

BOARD OF SCIENTIFIC COUNSELORS

CLEAN AIR SUBCOMMITTEE

Conference Call Summary Thursday, May 21, 2009 10:30 a.m. – 12:30 p.m. Eastern Time

Welcome

Dr. Kenneth Demerjian, Atmospheric Sciences Research Center, State University of New York, Subcommittee Chair

Dr. Demerjian, Chair of the Board of Scientific Counselors (BOSC) Clean Air Subcommittee, called the meeting to order at 10:33 a.m. He welcomed the Subcommittee members to the call and thanked them for their participation. He asked the Subcommittee members to identify themselves.

Dr. Demerjian explained that the Subcommittee's main objective is to review the U.S. Environmental Protection Agency's (EPA) Clean Air Research Program. Materials were sent to all Subcommittee members prior to this call; Tab A of those materials contains the Subcommittee's charge.

The Clean Air Research Program was reviewed by the BOSC in 2005, and a copy of the BOSC's report and EPA's response can be found in Tab G of the materials. At the time of that review, the Program was called the Particulate Matter (PM)/Ozone Research Program. Since then, the Program has shifted its focus to understanding air quality in a multi-pollutant environment and has been renamed the Clean Air Research Program. This Subcommittee will prepare a report that will be structured around the charge questions and will assess the Program based on its progress toward meeting its Long-Term Goals (LTGs). The Subcommittee will assign a rating of: Exceptional, Exceeds Expectations, Meets Expectations, or Not Satisfactory for each LTG.

This conference call and the subsequent call to be held on May 29, 2009, are intended to provide Subcommittee members with an overview of the Clean Air Research Program prior to the face-to-face meeting, which will be held in Research Triangle Park, NC, June 8-10, 2009. Hardcopies of the posters to be presented at the face-to-face meeting will be sent to Subcommittee members in late May or early June.

BOSC Designated Federal Officer (DFO) Remarks

Ms. Heather Drumm, U.S. Environmental Protection Agency (EPA)/Office of Research and Development (ORD), Subcommittee DFO

Ms. Drumm introduced herself as the DFO for the Clean Air Subcommittee and reviewed the Federal Advisory Committee Act (FACA) procedures that are required for all EPA BOSC Subcommittee meetings. As the DFO for the Subcommittee, Ms. Drumm serves as the liaison between the Subcommittee, the public, and EPA and ensures that all FACA requirements are met.

Jen Hurlburt, contractor from The Scientific Consulting Group, Inc., is taking notes to capture the discussion and prepare a summary, which must be certified by the Subcommittee Chair within 90 days of the call. After certification, the summary will be made available to the public on the BOSC Web Site (http://www.epa.gov/osp/bosc).

A Federal Advisory Committee for the U.S. Environmental Protection Agency's Office of Research and Development

All meetings and conference calls involving substantive issues, whether in person, by phone, or by e-mail, that include one-half or more of the Subcommittee members must be open to the public and a notice must be placed in the *Federal Register* at least 15 calendar days prior to the call or meeting. All documents must be made public as well. A notice for this call and the agenda were published on the electronic docket that was established for this Subcommittee via the federal docket management system (http://www.regulations.gov; Docket ID EPA-HQ-ORD-2009-0225).

Regarding financial conflict of interest, Ms. Drumm has been working with EPA officials to ensure that all of the appropriate ethics regulations are satisfied. Each Subcommittee member has filed a standard government financial disclosure report and completed ethics training. She asked the Subcommittee members to notify her if there is a potential conflict of interest with any of the topics being discussed as the Subcommittee performs its work.

The purpose of this conference call is to provide Subcommittee members an overview of ORD's Clean Air Research Program. All Subcommittee members should have received a binder containing background materials for this call. A second mailing of materials should have been received by Subcommittee members yesterday. PowerPoint presentations to be presented on this call were sent via e-mail on Tuesday, May 19, 2009.

No requests for public comment were submitted prior to the call, but the agenda allows time for public comment at 12:15 p.m. Ms. Drumm will call for public comments at that time, and each comment must be limited to 3 minutes.

