EPA United States Environmental Protection Agency

Clean Air Research
Multi-Year Plan
2008-2012

June 2008

Office of Research and Development

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Environmental Protection
Agency

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U.S. Environmental Protection Agency
Office of Research and Development
Research Triangle Park, NC 27711

Administrative Note

The Office of Research and Development's (ORD) Multi-Year Plans (MYPs) describe what research ORD proposes to accomplish over the next 5-10 years in a variety of areas. The MYPs serve three principal purposes: to describe where the research programs are going, to present the significant outputs of the research, and to communicate the research plans within ORD and with stakeholders and clients. Multi-year planning permits ORD to consider the strategic directions of the Agency and how research can evolve to best contribute to the Agency's mission of protecting health and the environment.

MYPs are intended to be "living documents." ORD will update MYPs on a regular basis to reflect the current state of the science, resource availability, and Agency priorities. This MYP was reviewed by ORD's Science Council in October 2007.

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List of Acronyms and Abbreviations

APG – Annual Performance Goal
APM – Annual Performance Measure
BOSC – Board of Scientific Counselors
CAA – Clean Air Act
CAIR – Clean Air Interstate Rule
CAMR– Clean Air Mercury Rule
CAVR– Clean Air Visibility Rule
CENR – Committee on Environment and Natural Resources
CMAQ – Community Multiscale Air Quality
CRC – Coordinating Research Council
DOE – Department of Energy
EPRI – Electric Power Research Institute
FACA – Federal Advisory Committee Act
HAP – hazardous air pollutant
HEI – Health Effects Institute
HHRA – Human Health Risk Assessment
HHRP – Human Health Research Program
IRIS – Integrated Risk Information System
L/C – Laboratory/Center
LTG – Long-term Goal
MACT – Maximum Achievable Control Technology
MYP – Multi-year Plan
NAAQS – National Ambient Air Quality Standard
NAS – National Academy of Sciences
NATA – National Air Toxics Assessment
NCEA – National Center for Environmental Assessment
NCER – National Center for Environmental Research
NHLBI – National Heart, Lung, and Blood Institute
NIEHS – National Institute of Environmental Health Sciences
NOx – nitrogen oxides
NRC – National Research Council
OPA – Office of Atmospheric Programs
OAQPS – Office of Air Quality Planning and Standards
OAR – Office of Air and Radiation
OMB – Office of Management and Budget
ORD – Office of Research and Development
OTAQ – Office of Transportation and Air Quality
PART – Performance Assessment Rating Tool
PM – particulate matter
RCT – Research Coordination Team
RFA – Request for Application
RPOs – Regional Planning Organizations
SERDP – Strategic Environmental Research and Development
SIP – State Implementation Plan
SOx – sulfur oxides

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I. INTRODUCTION

A. *Program Purpose*

Air pollution continues to have adverse impacts on the human and environmental health of the United States, despite clear evidence that overall air quality has improved.[1] The *EPA Strategic Plan 2006-2011* (Strategic Plan) identifies Clean Air and Global Climate Change (Goal 1) as a primary goal for environmental protection with its first objective being Healthier Outdoor Air, and its second objective, Healthier Indoor Air.[2] EPA's Strategic Plan Goal 1 also establishes an objective to provide and apply sound science to support the goal of clean air by conducting leading-edge research to support regulatory decisionmaking. This research provides the scientific foundation to develop regulations and advanced tools and models to implement air quality standards and controls by the States, EPA Regions, and tribes. At the same time, the research program strives to develop better ways to track progress in achieving health and environmental improvements under this goal. The Clean Air Research program targets this first objective by providing the science needed to review, attain, and maintain ambient air quality standards required to protect public health. This research, together with the rest of the Clean Air Research program, has the added benefit of addressing risk reduction from a number of toxic air pollutants, and increases in the number of Americans experiencing healthier indoor air in homes, schools, and office buildings. Although the Clean Air Research program considers within its overall goal the reduction of air pollution impacts on ecosystems and visibility, research specific to the protection of public health remains the top priority of the Office of Research and Development's (ORD's) clients.

In 2007, the White House Office of Management and Budget (OMB) found that reductions in hospitalizations and emergency room visits, lost work and school days, and premature deaths account for the greatest expected benefits of air pollution regulation. Between 1996 and 2006, OMB attributed an annual savings of $63 to $430 billion to the development and implementation of air pollution regulations–most notably from control of particulate matter (PM).[3] The benefits of air pollution regulation accounted for ~94% of estimated benefits from all EPA regulations and ~63 to 88% of estimated benefits across all federal agencies, while costing an estimated $25 to $28 billion to implement over this same period.

ORD has developed multi-year plans (MYPs) in a number of program areas to describe the research ORD proposes to accomplish over the next several years. The MYP is intended to provide a vision of the research program and the programmatic rationale for its intended directions. In addition, the MYP provides an up-to-date, structured listing and description of the significant expected outputs from its research, which serves to communicate across ORD and

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[1] These data are summarized in the 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). Risks from Hazardous Air Pollutants possess even greater uncertainty (http://www.epa.gov/ttn/atw/nata/natsa4.html). Additional information on trends in air quality and emissions can be found at the Office of Air and Radiation site: http://www.epa.gov/air/airtrends.
[2] EPA Strategic Plan 2006-2011 (Goal 1: Clean Air and Global Change; Objectives 1.1, 1.2, 1.6; p. 11) – http://www.epa.gov/ocfo/plan/2006/goal_1.pdf.
[3] Draft 2007 Report to Congress on the Costs and Benefits of Federal Regulations – Tables 1.1 and 1.2; pp. 7-8; - http://www.whitehouse.gov/omb/inforeg/2007_cb/2007_draft_cb_report.pdf.

with stakeholders, clients, and reviewers. Multi-year planning permits ORD to consider the strategic directions of the EPA and how research can evolve to best meet the EPA's mission of protecting public health and the environment.

This MYP supports the goal of Clean Air by defining the research needed to answer key questions regarding the development and implementation of National Ambient Air Quality Standards (NAAQS)–primarily targeting PM and ozone as high-risk pollutants. In addition, it also supports, although secondarily, the goals of managing hazardous air pollutants (HAPs)This MYP includes a major shift in the Clean Air Research program by combining several program areas that previously had targeted air pollutants individually (e.g., PM, ozone, HAPs)Although it is essential to provide support for the various NAAQS pollutants that continue to be regulated individually, a multipollutant research program better reflects the complexity of real-world air pollution problems and parallels the evolving scientific and regulatory context. The Clean Air Research program uses the science-based framework, shown in Figure 1, developed by the National Academy of Sciences' (NAS's) National Research Council (NRC) in 1998 and modified by the Air Quality Research Subcommittee (AQRS) of the Committee on Environment and Natural Resources (CENR) in 2007 to identify those pollutants and sources responsible for the greatest health risk. Critical components of this research are used to develop an understanding of how pollutants from sources impact ambient concentrations, how these concentrations relate to exposures, and, in turn, how exposures relate to health outcomes. This information provides the fundamental linkages for evaluating health impacts, ascertaining which sources are most egregious in terms of health risk, and in developing effective mitigation strategies.
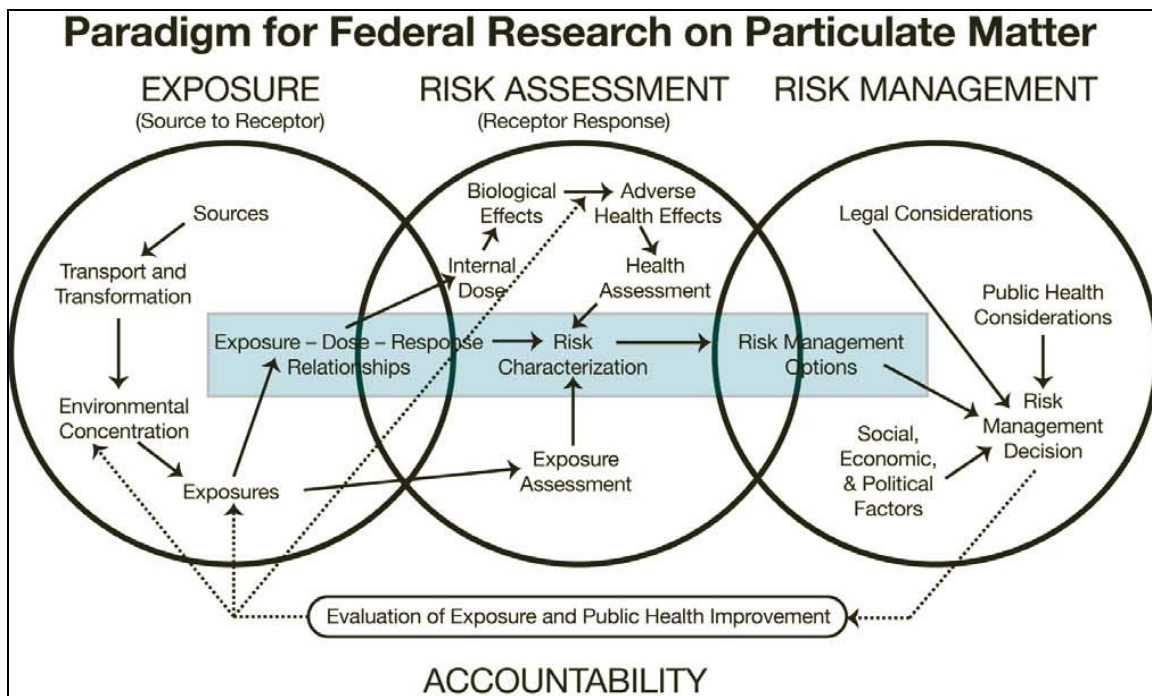

Figure 1. Paradigm for Federal Research on Particulate Matter[4]

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[4] From http://www.esrl.noaa.gov/csd/AQRS/reports/pmplan.pdf

The transition to an air research program emphasizing both "source to health outcomes" and multipollutant approaches reflects the recommendations of EPA advisory boards and the reorganization of the Office of Air Quality Planning and Standards (OAQPS). The NRC, over the period of 1998 to 2004, developed for EPA, under a Congressional directive, a series of documents to guide PM and copollutant research. The last report (April 2004) recommends that EPA adopt a broader multipollutant research perspective, and increase its efforts to link observed heath outcomes with specific components and sources of PM.[5] This approach was endorsed by EPA's Board of Scientific Counselors (BOSC) in 2005.[6] Likewise, following the lead of a related NRC report entitled "Air Quality Management in the United States," the Clean Air Act Advisory Committee (CAAAC)[7], consisting of representatives from EPA, State and local agencies, tribes, industry, and environmental and research organizations, also strongly endorsed a broad air quality, rather than a pollutant-by-pollutant, approach for more effective air quality management. Finally, in keeping with the CAAAC recommendation, OAQPS, which is a main client of the ORD Clean Air Research program, has reorganized away from pollutant-specific groupings to a more sector-based structure to improve HAPs control and air quality assessment. Based on the combination of guidance from external advisory boards and the evolving needs of our clients, the focus of the Clean Air Research program was adjusted to support this more realistic, yet complex air pollution approach.

B. Program Design

In support of the broader EPA and ORD Strategic Plans, this MYP provides a focused strategy for Clean Air Research for ORD laboratories and centers and identifies linkages to other relevant MYPs such as the Human Health Research program (HHRP) and the Human Health Risk Assessment (HHRA) program. It provides a "roadmap" built on the progress that ORD has made since 1998 when PM rose to prominence via Presidential and Congressional mandate.[8] The roadmap, however, is intended to be sufficiently flexible to facilitate responsiveness to unforeseen changes and developments in the complex scientific landscape ahead.

The development of this roadmap is reflected in the diagram illustrated in Figure 2, which outlines the progression of scientific research from the recognition of need to use the new information with its impact on human and environmental outcomes.

The fundamental problem-driven question that drives the Clean Air Research program is "How can we reduce health risks associated with exposure to air pollution?" The ability to adequately address this overarching question requires that ORD maintain and continue to develop its core research capabilities across a diverse range of scientific disciplines, including: cell, animal, and human toxicology; epidemiology and biostatistics; human exposure; source emissions characterization and analysis; source apportionment; ambient measurements; atmospheric chemistry; air quality modeling and forecasting; and technology evaluation and assessment.

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[5] National Academy of Sciences (NAS) National Research Council (NRC): Research Priorities for Airborne Particulate Matter: http://books.nap.edu/catalog.php?record_id=10957.
[6] BOSC Report on the PM-Ozone Program Review: April 2005 - http://www.epa.gov/osp/bosc/pdf/pm0508rpt.pdf.
[7] http://www.nap.edu/catalog/10728.html.
[8] "*Particulate Matter Research Program: Five Years of Progress*" released in February, 2004, which summarized the achievements of EPA's research program in advancing our understanding of both health/exposure and air quality issues through early 2003 (http://www.epa.gov/pmresearch/pm_research_accomplishments/).
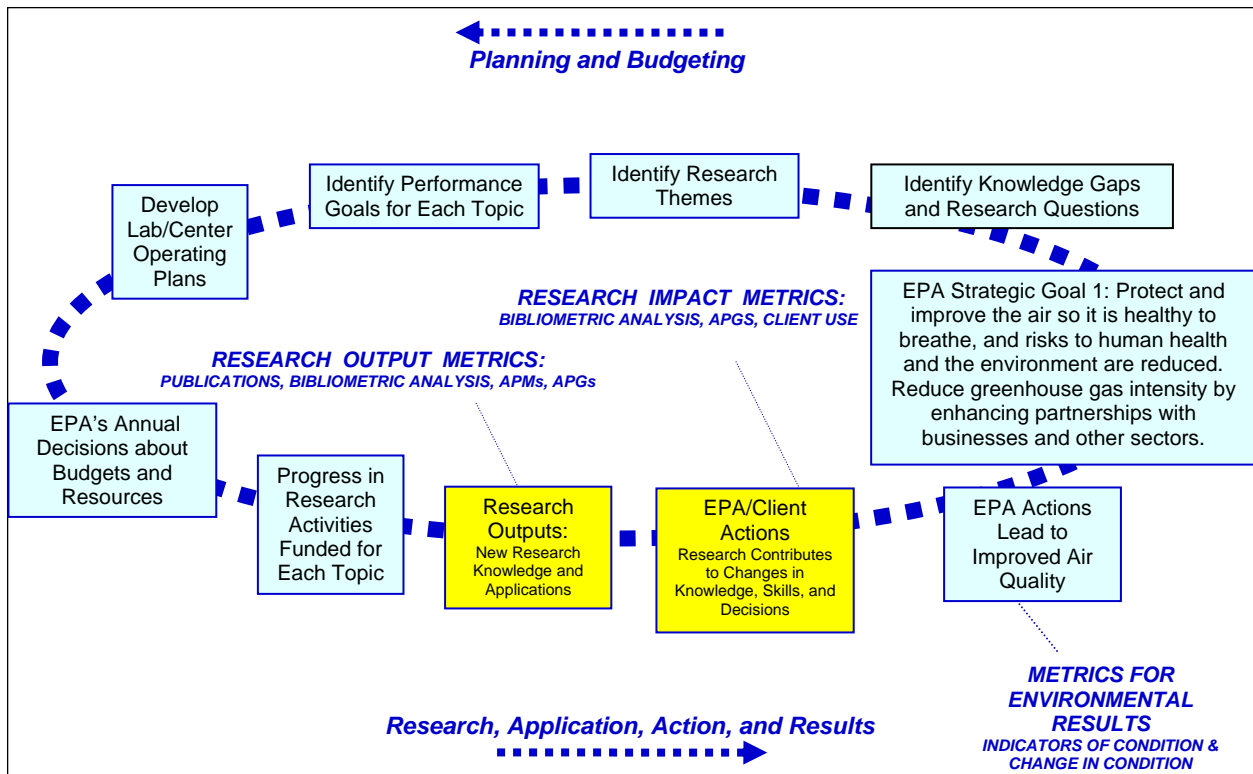
Figure 2. Logic Diagram.

