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April 22, 2008

Dr. George Gray
Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC 20460

Dear Dr. Gray:

The Board of Scientific Counselors (BOSC) has completed a mid-cycle review of the Office of Research and Development's (ORD) Air Research Program. This review focuses on the Agency's efforts and progress following a detailed BOSC program review of the Air Research Program conducted in March 2005 and subsequent BOSC report provided to ORD in August 2005. Drawn from the original program review subcommittee, a five-member BOSC subcommittee was charged to conduct the mid-cycle review. The Air Research Mid-Cycle Review Subcommittee was chaired by Dr. Rogene Henderson, Vice Chair of the BOSC Executive Committee, and another member of the Subcommittee, Dr. Kenneth Demerjian, also sits on the BOSC Executive Committee.

The Subcommittee conducted teleconference and face-to-face reviews of information and presentations provided by ORD in September 2007. The mid-cycle review report was submitted to the BOSC Executive Committee for review in March 2008. It was vetted by the Executive Committee and subsequently revised and approved for transmittal to ORD.

The purpose of the mid-cycle review is to provide general feedback on ORD's progress to date and, as appropriate, responsiveness to previous BOSC recommendations to assist in addressing issues and opportunities surrounding continued development of the Air Research Program's scope of work. Specific charge questions guided the BOSC Subcommittee in analyzing the materials prepared for the review and in developing the final report itself. Each of the charge questions has been addressed by detailed response in the BOSC Subcommittee mid-cycle review report.

The summary findings of the mid-cycle review point to a program that meets or exceeds the Subcommittee's expectations in progress to address concerns and recommendations of the previous 2005 program review. The Air Research Program provides a structured multi-year planning framework for

identifying priority research to meet regulatory mandates. The Program integrates particulate matter, ozone, and air toxics research in a coherent overall research plan as recommended by previous reviews and provides performance measures for indices of program progress.

This report is anticipated to further assist ORD in longer term program enhancement, comparative analysis with other programs, and intermediate research investment decision-making. The BOSC expects that the report will assist ORD in continuing to improve its science, and assist and inform clients within and outside the Environmental Protection Agency of the significance of the Agency's research and its utilization. On behalf of the BOSC Executive Committee and the Air Research Program Subcommittee, it is my pleasure to transmit this mid-cycle report to ORD.

Although the BOSC looks forward to an informal response to this report, the Program itself is making progress beyond expectations such that a formal response to the report is not required. Please feel free to contact me if you have any questions concerning this report.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary S. Saylor", with a long horizontal flourish extending to the right.

Gary S. Saylor
Chair



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**MID-CYCLE REVIEW OF THE OFFICE OF
RESEARCH AND DEVELOPMENT'S
AIR RESEARCH PROGRAM
AT THE
U.S. ENVIRONMENTAL PROTECTION
AGENCY**

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March 31, 2008

This report was written by the Air Mid-Cycle Subcommittee of the Board of Scientific Counselors, a public advisory committee chartered under the Federal Advisory Committee Act (FACA) that provides external advice, information, and recommendations to the Office of Research and Development (ORD). This report has not been reviewed for approval by the U.S. Environmental Protection Agency (EPA), and therefore, the report's contents and recommendations do not necessarily represent the views and policies of the EPA, or other agencies of the federal government. Further, the content of this report does not represent information approved or disseminated by EPA, and, consequently, it is not subject to EPA's Data Quality Guidelines. Mention of trade names or commercial products does not constitute a recommendation for use. Reports of the Board of Scientific Counselors are posted on the Internet at <http://www.epa.gov/osp/bosc>.

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I. SUMMARY

Background and Charge to the Subcommittee

The U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD) enlists its Board of Scientific Counselors (BOSC) to conduct independent expert reviews of ORD's environmental research programs every 4 to 5 years. Mid-cycle reviews, scheduled midway through the program review cycle, are a critical step in the process. Narrower in focus than the in-depth technical evaluation that constitutes a full program review, the objectives of a mid-cycle review are to gauge the program's progress and to offer advice and feedback with respect to future directions and performance and accountability.

The BOSC conducted a full program review of the Air Research Program (then the Particulate Matter and Ozone Research Programs) in March 2005, culminating in a BOSC report submitted to ORD in August 2005. Since that time, ORD has combined the Particulate Matter (PM), Ozone, and Air Toxics Research Multi-Year Plans (MYPs) and revised the scope of its long-term goals (LTGs). To assess progress in advancing the combined Air Research Program's activities and plans in line with the BOSC recommendations from the 2005 program review, ORD requested that the BOSC conduct a mid-cycle review. The BOSC Air Mid-Cycle Subcommittee was formed to conduct this review.

Following an administrative conference call on September 6, 2007, to discuss the review materials provided to the BOSC PM and Ozone (Air) Mid-Cycle Subcommittee, a public meeting was held on September 18, 2007, in Arlington, Virginia, to evaluate the progress of the Air Research Program. The mid-cycle review focused on ORD's response to the recommendations from the 2005 program review and on the detailed documentation of subsequent changes in the scope of the Program to include air toxics and to develop a "one atmosphere" approach to air research, in which all air pollutants are considered together, rather than one pollutant at a time.. Another area of focus was on the development of potential metrics of progress in linking sources of air pollution to outcomes in a two-step process that first links sources to exposures, and then links exposures to potential adverse health effects.

