BOARD OF SCIENTIFIC COUNSELORS



October 15, 2009

Mr. Lek Kadeli
Acting Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC

Dear Mr. Kadeli:

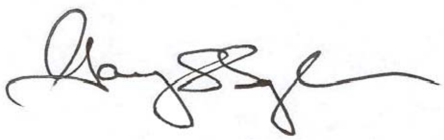
On behalf of the Board of Scientific Counselors (BOSC), I am pleased to provide you with a report of the review of the Office of Research and Development's (ORD) Clean Air Research Program at the U.S. Environmental Protection Agency. The Clean Air Research Program underwent a full BOSC program review in 2005 and a mid-cycle review in 2007. An eleven-member review committee, including the Chair who is a member of the BOSC Executive Committee, participated in the 2005, 2007, and the current program review, which culminated in a face-to-face review meeting held June 8-10, 2009, in Research Triangle Park, North Carolina. The Subcommittee's report was delivered for BOSC Executive Committee review and approval in September 2009. This report was fully vetted by the BOSC Executive Committee and approved for transmittal to ORD.

The objective of this review was to evaluate the relevance, quality, performance, scientific and managerial leadership, and outcomes of the Program and provide guidance and recommendations as to the progress and directions of the Clean Air Research Program to ORD.

The Subcommittee review and comments regarding the content of the Clean Air Research Program were, overall, very positive. The Program is an excellent example of an integrated, multidisciplinary scientific approach to undertake policy relevant science. The BOSC finds that ORD is doing a commendable job in its effort to move toward a multi-pollutant approach to air quality issues. The Program's research priorities are meeting the needs of the stakeholders and the research results are being used by the National Ambient Air Quality Standards (NAAQS) developers as well as by the state agencies that are responsible for implementing pollutant control strategies. The quality of the scientific research being conducted under the Program is unquestionably outstanding and the Program has produced many outputs (models, measurements, data analysis) that have been used in policy development and implementation, regulatory decision-making, and review of NAAQS. Both of the Clean Air Research Program's long-term goals received a rating of Exceeds Expectations, and the report offers some recommendations that will enhance and strengthen the impact of the Program.

We expect that this BOSC report will assist ORD in continuing to improve its science, and inform clients within and outside the EPA of the significance of its research and how it is being utilized. On behalf of the BOSC Executive Committee, it is my pleasure to transmit this program review report to you.

Sincerely,



Gary S. Sayler
Chair, Board of Scientific Counselors

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BOARD OF SCIENTIFIC COUNSELORS



# REVIEW OF THE OFFICE OF RESEARCH AND DEVELOPMENT'S CLEAN AIR RESEARCH PROGRAM AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY

## Final Report

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# I. EXECUTIVE SUMMARY

## Program Assessment

The Board of Scientific Counselors (BOSC) conducts independent retrospective and prospective expert reviews of ORD research programs on a periodic basis, typically every 4 to 5 years. This review process is consistent with the National Academies' recommendation that independent expert reviews are an effective way to evaluate federal research programs. This subject review document reports on the U.S. Environmental Protection Agency (EPA) Office of Research and Development's (ORD) Clean Air Research Program. This review focuses on the period since the last full BOSC review of this Program (which was entitled the "Particulate Matter and Ozone Research Program" at that time) in 2005, as well as findings from the mid-cycle review of the Program in 2007.

The objective of this review is to evaluate the relevance, quality, performance, scientific and managerial leadership, and outcomes of the Program and provide guidance and recommendations as to the progress and directions of the Program to ORD.

The program review was guided by a set of charge questions developed by ORD and coordinated with the BOSC Clean Air Subcommittee Chair (see Appendix B for the Charge Questions to the Subcommittee). The charge questions provided the basis for the Agency's preparation of the review materials and helped to focus the Subcommittee's considerations. The report is organized around the charge questions and the long-term goals (LTGs) that the Program has identified as part of its multi-year planning process. In this case, two overarching LTGs are identified in the Clean Air Research Multi-Year Plan (MYP) 2008-2012 (EPA, 2008):

LTG 1: In accordance with EPA's legislated mandate for periodic NAAQS assessments and assessment of hazardous air pollutant (HAP) risks, advances in the air pollution sciences will reduce uncertainty in standard setting and air quality management decisions; and

LTG 2: Air pollution research will reduce uncertainties in linking health and environmental outcomes to sources of air pollutants to improve the effectiveness of air quality management strategies.

These LTGs support the regulatory requirements of EPA's Office of Air and Radiation (OAR) while developing the science to link health effects to air pollution sources and components. The latter LTG approaches air pollution from its origin as source emissions, through atmospheric transport and transformation, to exposure/dose and human health outcomes. It emphasizes science planning coordination to leverage across programs and achieve efficiencies in both science and budget.

The Subcommittee met by conference call on two occasions to discuss the proposed charge questions and scope of the review. On these calls, the Subcommittee was provided an overview of EPA's ORD and the Clean Air Research Program and its major research elements organized by LTG. These briefings set the stage for the face-to-face meeting held June 8-10, 2009, in Research Triangle Park, North Carolina. At the Subcommittee's request, ORD prepared "a road map to the evidence addressing the charge" (included as Appendix E), which provided a template for reviewing the extensive materials provided by ORD. The Subcommittee has addressed each charge question and provided a summary of its findings in terms that highlight the strengths and weaknesses of the Program, as well as a performance rating with narrative for each of the LTGs.

The Subcommittee review and comments regarding the content of the Clean Air Research Program were, overall, very positive. The extensive preparations by EPA investigators, both intramural and extramural, provided a well-organized and comprehensive presentation of the work being performed under the Program. The "road map to the evidence addressing the charge" provided the Subcommittee with a clear understanding of EPA's approach in organizing and integrating its multi-pollutant air research program and facilitated review of the various materials.

The remainder of this Executive Summary highlights the overarching findings and recommendation of the program review.

## Program Design and Demonstrated Leadership

✧ *Is the Clean Air Research Program continuing to plan its program effectively with respect to:*

a) *responsiveness to the 2005 and mid-cycle BOSC recommendations regarding program design and implementation?*

The BOSC finds that ORD has been extremely responsive to recommendations provided in the full BOSC review of the Air Research Program (then the Particulate Matter and Ozone Research Program) completed in August 2005, and the progress reported in the mid-cycle BOSC review carried out in September 2007 and completed in March 2008. Both BOSC reports provided favorable reviews of the Program. Although the recommendation that ORD reconsider the decision to disinvest in the ozone research program because of lack of resources was not followed, it was pointed out by ORD that ozone is an element of the multi-pollutant approach recommended by the National Research Council (NRC) and now adopted by ORD.

b) *increasing emphasis on a multi-pollutant approach to ORD's air quality research?*

The Clean Air Research Program is an excellent example of an integrated, multidisciplinary scientific approach to undertake policy relevant science. The research conducted at ORD clearly captures a wide range of disciplines, including exposure science, toxicology, atmospheric modeling and measurements, emissions and epidemiology with linkages and extensions to assessments of ecosystems, public health exposure, and climate-air quality interactions, and the Program has made substantial progress in answering key science questions and in providing useful input to air quality planning at national, regional, state, and local levels.

The BOSC finds that ORD is doing a commendable job in its effort to move toward a multi-pollutant approach to air quality issues. The near road source–to-outcome studies are an excellent initial choice as case studies for the implementation of the multi-pollutant approach. Progress is being made to assess the "source-to-health outcome" paradigm through the implementation of the "near-road" program, with measurement programs in Las Vegas, Nevada; Detroit, Michigan; and Raleigh, North Carolina. The Detroit Exposure and Aerosol Research Study (DEARS) go beyond measurement to health linkage through an extramural award to the University of Michigan. Measurement and analytic technologies that will be needed for future intramural and extramural studies are being evaluated as part of the programs and should be an important addition to future studies. These studies will provide data to help assess the role of mobile source emissions in the design of State Implementation Plans (SIPs) in response to the 8-hour ozone standard, 24-hour $PM_{2.5}$ (particulate matter less than 2.5 micrometers) and future short-term $NO_2$ standard.

One overriding concern is that ORD (and, for that matter, scientific and regulatory communities) have not yet clearly and formally defined what it meant by "multi-pollutant approach", given the multiplicity of potential definitions and interpretations (e.g., air quality management, air pollution, control, health or ecosystem outcome driven).

**The BOSC recommends that ORD develop a working definition for the term "multi-pollutant approach" as it pertains to its LTGs and the expectations of its various stakeholders.**

*c) research priorities reflecting stakeholder needs?*

The BOSC finds that ORD research priorities are meeting the needs of the stakeholders concerned with PM exposure and health effects. Research results from its programs are being utilized by the National Ambient Air Quality Standards (NAAQS) developers as well as by the state agencies that are responsible for implementing pollutant control strategies. As ORD considers accountability to be an important research priority, the source-to-health outcome research framework is particularly relevant. The utility of this approach will be evident as research results become available that provide evidence of the direct human health benefits that result from air quality management actions.

Program research priorities are working towards meeting the needs of stakeholders concerned with near-road exposures and climate change issues. Many of the research priorities that involve these topics have been initiated recently and involve multifaceted research that, in some cases, requires close coordination with other Agencies. The intramural and extramural efforts in investigating the climate change-air quality interaction have been a successful science program. The April 2009 EPA report, "Assessment of the Impacts of Global Change on Regional U.S. Air Quality: A Synthesis of Climate Change Impacts on Ground-Level Ozone" is an excellent example of the application of outcomes of the Clean Air Research Program to policy development in the area of climate change-air quality interactions.

ORD research is meeting stakeholder needs at the national level and the interactions between the Clean Air Research Program and OAR's Office of Air Quality Planning and Standards (OAQPS) appear to be excellent. The OAR representatives declared their strong reliance on the research of the Clean Air Research Program for informing the NAAQS process, and the high number of citations of ORD-supported work in the Criteria Document for Particulate Matter (PM) is an important metric of impact and meeting stakeholder needs.

In addition, ORD's role in the development and refinement of models such as the Community Multiscale Air Quality (CMAQ), MOVES, UNMIX, and PMF has been valuable for both the scientists and decision-makers at the local, state and federal levels. In contrast, stakeholders at the regional level seemed less cognizant of how best to interact with the Clean Air Research Program and how to get their needs met.

*d) coordination and integration of research within and across the extramural and intramural programs to maximize [the benefit from]* resource investment?*

The intramural and extramural research coordination seems to be well thought out and ORD's Requests for Applications (RFAs) are designed to maximize the breadth of the knowledge of the outside research community. ORD has pointed out that extramural research is the most efficient way to address issues that cannot effectively be addressed by the resources and expertise available "in-house." One program aspect that has fallen short in recent years at ORD is ambient measurement methods development research. ORD has acknowledged that their in-house methods developments capabilities are less than they once were, and ORD has been reluctant to issue RFAs in this research area because of intramural and extramural resource limitations. There are scientists and engineers who are qualified to do applied research into the type of methods development useful for defensible and consistent NAAQS or HAPs measurements. The BOSC encourages ORD to either strengthen its in-house methods development program or solicit extramural assistance in this area.

✧ *Is the Clean Air Research Program providing strong science leadership and program management in both research planning and implementation?*

Clean Air Research program managers have demonstrated strong management skills through their: (1) responsiveness in addressing previous NRC and BOSC recommendations, (2) focus on meeting LTGs, (3) strong multidisciplinary orientation of the researchers, (4) integration of research across EPA laboratories and multiple partners, and (5) overall structuring of the MYP. Science leadership is demonstrated from the role EPA has assumed as the lead federal agency on air quality issues, including interactions with other environmental issues (e.g., climate change, ecosystem health), as well as from the high quality of the science products from the research program. Key opportunities to continue to provide science leadership will occur with the

* Note word change from original charge "…the benefit from…" added to charge question.

continued implementation of multi-pollutant research and the incorporation of the emission source-to-health outcome paradigm.

- ✧ *Is the Clean Air Research Program effective in communicating results to its stakeholders, program offices, regions, state and local regulatory agencies, the general public, and the broader scientific community?*

ORD's communication of research results through peer-reviewed journal articles, presentations, and periodic workshops and user groups to disseminate information regarding refinements to research tools such as air quality models, is both effective and efficient.

- ✧ *Does the Clean Air Research Program have LTGs and Annual Performance Goals (APGs) that will meet the goals of the ORD research program, address stakeholder needs, and are not unnecessarily duplicative of national and international work in this area?*

The APGs and related research priorities by pollutant are appropriately ranked based on the significance of the health effects and state-of-knowledge regarding mechanisms and toxicity pathways. Many of the research program elements and modeling efforts that deal with PM also involve work with other criteria co-pollutants and gaseous and semi-volatile HAPs and therefore are multi-pollutant in nature and not PM-specific. One exception is a lack of adequate APG in measurement methods development for state-of–the-science measurements for criteria pollutants and associated precursors in support of LTG 1.

**The BOSC recommends that ORD strengthen Federal Reference Method (FRM)/Federal Equivalent Method (FEM) methods development by ascertaining the state of the measurement science for each NAAQS pollutant ahead of the review cycle, and subsequently initiating intramural or extramural research programs to develop and improve methods as needed.**

**The BOSC recommends that ORD revise the procedures for designation of an approved instrument method, which will accommodate and provide incentives for the development and introduction of new measurement technologies for air quality monitoring.**

- ✧ *Is the relative resource distribution by LTG (i.e., relative % full-time equivalent [FTE], relative percent extramural vs. intramural resources) appropriate to address Agency goals, stakeholders' needs, and the goals of the ORD Clean Air Research Program?*

Although the relative resource distribution by LTG at first glance, seems appropriate to address the various goals of stakeholders, the Agency, and the Clean Air Research Program, it is important to note that the Program has been level funded since 1997, suggesting a systematic attrition that is not sustainable in the long term. The impact of this inflationary loss in funds over the years has affected the content of the program and forced a reduction in the areas of research focus. As a result, stakeholder needs are not being met as well as they could be in the areas of monitoring methods development, non-PM exposures and health effects, NAAQS setting, the identification of monitoring techniques for diesel emissions, estimation of emissions from various sources including ammonia, and indoor air issues. Some of these research needs are certainly related to the research priorities that ORD is undertaking and there will need to be improvements on some of these issues realized from ORD's current research program. Ultimately, however, more resources and a higher priority for some areas would have to be instituted to satisfy stakeholders' needs. Also, the planning and resource allocation for the Clean Air Research Program in addressing research priorities reflecting stakeholder needs are developed through negotiation between the National Program Director and participating ORD laboratories, which retain budgetary authority. Program responsibility without fiscal control is problematic.

**The BOSC recommends that ORD review the rationale for the current management and budgetary structure for the Clean Air Research Program and consider a more balanced approach for resource management under the direction of the Program.**

## Science Quality

- *Is the science being conducted by EPA-ORD research Labs and Centers of recognized high quality, high impact and appropriate to stakeholder needs?*

The quality of the scientific research being conducted under EPA's Clean Air Research Program is unquestionably outstanding. This is documented in the more than 650 publications that have appeared since the 2005 program review and the very positive findings drawn from the extensive bibliometric analysis of the 2,600+ publications coming from the Program (both intramural and extramural) during the decade of 1998-2008. The high quality of the science also was evident in the review of the posters presented at the review meeting and in conversations with the scientists who presented the posters.

Much of ORD's research results are translated into increased fundamental knowledge of air pollutant emission, transformation, and exposure pathways through the environment. These results are made available through peer-reviewed journal articles and presentations and in the refinements to research tools such as air quality models. State agencies and the EPA Regions effectively utilize the models that ORD provides in designing control strategies for attainment of ozone and $PM_{2.5}$ standards under their SIPs. In addition, NAAQS developers utilize ORD's research results through a review of published journal articles as well as through ORD's participation in the NAAQS development process.

- *Is the program fostering multidisciplinary research and taking advantage of opportunities for leveraging resources and expertise?*

There are few areas in environmental health research in which ORD has not had an impact. Further, ORD projects have increasingly adopted interdisciplinary research strategies, integrating multiple disciplines into a single research framework. Examples include simultaneously conducted toxicology and epidemiology studies with mutually reinforcing methods and conclusions and the near-roadway research program, which is bringing together experts on mobile source emissions, atmospheric transport and dispersion, atmospheric chemistry, human exposure, and health effects.

ORD has effectively leveraged resources and expertise through both the extramural and the intramural program. The extramural program is funding some of the top air pollution researchers in the country, both through the Particle Centers and other funding mechanisms. The Particle Centers are good examples of funding mechanisms that foster interdisciplinary research, encourage linkages—both among researchers at different academic institutions and with ORD staff, and that leverage resources by tapping into the extensive air pollution research conducted by Particle Center investigators outside of the Centers. There also are strong interactions with other research institutions such as the National Institute of Environmental Health Sciences (NIEHS), National Heart, Lung and Blood Institute (NHLBI), and Centers for Disease Control and Prevention (CDC) to avoid duplicate efforts by these federal agencies. A good example is the Multi-Ethnic Study of Atherosclerosis and Air Pollution (MESA) Study, in which an existing cohort was leveraged to incorporate air pollution exposures in investigating cardiovascular outcomes. The Health Effects Institute (HEI) is another example of the leveraging of EPA and industry funds in a highly successful program to study mobile source emissions and health outcomes.

## Relevance

✧ *Are the potential benefits from the research being conducted clearly articulated in terms of public health protection (support to policy, decision-making, and standards implementation)?*

The air quality research component of the Clean Air Research Program is quite diversified so as to meet the needs of a large client base of various EPA OAR offices (Office of Transportation and Air Quality [OTAQ], OAQPS, etc.), and many local, state, and regional governments. The Program has produced many outputs (models, measurements, data analysis) that have been used in policy development and implementation, regulatory decision-making, and review of NAAQS. The potential public health benefits of various policy and regulatory decisions based on the outputs of the air quality component of the Program have been articulated reasonably well by the Clean Air Research Program. The Program also has performed well in terms of the applicability of ORD's research products (e.g., the ORD-developed model, CMAQ, is being used with great success in the development of SIPs to demonstrate ozone NAAQS attainment).

The Clean Air Research Program's health and exposure research has made significant progress in understanding the public health implications of PM exposure and the benefits of abatement strategies with respect to health and exposure research. These include: advancements in CMAQ model applications; research directed at evaluating mechanisms of PM-related health effects and potential differential toxicity of particle constituents; progress towards developing the information necessary to characterize a "hierarchy of sources"; and more limited progress with respect to exposures and health implications for coarse particles.

Further development of CMAQ to improve the treatment of the chemistry and physics of primary and secondary organic aerosols and related biogenic and anthropogenic precursor emissions is required to support applications for PM SIPs.

*Are the products of ORD research being used by stakeholders in decision making or the formulation and implementation of policy?*

ORD's research has been well articulated and widely used in a timely manner by OAQPS in the recent setting of ozone and $PM_{2.5}$ standards. The ORD-developed model, CMAQ, is being used with great success in developing SIPs to demonstrate attainment of ambient standards for ozone. The recently revised NAAQS review process will require a clear articulation and a larger use of ORD research outputs in Clean Air Science Advisory Committee (CASAC) review of policy options that are based on integration and interpretation of information in Integrated Science Assessments (ISA) and Risk-Exposure Assessments (REA). This science-policy interface will need continued active participation of the Clean Air Research Program to inform the standard-setting process within EPA.

## Demonstrated Outcomes

✧ *Has the Clean Air Research Program made significant progress in the conduct of the planned research and in answering the key science questions related to public health benefits and pollution abatement?*

The air quality research component of the Clean Air Research Program (which includes source emissions, ambient measurements, air quality modeling, and linkages and extensions to assessments of ecosystems, public health exposure, and climate-air quality interactions) has made substantial progress in answering key science questions and in providing useful input to air quality planning at national, regional, state, and local levels. Recent intramural and extramural efforts on understanding the atmospheric processes of organic aerosols and potential incorporation of this research in the CMAQ model at ORD and Carnegie Mellon University (by incorporating the concept of volatility basis set), as well as coordinating this effort with the Electric Power Research Institute (EPRI)-funded research are commendable. The renewed emphasis on improving estimates of biogenic emissions by developing the MEGAN model and on use of satellite data to improve the temporal and spatial resolution of biomass burning emissions should lead to better predictions of ozone and $PM_{2.5}$ levels.

**The BOSC recommends that the judicious use of satellite data with existing ground-based measurements needs further evaluation by the Clean Air Research Program before embarking on more extended use of satellite data.**

The effort on quantifying emissions of $NH_3$ from soils (fertilized and natural) and animal sources has made good progress including better understanding of the bi-directional nature of ammonia fluxes and much better characterization of the local and regional nature of deposition of ammonia emissions sources. More studies are needed, however, to obtain ammonia emission estimates at temporal and spatial scales that are compatible for CMAQ modeling of $PM_{2.5}$ and ozone.

