B•O•S•C
BOARD OF SCIENTIFIC COUNSELORS

CLEAN AIR SUBCOMMITTEE

Conference Call Summary
Monday, July 27, 2009
1:00 p.m. – 3:00 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, welcomed the Subcommittee members to the teleconference and thanked participants for attending the call. He stated that the purpose of the call was to review the first draft of the Clean Air Research Program Review Report. The goal is to identify any gaps in the draft report and discuss additional information that should be included in the final version of the report.

BOSC DFO Remarks

Ms. Heather Drumm, EPA/Office of Research and Development (ORD), Designated Federal Officer (DFO)

Ms. Drumm asked ORD employees to introduce themselves and then reviewed Federal Advisory Committee Act (FACA) procedures, which are required for all BOSC Subcommittee meetings. She explained that all BOSC meetings and teleconferences involving substantive issues, whether in person, by phone, or by e-mail, which include one-half or more of the Subcommittee members, must be open to the public, and there must be an opportunity for public comment. Although no member of the public has requested time for comment, the public will have an opportunity for comment during this teleconference at 1:55 p.m.; public comments are limited to 3 minutes each. As the DFO, Ms. Drumm ensures that all FACA requirements are met and that records of board deliberations are made public. The minutes are being recorded by a contractor, Nanci Hemberger from The Scientific Consulting Group, Inc., who will prepare a summary of the meeting. Following review by the Subcommittee members and certification by the Chair, the summary will be made available to the public on the BOSC Web Site (http://www.epa.gov/osp/bosc). In accordance with FACA requirements, a notice of this conference call was posted in the *Federal Register*. The meeting materials can be accessed at the BOSC Web Site. Ms. Drumm has ensured that all appropriate ethics regulations have been satisfied, and she asked that Subcommittee members inform her if they discover a potential conflict of interest regarding any topics under discussion during this call.

This conference call was convened to discuss the draft review report of the Clean Air Research Program. Ms. Drumm noted that Subcommittee members should have received two draft reports; one report was sent by Dr. Demerjian, and a second report, which included line numbers to help the members review and discuss the report more easily, was e-mailed to Subcommittee members on Friday, July 24, 2009, and is dated July 27, 2009.

Ms. Drumm said she had heard some static and echoing on the line so she encouraged participants to use the mute function during the teleconference. She also asked the Subcommittee members to identify themselves for the record when speaking.

Executive Summary
Dr. Kenneth Demerjian, Subcommittee Chair

Dr. Demerjian stated that the draft report is organized by the charge questions. The names of contributors and the color-coded sections, which currently appear in the report to assist the Subcommittee members in reviewing the material, will not be included in the final draft. He compiled the materials provided by the working groups and task leaders and drafted the report in a way that was consistent with the BOSC review. He then developed the executive summary, which consists primarily of conclusions and recommendations. The executive summary is drawn from both text and input from Subcommittee members as they addressed the charge questions and Long-Term Goals (LTGs).

Dr. Demerjian asked the Subcommittee members if they had considered the conclusions in the draft and whether they had any comments or changes. He noted that he had done some preliminary editing on the conclusions to consolidate material. Currently, there are 18 conclusions in the report, and there still may be duplication. The Subcommittee may want to consolidate them into fewer conclusions so that they have a greater impact. In addition, several of the conclusions are single sentences and need additional text to explain the Subcommittee's position.

He wrote several recommendations based on the responses to the charge questions; he urged the Subcommittee members to discuss the recommendations, edit them as needed, and suggest additional recommendations as appropriate. The recommendations were not discussed as thoroughly at the last meeting as the charge questions; therefore, members also should consider them carefully and provide comments for the final version of the report.

Dr. Ira Tager suggested that the recommendations be prioritized. Several recommendations, such as methods development, were mentioned frequently and would be considered top priorities. The top priority or top-tiered recommendations will be key items for consideration within the reality of budget issues and resource constraints, and likely would include ozone and hazardous pollutant issues.

Dr. Rogene Henderson noted that the executive summary should include the ratings for LTGs 1 and 2 after the Subcommittee reaches a consensus on the ratings. In the 2005 review report, the ratings were embedded after the LTGs, but because summary recommendations are a key part of the charge process, she suggested that they be placed at the beginning of the report. Dr. Demerjian responded that he did not include the ratings in the current report because he was not sure what the Subcommittee had decided regarding the ratings. Dr. Dan Costa commented that he did not think the rating process was in place during the first program review.

In general, the Subcommittee members agreed that the recommendations should be prioritized, which will eliminate any overlap or duplication as well as provide better focus on the clean air message and possible future goals. Recommendations 1 through 3, which are brief single statements, probably should include more context. Regarding Recommendation 7, Dr. Henderson commented that ORD rarely if ever "shies away" from reporting results for any reason; therefore, the basis for this recommendation needs to be explored. Dr. Henry Felton explained that this recommendation is based on the problems created by researchers who are reluctant to report unsuccessful experiments and research when applying for grants; this frequently encourages duplicate experimentation by researchers unaware of prior unproductive research. Documentation of past research, particularly the methods used, however unsuccessful, could save scientists time and effort. Several members thought this recommendation should be more specific and possibly include an example; Dr. Felton replied that, if the recommendation seems too general to Subcommittee members, it could be deleted.

Dr. Jonathan Levy noted that Recommendation 3, regarding pursuing the multi-pollutant approach rather than setting a National Ambient Air Quality Standard (NAAQS) for every compound, also needs to be discussed because EPA is mandated to continue to set NAAQS for compounds. He added that

Recommendation 1 addresses low-threshold ozone research, but research on low-concentration particulate matter (PM) and other pollutants also should be included.

Dr. Praveen Amar suggested that text rather than numbers be used for either the recommendations or the conclusions rather than using numbering for both lists. Ms. Drumm responded that the guidelines agreed on at the most recent Executive Committee (EC) meeting advised using numbers when listing recommendations. The EC also recommends highlighting two or three recommendations for each charge question, followed by a table that includes all of the recommendations. Dr. Henderson said that including fewer recommendations in order of priority would be much more effective than the way the recommendations currently appear in the draft report.

Dr. Tager noted that there was a robust discussion at the June 8-10, 2009, meeting concerning the meaning, either operationally or conceptually, of multi-pollutant. Subcommittee members may want to consider including a recommendation regarding how to define multi-pollutant or offer a definition of the term. Dr. Henderson said that the italicized text on page 31 of the draft report reflected what Subcommittee members had agreed upon specifically (i.e., there had been a great deal of discussion but no conclusion reached regarding the definition of multi-pollutant). Page 11 of the draft report also includes a brief discussion of the multi-pollutant approach.

Dr. Tager asked if the Subcommittee members thought that defining multi-pollutant was a priority and warranted a recommendation in the Executive Summary; this would alert readers that the Subcommittee members think that the term requires some context in how it relates to air quality management and health outcomes. The first four conclusions address multi-pollutant issues, but the conclusions are inconsistent; some consolidation may be necessary.