The purpose of the mid-cycle review was to provide general feedback on ORD's progress to date, and to assist ORD in addressing issues and opportunities surrounding continued development of the Air Research Program's scope of work. This was accomplished through a set of specific charge questions (provided in Appendix A) that guided the BOSC Subcommittee through its review of the materials prepared for this process.

The BOSC Air Mid-Cycle Subcommittee members were drawn from the Subcommittee that conducted the 2005 program review—all of the five Air Mid-Cycle Subcommittee members participated in the 2005 program review. The BOSC Air Mid-Cycle Subcommittee developed responses to each of the charge questions and provided a number of recommendations for ORD based on the material reviewed and discussions organized as part of this mid-cycle review.

Readers are referred to the text of this report to understand the full context and detail of these comments, additional specific programmatic recommendations, and the full scope of the Subcommittee's efforts and detailed comments.

The findings of the Subcommittee are summarized below.

Charge Question 1: Do the currently planned revisions to the Air Research Program adequately address the BOSC PM and Ozone Subcommittee's 2005 program review recommendations?

The Subcommittee members found that the planned revisions adequately address the recommendations of the 2005 review and even exceed those recommendations in combining all air pollutants into one program. The only exception was the lack of reinstatement of the Ozone Research Program, which was not feasible because of a lack of adequate resources.

Charge Question 2: Does the proposed structure for the revised Clean Air Research MYP provide a coherent framework for addressing priority research needs?

The Subcommittee found that the proposed structure of the multiyear plan (MYP) meets all and exceeds some of its goals with respect to providing a coherent framework for addressing priority research needs. The quality of the research, as demonstrated in the bibliometric analysis, is exceptional.

Charge Question 3: Does the draft Clean Air Research MYP 2007–2012 (August 2007) adequately address critical research to meet the regulatory mandates of the Clean Air Act?

The Subcommittee found that the draft Clean Air Research MYP clearly addresses important research needs identified in EPA documents, such as the 2003 PM MYP, and in critical assessments undertaken by external organizations, most notably the 1998–2004 National Research Council (NRC) Committee on Research Priorities for Airborne Particulate Matter.

Charge Question 4: Does the approach used to integrate PM, Ozone, and Air Toxics into one overall research program address the concerns raised by the BOSC in the 2005 PM and Ozone program review?

The Subcommittee agreed that the integrative approach addresses the concerns the BOSC raised in the 2005 program review. The integration of all air pollutants under one multi-pollutant program should provide a more holistic approach to reducing adverse health outcomes from air pollution. ORD has provided a rationale for how ozone, along with other pollutants, will be factored into a multi-pollutant health assessment approach.

Charge Question 5: Do the existing program performance measures provide appropriate and quantifiable indices of progress? What improvements does the Subcommittee recommend?

The Subcommittee agreed with the approach of developing program performance measures that reduce uncertainties in linking pollutant sources to health outcomes. The Subcommittee also agreed with the choice of the three areas for emphasis: near roadways, near specific sources, and

in specific geographical areas impacted by several sources. The Subcommittee recommends that future research include a focus on the role of composition and of atmospheric chemistry on the toxicity of particles.

Charge Question 6: Please rate the progress made by the Air Research Program in moving the Program forward in response to the BOSC program review of 2005 as Exceptional, Exceeds Expectations, Meets Expectations, or Not Satisfactory.

The Subcommittee rated the progress of the Program as Exceeds Expectations. The transition of the Program from the PM and Ozone Programs to the Air Research Program has clearly been successful. The revised LTGs are intended to address regulatory needs and to build the knowledge base for a multi-pollutant approach to controlling air pollution. The response to the 2005 program review was highly positive. Overall, the Subcommittee found that the Air Research Program is meeting its goals and is conducting the appropriate high-quality science to meet those goals. For these reasons, the Subcommittee rated the progress of the program as Exceeds Expectations.

Because the Program is progressing well, there is no need for any response to this review.

II. CHARGE QUESTION 1:
**Do the currently planned revisions to the Air Research Program
adequately address the 2005 BOSC PM and Ozone Subcommittee's 2005
program review recommendations?**

The BOSC PM and Ozone Subcommittee provided nine recommendations to EPA as a result of its 2005 program review. This section describes whether the revisions made by EPA to its Air Research Program adequately address those recommendations. The current assessment is based on: (1) the response of EPA to the BOSC recommendations presented as an attachment to the letter of Dr. William H. Farland, EPA Acting Deputy Assistant Administrator for Science, to Dr. James H. Johnson, Jr., BOSC Chair, dated February 8, 2006; (2) the draft Clean Air Research MYP, dated August 2007; and (3) the presentation and responses to questions provided by Mr. Timothy Watkins at the BOSC Air Mid-Cycle Subcommittee meeting on September 18, 2007, in Arlington, Virginia. We provide our assessment for each BOSC recommendation below.

