Strategic Directions Descriptions for EPA Research Programs 2008-2012 (Background for the February 22-23, 2007 SAB Meeting)

A. AIR (NPD Dr. Dan Costa)

Clean Air Research Program

1. **Recent Key Accomplishments of the Current Program**

The Clean Air Research Program effectively integrates client-oriented intramural and extramural (STAR) research to solve air pollution problems consistent with the Agency goal, Clean and Safe Air. The Program is widely regarded as the nation's premier air pollution research program, integrating across the spectrum of exposure/health and atmospheric sciences to assess and reduce risks to human health and the environment. Out of an international array of PM literature, publications funded by the Program comprise ~40% of the citations in both the Science and the Policy Assessment documents used to support the recently promulgated PM NAAQS. The most recent 2006 NCEA Provisional Assessment requested by Congress showed a similar impact of ORD research. Selected recent notable accomplishments include:

- Sarnat et al. (2000, 2001, 2005, 2006) - Demonstrated that central monitoring sites serve as a reasonable exposure indicator for population studies of PM which form the basis of NAAQS decisions and NAAQS implementation..
- Riediker et al., (2003, 2004 a,b) – Panel study of NC patrol officers (COPPS Study) showed cardiovascular impacts of in-vehicle exposures to motor vehicles emissions and brake dust components. OAR cites as important source / component linkages to health (near-road).
- Jarrett et al (2005) – Found stronger and higher health impacts of PM (based on the ACS database) in a more intensively monitored urban air shed. Suggested that current risk estimates under-predict health impacts (06 Prov. Assess. / OAR citation as significant advance since completion of PM CD).
- Dominici et al. (2006) – Showed east / west coast differences in PM health impacts previously unappreciated. Supports fine PM NAAQS and potential compositional approaches in future decisions due to sulfate-related composition differences. (06 Prov. Assess. / OAR citation as significant advance since completion of PM CD).
- Gilmour / Linak et al. (2004 a,b,c, 2006) - Source attributed health studies conducted by NHEERL / NRMRL coalition (7 published papers / 3 in-press) cited by OAR as critical new-direction of research needed to support 'sector-based' concept of OAQPS.
- Edney / Kleindienst et al (2004, 2005, 2006) – A major uncertainty in the CMAQ air quality models is the atmospheric chemistry in secondary organic aerosols (SOA) formation. OAR has cited this effort as the most critical research need for NAAQS implementation.

2. **Strategic Directions for 2008-2012**

The Clean Air Research Program is driven by information needs to set and implement the National Ambient Air Quality Standards (NAAQS), with additional impetus provided by the need to ensure that EPA, states, tribes, and localities are adequately reducing risks associated with exposure to ambient and indoor hazardous air pollutants (Air Toxics). The Program relies on research conducted at EPA Laboratories, through extramural grants (including five PM Research Centers), and by co-funded partnerships (e.g. with HEI). The Program is organized around two long term goals (LTGs). The first goal focuses on providing information needed to set and implement the NAAQS and inform AT risk assessments and management options, while the second is designed to advance the science toward a more comprehensive (multi-pollutant) perspective of air quality management:

- LTG 1: Reduce uncertainty in standard setting and air quality management decisions due to advances in air pollution science
- LTG 2: Assess source-to-health linkages and reduce uncertainties that obscure these linkages

Historically, the ORD Air Research Program was structured into three "program-projects" (PM, Ozone and Air Toxics). In 2005/6, the changing landscape of budget and science supported the logical integration of these areas into a single Clean Air Research Program. This integration was supported by the earlier recommendations contained in NRC reports on research priorities and air quality, and the program reviews conducted by the BOSC, SAB and the OMB PART process. OAR offices (OAQPS, ORIA, and OTAQ) have been very supportive of this change, particularly the emphasis on the "source to health-outcome" theme of LTG-2. Discussions with Regional Air Offices (3, 9 and 5) indicate they are also enthusiastic about the prospect of leveraged activities to address important field implementation activities. Lastly in terms of program operations and infrastructure, OCFO recently authorized this structure for budgeting purposes, post FY07.

Over the new MYP period (~5yrs), the Clean Air Research Program will continue to support the regulatory decision processes of OAR Offices and provide tools and information to assist regions, states and tribes, who are tasked with rule implementation. OAR has repeatedly indicated that this program support activity of ORD is integral to their core mission and as such is their overarching priority. However, the vision of the ORD's Air Program to move to a multi-pollutant framework is consistent with OAR's conceptual shift to sector-directed (essentially synonymous to source) approach to air quality management. The emphasis within PM will remain on hazardous components as critically important to refinement of the PM NAAQS, but the source attribution and influence of co-pollutants is now identified as equally important in terms of the science underpinnings of the rule and cost-effective risk reduction.

The Clean Air Research Program will continue to move to a realization of the Air Multi-Pollutant Program, with coordinated efforts among STAR / PM Center and intramural investigators on the highest OAR priority issues (e.g., PM attributes, source profiling, exposure, and science to refine the quality and grid of AQ and receptor models).

The Clean Air Research Program is committed to advancing air pollution science to enable linkage between health effects to specific source types, PM attributes, and gaseous pollutants. The traditional pollutant-by-pollutant approach has achieved many gains for air quality over the last three decades, but further advances require refinements in the complex science and strategies of multi-pollutant scenarios. The forward-looking 'Source to Health Outcome' paradigm builds more effective and defensible AQ strategies to deal with the real-world "one-atmosphere" exposure interface. Over the next five years, the Clean Air Research Program will target three emerging issues as the foundation of the future program. The first is to address risks associated with Near-Roadway exposures, which have emerged as a major public health concern. The significant uncertainty and multi-pollutant character make this an ideal area for ORD investment as we move into the source to effects paradigm. As such the Program has designed a multi-faceted, interdisciplinary science approach that will provide information on contributing sources, exposures, health risks and possible mitigation options. The program is being leveraged with client offices, outside stake-holders and other federal agencies. The second major Air Research area relates to the hierarchy of toxicity and risk across prominent sources thought to be major contributors to regional and local air pollution.. Lastly, the Program is developing and assessing approaches to address the important question as to the effectiveness of regulatory decisions (accountability) in protecting health. OAR has a long-held interest in assessing the effectiveness or impact of its regulatory decisions on exposure and health. Several recent studies have suggested the feasibility of such assessments using various indicators. ORD intends to provide OAR a framework to structure hypothesis-based studies as recommended by the BOSC, building from controlled assessments to a large broad-based air quality accountability.

Key expected accomplishments:

Data and tools to support implementation of the NAAQS − Anticipated achievements (APGs across 2007-12) will decrease uncertainties in the NAAQS process and expand the capabilities of EPA, states, and tribes as they design effective implementation strategies. New and updated data and advanced methods and models to characterize and estimate source emissions will be a key component of this effort. Enhanced air quality models (e.g., 2008 CMAQ release) will incorporate this emissions information and more accurate secondary organic aerosol chemistry and meteorology in order to improve SIP development and the advanced public alerts to adverse air quality episodes. Advances in receptor-based models will more accurately identify which source categories contribute to ambient concentrations, providing the basis for targeted control strategies. Information on the cost and performance of technologies inform decisions on what technologies are eventually installed. Together with HEI and other research partners, EPA is undertaking a systematic evaluation of PM attributes that will expand our understanding of how these relate to a range of health outcomes (e.g. pulmonary, cardiovascular, immunological, neurological, reproductive and developmental). Specific 2008/9 APGs and APMs report the findings and impact of coordinated epidemiological and toxicological studies that link PM attributes (size and composition) to effects in healthy and susceptible sub-populations. In 2010, researchers in the ten-year, prospective epidemiological MESA-Air Study will report interim findings on potential cardiovascular disease from exposure to PM and other air pollutants.

Development of a Multi-Pollutant Research Program (PM attributes+/-co-pollutants) – A Multi-Pollutant strategy will be developed and implemented to address emission and health linkages to better inform the assessment of relative source risks. Approaches to determine and attribute the health effects of real world mixtures of air pollutants in healthy and susceptible populations will be developed to support management decisions. Sector-directed regulatory efforts and guidance for addressing indoor pollutant mixtures will be informed by the health and exposure research that address a mixture of Criteria and Hazardous pollutants and by evaluation of risk management options. The Near-Road program will be fully implemented during this period in cooperation with federal partners. An intensive cross-discipline assessment of AQ, exposure-health and emissions to test receptor and attribution models as aligned with health (empirical and field) will be performed.

Development of a framework for assessing AQ Decision Accountability − It is expected that a reasonable strategy to assess Air Accountability will be developed founded in controlled study and/or with opportunistic circumstance (e.g., changing local regulation, traffic adjustments, fuel changes, industry changes etc.). The temporal and spatial issues associated with finite accountability-situations will be used to develop approaches testable in *a priori* defined circumstances (2009 APG). Systems modeling or similar approaches will be developed with OAR to assess the potential broader scale testing at urban or regional levels (2011 APG).

B. GLOBAL CHANGE AND MERCURY (NPD: Dr. Joel Scheraga)

Global Change Research Program

Recent Key Accomplishments of the Current Program

1. Successful Integration of Program with EPA Mission and Statutory Requirements

- ***Deputy Administrator's Initiative:*** In 2006, ORD's Program became fully integrated into an Agency-wide framework through a process coordinated by the Deputy Administrator.
  - ***Agency Taxonomy:*** Agency "taxonomy" for climate activities includes: (1) *Mitigation* of greenhouse gas concentrations; (2) *Research and Assessment* (to support the U.S. Climate Change Science Program); and (3) *Adaptation* to support the Agency's mission and goals.
  - ***Focus on Regulatory and Programmatic Requirements:*** Focus on how climate change will affect the ability of Regional & Program Offices to fulfill their statutory/regulatory and programmatic requirements.
  - ***Program Justification:*** Tying climate change research to the EPA Strategic Plan justifies why work is being done in EPA as opposed to other federal agencies.
  - ***Agency-wide Workgroup:*** Co-chaired by ORD & OAR, will integrate research, programmatic, and policy activities across Agency, with focus on performance and outcomes.

2. Timely and Useful Assessments to Inform Decision Making

- ***Air Quality:*** Nationwide assessment of effects of *climate change* on air quality in the U.S. (Clients: Conducted in partnership with OAR/OAQPS; requested by Clean Air Act Advisory Committee; to be used to evaluate effectiveness of State Implementation Plans)
- ***Combined Sewer Overflow Events:*** Assessment of effects of climate change on combined sewer overflow events in the Great Lakes and New England Regions. (Clients: Being used by Regions 1 & 5, and their State and City partners, in redesign of systems.)
- ***TMDLs*:** Assessment of implications of climate change for pollutants and pathogens in surface waters. (Client: Being used by Office of Water to evaluate implications for State-level attainment of TMDLs.)
- ***Drinking Water:*** Implications of climate change and sea level rise for drinking water systems supplied by surface water (Clients: Office of Water; to be used by 6 systems serving 500,000 people to increase resilience to sea level rise)
- ***Drinking Water:*** Implications of climate change and sea level rise for Florida systems supplied by groundwater (Clients: Office of Water; Vulnerability assessment and maps to be used by water resource management programs in Florida counties)
- ***Coral Reefs:*** "Reef Manager's Guide to Coral Bleaching" (Partnership with NOAA, IUCN, and Australian Great Barrier Reef Marine Park Authority; to be used by reef managers to respond effectively to mass coral bleaching events)
- ***Millennium Ecosystem Assessment***: Partnered with WHO to produce "Health Synthesis" (Recipient of Zayed Award for scientific achievement in environment)
- ***Human Health/Aeroallergens:*** Assessment of implications of climate change for aeroallergens and resulting human health effects. (Clients: CDC; Climate Change Science Program [CCSP] "Human Contributions & Responses" Workgroup)

3. Information and Tools Developed to Inform OW Adaptive Management Decisions: Incorporated Climate Assessment Tool into new version of ***OW's BASINS System*** (v. 4) to enable water resource managers to evaluate implications of climate change (Clients: OW/OST; 3000 registered users of BASINS; Regional, State and local agencies performing watershed and water-quality based studies to support regulatory [TMDL] compliance)

Strategic Directions for 2008-2012

The strategic direction for the Global Change Research Program is to conduct innovative research and perform assessments that: 1) reduce uncertainties on the linkages between global change (with particular emphasis on climate variability and change) and air quality, water quality, and aquatic ecosystems; 2) enable EPA's Office of Air and Radiation to effectively account for global change while fulfilling its statutory requirements; 3) enable State and local air quality managers to consider global change in their decisions through improved characterization of the potential impacts of global change on air quality; and 4) enable EPA's Program (*e.g.,* OW, OPPTS) Offices, Regional Offices, and the States to consider global change in their decisions through improved characterization of the potential impacts of global change on water quality and aquatic ecosystems.

Evolution of the Global Program & Changes in Emphasis

Based upon the recommendations of the BOSC Subcommittee on Global Change, feedback from the OMB PART review, and discussions in the Deputy Administrator's Office Director Workgroup on Climate Change, ORD's Global Program is reorganizing itself around two Long-Term Goals (LTGs): 1) Climate Change and Air Quality, and 2) Climate Change and Water Quality/Aquatic Ecosystems. All of the program's work will continue to be place-based, but with a particular focus on ***decision support***.

It is anticipated that the program will maintain its current emphasis on understanding the implications of climate change for air quality in the United States. However, with the Office of Water's significantly increased interest in understanding the implications of climate change for its statutory and programmatic requirements (as articulated in a September 2006 memorandum transmitted from OWOW through Mike Shapiro, OW Deputy AA), we propose an increased emphasis on assessing the implications of climate change for water quality in the US. (This increased emphasis is also consistent with feedback received from the SAB in its review of the FY2007 Pres. Bud.) Also, with the CCSP's successful engagement of CDC in evaluating the effects of climate change on human health, we propose to decrease our emphasis on assessing the health effects of climate change.

Rationale

The work of EPA's Global Change Research Program is rooted in provisions of the Clean Air Act (CAA), Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) – as well as the Global Change Research Act of 1990 (1990 GCRA). Its focus on the implications of global change for air quality and water quality/aquatic ecosystems was reaffirmed by the BOSC Subcommittee on Global Change: *"The overall conclusion of the Subcommittee is that the Program on the whole has done the 'right work' and that it has done it 'well.' … The Subcommittee concludes that the Program has provided substantial benefits to the nation and that it is on course to make significant further contributions to societal outcomes by informing and facilitating decisions by the public and private sector actors who must consider the prospects of global change."*

Air Quality Focus: EPA is the <u>only federal agency</u> focusing on the effects of climate change on air quality – rather than the effects of air quality on climate change.

Water Quality/Aquatic Ecosystems Focus: Climate can impact water quality through a number of pathways, potentially affecting EPA's Office of Water's ability to fulfill its statutory requirements. Based upon the needs identified by OW, the Global Program will focus on three major research threads reflecting the concepts of designated uses and watersheds: 1) Human Uses, 2) Aquatic Life Uses, and 3) Watersheds. (The focus on "watersheds" is consistent with the shift of CWA programs over the last decade to more holistic watershed-based strategies.)

CCSP Activities: (1) *All* of the Global Program's activities must be consistent with, and coordinated by, the CCSP (*i.e.,* consistent with the NRC-reviewed 2003 CCSP *Strategic Plan*). Given its focus on supporting EPA's mission and the statutory requirements of its Program Offices, ORD's program fills a unique niche within the CCSP. (2) The 1990 GCRA mandates that the CCSP produce an assessment of the potential impacts of climate change on the United States at least every four years. Despite its size, ORD's program has been a leader in fulfilling this statutory requirement. ORD is the Lead Agency producing 2 of the 21 CCSP Synthesis & Assessment Products, and contributing to 8 others (nearly 50% of the reports).

How is this Global Change Research Program Different? Despite its size, ORD's Global Program unequivocally provides significant value beyond that of other federal departments and agencies within the CCSP. ORD's program is unique among federal agencies because of: 1) its unique focus on the potential impacts of climate change on air quality, water quality, and aquatic ecosystems; 2) its unique focus on providing ***decision support*** to air and water quality managers (which also meets the President's directive "that climate change activities be accelerated to provide the best possible scientific information to support public discussion and decisionmaking on climate-related issue"); and 3) its unique set of capabilities based upon EPA's particular mission and statutory requirements. As the Global Program focuses on meeting the science needs of EPA's Program and Regional Offices, it relies on these unique capabilities and provides value derived from its comparative advantage relative to other programs.

Key Anticipated Accomplishments Anticipated (2008-2012)

Air Quality (FY2011): Completion of Final Assessment, "Effects of *Global Change* on Air Quality in the United States" - in partnership with OAR/OAQPS (**to be used by OAR to effectively account for global change while fulfilling its statutory requirements):**

Water Quality (to be used by OW to answer the questions, "Which impacts are the most pressing and widespread for water resources?" and "Which impacts are supported by sufficient information to allow the National Water Program to act?"):

- **FY2008:** In partnership with OW, completion of 8 "scoping papers" on priority water-related impacts of climate change
- **FY2008:** Assessment of global change impacts and adaptation options in key watersheds
- **FY2009:** Assessment of effects of climate change on biocritera
- **FY2009:** Assessment of effects of climate change on invasive species

CCSP (mandated by 1990 Global Change Research Act):

- **FY2008:** Completion of CCSP Synthesis & Assessment Products: "Preliminary review of adaptation options for climate-sensitive ecosystems and resources," and "Analyses of the effects of global change on human health and welfare and human systems."
- **FY2009:** Completion of NRC study (co-sponsored with NOAA): "Strategies and Methods for Climate-Related Decision Support" (to be used by entire CCSP, as well as EPA & NOAA, to focus all future climate-related "decision support" activities.)
- **FY2012:** Completion of EPA contribution to third CCSP "National Assessment"

Mercury Research Program

Recent Key Accomplishments of the Current Program

1. "White Paper" Developed in Support of Clean Air Mercury Rule (CAMR)

- Paper summarized the status of mercury control technologies for coal-fired utility boilers and directly informed the regulatory proposals contained in the CAMR.
- Paper was placed in the regulatory docket to support the regulation after going through an exhaustive EPA and interagency review process.