Materials Overview

Dr. Dan Costa, National Program Director (NPD), Clean Air Research Program

Today's conference call will provide the Subcommittee an overview of the Clean Air Research Program. Next week's call will focus on the charge questions and the three sessions of the face-to-face meeting that will be held in Research Triangle Park, North Carolina—health and exposure, air quality, and multi-pollutant.

Prior to this call, the Subcommittee members were sent binders that included information about the Clean Air Research Program. Tab A of the binder includes the draft charge and a charge roadmap, which was developed to direct Subcommittee members to information related to the charge questions. Tab C includes a list of the supplementary materials that are on the CD that was sent with the binder; most of these materials are related to program leadership. Tab D includes an introduction to research at EPA. Tab E includes an overview of ORD's Clean Air Research Program. The Clean Air Research Program Strategic Direction document is in Tab F: Dr. Costa suggested that the Subcommittee members begin by reading this document. Tab G includes the Multi-Year Plan (MYP), which was revised after the 2007 Mid-Cycle Review. Not yet included in this Tab is subsection G(b), the Draft Accomplishments Report, as this report is still under development. Subcommittee members will receive that draft report along with the hardcopy posters in late May or early June. The Draft Accomplishments report presents the Program in the context of the overall risk assessment paradigm. Dr. Costa explained that the first accomplishments report was based on the National Research Council's (NRC) 10 priorities; the latest report has been restructured to focus on the source-to-health outcome paradigm. Also in Tab G are the 2007 Mid-Cycle Review Report, the 2005 BOSC Report, and EPA's response to the 2005 report. Tabs I, J, and K include the poster abstracts, organized according to the three sessions at the face-to-face meeting. Tab L includes a bibliometric analysis of Program publications. Tab M includes a Decision Document Analysis, which shows where and how information produced by the Clean Air Research Program is used. The Partner Survey Report in Tab N is still under development; it will detail how the Program is viewed by its clients.

Discussion

Dr. Demerjian asked the Subcommittee members if any other materials were needed or if there were any questions about the materials received to date. Dr. Praveen Amar asked how much time the Subcommittee members should spend reading the materials before the June meeting. Dr. Demerjian suggested that, at a minimum, each Subcommittee member should skim all of the materials. Each member will be assigned to a Workgroup and will be expected to read the materials relevant to that Workgroup's assignment. He suggested reading the 2005 BOSC Report to get an idea of what the Subcommittee has been asked to produce. Subcommittee members should read all of the charge questions and all of the relevant posters for their Workgroup. He estimated that it would take approximately 1 day to review the materials. Dr. Costa suggested also reading the MYP as it provides a comprehensive overview of the Clean Air Research Program. He suggested that the Subcommittee members read the Progress Report, the Clean Air Research Program Strategic Direction document, and the overview of each thematic session.

ORD Overview

Dr. Bruce Rodan, Senior Science Advisor, ORD

Dr. Rodan thanked the Subcommittee members for serving on this Subcommittee. He emphasized that the BOSC's recommendations are extremely valuable to ORD, and the time given to these reviews by the Subcommittee members is much appreciated.

Dr. Rodan displayed the U.S. EPA organizational chart, explaining that EPA's work is structured, for the most part, by the laws from which EPA receives its regulatory authority. Offices have been created to focus on EPA's work with air, water, solid waste, toxic substances, and pesticides. There also is an office dedicated to enforcement and compliance. Other offices include International Affairs, General Counsel, and Chief Financial Officer, to name just a few. EPA has 10 regional offices throughout the United States. Because of the legislative foundations on which EPA's authority rests (e.g., Clean Air Act, Clean Water Act), there is potential for stove-piping within the Agency. EPA is aware of this and works hard to bridge the issues in both its research and programmatic activities.

ORD's mission is to provide the scientific foundation to support EPA's mission by: conducting research and development to identify, understand, and solve current and future environmental problems; providing responsive technical support to EPA's programs and regions; collaborating with scientific partners in academia and other agencies, state and tribal governments, private-sector organizations, and nations; and exercising leadership in addressing emerging environmental issues and advancing the science and technology of risk assessment and risk management. ORD conducts both basic and applied research and the findings of this research are conveyed to the program and regional offices, which enact programs and develop policies to help achieve EPA's mission of protecting human health and the natural environment.