Dr. Tager suggested that it might be helpful to include a labeled or numbered recommendation after each specific conclusion as this would provide a direct connection between the summary and the recommendations. Dr. Demerjian agreed and said that Conclusion 11, for example, could be divided so that the second part of that paragraph, which concerns the Regional Applied Research Effort (RARE) Program, becomes a recommendation. This would shorten the conclusion and emphasize the need for the RARE Program to work more effectively. Conclusion 11 should emphasize that stakeholder needs are, in fact, being met rather than comparing the RARE Program and stakeholder needs equally.

There are several places in the conclusions where methods development is mentioned. In such cases, there may be more than one recommendation for the conclusion, and similar recommendations may be relevant to several conclusions.

Regarding Conclusion 13, Dr. Demerjian asked if there are any other funding mechanisms besides the Science To Achieve Results (STAR) Program; if not, the text should be revised. Ms. Stacey Katz noted that the Health Effects Institute (HEI) Research Program, which is not part of the STAR Program, is another funding source for air pollution researchers, so the wording is appropriate.

Dr. Demerjian requested that the Subcommittee members review the conclusions that they have written and consider ways to shorten the text. Currently, the conclusions account for 5 pages of the report, which may be too long for the Executive Summary. Also, Subcommittee members should highlight what they consider to be the top three or four recommendations in the report; additional recommendations also can be added to the report. Dr. Demerjian said that he made only minor edits to the text, so Subcommittee members should recognize the conclusions they submitted.

LTG 1: Health and Exposure Overview
Dr. Jonathon Levy, Department of Environmental Health, Harvard University, Subcommittee Member

Dr. Levy said that he is still working on this section, which he views as an amalgamation of the four charge questions. He added that he is paying particular attention to avoid writing material that contradicts the section that addresses the charge questions. Currently, the health and exposure overview has a range of ratings rather than a single rating. More material is being developed to answer questions and link with the program design section. Dr. Levy noted that he was unclear about the required length and the degree of focus for the broad-based conclusions but believes the text informs the rating well. Part of this section focuses on developing NAAQS, the necessary elements for the implementation phase, and improving air quality decision making. The beginning of this section in particular addresses the types of information needed to set NAAQS, and how the research agenda dovetails with those needs.

Dr. Demerjian asked the Subcommittee members to consider the rating Exceeds Expectations and whether enough material and examples have been presented to justify the rating. Dr. Tager noted that there are several negative comments toward the end of this section regarding methods development. Should these comments be moved to the beginning of the section? The Subcommittee members agreed that the negative comments on methods development should be placed at the beginning of the section. Dr. Murray Mittleman suggested that areas such as Community Multi-Scale Air Quality (CMAQ) model development, several emission categories, and air quality climate change interactions, which were rated exceptional, be noted at the beginning of the section.

Resource and personnel constraints often have adverse effects on research initiatives. The conclusion section could include a discussion of such limitations and offer examples of research that was well funded or initiatives that were hampered because of a lack of funds. Dr. Demerjian suggested that the Subcommittee be more proactive concerning its recommendations for methods development LTGs so that ORD better supports its client base. He also remarked that because funding allocations often are not readily known, it may be prudent not to comment on resource requirements and provisions. Instead, the recommendations will focus on data and research needs rather than resource needs.

LTG 1: Air Quality Overview
Mr. Bart Croes, California Air Resources Board, Subcommittee Member

Mr. Croes stated that the focus of this section was on the content of the posters, which were presented during the June 8-10, 2009, face-to-face meeting. The poster session was organized around four topics—ambient emissions, source emissions, air quality modeling, and extended applications of methods and modeling.

Concerning source emissions, one unresolved issue involves the PM program and how much of the work being done in criteria pollutants falls under a research category and how much falls outside of research. In the air quality modeling category, CMAQ is the model of choice throughout the country; CMAQ development continues to be impressive, and researchers have been able to address climate change and total nitrogen deposition within the CMAQ model.

Mr. Croes said that he believes the information in this section supports the rating of Exceeds Expectations; several areas of excellence are acknowledged in the report. Dr. Demerjian thought this section was very thorough. Dr. Levy asked if each section should include the same level of detail as this one; currently, there is some imbalance regarding section lengths and detail of discussion. Subcommittee members may want to condense their sections by focusing on the most salient points, adding necessary emphasis and urgency to the recommendations. Dr. Henderson noted that it was her understanding that the evaluations of the LTGs and their progress would be condensed, while the charge questions would provide greater detail. One source of confusion is that the LTG 1 charge questions had sub-questions associated with them, which Mr. Croes and his group attempted to answer in the air quality review section based on the review of the posters presented at the June meeting. In comparison, there was less material to review and fewer sub-questions to answer for LTG 2. Dr. Gregory Yarwood commented that the section highlights areas in which ORD is performing excellent work; he thought these examples were integral to this section and should remain in the document.

Members debated whether discussions concerning the quality of the research should be included in the charge questions section that addresses the relevance and quality of research. The LTG sections of the document could offer concise summaries of whether programs met their LTGs and how they accomplished these goals. In addition, the LTG sections include ratings. Dr. Amar noted that in the Air Quality Overview section, the goals are quite different. One goal is based on work already accomplished. The second goal is evolving and still being defined; the collective assessment should be based on whether the program is headed in the most effective direction.

Dr. Tager stated that it may be helpful to add a summary paragraph to this section that would merge all of the evaluative material presented on the posters. Mr. Croes said a brief summary paragraph is included, but it is not a complete summary of the category.

Public Comment

Ms. Heather Drumm, EPA/ORD, DFO

Ms. Drumm called for public comment at 1:55 p.m. No comments were offered.

LTG 2: Source-to-Health Outcomes

Dr. Ira Tager, School of Public Health, University of California, Berkeley, Subcommittee Member

Dr. Tager thought the overall recommendations were valuable but he would like an operational definition of multi-pollutant included in the conclusion section. He acknowledged that multi-pollutant may be defined differently depending on the issues (e.g., health outcomes, hazardous air pollutants, PM). Defining multi-pollutant will provide resolution and guide both the research and the support of the NAAQS.

Currently, the draft report notes that "a working definition of multi-pollutant has not been agreed upon by all . . . interested partners." Dr. Tager noted that this text could be moved into the conclusion section and highlighted as an issue that must be monitored for progress and resolved soon to motivate future research. Dr. Amar said that it must be clear to readers that multi-pollutant is not well defined for any research area.

In response to Dr. Henderson's question about giving a higher rating, Dr. Tager proposed that the rating remain Exceeds Expectations. He noted that future research likely will face many hurdles. After new research results are available, a rating of Exceptional may be warranted. Dr. Demerjian asked if there was enough material under the LTG 2 section to support the rating. Dr. Tager suggested adding a portion of the relevance section, which includes direct citations to presentations, to the LTG 2 section; Dr. Demerjian agreed with this suggestion.