2. Developed Scientific Basis for Chapter 3 of the Regulatory Impact Analysis (RIA) for the CAMR

- Delivered peer-reviewed model applications to evaluate the magnitude and timing of mercury reductions anticipated based on planned regulations of coal-fired utilities.
- Documented how mercury emission reductions will reduce residues of mercury in fish and the corresponding beneficial impacts human consumption of methylmercury.
- Estimated the magnitude and timing of fish mercury concentrations across a range of coastal ecosystem types that would occur given changes in emissions.

3. Confirmed Transport of Mercury to the West Coast of the United States from Asia.

- First research to confirm that large amount of mercury emitted in Asia can be transported to the U.S. and affect air quality.
- Mercury emissions measurements were made at two sites: Okinawa Japan and Mt. Bachelor, Oregon.

Strategic Directions for 2008-2012

The strategic direction for the Mercury Research Program is now the evaluation of the effectiveness of the Clean Air Mercury Rule (CAMR). Fate and transport research – particularly the "hot spots" issue and its implications for the effectiveness of the CAMR – is the key problem that the Mercury Program will address.

Evolution of the Mercury Program and Changes in Emphasis

EPA issued the Clean Air Mercury Rule (CAMR) in 2005 to permanently cap and reduce mercury emissions from coal-fired power plants for the first time ever. With the passage of the CAMR, EPA's research needs changed and expanded, and the strategic direction for ORD's Mercury Program began to evolve. The current strategic direction represents an evolution of the program away from research focused on development of the CAMR towards support for implementation of the Rule.

We have identified fate and transport research – particularly the "hot spots" issue and its implications for the effectiveness of the CAMR – as the key problem to be addressed by the Mercury Program. (This represents an area of increased emphasis for the program.) As noted by the BOSC and the SAB, it is impossible to undertake a complete evaluation of the effectiveness of the CAMR within the current budget for the Mercury Program. A complete evaluation would require significant advances in fate and transport research (including dry deposition issues), analysis of "hot spots" in the U.S., and measurement the "planetary flows" of mercury (*e.g.,* long-range transport of mercury from Asia to the US). Practically speaking, this is an impossible undertaking for the ORD Mercury Program. As noted by Dr. Granger Morgan (Chair, SAB):

While some of the mercury in our food and water comes from power plants and other human activities, much comes from natural sources or is carried across the Pacific from natural and anthropogenic sources in Asia. On a global scale, science cannot yet accurately tell us where all the mercury in the U.S. comes from, where it goes, or in what chemical forms it exists. If we are going to assess the adequacy and effectiveness of the costly mercury controls that EPA regulation is imposing on U.S. industry, we need to understand those planetary flows. However… EPA's research budget for mercury… is too small to even adequately address the issues that EPA-ORD has been addressing, let alone to allow any work on the key problem of planetary flows of mercury.

Given the significant resource constraints on the Mercury Program, we chose the "hot spots" issue and its implications for the effectiveness of the CAMR as the program's main focus because we believe this is one area in which ORD's Mercury Program can *make a difference* with its limited resources. This area of focus – within the broader issue of mercury fate and transport – is also consistent with the BOSC conclusion in its review of the Mercury Multi-Year Plan: *"Significant new research and assessments also will be needed to adequately monitor the effectiveness of regulations once they are in place... ORD has rightly chosen to focus on the area of research it is best equipped to do (*i.e., *the transport and fate of environmental mercury.*"

Although the Mercury Program will increase its emphasis on fate and transport issues related to the hot spots issue, it will continue to address mercury emissions from coal-fired boilers in a multi-pollutant context. (With level funding, we will decrease emphasis in this area.) This information will be critically important for the EPA, States, and utilities to ensure that necessary reductions will occur if certain technologies are installed as the new Clean Air Mercury Rule is implemented. Utilities continue to represent a significant national and international source of mercury releases, and the knowledge gained from the research will benefit implementation of the CAMR.

Leveraging Resources Across MYPs

The significant shortfall in resources necessary to assess the adequacy and effectiveness of the mercury controls called for under the CAMR requires that significant efforts be made to leverage resources across MYPs (particularly the Ecosystems MYP and the Air MYP) so that other key science questions are addressed. Particular opportunities may exist to investigate additional questions related to: 1) overall utility boiler emissions (since data from ORD research in this area can be used in guidance documents supporting implementation of multiple rules proposed and promulgated to reduce utility boiler emissions); 2) the wet and dry deposition of mercury; 3) the fate and transport of mercury through ecosystems; and 4) the uptake of mercury in fish consumed by people.

Recognizing that mercury is a global problem, the Program will also continue to work with the international community to address key mercury issues (though at a very minimal and decreased level of emphasis). Specifically, the Program will continue to support the UNEP Global Mercury Program to address global mercury pollution, and will actively participate in the UNEP Global Partnership focused on fate and transport issues.

<u>Key Anticipated Accomplishments Anticipated</u> (2008-2012)

- **Identification of Deposition "Hot Spots."** Building off the seminal Steubenville study, the Mercury Program will identify other significant deposition hot spots across the U.S. Hot spots will be identified under existing emissions profiles, and under projected profiles given implementation of the CAMR.

- **Development of geographical information for the States and EPA to site mercury monitors.** Using information derived from the hot spots research, the Program will begin to inform the choice of sites for mercury monitors. EPA and the States need to target resources so as to identify and protect sensitive subpopulations, fishes and waters from mercury contamination. ORD will develop the geographical information, and (resources permitting) conduct the necessary testing, required to effectively site mercury monitors.

- **Evaluation of Cost and Effectiveness of Viable Emission Control Devices.** ORD will focus on determining the cost and effectiveness of viable emission control devices, so that EPA & the States know the amount of mercury that can be reduced by various technologies or technology combinations. This information will be critically important for states and EPA who must ensure the necessary reductions will occur if certain technologies are installed, and <u>to assist the Agency defend its position on technology capabilities when it addresses court challenges associated with CAMR implementation</u>.

- **Evaluation of combustion residues.** OAR, OSW, the States, Regions and industry need to know the long-term, net effects of the CAMR, to make informed choices on reducing risks in a cost-effective manner. This includes anticipating unintended effects, such as secondary emissions of pollutants from ash or health effects from byproducts. The program will assess the effect of control systems on the characteristics of mercury-contaminated residues, and increases in cost or environmental risks from their management.

C. HOMELAND SECURITY (Director, National Homeland Security Center: Dr. Jonathan Herrmann)

National Homeland Security Research Center

Mission
The National Homeland Security Research Center (NHSRC) develops and delivers reliable, responsive expertise and products based on scientific research and evaluations of technology. Our expertise and products are widely used to prevent, prepare for, and recover from public health and environmental emergencies arising from terrorist threats and incidents.

Background
Following the terrorist attacks of September 11, 2001, and the mailing of anthrax contaminated letters later that year, the U.S. Environmental Protection Agency (EPA) developed a Strategic Plan for Homeland Security[1] committed to enhancing national security and protection of human health and the environment. The Strategic Plan and several Homeland Security Presidential Directives (HSPDs)[2,3,4] provided the basis for creation and mission of the National Homeland Security Research Center (NHSRC) in 2002. Originally formed with a three-year life, NHSRC was faced with addressing scientific and technical issues that required longer than three years to resolve. Reviews of NHSRC Programs by the National Academies of Science (NAS)[5,6] as well as commentaries by other federal organizations, recommended that NHSRC continue as an organization within EPA to address national security research needs related to protecting human health and safeguarding the environment. NHSRC became a permanent part of the Office of Research and Development (ORD) in late 2004 allowing it to address both short-term homeland security needs and long-term research and development topics. As part of its mission, NHSRC is also providing clear lines of communication and effective interaction within EPA and with other federal agencies, universities, and private sector research partners. The design, performance, quality and impact of the Homeland Security Research Program will be assessed in early FY08 by ORD's Board of Scientific Counselors.

Current Research Program

ORD's Homeland Security Research Program is aligned with EPA's Strategic Plans[1,7] and the HSPDs[2-4]. The research is organized into three broad themes: (1) water infrastructure protection, (2) decontamination and disposal, and (3) rapid risk assessment. Prioritization of research areas within these themes is established by (1) obtaining homeland security stakeholder input, and (2) analyzing threat scenarios. The current research activities associated with these three strategic research areas are

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[1] EPA (2003). Strategic Plan for Homeland Security.
[2] HSPD 7: Critical Infrastructure Identification, Prioritization, and Protection designates EPA as the sector specific agency for critical water infrastructure. Designation of EPA as the lead agency for these activities is consistent with the President's National Strategy for Homeland Security (July 2002), which designates EPA as the lead agency for protecting U.S. water resources, from source water through use, treatment, and discharge.
[3] HSPD 9: Defense of the United States Agriculture and Food directs EPA to develop a robust, comprehensive, and fully coordinated surveillance and monitoring program to provide early warning in the event of a terrorist attack using biological, chemical, or radiological contaminants. HSPD 9 also requires EPA to develop a nationwide laboratory network to support the routine monitoring and response requirements of the surveillance and monitoring program
[4] HSPD 10: Biodefense in the 21st Century, currently a classified document, reaffirms EPA's responsibilities under HSPD 9 while adding a clear directive regarding the Agency's responsibilities during decontamination efforts.
[5] NAS (2003). Review of EPA Homeland Security Efforts: Safe Buildings Program Research Implementation Plan.
[6] NAS (2003). Review of the EPA Water Security Research and Technical Support Action Plan: Parts I and II.
[7] EPA (2006). 2006-2011 Strategic Plan.

summarized below:

Water Infrastructure Protection: EPA scientists and engineers are conducting research on protecting drinking water systems from physical and cyber threats; identifying drinking water threats, contaminants, and threat scenarios; improving analytical methodologies and monitoring systems for drinking water; developing containment, treatment, decontamination, and disposal methods; planning for contingencies and addressing infrastructure interdependencies; targeting impacts on human health and informing the public of risks; and protecting wastewater treatment and collection systems.

Decontamination and Disposal: EPA scientists and engineers study chemical, biological, and radiological contamination of air and indoor surfaces, and radiological contamination of outdoor urban environments; provide methods for upgrading buildings in ways that increase occupant protection; supply information on decontamination methods (including safety, efficiency, and cost); and analyze disposal options for decontamination wastes. EPA researchers are working to develop new methods for detecting chemical and biological contaminants in buildings and radiological contaminants both inside and outside of buildings in order to provide better ways of cleaning up and disposing of contaminants following a terrorist attack.

Rapid Risk Assessment: EPA scientists and engineers are conducting research to provide first responders with information to facilitate hazard identification associated with potential terrorist attacks; to establish methodologies for rapidly evaluating and estimating risks from biological, chemical, and radiological agents during a terrorist incident; and to accelerate the development of risk assessment methodologies by adopting and/or modifying available approaches.

Strategic Research Directions

The research program just recently established and implemented research priorities, so no major changes in strategic direction are anticipated in the next several years. Research in many areas will continue the current trajectory including, for example:

- The development of Provisional Advisory Levels (PALs) for acute, short-term and long-term exposure to a priority list of approximately 120 chemicals. Draft PALs for 22 chemicals have been developed and are awaiting review by the SAB. The program is planning to develop additional PALs at a rate of approximately 10 chemicals per year.

- The development and validation of analytical methods for 122 chemical warfare agents and related degradation products will continue for the next several years and studies on sample methods efficiencies will commence.

The Program is considering expanding its efforts in two areas: in radiological agents (analytical methods, risks, remediation), and in how to effectively communicate homeland security research and risk The Program will work with stakeholders and experts to develop approaches to addressing these issues.

D. ECOLOGICAL PROTECTION (NPD: Dr. Rick Linthurst)

Ecological Research Program

Provide knowledge that enables proactive policy and management decisions to protect human well-being by conserving and enhancing ecosystem services.

RECENT KEY ACCOMPLISHMENTS OF CURRENT PROGRAM

Improved Monitoring and Assessments

- Made monitoring faster, cheaper, better for Office of Water, States, internationally:
  - First defensible national assessment of streams that is a baseline for future trends
  - First defensible national estimate of estuarine condition, and trends to follow
  - International technology transfer of EMAP design, indicators (e.g., Baltic Sea, China Sea, Bay of Bengal, Black Sea, and Mediterranean Sea)
  - Flexible design for national lake survey
- Determined that intermittent streams are important in the life cycle of coho salmon
- Developed chemical and biological assays to monitor reproductive hormones in effluents.
- Demonstrated the utility of molecular probes for detecting invasive species in ship ballast.
- Developed cost-effective and feasible methods for biological assessment of large rivers.

Developed New Tools for Environmental Protection and Management Application

- Combined reference sites and modeling for evaluating biological quality of streams
- Linked atmospheric and watershed/water quality modeling for Chesapeake Bay
- Developed and used fish genetic diversity as an ecological indicator of stream condition.
- Developed a database and decision support toolkit to seek balance between development and preservation of ecological functions of natural landscapes.
- Established the Virtual Reference Database to provide a baseline for testing and validating imagery and image processing methods.
- Developed an integrated database and decision support toolkit to identify ecosystems most vulnerable to loss or degradation within 5 to 25 years in the Mid-Atlantic area.
- Completed guidance on stream ecosystem restoration for managers
- Developed state-of-the-art Lake/Reservoir Decision Support Tool (LDST) software

Achieved Measurable Success in Protecting the Environment

- Demonstrated the effectiveness of Clean Air Act Amendments in restoring aquatic systems; provided deposition trends analysis showing clear evidence of sulfur and nitrogen reductions.
- Produced the first comprehensive before/after evaluation of the effectiveness of stream restoration to improve water quality in an urban watershed.

STRATEGIC DIRECTIONS FOR 2008-2015

The Ecological Research Program (ERP) strategic direction is to conduct innovative research to:

- Identify and clarify the impacts of human activities on *ecosystem services;*
- Convincingly articulate and measure the dependent and valuable relationship between *human well-being* and *ecosystem services;*
- Provide tools for *policy makers and managers* that enable them to protect and restore ecosystem services through informed decision making at *multiple spatial and temporal scales.*

RATIONALE

Our health, national security, economic potential and cultural connections are directly and intimately tied to ecosystem characteristics and quality. Yet our vulnerability to ecosystem degradation, though recognized at varying levels, has not regularly influenced policy and management decisions. A more comprehensive theory and practice for quantifying and characterizing ecosystem services, their vulnerability to human activities and influence on well-being, are essential to "safeguard the natural environment."

We propose to elevate **ecosystem services as our strategic focus.** This focus capitalizes on past ERP successes and represents a natural research progression that is responsive to EPA goals; it reflects guidance provided by the EC, is currently included in long-term goal 3 (LTG3), is consistent with the *EPA Ecological Benefits Assessment Strategic Plan***,** and was endorsed in the March 2005 BOSC review which stated that:

> *"The research, tools, and analytical technologies developed under the ERP represent the most comprehensive federal government research program examining the provision of ecosystem services and the communication of these to decision-makers*. ***LTG 3 is a highly relevant activity that is central to EPA's mandate of improving environmental quality and protecting and restoring the health of the nation's ecosystems.*** *ORD and particularly the ERP are uniquely suited and positioned to address these issues.[emphasis added].*

The 2005 UN Millennium Ecosystem Assessment states: *"Even today's technology and knowledge can reduce considerably the human impact on ecosystems. They are unlikely to be deployed fully, however, until ecosystem services cease to be perceived as free and limitless, and their full value is taken into account."* Our vision is to systematically challenge this misconception and transform decision-making by clarifying the impact of our choices, and offering alternatives that will enhance the type, quality and magnitude of the services we receive from ecosystems.

HOW IS THE ERP DIFFERENT?

- **Resource alignment.** Resources will be realigned to target ecosystem services as a key research theme.
- **Conceptual expansion.** Research will expand beyond chemical and biological endpoints used in risk assessments, incorporate multiple spatial and temporal scales, and explore alternative approaches for evaluating ecosystem services.
- **Interdisciplinary, and Intra- and Interagency planning and implementation.** The program will bring together natural and social scientists in partnership and cooperation for plan design and implementation (e.g., partnerships with the National Center for Environmental Economics in OPEI, program offices, and ORD's natural and social scientists). Interoffice and inter-program (e.g., other MYPs) collaboration, and collaborations with external partners and the academic community will bring essential skills, expertise, and experiences to complement our own.

ANTICIPATED CHANGES IN CURRENT PROGRAMS

Condition and Accountability—while maintaining essential technical support to Program Offices in monitoring and assessment, ORD will shift emphasis from data gathering to data processing; funds will be directed toward **creating geo-spatial data and techniques to describe and quantify ecosystem services and vulnerability,** e.g.,:

- Develop new monitoring strategy in 07 to assess ecosystem services

- Analyze EMAP ORD and Program Office data to test hypotheses.
- Shift EMAP toward developing methods and indicators to measure and assess changes in ecosystem services by 09. EMAP's current activities, now focused on monitoring of ecological condition, will decline annually and be terminated by 2011.
- Assess the impact of EPA's policies and programs on protecting, preserving and restoring the environment.

Diagnostics and Forecasting—ORD remains a critical source of information, tools and models for Agency decision-making. Under our new objective we will **create models to describe and forecast the response of ecosystem services to human actions and natural stressors at multiple scales over time,** e.g.:

- Develop models to predict changes in ecosystem services in response to human-generated and natural ecosystem alterations with robust uncertainty assessment.
- Create on-line decision support tools for assessing alternative scenarios, evaluating trade-offs and optimization, moving models from integration to implementation.

Assessment and Restoration—ORD is a leader in ***environmental*** risk assessment ***and risk management***. With this expertise we can create tools to allow the explicit and proactive examination of a range of management options at multiple scales. Our objective is to **create new ways to retain and enhance ecosystem services under scenarios of increasing human population and intensified use,** e.g.:

- Extend successful stream buffer restoration to evaluate restoration of ecosystem services at larger spatial and temporal scales.
- Develop on-line decision support systems to deliver information on ecosystem services and analyses for real world application.

