United States Environmental Protection Agency

Office of Research and Development

BOARD OF SCIENTIFIC COUNSELORS' Review of the

National Center for Environmental Assessment

Ecology and Human Health

ORD/NCEA

Office of Research and Development
U.S. Environmental Protection Agency

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INTRODUCTION

The Board of Scientific Counselors (BOSC) was established to provide objective and independent counsel to the Office of Research and Development (ORD) on the management and operation of ORD's research programs. The primary functions of BOSC are: (1) to evaluate science and engineering research programs, laboratories, and research-management practices of ORD and recommend actions to improve their quality and/or strengthen their relevance to the mission of the EPA; and (2) to evaluate and provide advice concerning the use of peer review within ORD to sustain and enhance the quality of science in EPA.

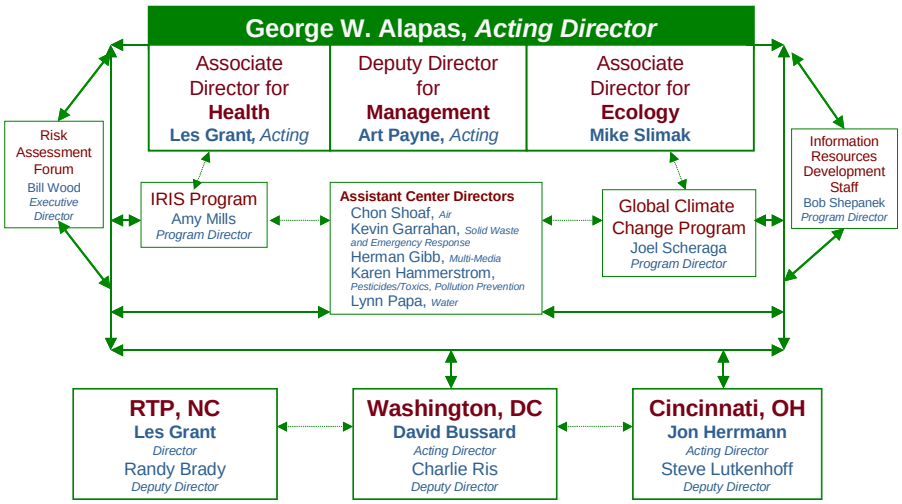
In September 1997, a programmatic review of ORD's National Center of Environmental Assessment (NCEA) by an *Ad Hoc* Subcommittee of the BOSC provided an opportunity for NCEA to look at its past, present, and future. As part of the review, the staff and management of NCEA prepared a "Self-Study Report," which was submitted to the BOSC Subcommittee for pre-meeting review. During the meeting, the Subcommittee discussed the Self-Study Report responses with NCEA management and staff. They gathered additional comments from the staff regarding the organization, management, human resources, and their professional relationships with the Agency and with external users of NCEA products. A final report from the BOSC *Ad Hoc* Subcommittee, dated April 1998, was submitted to NCEA. The final report included the conclusions and recommendations of the Subcommittee based on the input from the meeting, the Self Study Report, and the experience of the Subcommittee.

Since the 1998 report, NCEA has worked to refocus some of its activities and directions in response to the recommendations of the Subcommittee and in the context of the EPA and ORD Strategic Plans. NCEA has made progress on responding to recommendations in all of the following issue categories highlighted in the 1998 NCEA program review report: alignment of priorities and directions with the ORD Strategic Plan, Laboratory strategic initiatives, integration across and within divisions and within ORD, measures of performance and awards, organizational performance compared to others, interactions with the outside community, unique capabilities and their use, and appropriate mix of workforce, facilities, and infrastructure.

Attached are NCEA's responses to the BOSC's questions for Self-Study 2001. We hope that this self-study will illustrate to the BOSC our commitment to change and our directions for implementation of the ORD and EPA strategic plans and the previous BOSC recommendations. NCEA staff and management looks forward to this next opportunity for dialogue between the BOSC-NCEA Subcommittee and the Center.

BACKGROUND

NCEA serves as the national resource center for the overall process of human health and ecological risk assessments; the integration of hazard, dose-response, and exposure data and models to produce risk characterizations. Also, NCEA occupies a critical position in ORD between (1) the researchers in other ORD components who are generating new findings and data, and (2) the regulators in the EPA program offices and regions who must make regulatory, enforcement, and remedial action decisions. Thus, NCEA is uniquely positioned to influence ORD's future research agenda to assure that it addresses research needs identified by risk assessments and to serve as consultants to the programs and regions on the use of science in environmental decision making.



- Development of methodologies that reduce uncertainties in current approaches
- Dose-response models and factors
- Exposure models and factors
- Probabilistic models
- Community-based risk assessment
- Conduct assessments of contaminants and sites of national significance
- Provide guidance and support to risk assessors
- Data bases
- Risk assessment guidelines
- Expert tools
- Expert consultation and program support
- Risk assessment training

Also, through the Risk Assessment Forum staff, NCEA is responsible for coordinating and implementing the health and ecological assessment activities of the Forum. These activities include scientific and science policy analysis of selected precedent setting or controversial risk assessment issues of Agency-wide interest, such as risk assessment guidelines and development of cross-Agency positions on important risk assessment issues.

Other important goals of NCEA are to:

Advance the integration of ecological risk assessment with human health assessment as a fundamental approach in risk assessment activities.

Act as a catalyst for advances in the science of risk assessment brought about by cooperation and an exchange of ideas among environmental health professionals in the federal, state, industrial, academic, environmental, public interest, and international communities, and

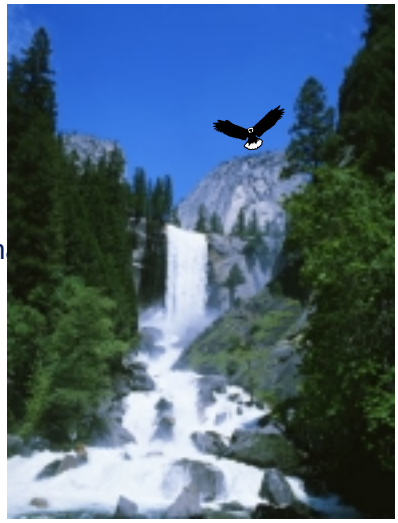
Fully characterize the impacts on ecological and human systems whether they result from exposure(s) to single, complex, or multiple physical, chemical, biological or radiological stressors.