Program Assessment

Dr. Murray Mittleman, Beth Israel Deaconess Medical Center, Subcommittee Member

Dr. Mittleman thought the draft report was balanced overall, but several sections need supplemental material. He agreed to send the additional text to Dr. Demerjian to be included in the next draft.

Specifically, the resource issue, which is the final question under Charge Question 1 (page 14 of the draft report), must be addressed. One critical aspect of this issue is the possible reallocation of funds and how resource allocation will affect methods development, and how to better balance declining resources among programs, particularly those related to methods development.

Another area that is tied to resource allocation is Question 2 under Charge Question 1 (page 13 of the draft report), which addresses leadership and program management. Dr. Mittleman noted that there is strong overall leadership within the Clean Air Research Program regarding resources for planning and implementation. Reallocation, however, can provide funding for methods development work that was previously funded when more resources were available.

Dr. Demerjian explained that initially the Clean Air Research Program was intended to cut across laboratories, and funding was to be allocated to the Program, which then would disperse the money to the laboratories that were involved. This, however, is not how funding currently is distributed. Instead, each laboratory or division has a budget, and the Clean Air Research Program must broker with the various laboratories/divisions for their participation to meet the LTGs of the Program. This arrangement creates challenges that could impact LTG 2 in the future as well as the connection between modeling work and multi-pollutant research. Dr. Demerjian asked members if this budget constraint should be presented in the report and if so, where in the document it should be included. Members strongly agreed that it should be included in the report. Dr. Henderson suggested that it be addressed in the conclusion as an example of a difficult managerial environment that could have negative ramifications on the Clean Air Research Program. Dr. Mittleman agreed to draft this text.

Dr. Amar said that he would like to include text on ammonia emissions, perhaps as a recommendation. He also suggested that the report address the use of satellite data for integrated modeling. The draft report contains some information on these topics (page 7, Line 15 in the draft report). Dr. Demerjian recommended condensing this section. Dr. Amar suggested that the paragraph be divided into two parts—some text will be framed as a recommendation, and the rest of the text will be incorporated into the conclusion.

Final Draft Preparations

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

Dr. Demerjian stated that he realized that the Subcommittee members may not have had enough time to analyze the draft report completely. He encouraged everyone to review the report in detail and provide him with comments as soon as possible, particularly on changes to the sections that they drafted. As members review the document, they should note any redundancies. The conclusions and recommendations sections should be evaluated carefully to ensure that these sections address the concerns discussed during today's teleconference. He reminded the Subcommittee members that the goal is to produce a document that represents the Subcommittee consensus.

Dr. Demerjian asked the Subcommittee members to send him changes and additional text by Monday, August 10, 2009. He will make edits and distribute the revised draft to Subcommittee members by the end of the week. Ms. Drumm said that the final draft should be sent to the EC by the beginning of September so that it is included on the agenda for review at the September meeting. After the EC reviews the document, the Subcommittee members may need to respond to questions regarding the report and revise the report as needed. After it is approved by the EC, it is sent to the Assistant Administrator for ORD along with a transmittal letter from the BOSC Chair.

Charge Question 3 is being written by Dr. Tina Bahadori. Dr. Demerjian expects to contact her regarding the specific issues that need to be addressed in that section.

In response to a question from Ms. Drumm, Dr. Demerjian replied that the technical issues had been sufficiently addressed during the teleconference. Ms. Drumm suggested reserving a time slot for another conference call during the week of August 24 to review the revised report. If Subcommittee members determine that a call is not needed, it can be cancelled. Ms. Drumm agreed to send an e-mail to the Subcommittee members regarding their availability that week, after which a date and time for a possible teleconference will be determined.

Dr. Demerjian thanked the Subcommittee members and the EPA staff for their participation. He then adjourned the meeting at 2:50 p.m.

Action Items

- ✧ Subcommittee members will review the draft of the *Review of the Office of Research and Development's Clean Air Research Program* and send comments, revisions, and edits to Dr. Demerjian by August 10, 2009.

- ✧ Dr. Mittleman will draft text concerning the possible impact of budget constraints on the Clean Air Research Program and the difficult managerial environment such constraints create; he will send the text to Dr. Demerjian.

- ✧ Dr. Demerjian will make edits to the draft report based on revisions and new material from Subcommittee members; he expects to distribute a revised draft to Subcommittee members by August 14, 2009.

- ✧ Dr. Demerjian will contact Dr. Bahadori concerning additional text for Charge Question 3.

- ✧ Ms. Drumm will send an e-mail to Subcommittee members inquiring about their availability for a teleconference during the week of August 24, 2009.

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BOARD OF SCIENTIFIC COUNSELORS

CLEAN AIR SUBCOMMITTEE

CONFERENCE CALL AGENDA
July 27, 2009
1:00 p.m. – 3:00 p.m. Eastern Time

Participation by Teleconference Only
866-299-3188
code: 202-564-8239#

1:00–1:05 p.m.	Welcome - Overview of Agenda - Report Status	Dr. Ken Demerjian Clean Air Subcommittee Chair
	BOSC DFO Remarks	Ms. Heather Drumm, Office of Research and Development (ORD)
1:05–1:15 p.m.	Executive Summary - Discussion	Dr. Ken Demerjian Clean Air Subcommittee Chair
1:15–1:35 p.m.	LTG 1 - Health Effects and Exposure - Overview - Discussion	Dr. Jonathan Levy Workgroup Lead Clean Air Subcommittee
1:35–1:55 p.m.	LTG 1 - Air Quality - Overview - Discussion	Mr. Bart Croes Workgroup Lead Clean Air Subcommittee
1:55–2:00 p.m.	Public Comment	
2:00–2:20 p.m.	LTG 2 - Source to Health Outcomes - Overview - Discussion	Dr. Ira Tager Workgroup Lead Clean Air Subcommittee
2:20–2:40 p.m.	Program Assessment - Overview - Discussion	Drs. Murray Mittleman/ Praveen Amar Workgroup Leads Clean Air Subcommittee
2:40–3:00 p.m.	Final Draft Preparations	Dr. Ken Demerjian Clean Air Subcommittee Chair
3:00 p.m.	Adjourn	

Appendix B: Roadmap to the Evidence of Addressing the Charge

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

DRAFT VERSION
JULY 27, 2009

BOSC SUBCOMMITTEE ON CLEAN AIR RESEARCH

Kenneth L. Demerjian (Chair) – State University of New York
Praveen Amar – Northeast States for Coordinated Air Use Management (NESCAUM)
Tina Bahadori – American Chemistry Council
Melvyn Branch – University of Colorado
Bart E. Croes – California Air Resources Board
Henry Felton – New York State Department of Environmental Conservation
Rogene F. Henderson – Lovelace Respiratory Research Institute
Jonathan Levy – Harvard University
Murray A. Mittleman – Beth Israel Deaconess Medical Center
Ira B. Tager – University of California, Berkeley
Gregory Yarwood – Environ Internationa Corporation

EPA CONTACT

Heather Drumm, Designated Federal Officer

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BOSC Subcommittee: Clean Air Research Program Review

Credits Page

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Executive Summary

Overall Goals, Charge and Structure of the Review

Introduction and Background

The Board of Scientific Counselors (BOSC) conducts independent, retrospective and prospective expert reviews of ORD research programs on a periodic basis, typically every four to five years. This review process is consistent with the National Academy of Science recommendation that independent expert reviews are an effective way to evaluate federal research programs. This subject review document reports on 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 of this program (entitled at the time as the "Particulate Matter and Ozone Research Program") 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 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]).