**The BOSC recommends that the Clean Air Research Program coordinate such ammonia and PM emission studies with current industry-funded research on concentrated animal feeding operations (CAFO) sources at various universities**.

From the perspective of health and exposure research, the Clean Air Research Program has made significant progress in understanding the public health implications of PM exposure and the benefits of abatement strategies. Progress in CMAQ model development (e.g., PM modules and advanced mechanisms for the treatment of secondary organic aerosol formation) are evident and provide a key modeling tool for quantifying the benefits of pollution abatement strategies. Attempts to nest higher-resolution models with CMAQ also are valuable, as is the direction toward using "near-roadway" as the template for initial multi-pollutant investigations.

Research directed at evaluating mechanisms of PM-related health effects and potential differential toxicity of particle constituents also has advanced substantially in a limited number of years. Although studies on differential toxicity have not yet provided the information necessary for developing a "hierarchy of sources," the insight is significantly greater than just a few years ago.

Regulatory impact analyses by EPA and CARB emphasize that the majority of the public health benefits of air pollution controls are generally attributable to $PM_{2.5}$, with the impact of ozone less than that of PM but far exceeding that of air toxics. This indicates that this distribution of resources is illogical from the perspective of the charge question, but the Subcommittee was concerned (as was the BOSC Subcommittee that conducted the mid-cycle review) that more balance may be necessary going forward towards the "source-to-health outcomes" paradigm. This may be particularly important for a multi-pollutant air quality management strategies, as large uncertainties regarding ozone impacts could contribute systematic biases in management plans (e.g., by mischaracterizing the benefits of $NO_x$ or volatile organic compound [VOC] controls relative to $SO_2$ controls). The November 2008 SAB evaluation of EPA's strategic research directions emphasized that areas such as air toxics exposures and health risk, air quality in indoor environments, and global cycling of mercury would merit increased attention. The BOSC agrees that these are important domains that have not received substantial attention in recent years, while recognizing that resource constraints preclude significant progress on all fronts.

## Summary Assessment of Long-Term Goals

**LTG 1: In accordance with EPA's legislated mandate for periodic NAAQS assessments and assessment of HAP risks, advances in the air pollution sciences will reduce uncertainty in <u>standard setting</u> and <u>air quality management</u> <u>decisions</u>. This LTG supports two research themes: (a) developing NAAQS and other air quality regulations, and (b) implementing air quality regulations.**

### Overall Rating of LTG 1: Exceeds Expectations

The ORD Clean Air Research Program exceeds expectations in delivering ambient measurements, source emission inventories, and air quality models and analyses to address LTG 1. There are several areas within this LTG that are exceptional; such as where ORD has demonstrated national leadership, including work on biogenic emissions and the emerging research on climate change-air quality interactions. Research regarding the health implications of PM exposure has made rapid progress in a relatively short amount of time, and the quality of this work clearly has been exceptional. The near-singular focus on PM is partly justified in light of the public health burden and significant regulatory decisions, but does imply that the Clean Air Research Program science has been relatively less effective in establishing NAAQS for other criteria pollutants or informing air quality management decisions related to air toxics. Additional direct emphasis on the health implications of low-level exposure (i.e., below the current NAAQS) would be valuable, particularly in controlled exposure multi-pollutant environments, where possible. It is difficult to argue that any of the work conducted under ORD's Clean Air Research Program is not relevant and important, and resource constraints imply that any expansion of effort on these topics would necessitate a redirection of resources away from important and relevant science. However, in the future, issues may arise that will require more research efforts from the Air Program in regard to the other criteria pollutants.

## Recommendations for LTG 1

1. CMAQ and other air quality models should continue to be a high priority for sequential refinement, given that this is one of the more efficient ways in which ORD's research results are utilized to make air quality management decisions. Emphasis on CMAQ development should focus not only on the size and mass of PM, but also on the components of PM, including the characterization of the chemistry and physics of organic aerosols (both primary and secondary aerosols), and the further characterization of anthropogenic and biogenic precursor emissions. Such developments have direct implications on meeting the near-term needs of OAQPS and states in the preparation of $PM_{2.5}$ SIPs.

2. The combined use of modeling tools such as CMAQ and inverse-CMAQ modeling, and ambient and satellite measurements to improve estimates of ammonia and elemental carbon emissions should be applied to other pollutants/sources and other areas to demonstrate their wider applicability.

3. ORD is encouraged to leverage its selection of emerging monitoring technologies and methods by selecting the ones that have the greatest potential for widespread use among state and local air quality monitoring agencies.

4. The potential health effects of coarse particles in urban and rural environments should be examined

## LTG 2: Air pollution research will reduce uncertainties in linking health and environmental outcomes to sources of air pollutants to improve the effectiveness of air quality management strategies.

This LTG is oriented towards supporting three research themes: (a) launching a multi-pollutant research program, (b) identifying specific source-to-health outcomes linkages with initial emphasis on "near roadway", and (c) assessing the health and environmental improvements due to past regulatory actions.

## Overall Rating of LTG 2: Exceeds Expectations

LTG 2 looks to the future in which it is expected that air quality management will be based more on regulating sources of pollutant mixtures rather than regulating individual pollutants. This is a multi-pollutant approach that has been recommended to EPA by both the Science Advisory Board (SAB) and by the NRC. The Clean Air Research Program has been responsive to that advice. The research program for LTG 2 is exceptional both in the quality of its science and the speed with which it has been accomplished.

The three research themes under LTG 2 are at various stages of development. ORD has launched a multi-pollutant research program and initiated a specific source-to-health outcome study with an emphasis on “near roadway exposures. These multi-pollutant themes are relatively new and it is too early to determine their overall impact on reducing uncertainty in air quality health outcomes. Because the real-world air pollutant environment is a multi-pollutant mix, this approach is more realistic in reflecting the exposure environment. There also is the possibility of synergistic, antagonistic, or other interactions among pollutants that can be considered more effectively with this multi-pollutant approach. A significant challenge in moving from a framework of managing individual pollutants, one pollutant at a time, to a multi-pollutant approach is reconciliation between the complex multi-pollutant mixture and the pollutant-specific NAAQS. The progress in developing these areas has certainly exceeded expectations.

The third theme, assessing the health and environmental improvements due to past regulatory actions, sometimes referred to as “accountability,” has been evolving with major efforts underway in collaboration with HEI. Accountability studies to address the impact of regulatory actions on health outcomes remain elusive, but increased interest in the area should stimulate research approaches and improve data resources. ORD’s contributions and performance in this area have exceeded expectations.

## Recommendations for LTG 2

1. Continue to pursue a multi-pollutant approach for both air quality management and research, but formally define the aspects of “multi-pollutant” that are of highest priority and will be pursued in the near term and long term.

2. The Clean Air Research Program should consider developing a research framework to explore multi-pollutant exposures as they relate to the co-pollutant complex of PM components, ozone, nitrogen dioxide, and air toxics and the potential positive and negative effects that may result from combinations of these pollutants on health outcomes.

3. More basic research on pollutant mixture exposure needs to be performed to support the design of multi-pollutant-based emission regulations and ambient standards. Because it is apparent that it will not be realistic to set air quality standards for pollutant mixtures or components of $PM_{2.5}$ in the near term, examining the health effect correlations from one or more source categories is a reasonable approach.

4. Continue to survey clients and stakeholders on perceptions of and satisfaction with ORD's role in the source-to-health outcomes process.

**Table 1. Summary of Clean Air Research Subcommittee Recommendations**

| | |
|---|---|
| **LTG 1** | 1. CMAQ and other air quality models should continue to be a high priority for sequential refinement and development with a focus not only on the size and mass of PM, but also on the components of PM, including the characterization of the chemistry and physics of organic aerosols (both primary and secondary aerosols), and the further characterization of anthropogenic and biogenic precursor emissions. |
| | 2. The combined use of modeling tools such as CMAQ and inverse-CMAQ modeling, and ambient and satellite measurements to improve estimates of ammonia and elemental carbon emissions should be applied to other pollutants/sources and other areas to demonstrate their wider applicability. |
| | 3. ORD is encouraged to leverage its selection of emerging monitoring technologies and methods by selecting the ones that have the greatest potential for widespread use among state and local air quality monitoring agencies. |
| | 4. The potential health effects of coarse particles in urban and rural environments should be examined |
| **LTG 2** | 5. Continue to pursue a multi-pollutant approach for both air quality management and research, but formally define the aspects of "multi-pollutant" that are of highest priority and will be pursued in the near term and long term |
| | 6. The Clean Air Research Program should consider developing a research framework to explore multi-pollutant exposures as they relate to the co-pollutant complex of PM components, ozone, $NO_2$ and air toxics and the potential positive and negative effects that may result from combinations of these pollutants on health outcomes. |
| | 7. More basic research on pollutant mixture exposure needs to be performed to support the design of multi-pollutant-based emission regulations and ambient standards. Because it is apparent that it will not be realistic to set air quality standards for pollutant mixtures or components of $PM_{2.5}$ in the near term, examining the health effect correlations from one or more source categories is a reasonable approach |
| | 8. Continue to survey clients and stakeholders on perceptions of and satisfaction with ORD's role in the source-to-health outcomes process |
| **General Overall Program** | 9. ORD develop a working definition for the term "multi-pollutant approach" as it pertains to its LTGs and the expectations of its various stakeholders. |

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| **General Overall Program** | 10. ORD strengthen Federal Reference Method (FRM)/Federal Equivalent Method (FEM) methods development by ascertaining the state of the measurement science for each NAAQS pollutant ahead of the review cycle, and subsequently initiating intramural or extramural research programs to develop and improve methods as needed. |
| | 11. ORD revise the procedures for designation of an approved instrument method, which will accommodate and provide incentives for the development and introduction of new measurement technologies for air quality monitoring |
| | 12. The planning and resource allocation for the Clean Air Research Program to address research priorities reflecting stakeholder needs is developed through negotiation between the Program Director and participating ORD laboratories, which retain budgetary authority. ORD review the rationale for this management decision and consider a more balanced approach for resource management under the direction of the Clean Air Research Program |
| | 13. ORD further evaluate the judicious use of satellite data with existing ground-based measurements before embarking on more extended use of satellite data |
| | 14. ORD coordinate ammonia and PM emission studies with current industry-funded research on concentrated animal feeding operations (CAFO) sources at various universities. |

# II. INTRODUCTION

The BOSC conducts independent, retrospective and prospective expert reviews of ORD research programs on a periodic basis, typically every 4 to 5 years. This review process is consistent with the National Academies' recommendation that independent expert reviews are an effective way to evaluate federal research programs. This document reports the results of the BOSC review of the Office of Research and Development's (ORD) Clean Air Research Program. The review focused on the period since the last major BOSC review of this program (which was entitled "Particulate Matter and Ozone Research Program" at that time) in 2005 as well as findings from the mid-cycle review of the Program in 2007.

The objective of this review is to evaluate the relevance, quality, performance, scientific and managerial leadership, and outcomes of the Program and provide guidance and recommendations as to the progress and directions of the Program to ORD to help:

- plan, implement, and strengthen the Program as it moves forward;
- make research investment decisions over the next 5 years;
- refine the integration of the Program both across ORD research programs (e.g., Human Health, Global Change) and across other federal agencies;
- prepare EPA's performance and accountability reports to Congress under the Government Performance and Results Act (GPRA); 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]).

The program review is guided by a set of charge questions developed by ORD and coordinated with the BOSC Subcommittee Chair (the Charge Questions to the Subcommittee are included as Appendix B). The charge questions provided the basis for the Agency's preparation of the review materials and helped to focus the Subcommittee's considerations. The report is organized around the charge questions and the LTGs that the Program has identified as part of its multi-year planning process. In this case, two overarching LTGs are identified in the Clean Air Research Multi-Year Plan (MYP) 2008-2012 (EPA, 2008):

LTG 1: In accordance with EPA's legislated mandate for periodic NAAQS assessments and assessment of HAP risks, advances in the air pollution sciences will reduce uncertainty in <u>standard setting</u> and <u>air quality management</u> decisions; and

LTG 2: Air pollution research will reduce uncertainties in linking health and environmental outcomes to sources of air pollutants to improve the effectiveness of air quality management strategies.

These LTGs support the regulatory requirements of OAR while developing the science to link health effects to air pollution sources and components. The latter approaches air pollution from its origin as source emissions, through atmospheric transport and transformation, to exposure/ dose, and human health outcomes. It emphasizes science planning coordination to leverage across programs and achieve efficiencies in both science and budget. A two-pronged approach has been adopted with the expectation to:

1. Continue to support the needs of EPA, and state and local governments, providing the underlying science for the development of health-based standards to regulate air pollution as well as the tools to implement air quality management strategies to meet those standards; and

2. Pursue the science that will lay a foundation for the next generation of air pollution standards and management strategies in the face of evolving environmental challenges.

The Clean Air Subcommittee met in May 21, 2009, by conference call to discuss the proposed charge questions and scope of the review. Also on this call, the Subcommittee was provided an overview of EPA's ORD. On a second conference call on May 29, 2009, the Subcommittee was briefed on the Clean Air Research Program and its major elements organized by LTGs as identified in the Clean Air MYP. These conference calls set the stage for the more detailed discussion that would follow at the face-to-face meeting that was held June 8-10, 2009, in Research Triangle Park, North Carolina. The Subcommittee Chair prepared and presented a plan that identified principal review and writing assignments for Subcommittee members for discussion during the May 21 conference call, and the plan was endorsed by the Subcommittee. At the Subcommittee's request, ORD prepared "a road map to the evidence addressing the charge" (provided in Appendix E), which provided a template for reviewing the extensive materials provided by ORD. The Subcommittee review plan identified work group leaders and members to address each of the charge questions and the two LTGs identified in the Clean Air MYP.

The Subcommittee has addressed each charge question and provided a summary of its findings in terms that highlight the strengths and weaknesses of the Program. The Subcommittee also provided a performance rating with narrative for each of the LTGs.

## Background for the Clean Air Research Program

The EPA Strategic Plan 2006-2011 identifies Clean Air and Global Climate Change as a primary goal for environmental protection with specific objectives aimed at Healthier Outdoor Air and Healthier Indoor Air. The Clean Air Research Program focuses on addressing the first objective, Healthier Outdoor Air, by providing the science needed to review, attain, and maintain ambient air quality standards required to protect public health. Although the Program considers the reduction of air pollution impacts on ecosystems and other welfare-related outcomes under its overall research goal, public health protection remains the top priority of its clients. The formal organization and management structure of the Clean Air Research Program evolved from three research strategies designed around PM, ozone, and HAPs to a single strategic plan to better coordinate and leverage research across these pollutants and to acknowledge the multi-pollutant perspective that these pollutant exposures occur simultaneously and in many cases share common precursors.

The Clean Air Research Program is conducted by investigators within ORD’s National Exposure Research Laboratory (NERL), National Health and Environmental Effects Research Laboratory (NHEERL), and National Risk Management Research Laboratory (NRMRL), and by awardees of its extramural Science To Achieve Results (STAR) grants program funded under the National Center for Environmental Research (NCER).

In fiscal year (FY) 2007, EPA allocated approximately $78 million dollars and 245 FTEs to the Air Research Program. Of the $78 million, $36 million was for research and support expenses spent via contracts and grants, and the remaining $42 million was for EPA personnel compensation and benefits, travel, infrastructure-related support, and operating expenses.

The Clean Air Research Program maintains collaborative working relationships with government agencies and research organizations including:  National Oceanic and Atmospheric Administration (NOAA); NIEHS; NHLBI; HEI; EPRI; and Coordinating Research Council (CRC). The Program also maintains working relationships with two key environmental coordinating bodies—the White House Committee on Environmental and Natural Resources Research (CENR) and the North American Research Strategy for Tropospheric Ozone (NARSTO). The Program’s participation helps coordinate and communicate ORD’s research agenda at the national and international level.

The Clean Air Research Program’s principal client is OAR.  The Program also provides research assistance to EPA Regions, states, tribes, and regional planning organizations (RPOs) in their activities to mitigate adverse air quality and to the National Center for Environmental Assessment (NCEA), which is responsible for NAAQS pollutant science assessments.

# III. CHARGE QUESTION 1: PROGRAM DESIGN AND DEMONSTRATED LEADERSHIP

The Air MYP was reviewed in 2007 as part of a "mid-cycle" review of Program progress. At that time, the BOSC commented on the plan and Program aspirations. In light of the fact that the MYP is now in its official form (2008) and the BOSC's recommendations at that time, the Subcommittee was asked to address the charge questions below.

✧ *Is the Clean Air Research Program continuing to plan its program effectively?*

- **Responsiveness to the 2005 and mid-cycle BOSC recommendations regarding program design and implementation**

  The BOSC finds that ORD has been responsive to the 2005 and 2007 reviews of the Air Research Program. The most recent full BOSC review of the Air Research Program (then the Particulate Matter and Ozone Research Program) was completed in August 2005. The review was quite favorable and provided an in-depth discussion of 10 conclusions and 9 recommendations centered on 4 charge questions and 2 LTGs. In February 2006, ORD provided a detailed response to the recommendations contained in the review. After the 2005 review, ORD combined the Particulate Matter, Ozone, and Air Toxics research programs into a combined Air Research Program and revised the scope of its LTGs. A BOSC mid-cycle review of the combined Air Research Program was carried out in September 2007 (the formal report was submitted to ORD in March 2008), with the charge to address ORD's response to the 2005 recommendations and assess the reorganization leading to the Air Research Program. That review was again quite favorable and no formal response was requested from ORD.

  The 2007 mid-cycle review considered six charge questions and the report included an executive summary and in-depth responses to each of the charge questions. Three of these questions addressed the responsiveness of ORD to the 2005 BOSC recommendations and are highlighted here.

  In response to Charge Question 1, the review found that ORD had adequately addressed the nine recommendations of the 2005 review. A survey was developed to assess the primary stakeholders' perceptions of and satisfaction with the source-to-health outcomes process. Although the response rate was not as high as desirable, useful results were obtained. As suggested by the BOSC, the wording of two LTGs was revised and pilot studies were initiated to test the source-to-health outcomes framework. The Research Coordination Team (RCT) has been active as a vehicle to solicit input and to coordinate with other federal agencies and states. ORD has demonstrated its commitment to a balance of intramural and extramural research with review by the RCT. Although the recommendation that ORD reconsider the decision to disinvest in the ozone research program due to lack of resources was not accommodated, it was pointed out that ozone is an element of the multi-pollutant approach recommended by the NRC and now adopted by ORD.

Charge Question 4 of the mid-cycle review addressed the effectiveness of the integration of the PM, Ozone and Air Toxics programs into one Air Research Program. The conclusion was that the integration provides a more holistic approach to reducing health outcomes. The BOSC strongly supported this integration in response to the 2005 review; further details are presented in the discussion of the charge sub-question below on the multi-pollutant approach.

Charge Question 6 of the mid-cycle review involved rating the progress made by the Air Research Program in moving the program forward in response to the 2005 BOSC program review. The rating provided was Exceeds Expectations and the reasons for the rating included the integration of the three programs into a single Air Research Program, the initial survey of stakeholders, efforts to link sources to health outcomes, and maintenance of strong relationships with other federal, state, and private organizations concerned with air quality research. Based on the review of the very recent program management of the Clean Air Research Program, the BOSC Clean Air Subcommittee concurs with this evaluation.

- **Increasing emphasis on a multi-pollutant approach to ORD's air quality research**

There are many advantages to moving from a single pollutant approach to a multi-pollutant approach to meet the LTG of (1) reducing uncertainty in standard setting and air quality management decisions and (2) reducing uncertainty in linking air pollution sources to health outcomes. Because the real-world air pollutant environment is a multi-pollutant mix, this approach is more realistic in reflecting the actual exposure environment. There also is the possibility of synergistic, antagonistic, or other interactions among pollutants that can be considered more effectively with this multi-pollutant approach. A significant challenge in moving from a framework of managing individual pollutants to a multi-pollutant approach is in reconciling the complex multi-pollutant mixture with the pollutant-specific NAAQS.

ORD is doing a commendable job in its effort to move toward a multi-pollutant approach to air quality issues. The choice of near-road emissions is an excellent pilot study to test the implementation of the multi-pollutant approach. State and local agencies have been experiencing difficulty in their attempts to formulate realistic $PM_{2.5}$ SIPs that deal with nonattainment of the annual and daily standards when mobile sources are a significant component of their pollutant mix. States (other than California) only have limited control over the regulation of mobile sources. They can regulate fuel volatility and encourage mass transit but these strategies are not likely to be sufficient in many areas. Even more stringent regulations on mobile source emissions are likely to be necessary for the design of SIPs in response to the 24-hour $PM_{2.5}$ standard. Because only the Federal Government has the authority to fully regulate mobile sources, it is very important for EPA to perform the research necessary to determine the significance of the mobile sources as well as the research needed to determine and implement mobile source control strategies.