These fundamental capabilities are leveraged within the Clean Air Research program and ORD to maximize project output, science relevance, and resource efficiencies. The goal is to not only address research questions of immediate importance to reducing air pollution health risks, but provide the foundation to anticipate and solve future environmental problems.

ORD structures its research agenda to address its clients' needs and the research priorities identified by the science community. As detailed below in the research plan, key long-term science goals (LTGs) are established from which critical questions are fashioned to frame the research over the next several (~5) years. Researchers work with their Laboratory/Center (L/C) representatives to develop annual performance goals (APGs) that collectively achieve the LTGs over a period of years. More specific annual performance measures (APMs) collectively provide the comprehensive body of research to support a given APG. As such, the APMs are the science building blocks that describe the products expected from the relevant scientific research. Thus, to reflect the overall program investment and to be effective, this MYP places considerable emphasis on the planning and the integration of research. Importantly, however, some latitude for novel and creative initiative is built within the program in an effort to link fundamental science and breakthroughs with known, pressing air pollution problems.

The plan and its science are reviewed at several stages along its development. A Research Coordination Team (RCT) comprised of senior scientists and managers from each ORD Laboratory and Center and multiple representatives from interested client Offices and Regions reviews the priority structure and overall framework of the various LTGs and APGs. The RCT also reviews the APMs and the descriptors that accompany them to gain insight into the plan and its anticipated products. Indeed, the APMs in many cases arise from discussions with members

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of the RCT in the early stages of MYP development.

To ensure the utility and recognition of delivered products, each APG has a designated ORD lead and a client (partner)-advocate who communicate throughout the life of the. This regular discourse is designed to ensure progress, the communication of findings, and appropriate distribution of the anticipated product to the client/partner office and broader community. Finally, the MYP has been reviewed by ORD's Science Council and an external review panel (i.e., BOSC) for scientific soundness. However, it is important to appreciate that the MYP is regarded as a "living document" meant to serve as a roadmap with important science milestones, while maintaining sufficient fluidity to absorb the newest findings and the ability to evolve from there. Naturally, as workforce and fiscal resources are increasingly constrained, the final MYP reflects primarily the highest research priorities, with the intent of achieving the most effective program possible within ORD's direct and leveraged resources. As described below, the program design and implementation considers major policy challenges, external program reviews, the capabilities of the ORD laboratories and centers, partner needs, ORD partner capabilities, and all available resources.

1. Major Policy Challenges and Science Needs

The Office of Air and Radiation (OAR) is responsible for multiple policy areas regarding the "air" environment and, as such, comprises several offices with specific, yet wide-ranging functions: OAQPS–ambient air regulation and rule implementation; the Office of Transportation and Air Quality (OTAQ)–fuels and mobile sources; the Office of Radiation and Indoor Air (ORIA)–indoor environments; the Office of Atmospheric Programs (OAP)–air quality through market systems, ecosystem protection, and climate; and the Office of Policy Analysis and Review (OPAR)–policy and rule analysis. Facing an array of complex policy decisions that rely on the latest and most robust science, OAR is a major user of clean air research. As a result, representatives of OAR are members of the RCT and provide invaluable advice to ORD as it develops its research agenda. Because the EPA Regions, States, and tribes are critical to rule implementation, they themselves frequently have specific and immediate needs (some research, some advisory) that ORD is challenged to address.

With finite resources, priorities or scaled emphases across needs are requisite if adequate and timely progress (products) is to be achieved. As already noted, program priorities are established within the RCT where partner needs and the appropriate science support can be negotiated collectively toward consensus products. Although resources are critical in the final program development, prioritization uses broad criteria, such as the likely magnitude of public health impact, the narrowing of the greatest uncertainties affecting decision-making, and the anticipation of information needed to support future OAR decisions or directions. The goal is to achieve a research program structure that best meets these criteria. Because PM and ozone score highly among these criteria and are NAAQS pollutants, they remain central to ORD's Clean Air Research program (for both standard setting and implementation) and garner considerable attention among other NAAQS and air toxic pollutants.

The challenges and needs of ORD's clients/partners in the program offices and as users in the field are many and multifaceted, and, therefore, this MYP cannot possibly address every research issue identified as a need. Instead, OAR's highest priority regulatory and policy challenges related to air quality that require the most significant research investment are highlighted below. Within the challenges and needs expressed below, an attempt was made to reflect the perspective of the user including those at the Office, Regional, State, or local levels.

a. NAAQS Setting and Implementation. The protection of public health (including susceptible populations) through the development and attainment of appropriate, protective air quality regulations is fundamental to the tasked mission of OAQPS. Clearly, meeting these regulations in the most cost-effective and efficient manner is in the best interests of public health, the environment, and the economy. There are six NAAQS that undergo repeated, periodic review to meet the statutory requirement of the Clean Air Act (CAA), yet the estimated impacts of reductions in ambient PM and ozone continue to drive the bulk of the public health benefit. The other NAAQS also factor into the overall air pollution burden, but their risks appear less substantial because of less exposure risk and/or ambient reductions, with lead recently gaining renewed emphasis because of public interest and health impacts at levels not previously appreciated. The uncertainties across the NAAQS are similar in magnitude and potential public impact, and, as a result, the uncertainties underlying the standard setting process for PM and ozone (with their potential impacts) sustains these two pollutants at the highest priority. Between these two NAAQS themselves, the risks and benefits associated with PM and its reduction in ambient air has retained the highest ORD interest and, hence, emphasis on PM.

More specific challenges related to the review of the PM and ozone NAAQS that require research support include:
- uncertainties surrounding the $PM_{2.5}$ standards,
- uncertainties surrounding the PM_{10} standard (*vis a vis* coarse PM),
- level and form of the ozone and PM standards,
- uncertainties regarding co-pollutants in PM-associated health effects,
- the potential for interactions between PM and ozone in health outcomes,
- definition / characterization of populations that may be susceptible to pollutant effects, and
- potential for an alternative to the mass-based PM standard through identification of hazardous components.

More specific challenges related to NAAQS implementation that require research support include:
- continuing nonattainment problems (post-sulfur/nitrogen controls),
- uncertainties around predicting impacts of control strategies on air quality,
- development of improved methods to effectively and rapidly measure pollutants,
- uncertainties around the input variables for refinement of air quality models,
- uncertainties around which sources contribute to ambient levels of PM, and
- development of improved emission inventories.

Much of the current Clean Air Research program focuses on these challenges. As will be detailed below under LTG 1, providing the research that underlies the development and implementation

of the NAAQS is at the core of the research program. As the program evolves, as described in this document, these research activities are being leveraged to expand both the level of understanding of these NAAQS and the broader array of air pollutants and their effects alone and as mixtures.

b. Mobile and Stationary Source Air Toxics. The 1990 CAA requires EPA to reduce emissions and exposures to 188 specified HAPs (also known as air toxics). Air toxics emissions arise from major stationary sources, smaller (area or point sources), on-road (cars and trucks), and non-road sources (trains, construction equipment, barges, airplanes, etc.)Through implementation of the Maximum Achievable Control Technology (MACT) program, many stationary sources have installed available technologies to address risks of the 188 air toxics. The key challenge now facing the EPA is to determine if there are unacceptable remaining ("residual") risks after these technologies have been installed. There is need for refined emission inventories of HAP emissions to support these residual risk determinations and to better estimate potential community exposures. Because air quality monitoring of the HAPS is more limited than with the NAAQS, the quality of the National Air Toxics Assessment (NATA) for the various HAPs is highly dependent on these inventories to model potential exposures.

One of the more significant challenges to upgrading the current emission inventory is the assessment of those sources emitting pollutants over a wide geographic area rather than from a single point source (e.g., a smoke stack). These sources can range from landfills to refinery leaks. It will be critical to get a better handle on these emissions and understand the associated public exposures to address such risks through residual risk standards or other regulatory designations (area source standards). The NATA focus at present is on 177 HAPs thought to be of greatest risk (by virtue of estimated exposure or compound toxicity) and on diesel exhaust emissions. The hazard and dose-response analyses to support assessment of noncancer and cancer risks from exposure to HAP compounds are being developed by the Integrated Risk Information System (IRIS) program (in the HHRA program) using published data. Nevertheless, there is significant need for information (e.g., mode of action, models) that can be used more broadly to reduce uncertainty in risk assessments related to HAPs in the ambient environment.

Research among the HAPs is targeted in certain areas and otherwise leveraged from the NAAQS program. The Health Effects Institute (HEI) provides a significant research base among selected HAPs as to their risk as point sources or local "hot-spots." [9] Other research utilizes source-based approaches to conduct health research (e.g., diesel) or emission assessments (including methods development) as described above. As these provide insight into the PM issue, their investigation has importance across client information needs. The use of specific HAPs as models that relate to PM or its effects is also supported; however, specific study of HAP toxicity or its dose-response for IRIS is generally not part of the sponsored program.

c. Near-Road/Traffic. Emerging information linking human proximity (living, working, or school environments) to roadways with a range of adverse health effects has led to growing public concern. These concerns have been communicated through OTAQ, ORIA, and OAQPS, as well as from the EPA Regions as an area of great uncertainty, despite its priority. In fact, concerns over potential health impacts from exposure to emissions near roadways have affected several

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[9] HEI publications on air toxics: http://pubs.healtheffects.org/topics.php?topic=1&sort_by=pubdate&order=desc.

transportation projects across the country, as well as a variety of policy decisions. Among these are findings with respect to "conformity" of transportation plans and projects with State Implementation Plans (SIPs) for attainment of the NAAQS and local decisions regarding the location of schools and other projects (e.g., freight terminals) as required under the National Environmental Policy Act (NEPA). These policy decisions are being made even though the scientific uncertainties for the linkages to exposure, hazardous agents, and adverse health effects vary greatly.

Near-road concerns cross a number of priorities among program clients. Mobile source emissions comprise several HAPs (e.g., benzene, aldehydes, butadiene) as well as several NAAQS (carbon monoxide, nitrogen dioxide, PM, lead). Most importantly, the emergence of traffic as a source signal in the PM arena presents this source category as ideal for study. As discussed further below, this source category has been selected as a prototype for multipollutant study.

d. Moving Toward a Multi-pollutant Program to Support Air Quality Management Decisions. Fundamental to a multi-pollutant approach to air quality management is the recognition of the demands on the science to unravel the complex nature of the contributing sources, the atmospheric chemistry, the human exposure/environmental deposition, and, of course, the associated health and ecosystem impacts. A venture into such a broader based perspective has begun with the recent review of the nitrogen oxides (NOx)/sulfur oxides (SOx) NAAQS (2007), where the ecological impacts of these pollutants were considered together. With NOx/SOx, the common theme of acidity and enhanced nutrients in the environment were used for the combined assessment. However, if a multi-pollutant framework is to be more widely embraced for the purpose of air quality management (human as well as environmental health), there is a real need for research to develop analytic approaches to assess multi-pollutant human and environmental health impacts, especially through multimedia pathways, with emphasis on indicators, benchmarks, and interaction-based algorithms. To achieve such a goal, the air pollution sciences will need unprecedented integration and will demand novel tools for assessment to aid interpretation, develop implementation plans, and assess their effectiveness (outcome). Adding to these needs as we move ahead in the 21st century, the challenge is heightened by the NAS recommendation that future policies for air pollution control be integrated with climate change criteria.[10]

OAQPS envisions the goal of a multi-pollutant approach to air quality as leading to a more effective means of achieving environmental benefits and recently has undergone a reorganization to reflect this multi-pollutant and sector-based (source) perspective. The office also has begun to evaluate the technical issues associated with multi-pollutant approaches[11] In this regard, a National Air Pollution Assessment (NAPA)–the next phase of NATA (for the year 2008)–is being developed to include both air toxics and NAAQS pollutants in the context of exposure and health risk and will further expand to include ecosystem and multi-media impacts. In addition, as OAQPS moves toward more comprehensive, "sector-based" approaches for addressing sources, there is a need to understand the amount and species of pollutants emitted from entire sectors and the technological options that are most cost effective in reducing highest source risks. This will

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[10] NAS "Radiative Forcing of Climate Change: Expanding the Concept and Addressing Uncertainties," Oct., 2005.
[11] The Multi-Pollutant Report: Technical Concepts & Examples: http://www.epa.gov/air/airtrends/studies.html.

require new tools and models that can be used by decision makers to evaluate sectors in an integrated manner.

Presently, the Clean Air Research program has a number of largely disconnected efforts regarding multi-pollutant research. These include varied efforts in atmospheric modeling, exposure measurements, and source characterization (methods and health). As described below in LTG 2, ORD multi-pollutant efforts are adopting a source-to-health outcome paradigm, with near-road impacts as the prototype for development of its research framework.

e. <u>Assessing Health and Environmental Improvements Attributable to EPA Actions.</u> There have been marked reductions in several of the NAAQS pollutants over the last two to three decades. Sulfur dioxide reductions and controls in combustion emissions have led to major environmental improvements with reduced acid rain and deposition, but the benefits of reductions in other pollutants have been more difficult to demonstrate in terms of health or ecology. Because of the tremendous complexities involved in attributing changes in health or ecological status to changes in air pollution alone, OAR has been challenged to find acceptable methods to show the benefits of its decision making. As such, OAR has communicated the need for tools to measure the impacts (in terms of benefits or reduced risk) of its decisions–an issue also known by the term, "accountability." CAAAC has called for an "overarching accountability framework" that includes a systematic effort to track air quality achievements and evaluate air program results. According to CAAAC, the EPA needs to move beyond the current approach of relying predominately on air quality measurements and develop and apply the capability and capacity to monitor, assess, and report on how changes in emissions impact air quality, atmospheric deposition, exposure, and effects on human health and ecosystems. There is also interest in ensuring that use of a specific technology or combinations of technologies to reduce air emissions in response to a particular regulatory requirement does not result in other unintended environmental emissions or releases of concern.