The program review is guided by a set of charge questions developed by the ORD and coordinated with the BOSC Subcommittee Chair (Appendix B for Charge Questions to Subcommittee). The charge questions provided the basis for the Agency's preparation of the review materials and helped to focus the subcommittee 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(ref):

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 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. 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 subcommittee met in May 21, 2009 by conference call to discuss the proposed charge questions and scope of the review as well as provided an overview of EPA's ORD. On a second conference call on May 29, 2009, the Subcommittee was provided an overview of the Clean Air Research Program and briefed on the major elements of the research program organized by long term goals as identified in EPA's Multi-year Strategic plan. These briefings set the stage for the more detailed discussion that would follow at the face-to-face meeting to be held on June 8-10, 2009 in Research Triangle Park, NC. The Subcommittee Chair prepared a plan, identifying principal review and writing assignments for subcommittee members for discussion and suggested revision during the May 21 conference call. The plan was endorsed by the subcommittee and with road map to the evidence addressing the charge (Appendix B) provided the template for reviewing the extensive materials provided by ORD. The Subcommittee review plan identified work group leads and members to address each of the charge questions and the long term goals identified with the Clean Air Research Program within ORD's Multi-year Strategic Plan.

The subcommittee has addressed each charge question and provided a summary of its findings in terms of that highlight strengths and weaknesses of the program as well as provided a performance rating with narrative for each of the LTGs.

Background for the Clean Air Research Program

Provide a brief description of the Clean Air Research Program, age, overview of organizational structure, number of FTE and budget for the review timeframe, key clients/partners. See Appendix X (ORD factsheet) for more detailed ORD program background. A description of key inter- and intra-agency interactions with other government and non-government entities doing similar work and describe any leveraging. Needs to be drafted - KLD

Overarching Conclusions and Recommendations

The Subcommittee review and comments regarding the content of the Clean Air Research Program was 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 preparation of the road map to the evidence addressing the charge (Appendix B) provided the Subcommittee with a clear understanding of EPA's approach in organizing and integrating its multipollutant air research program and facilitated the Subcommittee efforts in performing the review. In the course of the subcommittee's program review and preparation of responses to the detailed charge questions the following overarching conclusions and recommendations were highlighted by the Subcommittee.

Conclusions

1. The Subcommittee 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 Programs) completed in August 2005 and the progress reported in Mid-Cycle BOSC review carried out in September 2007 and completed in March 2008. Both reports provided favorable reviews of the program. 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 multipollutant approach recommended by the NRC and now adopted by ORD.

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

3. The Subcommittee finds that ORD is doing a commendable job in their effort to move toward a multipollutant approach to air quality issues, but suggest that ORD proceed cautiously. This is based on the premise that there is a current inherent inability to predict if a

regulation might violate the "do no harm" principle as air quality managers contemplate a multipollutant regulatory framework. The intramural and extramural research into the health effects of exposure to mixtures of pollutants will provide the information necessary to determine if it is realistic to set health based multipollutant standards in the future.

4. The Subcommittee finds that near road emissions studies as a test for the implementation of the multipollutant approach is an excellent choice. These studies will provide data to help assess the role on mobile source emissions in the design of SIPs in response to the 24-hr PM-2.5 or future NO2 standard.

5. The Subcommittee finds that ORD research priorities are meeting the needs of the PM science and exposure community. Research results from its programs are being utilized by the NAAQS developers as well as by the State Agencies who 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.

6. The Subcommittee finds that ORD 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 recently been initiated 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 due to 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.

7. The Subcommittee finds that ORD is faced with on-going resource constraints which have forced the reduction of their research focus in several areas. Stakeholder needs are not being met as well as they could be in the areas of method development, standard setting, the identification of monitoring techniques for diesel emissions and for 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.

8. The Subcommittee finds that 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 which ORD provides in a forecast mode to determine if potential pollution reduction strategies are viable. 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.

9. The Subcommittee finds that 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 multipollutant in nature and not PM specific. One exception is an adequate APG in method development for state-of–the-science measurements for criteria pollutants and associated precursors in support on LTG 1.

10. The Subcommittee finds that the quality of the scientific research being conducted under the US EPA Clean Air Research Program is unquestionably outstanding, backed up by extensive publications, high citation rates and significant numbers of publications in high impact journals and some keys papers that are sentinel in the field. The high quality of the science was also evident in the review of the posters presented and in conversations with the scientists presenting the posters.

11. The Subcommittee finds that the ORD research is meeting stakeholder needs at the national level and the interactions between the ORD Clean Air Research Program and the OAQPS appear to be excellent. The Air Office representatives declared their dependence on the research of the Clean Air Research Program for informing the setting of NAAQS standards and the high number of citations from ORD supported work in the Criteria Document for particulate matter as important examples. In addition, ORD's role in the development and refinement of models such as CMAQ, MOVES, UNMIX, and PMF have been valuable for scientists and decision-makers at the state and federal level. 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. An example is the RARE program, which is an excellent one for sponsoring projects at the regional level. However, participation in the RARE program requires getting a mentor at the national level and incentives for potential mentors are lacking. This appeared to be a roadblock for some regional stakeholders. The survey of partners in their air program research involved relatively few respondents (<30), but the response was generally positive.

12. The Subcommittee finds that 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.

13. The Subcommittee finds that there was evidence of effective leveraging of resources and expertise through 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 are also strong interactions with other research institutions such as NIEHS, NHLBI and CDC to avoid duplicate efforts by these federal agencies. A good example is the MESA Air study, in which an existing cohort was leveraged to incorporate air pollution exposures in investigating cardiovascular outcomes. The Health Effects Institute is another example of the leveraging of EPA monies with monies from industry in a highly successful program to study mobile source emissions and health outcomes.

14. The Subcommittee finds that the air quality research component of the Clean Air Research Program (CARP) is quite diversified so as to meet the needs of a large client base of various EPA air program offices (OAR, OTAQ, OAQPS, etc.), and many local, state, and regional governments. It has produced many outputs (models, measurements, data analysis) that have been used in policy development and implementation, regulatory decision-making, and review of National Ambient Air Quality Standards (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 CARP. The research program has also performed well in terms of a second measure of success that involves the actual use of the research products of the ORD research program. The most successful example being the application of the ORD-developed Community Multiscale Air Quality Modeling Systems (CMAQ).