One overriding concern is that ORD has not yet formally defined what it did and did not mean by “multi-pollutant approach,” given the multiplicity of potential definitions. ORD should proceed to first address elements of “multi-pollutant approach” that can be addressed by existing science and regulatory structures, such as development of multi-pollutant SIPs, multi-pollutant secondary NAAQS (as EPA is currently undertaking for secondary $SO_2$ and NOx standards) and continue to advance intramural and extramural research into more challenging elements of “multi-pollutant approach,” such as the health effects of exposure to mixtures of pollutants, which will provide the information necessary to determine if it is realistic to set health-based multi-pollutant standards in the future. Once more of the basic research on pollutant mixture exposure has been performed, it may be easier to design multi-pollutant-based emission regulations and ambient standards. Because it is apparent that it will not be realistic to set air quality standards for pollutant mixtures or components of $PM_{2.5}$ in the near term, the approach of examining the health effect correlations from a source category is sensible.

- **Research priorities reflecting stakeholder needs**

ORD’s research priorities are reflecting stakeholder needs in one of three ways. The priorities are either successfully meeting the stakeholder needs, are not meeting the stakeholder needs, or are in the process of meeting these needs.

In response to a recommendation from the 2005 BOSC review, ORD conducted a client survey designed to assess the primary stakeholders’ perceptions of and satisfaction with ORD’s role in the source-to-health outcomes process. Responses were received from 28 of 54 solicitations from OAR, EPA Regional Offices, and NCEA. In addition, ORD collected some examples and testimonials describing how ORD products and advice have been used by OAR, the regions, and NCEA.

The survey indicated a very high degree of satisfaction with the Program and regulatory support received from ORD. Reports and computer or Web-based tools and models were cited most frequently as the products most often used by stakeholders. In addition, the overall quality, timeliness, and responsiveness of research products were rated well above average. Also rated high was the ability of ORD to provide the science needed to do the client’s job. The weakest area identified by the survey was in the perception of ORD’s flexibility to rearrange research priorities to accommodate partner needs, and in ORD’s receptiveness to comments on critical needs. The conclusions related to the high quality of research products were repeated in the examples cited as “products valued by stakeholders.”

The Program is certainly meeting the needs of the PM science and exposure community. These research results already are being utilized by the NAAQS developers as well as by the state agencies responsible for implementing pollutant control strategies. It also is quite clear that ORD considers accountability to be an important component of this research priority. The source-to-health outcomes framework for this research naturally lends itself to a demonstration of accountability. The utility of this approach will be evident as the research results become available that provide evidence of the direct human health benefits that result from air quality management actions.

The Program's research priorities are working towards meeting the needs of stakeholders concerned with near-road exposures and climate change issues. Many of the research priorities that involve these topics have been initiated recently and involve multifaceted research that, in some cases, requires close coordination with other agencies. The stakeholder needs for these issues, particularly climate change, are more open-ended because of the scope and the scale of the issues. ORD is to be commended for taking a wide ranging approach to these issues, which should help to narrow the focus to the most important criteria as soon as possible.

ORD is faced with ongoing resource constraints that have forced reductions in its research focus in several areas. Stakeholder needs are not being met as well as they could be in the areas of methods development, standard setting, the identification of monitoring techniques for diesel emissions, and indoor air issues. Some of these research needs are certainly related to the research priorities that ORD is undertaking and there will be improvements on these issues realized from ORD's current research program. More resources and a higher priority for these issues would have to be instituted in order for more of these stakeholders to be satisfied with the research outcomes. In addition, ORD should continue to coordinate and collaborate on research with other funding agencies, such as it already is doing with NIEHS, NHLBI, CDC, and California Air Resources Board (CARB).

- **Coordination and integration of research within and across the extramural and intramural programs to maximize [the benefit from][†] resource investment.**

The intramural and extramural coordination seems to be well thought out and the RFPs are designed to maximize the breadth of the knowledge of the outside research community. ORD has pointed out that extramural research is the most efficient way to address issues that cannot effectively be addressed by the resources and expertise available "in-house". One program aspect that has fallen short in recent years at ORD is method development research. ORD has acknowledged that their in-house methods development capabilities are less than they once were, and that but they have been reluctant to issue RFPs in this research area as a result of intramural and extramural resource limitations. There are scientists and engineers who are qualified to do applied research into the type of method development useful for defensible and consistent NAAQS or HAPs measurements. ORD is encouraged to either strengthen the in-house method development program or solicit extramural assistance in this area.

[†] Note the word change from the original charge "…the benefit from…" was added to the charge question.

- *Is the Clean Air Research Program providing strong science leadership and program management in both research planning and implementation?*

  The responsiveness of the Clean Air Research Program to previous NRC and BOSC recommendations, focus on meeting LTGs, strong multidisciplinary orientation of the researchers, integration of research across EPA laboratories and multiple partners, and the overall structure of the MYP are all indications of successful program management. Science leadership is demonstrated from the role EPA has assumed as the lead federal agency on air quality issues, including interactions with other environmental issues (e.g., climate change, ecosystem health), as well as from the high quality of the science products from the research program. Key opportunities to continue to provide science leadership will occur with the continued implementation of multi-pollutant research and the incorporation of the emission source-to-health outcome paradigm.

- *Is the Clean Air Research program effective in communicating results to its stakeholders, program offices, Regions, State and local regulatory agencies, general public and the broader scientific community?*

  Much of ORD's research results are translated into increased fundamental knowledge of air pollutant emission, transformation, and exposure pathways through the environment. These results are made available through peer-reviewed journal articles, presentations, and in the refinements to research tools such as air quality models. State agencies and EPA Regions utilize the models that ORD provides in a forecast mode to determine if potential pollution reduction strategies are viable. ORD's continued refinement of air quality models is actually one of the more efficient ways in which its research results are utilized to make air quality management decisions.

  Air quality monitoring agencies receive ORD's research results on monitoring methods through periodic revision of the monitoring implementation regulations that are published in the *Code of Federal Regulations* (CFR).

  NAAQS developers utilize ORD's research results through a review of published journal articles as well as through ORD's participation in the NAAQS development process. By necessity, some of ORD's research projects are exploratory in nature and are not likely to result in breakthroughs that will be useful for future regulation development.

- *Does the Clean Air Research Program have LTGs and APGs that will meet the goals of the ORD research program, address stakeholder needs, and are not unnecessarily duplicative of national and international work in this area?*

  At first glance, the APGs are skewed towards PM-related research. This pollutant should be ranked highest on the list of research priorities because of the significance of the health effects and because not enough is known about the health-related mechanisms to ascertain the toxicity of PM components. Many of the research program elements and modeling efforts that deal with PM also involve work with co-pollutants and HAPs both gaseous and semi-volatile. These studies may be labeled as PM research but their results will be used to gain information about the co-pollutants as well as the PM components. The balance among

PM, ozone, and air toxics related research and priorities should be re-visited and the Clean Air Research Program should consider developing a research framework for addressing the multi-pollutant exposures of these criteria pollutants and their precursors apart from the source-to-health outcome model.

Methods development is one Agency goal that is in LTG 1 but is not well supported by the APGs. ORD should allocate some percentage of its resources to ascertain the state of the measurement science and a review of the existing data quality for each criteria pollutant prior to the review for that pollutant. Then, if it is found that a more thorough research program is needed, an internal research project or extramural RFA could be issued. This approach would reduce the length of time after an existing older FRM becomes outdated and is replaced with a newly designated method.

- *Is the relative resource distribution by LTG (i.e., relative % FTE, relative % extramural vs. intramural resources) appropriate to address Agency goals, stakeholders' needs, and the goals of the ORD Clean Air Research Program?*

Although the relative resource distribution by LTG at first glance seems appropriate to address the various goals of stakeholders, the Agency, and the Clean Air Research Program, it is important to note that the Program has been level funded since 1997, suggesting a systematic attrition of resources that is not sustainable in the long term. The Subcommittee members suspect that all the luxuries have been wrung out of the Program and the impact of the inflationary loss in funds over the years has affected the content of the Program. In addition, planning and resource allocation for the Clean Air Research Program is developed through negotiation between the Program Director and participating ORD laboratories, which retain budgetary authority. Program responsibility without fiscal control seems problematic. The BOSC recommends that ORD review the rationale for the current management and budgetary structure for the Clean Air Research Program and consider a more balanced approach for resource management under the direction of the Program.

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# IV. CHARGE QUESTION 2: SCIENCE QUALITY

✧ *Is the science being conducted by EPA-ORD research laboratories and centers of recognized high quality and high impact, and appropriate to stakeholder needs?*

The quality of the scientific research being conducted under EPA's Clean Air Research Program is unquestionably outstanding. More than 650 publications have appeared since the 2005 program review. The extensive bibliometric analysis of 2,600+ publications coming from the Program during the decade of 1998-2008 provides powerful, substantive evidence of the quality and impact of the research. The analysis is based in part on Thomson's Essential Science Indicators (ESI). One-third of the 2,600+ papers qualified as highly cited by the ESI and one-third was published in high impact journals, which are journals that are cited with a high frequency. More than one-half of the Clean Air Research Program papers were published in the top 21 journals as listed by ESI. In addition, Harvard University, a Program grantee, ranks #1 and EPA ranks #2 in ESI's list of the top 20 institutions publishing on air pollution. The high quality of the science also was evident in the review of the posters presented at the review meeting and in conversations with the scientists who presented the posters.

In addition to peer-reviewed literature publications, the Clean Air Research Program has voluminous documentation of models and methods that are available to the public and are heavily used by others. The Subcommittee recognized that performance metrics based on peer-reviewed publications can undervalue contributions in certain areas (e.g., emissions characterization or control technology assessment) that are nevertheless critical to making progress in improving air quality.

The publications have a high impact factor because they are highly cited, but even more important is the fact that some key papers have been sentinel in the field. Examples from ORD's extramural research include a new paradigm for formation of secondary aerosols (*Science* 2007;315:1259-1262); and demonstration of an improvement in life expectancy with reduced air pollution (*New England Journal of Medicine* 2009;360:376-386). Examples from intramural research include outstanding work on mixed-phase organic aerosol formation, natural and agricultural emissions of ammonia, and mobile source emission measurements that have supported EPA's new mobile source emission factor model (MOVES) developed by OTAQ. Both the extramural and intramural research conducted through ORD has provided advancements along multiple fronts relevant to PM health risks. In a relatively short amount of time, ORD research has added substantially to the evidence base regarding the mechanisms of PM health effects as well as the effects of composition and particle size.

There is concern, however, that erosion of ORD research capacity (a function of funding for Program and personnel) is creating research gaps in multiple domains, including development of new monitoring methods and support for emission inventories. Limited support for oxidant research is hampering new developments in aerosol and multi-pollutant research. Relatively little has been done in relation to air toxics, other than through the atmospheric modeling structure, which is a reflection of budgetary constraints. Although a multi-pollutant framework would encapsulate air toxics, more research in emissions, exposures, and health risks would be required to inform air quality management decisions. Work on ozone has been relatively less substantial than work on PM, again, reflecting resource constraints, but recent meta-analyses of the time-series mortality literature as well as new multicity studies have added to the evidence base and underpinnings of NAAQS revisions, and have provided indications of key next steps. ORD should consider developing a research plan that identifies the project/programmatic balance among PM, ozone, and air toxics related research for addressing the multi-pollutant exposures of these criteria pollutants and their precursors.

The question of the research meeting stakeholder needs requires a two-fold answer. At the national level, the interactions between the Clean Air Research Program and OAQPS appear to be excellent. At the review meeting, the OAR representatives declared their dependence on the Program's research for informing the setting of NAAQS standards. The high number of citations in the Criteria Document for PM is an important metric of impact and meeting stakeholder needs. Development and refinement of models such as CMAQ, MOVES, UNMIX, and PMF have been valuable for scientists and decision-makers. CARB also was pleased with the usefulness of the information from the Clean Air Research Program. The utilization of ORD products elsewhere at EPA provides demonstrable evidence of the research being appropriate to stakeholder needs, e.g., OAQPS air quality modeling studies with CMAQ and collaboration between ORD and OTAQ in collecting data for the MOVES mobile source emissions model.

On the other hand, stakeholders at the regional level seemed less cognizant of how best to interact with the Clean Air Research Program and how to get their needs met. An example is the Regional Applied Research Effort (RARE) Program, which is an excellent mechanism for sponsoring projects at the regional level. Participation in the RARE Program, however, requires a mentor at the national level and incentives for potential mentors are lacking. This appeared to be a roadblock for some regional stakeholders. Although there were relatively few responses to the survey of partners in the Clean Air Research Program (<30), the response was generally positive.

✧ *Is the Program fostering multidisciplinary research and taking advantage of opportunities for leveraging resources and expertise?*

The Clean Air Research Program is an excellent example of an integrated, multidisciplinary scientific approach to problem solving. The research conducted at ORD clearly captures a wide range of disciplines, including exposure science, toxicology, atmospheric modeling, epidemiology, and others; there are few domains in environmental health in which ORD has not had an impact. Further, projects in ORD have increasingly adopted interdisciplinary research strategies, integrating multiple disciplines into a single research framework. Examples include simultaneously conducted toxicology and epidemiology studies with mutually reinforcing methods and conclusions. The near-roadway program is bringing together experts on mobile source emissions, atmospheric dispersion, atmospheric chemistry, human exposure, and health effects. The different disciplines are interacting to address a problem that could not be addressed by each individual discipline alone. Such an approach would not be possible in most academic institutions and it is appropriate that EPA conduct this type of research.

There was evidence of effective leveraging of resources and expertise through the extramural and the intramural components of the Program. The extramural program is funding some of the top air pollution researchers in the country, both through the Particle Centers and other funding mechanisms. The Particle Centers are good examples of funding mechanisms that foster interdisciplinary research, encourage linkages—both among researchers at different academic institutions and with ORD staff, and that leverage resources by tapping into the extensive air pollution research conducted by Particle Center investigators outside of the Centers. There also are strong interactions with other research institutions such as NIEHS, NHLBI, and CDC to avoid duplicate efforts by these federal agencies. HEI is an example of the leveraging of EPA monies with monies from industry, foundations, and the World Bank in a highly successful program to reduce emissions from diesel engines.

The Clean Air Research Program also provides several examples of multidisciplinary work that is leveraging expertise within ORD and elsewhere at EPA. A good example is the MESA-Air Study, in which an existing cohort was leveraged to incorporate air pollution exposures in investigating cardiovascular outcomes. This also is evident in the near-roadway program, which relies upon measurement and modeling capabilities for emissions and atmospheric dispersion that then are interfaced to exposure assessments and health effects. As another example, ORD is applying regional air models with future climate scenarios to understand how climate change may impact future air quality. Building on this, ORD has developed regional emission forecasting tools for investigating how energy and planning decisions could interact with climate and air quality.

# V. CHARGE QUESTION 3: RELEVANCE

- *Are the potential benefits from the research being conducted clearly articulated in terms of public health protection (support to policy, decision-making, and standards implementation)?*

- *Are the products of ORD research being used by stakeholders in decision making or the formulation and implementation of policy?*

The air quality research component of the Clean Air Research Program is quite diversified so as to meet the needs of a large client base of various OAR offices (OTAQ, OAQPS, etc.), and many local, state, and regional governments. The Program has produced many outputs (models, measurements, data analysis) that have been used in policy development and implementation, regulatory decision-making, and review of NAAQS. The potential public health benefits of various policy and regulatory decisions based on the outputs of the air quality component of the Program have been articulated reasonably well by the Clean Air Research Program. The Program also has performed well in terms of a second measure of success that involves the actual use of the research products of the ORD Program.

Relative to LTG 1 (reducing uncertainty in science that supports NAAQS and air toxics), the Program's research has been well articulated and widely used in a timely manner by OAQPS in the recent setting of ozone and $PM_{2.5}$ standards. The ORD-developed model, CMAQ, is being used with great success in developing SIPs to demonstrate attainment of ambient standards for ozone. The recently revised process of NAAQS Review (April 2009), as presented by Ms. Lydia Wegman at the review meeting on June 8-10, will require a clear articulation and a larger use of ORD research outputs in CASAC review of policy options that are based on integration and interpretation of information in Integrated Science Assessments (ISA) and Risk-Exposure Assessments (REA). This science-policy interface will need active participation of ORD's Clean Air Research Program to inform the standard -setting process within EPA.

For $PM_{2.5}$ SIPs, however, the CMAQ is not as advanced and accurate as for ozone because of limitations in representing the chemistry and physics of organic aerosols (both primary and secondary aerosols), as well as characterization of anthropogenic and biogenic precursor emissions. The BOSC recommends that CMAQ and other air quality models should continue to be a high priority for sequential refinement, given that this is one of the more efficient ways in which ORD's research results are utilized to make air quality management decisions. Emphasis on CMAQ development should focus not only on the size and mass of PM, but also on the components of PM, including the characterization of the chemistry and physics of organic aerosols (both primary and secondary aerosols), and the further characterization of anthropogenic and biogenic precursor emissions. Such developments have direct implications on meeting the near-term needs of OAQPS and states in the preparation of $PM_{2.5}$ SIPs.

ORD also has provided highly relevant research outputs in three important new areas of research: (1) ecosystem assessment, (2) finer-resolution exposure characterization, and (3) climate-air quality interactions. The extension of CMAQ to estimate contribution of atmospheric deposition of nitrogen and sulfur to sensitive ecosystems in the United States is an excellent example of the use of ORD outputs in multimedia research. The hybrid approach combining CMAQ and AERMOD for use in exposure models (SHEDS and HAPEM) and investigating its feasibility in improving exposure assessment for the New Haven, Connecticut study is another good example of phasing the current research effort into the multi-pollutant, "source-to-health outcomes" paradigm to meet LTG 2. The intramural and extramural efforts in investigating the climate-air quality interaction have been an extremely successful extension of the traditional air quality research program to global change and implications for ground-level air quality. The recent April 2009, EPA report, "Assessment of the Impacts of Global Change on Regional U.S. Air quality: A Synthesis of Climate Change Impacts on Ground-Level Ozone," clearly articulates the need for, and use of, ORD's research.

# VI. CHARGE QUESTION 4: DEMONSTRATED OUTCOMES

✧ *Has the Clean Air Research Program made significant progress in the conduct of the planned research and in answering the key science questions related to public health benefits and pollution abatement?*

The Subcommittee addressed this charge question by evaluating three components of the Clean Air Research Program: (1) air quality, (2) health and exposure, and (3) source-to-health outcomes/multi-pollutant strategies. As noted in various ORD presentations and write ups, the first two components relate to meeting the first LTG of reducing uncertainties in setting of NAAQS and in designing and implementing SIPs and other air quality management decisions. The third research component is more recent and reflects the emerging "source-to-health outcomes" research paradigm. It addresses the second LTG of reducing uncertainties in linking public health effects to sources of air pollution and thus involves a "multi-pollutant" approach.

The air quality research component of the Clean Air Research Program (which includes source emissions, ambient measurements, air quality modeling, and linkages and extensions to assessments of ecosystems, public health exposure, and climate-air quality interactions) has made substantial progress in answering key science questions and in providing useful input to air quality planning at national, regional, state, and local levels. Recent intramural and extramural efforts on understanding the atmospheric processes of organic aerosols and potential incorporation of this research in the CMAQ model at ORD and Carnegie Mellon University (by incorporating the concept of volatility basis set), as well as coordinating this effort with EPRI-funded research, are commendable. The renewed emphasis on improving estimates of biogenic emissions by developing the MEGAN model and on use of satellite data to improve the temporal and spatial resolution of biomass burning emissions should help with better predictions of ozone and $PM_{2.5}$ levels. The BOSC recommends, however, that the judicious use of satellite data (which cover a wide area but may not be specific enough) with existing ground-based measurements (that are specific but do not cover a wide area) needs further evaluation by the Clean Air Research Program before embarking on more extended but meaningful use of satellite data.

The effort on quantifying emissions of $NH_3$ from soils (fertilized and natural) and animal sources has made good progress including a better understanding of the bi-directional nature of ammonia fluxes and much better characterization of the local and regional nature of deposition of ammonia emissions sources. More studies are needed, however, to obtain ammonia emission estimates at temporal and spatial scales that are compatible for CMAQ modeling of $PM_{2.5}$ and ozone. The BOSC recommends that the Program coordinate such ammonia and PM emission studies with current industry-funded research on CAFO sources at various universities.