NCEA develops contaminant-specific risk assessments used by EPA, the States, and international community that are of high concern to the public:

- ***Diesel*** - supports recent diesel truck rulemaking that will lead to reduced risks
- ***Dioxin*** - identifies major human exposure pathways
- ***Mercury*** - Congressional report that led to increased State and international attention on risks of ingesting fish and reducing use
- ***Fuel and fuel additives*** (e.g. MTBE, ethanol, methanol) - providing health risk evaluations and support cost/benefit analyses
- ***Air Quality Criteria Documents*** (Particulate Matter, Ozone) - supporting Clean Air Act standards
- ***PCBs*** - support Hudson River and other Regional site clean-up decisions

NCEA leads in the development of ecological assessments and guidance:

- ***Nationally relevant issues -*** potential impacts of introduced bioengineered organisms and invasive species
- ***Regional and watershed scale assessments -*** work with regional and State partners to demonstrate integrative approach to assessing ecological risk
- ***Integrated human health and ecological assessments -*** comparing risks of treatment vs. risks to human and ecological health (e.g. using pesticides to treat for West Nile Virus)
- ***Ecological Risk Assessment Support Center***; new center for EPA, State and public outreach; providing technical support to region Superfund risk assessors
- ***Ecological stressor identification research*** used by States to rank sources of water pollution
- ***Ecological Risk Assessment Guidelines*** (1998) -allowed risk managers to focus on what to do about the risk, not on how to calculate the risk



NCEA Self-Study 2001

Self-Study Questions

1. PLANNING AND INTEGRATION

A. *How does NCEA's strategic plan articulate with the EPA-ORD strategic plan (see Table 2 of ORD plan) and with EPA's strategic plan? Please append your draft strategic plan.*

NCEA's 2000 Draft Strategic Plan (Appendix I) is generally consistent with the 2000 EPA Strategic Plan and 2001 ORD Strategic Plan. Differences are primarily due to the development schedules of each of these documents. It is an NCEA management priority to update NCEA's Strategic Plan.

The Agency's Strategic Plan was updated in September 2000. It clearly states that, "Science is the foundation that supports all of EPA's work..." In a statement before U.S. House of Representatives' Committee on Appropriations on May 9, 2001, EPA Administrator Christine Todd Whitman said,

> " In all of the work we do at EPA, I am committed to ensuring that the policies we set are based on the best scientific information available. To help ensure the availability of solid scientific analysis, the President's budget supports a strong and rigorous research program..."

While many of the directions and priorities included in the September 2000 Strategic Plan have been embraced by Administrator Whitman, this Administration has also called for action on priorities not given considerable weight in the current EPA Strategic Plan. It is important to note that in the next several years priorities and directions for the Agency will be influenced by the priorities and directions of the Administration.

EPA's key priorities of clean air, clean water, healthy children, healthy ecosystems, and partnerships with stakeholders are the bases for the ORD Strategic Plan 2001. ORD is uniquely positioned to provide scientific support to the Agency's mission because of our ability to integrate interdisciplinary expertise in environmental and human health effects and exposure, risk assessment and risk management. No other research organization is designed or mandated to conduct a balanced and carefully-targeted interdisciplinary research program that addresses such key environmental topics as particulate matter and air toxics, safe drinking water, advanced integrated ecosystem monitoring and analyses, and protection of children's health. ORD is the principal scientific and research arm of the EPA and supports the Agency's unique mission of protecting both human health and the natural environment. The updated ORD Strategic Plan sets a solid platform for ORD's research and serves as a roadmap for how we will work to more efficiently and effectively support EPA's mission. Many NCEA staff and scientists were involved in the development of the ORD Strategic Plan at all stages in the process. In addition, many NCEA personnel took the opportunity to comment on direction and

content as the plan was developed.

As you know, five key strategic goals are outlined in the ORD Plan along with specific actions that will be take to achieve them:

- Support EPA's mission (to protect human health and safeguard the natural environment) by providing high quality, relevant, responsive, and timely science

- Be a high-performing organization; continuously improve the efficiency and effectiveness of our organization and infrastructure

NCEA's VISION
A High Performing Assessment Center Providing Timely and High Quality Risk Information to Environmental Decision-Makers.

We Make a Difference!

- Be a leader in the broader environmental research community; participate in scientific meetings, serve on professional committees, contribute to scientific debate, and play a leading role in shaping a national environmental agenda

- Integrate environmental science and technology to solve environmental problems; synthesize the broadest range of cutting-edge science and engineering into a comprehensive set of insights and an understanding of the increasingly complex environmental problems that we face

- Anticipate future environmental problems, before adverse effects materialize, to better inform our research planning and prioritization process.

A review draft of the NCEA Strategic Plan was developed following the 1997 BOSC review. Several documents such as the National Academy of Sciences' (NAS) 1994 "Science and Judgment in Risk Assessment," as well as internal ORD and NCEA discussions and dialogues with NCEA's key clients and research partners, informed the directions and priorities included in our draft plan. However, as the NCEA draft plan was progressing through review, ORD's strategic plan development activities were getting underway in earnest. Although the NCEA Strategic Plan took into account the directions in the ORD plan to the extent possible as they developed, it is clear that some revisions are necessary to make it consistent with the completed ORD plan. Most of the needed changes relate to format and organization to help external readers understand the relationships between the two plans. Now that the ORD plan is competed, it is an NCEA management priority to revisit and revise the NCEA strategic plan.

Nevertheless, there are some components of the current NCEA draft plan that illustrate how some of the efforts that NCEA has already made, and will continue to make, to enhance its ability to achieve success and its aim to be a high performing environmental research component of ORD. The draft NCEA Strategic Plan outlines an approach to bring focus and balance to the core and problem-

driven research capabilities in the assessment area to address ORD Strategic Plan elements. It also specifically addresses the critical issue of the balance between human health and ecological risk research and assessment activities (see Section VI of Appendix I). Progress has already been made in developing that balance through the hiring of several key ecological risk assessment personnel representing the scientific disciplines needed to create the critical mass required to develop a credible NCEA ecological risk assessment program. In addition, there has been a substantial increase in overall extramural resources to ecological assessment. Progress toward integrating human health and ecological risk assessment remains a high priority activity and a strategic direction for NCEA and was the subject of our recent science retreat.