Currently, there exists no formally sponsored ORD effort to address these needs largely because of the complexity of the task and the many factors that exist as potential confounding. The HHRP has initiated a cross-program discussion in an attempt to meet this need across program areas, but, to date, this generic program has lacked the resources to be implemented. The Clean Air Research program has been working with OAQPS to develop a framework tailored to its needs, which builds on pilot activities such that a broader model can be built and substantiated. This concept is being incorporated into the design of all planned Clean Air Research program undertakings.

f. <u>Indoor Air</u>. People spend upwards of 90% of their time indoors. Understanding the infiltration of outdoor air with its diverse pollutants into the indoor environment is further complicated by contaminants from indoor sources. The public looks to ORIA for advice on indoor air problems, as well as overall guidance on the issue. ORIA, in consultation with ORD, generated a document entitled *Program Needs for Indoor Environments Research*, which included some key research needs related to chemical and biological indoor contaminants to support future OAR guidance and policy related to indoor exposure risks and guidance. Ideally, characterization of indoor pollutant exposures, arising from either indoor sources or infiltration from sources outdoors, provides the foundation for development of methods and strategies for controls and minimization

of risk. Among the issues in the public eye are those related to asthma induction or exacerbation (from contaminants or biological allergens), especially in children. On a different note, there is also a growing movement related to green building design that increasingly will require information that can be used to perform unbiased analyses of building materials selection and installation procedures. For those buildings already in existence, the development of mitigation strategies with assessments for their effectiveness are of great interest, especially those that examine the effectiveness of EPA's Indoor Air Quality *Tools for Schools* guidance already in place (notably for schools located near major roadways). As such, in the implementation of the near-road research program, the Clean Air Research program is attempting to address selected information needs (e.g., school infiltration, effectiveness of solid and vegetative barriers).

g. <u>Ecological Research</u>. The impact of air pollution on the ecosystem has long been appreciated, especially with regard to acid deposition. To that end, the work of ORD has contributed significantly to the steady reduction and ongoing assessments of that environmental stressor. Given the need to review the secondary NAAQS that address welfare (notably ecological) impacts of air pollutants, OAR continues to request support for data collection in the field and associated assessments. With the passage of the Clean Air Interstate Rule (CAIR) and Clean Air Visibility Rule (CAVR) in 2006, OAR's requests are underscored by the desire to develop measures for eco-accountability. As such, identification of indicators and profiles of wet and dry sulfur deposition are voiced as priority needs by OAR. New technologies also have been requested to facilitate these assessments and to address related contaminants such as nitrogen deposition from atmospheric ammonia. With the recent Supreme Court decision on carbon dioxide (CO_2) and growing climate and global change concerns, there likely will be an amplified cry for tool development and broad based assessments related to the interface of land and water. However, ORD's investments in these activities are limited and have been diminishing because of increasing annual fiscal constraints.

h. <u>Global Climate Research</u>. The recent Supreme Court decision on CO_2 and climate has expanded greatly OAR's interest in quantifying climate impact on health, air quality, and other socioeconomic and environmental systems. The linkages between air quality and climate are of growing importance, but little is understood. OAR has increased interest and need for enhanced models to incorporate better chemical, transport, and meteorological parameters both regionally and globally. The interactions between climate change and air pollution loom as a major issue of the 21st century, crossing all offices and program areas. OAQPS, in particular, has the challenge of trying to forecast the impact of longer ozone seasons (compounded by enhanced PM by transformation) and perhaps higher ozone levels on exposed human populations and ecosystems. The Clean Air Research program is partnering with the Global Change Research program to frame the nature of the issues and define specific research issues that can be integrated into both programs to maximize effectiveness. At present, these activities are limited to assessments and the development of a research framework.

i. <u>Research to Support the Regions, States, and Tribes</u>. The implementers of rules and policy decisions are faced with many technical issues. They rely on tools and models developed by ORD, as well as the latest technologies for monitoring and analyses. Cost efficiencies and quality assurance are major concerns when applying technological changes especially for rule changes. ORD must communicate these technology advances and assist in their field applications. The

Regions, States, and tribes also have unique and often immediate needs because of their specific geographies, socioeconomics, etc., that deserve attention from ORD. Assistance in the way of advice and consultation frequently is provided and opportunities for real-world field testing opportunities for ORD research activities is constantly sought. Nevertheless, the balance between long-range policy targeted research and crisis or problem-solving research can, at times, be strained and, thus, requires continual communication and nurturing.

2. External Program Reviews

A number of external organizations have performed reviews of the Clean Air Research program and have provided critical feedback and recommendations that have been used to improve program design.

Under Congressional directive, the NAS NRC identified 10 priority research topics in a series of EPA sponsored reports published from 1998 to 2004. These documents provided key guidance to the development of the Clean Air Research program and continue to be a major influence on its evolution. The last report, released in April 2004, identified major science drivers and challenges associated with managing the science to address key remaining research questions. These are briefly articulated below along with the program's response.

Overarching Science Drivers
- *Completing the PM emissions inventory and PM air quality models necessary for NAAQS implementation and for informing health research.* New data on emissions are being added regularly to databases used by OAR and the States to upgrade their inventories, and new technologies are being developed and applied to sources previously poorly characterized. New volatile organic compound (VOC) transformation algorithms are being incorporated into the Community Multiscale Air Quality (CMAQ) modeling system that have improved accuracy and served specific program office needs.
- *Developing a systematic program to assess the toxicity of different components of the PM mixture.* Bioassays are being applied uniformly to sources and emission/PM attributes to assess their relative importance to toxic outcomes. Complementary study designs are being used in human and animal studies to enhance extrapolation.
- *Enhancing air quality monitoring for research.* Improved coordination with OAQPS, States, and Regions shift current air monitoring from primarily assessing compliance toward serving multiple purposes, such as air quality forecasting, episode alerts, exposure characterization, health studies, and impacts of regulations. Workshops have proved to be important venues for enhancing communication of research needs for input into monitoring strategies, as well as tool development for data clarity and access.
- *Planning and implementing new studies of the effects of long-term exposure.* EPA has funded new long-term studies including a 10-year prospective multicity study of atherosclerosis (MESA-Air; see below).
- *Improving the relevance of toxicological approaches.* Improved study designs, focus on the source-to-health outcome paradigm, and attention to species dosimetry will better link the toxicology and epidemiology. Interdisciplinary and cross-Laboratory/Center project planning allows leveraging of the science and complementary studies.

- *Integrating disciplines.* Discipline integration in study design and cross-project leveraging is enhancing program efficiency and data interpretation.
- *Moving beyond PM to a multi-pollutant approach.* A multi-pollutant program has been initiated in LTG 2 (see below) using a source-to-health concept design.
- *Accountability*: The concept of accountability (demonstrating an impact) is being incorporated in all program areas. While a framework is being developed for broader Clean Air Research application and OAR use, specific pilot projects have been initiated central to this goal and, wherever possible, programs such as near-road have incorporated accountability (e.g., impact of mitigation strategies) into project designs.

Challenges to Science Management
- *A higher level of sustained program-science integration and interaction.* Under the direction of a National Program Director, EPA's multiple air-related programs (NAAQS and HAPs) have been integrated into a single Clean Air Research program to improve integration, efficiency and science utility. As the climate issue grows, the linkages between air quality and climate must be strengthened to meet the evolving demands of a sustained high level of air quality management.
- *An integrated multidisciplinary research program that strives to elucidate the science and linkages across the source-to-health outcome framework.* Using the MYP as a guide, research planning and execution will move ahead to maximally leverage resources and provide the most complete understanding possible of the science questions vetted through the RCT in the development of the Clean Air Research program agenda.
- *Stronger tools are needed to synthesize the large amounts of new information being developed in the Clean Air Research program to support air quality decisions.* Program integration and improved access to and development of databases and web based information have been undertaken. Regularly scheduled cross-organizational (Laboratory and Center) meetings and coordination with other programs (e.g., HHRA, Global, HHRP) and client offices (e.g., OAQPS) help assure effective targeting of research and communication of findings.
- *A continuing mechanism for independent review and oversight of the program.* The program has been reviewed by an external panel of experts (BOSC). A program review occurred in March 2005 and a mid-cycle review was conducted in September 2007. These periodic programmatic reviews supplement independent science peer review of the program, along with Laboratory, divisional, and peer review mechanisms in the extramural grants program. A mechanism for gaining access to program science-oriented advisors to meet annually to provide insight and critique is being explored.
- *Multi-pollutant assessments require strong interdisciplinary research framed by its utility to the client/user*: The program has partnered with its OAR and its Regional clients to develop a research agenda that feeds their need to better understand the science linkages from source emissions to health outcomes that will lead to the development of better tools and models for decision-making.

The select-subcommittee of EPA's BOSC that reviewed the PM and ozone programs in March 2005 made a number of general and specific recommendations. These recommendations (see below) have been incorporated into the current MYP.

- *The LTGs be reworded to succinctly focus on the essential responsibilities and desired direction of the program.* The revised LTGs contained in this MYP are consistent with the BOSC recommendations.
- *The MYP include a discussion indicating how the goals set out by the NRC flow into the cross-cutting research issues and how these are embodied under the two LTGs. If this discussion is in the Research Strategy for the Program, the MYP needs to be organized to make the connection between the research and the NRC goals obvious.* The MYP as described under its LTGs provides this research strategy that now encompasses more than the NAAQS and orients to the source-to-health outcome paradigm. The PM program historically has been aligned closely with the NRC topic areas and continues to be so. PM publications are categorized as such, but across the Clean Air Research program, the research that flows from the two LTGs is envisioned to support the new paradigm.
- *The PM-Ozone Program should commit to maintain the strong balance between intramural and extramural research.* This MYP maintains that balance and fully integrates the extramural (NCER: *Science to Achieve Results–STAR)* program activities (approximately 35%) with the intramural program comprising approximately 65% (inclusive of staff and program infrastructure). The research activities complement or elaborate upon one another to provide the integrated research that addresses OAR priorities.

The full BOSC report can be found at http://www.epa.gov/osp/bosc/pdf/pm0508rpt.pdf, and EPA's response can be found at http://www.epa.gov/osp/bosc/pdf/pm0602resp.pdf. The mid-cycle (2007) BOSC report can be found at http://www.epa.gov/osp/bosc/reports.htm.

3. ORD Laboratories and Centers

The research described in the Clean Air Research program MYP is conducted by investigators of ORD's National Exposure Research Laboratory (NERL), National Health and Environmental Effects Research Laboratory (NHEERL), and National Risk Management Research Laboratory (NRMRL) and by awardees of its extramural grants program, funded through the NCER STAR program. In addition, the National Center for Environmental Assessment (NCEA), while not funded through this MYP, plays a major role summarizing the latest scientific findings related to the effects of PM, ozone and other criteria pollutants to support development of future NAAQS standards. NCEA also conducts risk assessments (IRIS values) for high priority air toxic pollutants including associated assessments of residual risk after implementation of controls. There are also collaborative projects between ORD Laboratories and Regional scientists referred to as RARE (Regional Applied Research Effort) to enhance real-world research applications or to pursue unique opportunities.

ORD Clean Air Research program investigators are in a unique position within the research community because they conduct research to address pressing science data gaps that underlie regulations, as well as develop models, tools, and strategies to implement regulations or otherwise mitigate air pollution. The diverse nature of problem-solving research requires both breadth and depth across diverse scientific disciplines. ORD acquires the needed skill mix through the coordinated use of its intramural scientists housed within ORD's Laboratory structure, as complemented by the many talents of the academic community accessed through the

STAR program in NCER. ORD supports leading-edge research across the air pollution sciences. These include integrated epidemiological, clinical, and toxicological investigations of the health effects of PM and co-pollutants, with a systematic focus on components and sources, the identification and quantification of factors influencing actual human exposures, the development of ambient monitoring methods and air quality models used for compliance purposes, the study of basic atmospheric sciences to support these air quality models, and the development of specialized technologies for the measurement and control of diverse emissions. ORD is also unique as a research institution because of the close proximity of its intramural exposure, health, atmospheric science, and engineering researchers. The Clean Air Research program continually strives to coordinate its research agenda to the extent possible to provide coherent and relevant data and to maximize its ever-strained resources.

4. Client-Partners for Air Research

ORD has a unique relationship with the prime users of its research products. The users are involved in the prioritization of its research and, depending on the nature of the research, the users function as collaborators. Such collaborations help shape the product and ensure its relevance and utility. The client-partner for the work described in this MYP is EPA's Air program office, OAR. ORD's research to address uncertainties in the standard-setting process also deals with the rule implementation needs. Implementation research assists EPA Regions, States, tribes, and regional planning organizations (RPOs) in their activities to reduce ambient concentrations of air pollution, exposures, and, ultimately, adverse health effects. ORD research is key to its own office (NCEA) responsible for NAAQS pollutant science assessments (and, secondarily, the air toxics) used by the Agency in risk management decisions as described in the HHRA MYP.

In addition to supporting EPA's regulatory process, ORD's Clean Air Research program also supports environmental protection standard setting beyond the borders of the United States. Several countries in the European Union rely on ORD's research in environmental decision-making, and international organizations such as the World Health Organization rely upon ORD outputs and expertise to inform their activities and conclusions. Similarly, ORD works with scientists and policy-makers from numerous countries (e.g., Canada, Mexico, Netherlands, Germany) through informal collaborations or more formal Memoranda of Understanding to promote the exchange of the latest scientific knowledge in support of policy development.

5. ORD Partners in Research

Air pollution research is also conducted outside the EPA, and ORD keeps abreast of this research and coordinates its own activities with these to the extent possible. In some cases, a close collaborative relationship exists, such as with the National Oceanic and Atmospheric Administration (NOAA). ORD has worked closely with NOAA for more than 35 years with a focus on the development of air quality models appropriate for atmospheric research, standard implementation, and pollution forecasting. This relationship remains strong with the growing need for integration with changing meteorological and climate sciences.

HEI, funded jointly by EPA and the motor vehicle industry, is another important partner in the support of ORD's mission. HEI-sponsored research is coordinated with ORD/EPA and conducted through requests for proposals, drawing from the diverse academic community to focus on issues or questions not readily pursued within the government laboratory structure. Notably, HEI-sponsored activities in the independent reassessment of epidemiological findings have been invaluable to EPA in the regulatory decision-making process. Research support also is provided by the National Institutes of Health, including the National Institute of Environmental Health Sciences (NIEHS) and the National Heart, Lung, and Blood Institute (NHLBI), and select industrial organizations, including the Electric Power Research Institute (EPRI) and the Coordinating Research Council (CRC)—the latter through its support of HEI. In recent years, ORD has co-funded requests for applications (RFAs) and workshops with NIEHS and NHLBI and continues to explore opportunities for similar co-funded initiatives. Most recently, the Clean Air Research program has initiated efforts to coordinate its extramural research with the funding agencies already noted along with the California Air Resources Board, which has a significant air pollution research agenda.