15. The Subcommittee finds that the air quality research component of CARP (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 CMAQ model at ORD and CMU (by incorporating the concept of volatility basis set), as well as coordinating this effort with EPRI-funded research is commendable. The renewed emphasis on improving estimates of biogenic emissions by developing MEGAN model and on use of satellite data to improve the temporal and spatial resolution of biomass burning emissions should help in better predictions of ozone and PM2.5 levels. However, the Subcommittee suggests 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 CARP before embarking on more extended but meaningful use of satellite data.

16. The Subcommittee finds that the extension of basic air quality research component to three areas: 1) ecosystem assessment, 2) finer exposure characterization, and, 3) climate-air quality interactions, has resulted in significant and useful outcomes. The extension of CMAQ to estimate contribution of atmospheric deposition of nitrogen and sulfur to sensitive ecosystems in the US is an excellent example of multi media 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 a good example of phasing the current research effort into multi pollutant, source to health effects paradigm. Finally, the intramural and extramural efforts in

investigating the climate-air quality interaction have been an extremely successful science program. 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" is an excellent example of application of outcomes of the CARP effort to policy development in the area of climate change-air quality interactions.

17. The Subcommittee finds that the CARP health and exposure research has made significant progress in understanding the public health implications of particulate matter exposure and the benefits of abatement strategies with respect to health and exposure research. Advancements in the CMAQ model are evident and provide a key modeling tool for quantifying the benefits of pollution abatement strategies. Attempts to nest higher-resolution models with CMAQ are also 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 has also advanced substantially in a limited number of years. While 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. Progress with respect to exposures and health implications for coarse particles has been more limited, with only one ongoing study addressing the important urban/rural question, raising questions regarding its general applicability.

18. The Subcommittee finds that 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, NV; Detroit, MI and Raleigh, NC. The Detroit DEARS study goes beyond measurement to health linkage through and 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. 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 (UFP) 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.

Recommendations

1. Initiate some low threshold Ozone research

2. Strengthen FRM / FEM method development

3. Continue to pursue multipollutant approach through source category regulation rather than by setting a NAAQS for every compound.

4. Provide a review of the existing data quality and the state of the measurement science for each NAAQS pollutant ahead of the review cycle.

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

6. More basic research on pollutant mixture exposure needs to be performed to support the design of multipollutant based emission regulations and ambient standards. Since 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.

7. 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. ORD should not shy away from reporting the results of studies when the expected results were not found or were inconclusive. It is exactly these small steps both forward and backward that will be used in the future to steer air quality research in a positive direction.

8. ORD's continued refinement of air quality models is actually one of the more efficient ways in which their research results are utilized to make air quality management decisions.

9. ORD should allocate some fairly small percentage of their resources to ascertain the state of the measurement science 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.

10. Emphasis on CMAQ development should focus on particulate matter mass and components and improvements in the chemistry and physics of organic aerosols (both primary and secondary aerosols), as well as characterization of anthropogenic and biogenic precursor emissions. Such developments have direct implications and near-term need by OAQPS and states in the preparation of PM2.5 state implementation plans (SIPs).

Charge Question 1. Program Design and Demonstrated Leadership[1] (**M. Mittleman,** T. Bahadori, M. Branch, B. Croes, H. Felton)

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:

1. 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

The Subcommittee finds that ORD has been extremely responsive to the most recent BOSC reviews of the Air Research Program. The most recent full BOSC review of the Air Research Program (then the Particulate Matter and Ozone Research Programs) was completed in August 2005. The review was quite favorable and provided an in-depth discussion of 10 conclusions and 9 recommendations centered on four charge questions and 2 LTGs. ORD provided a detailed response to the recommendations contained in the review in February 2006. After the 2005 review ORD combined the Particulate Matter, Ozone and Air Toxics research into a combined Air Research Program and revised the scope of its LTGs. A Mid-Cycle BOSC review of the combined Air Research Program was carried out in September 2007 (formally reported on in March 2008) with the charge to address ORD 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 included an executive summary and in-depth responses to each of the questions. Several of the questions address the responsiveness of ORD to the 2005 BOSC recommendations. 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 stakeholder's perception 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, the wording of two LTGs was revised and included pilot studies to test the source-to-health outcome framework. The Research Coordination Team has been active as a vehicle to solicit input and to coordinate with other federal agencies and states. The ORD has demonstrated its commitment to a balance of intramural and extramural research with review by the Research Coordination Team. 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 multipollutant approach recommended by the NRC and now adopted by ORD.

Charge Question 4 discussed by the Mid-Cycle Review team addresses the effectiveness of the integration of PM, Ozone and Air Toxics into one Air Research Program. The conclusion was that the integration provides a more holistic approach to reducing health outcomes. This BOSC subcommittee strongly supports this integration in response to the 2005 review; further details are presented in the discussion of the charge sub question below on the multipollutant approach.

Charge Question 6 asked the Mid-Cycle Review team to rate the progress made by the Air Research Program in moving the program forward in response to the 2005 BOSC Review. The rating provided was Exceeds Expectations and cited particularly the integration into an Air Research Program, the initial survey of stakeholders, efforts to link sources to health outcomes, and maintaining strong relationships with other federal, state and private organizations concerned with air quality research. Based on our review of the very recent program management of the Air Research Program, this BOSC Review Subcommittee concurs with this evaluation.

- Increasing emphasis on a multipollutant approach to ORD's air quality research

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

ORD is doing a commendable job in their effort to move toward a multipollutant approach to air quality issues. The intramural and extramural research into the health effects of exposure to mixtures of pollutants will provide the information necessary to determine if it is realistic to set health based multipollutant standards in the future. One of the reasons to proceed cautiously as air quality managers contemplate a multipollutant regulatory framework is the current inability to predict if a regulation might violate the "do no harm" principle. Once more of the basic research on pollutant mixture exposure has been performed, it will be easier to design multipollutant based emission regulations and ambient standards. Since 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.

The choice of near road emissions is an excellent choice as a test for the implementation of the multipollutant approach. State Agencies have been experiencing difficulty in their attempts to formulate realistic PM-2.5 SIPs that deal with non-attainment of the annual standard when mobile sources are a significant component of their pollutant mix. States 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 enough in some areas. Even more stringent regulations on mobile source emissions are likely to be necessary for the design of SIPs in response to the 24-hr PM-2.5 standard. Since only the Federal Government has the authority to fully regulate mobile sources, it is very sensible for the EPA to perform the research necessary to determine the significance of the source as well as to determine and implement control strategies.