RESEARCH OUTCOMES

With tools to predict and prevent losses and restore functions we will directly enhance our capability to achieve EPA's mission. We will:

- Provide guidance and tools for balancing the **protection and use** of ecological resources in a way that will "accelerate the pace of environmental protection while maintaining our nation's economic competitiveness."
- Create **accessible products** and **online applications** that are used by decision-makers and stakeholders that embody the best that natural and social sciences can offer and reflect the research needs of program offices and regions,
- Create tools, models, and understanding for meeting environmental goals in a context relevant to economic, socio-cultural and human health needs.

ENVIRONMENTAL RESULTS

Produce information powerful and useful enough to shape future policy and management decisions, on par with human health considerations, and stop the loss of ecosystem functions and services with their often irreversible consequences.

E. WATER QUALITY (NPD: Dr. Chuck Noss)

Water Quality Research Program (Rev)

Recent Direction of the Program
The Water Quality program supports customer needs as indicated in each of three Long-term Goal statements (*The Office of Water, EPA Regions and States use ORD research and expertise…*). This concept is supported by both BOSC and OMB, and results in significant client input in developing a research plan. The WQ MYP, now in draft form, deals with a number of major stressors (e.g. toxics, pathogens, nutrients, and sediments) and emerging contaminants, work related to various water resources (e.g. rivers, lakes, estuaries etc) and addresses the importance of aquatic habitat exposed to a gradient of multiple stressors and biocriteria. During the period from 2000-2005 the program published over 500 articles on the above mentioned topics

Strategic Directions for 2008-2012
The WQ Research Program seeks to help transform our national ethic of water use and protection, and to energize community support of watershed scale activities by delivering science that helps achieve desired water quality and quantity outcomes. To realize this goal, a two-fold strategy has been developed. First and foremost is to provide integration in the development and provision of watershed scale integrated modeling and decision support tools, and second is to target research products to client uses at local to national levels. This strategy supports our belief that national, regional, and local decision-makers need to apply leading edge and scientifically sound information, tools, methods, and models to restore and protect the nation's waters in a growing and changing world.

The Research Coordination Team working to develop this MYP has put great emphasis on identifying research that complements without duplicating research in the Ecosystems, Drinking Water and other related MYPs. To meet the most strategic needs, priorities are being considered for the most important sources of pollutants (e.g. agricultural or urban), and how the research will be integrated into tools used to improve watershed decisions. To help set these priorities, the Office of Water developed the following criteria, (examples of research are provided).

- information to meet short-term needs for criteria development (e.g., aquatic life criteria revisions, recreational water quality criteria)
- addressing high visibility issues (e.g., function of headwaters and isolated wetlands, use of wetlands in trading, improving and maintaining infrastructure, managing wet weather flows)
- conducting science to meet future needs(e.g., integrated monitoring, addressing combined water quality and quantity issues, emerging pollutants, managing multiple stressors)

Research Descriptions for each Long Term Goal
LTG 1 research is being considered for criteria development for nutrients, headwater streams, aquatic life guidelines, emerging pollutants, integrating multiple stressors, habitat, water quantity, and suspended and bedded sediments.

Nutrient research is important because it consistently ranks as a major impairment of the nation's waters on the 303(d) list and information is needed to support OW criteria development strategies for estuaries and wetlands. Key subjects include vulnerabilities of estuaries and wetlands, nutrient spiraling and flow relationships, nutrient gradient impacts on designated uses, relationships with HABs, and understanding environmentally sound trading approaches.
Impacts on navigable waters will be evaluated through classification efforts, studies on hydrologic connectivity, models, and rapid indicator assessment methods for use in determining whether streams and wetlands have significant downstream influence. This is in response to recent Supreme Court decisions

that isolated wetlands must have some significant nexus to navigable waters if they are to be regulated under the Clean Water Act.

Integrative watershed modeling frameworks are being developed to address complex issues associated with managing highly regulated river basins. The framework for developing criteria for suspended and bedded sediments was published in 2006 (streams) will require continued support in the area of technical methods development and validation, improving classification schemes, and case studies and technical support for lakes, large rivers, estuaries and wetlands.

Multiple stressors research will target integration of mechanistic and systems models to provide assessments of sensitivity, risk probability, and alternative future scenarios at the scales that are needed for decision-making. Habitat research will focus establishing relationships between habitat protection/restoration and biological integrity; linking these relationships to a biological condition gradient and Tiered Aquatic Life Use framework.

Research and technical guidance is needed to update the 1985 Aquatic Life Guidelines. Other emerging pollutant research will identify/categorize contaminants or classes of emerging pollutants and the risks posed to aquatic life, wildlife, or human health; and a framework for prioritizing the pollutants (e.g. chemicals, pathogens, nanoparticles) or classes of contaminants for criteria development. Research will also continue to support the BEACH Act to supply information on health risks for populations related to point and non-point sources of pathogens and fecal or pathogen indicators.

LTG 2 This LTG supports work divided among three watershed management themes: assessment, management measures, and incentives, with further subdivisions. The objectives are to provide data and tools for more integrated uses in determining impairments, managing resources and in assessing restoration and protection program effectiveness.

The Watershed Assessment theme builds on our understanding of baseline characterization and progresses to include condition assessments, threats/causal assessments, predicting/priority setting and targeting, and watershed program results assessment. Water quality priorities focus on research that supports TMDL decision-making processes. Specific areas include baseline characterization and quality/condition assessment. The change in status (ecological goods and services, benefits, or ability to meet designated uses) that reflects altered worth are focal areas.
Research of (1) threat/causal assessment will identify stressors or impending changes likely to impair water in the future without preventive action, and identifying attributes for successful interventions. Prediction/priority setting and targeting (2) will provide estimations of watershed condition and restoration potential to target interventions and funding. Watershed program results assessment (3) will evaluate CWA program effectiveness based on evidence linking program actions to environmental responses and their probable causes.

Watershed Management Measures is defined by four sub-themes: targeting priority watersheds for repair and/or protection, optimizing the use of management measures, measuring results, and cost-benefits of management measures. Priority research encompasses: (1) Building on the use of integrated modeling systems to account for hydrologic flows and stressor transport and fate and couple this with the performance and cost of individual management practices and aquatic ecosystem stressor response information; (2) Developing a methodology to enable community-based watershed managers to specify a minimum suite of physical, biological and chemical indicators that provide a meaningful measure of the ecologic health of the aquatic systems at the 12-digit HUC watershed; (3) Efforts will be made to quantify the monetary and non-monetary benefits of ecological services that are being protected to maintain water quality.

The Incentives theme includes water quality credit trading, direct payment programs to stimulate the installation and implementation of BMPs to address non-point source pollution, and regulatory relief/permit streamlining in exchange for permittees reducing effluent stressor concentrations more than required by law. Wetlands in water quality trading will focus on the performance of trading and incentive programs and document costs and benefits.

LTG 3 In this planning period for **s**ource control and management research, there is a significant focus on infrastructure and wet weather impacts. Aging wastewater infrastructure research needs deals with (1) improved inspection, condition assessment, and cost estimating tools for existing collection systems; (2) effective methods to determine performance and cost of innovative rehabilitation for wastewater collection systems; (3) approaches that can reduce construction costs and increase carrying capacity and storage capabilities; and (4) improved performance and extend service life of existing systems.

Major Wet Weather Flow research needs address occurrence, removal and consequence data for toxics, pathogens and emerging contaminants that affect the beneficial use of stormwater. Works will also address SSO, CSO, and blending policy informational needs. POTW research gaps include the extent to which pathogens, pathogen indicators and fecal indicators are effectively inactivated during the disinfection of wet weather effluents; the determination of the most useful microbial indicators for assessing the potential for pathogen survival in the treatment of wet weather flows; identification of best practices that allow a POTW to maximize treatment potential and handle larger flows during wet weather events.

Other POTW related research addresses the effectiveness of biosolids disinfection and stabilization methods for land application utilized by the almost 11,000 POTWs needs documentation. Methods (or improvement of existing methods) are needed for detection and identification of pathogenic organisms in animal wastes and manure to assess process effectiveness and for source identification and tracking. EPA plans to work more closely with USDA and others both in research and in the preparation of synthesis document(s) for use by regions and states.

EPA's 1997 *Response to Congress on Use of Decentralized Wastewater Treatment Systems* identified barriers to implementation in two categories: system performance, and watershed-scale effects. Information will be provided on the impact of both properly and poorly designed, operated and maintained systems. New or refined source tracking and remote sensing methods will be required to accomplish reliable watershed scale assessments.

GEOSS/AMI

Background

The vision for GEOSS (Global Earth Observation System of Systems) is to realize a future wherein decisions and actions are informed by coordinated, comprehensive, and sustained Earth observations and information. GEOSS will "take the pulse of the planet" by linking systems comprised of multiple databases (or systems), thus revolutionizing our understanding of how Earth works. Over time, GEOSS will provide important scientific information for sound policy and decision making in every sector of society. EPA has started down the pathway towards GEOSS by: 1) its leadership in both the international Group on Earth Observations (GEO) and the US Group on Earth Observations (US GEO); 2) its Science Policy Council (SPC) support; 3) ORD's 34 FY 2006 and 2007 Advanced Monitoring Initiative (AMI) "test bed" projects that inspired a short-term strategy (three thematic foci) using FY 2008 AMI funds to demonstrate some major tangible AMI results by September 2008:

1) **Air Quality Forecasting/Assessment and Decision-making for Human Health;**

2) **Coastal/Source Water Quality and Decision-making for Human Health; and**

3) **Integrated (Air-Water-Land-Biota) Decision-making for Healthy Communities & Ecosystems.**

Strategic Direction over next 3-5 years (FY2008 – FY2012)

1. Maintain Leadership within GEO and US GEO advocating on behalf of the users of observational data and the environmental health decision makers
2. Harmonize "Environmental Health Decision Making Opportunities," Sub-Objective's "Strategic Targets" and "Societal Benefit Areas"within EPA's, US GEO's, and GEO's Strategies
3. Achieve "Interoperability" (system of systems) along the information continuum (sensors, data, models, decision support systems, outcome indicators) with sensor, information, computing, and communications technologies
4. Build "Knowledgebase," through collaborative demonstrations or learning test beds, of improved environmental health decision making at EPA with the integrated systems of AMI, US GEO, and GEOSS

Highlights of Expected Achievements

1.A. In terms of measurable outcomes, demonstrate Societal Benefit Area impacts that are responsive to observational data users and environmental health decision makers (2011+)
2.A. Explicit GEOSS/AMI references embedded in next EPA Strategic Plan (2006-07)
2.B. Crosswalk of the strategic linkages between EPA's, US GEO's, and GEO's Strategic Plans (2008)
2.C. GEOSS/AMI multiyear strategy with strategic linkages to other ORD MYP APGs (2009)
3.A. EPA's Systems "Button Chart" becomes part of US contribution to GEOSS (2008)
3.B. EPA achieves interoperability in at least one of US GEO's Near-Term or Mid-Term Opportunities (2010)
4.A. AMI lessons learned captured and incorporated into a prototype knowledgebase (2008)
4.B. Baseline and performance metrics documented to track the evolution of improving environmental health decision making and forecasting at EPA due to GEOSS/AMI (2009)
4.C. At least one GEOSS/AMI case study (under one of EPA's Strategic Goals) prepared for independent review and evaluation (by 2011)

F. DRINKING WATER (Acting NPD: Dr. Audrey Levine)

DRINKING WATER RESEARCH

KEY RECENT ACCOMPLISHMENTS

ORD research assists implementation of the Arsenic Rule: Meeting the current arsenic standard is challenging for many small communities. The arsenic treatment technology demonstration program is providing information to the numerous small drinking water systems, States, and EPA Regions on the following:

- The best treatment technology to select given local raw water quality
- The relative costs of the various treatment technology alternatives (both capital and long-term operation and maintenance)
- Technology transfer through an aggressive communication plan.

To date, demonstrations are running or are completed at 36 locations in 21 states. For more info, go to http://www.epa.gov/ORD/NRMRL/arsenic.

ORD-developed methods enable EPA to determine DW contaminant occurrence: To help determine whether to regulate a contaminant, the Agency requires DW utilities to use specific analytical methods to gather occurrence data. ORD has developed many of the recently required methods including methods for explosives (Method 529), nitrosamines (Method 521), acetanilide degradation products (Method 535) and perchlorate (Method 332.0). Of the 600,000 measurements that will be required in the next 4 years, ORD methods will be used in two-thirds of them at 4,700 DW utilities. For more info, go to http://www.epa.gov/nerlcwww/ordmeth.htm.

ORD health effects information on pathogens important to recent surface and ground water rules: ORD collaborated with the Centers for Disease Control (CDC) for more that 30 years in the surveillance and investigation of waterborne disease outbreaks and in the study of endemic waterborne disease. Recent development and application of a serological method for *Cryptosporidium* infections have provided evidence of widespread *Cryptosporidium* infection that is associated with low-level waterborne exposure particularly to surface water. Findings of these studies coupled with waterborne disease outbreak information assisted the EPA in promulgating the recent Long Term 2 Enhanced Surface Water Treatment Rule and the Ground Water Treatment Rule.

STRATEGIC DIRECTIONS 2008-2012

The Agency used DW Research products to complete work on major rules in the last several years including implementation of the Arsenic Rule and promulgation of the M/DBP rules. This rule-making highlighted the mounting need to develop regulatory approaches that address classes of related contaminants (rather than one at a time) and that employ integrated, multiple-barrier risk management strategies (e.g., integrated source water protection and treatment strategies to meet MCLs). Concurrently, the SAB, BOSC and ORD's Executive Council have advised the DW Research Program (DWRP) to evolve our efforts toward the next DW scientific and engineering challenges, namely, providing the research our clients need to support decisions on pathogens, unregulated contaminants, distribution systems and source water protection.

Program Design

To facilitate new strategic directions, the Program is evolving toward a design that is consistent with the multiple-barrier, DW cycle. In the past, the Program was organized around Safe Drinking Water Act (SDWA)-based regulatory categories (regulated vs. unregulated vs. other). Although this old approach showed a clear connection to SDWA, we believe that the Program is best served by aligning itself with the water cycle to promote research on complex issues requiring cross-Program collaboration and coordination, and cross-Lab/Center interaction. For example, the benefit of coordinating the source water portion of the DW program with the Water Quality Research Program becomes quite evident in this new structure.

This change marks a shift in the DW Program from addressing single contaminants toward development of treatment strategies, exposure and analytical methods, and effects information that can be applied to classes of contaminants in the context of the complete drinking water hydrological cycle - source water, treatment, and distribution. Overall, this movement has the potential to realize considerable resource efficiencies (e.g., coordination, synergies, leveraging) and improved science and engineering research products.

All work will be organized into the following scheme:

Source Water → Treatment → Distribution → Safe Water (tap)

The PART-driven LTGs must remain to showcase the Program's success in producing outcomes for Agency's implementation of SDWA. Briefly stated, these LTGs are:

LTG1 – *Use of ORD products in six-year review and implementation decisions*
LTG2 – *Use of ORD products in CCL-related decisions*

Research Emphases

Implementing the advice from the SAB[8][9][10], BOSC[11] and EC, and embracing the recent findings by the National Academy[12][13] yields the following proposed emphases in strategic direction:

Increasing emphasis:

- ***DW Pathogens***: The potential acute human health effects associated with pathogens and the prevalence of gastrointestinal disease in the U.S. associated with DW indicates that greater understanding of the risk and risk management of pathogens is needed. Research areas will include health effects (especially epidemiological studies), development of methods for detection (viability, infectivity, virulence), treatment systems (for small systems and point-of-use/point-of-entry (POU/POE) needs), and understanding the impacts of distribution of managing pathogens. This research area must be well-coordinated with the complimentary effort in the Water Quality Research Program on pathogens in recreational waters.
- ***Protecting Source Water***: With increasing demand for limited water resources, the protection of source waters is of growing importance. The DW Program will increase emphasis on understanding

[8] SAB (2004). "Advisory Report on the Science and Research Budgets for the U.S. Environmental Protection Agency for Fiscal Year 2005; A Report by the EPA Science Advisory Board." EPA-SAB-ADV-44-003.
[9] SAB (2005). "EPA's Draft 2005 Drinking Water Research Multi-Year Plan; A Review of the Drinking Water Committee of the EPA Science Advisory Board." EPA-SAB-05-008.
[10] SAB (2005). "Science and Research Budgets for the U.S. Environmental Protection Agency (EPA) for Fiscal Year 2006; An Advisory Report by the EPA Science Advisory Board." EPA-SAB-ADV-05-002.
[11] BOSC (2005). "Review of the Office of Research and Development's Drinking Water Research Program at the U.S. Environmental Protection Agency: Final Report."
[12] NRC (2004). "Confronting the Nation's Water Problems."
[13] NRC (2005). "Public Water Supply Distribution Systems: Assessing and Reducing Risks."

the impact of water reuse strategies such as aquifer storage and recovery (ASR) on the safety of DW (health studies, monitoring methods, ASR best practices), the development of wellhead protection tools, the impacts of subsurface CO_2 storage on DW source quality, and the development of best management practices for point and non-point DW contaminant sources. This research area must be well-coordinated with complimentary effort on watershed management in the Water Quality Research Program.

- ***DW Distribution***: This last protection barrier for DW safety may be the least understood. The Program will expand work on (1) the impact of distribution on the quality of treated DW – corrosion, leaching, biofilms, water age – and (2) how to manage this aging infrastructure in a cost-effective manner while maintaining healthy water. This work will be coordinated with the water security research conducted by NHSRC.

Steady emphasis: ***Emerging, unregulated chemicals***. Emerging chemical contaminants that appear to pose a risk including those on the CCL will continue to require attention. Increasingly, the Program expects to address chemical mixtures (rather than single chemicals) and those resulting in non-cancer endpoints such as reproductive and neurological effects. Research on detection, health effects and management of the emerging byproducts of treatment (unregulated DBPs, cyanotoxins) will continue.

