. Global Change Research Program, "U.S. National Assessment of the Potential Consequences of Climate Variability and Change," submitted as a report to the U.S. Congress in 2000. His professional service includes: Multi-Ethnic Study of Atherosclerosis External Scientific Advisory Committee; American Heart Association, Expert Panel on Population and Prevention Science; American Thoracic Society, Environmental and Occupational Health Assembly and the Committee to Update the Statement on "Health Effects of Tremolite"; the ALAC Clean Air Technical Advisory Group; and the Advisory Committee, University of California at Davis, Environmental/Occupational Medicine Academic Award.

Peipei Ping, Ph.D.

Dr. Ping is a professor in the Department of Physiology and Division of Cardiology at the University of California at Los Angeles (UCLA) and Director of the Ischemia Biology Program and Proteomic Laboratory at UCLA. She received her Ph.D. in Physiology at the University of Arizona in 1990. From 1991 to 1992, she was a fellow at the University of North Carolina at Chapel Hill in Molecular Physiology and at the University of California at San Diego from 1992 to 1994 in Molecular Cardiology. Dr. Ping has numerous ongoing research projects including: PKC and Src protein tyrosine kinase signaling in preconditioning, the long-term objective of which is to elucidate the signaling mechanisms underlying the early and late phases of ischemia and NO donor-mediated preconditioning; signaling mechanisms in pharmacological preconditioning, the long-term objective of which is to explore the signaling mechanisms of Src tyrosine kinases in pharmacological preconditioning; mitochondria and Cardiac Cell death, the long-term objective of which is to explore the electrical property and signaling event of mitochondrial permeability transition in hypoxia-induced mitochondrial injury; and functional proteomic characterization of cardiac mitochondria, the objective of which is to identify and characterize multiprotein complexes in the cardiac mitochondria. Dr. Ping has received many honors including: University Scholar (University of Louisville), 2000; Young Investigator Award (American Heart Association [AHA]), 1998; Young Investigator Award (AHA), 1993; Henry Christian Memorial Award (American Federation for Clinical Research [AFCR]), 1993; Trainee Investigator Award (Association of American Physicians, American Society for Clinical Investigation, AFCR), 1993; Caroline tum Suden Professional Opportunity Award (American Physiological Society), 1992; and Excellence in Research Award (AHA), 1990. Her professional service includes: Fellow, American Physiological Society, Cardiovascular Section, 2001-present; Fellow, AHA Basic Science Council, 1999-present; Group Leader, Myocardial Ischemia/Basic Science Council AHA, 2002; Founding Council Member of Human Proteome Organization (HUPO), 2001; Member of Executive Committee, 2002; Co-Leader, Cell Model Proteome Initiative, 2002; Human Plasma Proteome Initiative, Member of the Executive Committee, 2002-present; Chair of Education/Training Committee; Chair of HUPO Award Committee, 2003-2006; Chair of Scientific Program Committee, HUPO, 2004 and 2006. Dr. Ping also is a consulting and associate editor and on the editorial board of the *American Journal of Physiology Heart and Circulatory Physiology*.

Charles E. Rodes, Ph.D.

Dr. Rodes is a Senior Research Environmental Engineer at the Research Triangle Institute (RTI) for planning, conducting, and managing technical research covering a wide range of topics and technologies associated with multimedia exposure assessment, with a focus on aerosols. Dr. Rodes received his Ph.D. in Environmental Engineering from the University of North Carolina at Chapel Hill in 1992. He received his M.S. in Chemical Engineering from North Carolina State University in 1971, and a B.S. in Chemical Engineering from Clemson University in 1966. Dr. Rodes has more than 38 years of experience in planning, conducting, managing, and reporting research, developmental, and assessment activities across a broad range of environmental insults.