In addition, by planning our FY2002 research program within the structure of EPA's and ORD's Strategic Plans, we are ensuring that NCEA's research program solidly supports EPA's program and regional offices, as well as ORD's goals and priorities. During the ORD annual planning process, NCEA actively seeks input on Agency priorities and our research program activities from staff and senior management. This assures that NCEA's plans result in credible, relevant, and timely research and technical support that is designed to inform EPA policy decisions.

B. *What are NCEA's priorities and directions for the next five years? Include your research portfolio and multi-year planning efforts.*

As you know, ORD's priorities and research portfolio are aligned along the Risk Assessment/Risk Management paradigm. The research program consists of two interrelated phases, risk assessment and risk management. Risk assessment is the process used to evaluate the degree and probability of harm to human health and the environment from such stressors as pollution and habitat loss. It entails evaluation of potential effects, pathways and levels of exposure and the dose-response relationships, and culminates with characterization of risk under various scenarios.

NCEA's role in ORD is to perform complex risk assessments of national interest and develop risk assessment methods, data bases, and tools based on ORD and other research results. NCEA serves an integrating function, bringing together hazard, dose-response, and exposure research results to address risk assessment issues. NCEA is also involved in research in areas that inform the work of all the ORD components as well as that of program and regional offices. Innovative methods and model development, whether in the area of dose-response, pharmacokinetics/pharmacodynamics, or exposure assessment have cross-ORD and cross-Agency utility, as well as national and international applications. This NCEA focus and expertise complements the expertise and contributions of the other ORD components to successfully address an environmental health or ecological issue using the risk paradigm as the foundation of the analysis.

NCEA'S RESEARCH PRIORITIES AND DIRECTIONS

NCEA's priorities and directions are both in the areas of management/organization and science/research. The sections below address the research priorities. Management and organizational issues are addressed in other parts of this self-study report.

Global Change Assessment: NCEA's Global Change Assessment Staff is an important component of the larger ORD Global Change Research Program. ORD's Global Change Research Program is an assessment-oriented program with primary emphasis on understanding the potential consequences of climate variability and change on human health, ecosystems, and socioeconomic systems in the United States. The Program's new *Research Strategy* articulates a vision of the long-term goals (through 2010) for developing comprehensive assessments of global change issues and the research to support such efforts. This entails: (1) improving the scientific basis for evaluating effects of global change in the context of other stressors and human dimensions (as humans are catalysts of and respond to global change); (2) conducting assessments of the risks and opportunities presented by global change; and (3) assessing adaptation options to improve society's ability to effectively respond to the risks and opportunities presented by global change as they emerge. NCEA's Staff has primary responsibility for producing the assessments, whereas the scientific basis for the assessments is provided through research conducted in other ORD laboratories and centers.

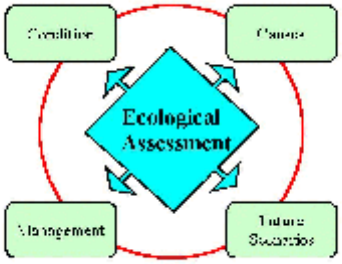
The *Research Strategy* also reflects the role that ORD's Global Program plays as part of the larger U.S. Global Change Research Program (USGCRP). As an assessment-oriented program and member of the USGCRP, ORD's Program has made a major commitment to and plans continued involvement in the ongoing U.S. National Assessment Process (mandated by the 1990 Global Change Research Act) which is evaluating the potential consequences of climate change and variability to the United States. As part of this process, ORD/NCEA is sponsoring the Mid-Atlantic Regional Assessment, the Great Lakes Regional Assessment, the Gulf Coast Regional Assessment, and the Health Sector Assessment. These assessments are conducted through public-private partnerships that actively engage researchers from the academic community, decision makers, resource managers, and other affected stakeholders in the assessment process.

The rest of the assessment program has four areas of emphasis: (1) human health; (2) air quality; (3) water quality; and (4) ecosystem health. These four focus areas are consistent with EPA's mission and the strengths of EPA's research program. More specifically, NCEA will conduct assessments that examine the potential effects of climate variability and change on: (1) human health: including the mortality and morbidity effects of heat stress; effects of climate change on air and water quality and the consequent health effects; and the potential spread of infectious diseases; (2) air quality: including changes in concentrations of tropospheric ozone and particulate matter, and the ability of urban areas to attain air quality standards; (3) water quality: including effects of global change on pollutants and microbial pathogens, and on biocriteria; and (4) ecosystem health: including effects on aquatic ecosystems, invasive non-indigenous species, and ecosystem services.

Ecological Risk Research Program: The core of ORD's ecological research program is captured in the 1998 Ecological Research Strategy and the evolving multi-year plan for the Agency's Goal 8.1 (Sound Science: Research for Ecosystem Assessment and Restoration). The ecological research program includes four broad research areas or themes:

- Defining ecological condition,
- Identifying the causes of ecological degradation,
- Predicating or forecasting ecological stressors and the resulting condition of ecological resources and services, and,
- Ecological management and restoration.

NCEA's ecological research program focuses on the development and implementation of ecological assessments, touching upon all four research areas, illustrated in the figure. Nearly all of the ecological assessments with which NCEA are involved include a risk-based focus. Our ecological risk research seeks to: Characterize and compare risks from multiple stressors, identify ecological resources or services that are at most risk and, evaluate management options that best reduce risk. One or more of these three risk assessment components are involved in all of the ecological risk assessment research activities conducted by NCEA.



These are complex subjects, and NCEA's ecological assessment staff must heavily leverage resources and expertise from other sources and selectively focus on well defined components of these risk subjects to effectively advance risk assessment science and met the needs of our clients. Leveraged resources and expertise include those within ORD and EPA Program Offices, as well as expertise available through contract, cooperative agreement, and grant mechanisms. Realizing the need for collaboration and partnerships with a wide variety of organizations and scientific disciplines, NCEA staff are building the skills and experience needed to leverage internal and extramural resources to effectively complete our ecological assessments.