Decreasing Emphasis:

- ***Arsenic***: Research to aid the implementation of the 2001 Arsenic Rule and the health and exposure studies assisting the upcoming six-year review are winding down (development of arsenic treatment technology synthesis documents will continue). Continuing work to elucidate the mode-of-action is needed and will be addressed in the Human Health Research Program (HHRP).
- ***Disinfection Byproducts (regulated):*** With the Stage 2 DBP Rule in place, all research on the regulated DBPs (THMs, HAAs) will be greatly reduced. ORD will continue targeted DBP research including investigating emerging DBPs (see above) in this Program, and the development of tools for estimating cummulative risk of DBPs in the HHRP.

DW Program-developed data is used by NCEA to conduct risk assessments. Thus, the DW and HHRA programs must be well coordinated.

ANTICIPATED KEY ACCOMPLISHMENTS 2008-2012

In addition to redesigning the Program (see above), the following are some examples of the key accomplishments this Program will produce in the next 4-5 years. This work will require a strategic combination of intramural research, extramural partnerships and STAR grants.

Tools to manage our aging DW infrastructure: Tools will be developed in four themes: (1) *condition assessment* - the collection of reliable data and information on the condition of DW assets including practice of failure analysis; (2) *system rehabilitation* - repair and replacement technologies developed to return functionality to a drinking water including the decision-making process for determining the proper balance of repair and replacement; (3) *advanced concepts* - the application or adoption of new and innovative infrastructure designs, management procedures and operational approaches, and (4) *integrated water resources and infrastructure management* - comprehensive asset management include maximizing benefits from low impact development, water reuse, source water protection and watershed management.

Pathogens - determining risk and developing risk management solutions: Research on pathogens is nicely suited to our new source-to-tap Program design: *Source Water* – best management practices and monitoring methods will be developed to protect surface and ground waters from pathogens; *Treatment* – treatment strategies, especially aimed at small and POU/POE systems, will be developed; *Distribution* – Studies will be conducted to understand and control the growth and colonization of pathogens in

distribution systems; and *Tap (safe water)* – the dose response of pathogens and monitoring methods will be developed to help assess the risk of pathogens in treated DW.

Continuing commitment to support the Agency's SDWA-mandated decisions: The office of Water and the SAB have emphasized that the DW Research Program must continue to produce science and engineering products that are needed by the Agency in its SDWA-mandated decision making including developing health effects data, monitoring methods, treatment strategies and performance information to support 6-year review of existing regulations (e.g., draft revision of the Total Coliform Rule in 2009) and to support the CCL process (e.g., regulatory determinations in 2011). The pathogen work described immediately above will support both aspects of SDWA.

Investigate new research areas: The Program will investigate the feasibility of new research areas including the impacts of desalination of DW quality and on nanomaterials – use in treatment, and the risk and risk management as contaminants in DW.

G. HUMAN HEALTH (NPD: Dr. Hugh Tilson)

Human Health Research Program (HHRP)

1. Recent Key Accomplishments of the Current Program:

- ORD research provided mechanistic information that decreased reliance on default assumptions used in Agency-related risk assessments for several chemicals, including atrazine; arsenic; 1,3 butadiene; bromate; chloroform; chlorpyrifos; dichloroacetic acid; dioxin and related chemicals, dimethoate; and methamidophos. These assessments were published in databases accessible to the general public (e.g., IRIS). These are used by Agency program and regional risk assessors, as well as international human health advisory bodies (e.g., OECD, IPCS/WHO) and governmental groups.
- ORD research provided data to support application of additivity default assumptions, crucial dose-response information, and statistical models to describe interactions based on MOA for the cumulative risk assessment of organophosphate compounds by OPPTS. ORD data were also used by OPPTS to develop relative potencies for the cumulative risk assessment of carbamate pesticides and chlorotriazine herbicides based on common MOA. This research supports provisions of the FQPA requiring the Agency to assess the cumulative risk of chemicals having a common MOA.
- ORD research developed a set of exposure tools (SHEDS, ERDEM, HEDS, CHAD) that can be used to predict human exposures to environmental contaminants and link these exposures to human activities and sources. Peer-reviewed protocols have been developed for characterizing environmental exposures for populations of interest and implemented to establish nationally representative databases for key pollutants in residential, daycare, and other microenvironments.
- ORD research developed a probabilistic exposure assessment for OPPTS to use to determine potential short-term, immediate, and lifetime cancer risks for children who contact chromated copper arsenate in outdoor environments.
- ORD research was instrumental in supporting the application of a safety factor by OPPTS to protect children who may be exposed to pesticides such as chlorpyrifos and aldicarb.
- ORD research provided mechanistic information in support of risk assessment decisions in criteria documents for ozone and particulate matter, the health assessment of diesel emissions, and the national ambient air quality standards for ozone, and developed prevention and intervention approaches implemented by local health departments, HUD, and other public health organizations.

2.Strategic Directions for 2008-2012:

Summarize the evolution of the research program:

The overall goal of the current HHRP is to reduce uncertainties in extrapolations inherent in the risk assessment process by providing a greater understanding of the fundamental determinants of exposure and dose and the basic biological changes that follow exposure to environmental toxicants. Research is currently organized around four LTGs: Risk assessors and risk managers use ORD's methods, models or data to: 1) reduce uncertainty in risk assessment using mechanistic (or mode of action) information, 2) characterize aggregate and cumulative risk in order to manage risk of humans exposed to multiple environmental stressors, 3) provide adequate protection for susceptible subpopulations, and 4) evaluate the effectiveness of risk management decisions.

For 2008-2012, it is proposed that the HHRP begins to focus on research that addresses limitations, gaps, and challenges articulated in the 2003 and 2007 Reports on the Environment (ROE). This proposal is based on several criteria:

- Response to legislative needs (i.e., GPRA) to develop outcome-based measures to determine if the Agency is fulfilling its mission to protect human health and the environment
- Response to recommendations from the 2005 BOSC program review directing the HHRP to develop a more focused program in this area
- Response to OMB in the 2005 PART review that the HHRP needs to develop performance measures for this research area
- Response to meeting performance measurement targets related to the Report on the Environment (ROE) indicated in the Agency 2006-2011 Strategic Plan
- Response to guidance from ORD Senior Management/Executive Council to place a greater emphasis on this area
- Response to recommendations from Program and Regional Offices during the planning cycle for more outcome-oriented performance measures

Several gaps, limitations and challenges were articulated in both the 2003 and draft 2007 ROE. For example, the 2003 ROE noted that the science underlying the Agency's key public health functions (e.g., describe, explain, predict, and evaluate) will need to be strengthened before it can begin to evaluate effectiveness of its regulatory decisions. In that regard, the ROE identified several gaps/limitations:

- The need to establish the necessary degree of predictive validity between indicators of each component of the source-dose-health continuum (this will be critical to define the degree to which one indicator can be used as a surrogate for another and for demonstrating that risk management actions result in reduced risks)
- The need to develop and evaluate methodologies for understanding the contribution of non-chemical risk factors to a given health condition
- The need to evaluate susceptible and vulnerable subpopulations
- The need to evaluate aggregate and cumulative risks
- The need to build collaborations with other federal agencies and non-governmental bodies to collect health surveillance and exposure data at national and sub-national levels

The draft 2007 ROE noted that determining effectiveness of risk management decisions is contingent on identifying the extent of human exposures and developing measurements of health outcomes. It reported on a number of national indicators of exposure to common environmental contaminants, but noted that these indicators do not enable assessment of trends over time, identify and explain possible differences among subpopulations, provide information of geographic foci of concern, reveal exposure conditions, provide information on a large range of chemical classes, consider exposure to multiple contaminants or environmental stressors, or provide information concerning the relationship of a measured level and potential human health outcome.

The 2007 ROE also identified a number of health concerns that can be monitored at the national level, but not at the regional level or lower. It also noted a lack of available data for conditions with likely environmental components, such as neurodevelopmental disorders, neurodegenerative diseases associated with aging, diabetes, reproductive disease, and renal disease.

The HHRP is in a unique position to be able to address many of the gaps and limitations noted in the ROE. The HHRP proposes to shift its primary focus from "reducing uncertainties in risk assessment" to "developing and linking indicators of risk" along the source-exposure-effects-disease continuum that can be used to demonstrate reductions in human risk. This strategic change would not necessarily require changes in the program's LTG structure. However, it will likely require reorganizing activities described in the current MYP.

ORD is proposing a program designed to identify indicators of risk (effects and exposure indicators) that can be used to demonstrate reductions in human health risks (i.e., evaluate effectiveness of risk

management or regulatory decisions or "accountability). For example, the ROE identifies national databases containing biomonitoring data and information on diseases having a potential environmental cause. However, interpretation of the relationship between exposure data and health outcome remains problematic. Research would focus on establishing the biological plausibility of specific indicators that predict or correlate with health outcomes. Research would then be done to determine if predictive indicators vary as a function of vulnerable populations, exposure scenario (acute versus chronic), or the presence of other chemical or non-chemical stressors. Tools would be developed to reconstruct/estimate real-world exposures, attribute these exposures to major sources and link the exposure indicators to indicators of effects that can then be used to attribute the exposure to an appropriate health endpoint. Validated indicators would then be used to develop predictive models to evaluate the effectiveness of risk management decisions. Principles established at the national level would then be applied to specific cases at the regional or municipal level.

Fundamental research to address key uncertainties would continue in each Laboratory/Center to provide support for the Agency's risk assessments. Mechanistic research would continue to address extrapolation uncertainties in risk assessment, as well as lead to the validation of bioindicators that could be used to link environmentally related diseases to exposures and better evaluate the results of risk mitigation efforts. Taken together, these efforts define a program that moves toward a broader systems approach considering multiple stressors, as well as multiple health outcomes.

The proposed programmatic shift would result in the following changes in emphasis within the current MYP structure:

Long-Term Goal 1 - Use of Mechanistic Information- overall decrease in effort:	
Methods and Models to Characterize MOA	Decrease
Linkages Between PK and PD Models	Increase
MOA Information to Address Extrapolation in Risk Assessment	Same
Long-Term Goal 2 - Cumulative Risk- overall increase in effort:	
Biomarkers for Cumulative Risk	Increase
Source-to-Dose Models for Cumulative Risk	Decrease
Application of Tools for Cumulative Risk of Chemical Mixtures	Decrease
Tools for Assessing Community Risk	Increase
Long-Term Goal 3 - Susceptible Subpopulations- overall decrease in effort:	
Research on Life-Stage	Decrease
Methods for Longitudinal Research	Decrease
Research on Asthma	Same or Increase
Long-Term Goal 4 - Assess Risk Management Decisions- increase in effort:	
Approaches to Evaluate Risk Management Decisions	Increase
Report on the Environment	Same

Anticipated key accomplishments anticipated between 2008 and 2015

- Research will identify a suite of biologically interpretable indicators for health effects and chemical classes of regulatory concern to the Agency that could be used in a temporal context (e.g., acute versus chronic exposures) at the national and regional levels
- Collaboration with federal partners will lead to a tracking system that captures health and biomonitoring information for a more inclusive list of diseases and interpretable battery of endpoints for environmental stressors over time for the national and regional level
- Research will establish generic approaches for assessing risk management decisions at the regional and local levels
- Provisional predictive models will be developed that will inform the potential consequences of risk management decisions as it applies to regional or local decisions
- Research will develop tools and approaches for assessing community risk

H. HUMAN HEALTH RISK ASSESSMENT (Associate Laboratory Director ORD/NCEA: Dr. John Vandenberg)

Human Health Risk Assessment Program (HHRA)

EPA's National Center for Environmental Assessment (NCEA) consolidated its program in 2003 to focus on health related risk assessment activities. This was to renew our focus on producing risk assessments in support of the core mission of the agency to protect public health and the environment. The Human Health Risk Assessment Program (HHRA) was formed to develop and apply new methods in state-of-the-art health risk assessments through a more integrated and focused program. The HHRA Multi-Year Plan was recently developed to serve as the strategic plan for implementing the new annual and long-term performance goals of the program.

1. Recent Key Accomplishments of the Current Program (2004-2006):

Integrated Science Assessments (Air Quality Criteria Documents) for Criteria Air Pollutants

These Integrated Science Assessments (formerly Air Quality Criteria Documents) are the key science documents that identify, evaluate and integrate atmospheric sciences, human exposure, toxicology and epidemiology data, and data on environmental effects, for each criteria air pollutant to support decisions on National Ambient Air Quality Standards (NAAQS). Each of these documents integrates thousands of peer reviewed publications and they are peer reviewed by the Clean Air Scientific Advisory Committee of the Science Advisory Board.

- Particulate Matter – completed October 2004; with a provisional update provided in 2005. This document was the first to integrate studies resulting from EPA's significant investment (>$500M) in new research (described in the Clean Air Research Program) including evaluation of significant new epidemiological studies associating PM exposures with mortality, plausible biological mechanisms underlying these findings, and source to effects linkages, which were important to the PM NAAQS decisions made in 2006.
- Ozone – completed February 2006. This document will support upcoming decisions on the ozone NAAQS and presents an integrated evaluation of thousands of new health effects studies including evaluation of mortality effects from acute exposures, as well as ecological effects studies.
- Lead –completed September 2006. This document will support upcoming decisions on the lead NAAQS and it includes significant new findings from epidemiological studies, including effects on neurocognitive effects in children and cardiovascular and renal effects in adults.

Integrated Risk Information System (IRIS)

The IRIS program produces key hazard and dose-response assessments used by Agency programs to support risk management decisions, and develops new systems to evaluate studies and communicate assessment activities to the public. For example,

- Final Toxicological Reviews and IRIS Summaries for perchlorate, n-hexane, toluene, 2-methylnaphthalene, lead, ethylene dibromide, boron, barium, zinc and phosgene assessments were posted on IRIS. Draft Toxicological Reviews were created for external peer review and public comment for Dibutyl Phthalate, 2,2,4-Trimethylpentane, Tetra-, Penta-, Hexa-, and Deca-bromodiphenyl Ethers, Mirex, and 1,2-, 1,3-, and 1,4-Dichlorobenzenes, ethylene oxide, and naphthalene.
- The IRIS Chemical Assessment Tracking System (IRIS Track) was created to show the public where chemical assessments are in the development process. The IRIS Literature Screening

Verification project was used to evaluate over 400 chemicals now on IRIS to reach a preliminary determination regarding the need for a full IRIS reassessment.

Risk assessment guidance, methods, and model development

New approaches to risk assessment are developed to address specific issues including new guidance for risk assessors, new approaches for evaluation of special populations, and new quantitative models. Example accomplishments include:

- Publication of final revised Cancer Guidelines and Children's Supplemental; Approaches for the Application of Physiologically-Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment; and of a Summary of the NCEA Colloquium on Current Use and Future Needs of Genomics in Ecological and Human Health Risk Assessment (Final Report)
- Updates of Bench Mark Dose (BMD) model for analysis of endpoints with continuous data; development of categorical regression (CatReg) models for analysis of endpoints across multiple domains for toxicity (e.g., functional observational data for neurological function): Use of Physiologically Based Pharmacokinetic (PBPK) Models to Quantify the Impact of Human Age and Interindividual Differences in Physiology and Biochemistry Pertinent to Risk (Final Report): and the All-Ages Lead Model (AALM) Version 1.05 (External Review Draft)
- Publication of A Framework for Assessing Health Risk of Environmental Exposures to Children (Final Report); Child-Specific Exposure Factors Handbook 2006 (External Review Draft); and Aging and Toxic Response: Issues Relevant to Risk Assessment (Final Report)

2. Strategic Directions for 2008-2012:
Summarize the evolution of the risk assessment program:

The overall goal of the current HHRA program is to provide high quality, scientifically credible human health assessments to EPA's program offices and regions. These health assessments reduce uncertainties in extrapolations inherent in the risk assessment process by providing a greater understanding of the fundamental determinants of exposure and dose and the basic biological changes that follow exposure to environmental toxicants. Efforts are currently organized around three Long-Term Goals (LTGs): Provide risk assessors, risk managers and decision makers with high quality peer reviewed health assessments employing state of the science methods, models and data in: *1)* Integrated Risk Information System (IRIS) and other health hazard assessments, *2)* Risk assessment guidance, methods and model development, *3)* Integrated Science Assessments for Criteria Air Pollutants.

For 2008-2012, the HHRA program will continue to focus on these risk assessment areas under the same three LTG's:

Integrated Risk Information System (IRIS) and other health hazard assessments: Peer reviewed, qualitative and quantitative health hazard assessments are prepared on environmental pollutants of major relevance to EPA's regulatory programs. These assessments are used by EPA's program and regional offices to support their decision-making, and are also disseminated to the public, principally on the IRIS internet database. IRIS is widely used throughout EPA and the risk assessment/risk management community as the premier source of hazard and dose-response information for environmental pollutants. At the end of 2006, there were over 540 health hazard assessments available through IRIS. NCEA is committed to the most appropriate level of peer review for all of its science assessments. In FY 2007, the Agency requested funding for an initiative to increase transparency in risk assessment by providing peer review and consultation from the National Academy of Sciences (NAS) on difficult and complex assessments. NAS consultations will continue in FY 2008 to assure the latest scientific views on difficult assessment issues are incorporated into Agency risk assessments.

Risk assessment guidance, methods and model development: Improved risk assessment guidance, methods, and models are developed to enhance the quality and objectivity of assessments through the incorporation of contemporary scientific advances for use in decision-making by EPA programs and regional offices. These scientific products are externally peer reviewed and disseminated through the published literature, EPA web sites, and incorporation in IRIS assessments. Funding in FY 2008 will enhance development of quantitative risk assessment methods to allow improved analysis and characterization of uncertainty in human health risk assessment to support informed risk management decisions by the air, water, solid waste and other program offices.

Integrated Science Assessments for Criteria Air Pollutants: Congress requires that EPA regularly summarize the state-of-the-science on the criteria air pollutants – ozone, particulate matter, sulfur and nitrous oxides, carbon monoxide, and lead – to assist EPA's air and radiation programs in determining the National Ambient Air Quality Standards (NAAQS). These Integrated Science Assessment summaries (formerly Air Quality Criteria Documents) are major assessments that undergo rigorous external peer review by the Clean Air Scientific Advisory Committee (CASAC). Increased funding in FY 2008 will also support the development and implementation of a new process to identify, compile, characterize, and prioritize new scientific studies for the assessment of criteria air pollutants. This increased funding will for the first time make it possible for NCEA to meet the deadlines set forth in the Clean Air Act for the development of integrated science assessments and NAAQS decisions every 5 years.