- 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 by the 2005 BOSC Review Team, ORD conducted a client survey designed to assess the primary stakeholders' perceptions of and satisfaction with the ORD's role in the source to health outcomes process. The survey had responses from 28 of 54 solicitations from OAR, EPA Regional Offices and NCEA. In addition, a collection of examples and testimonials describing how ORD products and advice have been used.

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 most often cited as the products most often used. The overall quality, timeliness and responsiveness of research products were also rated well above average. Also rated high was the ability of ORD to provide the scientific needs to do the client's job. The weakest area in the survey was in the perception of ORD's flexibility to rearrange research priorities to accommodate partner needs, and in 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 ORD research priorities are certainly meeting the needs of the PM science and exposure community. These research results are already being utilized by the NAAQS developers as well as by the State Agencies who are responsible for implementing pollutant control strategies. It is also quite clear that ORD considers accountability to be an important component of this research priority. The source to health outcome 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.

ORD 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 recently been initiated 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 due to 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 on-going resource constraints which have forced them to reduce their research focus in several areas. Stakeholder needs are not being met as well as they could be in the areas of method development, standard setting, the identification of monitoring techniques for diesel emissions and for 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.

- Coordination and integration of research within and across the extramural and intramural programs to maximize the benefit from[1] 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 method development capabilities are less than they once were, but they have been reluctant to issue RFPs in this research area. There are many scientists and engineers who would jump at the chance 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.

2. Is the Clean Air Research program providing strong science leadership and program management in both research planning and implementation?

(No comment on this item)

3. 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

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

Regions utilize the models which 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 their 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 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. ORD should not shy away from reporting the results of studies when the expected results were not found or were inconclusive. It is exactly these small steps both forward and backward that will be used in the future to steer air quality research in a positive direction.

4. 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 due to 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 one Agency goal that is in LTG 1 but is not well supported by the APGs is method development. ORD should allocate some fairly small percentage of their resources to ascertain the state of the measurement science 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.

5. 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?

(No comment on this item)

Charge question 2. Science Quality[1] **(R. Henderson,** J. Levy, G. Yarwood)

- 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 the US EPA Clean Air Research Program is unquestionably outstanding. Over 650 publications have appeared since the 2005 review. The extensive bibliometric analysis of 2600+ 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 2600+ papers qualified as highly cited by the ESI and one third were published in high impact journals, which are journals that are cited with a high frequency. Over half of the papers were published in the top 21 journals as listed by ESI. Harvard, an EPA 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 was also evident in the review of the posters presented and in conversations with the scientists presenting 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 committee 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 particulate matter health risks. In a relatively short amount of time, ORD research has added substantially to the evidence base regarding the mechanisms of particulate matter health effects as well as the effects of composition and particle size.

However, there is concern 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, reflecting budgetary constraints. While 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 particulate matter, again, reflecting resource constraints, but recent meta-analyses of the time-series mortality literature as well as new multi-city studies have added to the evidence base and underpinnings of NAAQS revisions, and have provided indications of key next steps.

The question of the research meeting stakeholder needs requires a two-fold answer. At the national level, the interactions between the ORD Clean Air Research Program and the OAQPS appear to be excellent. The Air Office representatives declared their dependence on the research of the Clean Air Research Program for informing the setting of NAAQS standards. The high number of citations in the Criteria Document for particulate matter 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. The California Air Resources Board was also 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 PRD 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 RARE program, which is an excellent one for sponsoring projects at the regional level. However, participation in the RARE program requires getting a mentor at the national level and incentives for potential mentors are lacking. This appeared to be a roadblock for some regional stakeholders. The survey of partners in their air program research involved relatively few respondents (<30), but the response was generally positive.

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

The Subcommittee finds that 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 were 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 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 are also strong interactions with other research institutions such as NIEHS, NHLBI and CDC to avoid duplicate efforts by these federal agencies. The Health Effects Institute is an example of the leveraging of EPA monies with monies from industry in a highly successful program to reduce emissions from diesel engines.

The Clean Air Research Program also provides several examples of multi-disciplinary 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 is also evident in the near roadway program, which relies upon measurement and modeling capabilities for emissions and atmospheric dispersion that are then 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.

Charge question 3. Relevance[1] (**T. Bahadori,** I. Tager, P. Amar)

- 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?

INPUT FROM P. AMAR (sent to Tina for comment & input)

The air quality research component of the Clean Air Research Program (CARP) is quite diversified so as to meet the needs of a large client base of various EPA air program offices (OAR, OTAQ, OAQPS, etc.), and many local, state, and regional governments. It has produced many outputs (models, measurements, data analysis) that have been used in policy development and implementation, regulatory decision-making, and review of National Ambient Air Quality Standards (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 CARP. The research program has also performed well in terms of a second measure of success that involves the actual use of the research products of the ORD research program.

Relative to LTG 1 (reducing uncertainty in science that supports NAAQS and air toxics), ORD research has been well articulated and widely used in a timely manner by OAAPS in recent setting of ozone and fine particulate matter standards. The ORD-developed model, CMAQ, is being used with great success in developing State Implementation Plans (SIPs) to demonstrate attainment of ambient standards for ozone.

For fine PM 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 Subcommittee recommends that ORD give this research area a higher priority (consistent with developments in basic science of organic aerosols) because of an important and a near-term need by OAQPS and states to develop fine PM SIPs.

The recently revised process of NAAQS Review (April 2009), as presented by Ms. Lydia Wegman at the BOSC 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 Assessment (ISA) and Risk-Exposure Assessment (REA). This science-policy interface will need active participation of the ORD's CARP to inform the standard -setting process within EPA.

In the emerging extensions of the ORD research, ORD has also 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 (posters LTG1::35-36-37). The extension of CMAQ to estimate contribution of atmospheric deposition of nitrogen and sulfur to sensitive ecosystems in the US is an excellent example of the use of ORD outputs in multi media 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 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.

Charge question 4. Demonstrated Outcomes[1] (**P. Amar,** J. Levy, I. Tager)
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 (CARP): 1) air quality, 2) health and exposure, and 3) source to health outcomes/multipollutant strategies. As noted in various ORD presentations and write ups, the first two components relate to meeting the first long-term goal of reducing uncertainties in setting of NAAQS and in designing and implementing State Implementation Plans (SIPS) and other air quality management decisions. The third research component is more recent and reflects the emerging "source to health outcome" research paradigm. It addresses the second long-term goal of reducing uncertainties in linking public health effects to sources of air pollution and thus involves "multi pollutant" approach.

The air quality research component of CARP (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 CMAQ model at ORD and CMU (by incorporating the concept of volatility basis set), as well as coordinating this effort with EPRI-funded research is commendable. The renewed emphasis on improving estimates of biogenic emissions by developing MEGAN model and on use of satellite data to improve the temporal and spatial resolution of biomass burning emissions should help in better predictions of ozone and PM2.5 levels. However, the Committee recommends 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 CARP before embarking on more extended but meaningful use of satellite data.