Prior to joining RTI, Dr. Rodes worked for 23 years at EPA (1966–1988) conducting both laboratory and field "bench" studies and managing research. His activities incorporate a diverse range of skills including: multimedia/multiroute human exposure assessment; personal, indoor air, and microenvironmental air sampling for size-specific aerosols and gases; characterization of particle and gas phase collection media performance for immune building application; designing sensor systems for bio-chem threats; compartmental, receptor, and dispersion modeling of contaminants in indoor and urban environments; relating exposures to health indicators in panel study settings for adults and children; dermal transfer characterization of dusts and residues; activity pattern assessments for adults and children; in-vehicle contaminant exposure assessment; indoor air velocity and turbulence characterizations; indoor aerosol resuspension studies from carpeted flooring; pollution prevention from indoor sources, $PM_{2.5}$, PM_{10}, PM_{coarse}, and total inspirable aerosol sampler evaluations; and $PM_{2.5}$ and PM_{10} ambient aerosol sampling studies in support of both health and visibility regulations. Presently, Dr. Rodes is the Principal Investigator for the Detroit Exposure and Aerosol Research Study in Detroit, Michigan, under contract to EPA. The contract is supporting an indoor/outdoor/personal exposure study of recruited adult participants in a multisource, multiseason metro area to assess the relative contributions of sources to selected aerosol and gaseous exposures in private residence settings. He has served in a number of advisory roles including: a peer reviewer for the Health Effects Institute, a topic-area expert (indoor aerosols) for the NRC, an invited attendee for EPA workshops in dermal assessment and exposure assessment planning for the National Children's Study, and an invited writer for chapters of EPA's Air Quality Criteria Documents. In addition to numerous conference presentations and peer-reviewed journal articles, Dr. Rodes has co-authored three book chapters in the area of aerosol exposure characterization, the most recent of which focuses on breathing zone exposure issues.

Christian Seigneur, Ph.D.

Dr. Seigneur currently is Vice President of the Air Quality Division at Atmospheric & Environmental Research, Inc. (AER). AER was founded in 1977 to provide government and industry with research and consulting services in the atmospheric and environmental sciences. Dr. Seigneur received his Ph.D. in Chemical Engineering from the University of Minnesota in 1978, and his M.S. in Chemistry from the Ecole Nationale Supérieure de Chimie, in Paris, France, in 1974. Dr. Seigneur has more than 20 years of experience in air quality modeling and has developed several atmospheric chemical kinetic mechanisms, including mechanisms for mercury, chromium, stack plumes, and acid formation in droplets and particles. He led the effort that provided the first published demonstration of the nonlinearities of the SO_2/sulfate and NO_x/nitrate relationships. He was the Principal Investigator for the development of several air quality models that now are used by regulatory agencies in the United States and abroad. His experience in the development, evaluation, and application of air quality models spans a wide range of air pollution issues, including photochemical smog (i.e., ozone and other oxidants), particulate matter ($PM_{2.5}$ and PM_{10}), air toxics (dioxins, mercury, volatile organic compounds, chromium, etc.), atmospheric

visibility, acid deposition, accidental releases of toxic and hazardous chemicals, and indoor air pollution. Dr. Seigneur has about 10 years of experience in public health risk assessments. He has conducted research for the development of new models and methodologies for risk assessment. He was the Principal Investigator for the development of a methodology to include uncertainties in risk assessments; this methodology provided the basis for the approach recommended by the NRC in the report entitled "Science and Judgment in Risk Assessment." He has managed health risk assessments for fossil-fuel fired power plants, refineries, oil production facilities, research and teaching facilities, incinerators, and hazardous waste treatment, storage, and disposal facilities. Dr. Seigneur was a member of the CASAC Panel on Particulate Matter that reviewed the new $PM_{2.5}$ NAAQS. He also has been invited to participate in numerous workshops, including the Expert Panel on Atmospheric Processes of Mercury, the Society of Environmental Toxicology and Chemistry Workshop on Criteria for Persistence and Long-Range Transport of Chemicals in the Environment, the Society for Risk Analysis Workshop on Probabilistic Risk Assessment, and several DOE and EPA workshops on air quality and risk assessment.

APPENDIX C: AGENDA FOR THE MARCH 30-31, 2005 MEETING

U.S. EPA BOARD OF SCIENTIFIC COUNSELORS
Particulate Matter and Ozone Program Subcommittee

MEETING AGENDA
March 30, 2005 – April 1, 2005

U.S. Environmental Protection Agency
109 T.W. Alexander Drive, Research Triangle Park, NC 27711

Wednesday, March 30, 2005 (Room C-111 B/C)