ORD is a research and development organization that employs 1,901 full-time equivalents (FTEs) and has a budget of approximately \$562.7 million (including \$60 million for the Science To Achieve Results [STAR] extramural research grants program). Across ORD, there are 13 locations with laboratories, centers, and/or offices.

The Assistant Administrator for ORD, an Presidentially appointed position confirmed by the Senate, is the equivalent of the chief executive officer (CEO) in most private companies; Lek Kadeli is ORD's Acting Assistant Administrator. ORD's laboratories and research centers were organized according to the risk assessment paradigm: effects, exposure, assessment, and management. These laboratories and centers include: the National Health and Environmental Effects Research Laboratory (NHEERL), the National Exposure Research Laboratory (NERL), the National Center for Environmental Assessment (NCEA), the National Risk Management Research Laboratory (NRMRL), the National Center for

Environmental Research (NCER), the National Homeland Security Research Center (NHSRC), and the National Center for Computational Toxicology (NCCT).

The Office of Resources Management and Administration (ORMA) controls the budget and the accounting for ORD. The Office of Science Policy (OSP) comments on the science informing proposed regulations and determines if that science has been properly characterized for decision-makers. Overall, ORD provides information and research to the Agency and also reviews the science informing EPA decisions.

A National Program Director (NPD) is responsible for planning and coordinating research in one area (e.g., air, homeland security, etc.) across all of the laboratories and centers and communicating the research results. Dr. Melvyn Branch asked if there was a BOSC subcommittee for each of the national program areas and Dr. Rodan confirmed that there was a BOSC subcommittee for each area and added that there also are subcommittees for some of the centers and laboratories. There are many BOSC subcommittees, but they are not all active at the same time. Each of the national programs undergoes a BOSC program review every 4 to 5 years. In response to a question from Dr. Demerjian, Dr. Rodan stated that the Clean Air Research Program both draws on and provides inputs for all four of the elements of the risk paradigm.

Decision inputs for ORD's research programs originate from various sources, including: programs and regions; EPA's Strategic Plan; the Administration's priorities; Congressional mandates; BOSC reviews; Science Advisory Board (SAB), National Academy of Sciences (NAS), and other external advice; stakeholders; and NPDs. The NPDs and the leadership of the laboratories and centers develop a research plan, which is submitted to the ORD Executive Council for review and approval. The research is conducted, and the results are communicated to the public and clients. Evaluation is an essential part of this process. Dr. Branch asked if the Subcommittee was supposed to perform the review and evaluation functions simultaneously. Dr. Rodan confirmed that the Subcommittee should do both simultaneously. The report that the Subcommittee produces will include recommendations for future research.

Implementing an ORD evaluation framework ensures that the research being conducted will ultimately lead to an output that will affect outcomes. Each program develops an MYP that includes LTGs. After the LTGs are generated, Annual Performance Goals (APGs) that will allow the program, over time, to achieve the LTGs, are generated. Annual Performance Measures (APMs) are developed for each of the APGs. APMs are the metrics and measures for each goal. These procedures encourage accountability across ORD.

ORD's research includes both program-targeted research, which is research that relates to one research program or a single priority, and cross-program research, which is research that goes beyond a single issue. One example of cross-program research would be nitrogen as it is an issue for both clean air and clean water.

BOSC program reviews are intended to help answer two primary questions: (1) Are we doing the right science? and (2) Are we doing the science right?

The Program Assessment Rating Tool (PART) was developed under the previous Administration and administered by the Office of Management and Budget (OMB) to evaluate federal programs. Although the PART is changing under the new Administration, ORD's research programs will continue to operate under performance accountability oversight. Dr. Amar asked if the Subcommittee should use the existing PART in its review of the Program. Dr. Rodan responded that the changes to the PART will not affect the work of the Subcommittee. The BOSC Subcommittees will continue to provide qualitative ratings to ORD on a four-level scale for each program's LTGs.

R&D criteria related to relevance, quality, and performance were developed by OMB and the Office of Science and Technology Policy (OSTP) to provide guidance for research and development investments. These three criteria are central to the structure of the Subcommittee's charge.

There is general recognition within ORD that the research must adapt to changing circumstances. New environmental problems are emerging, science is rapidly changing, and new tools are being developed to address environmental problems. ORD recognizes that science is interlinked and is committed to using its large cadre of experience and capabilities to address these issues.

