U.S. Environmental Protection Agency
Office of Research and Development
Research Approaches To Assessing Public Health Impacts of Risk Management Decisions

U.S. Environmental Protection Agency
Main Campus, Building C
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EXECUTIVE SUMMARY

INTRODUCTION AND OVERVIEW

The U.S. Environmental Protection Agency (EPA) Office of Research and Development (ORD) Workshop on Research Approaches to Assessing Public Health Impacts of Risk Management Decisions was held on January 22, 2008, in Research Triangle Park (RTP), North Carolina. The workshop brought together researchers from academia, private industry, regulatory agencies, and government to discuss ongoing and potential research on assessing public health impacts of risk management decisions. The meeting also served as a stimulus for increased collaborations among the various researchers and agencies. Approximately 136 individuals attended.

Ms. Kacee Deener, EPA, opened the meeting. She welcomed the participants, explained the logistics of the RTP meeting site, and introduced Dr. Rebecca Calderon.

Welcome and Goals of Meeting
Rebecca Calderon, U.S. EPA

Dr. Calderon welcomed participants to the meeting. She explained that the ORD Human Health Risk Assessment Research Strategy was developed in 2001. This marked the first time that the evaluation of public health outcomes appeared in an EPA research strategy. The long-term goal of public health outcomes research is to provide the scientific understanding and tools that assist the Agency and others in evaluating changes in environmental public health resulting from risk management actions. The current Human Health Research Program has the same goal, with an emphasis on methods and models. In addition to performing research that assesses risk and informs risk management options, EPA is now assessing the effectiveness of its decisions and their impact on public health. It was determined in 2001 that public health outcomes research would require the full participation of internal and external stakeholders, build on non-EPA research, include a strong collaboration across ORD and the Science To Achieve Results (STAR) Program, and need additional extramural dollars.

A timeline for this research was established in 2001. Per the timeline, by fiscal year (FY) 2003, during the development phase, an evaluation of available tools, systems, and methods that could be used to assess the impact of environmental decisions would be provided. During the implementation phase (FYs 2004–2007), a detailed plan for improving existing tools, systems, and methods would be created; a preliminary set of improved tools, systems, and methods would be provided; and a pilot evaluation of public health outcomes using case studies would be performed. The conclusion phase of the project called for delivery of a preliminary guidance with frameworks and tools for health outcomes evaluation, demonstration of the use of frameworks and tools via case examples, and delivery of a final guidance and tools for health outcomes evaluation by 2009. Toward this end, two pilot projects from an internal ORD solicitation, the 2004 and the 2008 *Report on the Environment*, and a white paper on accountability were completed. It has been decided that the implementation phase will continue beyond 2009.

Assessing the public health impacts of risk management decisions is a problem of linkages. One of the major tasks before ORD and the Agency is the identification of indicators. EPA has indicators that it has historically used to evaluate the effects of and compliance with regulatory actions and advisories; the indicators can be classified within six different levels (regulatory action, emissions, environmental concentrations, exposure/dose, and human health response), with the higher levels increasing in complexity and specificity. Dr. Calderon showed a diagram of a framework for indicator research, which integrates the source-to-outcome continuum with the indicators matrix. The indicators are essential for demonstrating the effectiveness of risk management decisions and understanding relationships across the continuum. Today, there is an increased role for models (including source-to-outcome models), epidemiology, and toxicology.

The overall goal of this workshop is to understand the research needed to develop and validate indicators that can be used to assess the public health impacts of risk management decisions. Outcomes of the workshop should include recommendations for research that correspond with the capabilities of ORD and information to develop an implementation plan for conducting needed research within ORD. Sample charge questions to guide discussions are: (1) Is there compelling Agency interest? (2) Are databases available for the endpoint? (3) Which environmental stressors have been associated with the health effect? (4) What is known about linkages in the source-to-outcome paradigm for the chemicals and health point of interest? (5) Are there linkages to issues addressed through problem-driven Multi-Year Plans (MYPs)? Dr. Calderon's charges to workshop participants are to: (1) choose wisely, but do not be afraid to take risks; (2) think outside the box; (3) be innovative regarding selection of endpoints; and (4) think in terms of multidisciplinary teams and new partnerships.

SESSION I: RELATED PUBLIC HEALTH PROGRAMS
Moderator: Andrew Geller, U.S. EPA

ORD's Framework for Assessing the Public Health Impacts of Risk Management Decisions—An Overview
Dan Petersen, U.S. EPA

The purpose of ORD's framework is to provide an understanding of research needed to develop and validate indicators of the source-to-exposure-to-outcome paradigm. These indicators are essential for developing subsequent approaches to assess public health impacts of risk management decisions. The *Report on the Environment* highlighted the need to tell a compelling story and identified research gaps. The Government Performance and Results Act (GPRA) emphasizes accountability measures that move away from process indicators toward outcome indicators. The Program Assessment Rating Tool also focuses on outcomes. Research is needed that identifies and tracks trends in human disease and conditions for which environmental contaminants may be a risk factor. Indicators that link source to outcome and/or assess the impact of environmental decision-making need to be developed. For these indicators to be useful, they must: (1) make an important contribution to answering a question, (2) be objective, (3) have sound underlying data, and (4) have underlying data that are timely and describe trends.

Existing paradigms fit into the process of assessing public health impacts of environmental decisions. The source-to-outcome paradigm can be used to assess critical data needs. The source-to-outcome continuum can measure flux at many different levels, such as toxicants; nutrients; chemical, physical, and microbiological stressors; fate; transport; exposure route, duration, and frequency; and precursor biological effects. Flux throughout the pathway is important and should be captured. Additionally, the *Report on the*

Environment details a variety of indicators at the six levels that Dr. Calderon mentioned in her presentation. Data available to the Agency drop precipitously at each level.

An essential framework has been developed that guides the research program on indicators, including developing linkages between indicators. There are a variety of different strategic approaches to performing this research, including the application of methods and data to risk assessment and risk management. Indicators are needed at each of the six levels in the guiding framework; within each indicator there are a variety of important factors (e.g., measurement methods, routine monitoring, data management and analysis, and communication). Elements are needed to provide linkages between components in the guiding framework. Application of the framework will be a driver for research. A variety of approaches will be used to identify the largest data gaps in indicators and linkages; some approaches will be better for specific toxicants. A variety of extramural partners are helping to perform the research.

Discussion

Dr. Linda Sheldon, U.S. EPA, stated that some regulations are based on societal pollutants and others are based on the prevention of new chemicals in the environment. The discussed framework coincides well with the first case, but can it be implemented in the latter case? Dr. Petersen responded that as decision-makers move from a reactive to a proactive approach toward regulatory issues, it is increasingly difficult to incorporate multiple safety factors into a risk assessment. The problem with emerging contaminants is the lack of data. The approach, however, still is meaningful. Capturing indicators closer to the outcomes side of the spectrum (i.e., higher levels) allow for less safety factors to be applied.