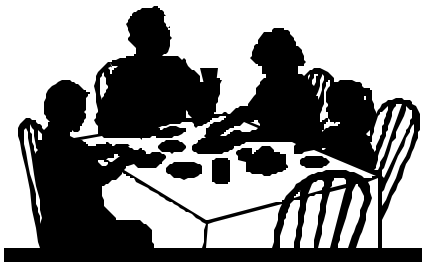
Within the background presented above, NCEA has identified three broad research themes for our ecological risk assessment research efforts. These broad research themes are:

- Place-based, watershed or regional scale ecological risk assessments, represented by our ongoing watershed risk assessment studies
- Identifying and comparing multiple stressors potentially effecting the condition of ecological resources or services, a theme represented by our stressor diagnostics research project, and,
- Integrating human dimensions into the ecological risk assessment, a theme represented now by some of the projects developed by the NCEA Global Change Research Staff.

As outlined in NCEA's draft strategic plan, in the next few years, we plan to expand the theme of integration. Building upon NCEA's core risk assessment strengths, we plan to build expertise and

experience to better integrate human health and ecological risk assessments and to expand these risk assessments to include greater attention to sociological, economic, and cultural drivers of environmental condition. Although not all assessment activities require broad integration, we believe that regional scale risk assessments involving multiple stressors will benefit from the development of integrated approaches. Ultimately, we believe that integrated risk assessment approaches will improve environmental decision-making, a thought shared by the SAB in their 2000 report entitled, "Toward Integrated Environmental Decision-Making."

Human Health Core Research: NCEA's priorities and directions are described in a series of research strategies and plans including the draft *ORD Human Health Research Strategy*, the *ORD Strategy for Research on Environmental Risks to Children*, the draft *ORD Multi-Year Plan for Human Health Risk Assessment*, and the draft *NCEA Strategic Plan.*



ORD has identified three research themes in the area of human health risk assessment:

1. ***harmonization of approaches*** *to assessing cancer and non-cancer endpoints*
2. *assessment of* ***aggregate and cumulative risk*** *(i.e., total risks from exposure to environmental agents via all routes and pathways and risks from exposure to multiple environmental agents)*
3. ***variability in susceptibility and exposure*** *within the population.*

NCEA participates in an integrated program across ORD in these three areas.

1. ***The ultimate goal of the harmonization program is to develop a set of principles and guidelines for harmonizing approaches to cancer and non-cancer risk assessments.*** *NCEA's priorities over the next five years in this area are to:*

- Develop guidance on evidence required to demonstrate that a substance acts via a particular mode of action to produce a particular toxic effect and to show that multiple effects are mediated by similar or different modes of action
- Use mechanistic data to develop a common way of expressing adversity across toxicities for use in the dose-response assessment
- Develop guidance for harmonized exposure and dose assessments and default dose-response assessment approaches, particularly with regard to the use of uncertainty and adjustment factors for inter- and intraspecies extrapolation.
- Develop prototype assessments for both data-rich and data-poor chemicals to illustrate how mode of action, Physiologically-Based Pharmacokinetic (PBPK), and biologically based dose response (BBDR) models may be used in lieu of default approaches.
- Develop principles to evaluate the results of hazard identification studies using genomic and proteomic methods to assess chemicals based on mechanism or mode of action information
- Develop approaches to characterize variability and uncertainty in reference toxicity values and to provide a probabilistic framework for estimating risks associated with exposures above and below the reference toxicity values.

2. ***Cumulative risk reflects the probability of adverse effects from exposure to multiple chemicals and other stressors.*** *NCEA's priorities in this area over the next five years are:*

- Characterize aggregate exposure using new data from the National Human Exposure Assessment Survey (NHEXAS), the National Health and Nutrition Examination Survey (NHANES), and EPA Science to Achieve Results (STAR) grants
- Develop databases, methods, and tools to quantify chemical-specific parameters such as bioavailability needed to combine exposures across routes will be developed
- Develop guidance on exposure averaging times appropriate for various health effects and population subgroups such as children
- Develop methods for predicting potential for toxicological interactions in chemical mixtures.
- Explore population-based (place-based) assessment methods and incorporate aggregate exposure and mixtures assessment to support development of Cumulative Risk Guidelines

3. ***ORD's program on susceptible and highly exposed subpopulations is focused on children.*** *In addition, the ORD Human Health Research Strategy identifies other potentially susceptible groups that are of high priority – people in other life stages, especially the elderly; the genetically susceptible; and those with pre-existing diseases that may increase susceptibility. While ORD's major investment will be in research on children over the next five years, NCEA plans to start addressing these other groups by exploring information on risk that is available in the literature. Over the next five years, NCEA priorities are to:*

- Develop guidance for assessing risks to children that addresses uncertainties in current default assumptions
- Develop risk assessment methods that incorporate mechanistic information, adjustments base on pharmacokinetics and physiological data for children, and dose metrics for children
- Update exposure factors for children based on new data collected in ORD research programs
- Support the design and implementation of the Interagency Longitudinal Birth Cohort Study, a joint project of EPA, the National Institute of Child Health and Human Development, the Centers for Disease Control and Prevention, and other federal agencies.
- Develop issue papers and assessment methods for other life stages, especially the aging and elderly
- Develop issue papers and assessment methods for use of genetic data in risk assessment

In addition to these three priority areas in human health risk assessment, NCEA is making an investment in two other areas:

- Evaluation of public health outcomes from risk management actions, as part of an ORD program described in the *ORD Human Health Research Strategy*
- Approaches to integrated assessments of risk to human health and ecology (NCEA has initiated several projects on this theme through a 2001 internal grants competition)

Integrated Risk Information System (IRIS): IRIS is and will continue to be the Agency's primary source for toxicity information for human health risk assessment. EPA will sustain and build the IRIS Program and data base over the next five years. The major function of the IRIS Program is to conduct chemical assessments and build Agency consensus on priority chemical substances, including those that drive cleanup decisions at Superfund sites and RCRA facilities, hazardous air pollutants, and chemicals found in drinking water. IRIS summaries and companion Toxicological Review support documents are prepared by NCEA and other sponsoring Program Offices, and after rigorous peer review and consensus review, are posted on the IRIS on-line data base. NCEA's IRIS Staff manages the priority-setting process, Agency consensus process, and the data base.

