***Section 1*: The ORD PM-O_3 Program**

Introduction

Over the last decade, a wealth of studies has underscored anthropogenic air pollution – notably particulate matter (PM) - as an environmental factor that can adversely impact human health and welfare, despite clear evidence that overall air quality has improved.[a] The White House Office of Management and Budget (OMB) has estimated an annual savings of $120 to $183 billion in hospitalizations and emergency room visits, lost workdays, and premature deaths between 1992 and 2002 that can be attributed to air pollution regulations – again most notably PM ("*Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*," available online at: http://www.whitehouse.gov/omb/inforeg/2003_cost-ben_final_rpt.pdf). To further increase these benefits, reducing the uncertainties regarding the source-associated attributes of PM responsible for these impacts and the biologic factors that underlie susceptibility to them will provide critical information to developing even more cost-effective strategies to environmental regulation and control.

By 1997, the scientific evidence, although still controversial, was sufficient for the EPA to conclude that ambient levels of PM presented significant risks to public health. Therefore, the existent National Ambient Air Quality Standards (NAAQS) for PM_{10}, was revised and an additional, new NAAQS for $PM_{2.5}$ was established. The promulgation of these standards, coupled with continuing concerns and uncertainties regarding PM health effects, prompted Congress to augment the President's recommended EPA budget of $27.8 million in 1998 with a $22.4 million per year Congressional add-on that year and an additional $18.0 million in FY 1999. These additional resources became part of the base PM Research Program and have been included in the Agency's budget requests since that time. The charge to EPA was to accelerate investigations of the role of PM in air pollution-associated health outcomes, and to implement health risk reductions via scientifically defensible regulatory actions. President Clinton emphasized the national scope of the issue when he stated, "The EPA, in partnership with other Federal agencies, will develop a greatly expanded coordinated interagency PM research program. The program will contribute to expanding the science associated with PM health effects, as well as developing improved monitoring methods and cost effective mitigation strategies." To assist in this national effort, Congress mandated the formation of a committee of air pollution experts via the National Academy of Sciences National Research Council (NRC). This NRC Committee met initially to define the scope of the issue and to compile the pressing research needs to advance the science and support the regulatory agenda (http://www4.nas.edu/cp.nsf/Projects+_by+_PIN/BEST-K-98-02-A?OpenDocument). The Committee met

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

periodically through 2004, completing a series of four documents delineating the PM research needs in health and, beginning with the second report, including aspects of air quality management. This series of documents also provided, most recently in Vol. IV published in April 2004 (http://www4.nas.edu/cp.nsf/Projects+_by+_PIN/BEST-K-98-02-A?OpenDocument), ongoing assessments of progress, both scientific and administrative, in reducing the uncertainties associated with the PM issue as well as recommendations regarding the direction and implementation of the program.

Following the release of another but related NRC report in 2004 entitled "*Air Quality Management in the United States*," the Clean Air Act Advisory Committee (CAAAC - http://www.nap.edu/catalog/10728.html), established in 1990 to periodically address issues more specific to air quality, formed a work group to develop recommendations for improvements to the air quality management. This 'Air Quality Management (AQM) Work Group' comprised representatives from EPA, state and local agencies, tribes, industry, and environmental and research organizations. The charge to the AQM Work Group was to evaluate the NRC AQM findings, and develop its own recommendations for consideration by the CAAAC.

The NRC and CAAAC reports have provided valuable guidance to ORD's PM and O_3 research program. Such formal guidance from these external panels is important in the identification of key research needs and opportunities for fruitful collaborations. However, informal discussions with scientific experts in the diverse range of topics associated with air pollution and its effects and close coordination with EPA's regulatory offices are also very important in formulating Program goals and ensuring that important emerging topics are not overlooked. The Program values the input from expert panels, clients and its expert science staff in the development of the research agenda.

Nearly seven years of intensive research activity have transpired since the initial NRC research Priorities Report, yielding significant advances in the understanding of PM. In February 2004, ORD released "*Particulate Matter Research Program: Five Years of Progress*" (http://www.epa.gov/pmresearch/pm_research_accomplishments/) which summarized the achievements of EPA's research program in advancing our understanding of both health / exposure and air quality issues. This report, although aimed at the knowledgeable public, is the most comprehensive account of the progress in the Program through early 2003. To that point, it was downloaded from the EPA web more than 11,000 times in its first month, more than any other EPA document in its first month.[b]. The Report summarized the advances in the PM Program over the last several years into three broad areas: (a) the credibility and extent of PM-associated health effects and the complex roles of PM attributes and human host factors that contribute to the health outcomes; (b) the factors determining public and individual exposures, including characterization of the sources and atmospheric processes needed to aid implementation of the NAAQS; and (c)