A participant commented that many of the examples given involve improvements that have been positively achieved with regard to public health and the environment. It also is important to develop quantitative methods to assess adverse effects that were prevented. Dr. Petersen agreed but responded that it is difficult to quantify what is not present (i.e., deaths that did not occur). By capturing early indicators of outcomes, hopefully, this type of quantification can be achieved.

Dr. Sheldon used the example of nanomaterials to illustrate one necessary avenue of research. It may not be feasible to predict all health effects of nanoparticles, but investigators should perform research to predict where nanoparticles would accumulate and develop indicators for these accumulations. These types of indicators can be as valuable as indicators of effects.

***U.S. EPA's* Report on the Environment**
Bill Nickerson, U.S. EPA

The *Report on the Environment* originated because then-Administrator Christine Todd Whitman wanted to compile high-quality information about the state of the environment to document whether EPA was making progress toward the goals of clean air, pure water, and better protected land. The report was delivered within the given timeframe; it asked 63 questions about trends in air, water, land, human health, and ecological condition and contained 143 indicators. The Science Advisory Board reviewed the draft report and suggested that: (1) questions be made more internally consistent and clearly linked to EPA's mission, (2) the term “indicator” be clearly defined, (3) formal criteria for indicator selection be established, and (4) gaps and limitations be treated more consistently. The 2008 *Report on the Environment* addresses these comments.

The current report includes five chapters focused on air, water, land, human exposure and health, and ecological condition. A total of 23 questions were addressed, and each question includes an introduction and scope; indicators that help answer the question; discussion; a summary of what the indicators say about the question; and important gaps, limitations, and challenges. The questions are the backbone of the document, and the right questions link to EPA's mission to protect human health and the environment.

Each question focuses on a broad topic and assesses trends and outcomes, including effects on human health and the environment. The three questions that form the structure of the human health section of the document are: (1) What are the trends in health status in the United States? (2) What are the trends in human disease and condition for which environmental pollutants may be a risk factor? (3) What are the trends in exposure to environmental contaminants?

For the *Report on the Environment*, an indicator is defined as "a numerical value derived from actual measurements of a pressure, state or ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment." Indicators identified in the report must meet this definition as well as the following six indicator criteria: (1) usefulness, (2) objectivity, (3) clearly stated assumptions and methods, (4) sound data and quality assurance, (5) timeliness, and (6) data comparable across time and space and representative of the target population. Each potential indicator was externally peer reviewed in 2005, with the result that some proposed indicators were discarded or modified. The rationale for not using some indicators from the 2003 report also was peer reviewed. In total, 85 indicators (e.g., blood lead levels, urinary pesticide level, cancer incidence, asthma prevalence) made it through peer review for use in the current *Report on the Environment*. Each indicator includes an introduction, a discussion of what the data show, limitations, data sources, references, and metadata.

EPA performs much work toward strategic planning, accountability, and performance. The focus tends to be accountability related to programmatic success in the short- to medium-term; however, because the Agency's mission is to protect the environment and human health, more than programmatic success must be measured. Two of the key accountability documents are the EPA Strategic Plan, which sets the Agency's goals, objectives, and strategic targets, and the EPA Annual Performance Report, which reports on the achievement of goals, objectives, and strategic targets. The *Report on the Environment* should complement EPA's strategic planning efforts and identify important gaps in information that hinder the Agency's decisions about how to invest in the future. For example, the chapter devoted to human health provides a frank discussion of limitations and identifies the following gaps: the role of exposure to environmental contaminants (including additional indicators of human exposure and the ability to link exposure back to source of contaminant); the strength of association between environmental contaminants and disease, including what proportion of a disease is caused by exposure to a given environmental contaminant; assessment of temporal trends; differences among subpopulations; and consideration of multiple contaminants.

The *Report on the Environment* can inform Agency research and strategic thinking by identifying important gaps and limitations; identifying trends that need attention; quantifying and communicating uncertainty in indicators; addressing scaling problems; using technology to improve cost effectiveness of existing or new indicators; determining the sensitivity of indicators to management actions; and making explicit connections between quarterly measures, annual progress, strategic goals, and environmental conditions. It must be considered, however, that this is a national report that does not address any issue below the state level. Researchers can contribute to the report by keeping *Report on the Environment* staff informed about current research. Additionally, researchers can approach this staff for guidance and input. Web sites that may provide additional information include http://www.epa.gov/roe/abouteii.htm, http://cfpub.epa.gov/eroe, or http://www.epa.gov/roe/publications.htm. Please contact Mr. Nickerson with further questions via e-mail at nickerson.william@epa.gov.

Discussion

Dr. Andrew Geller, U.S. EPA, asked if indicators will be continually updated. Mr. Nickerson responded that one of the functionalities of the electronic version of the report is the ability to update indicators before the next full version of the report is released in approximately 5 years.

Dr. Elaine Faustman, University of Washington, asked if indicators such as socioeconomic status were considered, because these types of indicators add another layer of complexity and additional targets of impacts. Mr. Nickerson responded that one of the early strategic decisions was to focus on indicators that measure human health and the environment. Therefore, some linkages and obvious connections to social status are not discussed in the report; an analytical boundary had to be drawn. The Agency does, however, make these linkages in other areas of its research, and data are available that have been examined by EPA (e.g., environmental justice).

Dr. Lucas Neas, U.S. EPA, commented that it was surprising that no surprises were expected. What if the Agency is wrong in its assessment of what environmental corrections are needed? Mr. Nickerson responded that the report allows for a better idea about whether these surprises are in fact happening, and there is no doubt that unexpected results will be obtained at some point. Recognition of this fact allowed analysis of why certain approaches did not work.

CDC's Environmental Public Health Tracking Program
Judy Qualters, Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) created the National Environmental Public Health Tracking Program in response to a Pew Commission report that recommended a "nationwide health tracking network for diseases and exposures." The mission is to provide information from a nationwide network of integrated health and environmental data that drives actions to improve the health of communities and people at all stages of life. The conceptual model of the program is based on the model of how an environmental agent produces an adverse affect presented by Dr. Stephen Thacker and colleagues in a 1996 article in the *American Journal of Public Health*. Hazard tracking is used to track agents present in the environment and for which a route of exposure exists. Exposure tracking involves hosts exposed to a hazardous agent and target tissues affected by the agent. Cellular and clinically apparent adverse effects are tracked via health effects tracking.

The National Environmental Public Health Tracking Program is public health surveillance "supersized" and involves integration, analysis, interpretation, and dissemination. The program provides a Web-based information system that exists at the local, state, and national levels; provides access to nationally consistent data and measures of environmental health status; serves the public, environmental public health agencies, health care providers, and researchers; includes public and secure portals; and protects the privacy of individuals. Many strategic partnerships for developing and implementing environmental public health tracking were fostered, including partnerships with other CDC and Agency for Toxic Substances and Disease Registry chief information officers; EPA; federal, state, and local agencies; health care and nongovernmental organizations; universities; and community groups and their members. The collaboration with EPA was achieved with a 2003 Memorandum of Understanding that was renewed in 2007. It has been a positive learning experience for CDC and EPA scientists to learn each other's "culture." Collaborative projects between the two agencies include the Public Health Air Surveillance Evaluation; development of indicators, interoperability procedures, and nationally consistent data and measures (NCDMs); and several workshops.