In an effort to better coordinate with the broader air pollution research arena, EPA takes the lead role in communicating its research goals and program structure with other public and private organizations through two coordinating bodies: 1) NARSTO[12] and 2) the White House CENR, AQRS.[13] These groups meet regularly (about monthly) to communicate program findings and directions to coordinate and leverage activities wherever possible. In addition, there are several groups conducting air quality studies, including ambient PM measurements by the U.S. Department of Energy (DOE) in the upper Ohio River Valley and multi-agency state efforts in California and Texas. Multi-state organizations such as Northeast States Coordinated Air Use Management and RPOs in the Midwest also are sponsoring studies of ambient air quality. In emission characterization and inventory development, the U.S. Department of Agriculture is providing support for research to improve emission inventories for ammonia from agricultural operations. There are also several projects related to emission inventory improvement and air quality model application being conducted by States and the RPOs. Further emission inventory and characterization work is being conducted or supported by EPRI, the American Petroleum Institute and Gas Technology Institute, and the CRC.

As noted earlier, EPA stays abreast of this work (both health and implementation research) via its formal participation in the CENR and NARSTO, continuous interactions with Federal colleagues, and through scientific and technical conferences and organizations. Information on these complementary research activities is taken into account by both principal investigators and ORD scientific and technical management when research needs are evaluated, and efforts are undertaken to meet the priorities of OAR and the goals of the MYP. Presently, ORD is co-leading an effort with HEI to promote coordination of ongoing research across these many sponsors and to provide a central resource of information for research on air pollution issues.

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[12] Formerly an acronym for "North American Research Strategy for Tropospheric Ozone," the term NARSTO has become simply a wordmark signifying the tri-national, public-private partnership for dealing with multiple features of tropospheric pollution, including ozone and suspended particulate matter.
[13] http://esrl.noaa.gov/csd/AQRS/ .

EPA also works cooperatively with the Department of Defense through the Strategic Environmental Research and Development Program (SERDP) to conduct research of interest to both agencies. SERDP annually issues statements of need, many of which have air emissions implications. Similarly, partnerships have been formed with DOE to evaluate promising technologies to reduce air emissions from coal-fired power plants and other energy sources.

6. Resources

The research described in this MYP covers the next 5 years and is based on an assumption that the total available resources will remain nominally constant. EPA allocated approximately $78 million dollars and 245 full-time equivalent personnel to air research in fiscal year 2007. Of the total funding, $42 million was for personnel compensation and benefits, travel, information technology, operating expenses, capital equipment, and repairs and improvements. The remaining $36M was for research and support expenses spent via contracts and grants. The president's fiscal year 2008 budget requests $81M and 236 full-time equivalent personnel for air research.

II. THE CLEAN AIR RESEARCH MULTI-YEAR PLAN

A. Changes from the Previous MYP

This MYP 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. Budgeting (both proposals and tracking) was also separate. As already noted, the science and regulatory programs are evolving toward a multi-pollutant perspective that better reflects the realities of human exposures and offers the potential for more effective control and public health protection.

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 L/C-focused 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, developing the underlying science for developing health-based standards to regulate air pollution regulations and developing tools to implement strategies to meet those standards to protect public health and the environment; and

2. Pursue scientific advances that will lay the foundation for the next generation of air pollution standards and management strategies.

B. Long-Term Goals

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.

(*Short title*: Reduce uncertainty in standard setting and air quality management decisions due to advances in air pollution science.)

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

(*Short title*: Reduce uncertainties in linking health and environmental effects to air pollution sources.)

The first LTG (LTG 1) supports the following two research themes:
1) Developing the NAAQS and other air quality regulations; and
2) Implementing air quality regulations.

The second LTG (LTG 2) is oriented toward three research themes
3) Launching a multi-pollutant research program,
4) Identifying specific source-to-health outcome linkages, with initial emphasis on "near roadway" impacts, and
5) Assessing the health and environmental improvements due to past regulatory actions.

C. LTGs in Relation to Air Program Needs, Priority Science Questions and APGs

EPA is mandated to periodically (at 5-year intervals) reassess the adequacy of the six NAAQS (PM, ozone, SO2, NO2, CO, and lead) and reaffirm or revise each specific standard. ORD provides and supports the science to conduct these assessments, as well as the science and engineering needed to implement the standards at the appropriate regulatory jurisdictions. In the case of HAPs, the CAA requires EPA to develop emission standards for sources, known as MACT standards, based on the best controlled similar sources. Following implementation of MACT, EPA must assess risks remaining to human health and the environment, and must promulgate additional emission standards if appropriate. Although secondary to the NAAQS in program priority, ORD can, under this revised MYP, similarly provide science related to these HAPs issues, particularly through project integration.

As can be seen in Figures 3 and 4, the critical science questions for the Clean Air Research program (as derived from the major policy challenges identified by our clients and external program reviews) flow into these two LTGs. The vision is that, over time, increasing emphasis will be given to multipollutant approaches. As critical steps in fulfilling the LTGs, the APGs will strategically reduce uncertainty in assessments, the impacts of which should be more readily and realistically measured. However, the progression of science is always incremental, and it is likely that in reducing some uncertainties others will be unveiled. Nevertheless, science has always built from such a process, and there is sufficient flexibility in the various products and the MYP to allow for midcourse adjustments. The specified APGs and related science products (APMs) to meet these goals evolved from deliberations within the EPA Air RCT and they have been vetted through senior management.
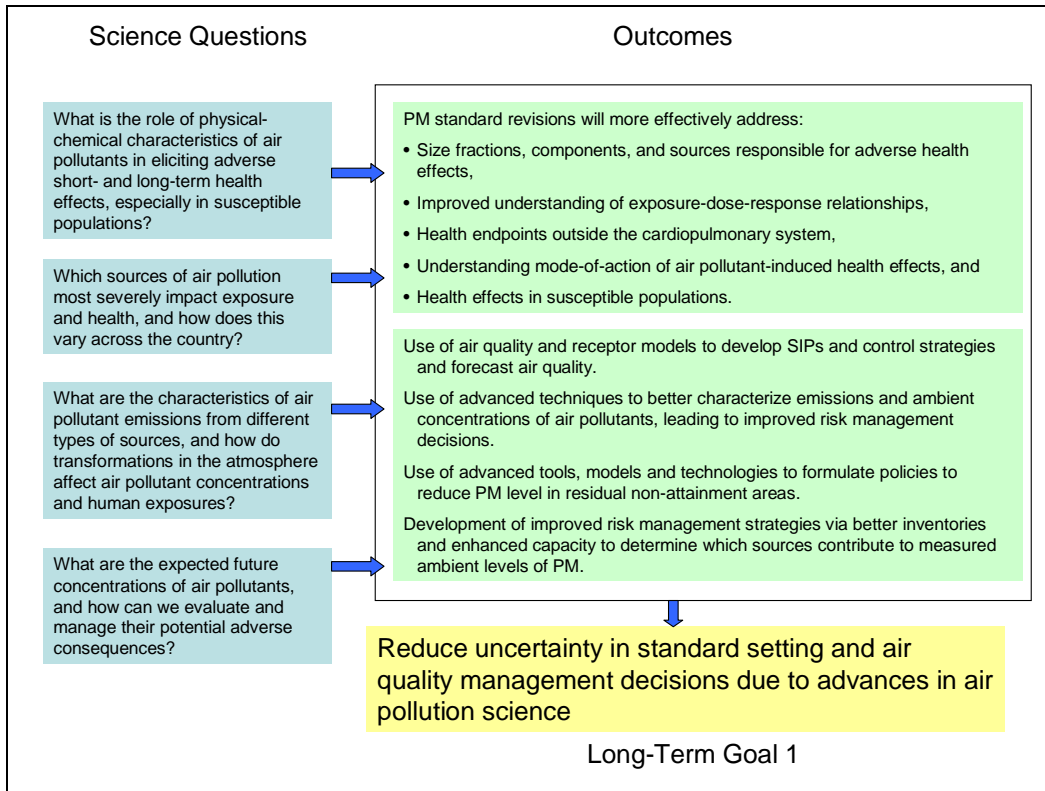
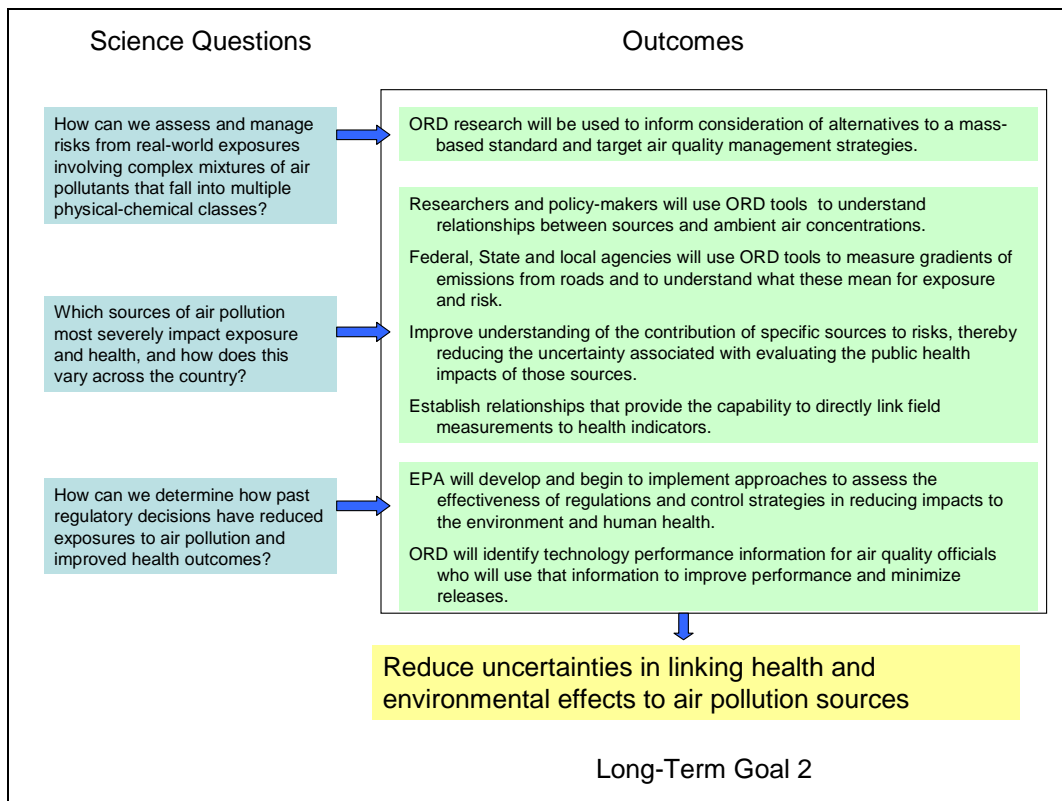**Figure 3. LTG I Critical Science Questions**

Figure 4. LTG II Critical Science Questions.

<u>*LTG 1*</u>
In accordance with EPA's legislative 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.

Under this goal, ORD highlights two themes that provide direct support to OAR's mission: 1) development of the NAAQS and other air quality regulations and 2) implementation of the air quality regulations (see Figure 4). These themes focus on the standards that are used to regulate air pollutants in keeping with the traditional roles of ORD relative to the OAR regulatory program. Theme narratives are provided to demonstrate the continuities within the program with underlining of phrases to note their linkage to APGs in Tables 1 and 2. Satisfaction of individual APGs generally does not necessarily conclude research under that topic but, rather, registers a time point for assessment of the knowledge at that time as it relates to the regulatory need. This may impact a level of emphasis of this research thereafter or shifting of focus based on that knowledge. Some fundamental questions (e.g., regarding size, composition, susceptibility, model delivery) may require continued investigation to address ongoing program office needs.

<u>Theme 1: Support for the development of the NAAQS and other air quality regulations</u>

ORD plays a key role in the development process of air quality standards. ORD peer-reviewed research results are the strong foundation on which ORD builds the assessment of both human health and environmental impacts for each air pollutant. ORD staff also is involved heavily in the design and review of the NAAQS policy options developed for the Administrator. Similarly, ORD staff is involved in the development of the toxicological data base and mode-of-action models, and their use in the HAPs risk assessment process, and in the various rule-making actions by OAR offices (e.g., OTAQ). At the highest level, ORD provides direct scientific consultation to the Administrator in proposed and final air regulatory decisions.

Uncertainties exist in all scientific investigations, and the Clean Air Research program directs its attention to those of highest priority to its clients and the scientific community. Uncertainties surrounding coarse particles ($PM_{10-2.5}$) were noted specifically in the promulgation of the most recent PM regulations. Also, there continues to be considerable interest in the significance of ultrafine particles, relative to fine particles ($PM_{2.5}$), as to their potential role in causing adverse health effects. To address these questions, one research goal is to investigate <u>exposures and the role of different PM size fractions in health outcomes (APG 1)</u>. Another priority of interest to OAR is exploring the potential for alternatives to the current PM mass-based standards. As the science has been more complex in this area than originally anticipated, research on <u>exposure and health effects of PM components (APG 2)</u> [some of which are among the 188 HAPs] is ongoing under LTG 1. Additional research on components is being conducted under LTG 2 (see below). Different views about the annual PM standard emphasize the need for additional studies on the <u>health effects of long-term exposure to $PM_{2.5}$ (APG 5)</u>.

Much work continues on the potential exposure and health outcomes associated with air pollution. As per RCT-determined priorities, PM research occupies much of the program effort; however, some health research addressing specific pollutant-relevant questions is conducted as well. Ozone, for example, is the most ubiquitous oxidant in the ambient air and has known

toxicity at regularly encountered levels. The essential database for ozone assessments largely has emanated from ORD research efforts over the past 30 years. In the past 10 to 15 years, PM has come to dominate the health program, but ozone questions are addressed as specific needs arise or when it can function as a model (e.g., genetic susceptibility). Recently, functional outcomes at concentrations well-below the NAAQS have been reported, and OAQPS has specifically requested that the research program conduct replicate studies at similar concentrations. However, these efforts remain modest. In another context, ozone has gained some prominence because of evidence of potential mortality impacts and morbidity at levels below the 1997 NAAQS. The Clean Air Research program monitors these studies but is not directly pursuing this issue.

On the other hand, questions about <u>PM and co-pollutant (including ozone) risks (APG 5)</u> is gaining prominence on the health science agenda. Air toxics research will be undertaken for specific HAPs that are most prominent in PM-polluted air sheds, especially if linked to mobile sources. To that end, the relative and interactive roles of specific pollutants in causing effects continue to be investigated <u>to define causation and refine our understanding of biologic modes of action (APG 6).</u> Most health research supporting air toxics IRIS assessments is found in other MYPs (e.g., HHRP, HHRA, and Homeland Security.)