No major programmatic shifts are anticipated and the following provides the relative level of effort and emphasis within the current HHRA MYP structure:

Long-Term Goal 1 - Integrated Risk Information System (IRIS) and other health hazard assessments: *Same*

Long-Term Goal 2 - Risk assessment guidance, methods and model development: *Same*

Long-Term Goal 3 - Integrated Science Assessments for Criteria Air Pollutants: *Increase*

3. Key accomplishments anticipated between 2008 and 2015

Revision of the IRIS process and the generation of new health assessments.

- Complete 16 health hazard and dose response assessments of high priority chemicals for interagency review or external peer review, and posting an increasing number of final assessments on IRIS each year. This will result in 128 health hazard assessments being completed during FY08-15.
- Complete 50 new or renewed provisional peer reviewed toxicity values (PPRTV's) to support OSWER, EPA regions and states' decision-making each year. This will result in about 400 PPRTV's being completed and/ or confirmed during FY08-15.

Improvements in methods, models and guidance are anticipated in the following areas: These methods models and guidance will improve extrapolation methods from animals to humans, across life stage, from higher observations to lower doses, and for route to route extrapolation in cases where limited exposure data exists for a given route. Other efforts will improve both qualitative and quantitative evaluation of variability and uncertainty in hazard characterization and dose response analysis

- Uncertainty analysis (e.g., Bayesian approaches)
- Application of modes of action information in risk assessments
- Physiologically-based pharmacokinetics (PBPK) modeling
- Approaches to quantification (e.g., BBDR, Categorical Regression, meta analysis approaches)
- Approaches for assessing risk of environmental exposures to age-susceptible populations (children, elderly; exposure, hazard and dose response)

- Less than lifetime assessments

Revision of the national ambient air quality standards (NAAQS) review process including development of a state-of-the-art scientific database system will result in the generation of new integrated science assessments for the six criteria air pollutants on a 5-year review cycle meeting Clean Air Act mandates.

I. CONTAMINATED SITES AND RESOURCE CONSERVATION (NPD: Dr. Randy Wentsel)

LAND RESEARCH PROGRAM

Recent Key Accomplishments of the Land Program

- Tech transfer: eight evapotranspiration covers for landfills that were under construction in 2006 are expected to save more than **$30 M**.
- Use of permeable reactive barriers over traditional pump & treat methods results in a O&M savings at two sites of **$12M**.
- Research products on monitored natural attenuation of metals resulted in a remedial decision that saved more than **$10 M** and earned a Regional award in 2006.
- Bioreactor research won a Kentucky Governor's Award in 2003 and a SWANA Landfill Management award in 2005.
- Enhanced F&T modeling incorporated at 3 major sediment sites
- The risk from arsenic bearing water treatment sludge residuals leaching from municipal landfills was shown by 3MRA to be minimal, potentially saving several million dollars per landfill.
- Evaluation of sediment resuspension models showed that they generally over- estimate the release and bioaccumulation of persistent organic contaminants from sediments after dredging operations. Key data were identified to improve the models.

Strategic Direction 2008 - 2012

Criteria
The Land Research Program is an essential component in the reduction and control of potential risks to human health and the environment by providing the science to OSWER and the Regions to enable them to accelerate scientifically defensible and cost-effective decisions for cleanup at complex contaminated sites. ORD is uniquely positioned to provide problem driven research focused on program office and regional needs. The program has many collaboration activities and agreements on leveraging of resources to address complex issues

In developing the research program, suggestions from a SAB review in 2004 and a BOSC review in 2005 are being incorporated into the research program. Emerging needs were stressed for areas such as nanotechnology, mining wastes, and resource conservation. Numerous reports from expert panels (National Academy of Sciences, the NACEPT subcommittee on Superfund, Resources for the Futures, etc.) indicate ongoing research needs for protection and restoration of land. The low priority of hazardous waste research within ORD was considered in assessing the strategic directions of the program.

OSWER Support: The July 2006 memo from Susan Bodine to George Gray stressed the importance of ORD research to OSWER programs. An EPA evaluation of the Superfund program "The 120 Day Study", stated in the final report that ORD should continue both research and technical support: "Therefore, ORD should strive to maximize technical support to the Regions without jeopardizing its longer-term research program." The National Regional Science Council submitted 14 "short term" priority research needs to ORD, 5 of these were in Land.

OSWER is involved in developing guidance and implementing programs that receive about 23% of EPA's resources. The research investment should remain commensurate with the overall Agency investment. Superfund Amendments and Reauthorization Act (SARA) authorized and directed EPA to conduct and support hazardous substance research with respect to the detection, assessment, and evaluation of the effects on and risks to human health of hazardous substances and detection of hazardous substances in the environment. (SARA 9660b)

LTG 1 Contaminated Sites

Sediments (level support): The contaminated sediments research integrates exposure, eco-effects, and remediation research to address client needs. Research themes include: development of a framework for modeling fate and transport of contaminants under different remedial alternatives, defining critical sediment and tissue residue thresholds between acceptable and unacceptable effects for aquatic biota, wildlife, and humans, development of alternative sediment remedies with the potential to be more cost-effective than conventional dredging or capping remedies, and improving the understanding of best management practices.

Ground Water (level support): Ground water research provides leadership to address fate and transport and remediation issues. Research themes include: improving characterization, sampling, and analytical methods to reduce the uncertainty in fate and transport models which will lead to improved exposure estimates supporting risk assessments, demonstrating, evaluating and optimizing remediation technologies to support the development of integrated source remediation approaches, and research on the long-term performance and efficiency of permeable reactive barriers (PRBs) for metals.

Multimedia: This research area includes analytical and statistical methods (decreased support), site specific technical support (level support), and mining as an emerging area of emphasis (increased support). Research themes include: development and application of electrochemical immunosensors, and coupled immunoassay/ mass spectrometry methods to for rapid, accurate, and precise quantification of contaminants in the field, development of statistical methods to reduce data uncertainty in the experiment or measurement process for environmental decision making, improving the quality (faster, cheaper, better science) of outcomes of site specific technical support, and for mining, focusing research to produce lower-cost management of waste materials and limiting drainage and sediment discharges to reduce environmental consequences.

LTG 2 Transition out of Hazardous Waste Research

For FY 2008, discussions were held with NERL, NRMRL, and NCER to transition 3MRA research to support nanotechnology fate and transport research. A critical mass of FTE with the right expertise is in place in the Land program to address the fate and transport research questions and we envision that EPA would be the Federal lead for environmental fate and transport research. This will support NCER's leadership in the cross agency approach to nanotechnology. Resources will support characterizing, modeling, and measuring the fate and transport of engineered nanomaterials in the environment. Analytical methods will be developed for detection and quantification of nanomaterials in the environment. The exposure research will predict and evaluate unintended exposure pathways of engineered nanomaterials and evaluate and develop fate and transport mechanisms for nanomaterial release from intended pathways, such as zero-valent iron used for groundwater remediation. Studies may be initiated coupling development of analytical methods for manufactured nanoparticles released to the environment with use of sensitive indicators of biologic response.

Materials Management Research

- Nanomaterials: fate, transport, and compatibility with disposal options
- Landfills: maintain bioreactors and work on energy recovery; tech transfer cover/liner work
- Reuse/ Revitalization: focus on bioavailability and leachability
- Debris management: construction/demolition and disaster wastes.

Key Accomplishments Anticipated Between 2008 – 2012

LTG 1 Contaminated Sites

- Development of a consensus framework for decision makers to model remediation options in large water bodies and estuaries.

- Publish critical sediment and tissue residues thresholds between acceptable and unacceptable effects for aquatic and aquatic dependent organisms.
- Assessing the significance of changes in bioavailability of organic and inorganic contaminants following resuspension and redeposition during remediation
- Develop application of PRBs for inorganic contaminants and continue tech transfer for organics with states and Regions. Projected savings estimated to be $4-10M per site.
- Continue transition of evapotranspiration covers technology to states and local governments to provide landfill covers that have increased effectiveness at a lower cost. Projected tech transfer savings of $30-50M/year.
- Publish a report on options to minimize the transport of contaminants from sediment remediation.
- Publish a field sampling guidance document to identify methods and techniques to eliminate bias that occurs during field sampling

LTG 2

- Measurement of physical, chemical, and geochemical surface reactions of nanomaterials in environmental settings.
- Development of a state of the art simulation model for nanoparticle transport in groundwater.
- Publish a report on hazardous material leaching test methods that consider pH, redox, liquid:solid ratio and other parameters to validate the predictive capability of these tests
- Screening and definitive studies on F&T of nanomaterials
- Impact of the disposal of products of nanotechnology as well as wastes resulting from nanotechnology manufacturing.

J. NANOTECHNOLOGY (Nanotechnology Project Leader: Dr. Nora Savage)

Nanotechnology

Research Framework

Nanotechnology has the potential to provide benefits to society and to improve the environment, both through direct applications to detect, prevent, and remove pollutants, the design of cleaner industrial processes and the creation of environmentally friendly products. However, some of the same unique properties that make manufactured nanoparticles beneficial also raise questions about the potential impacts of nanoparticles on human health and the environment.

Based on the fiscal year 2007 President's budget request of $8.6 million, EPA is developing a nanotechnology research strategy for fiscal years 2007-2012 that is problem-driven, focused on addressing the Agency's needs. The framework for this strategy, as outlined here, involves conducting research to understand whether nanoparticles, in particular those with the greatest potential to be released into the environment and/or trigger a hazard concern, pose significant risks to human health or ecosystems, considering the entire life cycle. EPA also will conduct research to identify approaches for detecting and measuring nanoparticles. This research framework is based on the recommendations from the EPA *Nanotechnology White Paper* and is consistent with the research needs identified by the Interagency Working Group on Nanotechnology Environmental and Health Implications, one of the working groups of the Nanoscale Science Engineering and Technology Subcommittee of the National Science and Technology Council.

While some studies have been done to determine potential toxicity of certain nanoparticles to humans and other organisms (both *in vivo* and *in vitro*), very little research has been performed on environmental fate and transport, transformation, and exposure potential. Research also is lacking on technologies and methods to detect and quantify nanomaterials in various environmental media. In addition, studies indicate that the toxicity of the nanomaterial will vary with size, surface charge, coating, state of agglomeration, etc. Therefore, in fiscal years 2007 and 2008, EPA will focus on the following high priority areas: environmental fate, transport, transformation and exposure; and monitoring and detection methods. Resulting data will be used to inform and develop effects and exposure assessment methods and identify important points of releases for potential management.

Specific activities will include:

- Identifying, adapting, and, where necessary, developing methods and techniques to measure nanomaterials from sources and in the environment
- Enhancing the understanding of the physical, chemical, and biological reactions nanomaterials undergo and the resulting transformations and persistence in air, soil and water
- Characterizing nanomaterials through their life cycle in the environment
- Providing the capability to predict significant exposure pathway scenarios
- Providing data to inform human health and ecological toxicity studies, as well as computational toxicological approaches, and aid in the development of the most relevant testing methods/protocols

Having laid a foundation for understanding possible material alterations under various conditions, EPA will direct a greater share of fiscal year 2009 and 2010 resources to exploring the effects, specifically toxicity of the altered materials as identified in the first two years. This approach will be informed and refined by case studies, initiating in fiscal year 2007, designed to elicit information on how EPA can address high-exposure-potential nanoparticles/nanomaterials. By 2011-2012, sufficient knowledge will

result in the development of systematic and integrated approaches to assess, manage and communicate risks associated with engineered nanomaterials in the environment.

To complement its own research program, EPA is working with other federal agencies to develop research portfolios that address environmental and human health needs. In addition, the Agency is collaborating with academia and industry to fill knowledge gaps in these areas. Finally, the Agency is working internationally and is part of the Organization of Economic Cooperation and Development's efforts on the topic of the implications of manufactured nanomaterials.

K. PESTICIDES AND TOXICS (NPD: Dr. Elaine Francis)

Safe Pesticides/Safe Products Research Program

1. Recent Key Accomplishments of the Current Program

- Provided technical support and wide range of research activities in support of numerous OPPTS chemical-specific assessments, e.g.,:
  - Toxicity, pK, analytical methods, degradation, exposure assessment, thermal generation, article aging studies for OPPT PFOA Risk Assessment and Enforceable Consent Agreement (ECA) activities (http://www.epa.gov/oppt/pfoa/).
  - Assessed the effectiveness of deck sealants to reduce exposure to arsenic in CCA-treated wood; contributing to OPP's communication strategy to the public
  - Developed/applied test protocols for characterizing the fate of OP pesticides/degradation products as they travel from natural source waters through conventional drinking water treatment plants (protocol website); used in OPP's draft cumulative risk assessment document on n-methyl carbamates
- Provided models, databases, and technical support to OPPTS for general use across pesticides/toxics assessments, e.g.,:
  - Structure-searchable metabolism pathways; characterizing/linking exposures to sources; developing metabolic simulator for evaluating bioactivation risks
  - Web-based interspecies extrapolation models for hazard assessment sin aquatic systems (ICE and ACE)
  - First generation models for predicting wildlife population effects in agroecosystems
  - Databases, a framework for spatial analysis, and test protocols to determine effects of herbicides on non-target crop and native plant species for terrestrial plant risk assessments http://www.epa.gov/wed/pages/projects/PesticideResearchFlyer.pdf
  - Ecological exposure models (PRZM/EXAMS/AgDrift) and databases in a probabilistic analysis framework (Express) for use in generating data required by FQPA (http://www.epa.gov/oppefed1/models/water/index.htm) and for registration and/or reregistration of pesticides (http://www.epa.gov/ceampubl/swater/express/index.htm)
  - Participated in development of the OPP document on how assessments of risk to threatened and endangered species would be conducted, resulting in development of the Counterpart Rule where ECOTOX is primary source to identify best available data; made available ECOTOX Release 4.0; used by many EPA Program/Regional Offices
- Established cooperative agreements for two Environmental Bioinformatics Centers that are partnering with ORD to develop and apply computational approaches to 'omics data to improve source to outcome linkages and quantitative risk assessments
- Developed cross-Laboratory/Center research program in biotechnology that is already resulting in data for use by OPP (e.g., methods for monitoring gene flow)
- Conducted the Agriculture Health Study Pesticide Exposure Study; provided NCI & NIEHS with exposure data for updating AHS exposure classification algorithms & future questionnaires

2. Strategic Directions for 2008-2012

The strategic directions for the SP2 research program have been developed in partnership among ORD's Laboratories/Centers/Offices and OPPTS. The directions presented here are consistent with those identified in the recently updated Multi-Year Plan. Priorities for the SP2 research program were assigned based upon an assessment of the importance of the research to OPPTS, and to a much lesser extent any other Agency Offices, on the magnitude of the uncertainties in the knowledge base, the sequence of research needed to obtain the final answer, the possibility that the research would result in a significant product for hazard identification, risk characterization or risk management, the scientific and technical

feasibility of conducting a successful project, and, finally either legislatively-mandated or Agency-set time frames. It is anticipated that the SP2 MYP that describes the research program will be updated sometime during the 2008-2012 time frame to incorporate input received from BOSC and PART reviews in 2007, to remain consistent with the EPA's Strategic Plan as it evolves, and to incorporate any significant new needs identified by OPPTS that we agree that ORD has the capacity and capability to address. There will be periodic discussions with leaders of the Computational Toxicology, Human Health, Ecology, and Drinking Water research programs to ensure continued coordination of research. Some thought will be given during this time as to the feasibility and advisability of merging the EDCs and SP2 Research Programs without compromising the support and mission of either program.

Long Term Goal 1: OPPTS and/or other organizations use the results of ORD's research on methods, models, and data as the scientific foundation for: A) prioritization of testing requirements, B) enhanced interpretation of data to improve human health and ecological risk assessments, and C) decisionmaking regarding specific individual or classes of pesticides and toxic substances that are of high priority. *The ultimate outcomes are the development of improved methods, models, and data for OPPTS' use in requiring testing, evaluating data, completing risk assessments, and determining risk management approaches. More specifically the outcomes are the development by ORD and implementation by OPPTS of more efficient and effective testing paradigms that will be better informed by predictive tools (chemical identification, improved targeting cost less, less time, and fewer animals); improved methods by which data from the more efficient and effective testing paradigms can be integrated into risk assessments; and that OPPTS uses the result of ORD's multidisciplinary research approaches, that it specifically requests, for near term decisionmaking on high priority individual or classes of pesticides and toxic substances*.

Emphasis will be level at first and then will increase when resources are freed from LTG 2. Additional resources will be used to address projected increasing needs such as development/ application of more sophisticated predictive tools for prioritizing and screening chemicals.

Long Term Goal 2: OPPTS and/or other organizations use the results of ORD's research as the scientific foundation for probabilistic risk assessments to protect natural populations of birds, fish, other wildlife, and non-target plants. *Results of this research will help the Agency meet the long term goal of developing scientifically valid approaches to extrapolate across species, biological endpoints and exposure scenarios of concern, and to assess spatially-explicit, population-level risks to wildlife populations and non-target plants and plant communities from pesticides, toxic chemicals and multiple stressors while advancing the development of probabilistic risk assessment.*

Within the next eight years, it is expected that ORD will be well on its way to have developed the needed tools under LTG 2 for OPPTS to use in their probabilistic ecological risk assessments. Once those tools are completed, delivered, and implemented, the level of effort in that LTG need no longer remain at its current level. At that time resources from LTG 2 will be shifted to LTGs 1 and 3 to address projected increasing needs in those areas.

Long Term Goal 3: OPPTS and/or other organizations use the results of ORD's biotechnology research as the scientific foundation for decisionmaking related to products of biotechnology. *OPPTS will use the results from this research program to update its requirements of registrants of products of biotechnology and to help evaluate data submitted to them.*

Resources will be level at first and then increase when they are freed from LTG 2.