[b] The PM Program has for several reasons come to be widely regarded as the 'model research program" of ORD. While seemingly self-laudatory by ORD's immediate past Assistant Administrator Dr. Paul Gilman, ORD's PM Program today is the product of the ongoing collaborative efforts of EPA and its academic associates as has evolved with the numerous independent reviews provided by a range of scientific and science-management peer groups. Collectively, these reviews have been instrumental in providing scientific guidance to EPA as the program as evolved

the development and improvement of 'tools' and state-of-the-art technologies needed by the Regions, States, and Tribes to implement the NAAQS to achieve EPA's Strategic Air Quality Goal ["*Protect and improve the air so it is healthy to breathe and risks to human health and the environment are reduced*"] (EPA Strategic Plan: http://www.epa.gov/ocfo/plan/2003sp.pdf). These advances are highlighted in updated fashion in this BOSC Review with representative poster presentations in three theme sessions that map to the Program's current and future directions. These theme areas, Health and Exposure, Air Quality Management, and Source to Health Outcomes, are discussed in detail in Chapter 7 of this briefing book, and in the context of the proposed Multi-Year Plan (MYP) structure introduced below. The session presentations themselves that introduce the three poster sessions of this Review are each framed in the context or what we knew in 1998, what we know now and where we are headed in the new PM-O_3 MYP.

Setting the Stage

Under the Clean Air Act (CAA), PM is one of six major air pollutants for which EPA has established a NAAQS. The CAA requires periodic review of the scientific basis or "criteria" for these standards and calls for EPA to lead the preparation of a comprehensive scientific assessment of the state-of-the-knowledge for each criteria air pollutant.[c] The 1996, the "*Air Quality Criteria for Particulate Matter Document*" (PM AQCD) provided the scientific basis for the current PM NAAQS set in 1997. At present, 7 years hence, a revised and updated PM AQCD has been reviewed by the Clean Air Scientific Advisory Committee (CASAC) and the public and has been accepted (see Footnote a). The PM Staff Paper which draws from the AQCD and integrates various risk estimates to be considered in the final decision by the Administrator is currently available in draft form (http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_index.html), and is under review by CASAC and the public (meeting scheduled for 04/06/05). The final decision on how, or whether, to revise the existing PM NAAQS is expected in December, 2005. The NAAQS deliberations include potential revisions of the $PM_{2.5}$ (fine mode) and $PM_{2.5-10}$ (i.e., coarse mode) as primary health-based standards and possibly secondary welfare standards. The Ozone AQCD is currently in draft form (see Footnote a) and also is under review by CASAC and the public (final version expected in February 2006). The 1st Draft Staff Paper is expected in September, 2005. This accelerated NAAQS review schedule follows that of PM with the NAAQS decision for O_3 decreed by the courts scheduled for December, 2007.

The mission of ORD is to conduct basic investigatory and evaluative research in support of the Agency's regulatory mandate. As such, ORD develops its research priorities with close cooperation with our primary clients, the Air Office (OAR) and EPA Regions. Within the Air Program, science and program questions and research needs frequently evolve iteratively among these interests. Through meetings and discussions not only within the Agency, but with the science community, the Executive and Congressional branches of the US government, sister

[c]The six criteria air pollutants are carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO_2), ozone (O_3), PM, and sulfur dioxide (SO_2). It is possible that PM will be separated into different categories to distinguish the fine and coarse fractions.

Agencies, state and local agencies (through OAR), as well as the public shape a national agenda from which Program priorities are identified and mature.

More to the science issues, expert panels are convened via independent organizations such as the National Academy of Sciences to provide insight and guidance to refine specific program and research goals and priorities. Among the most critical contributions to the process of establishing and refining Program science goals and priorities is through peer review evaluations. Peer review and advisory panels from the expert and stakeholder communities are convened to critically evaluate the Program structure, priorities, program plans, and performance to ensure appropriate and accountable use of the public trust in the production of sound and useful science. These reviews notwithstanding – individual elements of the Program and/or organizational units (e.g., divisions) of the ORD Labs/Centers undergo periodic science peer reviews. These reviews may comprise select *ad hoc* committees of experts or are formed as subcommittees of existent review bodies (e.g., this BOSC). The purpose of these reviews is to ensure the quality and performance of the Program and its science. All Program products, including journal publications, reports, recommendations, as well the strategic and work plans from which these products emerge, must undergo internal and external peer review.

A major issue to the Agency as well as the public is whether ORD is making progress toward its strategic goals. Has ORD accomplished what is planned and are the environmental results as were intended? The Government Performance and Results Act (GPRA) requires that EPA report annually to Congress to gauge overall progress in meeting its strategic goals. ORD functions within this structure, which includes goals, objectives, and sub-objectives, to plan, budget and account for resources in terms of products and overall performance. The ORD Air Program is encompassed within Goal 1 (of five), *Clean Air and Global Climate Change*, and is represented by Objective 1:1 – *Healthier Outdoor Air*. This Objective comprises the NAAQS as well as the Air Toxics Programs. The regulation, budgeting, and research considerations of these Sub-Objectives, however, remain essentially distinct activities. The CAA established this separation in 1970 in an attempt to create a foundation for manageable assessment and mitigation strategies, despite the undeniable compositional complexities within polluted air sheds that may well be reflected in resultant health outcomes.