Intrinsic to this research is the evolving importance of "who is susceptible to which effects," defining factors affecting <u>susceptibility (APG 3)</u> to adverse health outcomes, and examining gene-environment interactions. Recent work on susceptibility has uncovered the potential for health <u>effects of air pollutants beyond the cardiopulmonary system (APG 4),</u> which may have implications for additional susceptible subgroups. With risk assessments providing the basis for development of risk management options, providing up-to-date information on <u>exposure-dose-response relationships (APG 7)</u> is a key area of program support. Targeted studies to address the level and duration uncertainties with ozone have been considered and, if implemented, may displace lower priority PM research.

To the extent possible, the health research is interdisciplinary, not only across health disciplines but across the physical sciences, including exposure science and air quality assessments. As such, maximum power is gained to address potential interactions among pollutants, as well as to assessments of specific roles of other pollutants, including selected air toxics, in causing health effects.

2008

Improved information for hazardous air pollutants

Advanced air quality models

2009

Roles of different PM size fractions

Advanced techniques for source and ambient PM, precursors, and toxics

Integrated multiple pollutant research program strategy

Framework to assess the effectiveness of air pollution regulations and control strategies

2010

Tools to link health and ecosystem impacts to air pollution sources

2011

Factors affecting susceptibility to adverse health outcomes

Evidence for effects of air pollutants beyond the cardiopulmonary system

Effects of long-term exposure to $PM_{2.5}$

Data and tools to assess the importance of particles in residual nonattainment

Air quality modeling system that couples meteorology and provides early warning regarding ozone and $PM_{2.5}$

Emissions factors and chemical composition data for dispersed sources of air pollutants

2012

Exposure to PM components and their role in health effects

Importance of key biologic pathways

Ambient concentration and exposure-dose-response relationships

Improved source-receptor based methods and models

Significance of near road emissions/exposures and related health risks from mobile sources

Multi-city/multi-pollutant studies to assess the relative health impacts of sources

Approaches to relate sources/ambient air to health effects

Evaluate whether control technologies are achieving the reductions anticipated

Refine accountability framework

Research Themes

1 - Support development of NAAQS and other air quality regulations

2 - Support for implementation of air quality regulations

3 - Pursuing a multi-pollutant approach

4 - Identifying source-to-health linkages

5 - Assessing health and environmental improvements due to past Agency activities
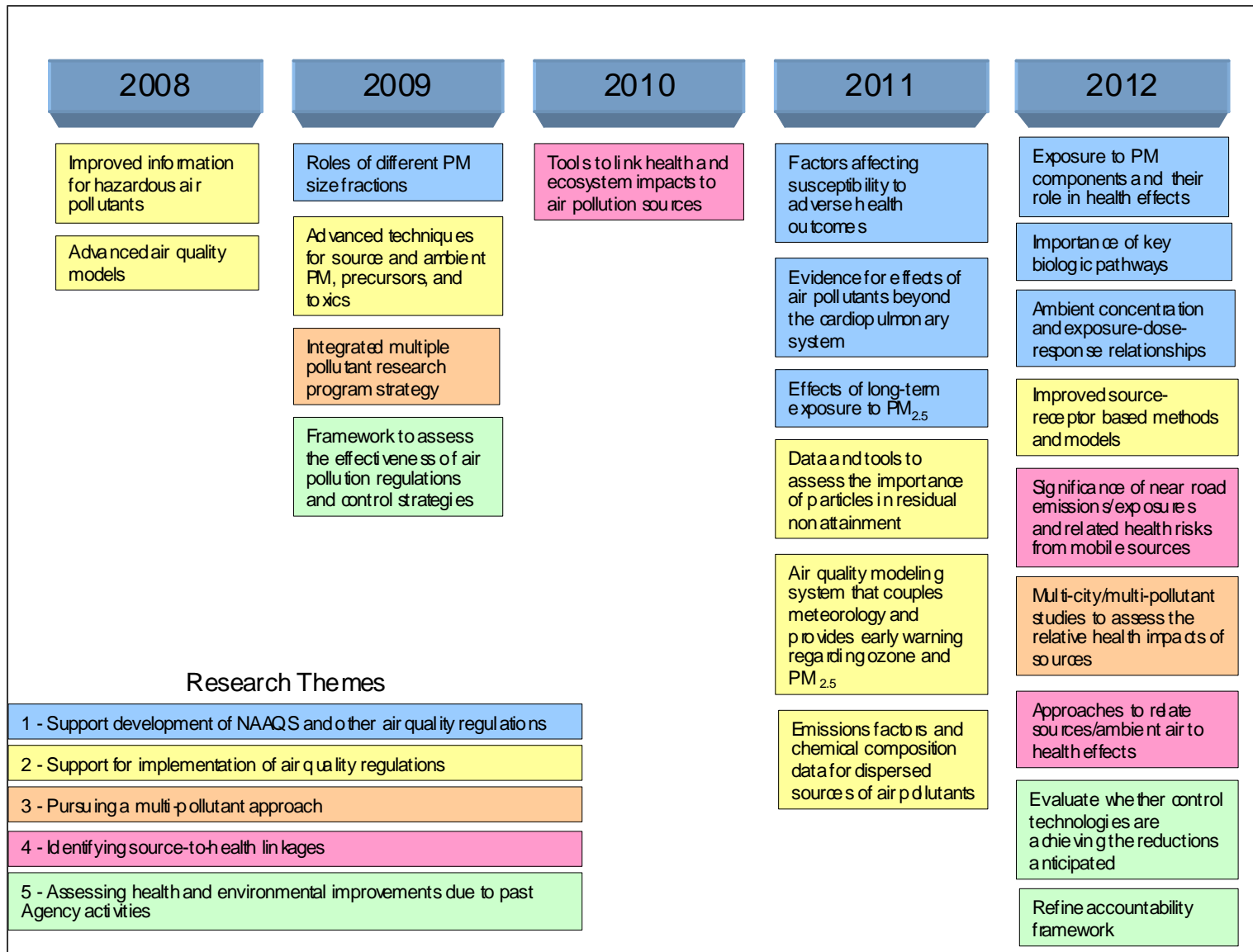
Figure 5. APGs by Theme. [Note that some APGs relate to more than one theme, but have been assigned to a primary theme.]

Table 1. APGs and APMs for LTG 1, Theme 1

	APG/APM Title	Year Due	Lead Lab
APG 1	**Evaluate exposures to different PM size fractions and determine the role of those fractions in particle-associated health effects**	2009	NHEERL
APM 1	Characterize physiologic and biochemical responses of individuals, animal models, or cultured cells to different size PM fractions and define the mechanisms by which each size fraction causes effects	2009	NHEERL NCER
APM 2	Provide exposure and health effects data on urban and rural coarse PM in support of the NAAQS	2009	NHEERL NCER
APG 2	**Evaluate exposure to PM components and the role of those components in particle-associated health effects**	2012	NHEERL
APM 3	Report on how the presence and levels of PM components impacts particle related health effects	2009	NHEERL
APM 4	Identify health effects associated with components of ambient particulate and gaseous co-pollutants	2012	NHEERL NCER
APM 5	Identify new biomarkers of exposure and/or effects to specific PM components and associated gases	2011	NHEERL NCER
APM 6	Provide a comparative toxicity testing framework and rank the relative potency of PM components, testing particles from a broad range of different sources including mobile and industrial sources	2012	NHEERL NCER NRMRL
APM 7	Develop data on the size distribution and detailed chemical composition of combustion-generated particles produced from full- and pilot-scale systems for use in real time inhalation toxicology studies	2008	NRMRL
APM 8	Complete field data collection for field studies to assess ambient, indoor, outdoor, and personal exposure to PM constituents and co-pollutants with potential for short-term health effects and compile a database of toxic agent concentrations, exposures, participant activities, and exposure factors	2008	NERL
APM 9	Develop data and models to evaluate relationships among PM size, components, sources, ambient concentrations, and personal exposures	2010	NERL
APG 3	**Elucidate the susceptibility and vulnerability factors that increase risk with adverse health outcomes associated with air pollutants**	2011	NHEERL
APM 10	Report on the results of studies illustrating how factors of susceptibility impact air pollution responses	2009	NHEERL
APM 11	Determine the extent to which genetic polymorphisms present in a significant portion of the population or differences in gene expression patterns in animal models explain why some people are more responsive to air pollutants than others	2011	NHEERL NCER
APM 12	Determine whether there are host susceptibility factors, such as disease phenotype, lifestyle, or life stage, that make people with cardiovascular and/or pulmonary disease more susceptible to the effects of air pollutants	2011	NHEERL NCER
APM 13	Evaluate whether there are pharmaceutical or dietary interventions that can protect susceptible populations from the effects of air pollutants, and, if so, what are the mechanisms by which these interventions protect people?	2011	NHEERL NCER
APM 14	Develop data and models to identify subpopulations with disproportionately high exposures to air pollutants	2011	NERL
APG 4	**Provide exposure-based evidence for systemic effects of air pollutants other than those on the cardiopulmonary system**	2011	NHEERL
APM 15	Characterize the long-term health effects of short- and long-term low-	2010	NHEERL

	APG/APM Title	Year Due	Lead Lab
	level exposure to air pollutants		NCER
APM 16	Evaluate the importance of early life exposures to air pollutants, and whether they are predictive of future effects later in life [also under Susceptibility]	2011	NHEERL NCER
APM 17	Characterize the mechanisms by which air pollutants affect extra-cardiopulmonary organ systems and associated effects	2010	NCER NHEERL
APG 5	**Provide an assessment of long-term exposures to fine particulate matter (PM$_{2.5}$) and gaseous co-pollutants, specifically nitrogen oxides, as determinants of regional and intra-urban differences in the prevalence of subclinical indicators of cardiovascular disease**	2011	NCER
APM 18	Develop a model for assessing regional and intra-urban differences in ambient long-term PM concentrations in nine U.S. communities	2009	NCER
APM 19	Evaluate the association of the prevalence of subclinical indicators of cardiovascular disease with regional and intra-urban differences in estimated long-term exposures to PM$_{2.5}$	2010	NCER
APM 20	Evaluate the modification by co-existing health conditions (e.g., diabetes, hypertension, obesity) and individual-level factors (e.g., race/ethnicity, gender) of the association of the prevalence of subclinical indicators of cardiovascular disease with estimated long-term PM exposures	2011	NCER
APG 6	**Evaluate the importance of key biologic pathways in explaining how air pollutants cause adverse health outcomes**	2012	NHEERL
APM 21	Determine if there is a common molecular mechanism (e.g., production of oxidative stress, phosphatase inhibition, disruption of iron homeostasis) through which air pollutants induce toxicity.	2012	NHEERL NCER
APM 22	Identify the mechanisms by which air pollutants cause adverse health effects	2012	NCER NHEERL
APG 7	**Characterize the ambient concentration and exposure-dose-response relationships for PM and other priority air pollutants**	2012	NHEERL
APM 23	Characterize the effects of ozone exposure in selected populations at exposure levels near the standard	2010	NHEERL
APM 24	Can predictive exposure-dose-response models be developed to improve the accuracy and precision of predictions of human health risk from experimental data from animal and in vitro experiments?	2012	NHEERL
APM 25	Report estimates from epidemiological studies of changes in health outcomes associated with changes in ambient PM$_{2.5}$	2010	NCER

Theme 2: Support for implementation of air pollution regulations

Development of strategies to meet national air pollution regulations for PM and ozone requires extensive knowledge about current ambient concentrations, sources that contribute to the measured levels, and the impact of emissions and associated atmospheric processes on future air quality. ORD provides fundamental science to develop and improve tools that are essential to air quality management at all levels, including OAR, Regions, States, and tribes. The State Implementation Plans (SIPs) that provide details on actions that will be taken to reduce emissions are heavily dependent on the models and other products produced under this research theme. CMAQ (APG 9, 11) is widely used by States to inform their SIP development. CMAQ is updated annually and improved based on the latest research on emissions (APG 8) and

atmospheric science (APG 12) from ORD and the broader air quality research community. In addition to these inputs, CMAQ must be coupled with meteorology models (APG 9) to generate future estimates and forecasts (APG 12) of ambient ozone and PM. Similarly, efforts are underway to link CMAQ to climate models as the science moves toward a more realistic approach to studying climate and air pollution interactions (found in the Global Change Research Program). As these multi-pollutant (one-atmosphere) models are refined, new emission factors (APG 13) and refinements are needed at local and community scales to better estimate population exposures to HAPs for risk assessment. Indeed, assessing exposures with empirical field data and model development are important links between source emissions, atmospheric transformation products, and human exposure. Source apportionment (APG 10) science is also a key component of this theme. It depends both on measurement techniques (APG 10) to characterize sources and ambient concentrations and receptor-based models (APG 14). The identification of source categories contributing to ambient concentrations provides the basis for targeted, cost-effective control strategies. Hence, the broad use of these implementation tools requires not only that ORD conduct high-quality relevant research, but also provide its key clients with the results in understandable and useful formats.

The issue of HAPs (air toxics) ranks highly among OAR and regional priorities, but second to PM and ozone. As such, compared with ORD's research investment on the PM issue, including co-pollutants, dedicated research on air toxics is relatively small. The MYP includes one goal to improve emissions, concentrations, and exposure estimates for HAPs (APG 8).