- 1. 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.*

EPA developed a survey form that was distributed to its clients (i.e., EPA Office of Air and Radiation [OAR] and regional office staff). The response rate was good with twenty-six clients (out of 31) completing the survey. Overall, responses showed a very positive evaluation of EPA's Air Research Program in terms of outreach, contributions to client activity, research activities; and decision-making, and scientific reputation. Two managers gave the lowest available rating in response to the question regarding EPA's research reputation. EPA did not provide specific reasons for these two outliers at the September 2007 meeting. The Agency should identify the reasons for such uncommon responses in the current survey and future surveys, so that the BOSC can assess whether those reasons result from unreasonable expectations from some of the Program's clients or from deficiencies (whether perceived or real) in the Air Research Program.

- 2. The wording of the two long term goals (LTGs) should be revised. (Suggestions were offered by the BOSC.)*

EPA revised its two LTGs along the lines of the recommendations provided by the BOSC in the 2005 program review. Short versions of those goals, which were developed by EPA, were found to be quite appropriate and useful by the BOSC Air Mid-Cycle Subcommittee.

- 3. The LTGs 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.*

EPA is using a few studies to test hypotheses according to the source-to-health outcome framework. The example presented by Program staff at the meeting is the set of near-roadway

studies that include monitoring and modeling of air toxics, exposure assessment, and health studies in the vicinity of roadways. Other examples proposed by the Program include multi-pollutant effects of coal-fired power plant emissions and the potential health effects associated with nickel emissions from oil-fired power plants in the northeastern United States.

4. EPA should reconsider the decision to completely disinvest in ozone health research.

EPA argued that the disinvestment in ozone health research was necessary because of budget constraints. At the BOSC Air Mid-Cycle Subcommittee meeting, the Program staff pointed out that, although no significant effort is occurring in ozone health research, some work is taking place through the multi-pollutant health studies related to PM (e.g., confounding effects) and that some low-dose ozone health studies are planned. This is the sole recommendation that has been only partially addressed by EPA. The Subcommittee thought that this was justified, however, by valid arguments given for not fully addressing the recommendation.

5. EPA should solicit input from and coordinate research with other federal agencies as well as states and private organizations.

The Program is coordinating its research through the Research Coordination Team (RCT). The Program also recognizes research efforts conducted by external organizations and agencies, including the Health Effects Institute (HEI), the National Institute of Environmental Health Sciences (NIEHS), the National Heart, Lung, and Blood Institute (NHLBI), the California Air Resources Board (CARB), some Regional Planning Organizations (RPOs), the U.S. Department of Agriculture (USDA), the U.S. Department of Defense (DOD), and private trade associations such as the Electric Power Research Institute (EPRI) and the Coordinating Research Council (CRC). In addition, EPA is a key member and funder of the North American Research Strategy for Tropospheric Ozone (NARSTO), the government-industry-academic research consortium focused on atmospheric sciences in North America. EPA mentions CRC through the HEI activities; however, CRC also funds some air research directly. Because EPA is involved in reviewing this CRC-funded research, this coordination also should be mentioned in the Clean Air Research MYP (on p. 11).

6. The PM and Ozone Programs should commit to maintain the strong balance between intramural and extramural research.

The Program has demonstrated that it continues to maintain strong extramural and intramural research efforts. For example, the Science To Achieve Results (STAR) grants are a major mechanism used to fund extramural research via a competitive program.

7. Funding decisions for any active intramural project should undergo review by the Air Research Coordination Team (RCT).

EPA has maintained the role of the RCT in the new format used within ORD to manage air research (i.e., with research coordinated by National Program Directors). One example provided by Program staff is the development and implementation of the Near-Roadway Research Initiative, which was reviewed by the RCT and the clients of this research project.

8. *The Clean Air Research MYP should include a discussion indicating how the NRC goals flow into the cross-cutting research issues and how these are embodied under the two LTGs.*

The draft MYP is clearly organized along those lines (for example, Figures 2 and 3, Tables 1 through 3). In particular, the Subcommittee found the organization of the annual performance goals (APGs) by theme in Figure 4 to be especially useful for understanding how the various research issues are interrelated within the source-to-health outcome framework.

9. *Funding should be set aside for anticipatory research needs and ORD should take steps to identify and highlight key anticipatory research needs.*

The Program staff indicated that it is not feasible to set aside special research funds that are not assigned to a specific research effort; however, each ORD principal investigator has the discretion to use 10 percent of his or her research budget for research items that are not determined *a priori*. This flexibility in the ORD research budget satisfies the BOSC recommendation.

III. CHARGE QUESTION 2:

Does the proposed structure for the revised Clean Air Research MYP provide a coherent framework for addressing priority research needs?

Our review of the updated Air Research Program finds that the proposed structure for the revised Clean Air Research MYP by ORD intramural research laboratories meets all and exceeds some of its goals with respect to providing a coherent framework for addressing priority research needs. In 2005, Dr. Dan Costa indicated to the BOSC that the PM Program was at a point of transition, and was working to differentiate the concepts of outputs versus outcomes. The Subcommittee found that the transition has been a success; the progress made in the past 2 years and the newly modified LTGs clearly demonstrate the Program's aims to benefit society, to protect the environment, and to improve human health.