Most of the work that the program achieves is with state and local partners. Between 2002 and 2006 the program funded 21 states, three local health departments, and four schools of public health to develop, implement, and test methods for linking health and environmental data. The goal is to determine true linkages and not just perform linking for linking's sake. Almost all of the funded institutions performed demonstration projects in at least one of the following areas: air, asthma, water, cancer, lead, birth defects, pesticides, reproductive health, carbon monoxide, or fish/shellfish. Johns Hopkins University evaluated the program during this time period and determined that four of the program's five goals were met; the fifth one is in progress. The goals were to: (1) build a sustainable National Environmental Public Health Tracking Network (in progress); (2) enhance the environmental public health tracking workforce and infrastructure; (3) disseminate information to guide policy, practice, and other actions to improve the nation's health; (4) advance environmental public health science and research; and (5) foster collaboration among health and environmental programs. One example of a successful collaboration at the state level was the reduction of emissions by a factory in Wisconsin.

The researchers learned that tracking can be very complex. At first it was believed that environmental and health data could be quickly linked, but tracking revealed that each layer that was revealed in turn reveals more issues that require extensive work to find answers. Several challenges were encountered in the pilot projects such as those involving data (e.g., access, quality, quantity, standardization); methods (e.g., resolution level, latency/induction, exposure estimation and misclassification); and interpretation and communication (e.g., sensitivity/specificity, confidentiality).

The program moved from the planning phase to the implementation phase in 2006. Federal, state, local, and other priorities were determined, and 16 states and New York City were funded. The charge to those funded was to compile and provide NCDMs; describe and discover data; exchange data; provide data management, analysis, and display tools; and inform and interact with the public. One approach in the implementation phase was to form three workgroups to ensure that stakeholders have input in important areas: (1) standards and network development, (2) program marketing and outreach, and (3) content. Within each of these three workgroups are several complex teams that are devoted to issues important in these areas. For example, the content workgroup was instructed not to start *de novo* but to build on existing content. The workgroup will identify, adopt, adapt, and develop pilot indicators and measures. Currently, the key issues for tracking are reaching local levels; measuring exposure; linking health, exposure, and hazard data and measuring its impact; and determining how to measure the program's utility to stakeholders.

Discussion

A participant stated that the waterborne disease occurrence surveillance system in the United States is passive, and there is a weakness in the ability of state and local agencies to recognize outbreaks and provide consistent reporting. How has the National Environmental Public Health Tracking Program addressed this? Also, how much of a priority does the state place on identifying chemicals and pathogens in water? Dr. Qualters responded that identifying chemicals and pathogens in water is a priority at the state level. It must be noted, however, that when the National Environmental Public Health Tracking Program was implemented, it was decided that infectious agents would not be a priority so that resources could be used in other areas that had not previously received much funding. Other areas within the CDC track infectious agents, and the overall goal is to bring all data into the overarching Public Health Information Network. Pathogens were the subject of many discussions and, ultimately, the water team decided to include pathogens. There will be some collaboration across CDC regarding waterborne outbreaks.

Another participant asked how the program deals with a lack of long-term patient history when tracking cancer. Dr. Qualters replied that the program currently is focusing on shorter latency cancers because of this issue. Cancer registries manage issues regarding longer latency cancers.

Assessing the Health Impact of Actions Taken To Improve Air Quality: HEI's Accountability Research Program
Aaron Cohen and Annemoon van Erp, Health Effects Institute

In North America and Western Europe, air quality has improved substantially over the past decades, but further improvements are becoming more costly. Accountability must be considered because there is a need to ensure that current and future regulations are achieving the intended public health benefits. It is important to measure indicators along the entire chain from regulatory actions through human health. To this end, the Health Effects Institute (HEI) published HEI Communication 11, *Assessing Health Impact of Air Quality Regulations: Concepts and Methods for Accountability Research*. This multi-authored monograph was published in September 2003 and provided an assessment of the task, a conceptual framework for future research, and research directions. The report can be downloaded at http://pubs.healtheffects.org.

The chain of accountability involves five levels in which improvements can be shown: (1) regulatory actions, (2) emissions, (3) ambient air quality, (4) exposure and/or dose, and (5) human health. Questions to be answered include: How do emissions, exposures, and health effects respond to different types of interventions? How can unique opportunities (intentional and unintentional) that arise relatively quickly be pursued? How can accountability studies provide stronger tests of causal relations and contribute to scientific research on health effects of specific sources? Methodologic concerns include design issues, selection of health outcomes, acquisition of pre-intervention baseline data, and comparison of model-based predictions with actual outcomes.

Dr. van Erp described several HEI-sponsored projects. Shorter term interventions included those related to traffic reduction, those targeting fuel and combustion, and those involving multiple sources. The shorter term traffic reduction interventions involved a study of the 1996 Olympic Games in Atlanta, which showed significant reduction in morning traffic, asthma acute care events, and peak daily ozone levels; a study involving a congestion charging scheme in London, which investigated changes in traffic and pollution following the implementation of a fee to drive in a heavily congested area of London; and a study investigating the effects of implementing a low-emission zone in London. Shorter term interventions targeting fuels and combustion include a study of cleaner wood stoves in Montana, which will assess particulate matter levels and relate air quality to children's respiratory symptoms, infections, and illness-related school absences; a study of the cardiovascular and respiratory effects of a coal burning ban in Ireland; and a study involving the reduction of sulfur in fuel in Hong Kong following a 1990 regulation. The multiple source intervention involves the study of the reduction of emissions from traffic and industrial sources in Beijing in association with the 2008 Olympic Games. Longer term interventions involved a project analyzing the effect of regulations requiring decreased sulfur dioxide emissions from power plants in the eastern United States and a study of changes in eastern Germany after reunification, such as switching from brown coal to natural gas and the increased use of catalytic converters and diesel engines.

HEI is preparing a program summary describing HEI's accountability research program; a manuscript will appear in the *Journal of Toxicology and Environmental Health*. Additionally, HEI will work with EPA, CDC's Environmental Health Tracking Branch, and states to apply newly developed environmental public health tracking methods to accountability. HEI also will pursue new research and methods development on long-term and short-term impacts of domestic air quality actions on public health.

Dr. Cohen described a workshop sponsored by HEI, CDC, and EPA on methodologic issues in environmental public health tracking of air pollution effects. Researchers determined that public health-oriented accountability research efforts would be strengthened if an environmental public health tracking system for the health effects of air pollution existed on the United States. It became clear to researchers working on indicators that key questions needed to be answered before robust tools could be developed. The workshop was born out of this realization and built on the work of CDC's National Environmental Public Health Tracking Program to develop indicators of air pollution-related health effects at the national, state, and local levels. It brought together participants in CDC's National Environmental Public Health Tracking Program, EPA's air quality programs, and national and international experts to address key methodologic issues in indicator development for public health applications. The workshop charge was to make recommendations to CDC regarding further development and application of indicators, including approaches for using state analyses of state data to generate state and substate impact estimates for acute effects of air pollution; approaches for using external concentration-response function estimates from the scientific literature to generate local estimates for chronic and acute effects; and approaches for communicating the estimates and their limitations to stakeholders.