Table 2. APGs and APMs for LTG 1, Theme 2

	APG/APM Title	Year Due	Lead Lab
APG 8	**Provide improved measurement systems, data to better quantify and estimate emissions, concentrations, and exposures, and health effects information for indoor and ambient hazardous air pollutants**	2008	NRMRL NERL NHEERL
APM 26	Demonstrate improved methods for measuring ambient and personal concentrations of acrolein and 1,3 butadiene	2008	NERL
APM 27	Enhance air quality and exposure modeling tools to address finer scale air toxics concentrations and exposures	2008	NERL
APM 28	Collect and analyze existing data to understand critical factors which influence relationships between human exposure and ambient air toxic concentrations (existing APM 32)	2008	NERL
APM 29	Develop and validate the Jet REMPI technology for real-time measurement of trace organic air toxics from multiple sources. (APMs 30 and 278 are consolidated)	2008	NRMRL
APM 30	Update AP-42 emission factors for landfills	2008	NRMRL
APM 31	Provide a summary report of past results and future directions for the air toxics research program under the Multipollutant Air Research Program and how IRIS risk assessment health effects support needs will be addressed	2008	NHEERL
APG 9	**Provide advanced air quality models that incorporate the latest atmospheric and emissions data to OAR and States**	2008	NERL
APM 32	Deliver to OAR the simplified and evaluated regulatory version of the PM chemistry model (existing APM 386)	2007	NERL

	APG/APM Title	Year Due	Lead Lab
APM 33	CMAQ model system release and evaluation, including improved capability for aerosol processes, especially secondary organic aerosol production	2008	NERL
APM 34	Release peer reviewed EPA receptor modeling tools to be used by States to enhance their ability to develop SIPs	2008	NERL
APM 35	Transfer information to OAR and States regarding characteristics of open burning of biomass in wild and prescribed fires (existing APM 224)	2008	NRMRL
APM 36	Produce a prototype tool to improve the geographic allocation of emissions for use in air quality models	2008	NRMRL
APG 10	**Deliver new and improved techniques to measure and characterize source and ambient concentrations of PM and PM-related precursors and toxics**	2009	NRMRL NCER
APM 37	Verification of Portable Optical and Thermal Imaging Devices for LDAR	2009	NRMRL NERL
APM 38	Evaluate and improve methods to characterize ammonia (including ammonia nitrate and ammonia sulfate) concentrations in the ambient environment	2009	NRMRL
APM 39	Provide to OAR, States, and the scientific community improved methods for organic speciation of fine particles (existing APM 319)	2007	NERL
APM 40	Provide to OAR, States, and the scientific community improved methods for measuring the organic carbon and elemental carbon fractions of PM (existing APM 320)	2007	NERL
APM 41	Improve measurement methods for molecular tracer species and identify new molecular tracers.	2009	NCER
APG 11	**Provide models, data, and tools to better manage PM in the atmosphere, including carbonaceous particles that contribute to high levels of PM in areas of the country where NAAQS attainment will linger even after national rules are implemented.**	2011	NRMRL NCER
APM 42	Study secondary organic aerosol formation mechanisms, including cloud processing, aromatic precursors, and biogenic precursors	2008	NCER
APM 43	Improve linkages between emission sources and atmospheric transformation processes for primary carbonaceous PM and secondary organic aerosol precursors	2008	NCER
APM 44	Complete development of novel analytical methods that can be used to determine the chemical and physical properties of combustion emissions and atmospheric aerosols and provide guidance on their use to OAR and State agencies	2008	NRMRL
APM 45	Integrate receptor, source-based, and inverse modeling for PM source apportionment.	2009	NCER
APM 46	Improve the SOA chemistry model for CMAQ to include additional anthropogenic SOA sources.	2011	NERL
APM 47	Produce an operational emissions allocation tool, compatible with the OAQPS Emissions Modeling Framework	2011	NRMRL
APM 48	Measurement of ammonia air-surface exchange in forest and agricultural landscapes	2011	NRMRL
APM 49	Evaluate computational atmospheric chemistry approaches to determine whether they can be used to develop chemistry sub-models	2011	NERL
APM 50	Improved CMAQ modeling system for use in urban-scale residual nonattainment areas	2011	NERL

	APG/APM Title	Year Due	Lead Lab
APM 51	Develop CMAQ linkages to global chemical transport model	2011	NERL
APG 12	**Develop modeling systems that couples air quality and meteorology models for better estimates and forecasts of ambient ozone and PM$_{2.5}$**	2011	NERL
APM 52	Develop and test a prototype 2-way coupled WRF-CMAQ modeling system	2008	NERL
APM 53	Analysis and evaluation of PM forecast simulations over the Continental United States using a developmental version of CMAQ	2009	NERL
APM 54	CMAQ modeling system used for fully operational daily forecasting of both ozone and PM$_{2.5}$	2011	NERL
APM 55	Develop improved chemistry model for CMAQ to predict ambient concentrations of organic and inorganic nitrates in PM2.5	2010	NERL
APM 56	An operational 2-way coupled WRF-CMAQ modeling system will be released publicly	2011	NERL
APM 57	Apply the prototype 2-way coupled WRF-CMAQ model to evaluate the regional air quality and climate impacts of future-year anthropogenic emissions scenarios	2011	NERL NRMRL
APM 58	Evaluate impact of two-way coupled WRF-CMAQ on regulatory applications	2011	NERL
APG 13	**Provide new emissions factors and chemical composition data for dispersed sources of air pollutants, including off-road vehicles (airplanes, ships, construction equipment) to directly support State efforts to improve emissions inventories**	2011	NRMRL
APM 59	Transfer data to OAR and the States on the chemical characterization of carbonaceous PM as a function of particle size.	2008	NRMRL
APM 60	Enhance and update the SPECIATE database of emission profiles by source category for air quality modeling and source-receptor modeling applications	2008	NRMRL
APM 61	Transfer to OAR and the States improved PM and HAP emission factors and chemical source profiles for commercial aircraft engines	2010	NRMRL
APM 62	Determine emission factors and characteristics of open burning of agricultural fires and wild and prescribed forest fires for ozone, PM, and HAPs	2011	NRMRL
APM 63	Characterize HAPs and other NAAQS-related pollutants from priority off-road sources.	2011	NRMRL
APM 64	Identify emissions of regulated and unregulated pollutants during the use of alternative fuels and fuel additives in on-road motor vehicles	2011	NRMRL
APG 14	**Provide new and improved source-receptor based methods and models, and associated input data (e.g., source markers) to better quantify ambient concentrations and human exposure for coarse and other PM size fractions, as well as related PM components identified by health researchers as important.**	2012	NERL
APM 65	Improve source apportionment through the development of enhanced sampling and analytical methods and receptor-based models.	2012	NERL
APM 66	Evaluate and improve receptor modeling for PM source apportionment	2009	NCER
APM 67	Provide new and improved source-receptor-based models to quantify the sources of coarse and other PM size fractions.	2011	NERL
APM 68	Evaluate exposures to sources of coarse and other PM size fractions identified by health researchers as important.	2012	NERL

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

This goal represents a major strategic change in the ORD's Clean Air Research program. It envisions an approach to air pollution research that attacks the problem from a multi-pollutant perspective, encompassing all aspects of air pollution from source to health outcomes. It brings together three themes that are complementary and support one another and yet relate and expand the two themes comprising LTG 1 (Figure 5). Following the two themes of LTG 1, the themes of LTG 2 include: 3) launch a multi-pollutant research program to better reflect the nature of real world air pollution; 4) develop a source to health outcome approach to more effectively address air contamination, starting with the near-road issue; and 5) develop a framework for assessing the health and environmental impacts of EPA regulatory activities (i.e., accountability). For each theme, Table 3 aligns the APGs abbreviated as underlined phases within the narrative below.

Implementing LTG-2 within the program promotes leveraging of ORD research activities to include under-funded goals within a broader framework, and more a logical orientation of the Clean Air Research program with the recent reorganization of our major client office, OAQPS.

Theme 3: Develop a multi-pollutant approach to research

Air pollution is a complex mixture comprising hundreds of primary emission products and secondarily transformed pollutants dispersed in ambient air. As such, in developing a multi-pollutant research activity to address associated risks, there must be consideration of the inherent toxicity of each constituent of the mixture, the likelihood of exposure to these constituents, and, even more challenging, the potential interactions among these constituents (which, in the end, may result from unique characteristics of toxicity or exposure because of these interactions).

From a health perspective, noncancer effects are seemingly dominated by just a few pollutants (e.g., PM, ozone, CO, aldehydes) and, likewise, cancer effects involve specific classes of polycyclic organic compounds, and select metals and organic vapors. Indeed, PM is itself a complex mix with health impacts (both noncancer and cancer) that, to date, are best described as associated with PM mass. However, it remains difficult to attribute health effect observations completely to any single pollutant or class of compounds. Further, the evidence available to evaluate hazard and dose-response is highly variable among pollutants, with human evidence rarely available for the hazardous air pollutants whereas substantial human evidence is typically available for the criteria air pollutants, resulting in greater uncertainty in characterizing potential health risks from exposure to the HAPs. Additivity, antagonism, and potentiation have all been observed with air pollutant mixtures, but because the phenomena are poorly understood, regulation is, at present, best achieved by single pollutant regulations.

Like PM itself, the chemistry of the general air pollution mix is more complex than the mere listing of the panoply of pollutants in ambient air. Many reactive gaseous and particulate components emanate from varied sources, which, through complex atmospheric chemistries, alter the atmospheric profile by consuming existent pollutants or creating new ones. Questions exist as to how PM as a complex mix in and of itself should be treated. Total mass is the default,

but as a measure composite mass is not necessarily robust across all health outcomes and end points. Hence, questions are raised relative to what is known about the toxicity of mixtures. Co-pollutants may interact chemically or may act through the exposed host altering his/her sensitivity; much remains unclear. If PM (as a collage of primary source emissions and secondary transformation products) and ozone (a gaseous product of atmospheric transformations) have the most impact on health outcomes, what might be the most effective strategy to minimize public health risk? Currently, measurement of PM only by mass regulates all contributors equally. In contrast, ozone is measured as a singular end product even though there are uncertainties remaining as to which source emissions are most significant in its formation. These enigmas beg the question, Can air pollution controls be better focused on sources from which the emissions are ultimately the most toxic?

The challenge is to design a research paradigm to foster a logical and relevant transition from a single-pollutant research focus to a multi-pollutant approach, with the goal of controlling at the source to optimize health risk reductions. Initially, ORD must develop an integrated multiple pollutant research strategy (APG 16) that complements the goals and needs of ORD clients. Traditionally, systematic approaches to the assessment of pollutant mixtures have either started with a mixture and attempted to assess the driving components and/or interactions, or started with the component parts and built toward the mixture. Both approaches have merit and weaknesses and work best when used in a complementary, strategic manner. New "systems" approaches offer some guidance but, as yet, have had limited influence on the air pollution sciences. Part of any strategy, however, must involve deductive and inductive components. To the former, the Clean Air Research program will include multi-city/multi-pollutant studies (APG 19) to establish a matrix of diverse source exposures from which component-driven health impacts might be discerned. Epidemiological and toxicological studies will determine whether adverse health outcomes are associated with the various exposure scenarios and PM source-derived components. These data and findings can be compared with toxicology studies of defined laboratory source emissions, as well as controlled exposures to concentrated air particulates or other pollutants. Research will also be conducted to determine which sources and components humans are actually exposed to across cities. Integrating information from studies of specific sources and a hierarchy of associated toxicological potential, along with studies from cities with differing source profiles, will refine the assessment of risk and the criticality of pollutant type, character and source (integrated with findings from Theme 4).

Theme 4: Identify specific source-to-health linkages, using "near-roadway" as the prototype

Research clearly is needed to understand relationships among air pollutants (PM hazardous components, co-pollutants, and HAPs) emitted from emission sources and the resulting ambient concentrations and transformation products that may be involved in human exposures and adverse effects. ORD will develop analytic methods and enhance models/tools to link health (and where possible ecosystem) impacts to air pollution sources (APG 17). For example, methods to identify which pollutant sources contribute to exposures need further refinement for routine application to studies of health outcomes. Likewise, efforts need to be made to avail new information resources, such as satellite data, and to develop statistical techniques that can combine and integrate diverse data to improve ambient air quality and exposure estimates. This issue will grow in importance as more is learned on air quality-climate interactions.

As an initial focus for research on source-to-health linkages, ORD will address <u>near-road emissions, exposures, and related health risks from mobiles sources and evaluate risk management options (APG 18)</u>. Near-road air pollution was selected as a central theme because it is a problem that is of pressing ORD partner interest/need; requires integrated, multidisciplined field and laboratory sciences; and allows the assessment the impacts of mitigation (accountability; see Theme 5 below).

A growing number of health studies have identified adverse health effects, including respiratory disease, cancer, and even mortality, for populations living near major roads. These initial reports are raising concerns about the building of schools near roadways, the quality of indoor air in existing schools near roadways, and the general health impacts on people living near roads. A number of ongoing but somewhat disparate efforts regarding near-road environments already exist within the ORD portfolio. A more directed near-road pilot research effort has been initiated, with preliminary studies of near-road emissions, distance from road measurements, development of local environment dispersion models, and assessments of low-cost mitigation strategies for the indoor school environment. This research theme expands these efforts to determine the broader significance of near-road emissions from varied traffic, vehicles, and conditions; potentials for exposure and related health risks; and the development of tools for addressing the problem.

Other research approaches will also be undertaken to systematically <u>evaluate linking air pollution sources and components to health effects for specific sources (other than roadway) and single geographic locations (APG 20)</u>. Research projects will include toxicological studies of source-specific emissions, epidemiological studies in communities impacted by specific sources or industrial sectors, and health and exposure studies in specific geographic locations impacted by multiple sources. This approach dovetails with the multi-pollutant/multi-city studies underway or planned within Theme 3. Research also will address methods for evaluating risk management options in a multi-pollutant context. It is clear from existing research and the new sector-based approaches being adopted by OAQPS that controls at the source targeting certain specified pollutants typically reduce other emission components, many of which are also of concern.

<u>Theme 5: Assess health and environmental improvements due to past regulatory actions</u>

Assessing the effectiveness or impact of regulatory decisions (often referred to as "accountability") on exposure and health is a complex and challenging undertaking. When a new environmental regulation is issued, the changes necessary to achieve the regulatory objective of improved public or environmental health are generally not instantaneous, so there is rarely a step change in the outcome. Development of implementation plans, promotion and adoption of new technologies or management strategies, and other activities all take place over an extended time period. Even with the phase-out of lead from auto fuels in the 1970's, the reductions in exposures and blood lead levels were not immediate, and even today vestigial lead (some from still uncontrolled sources such as piston aircraft fuels) and re-entrainment from deposition sites remain. During an implementation period, especially if extended over time, exposure and health also may be affected by other factors such as changes health care practices, changes in lifestyle (e.g., diet, smoking, obesity trends), or other changes resulting from regulatory or market forces. Research is underway to develop methodologies that can address the complexities of assessing

regulatory impacts. Several recent studies (intramural and from HEI) have suggested the feasibility of such assessments.

As part of this research program, ORD intends initially to develop a framework for accountability studies (APG 15). This in-house effort will be coordinated with related work underway through HEI. A broader based accountability framework is being conceptualized across ORD (centered in the HHRP), in which the Clean Air Research program effort is being highlighted as a prototype because considerable thought and effort has been applied in concert with OAQPS. As currently conceptualized, the Air accountability framework will provide methods and examples for assessing the benefits and impacts of regulatory or other mitigation activities. Initial efforts are underway to evaluate existing and emerging databases for potential use, and prototypic models will be proposed for refinement and testing. ORD will be conducting field studies to evaluate whether control technologies are achieving anticipated pollutant reductions or resulting in unintended health and environmental consequences (APG21). Also, ORD will coordinate with efforts initiated by other organizations with similar interests (e.g., NARSTO, which currently is developing an assessment document focusing on accountability in air quality). By 2012, ORD plans to refine the Air framework and report on studies (intramural and extramural partners) assessing the impact of actions taken to reduce air pollution (APG 22).