The revised MYP clearly articulates the framework and timeline for research to address the two updated LTGs. These two new goals define and promote the research aims and highlight the priorities for the Air Research Program with well-designed milestones. The revised LTGs identify the challenges in the themes and present approach to integrate across science and program objectives with a multidisciplinary approach. The first revised LTG reduces uncertainty in the science that supports standard-setting and air quality management decisions. The second revised LTG reduces uncertainties in linking health and environmental outcomes to air pollution sources.

The scientific investigative activities and achievement presented in the progress report by the Air Research Program demonstrated high quality in its scientific merits, high impact in its affiliated scientific community, and exceptional value in its scholarly activities. The outstanding progress made in the past 2 years with respect to addressing the research needs is determined based on supporting evidence as represented in the following categories: (1) merits in scholarship and advancement in scientific aims with superb productivity as represented by the number of peer-reviewed scientific publications; (2) significant impact of the Air Research Program in the scientific community as demonstrated by the strength of scientific publications; (3) success and progress of the Air Research Program as demonstrated by its key accomplishments; (4) success and progress of the Program as demonstrated by its contributions to building a knowledge base and information database; and (5) success and progress of the Air Research Program in its ability to better target the needs of the community with the revised LTGs.

The high quality of the work of the Air Research Program in addressing priority research needs is illustrated by the following:

- **Merits in Scholarship and Strong Productivity, as Represented by the Number of Scientific Publications.**
 - The bibliometric analysis presents data showing that, among 2,067 publications contributed by the EPA Air Research Program (1998–2007), 1,828 have received citations.

- During the past 2 years (2005–2006), the EPA Air Research Program contributed a total of 568 peer-reviewed publications, 19 reports, 3 books, and 19 book chapters.
- **Contributions and Impact in the Scientific Community, as Demonstrated by the High Quality of Scientific Publications.**
 - More than one-half of EPA’s air research papers are published in the Institute for Scientific Information’s (ISI) top 20 journals in air pollution.
 - More than one-third of EPA’s air papers are published in high-impact journals, as designated by the ISI.
 - One-third of the air publications are highly cited papers, based on ISI data.
 - Among the top 20 air pollution papers listed by ISI, 4 were contributed by EPA’s Air Research Program.
- **Significant Progress and Advancement Illustrate the Success of the Research Program, as Shown by its Key Accomplishments.**
 - The key accomplishments presented in the progress report are impressive. These accomplishments are true documentations of the impact of the Air Research Program, the success of the MYP in addressing the Program’s LTGs, and the well-integrated and cohesive benefit that this Program brings to the community.
- **The Revised Air Research Program Has Placed an Emphasis on its Contributions to Building a Knowledge Base and Information Database.**
 - Work in progress will contribute to new and updated data, methods, and models to estimate and characterize emission sources.
 - Work in progress will contribute to a multi-pollutant research program to better address the links between health effects and the risks posed by emission sources.
 - Work in progress will contribute to a strategy to develop a framework for assessing air quality decision accountability.
- **The Revised Research Program Better Addresses its Two LTGs and Links Research to Health Outcomes.**
 - The revised Air Research Program and draft Clean Air Research MYP are forward-looking with a focus on source-to-health outcome. This focus better targets the two revised LTGs.
 - The three specific areas or themes on which the draft Clean Air Research MYP focuses are well integrated. In particular, the risks associated with near-roadway exposures will have significant impacts and will enhance public awareness.

IV. CHARGE QUESTION 3:

Does the draft Clean Air Research MYP 2007–2012 (August 2007) adequately address critical research to meet the regulatory mandates of the Clean Air Act?

The Clean Air Act directs EPA to set ambient air quality standards with an adequate margin of safety and to plan and implement emission control programs to attain these standards. This legislative mandate represents the ultimate authority and rationale for EPA's Air Research Program, which is intended to provide studies on the health effects and exposures that underpin ambient air quality standards, as well as the understanding of emission sources and development of modeling tools necessary for establishing State Implementation Plans (SIPs) and other air quality management activities.

The Subcommittee found that the draft Clean Air Research MYP clearly addresses important research needs identified in EPA documents, such as the 2003 PM MYP, and in critical assessments undertaken by external organizations, most notably the 1998–2004 NRC Committee on Research Priorities for Airborne Particulate Matter, the 2004 NRC Committee on Air Quality Management, and the 2005 BOSC PM and Ozone Subcommittee's program review. The clearest evidence that the research framework aligns with the Clean Air Act is the formulation of the two LTGs of the new MYP. The first LTG is to reduce uncertainty in the science that supports standard-setting and air quality management decisions. This research will inform regulatory decision-making (e.g., National Ambient Air Quality Standards [NAAQS]), provide science on source-priority hazardous air pollutants (HAPs), and support implementation of regulations with tools (methods and models) and information provided to OAR, regions, states, and tribes. The second LTG is to reduce uncertainties in linking health and environmental outcomes to air pollution sources. The approach is to integrate across science and Program objectives, apply multidisciplinary approaches, and leverage with federal and other organizations. This framework leads to science questions and research outcomes that are directly relevant to standard-setting and air quality management needs. Although the Air Research Program is built around the source-to-health outcome paradigm, it also includes studies of climate change-air pollution interactions, an important topic in light of the recent Supreme Court ruling that EPA is obliged to address global warming.