IRIS program priorities for the next five years are: (1) to complete the chemical assessments and reassessments currently in progress and add them to the IRIS data base. There are currently 73 IRIS assessments in progress across the Agency (66 FR 11165, February 22, 2001, and updated by www.epa.gov/iris/whatsnew); (2) to identify the assessments on the IRIS data base most needing update on the basis of user needs and availability of new scientific information. Preliminary results from our literature screening of IRIS chemicals indicate that approximately 43% have new data available that could potentially produce a significant change in the existing assessment on IRIS. We are in the process of compiling results from our annual call for Agency priority chemicals and from our request for input from the public (66 FR 37958, July 20, 2001) into a "needs assessment" requested by Congress. The universe of needs will be analyzed in combination with available Agency staff and extramural resources to determine priorities for the future agenda; (3) to add and update as many assessments as possible in accordance with the agenda. Other improvements to IRIS have been suggested and are under consideration, however the three above are considered the most critical.

Importantly, as new assessments are added and existing ones are updated, the Agency not only incorporates new scientific data, but also has the opportunity to incorporate new methodologies and guidelines (e.g., new cancer assessment guidelines, peer review guidance, risk characterization policy, upcoming methods for considering less-than-lifetime exposure durations). For new and revised assessments, EPA prepares Toxicological Review (or equivalent) documentation that discusses how these methodologies and guidelines are applied. Toxicological Reviews address all relevant endpoints (cancer and non-cancer), susceptible populations, and data variability and uncertainty. The latter was emphasized in EPA's 2000 report, "Characterization of Data Uncertainty and Variability in IRIS Assessments", requested by Congress.

Risk Assessment Forum: The Risk Assessment Forum, a committee of Agency senior scientists, will continue to develop Agency-wide risk assessment guidance with NCEA scientists fulfilling their usual leadership and consensus building roles. The Forum will be focusing its attention on the following areas: cumulative risk, updating of the Agency's 1991 guidelines on exposure assessment, supplementary guidance related to the Agency's new cancer risk assessment guidelines, approaches to characterize risk for non-cancer endpoints and carcinogens that act through nonlinear modes of action, and integration of these methods with economic benefits assessments. Upon completion of ongoing activities to develop guidance on setting management objectives and selecting assessment endpoints for the purposes of ecological risk assessments, the Forum will develop case studies illustrating these principles which can further guide Agency risk assessors.

In the area of cumulative risk assessment, the Forum has a multi-year goal of developing Agency-wide guidelines on conducting cumulative risk assessments. These guidelines will reflect the Agency's growing experience with addressing cumulative risk issues. After completion this year of a framework for cumulative risk assessment, the next step will be for the Forum to assemble case studies (both retrospective and prospective) that will serve as the bases for future guidelines development. The Exposure Guidelines were published in 1991 and, although the principles articulated in the Guidelines still hold true, much has happened in the area of exposure assessment science and the Guidelines will be updated to reflect the latest approaches to assessing aggregate exposures, cumulative risk, and characterizing the exposure of special populations and during critical lifestages.

Finalization of the Agency's new Guidelines for Carcinogen Risk Assessment presents major implementation challenges for the Agency. These challenges which include both science policy and methodological issues will necessitate the development of guidance that supplements that contained within the Guidelines. Issues that are under consideration include: dose adjustment methods for specific life stages, quantitative approaches that can be utilized in determining an appropriate margin of exposure for nonlinear carcinogens, and case studies that illustrate use of the framework for judging the human relevance (including children) of mode of action data.

Currently, the Agency is not making full use of non-cancer risk assessments in quantifying the benefits of environmental regulations. There will be an analogous methodological problem in quantifying the benefits of reducing exposures to nonlinear carcinogens. The Forum will be initiating efforts aimed at developing case studies which will explore different approaches for addressing this problem. Based upon this experience, a consistent methodology will be recommended along with associated guidance on its application.

MULTI-YEAR RESEARCH PLANS (MYPS)

NCEA's priorities for the next five years and NCEA's research portfolio are being influenced by ORD's commitment to multi-year research planning activities. In 2001-2002, ORD will complete its first comprehensive set of multi-year research plans (MYPs) with a 5 to 10 year time frame. NCEA senior management and scientific staff have been closely involved in the development of the ORD-wide MYPs. In fact, NCEA staff had the lead on several MYPs including Air Toxics, Global Change, and Mercury. Other key staff were key writers on the Ecosystem Protection and Human Health MYPs.

It is expected that MYPs will serve as a tool to better plan and coordinate the direction of NCEA's research program within ORD, across the Agency, and with others. The Government Performance and Results Act's (GPRA) structure of goals and objectives served as a useful starting point while giving us milestones to monitor our performance (long term goals, annual performance goals and annual performance measures). The MYPs are a logical framework for integrating research across GPRA goals and are intended to both have more time-dependent detail than ORD's issue-specific research strategies and plans and to link with our annual plans, showing how we intend to meet our out-year goals. The MYPs provide a basis for more readily creating annual plans and a context to perceive how decisions made in annual planning impact the ability of ORD to meet future goals and outcomes. They also improve ORD's comprehension of the impact of Agency priorities and budget guidance, and they allow for a more thorough understanding of changes needed to emphasize a new research direction or accelerate an existing research effort. Since integration and collaboration across scientific disciplines and goals will be increased by providing an understanding of where similar work is needed and by broadly communicating possibilities for collaboration at all levels within ORD, cross-ORD Laboratory and Center integration is fostered. Finally, MYPs will improve Agency accountability by projecting work outcomes (annual performance goals), outputs (annual performance measures), and developing quantifiable measures of ORD's performance.

NCEA'S RESEARCH PORTFOLIO

In response to this request, three pieces of information are provided:

- *listing of NCEA's ongoing or recently completed research activities as they appear on NCEA's updated website (Appendix II);*
- *the NCEA's Internet address to access the complete project description; and*
- *a list of highlighted current projects with status and milestones.*

Complete List of Projects - NCEA is soon to activate ("go live") an improved, updated, and more user- friendly Internet site. The expected date for availability is September 19. One of the features of this new site is that users will be able to access NCEA projects and other information in several ways. One of the easiest ways is an alphabetical listing of all NCEA projects that appear in the EPA Science Inventory. The title of the project and two lines from the project description are included in the list. The user reads the title and descriptive information and, if interested in seeing the full text, clicks on the title which is "hot-linked" to the complete file (Appendix II).