Overview of Charge/Rating Program Performance

Dr. Kenneth Demerjian, Atmospheric Sciences Research Center, Subcommittee Chair Ms. Mya Sjogren, Accountability Team Leader, ORD

Dr. Demerjian stated that the Subcommittee members already had discussed the review objectives, the charge questions, and rating program performance. All of the materials related to these topics are located in Tab A of the binder. The Subcommittee's review of the Clean Air Research Program will be based on its effectiveness in meeting its LTGs, which are:

LTG 1 – Reduce uncertainty in the science that supports standard setting and air quality management decisions.

LTG 2 – Reduce uncertainties in linking health and environmental outcomes to air pollution sources.

Ms. Sjogren explained that in 2007, ORD asked the BOSC to begin rating the performance of programs in completing their LTGs. This Subcommittee is charged with assessing the progress made by the Clean Air Research Program in achieving its LTGs in terms of quality, relevance, and performance. The qualitative ratings and their definitions are found in Tab A of the Subcommittee's materials. The ratings are important, but even more important is the narrative feedback given to programs because this information is used to enhance program performance. She asked the Subcommittee members to refer to those definitions when rating the program. Based on previous feedback from the BOSC Executive Committee, it is recommended that the Subcommittee wait until after the face-to-face meeting to rate the program. If there are any questions during the BOSC review process, Ms. Sjogren said she will be happy to answer them.

Overview of ORD's Clean Air Research Program

Dr. Dan Costa, NPD, Clean Air Research Program

The Clean Air Research Program is a multidisciplinary, problem-oriented research program that relies on coordinated and leveraged science to better understand and reduce the risks associated with air pollution.

The Subcommittee has been provided with targeted and informative materials to assist with the review of the Clean Air Research Program. The rating and narrative comments provided by the Subcommittee will be very helpful in shaping the future direction of the Program.

Posters presented at the face-to-face meeting will focus on either program design (Is the Program moving in the right direction? Is the Program making an appropriate shift toward multi-pollutant? Is the Program integrating as much as possible?) or program performance (Is the science/program balance appropriate? Is the Program meeting its goals in terms of quality, relevance, performance? Is the Program meeting stakeholder needs? Is the Program making a difference? Is the Program enhancing public health?). The posters will take a larger perspective, including both intramural and extramural research, and look across programs. Each poster presents a programmatic science question and the most accurate answer based on

the current state of the research. The Clean Air Research Program leaders would like to know if the research is appropriately balanced between the two LTGs.

Prior to 1998, ORD had a Gases and Particles Program. In 1998, Congress added \$22.4 million per year to EPA's PM Research Program budget to expand both intramural and extramural research, establish an NAS/NRC expert panel on research priorities, expand the STAR PM grants program, and coordinate the PM work across all federal agencies. In 2005, the PM and Ozone Program, as it was called at the time, was reviewed by the BOSC. The BOSC review initiated a programmatic shift to pollutant sources. In 2007, PM and ozone were combined with air pollutants. The Clean Air Research Program was officially established in 2008.

NRC reports produced between 1998 and 2004 detailed research priorities for airborne PM with a focus on protecting human health. The NRC's 2004 report broadened the focus to the more general topic of air quality management, with a focus on health and other benefits of air quality. The NRC identified 10 PM research priorities, to which the Clean Air Research Program added technical support-atmospheric measurements and methods and source-to-health outcomes. This is the basic structure that the Program has been operating under since 2005.

Research priorities are established in a number of ways. NRC subcommittees, a research coordination team representing the Program's clients, the SAB, the BOSC, laboratory/center reviews, and the public all provide guidance in establishing the Program's research priorities. Information from clients is used to inform the development of the MYP. The MYP then goes to the ORD Executive Council where a budget is drafted. The draft budget goes to the EPA Administrator and ultimately is submitted by the President to Congress.

The Clean Air Act presents the Clean Air Research Program with the primary mandate for its work. Reviews of all of the National Ambient Air Quality Standards (NAAQS) air pollutants are occurring simultaneously. PM is still a major focus of the Program, but PM funding is leveraged to support ozone, outcomes, and source-to-outcomes research. The Program conducts some indoor air research as well. Study of host factors (e.g., age, disability, gene-environment interaction) is an emerging research area.