Table 3. APGs and APMs for LTG 2

	APG/APM Title	Year Due	Lead Lab
APG 15	**Develop a framework to assess the effectiveness of air pollution regulations and control strategies in reducing human exposure, ecosystem deposition, environmental and health impacts**	2009	NERL
APM 69	Produce a conceptual Air Accountability Framework, including best available indicators and linkage techniques	2009	NERL
APM 70	Develop a mesoscale pilot of approaches for identifying and tracking regulatory impacts	2009	NERL
APM 71	As a principal sponsor and contributing author, report on NARSTO Accountability Science Assessment	2009	NERL
APM 72	Report on studies assessing changes in air quality and health status from actions taken to reduce air pollution	2009	NCER
APG 16	**Develop an integrated multiple pollutant research program (MPP) strategy**	2009	NPD
APM 73	Multi-disciplinary workshop on developing a multi-pollutant research program	2008	NPD NHEERL
APM 74	Develop air multi-pollutant strategy	2009	NPD
APG 17	**Develop methods and enhance tools to link health and ecosystem impacts to air pollution sources, including remote sensing and data combination techniques.**	2010	NERL
APM 75	Develop and evaluate data combination techniques to improve human and ecological exposure assessments.	2010	NERL
APM 76	Identify new biomarkers of exposure or effect related to air pollution components or sources	2010	NHEERL
APM 77	Develop methods that provide more temporally and compositionally refined measurements of air pollutants that can be used to improve source apportionment analyses.	2010	NERL NCER
APM 78	Develop, improve, and evaluate advanced measurement techniques for SA of organic PM	2009	NCER NRMRL

	APG/APM Title	Year Due	Lead Lab
APG 18	**Determine the significance of near-road emissions/exposures and related health risks from mobile sources and evaluate risk management options**	2012	ORD
APM 79	Characterize "combustion-related emissions and components (including volatile compounds)" and relate them to exposures and health effects in near-roadway environments	2012	NRMRL NERL NHEERL NCER
APM 80	Characterize how "mechanically-generated emissions" (including urban coarse mode particles) relate exposures and health effects and determine their relative toxicity in near-roadway environments.		NHEERL NERL
APM 81	Determine how specific school mitigation approaches influence concentrations and exposures to near-roadway pollutants.	2012	NRMRL NERL
APM 82	Evaluate and identify assessment tools to aid urban planners in considering near-roadway health effects.	2012	NERL
APM 83	Provide information on the health effects and potential underlying mechanisms associated with exposure to diesel exhaust particles	2010	NCER
APG 19	**Conduct multi-pollutant, multi-city studies to evaluate the relative associations of PM, components/sources of the mixture, and gaseous co-pollutants, with key human health events in multiple U.S. cities**	2012	NCER
APM 84	Compile and analyze data on PM components from the speciation trends monitoring network	2010	NCER
APM 85	Strengthen national air monitoring databases for use in health studies	2011	NCER
APM 86	Compare health risks associated with PM components, sources and co-pollutants from locations across the U.S.	2012	NCER
APG 20	**Investigate relationships between sources, exposures, and health effects using a variety of approaches that focus on single geographic locations or specific sources (other than roadway) and identify options to reduce exposures for sources of concern**	2012	ORD
APM 87	Apply source apportionment and exposure tools to support health studies investigating effects associated with specific geographic locations	2012	NERL NCER
APM 88	Characterize susceptibility and health effects resulting from selected sources of air pollution (other than roadway) and assess their relative toxicity	2012	NHEERL NCER
APM 89	Develop prototype model for evaluating integrated multi-pollutant emissions reduction approaches for U.S. industrial sectors and provide information on emissions and risk management options for key sectors.	2009	NRMRL
APM 90	Provide test methods and protocols for the indoor environment to assess proposed standards for aldehyde emissions and other air toxics from composite wood products	2010	NRMRL
APG 21	**Evaluate whether control technologies deployed for major stationary and mobile sources are achieving the pollutant reductions anticipated and whether these technologies are having any unintended health and environmental consequences**	2012	NRMRL
APM 91	Evaluation of existing data to determine the national-level performance of control measures implemented under major EPA rules	2012	NRMRL
APM 92	Evaluate control measures for possible adverse unintended consequences that impact human health and the environment	2012	NRMRL

	APG/APM Title	Year Due	Lead Lab
APM 93	Describe health effects or toxic properties of manufactured nanoparticles intended for commercial use, pollution control, efficient energy use, or applications to modify air pollutants regulated by the Clean Air Act	2012	NHEERL
APG 22	**Refine the Air Accountability Framework through the use of pilot or test-bed activities or related environmental opportunities for proof of concept.**	2012	NERL
APM 94	Evaluate the progress assessment capability of the Air Accountability Framework and incorporate improved indicators and linkage techniques in an updated version	2012	NERL
APM 95	Develop and apply prototype methods identifying and tracking the regulatory impacts of CAIR	2012	NERL
APM 96	Report on studies assessing the impact of actions taken to reduce air pollution	2012	NCER

D. Linking Clean Air Research with other ORD Programs

The Clean Air Research program coordinates with other ORD programs to achieve the best science and maximal leveraging of resources. The programs with which the Clean Air Research program coordinates most closely include HHRP, HHRA, the Global Change Research program (GCRP), the Mercury Research program, and the Ecological Research Program (ERP). The level of program coordination varies considerably. Involvement ranges from that in strategic planning and MYP development to coordination of specific program or research elements at the L/C level where leveraged research activities might lead to more broadly applicable results and data.

Asthma exacerbation is an important issue to both the Clean Air Research program and HHRP. The Clean Air Research program supports asthma research within its susceptibility theme because the primary target organ system for air pollution is the lung and because of the clear predisposition of asthmatics to exaggerated responsiveness to inhaled toxicants. Asthma research is coordinated across both the Clean Air Research program and HHRP through coordinated APGs and APMs, project funding activities, and a local invited speaker series. Research being conducted to address asthma issues frequently involves humans and animal models exposed to various air contaminants (e.g., PM, ozone, HAPs, molds – all of interest to OAR clients). These studies provide data to assess susceptibility and basic modes of action that aid in extrapolation and risk avoidance recommendations for at-risk groups. Co-sponsored exposure research has also been applied to ambient pollutant environments to develop various receptor models used by risk assessors. In that spirit, the Clean Air Research program and HHRP recently cosponsored an intramural RFA to integrate the science and promote research coordination among asthma and other related indoor air research activities. In addition, the programs have leveraged support to studies assessing the health and environmental improvements resulting from past regulatory actions.

The Clean Air Research program is linked to the HHRA program as both collaborator and as a provider of information and support. As the HHRA program, located within NCEA, is charged

with the responsibility of developing the NAAQS Integrated Science Assessments and IRIS for the HAPs, they are dependent on the science information produced by the Clean Air Research program for inclusion into their documents and assessments. The Clean Air Research program has historically been the primary source of the NAAQS database and continues in that role. The HAPs contributions to the HHRA program has been less substantive and limited to dose-response model development for selected chemicals and toxicology information derived from mixture studies that include related HAPs. The Clean Air Research program also serves as an essential collaborator in document and workshop development and in the pursuit of core research underlying risk assessment methods (e.g., pulmonary dosimetry models, mode of action models, etc.). In their position as client, NCEA participates in the Clean Air RCT in setting priorities; likewise NCEA functions within the Assistant Laboratory/Center Director advisory group to the NPD in decision making and to ensure communication. The collaborative relationship between these programs is long-standing and is a strength of ORD's overall air pollution research efforts.

Atmospheric mercury is clearly an issue of concern to the Clean Air Research program. At present, this program is distinct from the Clean Air Research program because of unique EPA interests. Nevertheless, although the size of the program is relatively small when compared to Clean Air Research, actual mercury project planning and implementation are coordinated through Clean Air Research-funded program areas because many of the analytical and modeling tools overlap or are utilized similarly. Examples include specific coordinated projects to address targeted questions regarding control technologies (e.g., the use of selective catalytic reduction), and projects to monitor and assess mercury deposition and speciation in selected sensitive environmental areas.

The Clean Air Research program historically has coordinated with the GCRP to better quantify and understand factors that may have impacts on global climate and air quality. The recent U.S. Supreme Court decision (No. 05–1120; Massachusetts et al. v. EPA)[14] judged that EPA has the authority to assess the "greenhouse gas" CO_2 as an air pollutant. As such, EPA has initiated a series of steps to evaluate CO_2 from automobiles regarding potential "endangerment" to public health and the environment. The Court's decision and subsequent activities on the part of EPA forecasts changes in the assessment and potential regulation of CO_2, which likely will have implications regarding research in both the Global Change and Clean Air Research programs. Expanded research and program integration is possible. However, interactions have been ongoing. One example is research on emissions of elemental carbon, which recent evidence shows may have important implications for climate change because of its ability to absorb solar radiation. Other interactions involve the development of atmospheric models (such as CMAQ) and climate models, which are now advancing to sufficient sophistication to begin to address questions of air quality impacts on climate and vice versa. Tools are also under development to evaluate future technology change and how this could impact future levels of CO_2 and other air pollutants of concern. The goal of this research is not only to assess these cross-impacts of air quality and climate but to provide predictive tools for guidance to the policy directors and for public communication (e.g., AIRNow). This portion of the program may well see substantial change in the future.

Current coordination with the ERP is limited. Shifting program priorities and fiscal constraints

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[14] Decision: http://www.supremecourtus.gov/opinions/06pdf/05-1120.pdf.

have taken the programs in somewhat separate directions over the past several years. However, with recent changes in the ERP toward an "ecosystem services" focus, which relates more to issues associated with the air-ecosystem interface, it is anticipated that common research areas and activities will be identified for collaboration. Already in 2006-2007, the Clean Air Research program funded a pilot in ecosystems assessment to examine sulfur deposition profiles and the distribution of local acidification, in part as an accountability effort. Currently, the ERP is undergoing major revision, and these coordination issues will be addressed more fully in future MYP revisions.

E. Performance Assessment Rating Tool Long-Term Goals and Measures

Protection of public health and the environment from the adverse impacts of air pollution is the ultimate goal of ORD's Clean Air Research program. Achieving this goal is neither easy nor straightforward, given the complexity of anthropogenic and natural emissions and the potential for human health impacts. Lying between emissions and health impacts is a complicated array of atmospheric physicochemical processes and myriad human biological and behavioral factors that affect exposure and response to and recovery from environmental stressors. OMB utilizes the Performance Assessment Rating Tool (PART) as a means to periodically evaluate the progress and efficiency of the Clean Air Research program in its efforts to achieve the goals of improved air quality and reduced risk. The mission of PART is to establish clear measures and milestones against which the program can be monitored and assessed regarding overall stewardship of the public trust and progress toward outcomes that demonstrate or reflect benefit to the American public.

The MYP is constructed around two LTGs toward which progress can be evaluated. Structured under these goals are the APGs and APMs that provide products or building blocks, which, if accomplished or achieved in a timely and efficient manner, can be used as one tool to evaluate program progress and effectiveness. PART is clear on its distinction between program "products" and "outcomes." In effect, although products (research findings, models, and tools) are important to the science and the program, it is progress towards the *outcome* (public benefit) that is most important. Table 4 lists the long-term and annual measures being used to assess the Clean Air Research program.

Table 4. PART Measures

Measure	Type of Measure	Measure Language
Long-Term	Outcome	Progress in assessing the linkage between health impacts and air pollutant sources and reducing the uncertainties that impede the understanding and usefulness of these linkages
Long-Term	Outcome	Progress toward reducing uncertainty in the science that supports the standard-setting and air quality management decisions
Long-Term	Output	Percentage of program outputs appearing in the Office of Air and Radiation's National Ambient Air Quality *Risk and Exposure Assessment*
Annual	Outcome	Percent improvement in customer satisfaction and product usefulness survey score
Annual	Output	Percent progress toward completion of a hierarchy of air pollutant sources based on the risk they pose to human health
Annual	Output	Percentage of program publications rated as highly cited papers
Annual	Output	Percent of planned actions accomplished toward the long-term goal of reducing uncertainty in the science that supports the standard-setting and air quality management decisions

The Clean Air Research program must report to OMB PART its accomplishments as measured against the annual and long-term goals, and every 4-5 years the Clean Air Research program must undergo a full PART review to assess its long-term effectiveness. ORD has also developed Program Improvement Plans that identify specific actions to be taken to improve performance. For the Clean Air Research program, these include:

- Convene annual program reviews in which extramural expert discipline scientists and clients will assess the state of ORD science, ensure progress toward outcome goals, and determine the need for strategic mid-course adjustments to maximize program efficiency and assist with out-year planning.
- The program must develop at least one efficiency measure that adequately reflects the efficiency of the program.
- Improve multi-year plan (MYP) and financial data tracking systems and procedures to better and more transparently integrate grantee and program performance with financial information.
- Develop an annual measure that more directly demonstrates progress on toward the long-term goal of reducing uncertainty in identified research areas of high priority.
- Develop and implement adequate methods for determining progress on the program's two new long-term measures (uncertainty and source-to-health linkage measures) as well as for the new annual measure (customer survey measure).

For each of these elements, some action has been taken, but the overall goal has not been completed.

III.   CONCLUSIONS

A. *The Clean Air Research program supports OAR and other client-partners.*

The Clean Air Research program provides critical science to science-users (i.e., NCEA, OAR) to establish or refine the underpinnings of important regulatory decisions and public guidance. The program also provides the tools and models along with the technical support needed to implement these decisions in the field. These contributions derive from a science and engineering platform that is regarded, both within EPA and internationally, as integrated and high performing. Although the science has shown individual air pollutants have effects on health and welfare, mixtures of air pollutants truer to the realities of ambient air have the potential to interact in complex ways potentially altering its outcomes. As protection of public health is a primary EPA goal, minimizing health impacts may be more effectively achieved by strategic control of sources that contribute directly or indirectly to health outcomes. The potential value of multi-pollutant approaches has been recognized by OAQPS in its organizational structure and planning and as such, the timing is appropriate for the Clean Air Research program to make a science investment in this area. ORD will formulate its multi-pollutant research program from a source-to-health outcome paradigm. This paradigm is implicitly cross-discipline and integrated and, as such, provides opportunities for more effective control strategies and positive impacts on health.

B. *Air research will evolve as a multi-disciplined, integrated endeavor founded upon the NRC Priorities for PM as it builds upon the source-to-health outcome paradigm.*

The current MYP lays out a strategy that serves the current regulatory mandate of EPA and begins to move air pollution sciences that support regulatory decision-making to a more realistic, yet more complex, multi-pollutant paradigm. The three historic Air research themes are now organized into one Air program (Clean Air Research), although the impact return for PM research supports it as a primary program focus. The NRC priorities have been invaluable in organizing the PM research over the last decade and, as an approach, have been central in the prioritization of the multiple needs of Clean Air Research program clients. It is clear that these commitments to the NRC issues have been structured into the APGs and APMs as they relate to PM, including assessments of hazardous components, particle size, effects of long-term exposures, susceptibility, mechanisms, exposure assessments, atmospheric sciences, implementation model and tool development, emissions and controls, etc. What has evolved is the program vision to also undertake the challenge to link pollutant sources to their ultimate health outcomes within a multi-pollutant construct. This construct will continue to evolve as the MYP is implemented, and it will have multiple inputs from OAQPS as it develops its multi-pollutant policy test beds, NARSTO as it finalizes its assessment of multi-pollutant/accountability assessment document, and other client feedback. The near-road source-environment has been established as the MYP prototype for implementing this paradigm. The goal is better targeted and more efficient control and mitigation and improved public and environmental health.