NCEA Website URL - **http://www.epa.gov/ncea/**

GLOBAL CLIMATE CHANGE PROGRAM

First U.S. National Assessment Report delivered to Congress; November 2000

Scientific "Foundation" Report delivered to Congress; April 2001

Four major contributing assessments published:

Health Sector Assessment Report
- Public-private partnership with Johns Hopkins School of Public Health
- Published as special issue of *Environmental Health Perspectives*

Mid-Atlantic Regional Assessment "Foundation" Report
- Public-private partnership with Penn State University
- Documents the methods, findings and recommendations from the assessment

Great Lakes Regional Assessment Report
- Public-private partnership with University of Michigan
- Examined potential impacts on regional agriculture, forestry, water and land ecology, water resources, and quality of life

Gulf Coast Regional Assessment Report
- Public-private partnership with Southern University
- External peer review draft expected in November/December 2001

MAJOR ECOLOGICAL ACTIVITIES

Stressor Identification Guidance Document
- Published December 2000
- Joint effort of ORD (NCEA and NERL) and the Office of Water

Ecological Soil Screening Level Guidance Document
- Supplemental guidance for developing soil screening levels for Superfund sites
- Peer Review Draft published by OERR with NCEA leadership, Summer 2000
- Peer review, Fall 2001

Clinch and Powell Valley Watershed Ecological Risk Assessment
- Planned completion of the Report, September 2001
- U.S. Fish and Wildlife Service and Nature Conservancy

Middle Snake River Watershed Risk Assessment
- Planned completion of the report
- Jointly completed by ORD and Region 10

Ecological Risk Assessment Support Center
- Commenced operations, October 2000
- Jointly supported by ORD and OSWER
- NCEA, NHEERL, NRMRL, and NERL actively involved

Arctic Research Program
- Heavy metals assessment, 2002
- Bering Sea assessment, 2002

Integrating Ecological Risk Assessment and Economics for Place-Based Decision Making
- Case studies in three watersheds nearing completion Heavy metals assessment, 2002
- Draft framework for integrated assessment and management reviewed in July 2001 workshop
  Bering Sea assessment, 2002

MAJOR HEALTH ASSESSMENT ACTIVITIES

Disinfection By-Product (DBP) Mixtures in Drinking Water

- Submission of a document on Health Risk Estimation for DBP Mixtures to Office of Water (June 2001)
- Submission of a document on Multiple-Purpose Design Approach to Toxicological Evaluation of DBP Mixtures to Office of Water (June 2001)

Support Office of Solid Waste's Hazardous Waste Identification Rule (HWIR)

- Planned completion of 10-20 Provisional Toxicity Assessments for HWIR in FY 2001
- Developed risk-based chemical ranking scheme for chemical prioritization and screening purposes
- Major conference on Quantitative Structure Activity Relationship (QSAR); August 20-22, 2001

Conference on "Communication, Perception and Valuation of Risks"

- Conducted a national conference co-sponsored by DOD, ATSDR, FDA, NIOSH, and NIEHS to explore new/improved risk assessment and risk communication tools (April 23-26, 2001)
- Fostered interagency consensus on risk assessment and risk communication approaches for chemicals found at DOD/Superfund sites

Dioxin Reassessment

- Submission of SAB report to Administrator; May 31, 2001
- Complete internal review of revised reassessment; October 31, 2001

Health Assessment for Diesel Engine Emissions

- Summary assessment for IRIS completes consensus review; August 2001
- Inclusion on IRIS; September 2001
- Final diesel assessment publicly available; September 2001

Butadiene Assessment

- Summary assessment for IRIS completes consensus review; July 2001
- Inclusion on IRIS; August 2001
- Final butadiene assessment publicly available; August 2001

Trichloroethylene Assessment

- External peer review; Fall/Winter 2001

Perchlorate Assessment

- External Peer Review; Spring 2002

PCB Non-cancer Assessment

- External Peer Review; Fall/Winter 2001

AIR QUALITY CRITERIA DOCUMENTS (AQCD)

Particulate Matter (PM) AQCD

- CASAC Public Meeting (RTP, NC); Held July 23 and 24, 2001
- Revised PM AQCD; 2002

Ozone (O_3) AQCD

- Draft O_3 AQCD Development Plan release; Fall 2001
- Draft O_3 Research Needs Document release; Fall 2001
- CASAC review meeting; Winter 2001/2002 (Projected)

INTEGRATED RISK INFORMATION SYSTEM (IRIS)

Status:

- 83 IRIS health assessments in progress across the Agency [46 are NCEA-lead]; peer review completed on 20 [10 NCEA-lead]
- 8-10 assessments will be completed and posted on IRIS in FY01 [6 NCEA-lead
- Added 2 FTE to central IRIS staff; improving productivity, internal peer review, QA of documents

Congressional Activity:

- Completed report for Senate on uncertainty and variability
- Developed guidance to follow through on recommendations
- Starting “needs assessment” for Senate
- Requesting EPA and public input on need for updating IRIS

RISK ASSESSMENT FORUM

Guidelines for Carcinogen Risk Assessment

- Major science issues raised in SAB's January 2001 letter brought to Science Policy Council for discussion; Spring 2001
- Final Cancer Assessment Guidelines; Winter 2002

Supplemental Guidance on Health Risk Assessment of Chemical Mixtures

- Availability on Internet; June 2001
- FR Notice announcing public availability; early July 2001

Cumulative Risk Assessment Guidance

- Discussion of draft FRAMEWORK at National Conference of State Legislatures Cumulative Risk Stakeholder Meeting; May 2001
- Consultation with SAB; July 2001
- Public Peer Involvement Workshop on draft FRAMEWORK; August 2001

Benchmark Dose Guidance (Advancing Dose-Response Assessment)

- Completion of Guidance and public availability; Fall 2001

Improving Ecological Risk Assessment

- Two technical panels preparing guidance for ecological risk assessment at EPA
- Building on the Forum's landmark 1998 *Guidelines for Ecological Risk Assessment*
- One panel focusing on planning of ecological risk assessments and the other on assessment endpoints); Panel reports by the end of FY 2001

Applying the Toxicity Equivalence Factor (TEF) Approach for Dioxin-like Compounds to Fish and Wildlife

- Completion of Framework document that provides guidance and procedures for using TEFs in ecological risk assessments
- Completion in FY 2001

C. *How does NCEA integrate research with the other Labs and Centers of EPA-ORD according to the risk paradigm?*

NCEA continues to develop its relationship with its colleagues in the laboratories at all levels. At the staff level, through scientist-to-scientist meetings and ORD wide workgroups, NCEA scientists are developing an improved understanding of the work going on in the ORD laboratories.