The 2008 revised Clean Air Research Program MYP combined PM, ozone, and air toxics research under one Program. The Program takes multidisciplinary approaches whenever possible and is working to better communicate its results. New methods are being used to communicate the Program's progress toward achieving the APMs. In addition, the Program works closely with regulators on some of their public health outreach activities.

Why a source-to-health outcomes approach? This approach recognizes that health outcomes are linked to sources via interconnected biological, chemical, and physical behaviors. The prototype source-to-health outcomes approach is the near roadway studies. Some of the health outcomes that have been ascribed to road proximity include asthma, birth defects, cancer, and cardiovascular outcomes. The goal is to connect exposure and health implications.

The Clean Air Research Program works with regions and states; universities; the Health Effects Institute (HEI); other federal agencies, including the Federal Highway Administration, the National Oceanic and Atmospheric Administration (NOAA), the National Heart, Lung and Blood Institute (NHLBI), and the National Institute of Environmental Health Sciences (NIEHS); and may work in the future with the American Petroleum Institute. In addition to these partners, Dr. Costa co-chairs the Committee on the Environment and Natural Resources' Air Quality Research Subcommittee. A funders group representing the Clean Air Research Program, HEI, and NIEHS is developing a database that will allow researchers to share information about their research projects and better leverage their work.

Since 1998, the annual budget for the Clean Air Research Program has been approximately \$80 million. Considering inflation, that is essentially a reduction of approximately 40 percent in buying power over that time period. The number of FTEs supporting the Program has decreased approximately 20 percent since 1995. The budget allocations have been slowly shifting to emphasize source-to-health outcomes and the multi-pollutant perspective. In the past, 60 percent of the budget has been allocated to supporting LTG 1 and 40 percent to supporting LTG 2. After 3 or 4 years, it is expected that this will reverse. The Clean Air Research Program is working to expand the application of air quality models. Models have matured and now are able to measure air quality in smaller increments. As the Program focus shifts to a multi-pollutant approach, models will be developed to link atmospheric measurements to health outcomes, with the ultimate goal of improving health outcomes.

The Clean Air Research Program's scientific leadership is recognized worldwide and EPA's PM research has had significant regulatory benefits and impacts. The PM NAAQS have accounted for 63 to 88 percent of all of the benefits attributable to federal regulation and have resulted in a cost savings of between \$63-\$430 billion over the time period 1996-2006. For that same time period, the cost of NAAQS ranged between \$25-\$28 billion.

Discussion

Dr. Ira Tager asked if the focus will remain on PM as the Program begins to consider the full blending of that research with the ozone and air toxics research. Dr. Costa responded that the Program's resources are mostly driven by PM, so it will always have high visibility. That said, the Program works to leverage the PM resources to study related pollutants as well. Dr. Demerjian asked about recent discussions on ozone standards. Will the Program be able to reduce ozone uncertainties? Dr. Costa responded that recent ozone studies have shown both chronic and acute health impacts from ozone, particularly related to mortality. Dr. Amar asked if the term "reducing uncertainty" was referring to the explicit mathematical interpretation or was it being used in a more general sense. Dr. Costa confirmed that the term was being used in the general sense.

Public Comment

Ms. Heather Drumm, EPA/ORD, Subcommittee DFO

At 12:15 p.m., Ms. Drumm called for public comments. No comments were offered.

Preparation for Next Call and Face-to-Face Meeting

Dr. Kenneth Demerjian, Atmospheric Sciences Research Center, Subcommittee Chair

The next conference call will be held on Friday, May 29, 2009. Prior to the call, Dr. Demerjian or Ms. Drumm will send proposed Workgroup assignments to all of the Subcommittee members. Dr. Demerjian asked the Subcommittee members to review the face-to-face meeting agenda and the materials received yesterday to prepare for the upcoming call. The call will include presentations on the LTGs across the three programmatic areas and discussion of the Workgroup assignments.