C. *Future research issues are already emerging as current regulations, land use, transportation, and climate change impact both local and regional air quality.*

The Clean Air Research program is well positioned to address emerging air quality issues. Adopting a multi-pollutant future, changes in regulation (CO_2 impacts and controls) and climate-

air quality interactions at the local and regional scales are already under study by ORD. Intramural workgroups and STAR-supported projects (current awardees and planned RFAs) provide the foundation for expanded research as this issue evolves over the next few years.

Appendix A: Recent Program Accomplishments

ORD's Clean Air Research has a long history of responsiveness to client priorities, and delivering relevant and useful products that support decision-making and policy implementation. The report, "*Particulate Matter Research Program: Five Years of Progress*" (February 2004; referenced in footnote 8) summarizes notable PM-related achievements of the research program from 1998, when PM became prominent issue, through 2002. That report was organized around the 10 priorities noted earlier by the NRC (see footnote 5); a revised and updated ORD progress report is scheduled for release in 2009. In this appendix, selected achievements since 2005 are highlighted. This summary is not intended to be a complete overview but rather to provide insight into program value. Since 2005, the Clean Air Research program has built on its previous successes, with the goals of refining our understanding of the science necessary to reduce uncertainties in decision-making and improving the tools needed to assess and implement policy. The key to these advances lies in interdisciplinary science and integrated program execution. This section will cite selected achievements from across the entire program, not just PM. Because the Clean Air Research program is moving forward to a multi-pollutant framework, this accomplishments overview is presented using the core paradigm shown below.

Source →Atmospheric Transformation →Exposure →Dose →Health Outcome

Source
Emission characterization of prime sources contributing directly or indirectly to air pollution is fundamental to the value of the *source-to-health outcome* paradigm. Not only does it serve to reduce uncertainty in the development and implementation of effective mitigation or control strategies, emission characterization serves to link health risks to gaseous or particulate components, as well as to sources, with greater specificity. This goal was noted as high priority by both NRC panels (*Priorities* and *Air Quality*; see page 3, footnote 5) and as fundamental to integrated air quality assessments and to the development of appropriately targeted health-based standards. In this regard, significant advances in updating and improving emission inventories have been achieved on multiple fronts. Those sources pursued by ORD are generally not those assessed by State regulatory units but are more generic and poorly characterized. For example, diffuse sources are particularly problematic. Advancements in optical remote technologies have yielded new data from varying types of biomass burning to livestock waste ponds. Optical remote methods for precursor gases such as ammonia are not only important for general air hygiene but allow refinements in atmospheric models where ammonia is a major assumption in aerosol chemistry (e.g., acidity). Similarly, laser-based, time-of-flight instruments provide real-time analyses of trace organics, including aromatics and PAHs, in dilute vehicle exhaust and fugitive emissions. Engine emission characterizations from various vehicle types, such as idling versus moving diesel school buses, have likewise undergone detailed study not only of mass emissions but chemical speciation. Other sources heretofore not well characterized in the context of their relative impact on ambient air, ranging from dispersed seasonal wildfires to point sources such as airports, have begun to be characterized using analogous advanced optical and prototype satellite-based technologies.

Collectively, these data improve and update emission inventory databases maintained by EPA (e.g., SPECIATE) on which comprehensive atmospheric models used in OAR and State/Region/tribe implementation strategies (e.g., SIPs) depend. Advances in mobile source emission characterization also serve on the science investigatory front mainly in the area of sensitivity and response-time (e.g., deep UV differential optical absorption spectrometry – DUV DOAS) and, as such, will be important in the developing near road research program.

Advances in control technologies have demonstrated effective reductions and removal of NOx (most importantly NO_2) and mercury (Hg^0) from pilot plant coal-fired boilers. Refinements in these technologies are critical as coal combustion grows nationally. These same pilot plant operations have also been used for comparative emission toxicology studies and assessments of physical and compositional attributes of PM emissions. Analogous diesel studies have revealed significant compositional and toxicity variance. Real-world animal exposures to traffic emissions (diesel and gasoline) have shown varying effects (from pulmonary to neurological) likely because of varying concentration profiles and aging related changes in gases and particles. In general, proximity to the roadway has yielded the most consistent responses. Across ORD (intramural and extramural) there is increasing focus on source-based responses to ascertain hierarchical toxicity patterns and compositional relationships.

Atmospheric Transformation
Once pollutants are emitted, it is important to understand how they interact with other compounds present in the ambient environment. These transformations and interactions are critical inputs for our air quality models and directly impact the types and concentrations of pollutants the population is exposed to over time. Laboratory and field studies have made substantial gains in our defining atmospheric chemistries that play significant roles not only to achieve a better understanding of theses processes in ambient air but in refining the predictive accuracy of complex multipollutant atmospheric models like CMAQ. Each year, one or more upgrades of CMAQ is released for client as well as research use with the next major revision for SIP development due in 2008. ORD investigators have refined or overhauled chemistry modules that drive components of the model (e.g., photochemistry of mobile-source-derived aromatics). Similarly, other studies have been able to discriminate dominant biogenic hydrocarbons from other organics as critical drivers in ambient photochemistry. These refinements have advanced our understanding of carbon, nitrogen, sulfur, and even mercury chemistries in CMAQ and related but more specialized atmospheric models. The upgraded models are tested and validated against real-world temporal and spatial measurements before release. Also, the CMAQ model now has, for the first time, incorporated a new weather research and forecasting (WRF) meteorological model that will be the foundation of future air pollution and climate predictive models. As these models are multipollutant and are widely run for SIP development, ongoing refinements, especially in the highly complex organic arena, have been critical to accuracy and dissecting the relative prominence of the anthropogenic and biogenic (e.g., natural terpenes, isoprene, etc.) contributions. With the growing use of ethanol and biofuels as alternative fuels and the introduction of new additives with various functions, predictive models suggest changes in atmospheric chemistry that may alter transformation product profiles.

Atmospheric models, such as CMAQ, are being asked to refine to smaller area grid sizes for community application, to continually broaden the pollutant mix (e.g., HAPs have now been

incorporated), and to attempt to tie to dispersion models in an effort to find innovative approaches to couple with personal exposure models and, ultimately, health effect studies. Intramural work is ongoing in collaboration with OAR and the STAR program scientists and NCER-STAR has released an RFA to further develop these innovations. Linking across models and data to achieve better risk estimates and provide predictive information that may be amenable to AIRNow-like public broadcasting is an important goal of EPA.

Exposure
There have been marked gains in refining links between regional and local exposure metrics with those that relate to personal exposures for PM and some of its attributes (most notably size). Admittedly, less has been gained regarding co-pollutant exposures, although there are improved exposure measures for some HAP compounds. In the case of PM, comprehensive field studies have been conducted to evaluate the performance of sampling methods for measuring the coarse fraction of PM_{10} in ambient air. These have been conducted in several venues across the United States as part of the Federal Reference Method (FRM) development project. This FRM is complete and is being deployed by states. At the other end of the size spectrum, recent concerns regarding traffic exposures have prompted exposure profiles for ultrafine PM emissions relative to distance from roadways. There now exist some measures that tie to freeways, traffic volume and vehicle type. ORD has particular interest in the effect of various mitigation methods, especially as they relate to indoor penetration values. Building type and ventilation appear to be major factors in penetration of ultrafine and coarse mode PM, as well as oxidant gases, but appear to be less significant (on a relative basis) for fine PM and less reactive gases. Individuals considered "susceptible" because of age or pre-existing disease appear to have exposure profiles similar to those without susceptibility risk factors, with central monitors appearing to provide reasonable estimates of fine PM exposure for the associated population. Not inconsistent with this evidence for refined exposure metrics, a recent study in Los Angeles has demonstrated that increasing the areal density of monitoring can reveal neighborhood-by-neighborhood differences in health outcomes. These findings suggest greater PM risks than previously appreciated with regional monitors. On the other hand, this was not clear in New York City, leaving this provocative question to be further explored.

A large, multiyear, multi-season exposure study conducted in Detroit has completed its data collection (winter 2007) which is being compiled into databases for estimation of source-attributable exposures, regionally, locally, and indoors across the Detroit urban landscape. New speciation methodologies for organics have been developed and are yielding data refining $PM_{2.5}$ composition and its source links. These advancements should help refine existing receptor (e.g., SHEDS) and source apportionment models (e.g., UnMix) now in wide use but that have large uncertainties. Related intramural and leveraged health studies in asthmatic children and adults with cardiovascular disease in the Detroit area will yield refined risk estimates and better source attribution. As noted above, when coupled with the concept of developing linkages with atmospheric and receptor models that can track to the human effect level, clients will be able to better assess the impact of source-oriented mitigation strategies.

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Dose
Exposure estimates are inherently inaccurate biometrics for human dose. Variation in dose from individual to individual is often responsible for perceived biologic variability. Comparative dosimetry is also important in linking the toxicological databases from animal toxicology to the human condition. Dosimetry, when coupled with biological differences (e.g., species, pre-existing disease, age) and variable exposure scenarios (e.g., exercise, lifestyle, co-exposures), contributes to the uncertainties in final risk assessments. New findings with PM size modes in subjects with lung disease augment what has long been known in healthy individuals – that PM size is the major determinant to deposition profiles in the respiratory tract. Fine PM penetrates more deeply into the lung than coarse PM but recent human data shows that although ultrafine PM deposits penetrate the lung in large numbers per given mass, the deposition pattern in a within the lung was not unlike that of coarse PM. In other words, large numbers (and more relative mass) of ultrafine PM deposit in the airways and, therefore, ultrafine PM should not be considered a risk only for the deep lung. With regard to fine and coarse PM, but less so with ultrafines, individuals with airway disease show increasing heterogeneity in deposition with evidence of "hot spots" at airway bifurcations. Locally high doses of PM to lung tissues may result and may determine the degree of damage to that region and may well account for the exacerbation of responses (because of the higher dose) noted in people and animal models with pre-existing lung diseases (e.g., asthma, COPD).

There is also related evidence that solubilized components of fine PM (e.g., metals and polar organic compounds) permeate through the lung and distribute systemically, perhaps impacting the cardiovascular and other organ systems. Ultrafine particles, associated with combustion processes, may themselves also penetrate through lung tissues and move systemically by evading normal defense systems that remove larger particles from the lung surface. Given the concerns of traffic exposure and the predominant ultrafine PM profile near roadways, associations of health outcomes with traffic have been linked hypothetically to ultrafines, although research on co-pollutants and other road products continues. Studies also show that various organic compounds (through adsorption) associate with PM and can be transported deep into the lung. Once disassociated from the particles, these materials can act locally or distribute systemically within the exposed organism. Thus, health outcomes may reflect the inherent toxicities of particles and their co-associated materials.

Health Outcome
ORD-supported research has established the backbone of our understanding of air pollution health outcomes. In the PM arena, specifically, more than 40% of the research citations in the Criteria Document (called the Integrated Science Assessment for the NAAQS currently under review) and the Staff Paper (now called the Policy Assessment in rule decision-making) were ORD-supported products. Currently, PM maintains its distinction as that air pollutant most widely considered to pose a significant and widespread public health threat. A spectrum of epidemiological studies, including various observational and panel studies, show relatively consistent risk estimates for mortality in around the country, especially with regard to pulmonary and cardiac health impacts. Morbidity, as reflected in a wide range of end points or responses (e.g., hospitalization, school absenteeism) also relates to PM. An ever increasing group of outcomes now associate with PM, and in some better still when combined in analyses with its co-pollutants – infection, lung growth retardation, infant birth weigh and cardiac structure.

Cardiovascular-related mortality in adults, however, appears to be strongly related to PM exposure, both in terms of acute mortality risk as shown in a large study of older women as well in the general population. Additionally, a study of Medicare data for 11.5 million people living in 204 urban counties in the United States found region-specific differences between the eastern and western halves of the country when assessing hospital admission rates for cardiovascular and respiratory diseases. In the Northeast, cardiovascular dysfunction can be related temporally to PM exposures even within a few of the day. Interestingly, however, the Northwest, which is dominated by wood smoke emissions in the winter, did not show straightforward links between PM mass and cardiovascular events. As such, it appears that not all sources have similar impacts on cardiovascular functions. As already noted, refinement of spatial exposure metrics through more densely distributed monitors led to the discrimination of neighborhood-to-neighborhood differences in PM mortality in Los Angeles. It also appears that reductions in major industrial sources that contribute substantially to local and regional PM levels result in reductions in mortality and morbidity. Hence, sources do appear to vary in their potencies, and it may well be the mixtures (PM components and with co-pollutants) that drive the differences in response.

Collectively, the epidemiological findings are ever more strongly suggesting that there exist significant susceptibility factors in responses, including age (perhaps linked to greater exposures), syndrome complicated with cardiopulmonary impairments (e.g., diabetes), asthma (notably in children), and COPD or heart disease (especially in the elderly with congestive heart failure), as well as in selected genotypes. In the last case, the ability to withstand oxidant challenge may well be a survival factor, and those lacking certain genes (e.g., GST-M1) may have impaired antioxidant or related defenses. On the other hand, real-world exposures to healthy highway patrol officers suggest that components of complex roadway emissions (gases and particles, including metals) also show evidence of cardiac dysfunction.

Animal studies show analogous patterns of response and susceptibility, and strongly suggest that oxidative stress plays a role in the toxicity of PM. A role for oxidant pathways is largely borne out in *in vitro* studies. Markers of oxidant stress appear to tie to progression of diseases (e.g., atherosclerosis) in rodent models exposed to various PM (concentrated ambient particles [CAPs] and combustion emissions). Cardiac dysfunction in diseased animals has been seen with roadway emissions (mainly ultrafine) and combustion particles enriched with metals. Studies of CAPs in humans and animals show a more variable pattern of cardiac responses that do not always parallel the panel studies suggesting that the complexities of exposure (e.g., a role for co-pollutants) and biologic scenarios are important modifiers of response. Hence, although there appears to be credible evidence of health effects associated with PM, these are difficult to fully reproduce under controlled conditions, perhaps because of the lack of co-pollutant interactions. Similarly, compositional correlates are not always discernable. The likely involvement of multiple components in varied adverse health outcomes argues that the most effective means of study and control will emerge from source-oriented analyses. What does seem consistent from collective assessment is a likely critical role for oxidant stress, perhaps at various levels of organ and cellular bio-pathways, and that individual variability arises, at least in part, from susceptibility (inclusive of dose, frailty, and genetic determinants that may impart adequate defense).

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