Dr. Cohen shared his impressions of the main take-home points of the workshop. Developing and disseminating estimates of the health effects of air pollution at the state and substate level will be an increasingly critical component. Local estimates should make use of data collected locally regarding environmental and public health outcomes, but purely local analyses that do not incorporate a broader view will be limited in use. The network of tracking programs involves health impact assessment at the local level and development of local estimates of concentration-response functions; these activities are important, but the network must prioritize what activities can be performed in the near-term and what activities may need further methodologic work. An immediate priority is the development and testing of methods for local health impact assessment. There is a need for continued coordination between the various agencies, particularly those making health impact assessments.

Discussion

Dr. Sheldon commented that most studies illustrate a link between reduced pollution and a health outcome, but it would be most useful to determine expected air pollution concentration changes and health outcomes before performing the analysis; this allows the analysis to be more quantitative regarding level of impact and determine if predictions are correct. Researchers should be encouraged to examine the impacts the regulations have on air pollution and if predictive models are accurate. Dr. van Erp agreed and stated that the London studies she described are investigating these aspects.

A participant asked how HEI works with the international community. Are the studies in response to Requests for Applications (RFAs) or are the researchers approached by HEI? Dr. van Erp explained that the RFAs did not have the response from the academic community that HEI expected, so it was necessary for the investigators to determine which regulations would be explored. Dr. Cohen added that one challenge is how to initiate a research project when the window of opportunity is short and how to study the effects of the regulation in a timely fashion—regulations go into effect by a certain date whether a research plan is in place or not. HEI reviews each application critically and acts quickly so that a prospective study can be achieved before the regulations take affect.

SESSION II: OVERVIEW OF STAR GRANTS AND POSTER SESSION
Deborah Segal, U.S. EPA

Environmental Health Outcome Indicators STAR Grants: Introduction to Poster Session
Deborah Segal, U.S. EPA

The STAR Program is an extramural research funding program managed by ORD's National Center for Environmental Research (NCER). Its mission is to include the nation's universities and nonprofit centers in EPA's research program and ensure the best possible quality of science in areas of highest risk and greatest importance to the Agency. NCER manages about 1,000 active research grants and fellowships. In 2006, EPA issued its first RFA focused on the development of environmental health outcome indicators, and seven grants of approximately $500,000 each were funded. In June 2007, EPA issued a second RFA with a budget of $2 million to fund four applications; peer review was held on January 17, 2008. The "Environmental Health Outcome Indicators" RFA sought research to develop outcome-based indicators that reliably signal trends in: (1) source to exposure, (2) exposure to outcome, and (3) source to exposure to outcome relationships. Applications were required to focus on: (1) relationships between concentrations of chemicals in environmental media and exposure and dose metrics; (2) relationships between concentrations of chemicals or metabolites in biological samples and early indicators of disease; (3) temporal and spatial congruence of existing environmental monitoring, personal exposure measures, and health surveillance data systems; and (4) relationships between an environmental health or exposure indicators and an environmental risk assessment, decision, or policy change implemented at the national, regional, state, or local level. The goal is that research completed under this RFA will enhance the ability of environmental scientists and managers to assess progress toward meeting established local, regional, and national environmental health goals.

Overview of Projects Funded Under the Science To Achieve Results (STAR) Request for Applications on the Development of Environmental Public Health Outcome Indicators
STAR Grantees

Dr. Kaz Ito, New York University School of Medicine, described the project entitled "Near Real-Time Modeling of Weather, Air Pollution, and Health Outcome Indicators in New York City." Many environmental indicators (weather variables, air pollution variables) are available near real time, but real-time health outcomes are not currently available. The New York City Department of Health and Mental Hygiene (NYCDHMH) has been collecting the citywide daily syndromic data (e.g., emergency department visits) that are available next day. The NYCDHMH Syndromic Surveillance Systems were established in 1995 to detect outbreaks of waterborne illness; syndromic surveillance of emergency department visits was established after the 2001 World Trade Center attacks to track the acute health effects of the attacks and to detect possible biologic terrorism. The objectives of the research project are to: (1) develop models to describe relationships between weather variables, air pollution variables, syndromic data, hospital admissions, and mortality data; and (2) test the performance of the alternative prediction models developed. The relationships between real-time data and symptoms, hospitalizations, deaths, weather, and air pollution can be examined to create predictive models. The research project uses time-series modeling to: (1) characterize the sequence of events among weather, air pollution, and health outcome; and (2) develop alternative health effects models and test model performance. Spatial modeling is used to characterize the gradient of air pollution via land use regression and model the heterogeneity of health effects response to weather and air pollution within New York City. The prediction models will be useful tools to: (1) measure the health impacts of weather and air pollution; (2) help detection of unusual events (e.g., bio-terrorism); and (3) provide a near real-time means to predict and reduce health risks in response to developing meteorological and air pollution exposures.

Dr. Jean Johnson, Minnesota Department of Health, described the project entitled, "Measuring the Impact of Particulate Matter Reductions by Environmental Health Indicators." The project is a collaboration between the Minnesota Department of Health, the Minnesota Pollution Control Agency, and the Olmsted Medical Center in Rochester, Minnesota, and provides an example for using data collected from state agencies. The University of Minnesota School of Public Health, Clean Air Minnesota, and EPA also are involved in the project. The study area includes seven counties in the Minneapolis/St. Paul metro area, which accounts for 50 percent of the state's population, and Olmsted County, which includes the City of Rochester. The project is funded by EPA until 2010, and data from 2000–2009 will be analyzed. There have been several particulate matter (PM) reduction initiatives in Minnesota, including the Minnesota Emissions Reduction Project, which involves coal to gas conversion of two power plants in Minneapolis/St. Paul, and Project Green Fleet, which involves the retrofitting of school buses. The research project will measure impacts and accountability. Researchers will measure PM_{10}, $PM_{2.5}$, $PM_{2.5}$ species, ozone, pollen, hospitalizations, emergency room and clinic visits, prescriptions, and ambulance runs and consider regulatory or policy changes to determine reductions in both population exposures and population health outcomes. One unique data source is the Rochester Epidemiology Project, which provides data on individuals for the last 50 years. The expected results of the project are: (1) quantifiable outputs to demonstrate the impact of local and national PM reduction projects, (2) development of environmental health outcome indicators that can be tracked over time, and (3) informed environmental policy decision-making and accountability for public health interventions.

Dr. Julian Marshall, University of Minnesota, explained the project entitled, "Impact of Emission Reductions on Exposures and Exposure Distributions: Application of a Geographic Exposure Model."