In its 2005 evaluation, the BOSC PM and Ozone Subcommittee concluded that the ORD PM Research Program had been structured to address the 10 areas of emphasis—focusing mainly on issues related to health and exposure research used for setting ambient air quality standards—articulated by the NRC Committee on Research Priorities for Airborne Particulate Matter. The NRC research areas have formed a central intellectual core for all of EPA's PM research projects, both intramural and extramural, with a focus on reducing the inherent level of uncertainty in each area. In response to the main area of uncertainty highlighted in the 2006 PM NAAQS Review, EPA now is conducting research on the health effects of coarse particles in rural areas. (PM_{10-2.5}, which represents the subset of coarse particles that is small enough to be inhaled and to penetrate the thoracic region of the respiratory tract. The term PM stands for particulate matter; the subscript refers to the 50 percent cutoff point for the aerodynamic diameter of the particles collected in an appropriate sampler. In this case, the notation refers to particles between the size of PM₁₀ and PM_{2.5}.) Another key question for regulators is the portion

of premature deaths and other health effects attributed to PM_{2.5} that is actually caused by ultrafine particles (PM_{0.1}). Because OAR is very interested in these issues, ORD has fast-tracked these research areas and expects the Program to advance the understanding of the health effects of coarse and ultrafine particles by 2009. Although the research topic of a possible lack of a concentration threshold for PM-related health effects is integrated throughout the Program, it is important enough that an explicit focus in the MYP may be warranted.

In the 2005 program review, the BOSC PM and Ozone Subcommittee expressed concern about the divestment away from ozone research. Although budget reductions have made it difficult to focus on both, EPA took the initiative to fund three meta-analyses of the relationship between daily ozone fluctuations and premature death, and currently is planning a low-dose ozone exposure study to support the ozone NAAQS.

In terms of health research, EPA has conducted or funded research to advance the science of health risk assessments used in the regulatory program. These activities include research on concentration-response functions for PM_{2.5} and ozone for various health outcomes and improved exposure assessments and economic valuations. EPA also has been proactive about “accountability” research—studies to verify that sustained decreases in pollutant concentrations have resulted in the expected improvements in public health. ORD has been a key participant in natural experiments such as the Utah Valley steel mill closure in the mid-1980s and in the current NARSTO assessment.

EPA is also responsible for the development and application of air quality analysis and modeling tools to support SIPs. Although now more chemically detailed, three-dimensional ozone models have been in existence since the mid-1980s, but models of PM_{2.5} are a relatively recent development. EPA has formulated complementary emission-based models (e.g., Community Multiscale Air Quality) and observation-based models (e.g., Positive Matrix Factorization and Chemical Mass Balance) to help predict the sources leading to nonattainment issues. These tools have also been used to help predict daily air pollution forecasts to raise public awareness regarding air quality and to encourage nonregulatory, individual actions to reduce personal exposures to ozone and PM.

In 2005, the BOSC PM and Ozone Subcommittee recommended a formal process for assessing customer satisfaction. In response, ORD implemented a survey of OAR, the Program’s primary client, in the fall of 2005. Thirty-one clients within OAR received the survey and 26 responded (a response rate of 84%). The Air Research Program received an average score of 3.61 out of a possible 5 (best score). Although the comments were generally positive, they identified areas of potential improvement, including: (1) the Program should create opportunities to involve clients in planning and prioritizing science efforts and to improve communication between programs and ORD, and (2) the Program should investigate why a small number of managers think that their clients do not respect ORD’s scientific reputation.

Dr. Costa speculated that the perceived lack of respect may reflect the fact that the Program’s clients generally think that ORD is not doing enough to specifically address ecological issues. Also, regional offices often have questions or problems for which they need answers immediately, and this is not always possible given budget constraints. Dr. Costa explained that the Program is trying to improve communications with its clients to address some of these issues. The Subcommittee recommends that ORD periodically re-survey OAR and a cross-section of

other state, local, and tribal clients as a way to monitor progress toward improving the Program's relevance and timeliness and communication with its primary clients.

In summary, the Subcommittee concluded that the draft Clean Air Research MYP does adequately address critical research to meet the regulatory mandates of the Clean Air Act, and in some cases exceeds expectations. With periodic feedback from the primary research clients, the Program can become even more relevant to the most important regulatory and programmatic needs of the Agency and the nation's Air Research Program.

V. CHARGE QUESTION 4:

Does the approach used to integrate PM, Ozone, and Air Toxics into one overall research program address the concerns raised by the BOSC in the 2005 PM and Ozone program review?

The BOSC PM and Ozone Subcommittee was concerned that the redirection of the Program, which started in the late 1990s, from an emphasis on ozone to PM health research may have overshot a reasonable balance point and that ORD should reconsider its decision to completely divest of its ozone health research program.