The effort on quantifying emissions of NH3 from soils (fertilized and natural) and animal sources has made good progress including better understanding of bi-directional nature of ammonia fluxes and much better characterization of local and regional nature of deposition of ammonia emissions sources. However, a lot more needs to be done to obtain ammonia emission estimates at temporal and spatial scales that are compatible for CMAQ modeling of PM2.5 and ozone. The Committee recommends that CARP coordinate its efforts with current industry-funded research on CAFO (Concentrated Animal feeding Operations) sources at various universities.

The baseline ORD effort in developing new versions of CMAQ model incorporating new science and maintaining existing versions for use by client divisions within EPA and by state and regional US governments and 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 (operational, dynamic, diagnostic, and probabilistic) has already 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 has demonstrated its 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 in improving methods to use satellite data in a meaningful way (see above).

The extension of basic air quality research component to three areas: 1) ecosystem assessment, 2) finer exposure characterization, and, 3) climate-air quality interactions, has resulted in significant and useful outcomes. The extension of CMAQ to estimate contribution of atmospheric deposition of nitrogen and sulfur to sensitive ecosystems in the US is an excellent example of multi media 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 a good example of phasing the current research effort into multi pollutant, source to health effects paradigm. Finally, the intramural and extramural efforts in investigating the climate-air quality interaction have been an extremely successful science program. 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” is an excellent example of application of outcomes of the CARP effort to policy development in the area of climate change-air quality interactions.

From the perspective of health and exposure research, the Clean Air Research Program has made significant progress in understanding the public health implications of particulate matter exposure and the benefits of abatement strategies. Advancements in the CMAQ model (e.g., related to the treatment of secondary organics, as noted above) are evident and provide a key modeling tool for quantifying the benefits of pollution abatement strategies. Attempts to nest higher-resolution models with CMAQ are also 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 has also advanced substantially in a limited number of years. While 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 particulate matter). Thus, the CARP has unequivocally made significant progress in recent years regarding fine particulate matter.

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 fine particulate matter, with modest investment in ozone epidemiology and very limited consideration of air toxics. Regulatory impact analyses by US EPA and California Air Resources Board emphasize that the majority of the public health benefits of air pollution controls are generally attributable to fine particulate matter, with the impact of ozone less than that of particulate matter but far exceeding that of air toxics. This indicates that this distribution of resources is not illogical from the perspective of the charge question, but the committee was concerned (as was the committee in the last BOSC mid-cycle review) that more balance may be necessary going forward towards the “source to health outcome” 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 NOx or 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 committee 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 CARP’s research, “source to health outcome” 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, NV; Detroit, MI and Raleigh, NC. The Detroit DEARS study goes beyond measurement to health linkage through and 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. 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 volatile organic compounds in support of source apportionment, NAAQS for $PM_{2.5}$, O_3 and CO as well as 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 is 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 (UFP) 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 which is designed to meet this long-term goal. . The DEARS program has published several papers, but these have been limited to study implementation and exposure characterization. Poster LTG2-08 from the Johns Hopkins PM Center presented analysis of relevant time series data from various cities that 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 source to health paradigm.

Summary and Rating by Long-Term Goal 1

LTG1: 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 long term goal supports two research themes: a) developing NAAQS and other air quality regulations; and b) implementing air quality regulations.*

(Croes, Levy, Yarwood, Amar, Felton et al contribution)

Draft overall rating of LTG1: 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. The work under LTG1 can be categorized as <exceptional or exceeds expectations – thoughts?>. Research regarding the health implications of particulate matter 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 reasonably justified in light of the public health burden and significant regulatory decisions, but does imply that ORD CARP 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 emphases on the health implications of low-level exposure (i.e., below the current NAAQS) would be valuable. That said, it is hard to argue that any of the work conducted under ORD CARP 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 also 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, research is timely, and 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 AIRMOD and its extension to use of exposure models (SHEDS and HAPEM) should move the research agenda forward in this important area.

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

<u>Ambient Measurements</u>
The ORD Clean Air Research Program has the priorities 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, SOA, 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 particulate matter 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. Recently, however, OAQPS and Michelle Bell, an extramural research collaborator, have suggested that ambient ozone concentrations may be important for health correlations at levels well below the level of the current NAAQS. OAQPS has asked that ORD conduct follow-up studies to confirm these results, but to date ORD has decided to not pursue this issue. This is the type of study that must be initiated as soon as possible so that the results will be available for a future ozone NAAQS review.

Some of the non-NAAQS oriented ambient monitoring methods that ORD has chosen to concentrate on 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 their 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.

<u>Source Emissions</u>
The National Academy of Sciences committee that reviewed EPA's PM research program from 1998 to 2002 recommended a comprehensive, cohesive emission characterization research program led by EPA, even if some of the needed emissions characterizations would be 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 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 on-line 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 as soon as possible.

There is an impressive effort to improve the inventory of biomass burning emissions (wildland and prescribed fires) using satellite imagery, and work on ammonia emission factors from agricultural and natural sources using flux measurements. Primary organic aerosols, biological particles, and HAPs are also 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 policymakers are aware of both the strengths and weaknesses of the models.

The Community Multiscale Air Quality (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 by ORD 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 has been incorporated by OTAQ into the new MOVES mobile source emission model that is replacing the MOBILE model.

The extramural research program is providing high-quality science for consumption by EPA researchers and policy makers. Examples are new methods for modeling OA, global air pollution models and biogenic emissions models that are being incorporated into air quality models. Carnegie Mellon University (CMU) 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 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 is 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 LTG1 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 largely been appropriate toward addressing the aims of LTG1. As discussed earlier, ORD CARP research has predominantly focused on particulate matter (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 ORD CARP science in the most recent PM Draft Staff Paper. However, while 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 LTG1. Work related to personal exposure was relatively underrepresented, but the effects to better characterize spatiotemporal air pollution patterns and use models such as SHEDS to link those ambient patterns with time-activity data are appropriate and informative, and ongoing work targeting LTG2 (e.g., near-roadway studies, the DEARS study) are clearly relevant to the exposure component of LTG1. In general, there is a direct line between most of the research in the domain of health and exposure and key regulatory decisions facing EPA and other stakeholders.

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2. How high is the scientific quality of the program's research products?

Ambient Measurements

The majority of ORD's ambient monitoring research products are of high quality and are well received by others in the respective research fields, by data analysts and by pollution control planners. One recent disappointment was the last review of the PM2.5 FEM Class III evaluation criteria. ORD developed the testing criteria and missed two important issues that have thrown the validity of the results into jeopardy. The testing criteria allowed the candidate's filter samples to be removed immediately after the sample collection period rather than sit in the sampler for 8-72 hrs. The vendors were also required to combine the results of their winter and summer test campaigns. These mistakes have created the unfortunate situation where an approved PM2.5 FEM can potentially measure 25% or more mass than a collocated compliance network oriented FRM. This problem is now manifest in an inconsistent PM2.5 dataset that will be provided to health researchers, to future NAAQS reviewers and to monitoring agencies and EPA Regional offices who must make attainment determinations.