Dr. Costa said that the PM Center Directors had asked him to query the Subcommittee members about the types of questions they may have for the Directors at the face-to-face meeting. The 30-minute session with the PM Center Directors will be an opportunity to determine how the Centers function within the Clean Air Research Program and within EPA and to determine if the Agency is assisting them in meeting their objectives. Would a different structure better facilitate their research? Is EPA is using their expertise in the most effective and efficient way? Dr. Demerjian said that the Subcommittee would like to know how the PM Centers are contributing to meeting the Program's LTGs.

Dr. Amar asked if the Subcommittee members would be expected to stay after the last session of the faceto-face meeting to write their sections. Dr. Demerjian replied that it would not be necessary for the Subcommittee members to stay after the meeting to write their sections. Ideally, he would like to receive the members' written sections within 2 weeks after the face-to-face meeting.

Dr. Demerjian thanked everyone for their participation and adjourned the call at 12:45 p.m.

Action Items

✤ Dr. Demerjian or Ms. Drumm will send the Subcommittee members a list of proposed Workgroup assignments.



PARTICIPANTS LIST

Subcommittee Members

Kenneth Demerjian, Ph.D., Chair Atmospheric Sciences Research Center State University of New York

Praveen Amar, Ph.D., P.E. Northeast States for Coordinated Air Use Management (NESCAUM)

Tina Bahadori, D.Sc. American Chemistry Council

Melvyn Branch, Ph.D. Mechanical Engineering Department University of Colorado

Bart Croes, P.E. California Air Resources Board

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

Rogene Henderson, Ph.D. (not present) Lovelace Respiratory Research Institute

Jonathan Levy, Ph.D. Department of Environmental Health Harvard University

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

Ira Tager, M.D., M.P.H. School of Public Health University of California, Berkeley

Gregory Yarwood, Ph.D. Environ International Corporation

Designated Federal Officer

Heather Drumm Office of Science Policy

EPA Participants

Jeff Arnold, Ph.D. National Center for Environmental Assessment

Dan Costa, Sc.D. National Health and Environmental Effects Research Laboratory

Bob Devlin, Ph.D. National Health and Environmental Effects Research Laboratory

Stacy Katz National Center for Environmental Research

Bruce Rodan, M.D. National Center for Environmental Assessment

Laurel Schultz National Health and Environmental Effects Research Laboratory

Mya Sjogren Office of Resources Management and Administration

Alan Vette, Ph.D. National Exposure Research Laboratory

Tim Watkins National Exposure Research Laboratory

Contractor Support

Jen Hurlburt The Scientific Consulting Group, Inc.



CLEAN AIR SUBCOMMITTEE

Agenda May 21, 2009 10:00 a.m. – 12:30 p.m. EST

Participation by Teleconference Only 866-299-3188 Code: 2025648239#

ADMINISTRATIVE CALL (Closed to the Public)

10:00 – 10:15 am	Welcome - Introduction of Subcommittee Members - Overview of Subcommittee Objectives	Dr. Ken Demerjian, Subcommittee Chair
10:15 -10:30 am	Administrative Procedures - FACA Refresher - What to Expect - Roles and Responsibilities	Ms. Heather Drumm, Office of Research and Development (ORD)
PUBLIC CALL	-	
10:30 – 10:40 am	Welcome - Introduction of Subcommittee Members - Overview of Subcommittee Objectives - Overview of Agenda	Dr. Ken Demerjian, Subcommittee Chair
10:40 – 10:45 am	BOSC DFO Remarks	Ms. Heather Drumm, ORD
10:45 – 11:00 am	Materials Overview	Dr. Dan Costa, Clean Air National Program Director, ORD
11:00 – 11:30 am	ORD Overview Dr. Bruce Rodan, Senior Science Advisor, ORD	
11:30 – 11:45 am	Overview of Charge/Rating Program Performance	Dr. Ken Demerjian, Subcommittee Chair & Mya Sjogren, Accountability Team Leader, ORD
11:45 – 12:15 pm	Overview of ORD's Clean Air Program	Dr. Dan Costa, Clean Air
12:15 – 12:20 pm	Public Comment	
12:20 – 12:30 pm	Preparation for Next Call and Face-to-Face Meeting - Discuss Workgroup Assignments - Identify Additional Information Needs	Dr. Ken Demerjian, Subcommittee Chair
12:30 pm	Adjourn	