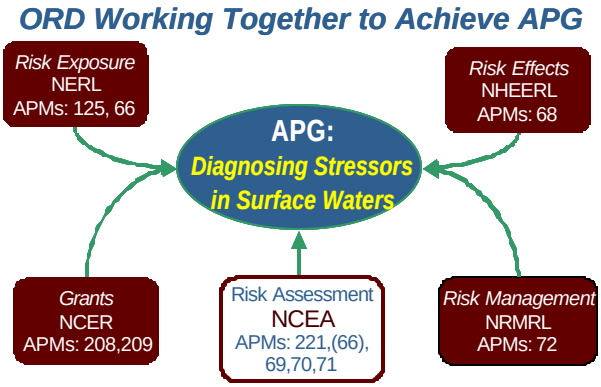
In particular, the NCEA internal grants program has encouraged development of collaboration with laboratory investigators on NCEA staff initiated responses to requests for applications. One specific project area of special interest is children's health research. Cross- laboratory and center research proposals continue to be of high quality and are often recommended for the awarding of an internal grant. NCEA scientists actively participate with other ORD laboratories and centers as well as program offices and regions to help the National Center for Environmental Research (NCER) administer the ORD extramural grants program. Participation includes recommendation of research topics, assistance in drafting and review and comment on Requests for Application (RFA), and review of proposals for relevance to the EPA and ORD missions and to the RFA. ORD periodically sponsors cross-ORD competitions for intramural grants to multidisciplinary grants that involve more than one ORD laboratory or center. NCEA scientists are co-investigators on two such grants in the area of children's health along with investigators from NERL and NHEERL.

At the level of the Assistant Center Directors (ACDs), the Research Coordinating Teams (RCT) afford NCEA ACDs the opportunity to learn the Laboratory research programs and to influence directions of those programs in keeping with risk-based priorities set out by ORD's Strategic Plan and with the research needs identified as part of the iterative risk assessment process. At the Associate Director (AD) level, NCEA's ADs have been influential in guiding important ORD Research Strategies and budget initiatives as members of ORD's Science Council. This is a role specifically called for in the current ORD Strategic Plan. In addition, both the ORD ADs for Ecology and the ADs for Health meet on a regular basis to enhance integration across the risk assessment/risk management paradigm across the labs and centers and foster collaboration on addressing critical environmental issues. NCEA's three Divisions are also integral to this process of cultivating improved relationships with various ORD and Agency partners on projects of mutual interest. At the Center Director and Deputy level, NCEA has made important strides to strengthen relationships with ORD laboratories and offices through active participation in the Executive and Management Councils, respectively. NCEA management and staff continue to be key participants in Agency-level Science Policy Council activities that afford more of these "bridge building" opportunities.

In addition, the multi-year planning process has helped to increase cross-lab and center communication. It has encouraged long-range, cross-ORD thinking on how to address Agency priorities and fostered improved communication and appreciation of the skill and capabilities in each of the labs and centers. NCEA has been a very involved ORD partner in the discussions around the MYPs and in their development process. As ORD experience with the MYPs increases and the process is improved and refined, the use of the MYP planning process will lead to better collaboration

and coordination across ORD center and labs. In fact, to have the all the BOSC subcommittee's follow ORD's progress with its MYP development and planning process would be a benefit for the entire organization, as well as the Agency.

One example of a successful cross-ORD, multi-lab/center annual performance goal (APG) project is the Development of Framework for Diagnosing Adverse Pollutants in Surface Waters. This watershed assessment will identify causes of ecological degradation in watersheds through monitoring and measuring approaches developed by ORD programs (EMAP, ReVA)and help to quantify degradation and evaluate ecological degradation caused by multiple stressors. Most ecological degradation is not related to toxic chemicals but to stressors such as habitat loss, invasive species, and nutrient over enrichment (eutrophication). The project will also address the cumulative impacts of multiple stressors difficult to assess. Focus of NCEA's work in this APG is to identify and quantify stressors that cause the greatest impacts (risk-based focus). The APG also crosses two MYPs, Goal 2: Water Quality Multi-year Plan and Goal 8: Ecosystem Protection Multi-Year Plan. This APG has already resulted in the December 2000 publication entitled, "Stressor Identification Guidance Document," which was jointly developed by NCEA and the National Exposure Research Laboratory (NERL).



Also, NCEA has actively pursued several cross-cutting strategic initiatives of note. First, NCEA led a successful effort to re-invigorate the Agency's consensus risk information system -- IRIS. This has resulted in the accrual of additional staff and extramural resources and has solidified the NCEA role as leader in this important effort. Second, NCEA has been a leader in information management initiatives across ORD and with Program Offices and Regions. These two initiatives have allowed advancements in NCEA's methods development and consultative roles. Third, NCEA has led the re-alignment of the ORD Global Change Research Program to be responsive to Administration effort to focus such programs on consequences of global climate change and variability. This has had a significant impact on NCEA's efforts to move toward integrating health and ecological risk assessment, a goal strongly supported by the BOSC reviewers. Finally, NCEA has had significant influence on ORD-wide initiatives on PM, mercury, children's risk, water microbes and disinfection issues, and global climate change. Each of these will provide NCEA with opportunities to develop methods, do assessments, and transfer approaches and information on these important issues.

However, NCEA has made limited progress in explaining the process and value of risk characterization to the laboratory scientists in other ORD components. Despite a good base of support, NCEA needs to do a better job of reaching out to other ORD organizations. Cross-ORD collaboration and communication has improved since the 1997 BOSC review, but ORD and NCEA still have work to do in this area.

D. *How does NCEA integrate research across and within the Divisions of our organization according to the risk paradigm?*

One of the areas of advancement in NCEA has been in its focus in the last several years on integration of NCEA science activities among the NCEA's Divisions. This also includes focus on improving communication in NCEA.