8:00-8:30 a.m.	Registration	
8:30-8:45 a.m.	Welcome and Opening Remarks Subcommittee Chair	Dr. Rogene Henderson
8:45-8:50 a.m.	DFO Welcome and Charge - Administrative Procedures and FACA Rules - Objective of This Subcommittee and Charge	Lawrence Martin (EPA) DFO
8:50-9:00 a.m.	ORD's Welcome Acting DAA–Science, ORD	Dr. William Farland (EPA)
9:00-9:30 a.m.	Overview of ORD's Air Program	Dr. Daniel Costa (EPA) ORD National Program Director for Air
9:30-9:45 a.m.	Discussion of General Program Issues	Dr. Daniel Costa (EPA) ORD National Program Director for Air
9:45-10:00 a.m.	Break	

Session 1: NAAQS Health and Exposure Research

10:00-10:30 a.m.	Overview: Health and Exposure	Dr. Robert Devlin (EPA) ORD/NHEERL
10:30 a.m.-12:00 noon	Poster Session (Atrium)	Subcommittee
12:00-12:30 p.m.	Discussion	Subcommittee
12:30-1:30 p.m.	Working Lunch	Subcommittee

Session 2: Air Quality Management Presentation

1:30-2:00 p.m.	Overview	James Vickery (EPA) ORD/NERL
2:00-3:30 p.m.	Poster Session (Atrium)	Subcommittee
3:30-3:45 p.m.	Break	
3:45-4:15 p.m.	Discussion	Subcommittee
4:15-5:30 p.m.	Working Session	Subcommittee
5:30 p.m.	Adjourn	

Thursday, March 31, 2005 (Room C-111 B/C)

8:30-8:40 a.m.	Review of Wednesday's Activities Overview of Today's Agenda	Dr. Rogene Henderson Subcommittee Chair

Session 3: Pollutant Source to Health Outcome: Moving Toward a "One Atmosphere" Understanding of Air Pollution

8:40-9:10 a.m.	Overview	Dr. Andy Miller (EPA) ORD/NRMRL
9:10-10:45 a.m.	Poster Session (Atrium)	Subcommittee
10:45-11:00 a.m.	Break	
11:00-11:30 a.m.	Discussion	Subcommittee
11:30-11:45 a.m.	General Discussion Across Sessions	Subcommittee
11:45 a.m.-12:45 p.m.	Working Lunch	Subcommittee

Session 4: Perspectives on the Air Program

12:45-1:10 p.m.	Science Perspective	Dr. Mark Utell Co-Director PM Center/ University of Rochester
1:10-1:30 p.m.	OAR Perspective	John Bachmann (EPA) OAQPS/OAR
1:30-1:50 p.m.	Public Perspectives	
1:50-2:00 p.m.	Science/Program Wrap-Up	Dr. Daniel Costa (EPA) ORD National Program Director for Air
2:00-5:00 p.m.	Break/Work Session	Subcommittee

5:00-5:30 p.m.	Debrief Oral Report on Charge Questions	Subcommittee
5:30 p.m.	Adjourn	

Friday, April 1, 2005 (Room C-111 B/C)

8:00-8:10 a.m.	Review of Thursday's Activities	Dr. Rogene Henderson Subcommittee Chair
8:10 a.m.-12:00 noon	Work Session	
12:00 noon	Adjourn	

PARTICULATE MATTER
RESEARCH PROGRAM REVIEW
List of Themes and Poster Titles

SESSION 1: HEALTH AND EXPOSURE RESEARCH	
What Are the Adverse Health Effects Associated With Exposure to PM and How Are These Effects Caused?	
What Is the Relationship Between Personal Exposure and Ambient Fixed Site Measurements?	Ron Williams (NERL)
What Are the Uncertainties Associated With the Epidemiological Estimates of PM Health Risks and the Methods Employed in Developing Those Estimates?	Joel Schwartz (Harvard University)
What Are the Physiological Mechanisms by Which PM Causes Adverse Cardiac Effects?	William P. Watkinson (NHEERL)
Does Inhalation of Air Pollution Particles Affect Vascular Function?	Mark W. Frampton MD (University of Rochester)
What Are the Physiological Mechanisms by Which PM Causes Adverse Respiratory Effects?	Steve Gavett (NHEERL)
What Are the Cellular and Molecular Mechanisms by Which PM Causes Adverse Health Effects?	James M. Samet (NHEERL)
What Are the Long-Term Health Effects of PM?	Morton Lippmann (New York University)
What Are the Long-Term Health Effects of PM?	Barbara Glen (NCER) Joel Kaufman (University of Washington)
ORD Science Contributes to the Development of National Ambient Air Quality Standards for PM.	Mary Ross (OAQPS)
ORD Research Affects Public Health Action and Community Outreach.	Susan Stone (OAQPS)
Who Is Susceptible?	
What Do Exposure and Dosimetry Studies Tell Us About the Dose to the Susceptible Populations?	Chong Kim (NHEERL)
How Does PM Impact Subpopulations with Cardiovascular Disease (Elderly)?	Wayne Cascio (East Carolina University)
Does Particulate Matter Cause or Exacerbate Asthma?	David B. Peden, University of North Carolina Center for Environmental Medicine, Asthma & Lung Biology