The baseline ORD effort in developing new versions of the CMAQ model incorporating new science and maintaining existing versions for use by client divisions within EPA and by state and regional governments in the United States as well as international entities has been a great success. Here, the recent intramural effort on developing a formal model evaluation framework that includes evaluation at four levels (i.e., operational, dynamic, diagnostic, and probabilistic) already has demonstrated its usefulness and needs to be developed further in the area of probabilistic evaluation. The combined use of modeling tools such as CMAQ and inverse-CMAQ modeling and ambient and satellite measurements to improve estimates of emissions have demonstrated their usefulness, at least for emissions of ammonia and elemental carbon. Such a combined approach should be applied to other pollutants/sources and other areas to demonstrate its wider applicability. This effort should be pursued in conjunction with efforts to improve methods to use satellite data in a meaningful way (see above).

From the perspective of health and exposure research, the Clean Air Research Program has made significant progress in understanding the public health implications of PM exposure and the benefits of abatement strategies. Progress in CMAQ model development (e.g., PM modules and advanced mechanisms for the treatment of secondary organic aerosol formation) are evident and provide a key modeling tool for quantifying the benefits of pollution abatement strategies. Attempts to nest higher-resolution models with CMAQ also are valuable, as is the direction toward using “near-roadway” as the template for initial multi-pollutant investigations.

Research directed at evaluating mechanisms of PM-related health effects and potential differential toxicity of particle constituents also has advanced substantially in a limited number of years. Although studies on differential toxicity have not yet provided the information necessary for developing a “hierarchy of sources,” the insight is significantly greater than just a few years ago. Both the intramural and extramural research on this front have been scientifically sound and recognized as important and relevant work by the scientific community (as indicated by the bibliometric analysis) and by OAQPS and other entities (as indicated by the citations of this work in the NAAQS Criteria Document for PM). Thus, the Clean Air Research Program has unequivocally made significant progress in recent years regarding $PM_{2.5}$.

Progress, however, has been more limited regarding exposures and health implications for coarse particles, with only one ongoing study addressing the important urban/rural question, raising questions regarding its general applicability. The rapid growth in mechanistic insight regarding ultrafine particles has not been matched with emissions characterization, exposure assessment, or epidemiological studies necessary to evaluate public health benefits of control strategies. In general, the planned and implemented research predominantly emphasized $PM_{2.5}$, with modest investment in ozone epidemiology and very limited consideration of air toxics. Regulatory impact analyses by EPA and CARB emphasize that the majority of the public health benefits of air pollution controls are generally attributable to $PM_{2.5}$, with the impact of ozone less than that of PM but far exceeding that of air toxics. This indicates that this distribution of resources is illogical from the perspective of the charge question, but the Subcommittee was concerned (as was the BOSC Subcommittee that conducted the mid-cycle review) that more balance may be necessary going forward towards the “source-to-health outcomes” paradigm. This may be particularly important for a multi-pollutant air quality management strategies, as large uncertainties regarding ozone impacts could contribute systematic biases in management plans (e.g., by mischaracterizing the benefits of $NO_x$ or volatile organic compound [VOC] controls relative to $SO_2$ controls). The November 2008 SAB evaluation of EPA's strategic research directions emphasized that areas such as air toxics exposures and health risk, air quality in indoor environments, and global cycling of mercury would merit increased attention. The BOSC agrees that these are important domains that have not received substantial attention in recent years, while recognizing that resource constraints preclude significant progress on all fronts.

The third major area of the Program's research, "source-to-health outcomes" can be assessed in terms of the characterization of sources, studies of health outcomes, and, most importantly, the linkage between the two. The most important accomplishment has been the implementation of the "near-road" program, with measurement programs in Las Vegas, Nevada; Detroit, Michigan; and Raleigh, North Carolina. The DEARS study goes beyond measurement to health linkage through an extramural award to the University of Michigan. Measurement and analytic technologies that will be needed for future intramural and extramural studies are being evaluated as part of the program and should be an important addition to future studies. Other documented and important outcomes that address both the scientific uncertainties related to the source-to-health paradigm and air quality management are: (1) research on deposition of $NH_3$ and estimation of amounts available for secondary particulates (as noted above); (2) demonstration that restarting of school bus engines is preferable to persistent idling provided idling after restart is not prolonged (exposure to school bus diesel is an important exposure for school-age children); (3) identification of new fingerprint organic chemical marker species and better characterization of uncertainty estimates that result from use of different methods and stability of molecular markers used in source apportionment work—these outputs obviously are critical for successful test of the source-to-health paradigm; (4) development of the SPECIATE Database to speciate emissions in support of source apportionment; and (5) models to better understand the contribution of natural source VOCs in support of source apportionment; NAAQS for $PM_{2.5}$, ozone, and CO; and OAR, regional offices, and state agencies with regard to their control strategies to meet SIPs and NAAQS targets. Further documentation of the extensive body of work that is being conducted on behalf of source characterization was found in the posters presented at the meeting that relate specifically to the multi-pollutant framework of the MYP.

An intermediate step in the source-to-health paradigm is characterization of exposure and doses that result from sources. A very important outcome at this level is the finding that ultrafine particles (UFPs) and coarse PM (PMC) deposit in the same regions of the lung. This clears up a misconception about the potential availability of components of PMC for important biological interactions in the respiratory system.

Although the documentation and presentation demonstrate considerable research progress on understanding biological and health consequences of exposures to ambient pollutants, little has been produced in this regard with respect to the source-to-health paradigm. Undoubtedly, this is the consequence of the relatively recent onset of the program that is designed to meet this LTG. The DEARS study has published several papers, but these have been limited to study implementation and exposure characterization. Time series analysis from various cities performed by the Johns Hopkins PM Center indicated that the large regional differences in daily increases in adverse health outcomes, attributed to $PM_{2.5}$, were related to composition difference in $PM_{2.5}$, particularly to vanadium and nickel. These data represent an important outcome in that they provide a clue as to a potentially important result on the source-to-health paradigm.

# VII. CHARGE QUESTION 5: SUMMARY AND RATING BY LONG-TERM GOAL

## Long-Term Goal 1

***LTG 1:*** *In accordance with EPA's legislated mandate for periodic NAAQS assessments and assessment of HAP risks, advances in the air pollution sciences will reduce uncertainty in standard setting and air quality management decisions. This LTG supports two research themes: (a) developing NAAQS and other air quality regulations; and (b) implementing air quality regulations.*

### Overall Rating of LTG 1: Exceeds Expectations

The ORD Clean Air Research Program exceeds expectations in delivering ambient measurements, source emission inventories, air quality models, and analyses to address LTG 1. There are several areas that are exceptional and where ORD has demonstrated national leadership, including work on biogenic emissions and the emerging research on climate/air quality interactions. Research regarding the health implications of PM exposure has made rapid progress in a relatively short amount of time, and the quality of this work has clearly been exceptional. The near-singular focus on PM is partly justified in light of the public health burden and significant regulatory decisions, but does imply that the Clean Air Research Program's science has been relatively less useful for establishing NAAQS for other criteria pollutants or informing air quality management decisions related to air toxics. Additional direct emphasis on the health implications of low-level exposure (i.e., below the current NAAQS) would be valuable, particularly in controlled exposure multi-pollutant environments, where possible. That said, it is difficult to argue that any of the work conducted under ORD's Clean Air Research Program is not relevant and important, and resource constraints imply that any expansion of effort on these topics would necessitate a redirection of resources away from important and relevant science.

### Extending applications of methods and models

ORD has applied major components of its air pollution science research to ecosystems, climate change/air quality interactions, and improvement in exposure assessments. Overall, this program area exceeds expectations for quality and timeliness.

The ecosystem assessment work has made substantial and timely contributions to scientific understanding of the relative contributions of nearby and remote sources of total reactive nitrogen (both oxidized and reduced). This effort has provided timely and important contributions to ecosystem management of the Chesapeake Bay and Tampa Bay Watersheds by reducing uncertainty in decision-making.

The research effort (both intramural and STAR grants) on climate change/air quality interactions has made substantial contributions to the rapidly emerging understanding of the role of climate change on regional ozone and PM levels. The quality of research publications is high, the research is timely, and it has resulted in a recent EPA policy-relevant document that assesses the implications of climate change on regional air quality planning.

The effort on extending existing methods and models to improve exposure assessment is quite useful for health studies. The hybrid approach using CMAQ and AERMOD and its extension to use of exposure models (SHEDS and HAPEM) should move the research agenda forward in this important area.

### How appropriate is the science used to achieve LTG 1, i.e., is the Program asking the right questions, with the most appropriate methods?

Ambient Measurements

A priority of ORD's Clean Air Research Program is to assess the risk from HAPs and to reduce the uncertainty in making air quality management decisions. The ambient measurement development program is collecting information on carbonaceous aerosols, secondary organic aerosols, inorganic aerosols, coarse and ultrafine particles, gas phase chemistry, HAPs (including mercury), and meteorology. Research on these topics is expanding the state of knowledge of gaseous compounds, HAPs and PM pollutants and their interaction in a multi-pollutant framework. Most of these program elements are basic applied research that will pay dividends as scientific understanding increases, method development improves, and innovative control strategies are implemented.

ORD has been putting less effort into the non-PM elements of the NAAQS standard setting process than it has in the past. Ozone was the most important ambient air pollutant before ambient PM rose to the forefront in the mid-1990s. Recent studies have suggested that ambient ozone concentrations may be important for health-effect correlations at levels well below the level of the current NAAQS. Additional studies to confirm these results are needed and will be important in support of the upcoming ozone NAAQS review. HEI currently has two RFAs in place that will address the health effects of ozone and multi-pollutant mixtures as part of the Clean Air Research Program.

Some of the non-NAAQS oriented ambient monitoring methods on which ORD has chosen to concentrate have been selected because they will either help address a specific science issue such as organic carbon source apportionment or ammonia air-surface exchange, or because they have been identified as a promising emerging technology. These non-NAAQS ambient measurement research programs will benefit the air quality management element of LTG 1. ORD is encouraged to leverage its selection of emerging monitoring technologies and methods by selecting the ones that have the greatest potential for widespread use among state and local air quality monitoring agencies.

Source Emissions

The National Academies committee that reviewed EPA's PM research program from 1998 to 2002 recommended a comprehensive, cohesive emission characterization research program led by EPA, and carried out by the states, industry, and other stakeholders. Additionally, the committee recommended the development of standardized test methods for the sources, other than motor vehicles, that contribute major fractions of ambient PM (e.g., coal-fired boilers, residential wood combustion, and wildfires). The overall goal was for EPA to develop a comprehensive plan for systematically applying new source-test methods in order to develop a complete, comprehensive national emissions inventory based on contemporary source tests of comparable quality.

Despite the chronic lack of resources for emission inventory development and the long-standing question of whether work on emissions inventory development for criteria pollutants should be labeled “research” and covered by the Program, ORD has demonstrated leadership in several important areas. Biogenic emissions are an important driver in most multi-pollutant air quality modeling studies. ORD has supported development of a new biogenic emissions model called MEGAN developed at the National Center for Atmospheric Research (NCAR). MEGAN has been adopted by many air quality models and implemented within the air quality model to provide online biogenic emission estimates (e.g., in WRF-CHEM). MEGAN provides better support for modeling PM than EPA’s existing biogenic emissions model (BEIS) because MEGAN includes additional compounds. Isoprene emissions from MEGAN and BEIS can differ significantly and ORD scientists are exceptionally well qualified to assist in understanding and, if possible, resolving these differences quickly.

There is an impressive effort to improve the inventory of biomass burning emissions (wildland and prescribed fires) using satellite imagery, and ammonia emission factors from agricultural and natural sources using flux measurements. Primary organic aerosols, biological particles, and HAPs also are getting increasing attention using novel techniques such as near-source measurements (to overcome artificially low dilution rates in laboratory studies) and new measurement capabilities and tracers.

Air Quality Modeling

Air quality modeling tools developed by ORD are being used to understand which sources are contributing to air pollution and what are the most effective strategies for reducing air pollution. ORD scientists are identifying where models are uncertain and conducting research to improve models and reduce these uncertainties. They are developing new ways of evaluating models to ensure that scientists and policy-makers are aware of both the strengths and weaknesses of the models.

The CMAQ model is at the center of ORD’s intramural research program for air quality modeling and is supported by research on model science algorithms, evaluation techniques, and applications. Notable achievements in model development for CMAQ are organic aerosols and boundary layer mixing. Organic aerosol (OA) is an important constituent of PM in many regions and OA modeling is subject to many uncertainties in emissions and physical/chemical processes. ORD scientists are commended for following a systematic and rigorous approach in using atmospheric data to guide CMAQ model improvements for OA. Mixing within the atmospheric boundary layer exerts strong influences on CMAQ predictions of pollutant concentrations and development of a new mixing algorithm (called ACM2) by ORD is an important contribution to air pollution modeling. Implementing ACM2 in the meteorological models that support CMAQ (namely WRF and MM5) represents a valuable contribution to the atmospheric modeling community. ORD research has benefited models developed elsewhere within EPA as exemplified by work performed in support of the near-roadway program. ORD researchers have developed new line-source dispersion algorithms that are being considered for inclusion in EPA's AERMOD near-source dispersion model. Mobile source emissions data collected in Kansas City by ORD scientists have been incorporated by OTAQ into the new MOVES mobile source emission model that is replacing the MOBILE model.

The extramural component of the Clean Air Research Program is providing high-quality science for use by EPA researchers and policy-makers. Examples include new methods for modeling organic aerosols (OA), climate change- air quality interactions, global air pollution, and biogenic emissions and their incorporation into air quality models. Carnegie Mellon University developed a new approach to OA modeling called the Volatility Basis Set (VBS) with STAR grant funding. The VBS offers a practical approach for using data obtainable by laboratory measurements with efficient modeling algorithms to describe the important features of OA formation such as chemical aging and evaporation/ condensation. The VBS was developed in the PMCAMx model and is being implemented in the CMAQ model.

The GEOS–Chem global tropospheric chemistry model from Harvard University receives ORD support and provides essential information on North American background pollution concentrations for consideration when setting air quality standards and to provide boundary conditions for regional air quality modeling studies. GEOS-Chem modeling also provides estimates of future background air quality that could be made available for use in regional air quality planning studies. ORD plans to apply CMAQ for the northern hemisphere and it is unclear whether this will complement or duplicate GEOS–Chem results.

Resource constraints limit the ability of ORD to fully support multi-pollutant air quality modeling. CMAQ development has a strong focus on PM but has not ignored other pollutants. For example, ORD has extended CMAQ to include gas-phase chemical reactions for a number of HAPs; however, more emphasis is recommended, maintaining the existing oxidant chemistry in CMAQ and considering integration between chemistry occurring in different phases. Oxidant chemistry was pioneered for ozone but is central to secondary PM and photochemical reactions of HAPs such as mercury. Developments in multi-pollutant chemistry that place new demands on gas-phase chemistry include aqueous-phase formation of secondary OA from gaseous precursors such as dicarbonyls and understanding the role of halogens in mercury oxidation and deposition.

Health and Exposure

The stated intent of the research under LTG 1 is to inform statutory needs related to NAAQS, air toxics, SIP tools, and models for stakeholders in OAR, regions, states, and tribes. From the perspective of research in the domain of health and exposure, the work has been appropriate for addressing the aims of LTG 1. As discussed earlier, the Program's research has focused predominantly on PM (largely $PM_{2.5}$ but also considering coarse and ultrafine PM), which is appropriate given the estimated public health burden of PM and the significant uncertainties related to mechanisms of toxicity and biological plausibility. The research presented is clearly informative for the $PM_{2.5}$ NAAQS, as exemplified by the large number of citations of Clean Air Research Program science in the most recent PM Draft Staff Paper. Although the Program is asking appropriate scientific questions regarding the physical/chemical attributes of PM associated with health outcomes, the mechanisms by which PM can cause adverse health effects, and the subpopulations susceptible to those effects, research appears to be lacking related to one of the central questions in establishing NAAQS—whether public health effects occur below the current NAAQS, and if so, what standard would be expected to adequately protect sensitive subpopulations. Given significant controversy associated with this step of the standard-setting process, more emphasis on this core question would have been warranted. That said, the work presented and conducted was appropriate and relevant.

Research on ozone exposures and health effects has been more limited but has emphasized the possibility of mortality effects (key to regulatory impact analyses and related management decisions) and the possibility of health effects below the current NAAQS, appropriate questions under LTG 1. Work related to personal exposure was relatively underrepresented, but the effects to better characterize spatiotemporal air pollution patterns and use of models such as SHEDS to link those ambient patterns with time-activity data are appropriate and informative, and ongoing work targeting LTG 2 (e.g., near-roadway studies, the DEARS study) is clearly relevant to the exposure component of LTG 1. In general, there is a direct link between most of the research in the domain of health and exposure and key regulatory decisions facing EPA and other stakeholders.

## How high is the scientific quality of the Program's research products?

Ambient Measurements

The majority of ORD's ambient monitoring research products is of high quality and well received by others in the respective research fields, by data analysts and by pollution control planners. Several shortcomings, however, are noted below:

- In the last review of the $PM_{2.5}$ FEM Class III evaluation criteria, test criteria developed by ORD introduced potential measurement uncertainties of 25 percent or more mass in the $PM_{2.5}$ FEM as compared to the collocated compliance network oriented FRM. This measurement uncertainty introduces inconsistencies and degrades the quality of the $PM_{2.5}$ dataset that is used by health researchers, NAAQS reviewers, and monitoring agencies and EPA regional offices for attainment determinations.

- In the latest revision of the lead (Pb) monitoring implementation regulation, in response to the recent revision of the Pb standard, accepts the 30-year-old Pb TSP FRM. This method has well-known sampling limitations (sensitivity to wind speed and direction) and limited scientific creditability.

- The current FRM for ozone is outdated and no longer commercially manufactured. This raises the issue that the ozone FEM evaluation protocols for which ORD is responsible, can no longer be met, because one requirement is that the candidate analyzer be compared to an FRM that is not available. The lack of a suitable FRM was noted recently in the Photochemical Assessment Monitoring Stations (PAMS) monitoring regulation, which specified that an Ozone FEM, not an FRM must be operated at PAMS sites.

- The designation of an approved instrument method essentially freezes the state of the science and in so doing, removes incentives for vendors to improve these instruments either for ease of use or technical upgrades and stifles innovation.

The BOSC recommends that ORD revise the procedures for designation of an approved instrument method, which accommodates and provides incentives for the development and introduction of new measurement technologies for air quality monitoring.

Source Emissions

The biogenic emission inventory research that ORD conducts and funds is of the highest quality as demonstrated by numerous publications in the scientific literature. There also is a major effort (STAR grant) to address uncertainties by systematically comparing observations of air quality (ground-based monitoring, satellite retrievals) with air quality model predictions as a method to iteratively improve overall emission estimates for PM and ozone precursors.

Air Quality Modeling

The research program being conducted by ORD is delivering air quality modeling products of very high quality. Within the intramural research program, several activities related to the CMAQ model stand out for both research quality and relevance to program goals. These include research on OA, which demonstrates how improvements to the representation of OA in the CMAQ model have been guided by source apportionment ambient PM and other published research as well as how aqueous-phase chemistry can form OA in quantities that are sufficient to influence the total PM burden. The Carnegie Mellon University development of the VBS approach to understanding OA formation is a particularly innovative concept. In addition, new approaches to model evaluation for CMAQ that demonstrated air quality benefits from EPA's "$NO_x$ SIP call" strategy to reduce power plant emissions in the eastern United States and other research presented in posters illustrate how ORD science is improving the tools available to decision makers and also providing accountability on the benefits from air quality management actions.

Health and Exposure

The research presented to the BOSC related to health and exposure is unquestionably of high quality, based on the extensive bibliometric analysis, the content of the posters and other materials presented, and Subcommittee interactions with both intramural and extramural researchers. Reflecting the funding associated with Particle Centers and the regulatory importance of enhanced understanding of the health implications of PM, many of the significant scientific advancements were associated with the biological plausibility of PM health effects, the public health benefits of air pollution reductions, and atmospheric modeling addressing the complexities of secondary aerosols and other constituents. Ongoing studies such as DEARS are high quality and provide key information about exposure in a multi-pollutant framework, targeting LTG 2 but also informing questions within LTG 1. In spite of the more limited emphasis on ozone, the research presented on the health effects of ozone represented high-quality epidemiological work that added to the evidence base for NAAQS revisions.

## To what extent are the Program results being used by environmental decision-makers to inform decisions and achieve results?

Ambient Measurements

As part of the NAAQS assessment process, ORD should evaluate the state of the knowledge with regard to the specific pollutant under review including an evaluation of the designated and alternative monitoring methods, method evaluation criteria, and the adequacy of existing data available to the EPA NAAQS reviewers. The review, including published research results, should be available to the NAAQS review team in a timely fashion to assure that it is a useful resource in the process.