The recent revision of the Pb standard has also demonstrated that ORD's attention to the quality and performance of existing FRMs is woefully lacking. The 30-year-old Pb TSP FRM should have been replaced many years ago with a sampler that is less sensitive to wind direction and speed. The fact that this existing poor performing FRM has been accepted in the latest revision of the Pb monitoring implementation regulation is simply not acceptable scientifically.

The FRM for ozone is also outdated and in fact is no longer commercially manufactured. The ozone FEM evaluation protocols that ORD is responsible for can no longer be met because one of the requirements is for the candidate analyzer to be compared to an FRM that is not available. The lack of a suitable FRM was recently pointed out in the PAMs monitoring regulation which specified that an Ozone FEM, not an FRM must be operated at PAMs sites.

ORD should also work on a way to prevent the designation of an approved method from stifling the innovation of that monitoring technology. The designation of an instrument essentially freezes the state of the science. Vendors are happy to continue selling the same instruments that received designation many years ago but they do not seem to have motivation to improve these instruments either for ease of use or through improved technology. It is the monitoring agencies that have to suffer with sometimes poorly functioning outdated approved monitoring methods.

Source Emissions

The source emission inventory research that ORD conducts and funds is of the highest quality as demonstrated by numerous publications in the scientific literature. There is also 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 EPA 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. The research on OA presented in the poster by Bhave demonstrated how improvements to the representation of OA in the CMAQ model have been guided by source apportionment ambient PM and other published research. The poster by Carlton demonstrated how aqueous-phase chemistry can form OA in quantities that are sufficient to influence the total PM burden. The extramural research program also demonstrates that ORD is delivering high quality research in air quality modeling. The VBS approach to understanding OA formation developed at CMU was published in Science and numerous other peer-reviewed journal articles. The poster by Schere on new approaches to model evaluation for CMAQ presented results from a dynamic evaluation that demonstrated air quality benefits from EPA's "NO_X SIP call" strategy to reduce power plant emissions in the eastern US. The research presented in these posters illustrates 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 high-quality, based on the extensive bibliometric analysis, the content of the posters and other materials presented, and committee 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 particulate matter 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 LTG2 but also informing questions within LTG1. 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.

3. To what extent are the program results being used by environmental decision-makers to inform decisions and achieve results?

Ambient Measurements

The ORD Clean Air Research Program has not been keeping up with the element of LTG 1 that relates to the periodic NAAQS assessments. The NAAQS assessments should encourage ORD to evaluate the state of the knowledge of 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. This review including published research results must be available to the NAAQS review team in a timely fashion in order to be a useful resource in the process.

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 State Implementation Plans (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. The poster by Possiel documents how OAR recently used CMAQ in a national rule making decision for Locomotive/Marine diesel engines. ORD engagement with CMAQ users is important and should be encouraged. Posters by Dennis and Nolte demonstrate ORD outreach to show how CMAQ can be integrated more broadly into environmental management decisions. 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 meets expectations.

Health and Exposure

The ORD CARP research on health and exposure is clearly being used by OAQPS in the process of setting NAAQS for $PM_{2.5}$, and to a lesser extent, ozone. Essentially no work is being done within ORD CARP regarding health impacts of air toxics, reflecting resource constraints, so statutory needs related to air toxics are not being met.

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4. 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 ORD'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 which are relied upon as the basis for SIP design must be able to accurately predict that the State's selected control strategies will effect the needed reduction in ambient pollutant concentrations in the time period specified in the SIP. State Agencies and their respective EPA Regional Offices, who have the responsibility to approve SIPs, have to work collaboratively because an approved SIP must be scientifically acceptable, 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 inevitable since 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 ORD Clean Air Research Program is being effective in promoting good science and meets expectations. 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 above).

Summary and Rating by Long-Term Goal 2

LTG2: 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 long term goal 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.*

(Tager, Branch, **Henderson** et al. contributions)

Draft overall rating LTG2: Exceptional. (I am suggesting Exceeds Expectations – KLD)

Long term goal 2 (LTG2) looks to the future in which it is expected that air quality management will be based more on regulating sources of pollutant mixtures than on regulating individual pollutants. This is a multipollutant approach that has been recommended to the EPA by both the Science Advisory Board and by the National Research Council. The Clean Air 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 which the program has led the world in clarifying the characteristics of PM that lead to increase morbidity and mortality and in clarifying mechanisms for these effect.

[We could rate them "exceeds expectations" and say they have not included ecosystem responses. But that was never part of their goals. RFH}

How appropriate is the science used to achieve LTG2, 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 (LTG2) has been to define what is meant by the term, "multipollutant." This problem was well discussed at the 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 we have epidemiological studies of the "outcomes." There is a need now to prioritize which other sources should be studied in the future.

The weakest area of air pollution research to be studied in the Clean Air Program is air toxics. The LTG2 offers an opportunity to fill in this gap, because air toxics are a part of the multipollutant mix in the atmosphere. Thus the LTG2 approach is relevant and appropriate to fill in this missing part of the air pollution problem.

Other areas of research emphasis are on the effect of atmospheric processing and the influence of the airshed on air quality and health effects. These are excellent multipollutant areas for the Clean Air Program 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. This research is done in collaboration with the Health Effects Institute, a research partner partially funded by the EPA.

One gap in the research program is the effect of multipollutants 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 LTG2 is outstanding, as indicated in the section of our review related to the overall quality of research in the Clean Air Program. The publications are highly cited and in top journals as illustrated in their bibliometric analysis. The quality of their research is enhanced by their research partners, which include both intramural and extramural participants. The PM centers have been central in providing excellent, high quality research. The STAR program has also 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, multipollutant approach is relatively new and therefore some parts of the program will exhibit increasing usefulness with time. The timeline for some of the goals reach out to 2012. However, some parts of the program are already heavily used by environmental decision makers. The air quality models developed by the Clean Air 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 2000 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. Multipollutant 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. These included the Puget Sound Clean Air Agency, the Center for Disease Control and Prevention, the OAQPS and the new Global Change program. The interaction of the EPA's Clean Air Program with many other groups and agencies (HEI, NIEHS, NHLBI, NOAA, FHA) allows them to leverage their work to enhance the usefulness of their program.

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 PM2.5 during the 1980's and 1990's are associated with an increased life expectancy of 0.5 years.

APPENDIX A: Charge Questions

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 can not 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 multipollutant 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.

Appendix I

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 B: Roadmap to the Evidence of Addressing the Charge

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)*

Appendix C: Biographical Sketches of the Subcommittee Members

Appendix D: Agenda for the June 8-10, 2009 Meeting

Appendix E: List of Major Research Themes and Related Poster Titles

Appendix F: List of Acronyms