How Does Underlying Cardiopulmonary Disease Influence Response to PM in Animals?	Urmila P. Kodavanti (NHEERL)
How Are Emerging PM Susceptible Populations Being Identified and Characterized?	Kevin Dreher (NHEERL)
How Do Gene/Environment Interactions Modulate PM-Induced Adverse Heath Effects?	Yuh-Chin Tony Huang (NHEERL)
What Physical/Chemical Attributes of PM Are Responsible for Adverse Health Effects?	
What Are the Effects of Ultrafine Particles?	Günter Oberdörster (University of Rochester)
What Are the Bioactive Components in Coarse Particulate Matter?	Ian Gilmour (NHEERL)
What Are the Effects of Metals?	Andrew Ghio (NHEERL)
Chemical Mechanisms of Particulate Matter Toxicity	John R. Froines, A.K. Cho, A. Nel, C. Sioutas (Southern California Particle Center and Supersite)
How Can Statistical Approaches (e.g., PCA) Be Used To Link PM Components With Health Effects?	John Godleski (Harvard University)

SESSION 2: AIR QUALITY MANAGEMENT

What Are the Sources of PM (and Co-pollutants)?	
How Have Recent Advances in Emission Estimation Methods and Models Improved Inventories of Primary PM and Precursor Gases That Form Secondary PM and Ozone?	David Mobley (NERL), Sue Kimbrough (NRMRL), Bill Kuykendal (OAQPS)
How Can We More Accurately Measure Emission Fluxes of Precursor Gases Emitted From Area Sources That Form Secondary PM?	Bruce Harris (NRMRL), John Walker (NRMRL)
What Are the Contributions to Ambient PM and Ozone From Biogenic and Other Natural Emission Sources?	Chris Geron (NRMRL), Tom Pierce (NERL)
What Are the Contributions to Ambient PM and Ozone Concentrations From On-road Diesel and Gasoline Vehicles?	Rich Baldauf (NERL), John Kinsey (NRMRL)
How Well Can We Control Emissions of Multiple PM Precursors From Coal-Fired Power Plants?	Andy Miller (NRMRL)
How Can Emissions Inventories Be Improved for Source Apportionment and Health Associations?	Ted Russell (Georgia Tech), Alice Gilliland (NERL)
What Is the Atmospheric Characterization of PM (and Co-Pollutants)?	
How Can We Measure Ambient Concentrations of Fine and Coarse PM Mass for Regulatory Purposes?	Bob Vanderpool (NERL)
How Can We Measure Ambient Concentrations of Speciated Fine and Coarse PM Mass To Support Improvements in the Ambient Air Quality Standards?	Paul Solomon, Tim Watkins (NERL)
ORD Science Supports Air Quality Modeling	Rich Scheffe (OAQPS)
How Can We Measure Rapid Fluctuations in Carbonaceous Aerosol Composition?	Jose Jimenez (University of Colorado at Boulder)
What Are the Processes That Govern PM (and Co-Pollutants)?	
What Are the Precursors to and Formation Processes for Secondary Organic Aerosols?	Ed Edney (NERL)
How Are Results From ORD's Community Multi-Scale Air Quality Model (CMAQ) Used To Forecast Air Quality?	Ken Schere (NERL)

How Well Does CMAQ Predict Ambient Concentration of PM Components, PM, and Ozone?	Alice Gilliland, Robin Dennis, Brian Eder, Prakash Bhave (NERL)
Air Quality Models Are Used To Predict Reductions in Air Pollution	Joe Paisie (OAQPS)
What Characteristics of Source Emissions Can Be Used to Identify the Contribution of Different Source Types to Ambient PM Concentrations?	Mike Hays (NRMRL)
How Is CMAQ Used To Support State and Tribe Implementation Plans for Regional Haze?	Gail Tonnesen (University of California at Riverside)
How Can Receptor Models Be Applied To Estimate the Contribution of Different Source Types to Ambient PM Concentrations?	Shelly Eberly (NERL)