The researchers took several issues into consideration: improving air quality involves prioritizing among sources; exposure and health impacts vary among sources (i.e., the intake fraction); and exposure disparities (e.g., race, income) exist. The objectives of the research project are to: (1) compare various emission-reduction strategies among sources and their impact on average exposure and exposure distributions, and (2) determine the resulting policy and management implications. Researchers have developed an exposure model of roughly 25,000 people for California's South Coast Air Basin and will use the model to systematically reduce emissions from various sources and determine the impact on average exposures and exposure distributions. The exposure model includes four main inputs: (1) ambient concentrations, (2) time-location-activity survey, (3) breathing rates, and (4) microenvironments. Results will be plotted on a graph that examines two axes, reduction in exposure inequity and reduction in average exposure. This graph will help to identify suboptimal policies and preferred options.

Dr. Ying-Ying Meng, University of California at Los Angeles Center for Health Policy Research, described the project entitled, "Developing Indicators for Asthma or Other Respiratory Problems." The objective of the research project is to investigate the feasibility of combining existing environmental monitoring and health survey data from the California Health Interview Survey (CHIS) to develop health outcome indicators. The CHIS is a two-stage, geographically stratified, random-digit-dial telephone survey conducted biannually since 2001. Interviews are conducted in five different languages, and information is collected about more than 54,500 noninstitutionalized California residents during each survey. The surveys ask many standard health questions, including those related to asthma. The survey provides geocodable residential address information and duration of residence. Asthma mortality and hospital visit information are available, but more indicators of health outcome are needed. Exposure indicators for all CHIS 2003 respondents and CHIS 2005 asthmatic respondents include long-term criteria air pollutant exposure using existing measurement data for ozone, nitrogen dioxide, PM_{10}, and $PM_{2.5}$. Geostatistical exposure modeling also is being employed. Traffic-related exposure indicators, such as traffic density and proximity to roadways, will be determined. Statistical modeling will be used to quantify spatial and temporal links between the exposure indicators and health outcome indicators after adjusting for other risk factors (e.g., smoking and secondhand smoke). Researchers also will evaluate whether the estimated associations differ by geographic region (e.g., rural or urban) and for potentially susceptible subpopulations (e.g., children and the elderly).

Dr. Ted Russell, Georgia Institute of Technology, described the project entitled, "Development and Assessment of Environmental Indicators: Application to Mobile Source Impacts on Emissions, Air Quality, Exposure, and Health Outcomes." The objectives of the research project are to: (1) develop and assess air quality and health indicators of the impact of mobile sources in Atlanta from 1998–2004, (2) test integrated indicators and their impact on air quality and cardiovascular health, (3) assess indicators for outcomes associated with mobile source emissions and policies, and (4) evaluate the results using an independent data set for 2005–2009. The researchers will utilize a rich data set derived from 39 air monitors in the Atlanta area and emergency department visits to 41 Atlanta hospitals. Researchers will examine mobile source indicator risk ratios for respiratory and cardiovascular events. Mobile source indicators tend to appear with cardiovascular endpoints. The approach will be to: input data for air quality, meteorology, emissions, population, policies, and health; test a number of indicator development methods; and derive indicators and health associations. One unique feature will be to develop indicator sets that provide structure, outcome relationships, and uncertainties as a set. The indicator set will include indicators (e.g., species concentrations, meteorology, integrated measure of impact, population); associated outcomes (e.g., cardiovascular hospital admissions, other pollutant concentrations, pollutant exposures, emissions); and attributes and uncertainties (e.g., indicators, outcomes).

SESSION III: AVAILABLE TOOLS AND LESSONS LEARNED
Moderators: Laura Jackson and Kacee Deener, U.S. EPA

Indicators—Lessons Learned From Environmental Monitoring
Jay Messer, U.S. EPA

In terms of broad accountability, the *Report on the Environment* focuses on long-term, "big picture" trends in air, water, land, health, and ecology; the indicators described in the report are not tied to specific programs or short-term management objectives. EPA's Strategic Plan and annual performance reports concentrate more on focused accountability. The Strategic Plan sets Agency goals and 5-year performance objectives, whereas the annual performance reports describe achievement toward performance objectives. The GPRA sets the idea for establishing performance goals. The Risk and Logic Models are used to measure accountability in environmental monitoring.

Good performance indicators are important, specific to action, sensitive, representative, have acceptable measurement uncertainty, provide timely results, and possess an appropriate scale. Dr. Messer used the cases of stratospheric ozone, acid rain, and surface waters as an example. To ensure that probability distribution is unbiased when performing a probability sample, a population sample is necessary, as in the case of dissolved oxygen in Gulf Coast estuaries and wadeable stream indicators. In the case of wadeable stream indicators in Delaware, comparisons of traditional target monitoring and probability surveys showed opposite results. Representativeness of the indicator is the issue. An example of a sensitive indicator is submerged aquatic vegetation in the Chesapeake Bay.

Regional variability also must be taken into account. Measurement uncertainties provide the power to detect a trend or achieve a target in two different indicators. How many years it takes to detect a change must be considered, because accountability targets that cannot be measured are not useful. One example of a pollutant-specific response indicator that is not useful as a result of regional differences is ozone injury to forest plants. Indicator scale also must be taken into consideration because national trends may mask important regional, state, and local variation; each concern may require an indicator or performance measure with a time and space scale that is "just right." The existence of large facilities must be considered, because one or two large facilities can skew the results, as in the case of toxic release inventory chemicals released to land.

In summary, when constructing performance indicators, consider the importance, sensitivity, measurement uncertainty, timeliness, and representativeness of the indicator; consider the potential importance of scale and hierarchy; and be aware of factors that can skew results.

Connections Between Public Health and Ecosystems Services
Hans Paerl, University of North Carolina at Chapel Hill

There is a direct connection between humans, climate, and ecosystem services. Human activities contribute to nutrient and pollutant loading, which in turn leads to eutrophication, hypoxia, and water quality and habitat decline. In the example of the Pamlico Sound System, nitrogen, phosphorus, and pathogen loads have increased, and the area is highly susceptible to eutrophication. Additionally, this is the site of increased tropical storm and hurricane activity. Hurricanes and tropical storms are concerns because of the large hydrologic perturbations; nutrient, sediment, and contaminant (e.g., pathogens) inputs; biotic alterations (e.g., water quality, habitat, fisheries impacts); and enormous economic and health impacts. Dr. Paerl presented a conceptual working model for system response that combines biogeochemical, ecological, and human health factors.

As indicators of nutrient and other environmental stresses, microbes are sensitive and meaningful markers for physical and chemical change. They determine productivity, nutrient cycling, water quality, and health and can be sensed and characterized by a variety techniques over a wide range of scales from cellular through global. Additionally, in the Pamlico Sound, ferries are used to gather such data because they allow the collection of space-intensive data in areas representative of the system.