The BOSC recommends that ORD strengthen FRM/FEM methods development by ascertaining the state of the measurement science for each NAAQS pollutant ahead of the review cycle, and subsequently initiating intramural or extramural research programs to develop and improve methods as needed.

Source Emissions

To the extent that CMAQ modeling applications are being used by regulatory agencies and other decision-makers, the EPA source emission inventory is being used to inform decisions and achieve results.

Air Quality Modeling

The CMAQ air quality model developed by ORD is used extensively by environmental decision-makers at EPA, states, and other bodies with air quality management responsibilities. States are using CMAQ to develop SIPs for PM, ozone, and visibility. OAR has used CMAQ for modeling PM, ozone, mercury, and HAPs, taking advantage of the multi-pollutant capability of the model and OAR recently used CMAQ in a national rulemaking decision for locomotive/marine diesel engines. ORD engagement with CMAQ users is important and should be encouraged. Examples of ORD outreach showing how CMAQ can be integrated more broadly into environmental management decisions were provided. Products from extramural research also are having direct and important impacts on air quality management decisions. The GEOS-Chem model and scenario results, discussed above, provide valuable insight into background air quality for North America and there is potential for even greater leveraging of GEOS-Chem estimates of future air quality background. Utilization of ORD Clean Air Research Program models by environmental decision-makers exceeds expectations.

Health and Exposure

The Program's research on health and exposure clearly is being used by OAQPS in the process of setting NAAQS for $PM_{2.5}$, and to a lesser extent, ozone. Limited work (mainly that carried out under the near roadway study) is being done within the Clean Air Research Program regarding health impacts of air toxics, reflecting resource constraints and stakeholder priorities.

**The appropriateness, quality, and use of ORD science by program and regional offices, ORD partners, and other organizations to establish air quality standards and make air quality management decisions.**

Ambient Measurements

Much of the Program's research results are translated into increased fundamental knowledge of air pollutant emission, transformation, and exposure pathways through the environment. This information is critical to the development of realistic air quality standards and to the continuing improvement of air pollution models. State agencies are required to utilize EPA-approved air pollution models to forecast the viability of proposed control strategies. These models are the basis for SIP design and are expected to accurately predict the impact of selected control strategies on needed reduction in ambient pollutant concentrations in the time period specified in the SIP. State agencies and their respective EPA regional offices have the responsibility to approve SIPs, have to work collaboratively because an approved SIP must be scientifically acceptable and legally defensible, and must meet the expectations of the many varied stakeholders who are affected by this process.

Source Emissions

The EPA source emission inventory is the primary information source for many states, but others with in-house modeling capabilities and their own resources to conduct field studies for development of air quality modeling inputs, generally develop their own emission inventories. For example, California has its own mobile source emission model and PM and VOC speciation profiles. Perhaps this is inevitable because emission inventory development is a resource-intensive activity and states and other local jurisdictions want to have specific information on sources in their jurisdiction.

Air Quality Modeling

Widespread use of the CMAQ air quality model by air quality regulators and researchers demonstrates that the Clean Air Research Program is effective in promoting good science and meeting the expectations of its clients. The influence of the Program extends outside EPA and the states as numerous universities use the CMAQ model in research spanning from emission inventories to climate change. The Program influence also spreads beyond the CMAQ model as other atmospheric models (e.g., WRF, MM5, PMCAMx, CAMx) take advantage of science developed and/or sponsored by EPA (e.g., the VBS and ACM2 algorithms discussed in the poster session).

Health and Exposure

ORD Clean Air Research Program work in health and exposure is clearly appropriate and of high quality in relation to establishment of air quality standards. As discussed previously, this linkage is most evident for $PM_{2.5}$, with relatively less direct emphasis on ozone, other criteria pollutants, and air toxics .While some ORD science (both intramural and extramural) is not directly tied in to standard setting and air quality management decisions in the near term (e.g., work on ultrafine particles), these topics are generally quite relevant to potential future decisions, and the research reasonably reflects future anticipated air quality management needs.

## Long-Term Goal 2

***LTG 2:*** *Air pollution research will reduce uncertainties in linking health and environmental outcomes to sources of air pollutants to improve the effectiveness of air quality management strategies. This LTG is oriented towards supporting three research themes: (a) launching a multi-pollutant research program ;( b) identify specific source-to-health outcomes linkages with initial emphasis on "near roadway"; and (c) assessing the health and environmental improvements due to past regulatory actions.*

### Overall Rating of LTG 2: Exceeds Expectations

LTG 2 looks to the future in which it is expected that air quality management will be based more on regulating sources of pollutant mixtures rather than on regulating individual pollutants. This is a multi-pollutant approach that has been recommended to EPA by both the SAB and the NRC. The Clean Air Research Program has been responsive to that advice. The Program is exceptional both in the quality of its science and the speed with which it has been accomplished. The section on quality in this report adequately describes the basis for the exceptional quality of the science. The speed of the work is documented by the rapidity with which the Program has led the world in clarifying the characteristics of PM that lead to increased morbidity and mortality and in clarifying mechanisms for these effects.

The three research themes under LTG 2 are at various stages of development. First, the Clean Air Research Program has launched a multi-pollutant research program. Second it has initiated a specific source-to-health outcomes study with an emphasis on "near- roadway" exposures. These two multi-pollutant themes are relatively new and it is too early to determine their overall impact on reducing uncertainty in air quality health outcomes. The Program's progress in developing these areas has certainly exceeded expectations. The third theme, assessing the health and environmental improvements due to past regulatory actions, sometimes referred to as "accountability" has been evolving with major efforts underway in collaboration with HEI. Accountability studies to address the impact of regulatory actions on health outcomes remain challenging, but increased interest in the area should stimulate research approaches and improve data resources. ORD's contributions and performance in this area have exceeded expectations

### How appropriate is the science used to achieve LTG 2, i.e., is the Program asking the right questions, with the most appropriate methods?

One of the initial problems faced by the source to outcome portion of the Clean Air Program (LTG 2) has been to define what is meant by the term, "multipollutant", which has a multiplicity of potential definitions (ranging from simultaneous consideration of multiple pollutants when establishing SIPs to detailed evaluation of health effects of pollutant mixtures). This problem was directly acknowledged by ORD and was well discussed at the program review, but no solution was presented. *Although ORD acknowledges that a working definition of "multi-pollutant" has not been agreed upon by all of the interested partners, they have proceeded to choose an initial source for study to test the paradigm and the research needed to support it.* The near-roadway research program represents the first source-to-outcome paradigm to be studied. This is appropriate because it is a source for which there are epidemiological studies of the "outcomes.", and it represents an excellent example of the need for source-to-outcome multipollutant research. However, the research program would benefit from a clearer articulation of the precise aspects of "multipollutant" that will be captured within this project. This will also be helpful in prioritizing which other sources should be studied in the future, as this may depend to some extent on which aspects of "multipollutant" ORD considers most pressing.

As articulated under LTG 1, the weakest area of air pollution research the CARP is air toxics. LTG 2 offers an opportunity to fill this gap, because air toxics are a part of the multi-pollutant mix in the atmosphere. Thus, the LTG 2 approach is relevant and appropriate to fill in this missing part of the air pollution problem.

Other areas of research emphasis include the effect of atmospheric processing and the influence of the airshed on air quality and health effects. These are excellent multi-pollutant areas for the CARP to investigate and these choices make good use of the expertise of the scientists within the Program.

The final part of the program is to address the effectiveness of regulations. This accountability research is extremely important and appropriate for a regulatory agency. The research is done in collaboration with HEI, a research partner partially funded by EPA.

One gap in the LTG 2 research program is the effect of multi-pollutants on ecosystems. The outcomes under study seem to be focused on health outcomes, not ecosystems outcomes. This is almost certainly due to funding constraints.

### How high is the scientific quality of the Program's research products?

The quality of the research conducted for LTG 2 is outstanding, as indicated in the section of this report related to the overall quality of research in the Clean Air Research Program. The publications are highly cited and appear in top journals as illustrated in the bibliometric analysis. The quality of the research is enhanced by the Program's research partners, which include both intramural and extramural participants. The PM Centers have been central in providing excellent, high-quality research. The STAR Program also has contributed valuable scientific results.

### To what extent are the Program results being used by environmental decision makers to inform decisions and achieve results?

The source-to-outcome, multi-pollutant approach is relatively new and therefore some parts of the Program will exhibit increasing usefulness with time. The timelines for some of the goals reach out to 2012; however, some parts of the Program already are heavily used by environmental decision-makers. The air quality models developed by the Clean Air Research Program, such as CMAQ, MOVES, and MEGAN, have been used by air pollution managers and researchers all over the globe. The Center for Community Modeling and Analysis System (CMAS) has 2,000 registered users from 90 countries. These users requested more than 5,000 model downloads in 2008. These models are part of the source-to-air quality portion of the source-to-outcome paradigm. Multi-pollutant models are available and are applied to assist in the development of criteria pollutant mitigation strategies. These models will provide the foundation for the further development and the consideration of a more expansive set of pollutant parameters for use in integrated risk assessments.

Stakeholders who found the research of the Clean Air Program useful spoke at the review meeting. These included the Puget Sound Clean Air Agency, the CDC, OAQPS, and the new Global Change Program. The interaction of ORD's Clean Air Research Program with many other groups and agencies (HEI, NIEHS, NHLBI, NOAA, Federal Highway Administration [FHWA]) allows the Program to leverage its work to enhance the usefulness its research.

The new emphasis on accountability (effectiveness of regulations) provides much needed information for use by decision-makers. An example is the study showing that long-term reductions in $PM_{2.5}$ during the 1980s and 1990s are associated with an increased life expectancy of 0.5 years.

# VIII. APPENDICES

## Appendix A: Clean Air Subcommittee Members

**Kenneth L. Demerjian, Ph.D. (Chair)**
State University of New York

**Praveen Amar, Ph.D., P.E.**
NESCAUM

**Tina Bahadori, D.Sc.**
American Chemistry Council

**Melvyn Branch, Ph.D.**
University of Colorado

**Bart E. Croes, P.E.**
California Air Resources Board

**Henry Felton, P.E.**
New York State Department of Environmental Conservation

**Rogene F. Henderson, Ph.D.**
Lovelace Respiratory Research Institute

**Jonathan Levy, Sc.D.**
Harvard University

**Murray A. Mittleman, M.D.**
Beth Israel Deaconess Medical Center

**Ira B. Tager, M.D., M.P.H.**
University of California, Berkeley

**Gregory Yarwood, Ph.D.**
Environ International Corporation

# Appendix B: Charge for the BOSC Subcommittee on Clean Air 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 the Office of Research and Development's (ORD's) Clean Air Research program. The focus of this review is on the period since the last major BOSC review in 2005. The panel's evaluation and recommendations as to the progress and directions of the program in light of the elements stated above will provide guidance to ORD to help:

- plan, implement, and strengthen the program as it moves forward;
- make research investment decisions over the next five years;
- refine the integration of the ORD program both across ORD programs (e.g., Human health, Global Change) and across 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 Science 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 multi-disciplinary 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 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 Coordination Teams (RCTs). These teams help assist in research program development by identifying research needs and priorities with significant decision-making value, and they also help plan for research product transfer and application.

For EPA's environmental research programs, periodic retrospective analysis at intervals of four or five 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.

The ORD's Clean Air Research program is described in a Multi-Year Plan[11] (MYP) that combines and integrates three previous MYPs and research strategies (PM, ozone, and HAPs) into a single plan to better coordinate and leverage research across all themes. Earlier MYPs approached each program area separately with little cross-theme coordination and integration. At the core of this MYP is a major shift in ORD's approach to research in the air pollution sciences. Previously, each MYP relied on several loosely connected long-term goals (LTGs) addressing a wide range of specific science supporting regulatory functions. The present MYP is shaped around two overarching LTGs that continue to support the regulatory requirements of the program office while developing the science to link health effects to air pollution sources and components. The latter approaches air pollution from its origin as source emissions, through atmospheric transport and transformation, to exposure / dose, and human health outcomes. It emphasizes science planning coordination to leverage across programs and achieve efficiencies in both science and budget. To this end, this MYP has adopted a two-pronged approach:

1. Continue to support the needs of EPA, and state and local governments, providing the underlying science for the development of health-based standards to regulate air pollution as well as the tools to implement air quality management strategies to meet those standards; and
2. Pursue the science that will lay a foundation for the next generation of air pollution standards and management strategies in the face of evolving environmental challenges.

This dual approach is reflected in the adoption of two LTGs for this research plan:

> LTG 1. In accordance with EPA's legislated mandate for periodic NAAQS assessments and assessment of HAP risks, advances in the air pollution sciences will reduce uncertainty in <u>standard setting</u> and <u>air quality management</u> decisions.
>
> LTG 2. Air pollution research will reduce uncertainties in linking health and environmental outcomes to sources of air pollutants to improve the effectiveness of air quality management strategies.

## 3.0 Charge Questions for ORD's Clean Air Research Program

(A) Program Assessment. The following charge questions will help evaluate the relevance, quality, performance, as well as management and scientific leadership of ORD's Clean Air Research program emphasizing the period since the last review in 2005:

1. Program Design and Demonstrated Leadership

The MYP was reviewed in 2007 as part of a "mid-cycle" review of program progress. At that time, the BOSC commented on the plan and program aspirations. In light of the plan now in its official form (2008) and the BOSC recommendations at that time:

- Is the Clean Air Research program continuing to plan its program effectively? Please consider the following:
  - Responsiveness to the 2005 and mid-cycle BOSC recommendations regarding program design and implementation
  - Increasing emphasis on a multi-pollutant approach to ORD's air quality research
  - Research priorities reflecting stakeholder needs
  - Coordination and integration of research within and across the extramural and intramural programs to maximize resource investment.
- Is the Clean Air Research program providing strong science leadership and program management in both research planning and implementation?
- Is the Clean Air Research program effective in communicating results to its stakeholders – program offices, Regions, State and local regulatory agencies, general public and the broader scientific community?
- Does the Clean Air Research program have LTGs and APGs that will meet the goals of the ORD research program, address stakeholder needs, and are not unnecessarily duplicative of national and international work in this area?
- Is the relative resource distribution by LTG (i.e., relative % FTE, relative % extramural vs. intramural resources) appropriate to address agency goals, stakeholders' needs, and the goals of the ORD Clean Air research program?

2. Science Quality

- Is the science being conducted by EPA-ORD research Labs and Centers of recognized high quality, high impact and appropriate to stakeholder needs?
- Is the program fostering multidisciplinary research and taking advantage of opportunities for leveraging resources and expertise

3. Relevance

- Are the potential benefits from the research being conducted clearly articulated in terms of public health protection (support to policy, decision-making and standard implementation)?
- Are the products of ORD research being used by stakeholders in decision making or the formulation and implementation of policy?

4. Demonstrated Outcomes

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

(B) Summary Assessment (rate program performance by LTG): A summary assessment and narrative should be provided for each LTG. The assessment should be based primarily on 3 of the questions included above, which are:

1. How appropriate is the science used to achieve each LTG, i.e., is the program asking the right questions, with the most appropriate methods?
2. How high is the scientific quality of the program's research products?
3. To what extent are the program results being used by environmental decision makers to inform decisions and achieve results?

**Elements to include for Long-Term Goal 1:**

The appropriateness, quality, and use of ORD science by Program and Regional Offices, ORD partners, and other organizations to establish air quality standards and make air quality management decisions.

**Elements to include for Long-Term Goal 2:**

The appropriateness, quality, and use of ORD science by Program and Regional Offices, ORD partners, and other organizations to link sources of air pollutants to health and environmental outcomes to support air quality management decisions.

In developing the summary assessment for each LTG, the BOSC Clean Air Subcommittee will assign a qualitative score that reflects the quality and significance of the research as well as the extent to which the program is meeting or making measurable progress toward the goal—relative to the evidence provided to the BOSC. The scores should be in the form of the adjectives that are defined below and intended to promote consistency among BOSC program reviews. The adjectives should be used as part of a narrative summary of the review, so that the context of the rating and the rationale for selecting a particular rating will be transparent. The rating may reflect considerations beyond the summary assessment questions, and will be explained in the narrative. The adjectives to describe progress are:

- Exceptional: indicates that the program is meeting all and exceeding some of its goals, both in the quality of the science being produced and the speed at which research result tools and methods are being produced. An exceptional rating also indicates that the program is addressing the right questions to achieve its goals. The review should be specific as to which aspects of the program's performance have been exceptional.
- Exceeds Expectations: indicates that the program is meeting all of its goals. It addresses the appropriate scientific questions to meet its goals and the science is competent or better. It exceeds expectations for either the high quality of the science or for the speed at which work products are being produced and milestones met.

- Meets Expectations: indicates that the program is meeting most of its goals. Programs meet expectations in terms of addressing the appropriate scientific questions to meet their goals, and work products are being produced and milestones are being reached in a timely manner. The quality of the science being done is competent or better.
- Not Satisfactory: indicates that the program is failing to meet a substantial fraction of its goals, or if meeting them, that the achievement of milestones is significantly delayed, or that the questions being addressed are inappropriate or insufficient to meet the intended purpose. Questionable science is also a reason for rating a program as unsatisfactory for a particular long term goal. The review should be specific as to which aspects of a program's performance have been inadequate.

## 4.0 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," pages 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," pages 5-10.

3 Evaluating Federal Research under the Government Performance and Results Act (National Research Council, 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, 1997).

6 Building a Foundation for Sound Environmental Decisions. (National Research Council, 1997).

7 "Renewing the Compact between Science and Government," Stokes, D.E., in *1995 Forum Proceedings, Vannevar Bush II—Science for the 21st Century*. Pages 15-32. Sigma Xi, 1995.

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

9 Strengthening Science at the U.S. Environmental Protection Agency. (National Research Council, 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 (www.nap.edu; Report IV - http://www.nap.edu/books/0309091993/html/)

11 Clean Air Research Multi-Year Plan 2008-2012. U.S.EPA. EPA 620/R-08/001.

## Attachment: OSTP/OMB Research and Development Investment Criteria

The Relevance, Quality, and Performance criteria apply to all R&D programs. Industry-relevant applied R&D must meet additional criteria. Together, these criteria can be used to assess the need, relevance, appropriateness, quality, and performance of federal R&D programs.

### I. Relevance

R&D investments must have clear plans, must be relevant to national priorities, agency missions, relevant fields, and "customer" needs, and must justify their claim on taxpayer resources. Review committees should assess program objectives and goals on their relevance to national needs, "customer" needs, agency missions, and the field(s) of study the program strives to address. For example, the Joint DOE/NSF Nuclear Sciences Advisory Committee's Long Range Plan and the Astronomy Decadal Surveys are the products of good planning processes because they articulate goals and priorities for research opportunities within and across their respective fields. Programs that directly address Presidential priorities may receive special consideration for support, with adequate documentation of their relevance to those priorities.

OMB will work with some programs to identify quantitative metrics to estimate and compare potential benefits across programs with similar goals. Such comparisons may be within an agency or among agencies.

A. **Programs must have complete plans, with clear goals and priorities.** Programs must provide complete plans, which include explicit statements of: specific issues motivating the program; broad goals and more specific tasks meant to address the issues; priorities among goals and activities within the program; human and capital resources anticipated; and intended program outcomes, against which success may later be assessed.

B. **Programs must articulate the potential public benefits of the program.** Programs must identify potential benefits, including added benefits beyond those of any similar efforts that have been or are being funded by the government or others. R&D benefits may include technologies and methods that could provide new options in the future, if the landscape of today's needs and capabilities changes dramatically. Some programs and sub-program units may be required to quantitatively estimate expected benefits, which would include metrics to permit meaningful comparisons among programs that promise similar benefits. While all programs should try to articulate potential benefits, OMB and OSTP recognize the difficulty in predicting the outcomes of basic research. Discovery is a legitimate object of basic research, and some basic research investments may be justified on external judgments of the opportunity for discovery.

C. **Programs must document their relevance to specific Presidential priorities to receive special consideration.** Many areas of research warrant some level of federal funding. Nonetheless, the President has identified a few specific areas of research that are particularly important. To the extent a proposed project can document how it directly addresses one of these areas, it may be given preferential treatment.

D. **Program relevance to the needs of the Nation, of fields of science and technology, and of program "customers" must be assessed through prospective external review.** Programs must be assessed on their relevance to agency missions, fields of science or technology, or other "customer" needs. A customer may be another program at the same or another agency, an interagency initiative or partnership, or a firm or other organization from another sector or country. As appropriate, programs must define a plan for regular reviews by primary customers of the program's relevance to their needs. These programs must provide a plan for addressing the conclusions of external reviews.