ORD has indicated that, given the input of internal clients and external scientific panels, the rising congressional interest in PM, and fiscal constraints (zero and/or negative growth), it had no choice but to divest of its ozone research portfolio to support expanding PM research demands. There are aspects of the process science and modeling associated with PM that have common elements with ozone and can be viewed as a shared resource between the two areas, regardless of whether it is identified as PM or ozone research. This is less likely the case for ozone health research, however, which shares common elements with secondary PM components during summertime photochemical production, but has different attributes under winter conditions, when secondary PM photo-production is limited (except in southern latitudes) and the mix of primary PM emissions (e.g., residential heating, including wood burning in some regions) is somewhat different.

EPA's Office of Air Research (OAR) has embraced the 2004 NRC report entitled "Air Quality Management in the United States," which suggested that the EPA might want to consider a multi-pollutant air quality management strategy. The vision was that common elements and economies of scale would be realized, providing advantageous management opportunities for air quality in total (i.e., the "one atmosphere" paradigm).

ORD expects to advance a rational approach for supporting a Multi-Pollutant Program that would, if viable, employ a more holistic approach to health outcomes associated with National Ambient Air Quality Standards (NAAQS), Hazardous Air Pollutants (HAPS), and PM. It remains to be seen if the epidemiology community can support this paradigm. Embedded within this construct, ORD has initiated two demonstration projects—a source-to-health outcome model and a near-road exposure assessment study. Both approaches have elements associated with multi-pollutant exposure and health outcomes, although the health component of the traffic study will not get underway until late 2009.

The ability to depart from the pollutant-by-pollutant NAAQS paradigm will depend on assessing interactions in health outcomes resulting from multi-pollutant exposures. This is a laudable goal, but one that may be unrealistic in the near term.

In summary, ORD has responded to the BOSC PM and Ozone Subcommittee, indicating that it is not fiscally feasible to continue with an independent ozone health research program and meet the needs of the Air Research Program. ORD has provided a rationale for how ozone, along with other pollutants, will be factored into a multi-pollutant health assessment approach. The

Subcommittee concluded that ORD has addressed the concerns of the BOSC PM and Ozone Subcommittee regarding Charge Question #4 as well as can be expected given the current constraints.

VI. CHARGE QUESTION 5:
Do the existing program performance measures provide appropriate and quantifiable indices of progress? What improvements does the Subcommittee recommend?

Progress has definitely been made since 2005 in thinking through the appropriate performance measures for the Air Research Program. At the time of the program review, both the Subcommittee members and the scientists in the PM and Ozone Research Programs were struggling with the measures that could be used to evaluate useful outcomes of scientific research. At this time, it is evident that the managers of the Air Research Program have given considerable thought to this question and have begun to produce appropriate and quantifiable measures of progress.

The Air Research Program has used a client satisfaction survey instrument to document how well it is meeting the needs of the OAR staff members who use its data. The BOSC encourages the Program to follow up on its plans to refine the survey, conduct the survey annually, and expand the use of the survey to include, not only the OAR, but also regional, state, and tribal groups.

Another performance measure is the use of external review bodies to evaluate Program goals and progress. The Air Research Program is making good use of this tool as evidenced by the excellent preparation for both the full program review by the BOSC in 2005 and for the current BOSC mid-cycle review. The response to the suggestions of the external review also has been positive, as described in the response to Charge Question #1.

Appropriate Program Assessment Rating Tool (PART) measures for annual and long-term outputs and outcomes have been provided in Table 4 of the draft Clean Air Research MYP. They are quite general in nature, however, and most do not specify how the measures will be quantified. The Program Improvement Plan presented below Table 4 describes the goals of the Air Research Program to develop such quantifiable measures and the BOSC encourages the Air Research Program to complete those goals. The Subcommittee offered the following editorial comment on Table 4: the NAAQS Staff Paper mentioned in the third box on “measure language” no longer exists; a more general term, such as “NAAQS documentation,” could be substituted.

The completion of the LTGs and associated APGs and measures can provide a basis for measuring progress. The APGs, as presented in Figure 4 of the draft Clean Air Research MYP, are especially helpful; however, as mentioned in Table 4, the percentage of these planned activities that are accomplished annually is a measure of output more than it is a measure of outcome.

The difficult task is to measure progress in achieving positive outcomes for the major goals—in other words, reducing uncertainty in the science that supports the standard-setting and air quality management decisions and in assessing the linkage between health impacts and air pollutant sources. The presentations of expected outcomes from the two LTGs shown in Figures 2 and 3

are appropriate. For the first LTG, the Air Research Program already is planning to measure the percentage of Program outputs appearing in NAAQS documents. Surveys of the satisfaction that OAR staff members have with the reduction of uncertainties by the Air Research Program investigations is another measurable outcome. Another measure might be the money saved from the setting of new standards, based on the cost-benefit analysis of the new standards. For the second LTG, the planned accountability studies and associated cooperative programs should offer measurable outcomes. This is particularly true for assessing the source-to-health linkages.