Space-time intensive monitoring was used to examine the effects of seasonal versus episodic (i.e., hurricane) nitrogen loading on algal production in the Neuse River Estuary. A connection to hypoxia was determined; increased algae correlated to increased hypoxia. Additionally, there is good correlation between increased hypoxia and increased fish kills. As a result, it was determined that there was a need to reduce estuarine primary production (i.e., chlorophyll *a* from algae) by establishing a nitrogen input threshold (i.e., total maximum daily load). The scientific consensus was a 30 percent reduction in nitrogen input. Photopigments were used to assess algal growth response to nitrogen reduction. Dilution bioassays determined the amount of nitrogen needed to control algae. One issue that must be considered is that nitrogen comes in many different forms (e.g., nitrate, ammonium), and different algae species prefer different forms of nitrogen.

Cyanobacterial harmful blooms (CHABs) are linked to human and climatic alteration of aquatic environments. Urban, agricultural, and industrial expansion cause increasing nutrient (e.g., nitrogen and phosphorus) inputs. Additionally, water use, hydrologic modification, and climate change play key roles in the intensifying and spreading blooms. CHABs are toxic to zooplankton, fish, shellfish, domestic animals, and humans; cause hypoxia and anoxia, which leads to fish kills; produce odor and taste problems; and are responsible for the loss of recreational and fishing value of waters worldwide. CHABs enter the human food chain via zooplankton, fish, and drinking water. Levels of CHABs oscillate in response to hydrology and climatic events. The presence of CHABs has many ecosystem services ramifications. Chlorophyll *a* can be used as an indicator for rapid identification and detection of CHABs. Additionally, remote sensing via a low-flying aircraft can be used to identify CHABs and other problems. Diagnostic pigment indicators are used to calibrate remote sensing data.

Dr. Paerl described the impacts of several hurricanes on the Pamlico Sound, including significantly increased nitrogen loads, formation of post-storm CHABs, and increased *Vibrio* species. There have been predictions of increased frequency and strength of Atlantic hurricanes during the next several decades. This could cause perturbation of the system before the recovery from the previous perturbation is complete. Nutrient and pathogen loadings are largely anthropogenic and complicated by hurricanes and floods, which are natural events exacerbated by human development in coastal watersheds. Hurricanes are individualistic in terms of hydrologic, nutrient, and other pollutant impacts. Water quality, habitat, and health impacts are highly variable. As a result, understanding water quality human health impacts requires appropriate indicators of spatial and temporal “scaling up.” Adaptive management is needed in response to climatic change (e.g., hurricane frequency) and sea level rise.

Linkages and Process Models
Larry Cupitt, U.S. EPA

EPA is concerned with classifying how it has performed. One method to do so involves a hierarchy of indicators from regulations and activities at the lowest level to ultimate impacts on health, ecology, and welfare at the highest level. This builds the basis of the framework for indicator research. The five areas of focus in the framework are indicator development (e.g., indicators); methods (e.g., measurements); networks and databases (e.g., monitoring systems); linkages of indicators (e.g., analysis, synthesis, and models); and communication of results (e.g., visualization, technology transfer, and knowledge translation). It is possible to quantify and classify each level of the framework, but the challenge is to link each level with something meaningful. Scientific knowledge depends on understanding processes and linkages (e.g., physiologically based pharmacokinetic [PBPK] pharmacodynamic [PD] modeling).

Accountability is only part of what must be accomplished, and answers to the following questions are needed: Is mitigation necessary? How best to mitigate? Was mitigation successful? Impact assessment can be accomplished by answering the following questions: How much of the observed effect can be attributed to a specific factor or agent? What effect will a specific factor or agent have on exposure and health? Assessing the impact of a specific agent can be overwhelming. Apportioning cause (e.g., determining which of the many emissions/discharges caused the health response) must start at the other end of the spectrum, at the health response. In assessing evidence for causation, the nine Bradford-Hill criteria—strength, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment, and analogy—do not necessarily prove causation but are factors that might be expected to be found. For example, in a study of PM epidemiology data, PM mass and mortality appear to be linked. One of the postulated causal agents, ultrafine particles, however, was not spatially and temporally integrated. Plotting data found a negative correlation. Public health outcomes must be characterized in a way that allows the collection of data stratified by proximity to the source in question. If it can be stratified in a way that makes sense, the appropriate signal may be seen in the data. One example of this is the observation that the NO_x State Implementation Plan (NO_x SIP) resulted in lower ozone. To accurately assess impact, attribution approaches must be combined with predictive, specific impacts. Additionally, understanding processes and linkages between indicators is critical for indicator selection and for indicator interpretation.

Molecular Epidemiology—Linking Source, Exposure, and Effects
Elaine Faustman, University of Washington

Dr. Faustman noted that there were eight important messages that she had noted during the day's presentations: (1) The topic is full of complexities. (2) There is tremendous optimism despite the complexities. (3) Indicators without linkages are not meaningful. (4) It is an iterative process. (5) There is a need for multidisciplinary teams. (6) Other sources of uncertainty must be considered. (7) The source-to-outcome continuum is nicely placed in a V shape for victory. (8) There needs to be a higher emphasis placed on other aspects of the source-to-outcome continuum.

Dr. Faustman then described her research. Three types of studies were examined to understand which pesticide exposures were occurring in children. The three types of studies were a community-based participatory research (CBPR) project, a longitudinal multiple sampling project aimed at understanding between- and within-family variability, and a longitudinal cohort study. The study investigated four Washington State counties where significant amounts of organophosphate and carbamate pesticides are applied each year to apples and potatoes; the amounts vary each year and are unpredictable.

The CBPR project examined 12 communities. Subjects were paired within and across households, and the researchers reassessed random individuals 4 years after the initial baseline collection. Project researchers educated more than 6,000 community members at more than 250 events, such as community health fairs. Additionally, community members held more than 1,000 home health parties, and the overall number of participants in all levels of community activities was more than 18,000. At the heart of the analysis is the V diagram (source-to-outcome continuum). An Integrated Framework Tool was necessary to perform the assessments. The researchers developed of a series of models that allowed them to examine, predict, and understand what the results meant at the individual, community, and population levels. The methodology underlying the Integrated Framework Tool involves the Bayesian Based Mixed Effects Model, in which the correlational structure of a multivariate distribution is used to estimate correlations between pesticide concentrations, metabolites, gene expression levels, and other variables. Additionally, Markov chain Monte Carlo methods are used for parameter estimation.

Research showed that quantifiable levels of two or more organophosphates in dust were found in 36 percent of homes and 42 percent of cars, and 60 percent of households (defined as home and vehicles together) had evidence of two or more organophosphates in collected dust. Results also indicated that 86 percent of children had quantifiable levels of at least one dialkyl metabolite, and 36 percent had quantifiable levels of both dimethyl and diethyl metabolites. The chlorpyrifos metabolites diethylthiophosphate, 3,5,6-trichloro-2-pyrindinol, and diethylphosphate can be measured, but chlorpyrifos oxon, thought to be the most volatile intermediate, cannot be measured. By understanding the formation of the various metabolites it is possible to ascertain differences in exposures to organophosphates and genetic variability within individuals. Cytochrome p450 also is included in the research.