E. **Program relevance to the needs of the Nation, of fields of science and technology, and of program "customers" must be assessed periodically through retrospective external review.** Programs must periodically assess the need for the program and its relevance to customers against the original justifications. Programs must provide a plan for addressing the conclusions of external reviews.

## II. Quality

Programs should maximize the quality of the R&D they fund through the use of a clearly stated, defensible method for awarding a significant majority of their funding. A customary method for promoting R&D quality is the use of a competitive, merit-based process. NSF's process for the peer-reviewed, competitive award of its R&D grants is a good example. Justifications for processes other than competitive merit review may include "outside-the-box" thinking, a need for timeliness (e.g., R&D grants for rapid studies in response to an emergency), unique skills or facilities, or a proven record of outstanding performance (e.g., performance-based renewals).

Programs must assess and report on the quality of current and past R&D. For example, NSF's use of Committees of Visitors, which review NSF directorates, is an example of a good quality-assessment tool. OMB and OSTP encourage agencies to provide the means by which their programs may be benchmarked internationally or across agencies, which provides one indicator of program quality.

A. **Programs allocating funds through means other than a competitive, merit-based process must justify funding methods and document how quality is maintained.** Programs must clearly describe how much of the requested funding will be broadly competitive based on merit, providing compelling justifications for R&D funding allocated through other means. (See OMB Circular A-11 for definitions of competitive merit review and other means of allocating federal research funding.) All program funds allocated through means other than unlimited competition must document the processes they will use to distribute funds to each type of R&D performer (e.g., federal laboratories, federally funded R&D centers, universities). Programs are encouraged to use external assessment of the methods they use to allocate R&D and maintain program quality.

B. **Program quality must be assessed periodically through retrospective expert review.** Programs must institute a plan for regular, external reviews of the quality of the program's research and research performers, including a plan to use the results from these reviews to guide future program decisions. Rolling reviews performed every 3-5 years by advisory committees can satisfy this requirement. Benchmarking of scientific leadership and other factors provides an effective means of assessing program quality relative to other programs, other agencies, and other countries.

**III. Performance**

R&D programs should maintain a set of high priority, multi-year R&D objectives with annual performance measures and milestones that show how one or more outcomes will be reached. Metrics should be defined not only to encourage individual program performance but also to promote, as appropriate, broader goals, such as innovation, cooperation, education, and dissemination of knowledge, applications, or tools.

OMB encourages agencies to make the processes they use to satisfy the Government Performance and Results Act (GRPA) consistent with the goals and metrics they use to satisfy these R&D criteria. Satisfying the R&D performance criteria for a given program should serve to set and evaluate R&D performance goals for the purposes of GPRA. OMB expects goals and performance measures that satisfy the R&D criteria to be reflected in agency performance plans.

Programs must demonstrate an ability to manage in a manner that produces identifiable results. At the same time, taking risks and working towards difficult-to-attain goals are important aspects of good research management, especially for basic research. The intent of the investment criteria is not to drive basic research programs to pursue less risky research that has a greater chance of success. Instead, the Administration will focus on improving the management of basic research programs.

OMB will work with some programs to identify quantitative metrics to compare performance across programs with similar goals. Such comparisons may be within an agency or among agencies.

Construction projects and facility operations will require additional performance metrics. Cost and schedule earned-value metrics for the construction of R&D facilities must be tracked and reported. Within DOE, the Office of Science's formalized independent reviews of technical cost, scope, and schedule baselines and project management of construction projects ("Lehman Reviews") are widely recognized as an effective practice for discovering and correcting problems involved with complex, one-of-a-kind construction projects.

A. **Programs may be required to track and report relevant program inputs annually.** Programs may be expected to report relevant program inputs, which could include statistics on overhead, intramural/extramural spending, infrastructure, and human capital. These inputs should be discussed with OMB.

B. **Programs must define appropriate output and outcome measures, schedules, and decision points.** Programs must provide single-and multi-year R&D

objectives, with annual performance measures, to track how the program will improve scientific understanding and its application. Programs must provide schedules with annual milestones for future competitions, decisions, and termination points, highlighting changes from previous schedules. Program proposals must define what would be a minimally effective program and a successful program. Agencies should define appropriate output and outcome measures for all R&D programs, but agencies should not expect fundamental basic research to be able to identify outcomes and measure performance in the same way that applied research or development are able to. Highlighting the results of basic research is important, but it should not come at the expense of risk-taking and innovation. For some basic research programs, OMB may accept the use of qualitative outcome measures and quantitative process metrics. Facilities programs must define metrics and methods (e.g., earned-value reporting) to track development costs and to assess the use and needs of operational facilities over time. If leadership in a particular field is a goal for a program or agency, OMB and OSTP encourage the use of benchmarks to assess the processes and outcomes of the program with respect to leadership. OMB encourages agencies to make the processes they use to satisfy GPRA consistent with the goals and metrics they use to satisfy these R&D criteria.

C. **Program performance must be retrospectively documented annually.** Programs must document performance against previously defined output and outcome metrics, including progress towards objectives, decisions, and termination points or other transitions. Programs with similar goals may be compared on the basis of their performance. OMB will work with agencies to identify such programs and appropriate metrics to enable such comparisons.

## IV. Criteria for R&D Programs Developing Technologies That Address Industry Issues

The purpose of some R&D and technology demonstration programs and projects is to introduce some product or concept into the marketplace. However, some of these efforts engage in activities that industry is capable of doing and may discourage or even displace industry investment that would occur otherwise. Programs should avoid duplicating research in areas that are receiving funding from the private sector, especially for evolutionary advances and incremental improvements. For the purposes of assessing federal R&D investments, the following criteria should be used to assess industry-relevant R&D and demonstration projects, including, at OMB discretion, associated construction activities.

OMB will work with programs to identify appropriate measures to compare potential benefits and performance across programs with similar goals, as well as ways to assess market relevance.

A. **Programs and projects must articulate public benefits of the program using uniform benefit indicators across programs and projects with similar goals.** In addition to the public benefits required in the general criteria, all industry-relevant programs and projects must identify and use uniform benefit indicators (including benefit-cost ratios) to enable comparisons of expected benefits across programs and projects. OMB will work with agencies to identify these indicators.

B. **Programs and projects must justify the appropriateness of federal investment.** Programs and projects must demonstrate that industry investment is sub-optimal to develop a technology or system and explain why the development or acceleration of that technology or system is necessary to meet a federal mission or goals.

C. **Programs and projects must demonstrate that investment in R&D and demonstration activities is a more effective way to support the federal goals than other policy alternatives.** When the federal government chooses to intervene to address market failures, there may be many policy alternatives to address those failures. Among other tools available to the government are legislation, tax policy, regulatory and enforcement efforts, and an integrated combination of these approaches. Agencies should consider that the legislation, tax policy or regulatory or enforcement mechanisms may already be in place to achieve a reasonable expectation of advancing the desired end.

D. **Programs and projects must document industry or market relevance, including readiness of the market to adopt technologies or other outputs.** Programs must assess the likelihood that the target industry will be able to adopt the technology or other program outputs. The level of industry cost sharing or enforceable recoupment commitments in contracts are indicators of industry relevance. Agencies must be able to justify any demonstration activities with an economic analysis of the public and private returns on the public investment.

E. **Program performance plans and reports must include "off ramps" and transition points.** In addition to the schedules and decision points defined in the general criteria, program plans should also identify whether, when, and how aspects of the program may be shifted to the private sector.

# Appendix C: Clean Air Research Program Review Meeting Agenda

**U.S. EPA BOARD OF SCIENTIFIC COUNSELORS**
**Clean Air Research Program Subcommittee**
**MEETING AGENDA**
**June 8 - 10, 2009**

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

## Monday, June 8, 2009 (Room C111 B/C)

| | | |
|---|---|---|
| 11:00-11:30 a.m. | Registration | |
| 11:30-11:45 a.m. | Welcome, Introductions, & Opening Remarks | Dr. Ken Demerjian<br>BOSC Clean Air<br>Subcommittee Chair |
| 11:45-11:50 a.m. | DFO Welcome and Charge<br>- Administrative Procedures & FACA Rules<br>- Objective of this Subcommittee & Charge | Lori Kowalski (EPA/ORD) |
| 11:50-12:00 p.m. | ORD's Welcome | Dr. Larry Reiter<br>Acting Deputy Assistant<br>Administrator for<br>Management (EPA/ORD) |
| 12:00-12:15 p.m. | Break to Get Lunch From Cafeteria | |

**--WORKING LUNCH--**

| | | |
|---|---|---|
| 12:15-12:35 p.m. | Welcome & Synopsis of ORD's Air Program | Dr. Dan Costa (EPA/ORD)<br>National Program Director<br>(NPD) for Air |
| 12:35-12:55 p.m. | Discussion of General Program Issues | Dr. Dan Costa, NPD for Air<br>(EPA/ORD) |
| 12:55-1:15 p.m. | General Program Questions | Dr. Ken Demerjian &<br>BOSC Clean Air<br>Subcommittee |

**Session 1: Health and Exposure Research**

| | | |
|---|---|---|
| 1:15-1:45 p.m. | Synopsis/Orientation | Dr. Robert Devlin (ORD) |
| 1:45 -3:15 p.m. | Poster Session (Atrium) | BOSC Clean Air Subcommittee |
| 3:15-3:30 p.m. | Break | |

| | | |
|---|---|---|
| 3:30-4:15 p.m. | Discussion | Presenters & BOSC Clean Air Subcommittee |
| 4:15-4:30 p.m. | OAQPS Perspective | Lydia Wegman, Director<br>Health & Environmental Impacts Division (EPA/OAR) |
| 4:30-4:45 p.m. | Public Health Perspective | Dr. Michael McGeehin (CDC) |
| 4:45-5:00 p.m. | Human Health Research Program Coordination | Dr. Sally Darney, Acting NPD<br>Human Health (EPA/ORD) |
| 5:00 p.m. | Adjourn | |

## Tuesday, June 9, 2009 (Room C-111 B/C)

| | | |
|---|---|---|
| 8:00-8:45 a.m. | Review of Yesterday's Activities<br>Overview of Today's Agenda<br>Discussion | Dr. Ken Demerjian &<br>BOSC Clean Air Subcommittee |

**Session 2: Air Quality Management**

| | | |
|---|---|---|
| 8:45-9:00 a.m. | Synopsis/Orientation | Mr. Ken Schere (EPA/ORD) |
| 9:00-10:00 a.m. | Poster Session (Atrium) | BOSC Clean Air Subcommittee |
| 10:00-10:15 a.m. | Break | |
| 10:15-11:00 a.m. | Discussion | Presenters & BOSC Clean Air Subcommittee |
| 11:00-11:15 a.m. | State Perspective | Michael Gilroy, Manager<br>Meteorological & Tech Services<br>Puget Sound Clean Air Agency |
| 11:15-11:45 a.m. | Lunch | |
| 11:45-12:30 p.m. | Discussion | BOSC Clean Air Subcommittee |

**Session 3: Source-to-Health Outcome: Multi-Pollutant**

| | | |
|---|---|---|
| 12:30-12:50 p.m. | Synopsis/Orientation | Dr. Alan Vette (EPA/ORD) |
| 12:50-2:20 p.m. | Poster Session (Atrium) | BOSC Clean Air Subcommittee |

| | | |
|---|---|---|
| 2:20-3:00 p.m. | Discussion | Presenters & BOSC Clean Air Subcommittee |
| 3:00-3:30 p.m. | Q/A With PM Center Directors | Dr. Ken Demerjian & BOSC Clean Air Subcommittee |
| 3:30-3:40 p.m. | Public Comment | |
| 3:40-4:00 p.m. | Global Climate Program Coordination | Dr. Joel Scheraga, NPD for Global Change (EPA/ORD) |
| 4:00-4:30 p.m. | Cross-Program Discussion and Wrap-Up | Air Program ORD |
| 4:30-5:00 p.m. | Discussion | BOSC Clean Air Subcommittee |
| 5:00 p.m. | Adjourn | |

## Wednesday, June 10, 2009 (Room C-111 B/C)

| | | |
|---|---|---|
| 8:00-8:10 a.m. | Review of Yesterday's Activities | Dr. Ken Demerjian<br>BOSC Clean Air Subcommittee<br>Chair |
| 8:10-10:30 a.m. | Work Session | BOSC Clean Air Subcommittee |
| 10:30-10:45 a.m. | Break | |
| 10:45-11:15 a.m. | Debrief<br>Oral Report on Charge Questions | Dr. Ken Demerjian & BOSC Clean Air Subcommittee |
| 11:15 a.m. | Adjourn | |

# Appendix D: Clean Air Research Program Fact Sheet

www.epa.gov/airscience

science in ACTION

BUILDING A SCIENTIFIC FOUNDATION FOR SOUND ENVIRONMENTAL DECISIONS

CLEAN AIR RESEARCH PROGRAM

## AIR POLLUTION RESEARCH IMPROVES UNDERSTANDING OF MULTIPOLLUTANT IMPACTS ON HUMAN HEALTH

### Issue:

People are exposed to mixtures of air pollutants throughout life. Clear advances have been made in understanding and minimizing the risks associated with some air pollutants with known singular toxicity risk, but the impacts of mixtures of low levels of air pollutants are still uncertain.

Historically, outdoor air research has largely focused on individual air pollutants like particulate matter (PM), ozone, or priority hazardous air pollutants (HAPs). This research has been critical for the development and implementation of clean air standards by the U.S. Environmental Protection Agency. As a result, air quality in the United States has improved.

To further advance air quality management, EPA is adding a multipollutant component. This "one atmosphere" approach takes into account that humans and ecosystems are exposed to many air pollutants at the same time, and that there exist many atmospheric processes and conditions that underlie this mix of pollutants.

Currently, each pollutant is assessed separately and controlled by independent measures. A multipollutant approach offers an opportunity to more effectively target air pollutants at their sources and reduce more than a single pollutant with control measures. The desired outcome is to have a broader impact on outdoor air pollutant levels and reduce the cost of pollution control.

Multipollutant approaches to environmental decision making require new science to understand and appreciate the complexities of co-pollutant interactions (chemical and biological). More advanced scientific methods, models and tools are needed.

In response, the Clean Air Research Program in EPA's Office of Research and Development is shifting toward a multipollutant approach to air research. This research emphasis is based on recommendations by science advisory groups, including the National Research Council, Science Advisory Board, and Board of Scientific Counselors, which have encouraged EPA to transition from individual pollutant control and regulation to an air quality management theme that includes multipollutants.

### Scientific Objective:

The Clean Air Research Program has developed a three-pronged strategy to address multipollutant issues that builds on earlier scientific contributions in this area. The strategy integrates the

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# science in ACTION

BUILDING A SCIENTIFIC FOUNDATION FOR SOUND ENVIRONMENTAL DECISIONS

## CLEAN AIR RESEARCH PROGRAM

*continued from front*

many scientific disciplines that advance knowledge about air pollution. These disciplines include the study of sources and atmospheric processes, the study of how people are exposed, and subsequent health implications.

The strategy includes:

- Conducting laboratory studies to evaluate controlled source emissions and health effects. Conducting laboratory studies of artificial mixtures that test hypothetical interactions that may be driving more generalized atmospheric exposure mixtures.
- Conducting real-world studies in cities where emission, exposure, and health data can be collected or integrated on multipollutant exposures that may impact human health.

Areas of scientific focus include:

- Understanding the relationships between sources of air pollutants and atmospheric transformation (secondary) air pollutant products.
- Understanding the health risks posed by mixtures of air pollutants.
- Advancing atmospheric and exposure modeling of multipollutants.
- Developing methods and controls for sources or air pollutants that impact health relevant emissions or products.
- Determining a hierarchy of sources and related emission components regarding relative health risks.

As part of this effort, there is an initial emphasis directed to near-road exposures since mobile sources emit a complex mix of gases, vapors, and particles.

### Application and Impact

The Clean Air Research Program has already made significant contributions to our understanding of multipollutants. Work has revealed how multipollutants are generated as primary emissions as well as secondary transformation byproducts. Scientists have also expanded the capabilities to measure multipollutants.

There also have been advances in our understanding of how people are exposed and impacted by mixtures of pollutants.

The research program has led the way in multipollutant assessments. The atmospheric model called the Community Model for Air Quality (CMAQ) has recently been expanded beyond just predicting ozone pollution to include PM and a host of air toxics or hazardous air pollutants as well. This model is used by states and local air quality managers to develop implementation plans to meet EPA's air quality standards and is used by other researchers conducting epidemiology studies.

#### REFERENCES

Office of Air Quality Planning and Standards: The Multi-pollutant Report: Technical Concepts & Examples
http://www.epa.gov/air/airtrends/studies.html

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**JANUARY 2009**

U.S. Environmental Protection Agency
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# Appendix E: Roadmap to the Evidence Addressing the Charge

**Purpose of the Roadmap.** The following roadmap is provided to assist in linking program materials with the Charge Questions. The material listings are not comprehensive but rather point to those documents which contain relevant highlights. This 'roadmap' is not meant to be prescriptive or restrictive in any way but merely to help navigate through the large amount of material provided – despite our efforts to be as selective as possible.

**1. Program Design and Demonstrated Leadership**

The MYP was reviewed in 2007 as part of a "midcycle" review of program progress. At that time, the BOSC commented on the plan and program aspirations. In light of the plan now in its official form (2008) and the BOSC recommendations at that time:

- **Is the Clean Air Research program continuing to plan its program effectively?** Please consider the following:
  - **Responsiveness to the 2005 and mid-cycle BOSC recommendations regarding program design and implementation**
    - *Letter & Report from Midcycle BOSC April 22, 2008 (Materials book: Tab G-c)*
    - *2007 Midcycle (CD) & 2009 Progress Report (Materials book: Tab E)*
  - **Increasing emphasis on a multipollutant approach to ORD's air quality research**
    - *Overview presentation by Dan Costa (05/21 & 05/29)*
    - *Presentation and overview paper of the MP session by Alan Vette*
    - *Multipollutant posters (Posters #s LTG 2: 01-16)*
    - *MP workshop (03/08); planned for 09/09)*
    - *Dialogue with OAQPS SIP development in Detroit*
    - *Clean Air Act Section 103(c)(1)*
  - **Research priorities reflecting stakeholder needs**
    - *OAR Priority Research 12-15-08 (CD)*
    - *Multiyear Plan( pgs 4-5, 14) (Materials book: Tab G-a)*
    - *Decision analysis / utility stakeholder (Materials book: Tab M)*
    - *Partner survey (Materials book: Tab N)*
    - *2009 Progress Report (Materials book: Tab E)*
    - *Presentations / overviews by Dan Costa (05/21 & 05/29) and Poster Session Leads (05/29: Robert Devlin, Kenneth Schere, Alan Vette)*
    - *Client Posters (#s LTG 1: 16-18, 35-37; LTG 2: 15, 16.)*
  - **Coordination and integration of research within and across the extramural and intramural programs to maximize resource investment.**
    - *Presentations / overviews by Dan Costa (05/21 & 05/29) and Poster Session Leads (05/29: Robert Devlin, Kenneth Schere, Alan Vette)*
    - *The Posters – all multidisciplined; cross-Lab / Center / Academic Partners*

  - *2007 Midcycle (CD) & 2009 Progress Report (Materials book: Tab E)*
  - *(Example) Near Road STAR RFA (CD)*
    - *http://es.epa.gov/ncer/rfa/2008/2008_star_healtheffects.html*

- **Is the Clean Air Research program providing strong science leadership and program management in both research planning and implementation?**
  - *Summary tables of science leadership (committees, panels, academic appointments, students) (Materials book: Tab O)*
  - *Overview presentation by Dan Costa (05/21)*
  - *Bibliographic / citation analysis (Materials book: Tab L)*
  - *The Posters (all 3 sessions)*

- **Is the Clean Air Research program effective in communicating results to its stakeholders – program offices, Regions, State and local regulatory agencies, general public and the broader scientific community?**
  - *Clean Air Research Program web site (CD)*
    - *www.epa.gov/airscience*
  - *ORD labs and centers' web sites (an example on the NERL site)(CD)*
    - *http://yosemite.epa.gov/opa/MMwebcon.nsf/HTML/KCHK-7DWQE4?OpenDocument*
  - *Bibliographic / citation analysis (Materials book: Tab L)*
  - *2009 Progress Report*
  - *Overview presentations by Dan Costa (05/21 & 05/29)*
  - *Client presentations (Wegman – OAQPS; Gilroy – Puget Sound; McGeehin - CDC )*
  - *Posters on outreach (Poster #s LTG 1: 17; 18; 19)*