The Subcommittee agreed with the suggestions of Air Research Program staff that potential Program performance measures are related to the goal of reducing the uncertainty in understanding relationships between air pollutant emission sources and health outcomes. EPA proposed the possibility of identifying 10 to 15 source categories (or sectors) that contribute the vast majority of air pollutant emissions and measuring progress toward understanding relationships between emissions from these sources and health by taking a two-phased approach. The first phase would be designed to reduce uncertainty in understanding relationships between sources and air quality, and the second phase would be designed to reduce uncertainty in understanding relationships between air quality and public health. Although measuring progress in either phase presents significant challenges, progress in the second phase (relationships between air quality and health) is particularly difficult to measure.

Possible measures of outcome for the first phase are apparent. Performance measures in this area can be quantitated by *monitoring* changes in emissions and *modeling* resultant changes in exposures following the institution of regulations or following some type of intervention. Possible measures of outcome for the second phase are less apparent because they depend on available epidemiology data to quantify the expected adverse health effects of the exposures. The most successful example of such a metric for a single pollutant is the lowering of blood lead levels associated with removing a major source (lead in gasoline) and the known relationship of such blood lead levels to adverse health effects. The studies of Pope, et al., on the reduction of various clinical endpoints in a population in Utah when the steel mills shut down temporarily provide another good example of such a metric for multi-pollutant exposures.

The Air Research Program has suggested focusing on similar areas for its future efforts in linking sources to outcomes. Those areas are (1) near roadways, (2) near other specific sources, and (3) in specific geographical areas impacted by several sources. The Subcommittee agreed with this approach. The Air Research Program plans research projects that include toxicological studies of source-specific emissions, epidemiological studies in affected communities, and modeling studies to determine exposures.

The Subcommittee recommends that the Air Research Program continue to contribute to information that is lacking on the characteristics of emissions that are associated with adverse health effects. The elements that have been studied in the past are mass and size for particles. Future research should focus on the role of composition and of atmospheric chemistry on the toxicity of particles.

The best metrics to evaluate the progress of the Air Research Program will be those that can quantify the source-to-outcome links that can be used to improve public health.

VII. CHARGE QUESTION 6:

Please rate the progress made by the Air Research Program in moving the Program forward in response to the BOSC program review of 2005 as Exceptional, Exceeds Expectations, Meets Expectations, or Not Satisfactory.

It was the consensus of the Subcommittee that the progress of the Air Research Program in response to the 2005 BOSC PM and Ozone program review and recommendations Exceeds Expectations.

This evaluation is based, in part, on ORD's positive responses to the recommendations of the earlier review, as noted in the section of this report related to Charge Question #1. Some responses had to be less positive than others due to budgetary constraints, but the Subcommittee thought that ORD gave all the recommendations serious consideration and responded as positively as it could. The Subcommittee also found that the draft Clean Air Research MYP clearly addresses important research needs to implement the provisions of the Clean Air Act identified in critical assessments undertaken by the NRC, specifically the 1998–2004 NRC Committee on Research Priorities for Airborne Particulate Matter and the 2004 NRC Committee on Air Quality Management.

A survey has been conducted of at least some of the Air Research Program's customers or stakeholders and the response was generally positive. The Subcommittee agreed with the managers of the Air Research Program that the survey should be extended to include more of the Program's stakeholders and that there should be a followup to determine the reason for the few negative responses received.

In addition to responding positively to the earlier recommendations, the group has expanded the Air Research Program to include all airborne pollutants, including air toxics. The Subcommittee thought this was an appropriate move.

The 2005 BOSC PM and Ozone Subcommittee had suggested developing hypothesis-driven studies to help develop metrics of outcomes of the research. The managers of the Air Research Program have suggested three such studies and are making progress in developing metrics of progress.

The Air Research Program also has begun to determine the steps in the links among source emissions, exposures, and health outcomes. This is a reasonable and logical framework for developing quantifiable metrics of progress.

EPA also should be commended for the strong relationships it has established with other funding organizations, including HEI, NIEHS, NHLBI, CARB, some RPOs, USDA, DOD, and private trade associations such as EPRI and the CRC. Research collaboration and coordination with these individual funding agencies, and multi-agency organizations such as NARSTO, helps

ensure that the scientific and technical needs of the nation's Air Research Program are being met with minimal duplication of effort.

The bibliometric analysis was quite impressive and was classified by some members of the Subcommittee as exceptional. Overall, the Subcommittee members thought that the Air Research Program is meeting its goals and is conducting the appropriate high-quality science to meet those goals. Thus, the Subcommittee rated the Program's progress as Exceeds Expectations.

Finally, the Subcommittee found that the program was progressing well and no response to this review is necessary.

VIII. APPENDICES

Appendix A: Subcommittee Charge

**Board of Scientific Counselors
Air Mid-Cycle Subcommittee
Draft Charge
September 6, 2007**

1.0. Objectives. The objectives of this mid-cycle review are to:

- Evaluate the progress made by the Office of Research and Development's (ORD) Air Research Program relative to the commitments it made following the 2005 review of the Particulate Matter (PM) and Ozone Research Programs; and
- Obtain advice and feedback on issues related to the future directions of the research program and performance and accountability.