Evidence of a take-home pathway was determined via the observation that workers who thinned crops were more likely than those who did not thin to have detectable levels of azinophos-methyl in their house dust and vehicles, and children of thinners also were more likely to have detectable levels. Contrary to expectations, workers who reported mixing, loading, or applying pesticides had lower incidence of detectable pesticide residues; this may be a result of mandated safety training for this occupation versus thinners. These data were compared to National Health and Nutrition Examination Survey (NHANES) data, which showed that community farmworkers and their children possessed higher urine concentrations of metabolites versus the NHANES population. Farmworkers and their children also have higher concentrations when compared to nonfarmworkers and their children within the same community. Children had higher levels than adults, including an increase in later years. Additionally, many values are below the limits of detection, which skews the data; this challenge must be overcome. When examining graphs of concentration, it is necessary to understand what factors contribute to the width of distribution. The width of children's concentrations are not as wide as those of adults; it is necessary to examine the source of uncertainty. In terms of crop variation, urinary metabolites were higher in adults who worked with pome fruit (vs. non-pome fruit) and their children. Additionally, levels in children were higher postintervention.

Several sources of uncertainty were examined: characterization of within and between person variability; year-to-year variability; observations below the limits of detection; crop versus agricultural job task; and identification of highly exposed individuals. Sources of uncertainty can be identified in the researchers' conceptual models of children's organophosphate exposure. Additionally, researchers are attempting to link biomarkers with early biological effect; biomarkers of exposure and biomarkers of effect are being investigated. Other tools, such as quantitative pathway analysis based on gene ontology, also are being explored and developed.

SESSION IV: PILOT PROGRAMS FROM THE OFFICE OF RESEARCH AND DEVELOPMENT—EXPERIENCES AND LESSONS LEARNED

Moderator: Lucas Neas, U.S. EPA

Waterborne Disease Pilot Project

Tim Wade, Andrey Egorov, and Shay Fout, U.S. EPA

Mr. Wade explained that the project involved a cross-office, interlaboratory, multidisciplinary team. The study objectives were to: (1) test and validate a novel infection surveillance technique that uses a salivary antibody as a biomarker of infection, (2) apply this technique to assess the health benefits of EPA water quality regulations in a selected community, and (3) identify sites for future studies utilizing this methodology. Region 1 selected Lawrence and Lowell, Massachusetts, as the study and control sites, respectively. The data analysis plan was to use immunoconversion as an indicator of infection, compare the incidence of immunoconversions before and after new water treatment by comparing temporal changes in Lawrence with those in Lowell, and compare the results of the risk assessment with the epidemiological results. The study population consisted of a mostly low-income, Hispanic population; almost 1,400 individuals from 400 families were recruited. There was relatively low consumption of untreated tap water in Lawrence and extensive use of home water filters (but not in Lowell).

The advantages to choosing the salivary antibody technique were that the sampling was well tolerated and multiple samples were possible. The challenges included the substantial variability in antibody concentrations, precipitation of antibody-protein complexes, nonspecific reactivity, and lower concentrations of antibodies in saliva versus serum. Luminex™ multiplex microbead immunoassay was used for analysis. In this assay, a microscopic bead is coupled with one specific protein, and saliva is incubated with the beads. The salivary antibodies react with protein. Samples then are incubated with biotinylated antihuman detection antibody, and a fluorescent stain is added to the wells. Finally, microplates are analyzed using a Luminex™ instrument. The multiplex assay allows the analysis of up to 100 analytes in the same assay; the researchers analyzed 12 analytes in their study. The researchers chose to study *Cryptosporidium*, two noroviruses, two rotaviruses, and two pathogens causing chronic infections, *Helicobacter pylori* and *Toxoplasma gondii*. The *H. pylori* proteins selected were the small subunit urease and soluble antigen extract. *T. gondii* proteins selected for the study were soluble proteins from tachyzoites and P30 protein purified from HeLa cells. Recombinant 27 kDa *C. parvum* protein was selected for testing as well. Dr. Fout explained that noroviruses were chosen for the study because they are the major cause of gastroenteritis in adults, highly infectious, and resistant to chlorine. The norovirus proteins chosen for the study were genogroup II strain VA387 recombinant capsid protein and genogroup I Norwalk virus recombinant capsid protein. Rotavirus was chosen because it is a major cause of gastroenteritis in children. DS1 and WA strain proteins were chosen for the study.

Dr. Egorov described some of the results of the project. It is possible to see which samples are positive and which are negative even at a 1:128 dilution. Validation of the *H. pylori* tests with enzyme-linked immunosorbent assays illustrate that the salivary antibody technique appears to be a good test, although the small sample size must be considered. Similar results were obtained for the other pathogens as well. Thus far, toward the first objective of the project, the researchers have completed development of the assays for all target pathogens and developed multiple internal controls. Work on the second objective is underway. Additionally, more antigens—such as *Giardia lamblia*, recreational water pathogens, and biofilm-associated pathogens—can be added to the multiplex assay at relatively low cost.

New Haven Pilot Project
Hâluk Özkaynak and Danelle Lobdell, U.S. EPA

Dr. Lobdell explained that the "Environmental Public Health Indicators for Children and Elderly in New Haven, Connecticut" project originated from an ORD-wide solicitation focusing on Long-Term Goal 4 of the Human Health Research Program MYP that involves assessment of risk management decisions. Regions submitted preproposals, and ORD design teams were established and created full proposals. The objective of this project is to assess the feasibility of conducting a cumulative air accountability study at a local scale. The study aims to: (1) identify existing human health, ambient air quality, and human exposure-related data in New Haven, Connecticut; (2) determine the air pollution reduction activities and associated changes in emissions for multiple pollutants; (3) refine, apply, and evaluate air quality and human exposure models that can be used with local health data; (4) assess the feasibility of using this existing information to conduct an air accountability study; (5) develop collaborations and partnerships with state and local agencies including government, academia, and the New Haven community; and (6) provide the methodologies developed under this project to future projects in other areas in the United States. New Haven was chosen with the help of Region 1 because it has the highest child asthma emergency room visits in Connecticut; is located in the county with the second highest National Air Toxics Assessment (NATA) risks; is noncompliant in terms of ozone and PM; and possesses many city, state, and community partnerships and actions. Additionally, it was chosen because of its inventory of source categories, which include point, area, on-road mobile, and nonroad mobile sources. National regulations and voluntary actions for mobile sources (road and nonroad), national regulations and voluntary actions for stationary sources, and indoor air reduction activities were considered.

Progress to date includes completion of a white paper that outlines methodologies and tools that can be used for accountability research on a local city scale with the use of existing data; this will be used as a tool for assessing feasibility. Possible data sources identified included existing ambient air quality data from six ambient air monitors in the City of New Haven and existing human health data from a variety of sources, including hospital discharge data, birth defects registries, and the Connecticut Department of Public Health's Asthma Program. Identification of data sources did not guarantee quality or accessibility. No existing sources of exposure data were identified.