- **Does the Clean Air Research program have LTGs and APGs that will meet the goals of the ORD research program, address stakeholder needs, and are not unnecessarily duplicative of national and international work in this area?**
  - *OAR Priority Research 12-15-08 (CD)*
  - *Multiyear Plan (pgs 4 -5 and 14-16) (Materials book: Tab G-a)*
  - *Letter & Report from Midcycle BOSC April 22, 2008 (Materials book: Tab G-c)*
  - *Clean Air Vision Overview (Materials book: Tab B)*
  - *Coordination with HHRP and Global Climate (NPD Program testimonials)*
  - *Overview presentations by Dan Costa (05/21 & 05/29)*

- **Is the relative resource distribution by LTG (i.e., relative % FTE, relative % extramural vs. intramural resources) appropriate to address agency goals, stakeholders' needs, and the goals of the ORD Clean Air research program?**
  - *Overview presentation by Dan Costa (05/21)*

## 2. Science Quality

- **Is the science being conducted by EPA-ORD research Labs and Centers of recognized high quality, high impact and appropriate to stakeholder needs?**
  - *Bibliographic / citation analysis (Materials book: Tab L)*
  - *Presentations / overviews by Dan Costa (05/21 & 05/29) and Poster Session Leads (05/29: Robert Devlin, Kenneth Schere, Alan Vette)*
  - *The Posters (all 3 sessions including stakeholder posters)*
  - *Decision analysis / utility stakeholder (Materials book: Tab M)*
  - *OAR Priority Research 12-15-08 (CD)*

- **Is the program fostering multidisciplinary research and taking advantage of opportunities for leveraging resources and expertise?**
  - *Overview presentations by Dan Costa (05/21 & 05/29)*
  - *Near road co-op with FHW, MESA-Air partnership, NRMRL combustion facility and assistance to NHEERL exposure-effect studies*
  - *2007 Midcycle (CD) & 2009 Progress Report (Materials book: Tab E)*
  - *Air Research Inventory*
    - *(CD contains 3 screen version of database – not yet released)*

## 3. Relevance

- **Are the potential benefits from the research being conducted clearly articulated in terms of public health protection (support to policy, decision-making and standard implementation)?**
  - *Client posters with each session (Poster # LTG 1: 16-18, 35-37; LTG 2: 15, 16)*
  - *Overview presentations by Dan Costa (05/21 & 05/29)*
  - *Client office presentations (Wegman - OAQPS, Gilroy – Puget Sound; McGeehin - CDC)*
  - *2009 Progress Report (Materials book: Tab E)*

- **Are the products of ORD research being used by stakeholders in decision making or the formulation and implementation of policy?**
  - *Overview presentations by Dan Costa (05/21 & 05/29)*
  - *Client office presentations (Wegman - OAQPS, Gilroy – Puget Sound; McGeehin - CDC)*
  - Client posters *(Poster # LTG 1: 16-17, 35-37; LTG 2: 15, 16)*
  - *Decision analysis / utility stakeholder (Materials book: Tab M)*

## 4. Demonstrated Outcomes

- **Has the Clean Air Research Program made significant progress in the conduct of the planned research and in answering the key science questions related to public health benefits and pollution abatement?**

- *OMB 2007 Report on benefits of Clean Air Regulations/Abatement (CD)*
  - *http://www.whitehouse.gov/omb/inforeg/2007_cb/2007_draft_cb_report.pdf*
    - *Pg 2 Exec Su; Pg 8 Table 1-2 of the OMB report*
- *SAB Report 11-26-08 on PM Centers (CD)*
- *Letter & Report from Midcycle BOSC April 22, 2008 (Materials book: Tab G-c)*
- *Bibliographic / citation analysis (Materials book: Tab L)*
- *2007 Midcycle (CD) & 2009 Progress Report (Materials book: Tab E)*
  - *Many Highlights: (impact pubs) – e.g., Pope/Dockery paper on life expectancy, Bell paper on ozone and mortality, Oberdorster paper of the year for SOT 07, Nel work highlighted in NAS tox in the 21st century, Hopkins JAMA paper on Medicare pop and E-W coast differences, McConnell paper on kids with asthma and traffic, Surrat, Edney, on SOA model for CMAQ,, etc*

# Appendix F: ORD Response to the 2005 BOSC Program Review

Office of Research and Development (ORD)
Response to the Board of Scientific Counselors (BOSC)
August 2005 Final Report That Reviews
ORD's Particulate Matter and Ozone Research Program

**BOSC Particulate Matter/Ozone Subcommittee:**
Dr. Rogene Henderson, Chair
Dr. Juarine Stewart, Vice Chair
Mr. Bart Croes
Dr. Kenneth Demerjian
Dr. Brian Lamb
Dr. Michael Lipsett
Dr. Peipei Ping
Dr. Charles Rodes
Dr. Christian Seigneur

**Submitted:**
Dan Costa, PhD
National Program Director
Particulate Matter and Ozone Research Program
Office of Research and Development

ORD Response to BOSC August 2005 Particulate Matter and Ozone Report

The following is a narrative response to the comments provided by the BOSC review of ORD's Particulate Matter and Ozone Research Program. A Subcommittee of the full BOSC (chaired by Dr. Rogene Henderson) convened March 30 – April 1, 2005 in Research Triangle Park, NC. A draft report was produced by the subcommittee, and after review by the BOSC Executive Committee, the final report was released in August 2005. In the conduct of the review, the Subcommittee responded to a series of charge questions framed by the PART Criteria (relevance, quality, and performance). The assessment comments on several areas of management and science progress: demonstrated program outcomes, client orientation, scientific leadership, Program design and direction, as well as consistency with resources. The Subcommittee summarized their views on these topics as *Overarching Conclusions and Recommendations*.

The Subcommittee was generally pleased with the content and progress of ORD's PM-$O_3$ Research Program. The Subcommittee noted that the large group of investigators, both within and outside EPA (STAR grantees), had worked together diligently to present the Program in an integrated and readily comprehensible manner. The materials and presentation format of the Program was also noted as to have facilitated the task of the reviewers. There was consensus that the quality of the science was high, that it was relevant to Agency and user clients. It was felt that the science was also highly informative to the science community itself, and that there was evident progress and Program evolution with the advancement of the respective science fields. The Subcommittee also emphasized the importance of collaborations and felt positively that there was substantial Program integration and ongoing collaboration. The *Overarching Conclusions and Recommendations* section that follows summarizes the Subcommittee's views. The Subcommittee's comments are presented in italics. The first section, *Conclusions,* is provided for background purposes and has no formal ORD response. ORD PM-$O_3$ Program does, however, thank the Subcommittee for its positive comments and encouragement as it strives for further improvement. In the case of the *Recommendations* provided by the Subcommittee, comments are addressed individually and ORD's response follows each in regular typeface. Attached to this document is a summary table which provides a summary of BOSC *Recommendations* and proposed ORD actions and timeline.

## BOSC Overarching Conclusions and Recommendations

### *CONCLUSIONS*

*1. The PART process for evaluating the useful outcomes of the activities of governmental agencies is difficult to apply in evaluating scientific research. The purpose for the EPA research effort is to reduce the uncertainties associated with setting regulations to protect the 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 EPA 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 the public health and the environment (outcome).*

- 2 -

ORD Response to BOSC August 2005 Particulate Matter and Ozone Report

*2. 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 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.*

*3. 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.*

*4. 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.")*

*5. There is a high degree of integration in the conduct of intramural and extramural research across the various laboratories, centers and scientific disciplines.*

*6. 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 overall science being conducted by the ORD PM-$O_3$ 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 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 National Program Director, high-level representatives of ORD's laboratories and the extramural research program, a regional representative, senior scientists from OAR, and others.*

ORD Response to BOSC August 2005 Particulate Matter and Ozone Report

*9. 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. Intra- and interagency communications is 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 website and through press releases.*

***BOSC RECOMMENDATIONS FOLLOWED BY ORD'S RESPONSE***

*1. 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 a review 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 the public health and the environment.*

ORD recognizes the need to develop a means of assessing client satisfaction and agrees strongly with this recommendation. In the past, the issue of 'satisfaction' in the Air Program was communicated informally through management or, at times, directly to ORD staff as products were delivered. Since the BOSC report, ORD (through its Office of Research Management and Administration) has developed a survey instrument (using an online platform) to assess client satisfaction and attitudes regarding ORD support. The surveys are tailored to the missions of the respective program offices. The survey, developed in the fall of 2005, was administered to 31 representatives of OAR. These representatives were selected by OAR's Senior Science Advisor, representing a cross-section of the Air Office and its sub-offices. The survey was administered using a series of questions that focused on four basic areas: Satisfaction; Attitude; Contribution; and Extent of Use (with regard to tools, models, and data). The response rate was 84% (26/31) and the respective scores (with a possible high score of 5) were:

- Satisfaction – 3.46
- Attitude – 3.78
- Contribution – 3.73
- Extent of use – 3.46

The composite score was 3.61 with 84.6% of the scores rating 3 or higher. These data were provided to OMB as one PART measure that could be used to assess performance, quality and relevance. While welcomed by the OMB examiner, the measure was not used in this PART review since the survey itself is yet to be sanctioned by OMB for this intended purpose. Of the program offices surveyed this cycle, OAR provided ORD's Air Research Program with the highest overall rating.

ORD intends to refine this survey instrument and use it annually to assess client satisfaction. Additionally, the distribution of the survey in 2006 will be expanded beyond our major client, OAR, to include regional, state, and tribal assessments. While as yet an unofficial measure for the PART, implementation of the client survey (as recommended by the BOSC) as an annual assessment is expected to function eventually as a measurable index for the PART process, as well as serve as a self-assessment tool for the Air Research Program to ensure appropriately targeted priorities and high client responsiveness.

*2. The wording of the two long-term goals be revised to read:*
*1) In 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.*
*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.*

The suggestions of the BOSC Subcommittee to revise the LTGs that were proposed initially have been helpful. With the ongoing development of the MYP, there has been a continued evolution of the two LTGs to better reflect the overall program structure and direction. The vision of the Program is to move to a Multiple Pollutant Program (sometimes referred to as "one atmosphere" program). There is movement within the Air Office (OAR) to begin to conduct assessments from the multi-pollutant perspective; however, its legislative mandate remains a single pollutant regulatory platform. Nevertheless, this new perspective is reflected in the recent reorganization of that OAR. The development of new Air MYP encompasses research not only in PM-$O_3$, but also Air Toxics. The combined impact of budget reductions in Air Toxics and the clear scientific rationale for complex atmosphere studies have moved the program to consider more integrated approaches. The MYP, which is currently being rewritten by the Research Coordination Team (RCT) and ORD Air Team, is working from what are still two 'draft' LTGs:

- By 2012, reduce uncertainty in <u>standard setting</u> and <u>air quality management</u> decisions due to advances in air pollution science.
    - Inform regulatory decision-making (i.e., NAAQS; Air Toxics)
    - Support implementation of regulations with tools, models, and information (OAR, regions, states etc.)

- By 2011, provide assessments of <u>source to health linkages</u> and reducing uncertainties that obscure these linkages.
    - Integrate across science and Program objectives
    - Apply multi-disciplined approaches
    - Use various source profiles of constitutive contaminants to assess those most hazardous
    - Refine / develop advanced atmospheric models that link to exposure and health

- Demonstrate effectiveness of the science and its dependent policy decisions

The draft MYP is currently being configured as a ~6 year plan that extends through the next assessment of PM-$O_3$. The cyclic nature of NAAQS review process is such that projections beyond the current cycle have dubious practical value. Nevertheless, important research remains beyond the MYP period – such as residual non-attainment and tool refinements for SIP use – and will continue into the out-year period. Research conducted in the period beyond 2012 is expected to be structured to meet the Multiple Pollutant Program or one-atmosphere target, but this program design will be highly dependent upon the Air Office operational plan. To plan beyond these limits at this time would be overly speculative, even from a strictly scientific perspective.

*3. Structure 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.*

ORD is endeavoring to focus on two or three issues within this LTG to establish a line of reasoning that can advance the Multiple Pollutant Program vision. With regard to the hypothesis-driven approaches suggested by the BOSC, ORD in 2006 received special one-year funds to initiate work in areas of particular and pressing temporal interest to OAR. The RCT has worked with OAR to develop a short-term (~2-3 years) plan to address OTAQ and region concerns regarding health risks associated with near-road exposures. A stakeholders' workshop was conducted late in 2005 by the Air Research Program to gather perspectives on the strength of existing science, major data gaps, and short/long-term research needs associated with this issue. A subsequent "white-paper" was developed by ORD in concert with OTAQ currently exists in draft form and will be reviewed internally, by the OTAQ and other offices within Air, and by participating stakeholders (Health Effects Institute, Federal Highway Administration, state (CA) and EPA Region (R1) representatives, Sierra Club, and others). This draft white-paper has served as a guide for the development of a 'straw' plan within the scope of the funds available, and project proposals are currently being drafted to meet identified needs. These initial projects are clearly targeted to, but they are intended to serve as the base for more expansive investigations over the next few years. The effort represents a specific APG within LTG2.

Similarly, in response to OAR requests, ORD has initiated conceptual work on the feasibility of studies that can address the issue of "accountability." The issue of accountability is assesses the evidence of beneficial impacts of regulatory actions. These benefits may be measured at the atmospheric and exposure end, but are most meaningful if they are measurable with bio-indicators of human and environment health. This accountability framework is being designed build on a foundation of smaller study units that can be reasonably (in time and resources) pursued – some of which may be opportunistic (e.g., Utah Valley) while others the result of specific regulatory actions (e.g., school bus diesel retrofits). The goal would be to extend the approach to broader more uncertain test areas that in theory should benefit from national regulations such as the Clean Air Interstate Rule and the Clean Air Mercury Rule. Some feasibility work in the latter domain is being considered in "test bed" areas with known and currently active databases in air quality measurements and health reporting.

These core projects are being developed to complement existing and related work supporting NAAQS and Air Toxics, inclusive of health and implementation. It is intended that the science underlying these plans and annual progress in critical science areas of health, atmospheric chemistry, modeling, and engineering will be provided by a contracted panel of experts. These experts would not act as a consensus group as per FACA but rather would be part of a science critique of annual research progress in specific area. The details of this process remain in planning as the MYP is developed and as alternate mechanisms to FACA are explored for the discipline-specific annual progress reviews.

*4. Recognizing that EPA faces serious research resource constraints, the Subcommittee nevertheless recommends that ORD reconsider the decision to completely disinvest in ozone health research.*

Despite the 1998 Congressional add-on for PM research, resources to support to ORD's Air Research Program are constrained. By necessity, the shift to PM research in the mid-90s has been at the expense ozone program which until that time was the dominant ORD Air research project. The need for emphasis on PM within the Air Program left no choice but to redirect resources. Fiscal and personnel constraints over the last several years have moved virtually all Air research into PM (with the exception of a small amount of Air Toxics). The remaining ozone research rests primarily in atmospheric chemistry and modeling where ozone plays a requisite role in PM formation – hence the work is supported by PM funds. Other ozone work continues in studies trying to address co-pollutant issues, and thus may expand somewhat in the future with the Multiple Pollutant Program proposal. PM-ozone interaction studies are planned within the UC Davis PM Center recently funded with the second round of PM Centers. Similarly, some ozone work continues under other auspices or collaborations (e.g., a UNC – NIEHS funded grant) where ozone is being used as a model to address questions of genetic susceptibility (e.g. single nucleotide polymorphism identification). It is doubtful at this time that ozone will increase as a focus of health studies within the Air Program (intramurally or extramurally). However, the mandated review of ozone literature related to the Criteria Document in support of the OAR NAAQS review will continue.

*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 a 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.*

ORD agrees with this recommendation and is taking steps to take a more expansive and proactive leadership role with regard to coordination of interagency research. To date, EPA has had a very visible and active role in the Air Quality Research Subcommittee activities of the *Committee on the Environment and Natural Resources*. The Subcommittee's PM Research Coordination Working Group, co-chaired by EPA and the National Institute of Environmental and Health Sciences (NIEHS), meets bi-monthly with a goal of "enhancing the scientific information base for public policy that protects the public health (of primary importance) and the environment from harmful effects due to airborne particulate matter." The Air Quality Research Subcommittee comprises 22 member agencies which for varied reasons have interest in or otherwise support research in air pollution – mostly PM. The workgroup has released its *Strategic Research Plan for Particulate Matter* (www.al.noaa.gov/AQRS/reports/srppm.html) that serves as a guide to the coordinated federal research efforts. Similarly, the Air Quality Subcommittee has prepared a formal response to the NRC IV recommendations for future research in PM which is expected to be released in the next few months.

Recently, the Air Quality Research Subcommittee has begun discussion of future directions and emphasis, especially in light of leadership transitions of the Subcommittee. The Subcommittee has served well to communicate and coordinate the federal research portfolio and provide a 'big picture' view of the cross government activities. It has served well as a forum for communication. EPA would like to expand the subcommittee's role in promoting and coordinating research to better leverage generally shrinking resources. There remain pressing questions regarding PM as noted by the NRC IV as well as the recent call by the Clean Air Act Advisory Committee and the NRC Committee on Air Quality Management in the United States to begin to address air quality more broadly. Cross government resource restrictions are moving members to consider leveraging opportunities across the various federal agencies and EPA sees this as an opportunity to take a leading role. One proposal under consideration presently is for the co-chairmanship to be shared between the ORD Air NPD and the equivalent within NOAA to better coordinate research leveraging. As EPA's program is broader than that of NOAA, it is expected that EPA's influence on the Subcommittee direction can be strengthened. One example of potential leveraging with a CENR – AQRS member is to be planned in meetings with the FHWA in late February '06 with regard to the near-road issue discussed above.

*6. The PM-$O_3$ Program should 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 should still be maintained.*

ORD greatly values its STAR grantees, and especially the PM Centers, as having made substantial contributions to the knowledge base of PM. ORD publications cited in the PM Criteria Document in 1996 comprised 16% and with the shift in Program emphasis (and substantial STAR growth) resulted in a doubling of that contribution in the most recent CD in 2004. The Centers were recently recompeted and the awardees have, late in 2005, been funded to begin work that will extend for five years. ORD is committed to fully funding these Centers through the five year award period. Additionally, EPA has funded the University of Washington ($30M) to conduct a 10 year prospective study to assess potential cardiovascular disease pathogenesis associated with air pollution. When combined with the additional topic-specific RFA grants in health and implementation, the extramural Science To Achieve Results air quality research program is funded at $17M/year. This level of funding is likely to stay at or near this level in the foreseeable future, certainly fulfilling current obligations as well as addressing other Air research needs through RFA development. The STAR program is an integrated portion of the overall Air Program and is assessed through the BOSC and PART process as part of the overall ORD effort. When possible, ORD has endeavored to leverage the STAR RFA process with other funding agencies. Most notable was the recent cardiovascular RFA co-release by ORD and NIEHS which resulted in 6 awardees funded by each agency. These awardees are coordinated through annual workshops and other communications. The extramural STAR program is therefore an integral component of the ORD Air Program. It is not viewed as a bank for resources to meet intramural goals, but as part of the Program, it does undergo program prioritization in the RCT process to ensure coordination. As the intramural program has experienced tightened resources over the last few years and likely will endure more in the future, it is critical that the STAR program is directed to complement or, if needed, replace capabilities to meet NRC research priorities through the RFA development process.

*7. Funding decisions for any active intramural project undergo review by the Air RCT.*

ORD agrees that all projects merit review for science quality and programmatic relevance. Although the planning process within ORD has recently undergone some change, especially with the advent of the NPDs, the RCT structure has been retained – at least in the Air Program – to assist with project prioritization and funding decisions on an annual basis, and to provide guidance on new research areas. A good example of this process is that associated with the near-road initiative in 2006. Projects are being developed in close cooperation with the clients who stand to benefit from the data. The clients are represented on the RCT along with senior ORD scientists and thus as each project is reviewed, there will be opportunity for refocusing and assurance of relevance and science quality. In other Program areas, project proposals for research undergo more involved reviews if the Program area is one which would benefit from extramural science review – e.g., special expertise. For example, the ORD asthma initiative in Human Health (which has a significant Air relevance) was set aside for formal extramural peer review to ensure the adequacy of the review and because the program area was considered to have high visibility. General continuations of projects also get reviewed within the Program staff or RCT. The goal of ORD to provide high quality and useful science (data, tools, and models) to its clients reinforces the need for RCT input and review throughout the planning and MYP development process.

*8. The MYP include a discussion indicating how the goals set out by the NRC flow into the cross-cutting 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 the connection between the research and the NRC goals obvious.*

The ORD Air Research Program is fully committed to ensure that the MYP currently under development fully meets this objective. To date the Program has been configured within the NRC research goals, from the first meeting in June 1998 with the NRC Subcommittee on PM Priorities in RTP to the PM Accomplishments Report[1] of 2003. The NRC priority structure is retained even for ORD research to address implementation needs, which were outside the original scope of the NRC Subcommittee. This structure extends to the organization of the ORD PM bibliography of research publications, which is arranged along the NRC research topics. The series of four volumes of the NRC on Research Priorities has been invaluable in organizing ORD's research agenda, prioritizing research, and in making budget adjustments. As such, the MYP discussion of its research APGs is fully aligned with the NRC priorities. The narrative, as well as the APG / APM structure will fully reflect their NRC linkage and the logical progression to the Multiple Pollutant Program – noted in the NRC IV as the logical next step in the evolution of PM science.