SESSION 3: SOURCE TO HEALTH OUTCOME

Do Exposures to Mobile Source Particles Damage Health?	Helen H. Suh (Harvard PM Center)
Physical and Chemical Characteristics of PM Near Freeways Impacted by Heavy- and Light-Duty Traffic	Constantinos Sioutas, John R. Froines (Southern California Particle Center and Supersite)
Health Effects Associated With Particulate Matter Near Southern California Freeways	John R. Froines (Southern California Particle Center and Supersite)
What Are the Effects From Controlled Exposures to Specific Sources?	Michael Madden (NHEERL)
Pulmonary Toxicity of Utah Valley PM: Are Empirical Indices of Adverse Health Effects Coherent With the Epidemiology?	Janice A. Dye (NHEERL)
Source Apportionment and Multi-City/Multi-Pollutant Studies	Lucas Neas (NHEERL)
Can Laboratory Chambers Be Used To Create a Complex Atmosphere for Use in Animal Exposure Studies?	Tad Kleindienst (NERL)
How Can Organic Tracers and Source Apportionment Modeling Be Used in Health Studies?	James Schauer (University of Wisconsin)
How Can Concentrated Ambient Particles Used in Health Studies Be Tied to Specific Source Types?	Gary Norris (NERL)
How Can Air Quality Models Provide Detailed Source Attribution and Component Distributions for Health Studies?	Mike Kleeman (University of California at Davis)
How Are Ambient Monitoring, Personal Exposure, and Health Related?	Allen Vette (NERL)
ORD Research Supports Mobile Source Regulatory Decisionmaking	Rich Baldauf (OTAQ/NERL)
Accountability: Measuring Improvements in Public Health From Reduced Air Pollution	Susan Stone, John Bachmann (OAQPS)

APPENDIX D: LIST OF ACRONYMS

AER	Atmospheric & Environmental Research, Inc.
AFCR	American Federation for Clinical Research
AHA	American Heart Association
ALAC	American Lung Association of California
APGs	Annual Performance Goals
APMs	Annual Performance Measures
AQCD	Air Quality Criteria Document
AQI	Air Quality Index
AQM	Air Quality Management
BEIS3	Biogenic Emission Inventory System
BOSC	Board of Scientific Counselors
CAAAC	Clean Air Act Advisory Committee
CASAC	Clean Air Scientific Advisory Committee
CENR	Committee on Environmental and Natural Resources
CMAQ	Community Multiscale Air Quality
DOE	U.S. Department of Energy
EPA	U.S. Environmental Protection Agency
FY	Fiscal Year
GPRA	Government Performance and Results Act
HEI	Health Effects Institute
HSD	Human Studies Division
HUPO	Human Proteome Organization
LRRI	Lovelace Respiratory Research Institute
LTGs	Long-Term Goals
MYP	Multi-Year Plan
NAAQS	National Ambient Air Quality Standards
NARSTO	North American Research Strategy for Tropospheric Ozone
NAS	National Academy of Sciences
NCER	National Center for Environmental Research
NERL	National Exposure Research Laboratory
NHEERL	National Health and Environmental Effects Research Laboratory
NIEHS	National Institute of Environmental Health Sciences
NPD	National Program Director
NRC	National Research Council
NRMRL	National Risk Management Research Laboratory
O_3	Ozone
OAQPS	Office of Air Quality Planning and Standards
OAR	Office of Air and Radiation
OMB	Office of Management and Budget
ORD	Office of Research and Development
OTAQ	Office of Transportation and Air Quality
PART	Program Assessment Rating Tool
PIs	Principal Investigators

LIST OF ACRONYMS (CONTINUED)

PM	Particulate Matter
PPM	Parts Per Million
RCT	Research Coordination Team
RFA	Request for Applications
RTP	Research Triangle Park
SCAQMD	South Coast Air Quality Management District
SCOS	Southern California Ozone Study
STAR	Science To Achieve Results
UCLA	University of California at Los Angeles
UFPs	Ultrafine Particles
VOCs	Volatile Organic Compounds
WSU	Washington State University