It is anticipated that in the span of 2008-2012, that an additional Long Term Goal will be added to the SP2 research program (when recommended by the Executive Council) to incorporate elements of the Nanotechnology Research Program most relevant to OPPTS.

Anticipated key accomplishments (2008-2012) that will be used by OPPTS and/or have broader applications as noted:

- Development of assays to screen chemicals for their potential toxicity across a number of end points, e.g., developmental neurotoxicity, immunotoxicity, non-endocrine-mediated reproductive toxicity[1]
- Development of multiple approaches (e.g., QSARs, metabolic pathways, ASTER) for prioritizing chemicals for testing[1]
- Significant advancement in the development of computational approaches applied to 'omics data that will improve linkages in the source to outcome paradigm and quantitative risk assessments through cooperative agreements with the Environmental Bioinformatics Research Centers[2]
- Near completion of a multi-disciplinary research program on the toxicity, pK, and environmental pathways and fate of perfluorinated chemicals[2]
- Completion of treatment study results of at least six additional individual/classes of pesticides in drinking water[3]
- Significant advancement in the development of methods for extrapolating toxicological data across wildlife species, media, and individual-level response endpoints[2]
- Development of modeling approaches for characterizing spatial population level effects in aquatic life and wildlife for use in support of addressing the Endangered Species Act[2]
- Development of multiple models (e.g., rodent, serum, databases) to assess potential allergenicity to genetically modified crops[1]
- Provide guidelines and tools to mitigate gene-transfer and non-target effects and the development of resistance in targeted pest populations to aid the management of environmental risks associated with PIP crops[2]

[1] may become incorporated into EPA and/or international (e.g., OECD) testing guidelines/approaches
[2] of value to broader regulatory and scientific communities
[3] of interest to OW also

Endocrine Disruptors Research Program

Recent Key Accomplishments of the Current Program

- Conducted the underlying research, developed and standardized protocols, prepared background materials for transfer, briefed Agency advisory committees, participated on international committees on harmonization of protocols, and/or participated in validation of 18 different *in vitro* and *in vivo* assays for the development and implementation of the Agency's two tiered Endocrine Disruptors Screening Program (EDSP)
- Provided data on low dose extrapolation and mechanisms of action for multiple phthalate compounds, vinclozolin, and atrazine for use in US and/or EU risk assessments; data on vinclozolin and atrazine were used by EPA to set allowable levels of exposure
- Conducted pioneering research on the impacts of thyroid disruptors: characterized adverse developmental effects, demonstrated dose-additivity with mixture of 18 chemicals at low dose exposures, developed consortium among EPA and grantee scientists to identify critical factors that influence the shape of the dose-response relationship looking at low dose effects – of critical importance in determining whether current risk assessment practices need to be modified to evaluate suspected endocrine disruptors
- Developed/evaluated/applied/transferred DNA-based molecular indicator method for EDC exposures to aquatic organisms; used to characterize exposures from CAFOS, WWTPs, experimental waters; transferred technology to and being used in Regions/California
- Characterized environmental sources of EDCs - Built two pilot wastewater treatment plants and developed analytical methods to monitor EDCs in the ηg/L level in all relevant matrices; sampled 50 wastewater treatment effluents from around the US to determine levels of reproductive hormones and estrogenicity using a fish vitellogenin bioassay developed by ORD; developed methodology to determine levels of estrogens/conjugates in swine waste and characterized ground water contamination from swine lagoons; determined androgenicity downstream from cattle CAFOS – all of interest to OW; determined androgenicity of products of combustion – of interest to OAR
- Determined that under certain conditions as seen in a rodent model, that adverse effects of EDCs may occur for multiple generations in the testes following *in utero* exposure to only the first generation– first report of such a transgenerational effect
- Determined, in a preliminary study, that the anogenital distance of infant boys whose mothers had been exposed to higher levels of phthalates was shorter ("unmasculinized") than that of boys born to mothers with lower exposures, thus, for the first time applying to human evaluations an approach used in testing rats and mimicking results seen in the rat model

Strategic Directions for 2008-2012

The strategic directions for the EDCs research program have been developed in partnership among ORD's Laboratories/Centers/Offices and mainly OPPTS, but also with OW and Regional Offices. The directions presented here are consistent with those under consideration in the Multi-Year Plan that is being updated. Priorities for the EDCs research program were assigned based upon an assessment of the importance of the research to OPPTS, and to a lesser extent other Agency Offices, on the magnitude of the uncertainties in the knowledge base, the sequence of research needed to obtain the final answer, the possibility that the research would result in a significant product for hazard identification, risk characterization or risk management, the scientific and technical feasibility of conducting a successful project, and, finally either legislatively-mandated or Agency-set time frames. The updating of the MYP is incorporating recommendations made by the BOSC and input received through the PART reviews. It is anticipated that it will be further updated sometime during the 2008-2012 time frame to incorporate input received from subsequent BOSC and PART reviews, to remain consistent with the EPA's Strategic Plan as it evolves, and to incorporate any significant new needs identified by OPPTS, OW, and/or the Regions that we agree that ORD has the capacity and capability to address. Some thought will be given during

this time as to the feasibility and advisability of merging the EDCs and SP2 Research Programs without compromising the support and mission of either program.

Long Term Goal 1: Reduction in uncertainty regarding the effects, exposure, assessment, and management of endocrine disruptors so that EPA has a sound scientific foundation for environmental decision-making. ORD's research will be determining classes of chemicals that act as endocrine disruptors and their potencies; characterizing modes of action and the shape of the dose-response curve; developing approaches for assessing cumulative risk and extrapolating results across species. Consistent with BOSC recommendations, some efforts will include applying 'omics approaches. *OPPTS and other Program Offices, Regions, and outside EPA organizations will use this information to evaluate manufacturers' data submitted to the Agency through EDSP and/or from other sources, and develop integrated risk assessments on EDCs*. ORD's research will also be developing molecular indicators of exposure and analytical methods for detecting certain EDCs; identifying the key factors that influence human exposures to EDCs; identifying sources of EDCs entering the environment, focusing on: WWTPs, CAFOs, and drinking water treatment plants; developing tools for risk reduction and mitigation strategies. *These tools and data will be applied in field studies by EPA and/or others to determine the levels of exposure to EDCs in environmental media and the extent to which and efficacy with which they could be reduced or eliminated (e.g., LTG 2).*

Level of emphasis for LTG 1 increase from level as resources are freed from LTG 3. Additional resources will be used to address projected increasing needs such as providing the necessary underlying science for OPPTS to use in interpreting data submitted from EDSP.

Long Term Goal 2: Determination of the extent of the impact of endocrine disruptors on humans, wildlife, and the environment to better inform the federal and scientific communities. ORD's research, in partnership with grantees and other federal agencies, will be applying methods, models, and tools developed under LTG 1 and elsewhere to characterize the impact of environmental mixtures of EDCs on environmental media and aquatic organisms. Sources of EDCs to be examined include wastewater treatment plants, CAFOs, and drinking water plants. There is consideration being given to expand this program to assess the impact of endocrine-active pharmaceuticals; this would be consistent with directions of CENR IWG. *ORD's resources will be leveraged with those of other organizations (consistent with BOSC recommendations) to characterize the impact of EDCs on the environment and humans*.

Level of emphasis for will be level at first and then increase when resources are freed from LTG 3. Additional resources will be used to address projected increasing needs to better understand the impact of endocrine disruptors in the environment (e.g., Congressional and public pressure).

Long Term Goal 3: **OPPTS uses endocrine disruptor screening and testing assays developed by ORD to create validated methods that evaluate the potential for chemicals to cause endocrine-mediated effects in order to reduce or prevent risks to humans and wildlife from exposure to endocrine disrupting chemicals (EDCs)**. ORD's research will be focusing on finishing the first generation of assays in the amphibian model and finalizing the next generation of assays to be used by the Agency's EDSP, using newer technologies (consistent with BOSC recommendations). The development of second generation screens will have a profound impact not only on the future testing paradigm used in EDSP but also will serve as a model for other toxicity testing programs. *The ultimate outcome is the development of assays that will be used by OPPTS and/or internationally for screening and testing of chemicals for endocrine activity.*

Within the next five years, it is expected that ORD's level of effort into developing screens and tests will be decreasing since the first round of the EDSP will already be implemented and ORD's research on subsequent generations of assays will be winding down.

Anticipated key accomplishments (2008-2012) that will be used by OPPTS, OW, the Regions, and/or have broader applications as noted:

- Finalization of methods development for evaluating endocrine effects on amphibian development, growth, and reproduction using whole animals and an abbreviated assay based on use of molecular/biochemical endpoints[1]
- Finalize development of comprehensive battery of assays with recombinant receptors and steroidogenic enzymes and EDC-responsive gene expression assays in stable cells lines from several classes of vertebrates for chemical prioritization and screening[1]
- Enhanced *in utero* lactational protocols that would include addressing gaps in the areas of exposures to mixtures and dose response in low dose region[1]
- Through cross-Laboratory/Center efforts, developing/applying new analytical and *in vitro* methods and other tools to evaluate environmental samples (e.g., effluents from CAFOs, WWTPs, industrial discharge, drinking water treatment plants, biosolids, combustion byproducts) for endocrine activity and determine their potential impact on fish, wildlife, and human health using a combination of lab and field studies; determining the efficacy of operations to reduce EDCs – will contribute to site-specific risk assessments and development of risk management options[2]
- Developing an approach for utilizing genomics data in EPA risk assessments[2, 3]
- Providing a better understanding of the potential impact of certain EDCs on human development/reproduction[3] – completion of 12 epidemiology studies funded through CENR
- Developing frameworks for: cross-species models of TH and aromatase disruption for more accurate extrapolation from animals to humans; improved linkages between TH alterations in short term screens and adverse outcomes; characterization of impact of EDCs on toxicity pathways associated with neuroendocrine regulation of puberty and of epigenetic mechanisms of transgenerational transmission of EDC induced reproductive tract lesions[4]
- Training of Program Offices, Regions, States, Tribes on molecular assay for environmental assessment; further application, e.g. characterize impact of CAFOs, endocrine-active pharmaceuticals in WWTPs on fish populations[2,3]

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[1] may become incorporated into EDSP and/or international (e.g., OECD) testing guidelines
[2] consistent with BOSC recommendations
[3] of value to broader regulatory and scientific communities
[4] providing OPPTS with tools to evaluate EDSP data and integrate into risk assessments

L. COMPUTATIONAL TOXICOLOGY (Acting NPD: Dr. Jerry Blancato)

Computational Toxicology Research Program (CTRP)

1. Recent Key Accomplishments of the Current Program:

- Continued effort on the ToxCast Program for Prioritizing Toxicity Testing of Environmental chemicals, to develop the ability to forecast toxicity based on bioactivity profiling and, ultimately, to develop methods of prioritizing chemicals for further screening and testing to assist EPA in the management and regulation of environmental contaminants. Collaborations with NIH (the NCGC and NIEHS) and research contracts are creating the foundation upon which to bring these technologies to bear on EPA problems.
- Partnering with the Office of Pesticide Programs, an electronic database (ToxRef) is being developed that will, for the first time, electroncially house the legacy data on effects of pesticides in traditional toxicity assays. This relational database will allow the Agency to discern patterns of toxicity in the assays and to assess the value of the design of the assays in assessing risk. It will also be invaluable in the interpretation of the high throughput screening data derived in the ToxCast Program.
- Design and early implementation of "virtual liver" a computer model of the organ that will simulate its molecular processes to predict the possible toxic effects of chemicals on liver function
- Working with EPAs Genomic Task Force, an enterprise solution to the submission, storage, analysis and interpretation of genomic data is being pursued. The Computational Toxicology research program is providing the scientific and technical leadership for this effort. ACToR (the Aggregated Computational Toxicology Resource) is currently in the hardware and software design phase.
- Hiring of two Title 42 scientists in FY06 (a computational systems biologist and a bioinformatician), and one in FY07 (computational developmental biologist).
- Providing expert advice to EPA program offices on the risk assessment of specific chemicals or classes of chemicals (e.g., PFAAs, carbamates, pyrethroids, methyl iodine, MTBE) and participation in ILSI and WHO Advisory Committees on computational modeling.
- Co-hosting of an international workshop on uncertainty and variability in physiologically based pharmacokinetic models that has helped lay the groundwork for development of best practices and regulatory acceptance criteria of PBPK Models.
- Acceptance by the OECD to host a meeting of the Molecular Screening Project to organize international cooperation related to the ToxCast project.

2.Strategic Directions for 2008-2012:

Summarize the evolution of the research program:

The main objectives of the CTRP are to develop enhanced tools for prioritization of hazard, and improved methods of quantitative risk assessment, respectively. It is well recognized that the traditional approaches for chemical hazard and risk are not capable of keeping pace with the increasing demands being placed upon multiple Program Offices. Thus, the vision of the program is that the modern tools of molecular biology, information management, and computational models will become pervasive in risk assessments being conducted by the Agency so that we increase the efficiency and effectiveness of those activities. This area of science is expected to result in several approaches to make identification and characterization of hazard and risk faster, cheaper, and more scientifically robust. Ultimately this work will lessen the total reliance on animal studies by systematically using in-vitro and in-silico derived information with a more limited set of in-vivo studies to help assess risk. This work will also be a big step forward in establishing molecular based mechanisms of toxicity which will replace current default

assumptions in risk assessments and better characterize sensitive sub-populations. These characterizations will be based on actual mechanisms of toxicity rather than default binning based on age or gender alone.

For 2008-2012, the proposed programmatic increase would result in the following changes within the current CTRP research plan:

Long-Term Goal 1 -: *EPA risk assessors use improved methods and tools to better understand and describe linkages across the source to outcome paradigm*

Work is directed towards computational models and modeling systems that represent comprehensive descriptions of the underlying biology of adverse impacts caused by exposure to environmental agents. The whole-systems biology modeling approach will develop a range of models, from those describing pharmacodynamic connections between exposure and effects to those describing complex endogenous pathways and the perturbations in such pathways resulting from environmental exposures. Also, ways to incorporate and use "omics" information in these models will be explored. Finally, attempts will be made at formulating models of common, but complex, disease processes which are then exacerbated by exposures to exogenous substances and stressors through the development of virtual organ models, the first being the virtual liver.

Increase - More receptors and more chemicals to help identify key pathways for liver and expanding model application to other organs

Increase – Expand the qualitative models for other organs and use SBML or like languages for organ models

Increase – Determine and conduct the necessary experiments to determine key rate constants for use in physiologically based pharmacokinetic models.

Long-Term Goal 2 - *EPA Program Offices use advanced hazard characterization tools to prioritize and screen chemicals for toxicological evaluation*

Molecular biological tools will be employed to develop fingerprints of biological activity of chemicals of concern to the EPA. Computational models will be applied to the fingerprints to derive associations with classical measures of toxicity derived from animal studies so that predictive models can be developed leading to more efficient testing paradigms and reduction in uncertainties in inter-species extrapolation. Proof-of-concept demonstration of ToxCast, the forecasting tool, will provide a number of EPA program offices with an extremely useful tool to improve the efficiency and effectiveness of hazard identification and risk assessment methodologies. There will also be new and innovative ways will be developed to assimilate, evaluate, and use the myriad of data assorted with molecular and chemical information. Development of advanced computational chemistry methods will also provide in-silico means to predict complex interactions of environmental chemicals with biochemical receptors which can then lead to adverse effects.

- Increase – specifically, will be used to increase number of chemicals above the 300 currently being planned for Phase 1 of ToxCast. The per chemical cost is approximately $15-20K. The additional chemicals will include a greater number of pesticides, pesticidal inerts, and possibly water contaminants and help reduce reliance on animal testing.

- Increase – will add at least four new toxicological databases to the distributed structure-searchable toxicity (DSST) system.

Long-Term Goal 3 - *EPA risk assessors and regulators use new models based on the latest science to reduce uncertainties in dose-response assessment, cross-species extrapolation, and quantitative risk assessment.*

- Develop additional key modules for computational models of biological processes relevant to the induction of toxicity for high priority environmental contaminants. These modules would help assess the interaction of exposure to environmental chemicals with other processes such as underlying disease and concomitant intake of pharmacological agents.
- As a result of this increase, EPA will be less reliant on default assumptions for risk assessment and better able to accurately characterize the true uncertainty associated with risk predictions for various chemical classes (e.g., EDCs) under conditions more relevant to actual exposures and lifestyles

Anticipated key accomplishments anticipated in 2008 and beyond

- Increased development of in-vitro and in-silico methods to identify and quantify toxicity pathways for exogenous chemicals, with especial emphasis on nuclear receptor mediated cellular events.

- 2008: Biologically based model of prostate androgen dependent gene regulation incorporating genomics data

- 2008: Evaluatation of modeled dosimetry for rat fetus and pup for a series ofcompounds selected on the basis of possessing varying degrees of biological persistence and lactational transfer to inform the uncertainty in use of maternal exposure dose in risk assessments

- 2008: Assisting with the development of procedures and capabilities for deriving chemical signatures for predicting toxicity outcomes from the complete profile of Distributed Structure-Searchable Toxicity (DSSTox) data files

- 2008: Publication of the results of Phase I (initial proof of concept) of the ToxCast program, and launch of Phase II (signature extension and validation).

- 2011: Development of virtual liver a multi-scale, computational model of the liver that incorporates anatomical and biochemical information relevant to toxicological mechanisms and responses

- 2008 and beyond: pharmacodynamic and pharmacokinetic models better describing pathways of toxicity and relationship to environmentally relevant exposure levels for arsenic as a prototype for how multiple modes of postulated action can be empirically examined and computationally modeled.

M. SCIENCE AND TECHNOLOGY FOR SUSTAINABILITY (Director for Sustainable Development: Dr. Alan Hecht)

Science and Technology for Sustainability Research Program

General Guidance

The Science and Technology for Sustainability (STS) Research Program, scheduled to begin on October 1, 2007, is the first coordinated effort to address research questions raised within ORD's Sustainability Research Strategy, a document which lays out a strategic view to advance sustainability across all ORD research programs.