*9. Funding be set aside for anticipatory research needs, and that steps be taken by ORD to identify and highlight key anticipatory research needs in order to inform longer-term research, and to assure that current and out-year funded levels of research will be consistent with potential long-term regulatory needs.*

ORD agrees with the importance of anticipatory research. At present, however, there is no formal discretionary fund for such work other than a small amount of resources at the disposal of the NPD for meetings, small contracts, and pilot efforts. Discretionary funds of any size that are uncommitted or are redirected are

[1] www.epa.gov/pmresearch/pm_research_accomplishments/pdf/pm_research_program_five_years_of_progress.pdf

often at jeopardy for disinvestment unless they are part of the formal planning process. During the annual planning process, there may be a call for initiatives which are considered by senior management and if accepted are put forth in the formal EPA budget to OMB and then to Congress. Unfortunately, this is a two year process. Hence, as new issues arise, ORD tries to bring them into the process as soon as possible. If deemed appropriate and critical, resources are redirected to meet the need but of course this redirection is typically at the expense of other ongoing work. However, each PI within ORD has implicit in his/her performance agreement the discretion to use ~10% of his/her time towards research that is exploratory / high risk. While this index is subject to the discretion of staff and the reporting supervisor, and relevance to the Program is retained, it allows seed efforts to be initiated and progress sufficient to argue for more robust support in the annual planning process. Each of the ALDs of the National Laboratories works with line management and PI staff to identify new ideas or emerging issues that merit support. These are promoted to the extent possible until they are developed sufficiently to rise to the level of an initiative or to compete in the prioritization in planning. Future needs arise from frequent contact with clients, submission of specific needs by clients, and the involvement of science staff in premier international science meetings.

ORD Response to BOSC August 2005 Particulate Matter and Ozone Report

**Particulate Matter/Ozone Research Program**
**Summary of BOSC Comments From August 2005 Final Report and Proposed ORD Actions**

| Recommendation | Action Items | Timeline |
|---|---|---|
| *ORD should develop and maintain a periodic, formalized process for assessing its primary stakeholders' perceptions of and satisfaction with its role in the source-to health-outcome process.* | Since the BOSC report, ORD (through its Office of Research Management and Administration) developed a survey instrument in the fall of 2005 to assess client satisfaction and attitudes. The response rate was 84% (26/31) and ORD's composite score was 3.61 (from a total of 5). While as yet an unofficial measure for the PART, the annual assessment is expected to provide not only a measurable index for the PART process, but also a self-assessment tool to assess the research program priorities. The survey is to be expanded to the region, state and tribal clients. | October, 2005<br><br>Current and on-going<br><br>August, 2006 |
| *The wording of the two long-term goals should be revised (suggestions offered).* | With the ongoing development of the MYP, there has been a continued evolution of the two LTGs to better reflect the overall program structure. The vision of the Program is to move to a Multiple Pollutant that would encompass research not only in PM-Oz, but also Air Toxics. The MYP, which is currently being rewritten by the RCT has the following 'draft' LTGs:<br><br>• By 2012, reduce uncertainty in standard setting and air quality management decisions due to advances in air pollution science.<br>• By 2011, provide assessments of source to health linkages and reducing uncertainties that obscure these linkages. | Current and ongoing.<br><br>Expect review draft in April, 2006 |
| *LTG should embrace two to three hypothesis-driven pilot studies that would demonstrate the source-to-health outcome concept to provide a reasonable metric to measure the success of the program.* | ORD is endeavoring to focus on two or three issues within this LTG to establish a line of reasoning that can advance the MPP vision. The RCT worked with OAR to develop a short-term (~2-3 years) plan to address OTAQ and region concerns regarding health risks associated with near-road exposures. Stake-holders and the RCT | Current and on-going |

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ORD Response to BOSC August 2005 Particulate Matter and Ozone Report

| Recommendation | Action Items | Timeline |
|---|---|---|
| *An expert panel or workshop to review the pilot studies and to follow their progress on a regular basis. The expert panel can assess the reduction of or alterations in uncertainties at regular intervals.* | have led to a white-paper and research plan with initial projects targeted to specific needs. Similarly, in response to OAR requests, ORD has initiated conceptual work on the feasibility of studies that can address the issue of "accountability." The issue of accountability is assesses the evidence of beneficial impacts of regulatory actions. This framework is being designed to build a foundation of smaller study units and extend to broader more uncertain test areas that in theory should benefit from national regulations such as CAIR & CAMR.<br><br>A contracted panel of experts is proposed to act not as a consensus group as per FACA but rather would be part of a science discipline critique of annual research progress in specific areas and on these projects. | |
| *Recognizing that EPA faces serious research resource constraint, ORD reconsider the decision to completely disinvest in ozone health research.* | Emphasis on PM evolved from the ozone program which was the dominant ORD Air research project for more than decade. Congress specifically called for PM emphasis and there was not choice but to redirect at the expense of ozone. Continued fiscal constraints have moved all research into PM (with the exception of a small amount of Air Toxics). What ozone research exists rests in atmospheric chemistry and modeling and is currently supported by PM funds. Some ozone health work continues in studies of mixed atmosphere and alternatively funded studies | N/A |
| *The NRC recommendation that includes the establishment of multi-agency goals and measures of success in meeting national goals merits input and coordination with other federal agencies as well as states and private* | To date, EPA has had a very visible and active role in the Air Quality Subcommittee activities of the *Committee on the Environment and Natural Resources*. The workgroup has completed and recently released its *Strategic Research Plan for PM* (www.al.noaa.gov/AQRS/reports/srppm.html). The AQSC has prepared a response to the NRC IV recommendations for future research. | On going |

ORD Response to BOSC August 2005 Particulate Matter and Ozone Report

| Recommendation | Action Items | Timeline |
|---|---|---|
| *organizations for the purposes planning. ORD can assume a leadership role* | Recently, future directions and emphasis have been discussed with impending leadership AQSC transitions. One proposal is for the co-chairmanship to be shared between the ORD Air NPD and the equivalent within NOAA to better coordinate research leveraging at the science leadership level. | |
| *The PM-O3 Program should commit to maintain the strong balance between intramural and extramural research.* | The STAR program is funded at $17M/year. This level of funding is likely to stay at or near this level in the foreseeable future, certainly fulfilling current obligations as well as addressing other Air research needs through RFA development. The STAR program is an integrated portion of the overall Air Program and is assessed through the BOSC and PART process as part of the overall ORD effort. | FY 2006 and beyond |
| *Funding decisions for any active intramural project undergo review by the Air RCT.* | Although the planning process within ORD has recently undergone some change, especially with the advent of the NPDs, the RCT structure has been retain – at least in the Air Program – to assist with project prioritization and funding decisions. A good example of this process is that associated with the near-road initiative. Projects are being developed closely with the clients who stand to benefit from the data and each will undergo review and comment from the RCT. | FY 2006 and beyond |
| *MYP should include a discussion indicating how the goals set out by the NRC flow into the cross-cutting research issues and how these are embodied under the two long-term goals.* | To date the Program has been configured within the NRC research goals. The PM Accomplishments Report '03 reflects this - (www.epa.gov/pmresearch/pm_research_accomplishments/pdf/pm_research_program_five_years_of_progress.pdf) The ORD PM bibliography of research publications also so organized. The MYP discussion will fully align the research APGs with the NRC priorities and will show their links and the logical progression to the MPP. | April, 2006 |
| *Funding should be set aside for anticipatory research needs, and that* | At present, there is no formal discretionary fund for such work other than a small amount of resources at the disposal of the | On-going |

ORD Response to BOSC August 2005 Particulate Matter and Ozone Report

| Recommendation | Action Items | Timeline |
|---|---|---|
| *steps be taken by ORD to identify and highlight key anticipatory research needs.* | NPD for meetings, small contracts, and pilot efforts. Care is taken not to jeopardize uncommitted funds. Each PI within ORD has implicit in his/her performance agreement the discretion to use ~10% of time towards research of specific personal interest or high risk. While this index is highly subjective, and relevance to the Program is retained, it allows seed efforts to progress to substantiate an argument for more robust support in the annual planning process. . Future needs arise from frequent contact with clients, submission of specific needs by clients, and the involvement of science staff in premier international science meetings. | |

# Appendix G: List of Major Research Themes and Related Poster Titles

**LTG 1: Health Effects and Exposure Posters**

| Poster # | Title | Presenter(s) |
|---|---|---|
| **What are the physical/chemical attributes of PM that are associated with adverse health effects?** | | |
| LTG 1-01 | Do different size fractions of PM cause different health effects? | Terry Gordon, NYU |
| LTG 1-02 | What are the effects of ultrafine particles? | Gunter Oberdorster, Rochester PM Center |
| LTG 1-03 | What are the effects of coarse particles? | Martha Carraway, ORD |
| LTG 1-04 | What is the influence of different components on the health effects of PM? | Urmila Kodavanti, ORD |
| **How and to what extent does air pollution cause adverse health effects?** | | |
| LTG 1-05 | Does long term exposure to PM caused increased atherosclerosis? | Joel Kaufman, University of Washington |
| LTG 1-06 | What are the physiological mechanisms by which PM affects the vascular system? | Rob Brook, University of Michigan |
| LTG 1-07 | How does PM affect the nervous system? | Mike Kleinman, Southern California PM Center |
| LTG 1-08 | Is Exposure to Ozone Associated with Increased Risk of Human Mortality? | Michelle L. Bell, Yale University |
| LTG 1-09 | What novel approaches are being developed and applied to improve exposure characterization and risk estimates of air pollution health effects? | Tim Watkins/Lisa Baxter, ORD |
| LTG 1-10 | How would PM cause adverse health effects through oxidative stress mechanisms? | Art Cho, Southern California PM Center |
| LTG 1-11 | What are the underlying cellular and molecular mechanisms by which PM causes adverse health effects? | Jim Samet, ORD |
| **Who is Susceptible to PM?** | | |
| LTG 1-12 | How does pre-existing disease set the stage for unusual sensitivity to PM? | Aimen Faraj, ORD |
| LTG 1-13 | How does PM affect people with asthma? | Dave Peden, University of North Carolina |
| LTG 1-14 | How does PM affect people with Diabetes? | Mark Frampton, Rochester PM Center |
| LTG 1-15 | How do genetic or epigenetic factors modify the response of individuals to PM? | Joel Schwartz, Harvard PM Center |
| **Client Posters** | | |
| LTG 1-16 | How ORD Air Research Supports OAR's Reviews of the National Ambient Air Quality Standards (NAAQS) | Lindsay Stanek, National Center for Environmental Assessment |

| Poster # | Title | Presenter(s) |
|---|---|---|
| LTG 1-17 | Enhancing Scientific Interaction and Communication Between ORD and OAR for Ambient Air Quality Monitoring and Human Health Risk Research | Beth Hassett-Sipple, OAQPS |
| LTG 1-18 | ORD Air Pollution Research Spurs Action to Protect Public Health | Susan Stone, OAQPS |
| LTG 1-19 | Health Effects Institute: A Unique Model of Public-Private Partnership | Rashid Shaikh, Health Effects Institute |

**LTG 1: Air Quality Posters**

| Poster # | Title | Presenter(s) |
|---|---|---|
| **What are the physical/chemical attributes of PM that are associated with adverse health effects?** | | |
| LTG 1-20 | How is our evolving understanding of biogenic emissions helping to represent their role in multipollutant atmospheric chemistry? | Chris Geron, ORD |
| LTG 1-21 | What is the significance of emissions from wildland and prescribed? | Tom Pierce, ORD |
| LTG 1-22 | How do we quantify emissions of ammonia from agricultural and natural sources? | John Walker, ORD |
| LTG 1-23 | How are source sampling and characterization techniques evolving to measure criteria and toxic air pollutants emitted from anthropogenic combustion sources? | Mike Hays, ORD |
| LTG 1-24 | How can measurement and modeling tools be used to characterize and improve emission estimates? | Ted Russell, Georgia Institute of Technology |
| **Ambient Measurements: Air Quality Characterization and Process Insights** | | |
| LTG 1-25 | How does ambient measurement methods research support development and implementation of air quality regulations? | Bob Vanderpool, ORD |
| LTG 1-26 | How have ambient measurements improved the understanding of secondary organic aerosol (SOA) formation? | John Offenberg, ORD |
| LTG 1-27 | How can measurements and modeling be used to improve the understanding of mercury fate and transport? | Jesse Bash, ORD |
| LTG 1-28 | How do coarse particles vary regionally and within specific locales? | Mike Hannigan, University of Colorado |
| **Air Quality Modeling: Applications Driving Development and Evaluation** | | |
| LTG 1-29 | How have atmospheric chemical kinetic mechanisms been expanded for multipollutant atmospheric modeling? | Deborah Luecken, ORD |
| LTG 1-30 | How have PM model estimates improved with advances in aerosol process representations? | Prakash Bhave, ORD |

| Poster # | Title | Presenter(s) |
|---|---|---|
| LTG 1-31 | How do new concepts of the formation of secondary organic aerosols improve our modeling of particulate matter? | Allen Robinson, Carnegie Mellon University |
| LTG 1-32 | What is the role of atmospheric mixed-phase chemistry in multipollutant modeling? | Annmarie Carlton, ORD |
| LTG 1-33 | How do we minimize meteorological model uncertainties for use in air quality modeling? | Jon Pleim, ORD |
| LTG 1-34 | How do evaluation techniques establish the credibility of air quality model estimates of ambient pollution levels? | Ken Schere, ORD |
| **Extending Applications of Air Quality Management Methods and Models** | | |
| LTG 1-35 | How can air quality management tools be used to support ecosystem assessments? | Robin Dennis, ORD |
| LTG 1-36 | How can air quality management tools be used to inform climate policy? | Chris Nolte, ORD |
| LTG 1-37 | How can air quality management tools be used to improve exposure assessment? | Vlad Isakov, ORD |
| **Client Posters** | | |
| LTG 1-38 | How ORD Air Research Helps Inform the Multi-pollutant Review of a Secondary National Ambient Air Quality Standard (NAAQS) for Oxides of Nitrogen and Sulfur (NOx and SOx) | Anne Rea, OAQPS |
| LTG 1-39 | Using ORD's Community Multiscale Air Quality (CMAQ) Model to Support Development of OAR Regulations and Air Quality Management | Norm Possiel, OAQPS |
| LTG 1-40 | ORD Mobile Source Emissions Research Provides Data to Improve EPA Models and Regulatory Decision-Making | Rich Cook, OTAQ |

**LTG 2: Source to Health Outcomes/Multipollutant Posters**

| Poster # | Title | Presenter(s) |
|---|---|---|
| **Linking Multipollutant Sources and Health Effects** | | |
| LTG 2-01 | What impact do mobile sources have on near-road air quality and human exposures? | Rich Baldauf, ORD |
| LTG 2-02 | What health effects result from exposures to mobile source related air pollutants? | Lucas Neas, ORD |
| LTG 2-03 | What are the impacts of stationary and area sources of air pollution on air quality and human exposures? | Janet Burke, ORD |
| LTG 2-04 | What health effects result from exposures to stationary and area sources of air pollutants? | Mike Madden, ORD |

| Poster # | Title | Presenter(s) |
|---|---|---|
| **Atmospheric Transport and Transformation** | | |
| LTG 2-05 | What effect does atmospheric chemistry/secondary transformations have on air quality and human health effects? | Mike Kleeman, UC Davis PM Center |
| LTG 2-06 | How can simulated atmospheres be used to understand the impact of atmospheric processes on air quality and human health effects? | Petros Koutrakis, Harvard PM Center |
| LTG 2-07 | How can source-receptor models be used to understand the relationship between sources and effects of multiple air pollutants? | Rachelle Duvall, ORD |
| **Influence of Airshed on Multipollutant Air Quality and Health Effects** | | |
| LTG 2-08 | How do health effects from exposure to air pollution vary in different cities? | Francesca Dominici, Hopkins PM Center |
| LTG 2-09 | What impact do multiple sources have on an airshed? | Gary Norris, ORD |
| LTG 2-10 | How effective are airshed/sector-specific regulatory actions? | Val Garcia, ORD |
| **Assessing and Managing Multipollutant Exposures and Health Effects** | | |
| LTG 2-11 | What are the combined effects of multiple pollutants (e.g. synergistic, additive, antagonistic)? | Kent Pinkerton, UC Davis PM Center |
| LTG 2-12 | What are exposures to multiple pollutants in an airshed? | Ron Williams, ORD |
| LTG 2-13 | What is the relative toxicity of air pollutants from multiple sources? | Tony Wexler, UC Davis PM Center |
| LTG 2-14 | How can stationary source emissions be reduced using a multipollutant control strategy? | Nick Hutson, ORD |
| **Client Posters** | | |
| LTG 2-15 | ORD Air Research Supports OAR's Forward-looking Priorities | Scott Jenkins, OAQPS |
| LTG 2-16 | ORD Air Research Support to the Office of Air and Radiation for Multi-scale and Multi-pollutant Measurements and Models of Traffic Emissions to Help Characterize Human Health Effects | Rich Cook, OTAQ |

# Appendix H: List of Acronyms

| | |
|---|---|
| APGs | Annual Performance Goals |
| BOSC | Board of Scientific Counselors |
| CAFO | Concentrated Animal Feeding Operation |
| CAMx | Comprehensive Air Quality Model |
| CARB | California Air Resources Board |
| CASAC | Clean Air Science Advisory Committee |
| CDC | Centers for Disease Control and Prevention |
| CENR | Committee on Environment and Natural Resources |
| CFR | Code of Federal Regulations |
| CMAS | Community Modeling and Analysis System |
| CMAQ | Community Multiscale Air Quality |
| CRC | Coordinating Research Council |
| DEARS | Detroit Exposure and Aerosol Research Study |
| EPA | U.S. Environmental Protection Agency |
| EPRA | Electric Power Research Institute |
| ESI | Essential Science Indicators |
| FACA | Federal Advisory Committee Act |
| FEM | Federal Equivalent Method |
| FHA | Federal Highway Administration |
| FRM | Federal Reference Method |
| FTE | Full-Time Equivalent |
| FY | Fiscal Year |
| GPRA | Government Performance and Results Act |
| HAP | Hazardous Air Pollutant |
| HAPEM | Hazardous Air Pollutant Exposure Model |
| HEI | Health Effects Institute |
| ISA | Integrated Science Assessment |
| LTG | Long-Term Goal |
| MESA | Multi-Ethnic Study of Atherosclerosis |
| MOVES | Motor Vehicle Emission Simulator |
| MYP | Multi-Year Plan |
| NAAQS | National Ambient Air Quality Standard |
| NARSTO | North American Research Strategy for Tropospheric Ozone |
| NCAR | National Center for Atmospheric Research |
| NCEA | National Center for Environmental Assessment |
| NCER | National Center for Environmental Research |
| NERL | National Exposure Research Laboratory |
| NHEERL | National Health and Environmental Effects Research Laboratory |
| NHLBI | National Heart, Lung and Blood Institute |
| NIEHS | National Institute of Environmental Health Sciences |
| $NO_2$ | Nitrogen Dioxide |
| $NO_x$ | Nitrogen Oxides |
| NOAA | National Oceanic and Atmospheric Administration |
| NPD | National Program Director |

| | |
|---|---|
| NRC | National Research Council |
| NRMRL | National Risk Management Research Laboratory |
| OA | Organic Aerosol |
| 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 |
| PAMS | Photochemical Assessment Monitoring Stations |
| Pb | Lead |
| PM | Particulate Matter |
| PMCAMx | Particulate Matter Comprehensive Air Quality Model |
| PMC | Coarse Particulate Matter |
| RARE | Regional Applied Research Effort |
| RCT | Research Coordination Team |
| R&D | Research and Development |
| REA | Risk-Exposure Assessment |
| RFA | Request for Applications |
| RPOs | Regional Planning Organizations |
| SAB | Science Advisory Board |
| SHEDS | Stochastic Human Exposure and Dose Simulation |
| SIPs | State Implementation Plans |
| $SO_2$ | Sulfur Dioxide |
| $SO_x$ | Sulfur Oxide |
| SOA | Secondary Organic Aerosol |
| STAR | Science To Achieve Results |
| UFPs | Ultrafine Particles |
| VBS | Volatility Basis Set |
| VOC | Volatile Organic Compound |