In the ideal, the assessment and regulation of air pollution should embrace a “holistic” concept. One variant of such an approach is termed “one-atmosphere.” While a practical “one-atmosphere” approach to air pollution assessment and regulation is yet to be developed, the ‘reality’ of this model is recognized and is garnering more attention, particularly among the state agencies which have the responsibility for ultimate implementation of the NAAQS. It has long been known that when controls are placed on sources contributing to one pollutant, the impact is generally measurable in associated co-emissions or pollutants. On the assessment side, ever-improving atmospheric models attempt to incorporate the dynamic complexities of emissions and their chemistries in the atmosphere to predict air pollution to guide the implementation of standards and the development of mitigation plans. Fortunately, increasingly sophisticated statistical models have become available that allow health studies to sort pollutant-specific

effects and give some insight into their interactions. Clearly, the goal is ultimately to fully incorporate the concept of air pollution complexity into both its assessment and its control.

Particulate matter is itself an inherently complex air pollutant, despite its designation as one of the six Criteria Pollutants. Its complexity is in part responsible for the difficulties and challenges in determining the causative attributes(s) that underlie its health impacts, and likewise, in discerning the critical processes and constituents that govern atmospheric transformation processes, and must be modeled for real-world implementation. As PM has grown in prominence for its health implications, it has come to dominate the other Criteria air pollutants and as such it predominates in the prioritization of the Air research budget. Intramurally, the PM Program arose from redirection of the Ozone Program of the 80's and early 90's. During this transition, significant insight was gained into the complex origins, behaviors, and impacts of PM. While the air quality program of necessity was already vested to a degree in PM as it related to visibility and atmospheric modeling, O_3 was also of prime interest. Thus, to move ahead with PM research, the air quality research efforts needed expansion while the health research program needed to shift from O_3 to PM, and did so in the late 90's.

Today, the evolution of the science and the changing nature of budgetary support to PM and O_3 research now encourage their merger of within the Air Research Program. While this mergence of the PM and O_3 programs will take place in the research planning process and seemingly parallels the direction of the atmospheric research, the atmospheric science program has not been under-written by a cumulative mergence of their respective research funds. Further atmospheric research involving PM and O_3 will be supported under PM funding only, with no augmentation from prior O_3 support. It should be noted of course, that the Agency has not further merged these pollutants at the regulatory level given the structure of the Clean Air Act. This Program review now being undertaken will provide a proposed structure for combining the research related to PM and O_3 (where PM is clearly dominant) in the development of ORD's MYP and associated performance measures.

Within the Agency, there is a move to now call the PM – O_3 Research Program the NAAQS Research Program, especially in the budget programming activities. However, this moniker scientifically implies more than just PM – O_3, and while the atmospheric models do involve other NAAQS pollutants, their involvement can not be construed as full-blown programs focused on these specific pollutants. There is little doubt that the Air Research Program in the long run is moving to a "one atmosphere" concept, which will of necessity consider the NAAQS and the Air Toxic pollutants, the latter of which is currently a separate, but relatively small program. Air Toxics, although some of its listed pollutants – such as metals, as a program, is not part of this review. Nevertheless, it is well appreciated that, as noted by the Science Advisory Board, that the science of air pollution is grounded in the complexity and the Program of necessity is moving in that direction.

Summary

Since 1998, the public trust has invested substantial funds into investigations of the health impacts associated with exposure to ambient PM. This investment has been made, and continues to be made, with the aim of reducing the uncertainties associated with how ambient PM, derived primarily or secondarily from emission precursors, ultimately leads to increased illness and premature mortality, with the goal of cost-effective pollution mitigation.. During the life of the PM Program, significant progress has been made in identifying potential biological mechanisms of damage, validating that local PM monitors reflect exposures to people, describing how particles are formed in the atmosphere, and determining the sources of PM and its precursors. While many uncertainties have indeed been reduced, as is common to science, discovery has led to more questions – questions just as important as the original group that appeared seemingly straight-forward at the outset. As noted by the NRC, much remains to be learned if the risks associated with exposure to ambient PM are to be efficiently and more effectively reduced.

As the Program moves ahead, the widely appreciated reality that air pollution is an issue of complex mixtures is being realized in the programmatic agenda. With changes in Program support and the advancement of the science, PM and O_3 are being combined within a single Multiyear Plan. This restructured MYP is the first step in the movement to a “one atmosphere” concept. While we are not there yet, the combined PM and O_3 efforts will focus on air quality issues, specifically in the refinement of atmospheric models. In our efforts toward achieving the goal of clean and healthy air, we strongly believe that the investments made in the research program to date has returned tremendous dividends, and we are committed to ensuring that the program continues this exceptional level of accomplishment through a clearly defined, multidisciplinary approach directed to the scientific and programmatic needs of EPA.