The STS Research Program is designed to ultimately position ORD to provide technical support to regional and national sustainability policies and initiatives. Toward this end, the STS Research Program has established 3 research tracks. The first track acknowledges the important role that metrics and indicators must play as the sustainability work evolves. It starts with a formal research effort to critically examine those metrics currently in use and plans to tap into the on-going Innovation Action Council (IAC) Sustainability Outcome's workgroup of which ORD is the lead. It also calls for the establishment of collaborative projects to develop and test new metrics. In the end, this work will lead new measures suitable for inclusion in the Report on the Environment. The second track seeks to influence decision makers through the development of decision support tools that promote environmental stewardship and sustainable management practices. Based in large measure on the adoption of the life cycle perspective and sustainability metrics, this work encompasses both core research (in furthering methods and techniques) and applied research (with tools for specific clients). The third track emphasizes the role that technologies have in creating sustainable outcomes. Through programs such as SBIR, P3, ETV efforts will be placed on finding solutions to client driven problems while promoting sustainable design and implementation practices.

Specific Guidance

1. **Recent Key Accomplishments of the Current Program:** The following represent accomplishments of the Pollution Prevention and New Technologies (P2NT) Program that will migrate over to the STS Research Program.

- P3 National Design Competition for Sustainability: Launched in 2004, in conjunction with over 40 partners, enables college students to research, develop and design innovative solutions to sustainability challenges. One award winning team has developed an energy saving system for buildings, which has spun off into a small business, and has supported EPA/OAR Green Buildings Workgroup's implementation strategy.
- The Environmental Technology Verification Program. The program has completed 380 environmental technology verifications and 88 testing protocols. This work has provided quality assured information to decision-makers inside the Agency, states and other organizations who make choices on technology options. Numerous examples can be pointed to where the verification reports facilitated the adoption of the technology. A recent example is the Office of Air who listed verified technologies that in turn provided access to diesel retrofit grant programs. Leading an effort to promote technology verification internationally and interest is growing. Environmental outcome studies have been completed to estimate the impact of the technologies on eco and human health.

- Decision Support Tools: NRMRL's in-house research staff has had great success in developing Life Cycle Assessment (LCA) methods and promoting their use. From the popular LCAccess web page, through the wide adoption of TRACI, and environmental impact assessment tool, decision support tools and methods continue to attract interest from EPA program offices such as OPPT and OSW, as well as groups such as NIST, the U.S. Marine Corps, and the U.S Green Building Council.
- Collaborative Science and Technology Network for Sustainability (CNS): Launched in 2004, the CNS Grants Program directly supports sustainable outcomes. By focusing on communities and the built environment, and well as industrial ecology and organizational behavior, CNS grantees are developing new approaches to providing sustainable outcomes.
- Environmental Systems Management: Demonstrated the viability of using a systems-base approach to managing a complex environmental problem. Through the efforts of a multi-disciplinary team of researchers, this effort has demonstrated the technical, economic, and legal feasibility of an innovative systems-based method to decentralize stormwater management. Clients for this project include Agency program offices and several local and state agencies.

2. **Strategic Directions for 2008-2012:**

- The STS Research Program begins with the start of FY08. The creation of the research program, and its three research tracks of metrics, decision tools, and technologies was done using the follow five criteria:
    - Resource Availability.
    - Relevance to the Agency's Mission and the needs of Program and Regional Offices. (Based on a 2005 Agency-wide survey of research needs.)
    - True to ORD's Research Capabilities. (Balancing intra and extramural programs.)
    - Potential for High Impact. (Through application of unique in-house skills, leveraging outside resources, addressing nationally compelling problems.)
    - Systems Based Research. (Reflecting the fundamental idea that sustainability is best addressed on systems-based solutions.)
- The three areas of research are:
    - Metrics and Indicators: As a new line of inquiry, this effort will be ramping up with half the in-house extramural resources.
    - Decision Support Tools: While this work extends efforts begun under the P2NT Research Program, its new strategic direction will be focused on the decision tools that specifically address sustainable outcomes and on the demonstration of those tools in real-world applications.
    - Technologies: SBIR and ETV will continue, as will the P3 Student Design Competition for foreseeable future
- The MYP has indicated that the first priority should be to reestablish the CNS Grants Program. In addition, there appears to be strong support for the verification services provided by the ETV Program. There is recognition that this program, with the modest resource allocations, is unable to support a grants effort which targets fundamental research within the field of sustainability sciences.
- ORD's Sustainability Research Strategy and the STS MYP underwent a review by the SAB in the summer of 2006. The review was overwhelmingly favorable. While their formal report is expected to be issued shortly, their preliminary comments and recommendations have been incorporated into both documents. The BOSC is scheduled to review the STS MYP in March of 2007.
- **Key accomplishments anticipated** between 2008 and 2012 are: including how it will be used and who will use it.:

- Annually, will continue to fund the development of new innovative technologies through the SBIR and P3 programs, will also continue to verify innovative technologies through the ETV program. Users include the Agency, states, technology purchasers and others who will use verification information to make technology choices. Will continue to advance the development of international environmental technology testing protocols and the development of a global environmental technology network.
- By FY011, the program anticipates the delivery of sustainability metrics which will be suitable for use within the Report on the Environment. Building upon a new in-house research effort, work on metrics will be informed by the ongoing "sustainability outcomes" discussions being conducted by IAC, and will take real world experiences with outside collaborators, to perfect a suite of metric to support broad Agency sustainability goals.
- By FY012, will develop a framework to determine the information that must be assembled to assist decision makers at various levels advance sustainability. This framework will then be used to evaluate currently available models and decision support tools. Work will advance to develop an optimal suite of decision support tools through modification of current tools or development of new tools.

N. <u>Economics and Decision Sciences</u> (NCEE DIRECTOR: Dr. Al McGartland)

[Note: This program would shift from ORD to the National Center for Environmental Economics under the FY 2008 Budget as proposed.]

Economics and Decision Sciences

NATIONAL CENTER FOR ENVIRONMENTAL ECONOMICS - - HIGHLIGHTS OF NCEE'S FY2006 ACCOMPLISHMENTS

ECONOMIC AND HEALTH SCIENCE RESEARCH

NCEE economists and scientists engage in research to fill gaps in knowledge, often with support from other EPA offices. NCEE has been quite prolific in the last year, publishing 31 papers in peer-reviewed journals in FY 2006. Topics range from mortality risk valuation to ecological benefits to epidemiology. NCEE has also been actively engaged in presenting our work to a variety of audiences, including the Science Advisory Board and the Children's Health Advisory Committee at the Agency; the University of California-Santa Barbara and University of British Columbia; the American Public Health Association, the Allied Social Sciences Association, the Ecological Society of America, and the Air and Waste Management Association; the Department of Commerce, National Academy of Sciences, and the National Center for Health Statistics; as well as to international audiences including the World Congress of Environmental and Natural Resource Economists, the International Society of Environmental Epidemiology and the audience at the Eighth International Conference on Mercury as a Global Pollutant, to name just a sample.

REGULATORY AND POLICY SUPPORT

NCEE collaborates on economic analysis with programs and engages in reviews of economic analyses supporting regulatory activities for those rules classified as economically significant according to EO 12866. In the last year, NCEE has been involved in reviewing 19 economic analyses. NCEE is also engaged in the development of appropriate and scientifically sound approaches for the Agency in a number of areas through the Science Policy Council, Economics Forum, Stewardship Program for Nanoscale Materials, and the Pollution Abatement and Control Expenditures (PACE) Project, among others.

LINKING SCIENCE AND POLICY

Linking the natural sciences and social sciences can improve risk assessments and benefit-cost analyses. In FY 2006, NCEE worked on a number of projects designed to improve the connections between these two disciplines.

STRATEGIC DIRECTIONS FOR EPA

NCEE has provided leadership in a number of other important areas, including the Agency's Ecological Benefits Assessment Strategic Plan, Environmental Economics Research Strategy, PBDEs, Nanotechnology Initiative, and AO's Quality of Work Life Initiative.

COMMUNICATION OR LIAISON TO ACADEMIC COMMUNITY NCEE communicates EPA's research priorities to economics professionals across the nation through seminars, workshops, and a website with on-line resources. In addition, NCEE helps academicians identify topics pertinent to the Agency's needs and funds research in those areas through grants and cooperative agreements with universities. In the last year, NCEE hosted four workshops, helped support eight workshops, and updated its website on America's children and the environment.

DEVELOPMENT OF GUIDANCE MATERIALS AND REFERENCE HANDBOOKS
NCEE produces guidance on priority areas identified by EPA programs and support offices, and provides training courses on improving the development and use of economics by EPA staff. In the last year, this included supplemental work on the Agency's Cancer Guidelines, updating the Agency's Economic Analysis Guidelines, and work toward development of a Handbook on the Benefits, Costs and Impacts of Land Cleanup and Reuse

MORE INFORMATION ON BUDGET AND EFFORT IN RECENT YEARS

FY2006
Budget = $3.0M; FTEs = 48
Estimate of distribution of research funds among project categories (in $1000s)

	Proposed	Actual	Research (of Actual)
Regulatory Analysis and Support	$980	$900	$ 570 (competition)
Ecological Valuation	$ 70	$330	$ 80 (invasive species)
Cost Analysis/PACE	$640	$640	$ 620 (PACE survey)
Benefits Studies/Surveys	$200	$ 0	--
Market Incentives	$ 0	$ 0	--
Economic Modeling/Impacts	$ 50	$ 45	--
Science Policy/Modeling	$200	$310	--
Communications (website/library)	$100	$220	-- (access to reports)
Administration	$120	$140	--
Special Projects	$600	$440	--
	$3.0M	$3.0M	$1.3M (~40% of total)

FY2007
Budget = $3.0M; FTE = 48
Expected Distribution (still tentative, but in the general range).

	Proposed
Regulatory Analysis and Support	$1,350 (~30% of $ competition)
Ecological Valuation	$ 100 (invasive species, indicators)
Cost Analysis/PACE	$ 800 (PACE data collection)
Benefits Studies/Surveys	$ 200 (water quality benefits)
Market Incentives	$ 0
Economic Modeling/Impacts	$ 50
Science Policy/Modeling	$ 200 (risk sciences related work)
Communications (website/library)	$ 150
Administration	$ 150
	$3.0M

FY2008
Budget = $3M base + $1.1M EDS transfer
FTE = 46 baseline + 3 EDS (reduction in base of 2.0 FTEs; transfer) Some questions about 2008 that could affect research agenda and projects to be pursued

- Establishing fixed price and funding sources for future PACE surveys

- Management of EDS with reduction in proposed budget and change in management (from ORD to OPEI)
- Selection of projects to help implement recommendations in EBASP and EERS
- Efforts to formally address treatment of uncertainty in risk and economic assessments
- New risk science issues – (e.g., genotoxicity, nanotechnology, IRIS)
- New guidance and implementation procedures on Information Quality, Peer Review, Risk Bulletin and Economic Analysis (issued by both EPA and OMB)

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NCEE APPENDIX - DETAILS

ECONOMIC AND HEALTH SCIENCE RESEARCH

NCEE economists and scientists engage in research to fill gaps in knowledge, sometimes with support from other EPA offices. Focused on benefits and costs of environmental regulation, recent economic research efforts include, but are not limited to:

Valuation of Cancer Risk Reductions to Children and Adults: Currently, little is known about how individuals value reductions in risk to health for children. To begin addressing these gaps, the NCEE, in collaboration with the Office of Children's Health Protection, is designing a survey instrument to elicit willingness to pay values for cancer risk reductions to children and adults. Several versions of the survey instrument are planned so as to adequately address differences in values for these two populations as well as to assess differences in public and private scenarios.

Valuation of Changes in Environmental Quality: This research develops and applies bioeconomic and recreation demand models to value changes in environmental quality. A number of research projects are ongoing in this area.

Valuation of Avoiding Exposure to Arsenic in Drinking Water: To fully assess behavioral responses to exposure to arsenic in drinking water, this study is combining the results of three analyses: a hedonic property-value study, an averting behavior study, and a conjoint analysis. One survey instrument, with two versions, will be used to collect data for the averting behavior and conjoint studies. The survey will focus on public support for government programs aimed at reducing arsenic levels in drinking water and household decisions to avoid risks associated with arsenic in drinking water. The results of this research will facilitate the estimate of value of statistical life and value of statistical cancer estimates which will assist in assessing the value households place on programs aimed at reducing such exposure. This project is being conducted in conjunction with the University of Maine via a cooperative agreement.

Fish population modeling: This research involves development and application of ecological models for estimating the effects of cooling water withdrawals on fish populations and aquatic ecosystems. It was originally inspired by review of the Cooling Water Intake Rule benefits analysis, and also includes other applications of fish population modeling applied to Pacific Salmon.

Publications and Presentations:

NCEE economists and scientists have recently published in peer-reviewed journals in these selected areas:

- Health Risk Valuation (2)
- Children's Health Risk Valuation (1)
- Cost measurement (1)
- Productivity (5)
- Water quality benefits (4)
- Ecological benefits (8)
- Risk Assessment, Epidemiology, and Environmental Health Tracking (7)
- Land Use (2)
- Environmental Justice (1)

ORD STAR Grant Program

NCEE staff members continue to assist in preparing the solicitations and reviewing proposals received by ORD on several of their extramural grant programs. In FY 2006, NCEE economists helped write and review proposals for the Methodological Advances in Benefit Transfer Methods RFA, helped review proposals from the Valuation for Environmental Policy RFA, and helped write the Market Mechanisms and Incentives: Case Studies and Experimental Testbeds for New Environmental Trading Programs RFA. In addition, NCEE staff reviewed proposals received by ORD as part of its STAR Graduate Fellowship program.

NCEE Working Paper Series

The NCEE Working Paper Series provides an outlet for NCEE research that is in an early stage and not yet ready for submission to a journal or that does not necessarily fit in peer-reviewed journals but is sufficiently important to disseminate to the broader research community for information and discussion. The Working Paper Series is an important outlet for NCEE's work. Additions to the series in 2006 are included in the attached list of NCEE publications.

LINKING SCIENCE AND POLICY

Linking the natural sciences and social sciences can improve risk assessments and benefit-cost analyses. In FY 2006, NCEE worked on a number of projects designed to improve the connections between these two disciplines.

Cessation Lag

Cessation lag refers to the amount of time it takes, once exposure to a risk is eliminated or reduced, for the risk level of an exposed individual to decrease to the risk level associated with a lifetime of exposure to the lower level. This is different from the latency period, which refers to the time period between the start of exposure and an increase in risk. While these two concepts are similar, the time periods of the cessation lag and latency are not necessarily equal. For example, the latency period for smoking and increased lung cancer risk is on the order of 20 years. In contrast, the cessation lag between the time an individual stops smoking and when their

risk of lung cancer returns to that of a non-smoker is considerably shorter, potentially on the order of five years.

While the EPA has information on the latency of various regulated substances, it has relatively less knowledge of the cessation lag for these chemicals. Understanding cessation lag effects has implications for both risk and benefit analysis. Some work has already been done on the implications for risk assessment, however, to our knowledge, this work has never been carried through to an economic benefits analysis. NCEE is working to extend the cessation lag research by modifying and improving the mathematical models used for risk assessment. These models will then be applied to an appropriate contaminant and used to estimate the economic benefits of reducing exposure to this contaminant. The implications of including the correct measure of the cessation lag will then be evaluated.

OMB's draft Risk Assessment Bulletin

NCEE reviewed OMB's draft Risk Assessment Bulletin and actively participated in the workgroup formulating EPA response and comment. NCEE staff developed an analytic crosswalk between bulletin requirements and related EPA guidance, policies, etc., demonstrating how existing policies, guidance etc. accomplished the scientific goals of the bulletin. This was the basis, to a large extent, for EPA's general comment to OMB that the Agency use existing polices, guidance to implement the bulletin.

Modeling Benefits from Reduced Mercury

In 2005, EPA promulgated the Clean Air Mercury Rule (CAMR) to permanently cap and reduce mercury emissions from coal-fired power plants. During the final stages of promulgating this rule, an article was published by Trasande et al. that raised some issues regarding how to measure benefits from reducing mercury. Using one of the models presented by Trasande, NCEE introduced the assumptions that the EPA used in its CAMR analysis and discussed the implication of introducing these assumptions. The impact of introducing all of the EPA assumptions except for those related to discounting would decrease the estimated monetized impact of anthropogenic emissions in the Trasande model by 81% and would decrease the estimated impact of U.S. sources (including power plants) by almost 97%. Including discounting decreases Trasande's estimate of global impacts by 88%, and decreases the impact of American and U.S. power plant impacts by 98%.

STRATEGIC DIRECTIONS FOR EPA

Ecological Benefits Assessment Strategic Plan

The Ecological Benefits Assessment Strategic Plan is a roadmap of strategic actions that EPA can take to enhance its ability to identify, quantify, and value the ecological benefits of its environmental protection policies. It identifies the major technical and institutional advancements that would facilitate performance of rigorous and comprehensive ecological benefits assessments on a routine basis. The EBASP describes the challenges currently faced by EPA in conducting comprehensive and rigorous ecological benefits assessments. It encourages a model of interdisciplinary participation in benefits assessments and research. Collaboration among economists, ecologists, and other natural and social scientists will promote identification

and characterization of the important ecological benefits of Agency actions. The target audience is the managers and analysts in EPA Program Offices, and natural and social scientists across the Agency.

The EBASP focuses on opportunities to improve ecological benefits assessments conducted at a national level, but the actions are relevant for a broad range of local and regional assessments as well. It also communicates priority research needs to EPA's principal natural and social science organizations, the Office of Research and Development (ORD) and the Office of Policy, Economics, and Innovation (OPEI). The EBASP also may be of interest to EPA Regional Offices, other federal agencies, and state and local decision-makers.

The EBASP was developed by a cross-Agency workgroup. In November 2004, the workgroup delivered a draft of the Plan to the Science Advisory Board (SAB) Committee on the Valuing the Protection of Ecological Systems and Services for review. The SAB committee review was completed in July 2005. The workgroup has revised the Plan substantially and as of September 2006 is in the process of preparing the EBASP for publication on the EPA website and for briefings to relevant EPA offices.