2.0. Background Information. Independent expert review is used extensively in industry, federal agencies, congressional committees, and academia. The National Academy of Sciences has recommended this approach for evaluating federal research programs.¹

For the Agency's environmental research programs, periodic independent reviews are conducted at intervals of 4 or 5 years to characterize research progress, to identify when clients are applying research to strengthen environmental decisions, and to evaluate client feedback about the research. Mid-cycle evaluations are an important part of this program review process. Scheduled midway through the review cycle, these independent assessments give ORD an opportunity to gauge the program's progress relative to the commitments it made following its last review.

For the upcoming mid-cycle review, the Air Research Program has prepared a progress report that will provide the context for our discussions during the meeting. The report outlines the changes implemented by the program in response to the major recommendations from the BOSC 2005 review of the Particulate Matter (PM) and Ozone Research Programs. The Clean Air Research Multi-Year Plan (MYP) is undergoing revision, and a synopsis of the revised MYP is included in the progress report. One of the major changes is the consolidation of the PM, Ozone, and Air Toxics Programs into an integrated Air Research Program. The revised MYP lays out the context and presents a timeline for research on the two new long-term goals (LTGs):

- LTG 1: In accordance with EPA's legislative mandate for periodic National Ambient Air Quality Standards and hazardous air pollutants assessment, advances in the air pollution sciences will reduce uncertainty in *standard setting* and *air quality management*

¹ Evaluating federal research under the Government Performance and Results Act. National Research Council, 1999.

decisions.

- LTG 2: Air pollution research will reduce uncertainties in linking health and environmental outcomes to air pollution sources to support effective air quality strategies.

This review is not intended to be the in-depth technical evaluation of a full program review.

Presentation time will be minimized in favor of discussion.

3.0. Draft Charge Questions for ORD's Air Research Program. ORD is interested in receiving feedback concerning the following questions:

- Do the currently planned revisions to the Air Research Program adequately address the BOSC PM and Ozone Subcommittee's 2005 program review recommendations?
- Does the proposed structure for the revised Clean Air Research MYP provide a coherent framework for addressing priority research needs?
- Does the draft Clean Air Research MYP 2007–2012 (August 2007) adequately address critical research to meet the regulatory mandates of the Clean Air Act?
- Does the approach used to integrate PM, Ozone, and Air Toxics into one overall research program address the concerns raised by the BOSC in the 2005 PM and Ozone program review?
- Do the existing program performance measures provide appropriate and quantifiable indices of progress? What improvements does the Subcommittee recommend?
- Please rate the progress made by the Air Research Program in moving the Program forward in response to the BOSC program review of 2005 as Exceptional, Exceeds Expectations, Meets Expectations, or Not Satisfactory.

For the last question, the BOSC Air Mid-Cycle Subcommittee is being asked to assign a qualitative score that reflects the extent to which the Program is making progress in moving the Program forward in response to the previous BOSC review. The score should be in the form of one of the adjectives defined below and is 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. For mid-cycle reviews, the rating should be based on the quality, speed, and success of the Program's actions in addressing previous BOSC recommendations. The adjectives to describe progress are as follows:

- **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. Satisfactory programs live up to 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. Potential Subcommittee Approach for Mid-Cycle Review

- Hold one administrative call in the month preceding the face-to-face meeting.
 - * Allows the Subcommittee Chair to make review and writing assignments.
- Hold one teleconference call in the month preceding the face-to-face meeting.
 - * Allows the ORD to present background and other relevant materials to the Subcommittee.
 - * Allows the Subcommittee to ask clarifying questions.
- Distribute background materials and documents requested by the Subcommittee in advance of the teleconference call.
- Hold a one-day face-to-face meeting for the mid-cycle review.
 - * The meeting will include ORD presentations on Program progress and discussions with members of the Air Mid-Cycle Subcommittee.
 - * The meeting will conclude with the presentation of a draft report that addresses all of the charge questions.
- If needed, hold one teleconference call within one month following the face-to-face meeting to finalize the draft report.

Appendix B: Air Mid-Cycle Subcommittee

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Appendix C: List of Acronyms

APG	Annual Performance Goal
BOSC	Board of Scientific Counselors
CARB	California Air Resources Board
CRC	Coordinating Research Council
DOD	U.S. Department of Defense
EPA	U.S. Environmental Protection Agency
EPRI	Electric Power Research Institute
FACA	Federal Advisory Committee Act
HAP	Hazardous Air Pollutant
HEI	Health Effects Institute
ISI	Institute for Scientific Information
LTG	Long-Term Goal
MYP	Multi-Year Plan
NAAQS	National Ambient Air Quality Standards
NRC	National Research Council
NARSTO	North American Research Strategy for Tropospheric Ozone
NHLBI	National Heart, Lung, and Blood Institute
NIEHS	National Institute of Environmental Health Sciences
OAR	Office of Air and Radiation
ORD	Office of Research and Development
PART	Program Assessment Rating Tool
PM	particulate matter
RCT	Research Coordination Team
RPO	Regional Planning Organization
SIP	State Implementation Plan
STAR	Science To Achieve Results
USDA	U.S. Department of Agriculture