Dr. Özkaynak explained that it is a challenge to perform these assessments using available ambient monitoring data. The aim is to examine cumulative exposures to multiple criteria pollutants and air toxics. Physical modeling is the approach that is being promoted, developed, and tested during the study. Ozone, PM, and selected air toxics were chosen as pollutants of interest for the ambient concentration modeling. A hybrid modeling approach was used to resolve local scale, with the Community Multiscale Air Quality (CMAQ) models providing regional background and contribution from chemically reactive pollutants. Near-source concentrations are necessary and provided by local-scale dispersion models; total (combined) concentrations are used as an input to estimate inhalation exposures. Local impact from stationary sources, near-road impact from mobile sources, and regional background from CMAQ comprise the combined model results for multiple pollutants for each of the 380 Census Block Group centroids in the New Haven area. Where the population is located is an important factor that must be determined. The results are an output from the hybrid model that demonstrates predicted ambient average concentrations of benzene in New Haven. The researchers compared data for benzene, nitrogen oxides, sulfur dioxide, and carbon monoxide and are confident in the results. Therefore, air quality models can identify linkages and can be linked to exposure models.

Exposure modeling can be used to evaluate alternative techniques for estimating cumulative exposures to selected air toxics, PM, and ozone. Two probabilistic cumulative exposure models, the Hazardous Air Pollutant Exposure Model 6 (HAPEM6) and Stochastic Human Exposure and Dose Simulation (SHEDS) Air Toxics Model, were used. HAPEM6 was modified to fit the study needs. Representative microenvironment factors from the recent HAPEM application for the NATA study were used to run the modified HAPEM6 and SHEDS-Air Toxics to predict cumulative exposures to selected air toxics in New Haven.

Researchers initially met with data owners in New Haven to discuss the project and begin a dialogue; this dialogue is continuing. Currently, the researchers are updating the white paper, determining the air pollution reduction activities and associated changes in emissions for multiple pollutants, and linking air quality models to exposure models. The next steps will be to assess whether the health data can be linked with the exposure data, assess whether the use of existing databases will be sufficient for demonstrating the impacts of different voluntary and regulatory actions, determine what additional data will be needed if it is not feasible to adequately link exposure-related information with the health data, and examine the possibility of utilizing developed techniques and lessons learned in other local areas.

Discussion of the Day's Sessions

Dr. Geller asked what monitoring data and modeling is available for water or other media that is analogous to the sophisticated models available for linking air monitoring data and human exposure. Dr. Lobdell responded that air monitoring stations are in use as a result of the Clean Air Act and provide continuous measures. The Clean Water Act only requires commercial entities supplying water to the population to monitor for certain types of contaminants and only report their data if they are out of compliance. This causes the disconnect between air and water monitoring. Dr. Sheldon added that a current challenge is to determine how watershed and drinking water models can be developed that take into account watershed characteristics, including microbes. Dr. Fout responded that cost is a limiting factor for microbes. Dr. Geller replied that this fact underscores the need for models. Dr. Fout responded that without data, models are not useful.

Dr. Sheldon commented that in the New Haven project, the CMAQ model shows a great deal of regional background that is causing most of the pollution with spikes for sources and along roadways. Can the models be used to determine the kind of differences that can be expected and identify the size of the population that is needed to be able to observe the health effect? Researchers should actively be looking for surprises. Dr. Özkaynak responded that this is very important and, currently, the researchers are assessing the feasibility of whether or not the use of existing databases will be sufficient for demonstrating the impacts of different voluntary and regulatory actions.

Dr. Geller commented that toxicologists are hopeful that the mode of action work will provide some of the markers that can link specific pollutants to specific health outcomes so that when risk or exposure mitigation efforts are propagated, scientifically defensible links to the health outcomes are available. This type of chain will allow researchers to predict the results of mitigation actions or to go backward from the monitoring data to determine the cause of health outcomes.

A participant commented that most of the day's presentations were about issues that have a good deal of regulation and Agency support. What about emerging issues? How can work be done to illustrate to the public that researchers and regulators are reacting in an appropriate manner? Dr. Faustman responded that most communities are receptive to the source-to-disease (outcome) framework. The public cannot be expected to understand complex issues that researchers are only beginning to understand. Despite this, it still is fairly easy to explain to individuals and communities that researchers are attempting to link exposure and disease (e.g., breast cancer). She illustrated the example from her research in which a community identified an exposure source that was not originally going to be explored by investigators.

Dr. Geller commented that the National Research Council's *Toxicity Testing in the 21st Century* discussed toxicity testing in both risk and exposure contexts. Placing hazard identification and targeted toxicity testing into the risk and exposure contexts will help to shape factors that still are unknown. Dr. Qualters added that efforts for bioterrorism event detection have been included in attempts to identify data sources so that the information is present, and research, surveillance, and accountability efforts can be accomplished.

Mr. Brad Schultz, U.S. EPA, commented that communities welcome investigations of source to effects. There is not a one-size-fits-all answer to the questions that researchers and regulators face. Dr. Fout added that researchers should think in terms of synergistic effects.

Wrap-Up
Herbert Frederickson, U.S. EPA

It is necessary to step back to gain a perspective and realize that there are a whole series of nested processes that are connected. Dr. Frederickson illustrated some environmental highlights of the last four decades, including the fact that many environmental events occurred in the 1970s. There was a slowdown during the 1980s and 1990s, but one shift that occurred during that time was from an introspective national view to an international view. Currently, the breadth and depth of the public's environmental knowledge is increasing, and there has been success in remedying more tractable problems. There are increasing international regulatory authorities, but impacts cover large geographic areas in an age of increasing population and urbanization. This increased urbanization is key, as 50 percent of the world's population now lives in urban areas. This causes an "urban footprint funnel" whereby more and more resources are pulled from rural areas to urban areas and more urban waste is returned to those areas.

EPA's mission is to protect human health and the environment, whereas the National Risk Management Research Laboratory's mission is to advance scientific and engineering solutions that enable EPA and others to effectively manage current and future environmental risks. The Sustainable Environmental Systems Paradigm involves complex, dynamic, coupled systems (i.e., ecology, society, and economy) that are continuously evolving; growth is a “natural” behavior. A change in any one system causes a change in the whole. One strategy to effect change is to use entrepreneurism to affect environmental change. Stakeholders must realize that there has been a paradigm shift from what was occurring during the 1970s through the mid-1990s as compared to what is occurring today. EPA now has a major role in environmental technology and policy development. The policy toolbox, which contains prescription, penalties, property, and persuasion, can be powerful but also can have unintended consequences.

The EPA Ecosystem Research Program involves transdisciplinary systems research on ecological sustainability. It will involve approximately 300 full-time equivalents from 2007 through 2014. EPA’s research and development challenges are to measure, manage, and improve. Science-based, legally defensible metrics that support market trading are needed, which will lead to nontraditional ORD research in the areas of economics, decision science, outreach, and sociology. Society must be educated so that it can make informed political and commerce decisions that affect the environment. The EPA Science Forum is an important part of this. Additionally, unique research opportunities must be grasped as they arise.

The meeting was adjourned at 6:10 p.m.