Environmental Economics Research Strategy

NCEE staff economists, in collaboration with ORD's NCER staff, completed EPA's first Environmental Economics Research Strategy which was released in January 2006. The research strategy identifies and prioritizes environmental economics and decision science research that will be conducted over the next several years to improve the scientific foundation for EPA's decision-making and policy initiatives. The Environmental Economics Research Strategy was developed to guide future environmental economics research directions at the Agency. The authors interviewed EPA staff and managers to identify research priorities. These priorities were compared with existing research to establish strategic objectives whereby allocation of EPA resources could help the Agency and its clients to achieve their missions. The environmental economics research described in this strategy will become a cornerstone of the economic analyses that EPA needs to develop environmental policy. The research strategy is intended for EPA Program Offices, other federal agencies, academics, states, local governments, and other researchers to consult to understand what EPA (in particular, the National Center for Environmental Economics and the National Center for Environmental Research) has planned and the results the Agency expects. These parties can use the strategy to plan their own research or analyses to make the best use of EPA's efforts.

PBDE

Polybrominated diphenyl ethers (PBDEs) are flame retardant chemicals used in a variety of consumer products (computer monitors, televisions, textiles, plastic foams, etc.). Because they are mixed into plastics rather than bound to them, they can leave the plastic and find their way into the environment.

NCEE chairs EPA's workgroup on PBDEs. In FY06, the workgroup completed EPA's Polybrominated Diphenyl Ethers (PBDEs) Project Plan, which was released to the public in March2006. The workgroup is now tracking implementation of the "Key Activities" identified in the Project Plan. NCEE has played a strong leadership role in this effort since its inception,

including: planning and leading regular meetings of workgroup comprised of 20 representatives from EPA program offices, regions, and ORD; planning management-level meetings with representatives from the same EPA offices and regions; drafting the majority of the text of the Project Plan; incorporating input from across the Agency and from other Federal agencies; addressing OMB comments; and preparing communications materials for the release of the project plan. NCEE plays a critical role in ensuring that activities around the Agency are coordinated and identifying areas needing further attention, and in making public presentations to inform key stakeholders about EPA's activities.

Nanotechnology Initiative

NCEE staff made major contributions as participants in an agency-wide effort to develop capacity to conduct risk assessments for nanomaterials. These contributions include participation and planning of the document as well as being primary authors on both the health and exposure sections of the nanotechnology white paper. This project is commissioned under the Science Policy Council Steering committee.

COMMUNICATION OR LIAISON TO ACADEMIC COMMUNITY

Futures Workshop

EPA's National Centers for Environmental Economics (OPEI) and Environmental Research (ORD) held a one-day workshop on Socio-Economic Causes and Consequences of Future Environmental Changes. This workshop was the 11th in the Environmental Policy and Economics Workshop Series that NCEE co-hosts with ORD's NCER. This workshop, held on November 16, 2005 at EPA's Region 9 Office in San Francisco, CA, highlighted research results from EPA's Science to Achieve Results (STAR) grants. Topics covered in this workshop included environmental impacts of land use changes, environmental consequences of growth on the U.S. aquaculture industry , and the role of demographic changes in future greenhouse gas emissions. Additional research on the consequences of global change, including climate and climate variability, land use, economic development, and technology on air quality was also presented. There were approximately 85 attendees, plus teleconference attendees who did not have to register.

Morbidity and Mortality Valuation Workshop

EPA's National Centers for Environmental Economics (OPEI) and Environmental Research (ORD) held a two-day workshop on "Morbidity and Mortality: How Do We Value the Risk of Illness and Death?" This workshop, held on April 10-12, 2006 in Washington, DC, was the 11th in the Environmental Policy and Economics Workshop Series that NCEE co-hosts with ORD's NCER. The workshop highlighted research results from EPA's Science to Achieve Results (STAR) grants. Topics included risk assessment and valuation of health effects from air pollution, issues with morbidity valuation, and a panel discussion on the use of the Internet in valuation surveys, valuation of effects from pesticides and toxics and drinking water, and empirical issues associated with mortality risk valuation.

Modeling the Oil Transition Workshop

DOE and EPA jointly sponsored a workshop on Modeling the Oil Transition: A workshop on the Economic and Environmental Implications of Global Energy Transitions. The workshop was held on April 20-21, 2006. This international workshop described and evaluated alternative approaches to understanding (forecasting, analyzing, planning) global energy transitions and their economic and environmental consequences, focusing as a specific case on the transition from conventional to unconventional oil and other energy sources likely to result from a peak in non-OPEC and/or global production of conventional oil. It identified useful models and methods as well as improvements needed to analyze and plan for large scale energy transitions.

Benefits of Cleanup and Reuse Workshop

NCEE co-sponsored a workshop with OSWER on "Methods for Estimating Social Benefits of EPA Cleanup and Reuse Programs." The purpose of this workshop was to explore methods for estimating the social benefits of the Agency's land cleanup and reuse programs. The workshop took place in Washington D.C. on September 28 – 29, 2006. It involved a facilitated discussion on the potential for measuring cleanup and reuse benefits presented by different approaches to valuation, including the hedonic property value method, stated preference techniques, and a risk-assessment-based approach. The outcome will be a written assessment of which valuation methodology is most effective for a generalized cleanup and reuse scenario, including the possibility that different methods may be better suited to particular subsets of benefits. This workshop provided valuable feedback to help inform the Agency's work to produce high quality benefit estimates.

NCEE Supported Workshops

NCEE undertook a major effort in FY2004 to establish a competitive assistance agreement award process to help to finance a series of workshops designed to support the advancement of environmental economics. The workshops are expected to accomplish several objectives including: attracting the best and brightest graduate students/new PhDs and improve the quality of current research topics; providing guidance and training on a specific analytical activity of importance in environmental economics; and advancing the field of environmental economics by exploring current and emerging issues of national or regional significance. Seven NCEE-supported workshops were held in FY2006:

> "8th Occasional California Workshop on Environmental and Natural Resource Economics," University of California-Santa Barbara, October 28-29, 2005. UCSB conducts their "Occasional" two-day workshop series on new research on environmental economic subjects. The two main objectives for the workshops are: (1) to bring together faculty and Ph.D. students working at different universities in California (in recent years this has been broadened to include the west more generally); and (2) to serve as a "friendly" forum for graduate students to convey their research ideas and thoughts and to obtain valuable feedback on their ideas.

"A Workshop on Environmental Credits Generated Through Land-Use Changes: Challenges and Approaches," Texas A&M University Department of Agricultural Economics, The Environmental Trading Network, Environmental Defense Climate and Air Program, March 8-9, 2006 -- Baltimore, Maryland. The workshop examined key, common issues facing trading programs designed to address land-based emissions from non point sources in the agriculture and forestry sectors affecting water quality and climate.

"The Role of Ecosystem Service Indicators in Environmental Benefit Assessment," Resources for the Future, May 25-26, 2006. Workshop addressed economic indicators of ecological benefits.

"Climate Policy Without Cost? Can Technology Solve the Climate Problem?" Syracuse University, Maxwell School of Citizenship and Public Affairs, Environmental Finance Center, July 18, 2006.

NBER: Summer Institute Public Policy and the Environment, July 27-28, 2006. Environmental economic research with application to empirical measurement of welfare effects - forum for presenting and discussing papers and the latest developments in applied research.

Camp Resources 2006 - Center for Environmental and Resource Economics and Policy and NC State, August 10-11, 2006. Environmental and natural resource economic research - forum for presenting and discussing papers, and receiving training in selected tools used in economic analysis.

2006 Heartlands Environmental and Resource Economics Workshop - Iowa State Univ. September 17-18, 2006. Environmental economic research with application to empirical measurement of welfare effects - forum for presenting and discussing papers.

"Advantages and Disadvantages of Web-Based Survey Instruments," Resources for the Future, October 2, 2006. The purpose of the workshop is to begin developing a common understanding of the advantages and disadvantages of web-based survey methods as well as protocols to minimize their drawbacks.

"New Frontiers in Environmental Economics," Resources for the Future. NCEE has funded a workshop on New Frontiers in Environmental Economics to be held at Resources for the Future (RFF) in early 2007. The objective is to encourage research at the frontiers of environmental economics in areas that are of direct interest to EPA (as opposed to some of the more traditional areas such as fisheries…). The contractor's panel of distinguished economists held a competition for papers, selecting 8 innovative papers for financial support out of over 150 submitted. In addition, several panels of experts will address Frontier issues.

America's Children and the Environment: Website Update

In March 2003, EPA published its second *America's Children and the Environment* report, and later that year put the contents of the report on the web at www.epa.gov/envirohealth/children.

America's Children and the Environment presents trends in environmental factors related to the health and well-being of children in the United States. This is accomplished through a set of measures on levels of environmental contaminants in air, water, food, and soil; concentrations of contaminants measured in the bodies of children and women; and childhood illnesses that may be influenced by exposure to environmental contaminants. *America's Children and the Environment* is produced by a partnership between the Office of Children's Health Protection and the National Center for Environmental Economics in the Office of Policy, Economics and Innovation.

In order to keep information on EPA's web site up-to-date, in 2006 OPEI and OCHP prepared an update to the data presented in the ACE website. For each of the ACE measures on environmental contaminants, body burdens and childhood illnesses, an additional 2-5 years of data are being added to the versions published in 2003. Text has been modified where necessary to reflect the updated data.

NCEE Seminar Series

The NCEE Seminar Committee hosts seminars on applied research of particular interest to the agency. NCEE hosted 4 seminars between September 2005 and June 2006:

September 29, 2005
Sarah L. Stafford, College of William and Mary
"Should You Turn Yourself In? The Consequences of Self-Policing"

October 25, 2005
Randy A. Becker, U.S. Census Bureau, and Ronald J. Shadbegian, University of Massachusetts, Dartmouth, and U.S. EPA, National Center for Environmental Economics
"Green Pastures for the Green Industry? An Examination of Environmental Goods Producers"

June 1, 2006
Anna Alberini, University of Maryland
"Paying for Permanence: Public Preferences for Contaminated Site Cleanup"

June 20, 2006
Richard D. Morgenstern and William A. Pizer, Resources for the Future
"Evaluating Voluntary Climate Programs: The Case of Climate Wise"

Journal Peer Review

NCEE staff members serve as peer reviewers of scientific and economic materials for numerous journals, including *Environmental Research*, *Environmental Management*, *Journal of Comparative Economics*, *Journal of Development Economics*, *Journal of Environment and Development*, *Journal of Environmental Economics and Management*, *The Energy Journal, China Economic Review,* and *Marine Resource Economics*, to name a few.

DEVELOPMENT OF GUIDANCE MATERIALS AND REFERENCE HANDBOOKS

Cancer Guidelines

EPA's Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens was issued in 2005. The Supplemental Guidance indicates that, for carcinogens identified as operating via a mutagenic mode of action, multiplicative age-dependent adjustment factors (ADAFs) should be applied to the cancer potency estimate - in effect increasing the estimated risk. After release of the document, several program offices and regions raised a number of questions about implementation of the Supplemental Guidance, including processes and procedures for identifying and characterizing assessments for which the ADAFs should be applied. NCEE staff participated actively in a workgroup that addressed these contentious implementation issues, and contributed substantially to the implementation documents prepared by the workgroup.

Economic Analysis Guidelines

EPA's *Guidelines for Preparing Economic Analyses* establish a sound scientific framework for performing economic analyses of environmental regulations and policies. The Guidelines provide guidance on analyzing the economic impacts of regulations and policies, and assessing the distribution of costs and benefits among various segments of the population, with a particular focus on disadvantaged and vulnerable groups. The Guidelines were last issued in September 2000. Since that time, the valuation literature has grown considerably and OMB issued Circular A-4, providing guidance to regulatory agencies on the development of regulatory analysis. Although Circular A-4 is largely consistent with the current version of the Guidelines, it does describe several new analytic requirements. As such, our Guidelines are undergoing revision to reflect all of these important changes.

For several issues such as mortality risk valuation and uncertainty analysis, we are actively seeking input from the Science Advisory Board's Environmental Economics Advisory Committee (SAB-EEAC). The SAB-EEAC met on September 14 and 15, 2006 to address issues related to mortality risk valuation. Specifically, issues related to the use of meta-analysis in deriving a default value of mortality risk for policy analysis were discussed on the first day, and valuing changes in mortality risk resulting in life expectancy losses of different lengths were taken up the second day.

Individual chapters of the Guidelines have been undergoing revision by teams of NCEE economists. As the chapters have been revised, they have been distributed to Econ Forum members for review. New chapters on economics framework and cost-effectiveness analysis are also under development. A full draft of the revised document is expected at the end of 2006 for external peer review.

Handbook on the Benefits, Costs and Impacts of Land Cleanup and Reuse

The NCEE Land Reuse Team is working with OSWER's Land Revitalization Office to develop the Handbook on the Benefits, Costs and Impacts of Land Cleanup and Reuse. Currently the Team is working on four projects to inform development of the Handbook. First, three of the team members collaborated on a paper that was presented on June 30 at the Western Economic

Association Meetings in San Diego. The paper provides general background for discussing methods for estimating the benefits of reuse; in particular, it describes EPA's cleanup and reuse programs, identifies social benefits associated with them, and reviews relevant empirical literature. A second Land Reuse Team project is to commission three white papers targeting gentrification, the externalities of employment, and the importance of asymmetries in land market transactions. Third, the Reuse Team is planning a workshop on methods for estimating the benefits of land cleanup and reuse. On September 28 and 29, we will have approximately 10 experts discuss four potential methods for estimating the social benefits of EPA land cleanup and reuse programs. Approximately 20 observers from OSWER and NCEE will be invited as well. Fourth, another team member is writing an economic impacts analysis of reused contaminated sites in Baltimore, MD. NCEE presented an early version of this paper at the Western's session identified above. As mentioned, all four projects will inform development of the Handbook. The Handbook and the four supporting projects will support not only OSWER's Land Revitalization Office, but reuse programs across OSWER, including the Superfund Office, RCRA, Underground Storage Tanks, Federal Facilities and Brownfields.

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Congressional Justification Language on Pending Shift of EDS:

In the 2008 Congressional Justification, the National Center for Environmental Economics (NCEE) Program Project description contained the following narrative that pertains to the transfer of the Economics and Decision Sciences (EDS) program from ORD to OPEI:

(as found on pp. EPM 175-177) http://www.epa.gov/ocfopage/budget/2008/epm.pdf

FY 2008 Change from FY 2007 President's Budget (Dollars in Thousands):

(+$1,070.8) This increase is the result of the transfer of the Office of Research and Development's Research: Economics and Decision Science (EDS) program, including 3.0 FTE and associated payroll into the Office of Policy, Economics and Innovation's (OPEI) Regulatory/Economic-Management and Analysis program. Under the new oversight of OPEI, EDS research will be directed at critical applied research needs of EPA. The selection of research areas to be funded will draw on EPA's Environmental Economics Research Strategy, and will continue to use a collaborative process with EPA's media and research offices to ensure research priorities are addressed, and the products of the research continue to be relevant, rigorous and are high quality.

(+3.0 FTE) This increase represents the transfer of 3.0 FTE from the Office of Research and Development's Research: Economics and Decision Science (EDS) program.

In the narrative section of the document, these bullets pertain to our research function in OPEI, and would also be related to OPEI's own resources and the transferred ORD, EDS resources:

FY 2008 Activities and Performance Plan:

Program activities planned for FY 2008 include:

> Continue to conduct and support research on methods to integrate ecological and economic models and improve household surveys to quantify the impacts and value to improvements in ecological services and functions, as called for in EPA's Ecological Benefits Assessment

Strategic Plan. The Agency also will continue to establish effective management systems in order to improve the quality and consistency of EPA's economic and risk assessment studies.
Continue support for data collection and dissemination of information on the economic benefits, costs and impacts of environmental regulations, including pollution abatement and control expenditures by US manufacturing industries.[2]
Continue to organize workshops on priority economic and environmental policy issues, i.e., benefits valuation, market mechanisms and incentives, and treatment of uncertainties in risk and economic analyses.

The information that is reported in the Science and Technology appendix on the EDS transfer is pasted below (S&T, pp 120-121) http://www.epa.gov/ocfopage/budget/2008/sciencetech.pdf

Program Project Description:

Economics and Decision Science (EDS) research is designed to improve EPA's decision making, cost-benefit analyses, and implementation strategies.[1] EDS research focuses on areas such as:

How people value their health and the environment;
Corporate and consumer environmental behavior; and
Market mechanisms and incentives.

Since its inception, the EDS program has produced dozens of published, peer-reviewed articles that have contributed to the field of environmental decision making and have been used in crafting state and Federal environmental policies. For example, EPA's Agencywide guidelines for cost-benefit analyses cite 10 peer-reviewed, academic articles sponsored by the EDS program (R&D Criteria: Quality).

FY 2008 Activities and Performance Plan:

In FY 2008, EPA's resources for Economics and Decision Science will move to the Office of Policy, Economics, and Innovation under the Regulatory and Economic Analysis program. Refer to the Regulatory and Economic Analysis program for a discussion of activities in FY 2008.

FY 2008 Change from FY 2007 President's Budget (Dollars in Thousands):

(-$1,070.8) This reduction represents a redirection from the Office of Research and Development's (ORD's) Science to Achieve Results (STAR) program for Economics and Decision Science research to the Office of Policy, Economics, and Innovation's Regulatory and Economic Analysis program. Beginning in FY 2008, EDS activities will be directed at critical applied research needs of EPA. The selection of research areas to be funded will draw on EPA's Environmental Economics Research Strategy.

(-$994.6) This reduction represents a discontinuation of the Economics and Decision Science research program in FY 2008.

(-$429.2/-3.0 FTE) This change reflects EPA's workforce management strategy that will help the Agency better align resources, skills and Agency priorities. This represents the transfer of this program's personnel and related payroll resources to the Office of Policy, Economics, and Innovation. These reductions will not impede Agency efforts to maximize efficiency and effectiveness in carrying out its programs.