NCEA has made significant progress toward improved internal communication, particularly with regard to strategic thinking and new initiatives. Among these efforts are the development of first rate Internet and Intranet sites, both of which are currently being upgraded. These sites have allowed the posting of work plans, initiatives, requests for application, relevant budget and legislative documents and work products which have been used by NCEA staff as a resource for understanding ongoing NCEA activities. In addition, as part of NCEA's Continuous Improvement Plan, the NCEA senior management committed to visits and "skip-level" meetings with staff to discuss strategic directions and receive input. Response from the staff has been favorable and the recent employee survey noted improvement in internal communication.

In addition, since the 1997 BOSC review, NCEA has held both an annual NCEA "eco retreat" and "human health retreat." These retreats bring together all the scientists working in the respective area and offer opportunities for lively input on strategic planning, priorities , and direction. This year, in the spirit of one of the key goals in the ORD Strategic Plan - the integration of ecological and human health effects assessment -, NCEA held its first combined health and eco science retreat. This meeting brought together over 110 NCEA scientists from scientific disciplines related to ecological and human health risk assessment. These scientists were from all three division as well as the immediate office of the Director. The retreat provided a very good opportunity to discuss strategic directions and priorities in light of the ORD Strategic Plan, the ORD Ecological Research Strategy, and the draft MYPs. The results of this NCEA-wide science meeting are being used in the development NCEA's

Science Retreat 2001

Background:
- *Theme: "Improving the Science of Assessment through Integration"*
- *May 14-17 at the Tidewater Inn in Easton, MD*
- *Over 110 NCEA scientists attended*

Objectives
- *Identify ways to improve risk assessments through integration*
- *Discuss and develop integrated research programs*
- *Identify opportunities for collaboration*

Charge to participants
- *Be excited*
- *Build towards the future; the role of GPRA and MYPs*
- *Get involved*

Were we successful?
- *Yes, 65 out of 68 respondents to post retreat survey said it was beneficial*
- *Many expressed that it had that "Williamsburg and Baltimore" feel*

Science Retreat -- Messages From the Scientists

- ✓ *A vision for NCEA*
  - A Center of Excellence
  - Attracting and nourishing staff with assessment skills
  - Working with, but distinct, from our ORD partners
  - Connected with and responsive to our customer needs
- ✓ *Integrated Assessment*
  - Many different types and levels of integration
  - Health focus on chemicals; eco focus on places
  - Integration includes health, ecological, economic and cultural risks
  - GIS is an integrating tool
  - Integration requires good communication
  - Develop cross-divisional assessment teams
- ✓ *Communication*
  - Improving communication within and outside NCEA critical
  - Initiative; NCEA monthly seminar series open to entire agency
  - Improve NCEA web page; create NCEA newsletter
  - Revise and finalize NCEA strategic plan

strategic plan, as well to inform the planning process and the development of the final MYPs.

Additional efforts to enhance communications across NCEA units are underway or being considered. These include the ongoing distribution of a monthly activities report by NCEA's RTP Division to all of NCEA and the subsequent expansion of these reports to include all Divisions and the Office of the Director, the holding of video seminars on timely, high-priority science issues being addressed by one of the NCEA Divisions, and the successful establishment of the NCEA Internal Grants Program. Finally, the Washington Division is implementing a "program manager" pilot program where senior level staff are responsible for being advocates for scientific program direction.

Other methods to enhance the integration and communications of research directions and goals across NCEA include:

Weekly NCEA "roundtable" discussions. NCEA management holds these discussions every week. Lasting usually about one hour, these discussions are open to everyone in NCEA. Cross-cutting science issues are discussed, upcoming high profile activities about which all of NCEA should be aware are presented, and problems and concerns are raised. They are well attended.

Cross-NCEA Projects. Projects in both ecological and human risk are already in progress and this approach -*NCEA teams* -will become more commonplace. An example of a cross-NCEA ecological project is the Watershed Assessment. An example of a cross-NCEA human health project is the diesel assessment.

Planners Meetings. NCEA holds weekly meetings of NCEA science planners and administrative management staff involved in the planning process. These meetings bring together all five of NCEA's Assistant Center Directors for each of the Water, Air, Toxics/Pesticides, Solid/Hazardous Waste and Multimedia, the NCEA Director and Deputy Directors, the Associate Directors for Health and Ecology, the three Division Directors, and various staff involved in budget and finance.

In addition, not only have we improved on cross-NCEA integration and communication in the science/research area but also integration of the administration management and science research management. An example of this area of improved integration is the planning process where all NCEA divisions are represented, and both science and administrative staff work very closely to build a focused NCEA program that meets NCEA's priorities, the goals of the ORD Strategic Plan and the needs of the Agency.

It is envisioned that efforts like those mentioned above will continue to foster improved communication from and to all levels of the organization.

E. *How does your Center integrate research with regional offices of EPA, other federal agencies, and other research centers world-wide?*

NCEA has established a strong track record of broad-based interactions with the scientific community, inside and outside of the Agency, through numerous peer-participation and peer-review activities. Our external peer review program facilitates broad scientific interaction in the national and international scientific community. Also, NCEA understands the importance and benefits of international harmonization of risk assessment methodologies and approaches, as well as international collaboration and consultation on scientific and chemical issues of mutual interest. To this end, NCEA has cooperative agreements in place with the World Health Organization and Pan American Health Organization, and has had for several years. To a great extent, it is through these cooperative relationships that NCEA has established its role as an international leader in risk assessment. NCEA scientists are also leaders in the harmonization project of the International Programme on Chemical Safety.

Also, NCEA has lead roles in several high profile ORD and Agency activities that are of significant interest to EPA regional offices, other federal agencies, and other national and international research centers:

IRIS - NCEA is the "home" of the staff responsible for the development and management of IRIS, the Agency's Integrated Risk Information System. This information system is a key information and communication resource for a broad cross-section of users groups throughout the U.S. and the world.

Global - NCEA's Joel Scheraga is the National Program Director of the ORD Global Change Research Program. The program has been realigned to be responsive to Administration effort to focus such programs on consequences of global climate change and variability. The Global program is a very visible activity for NCEA that is of high interest across the EPA, federal government, and in the international community.

Forum - NCEA houses the staff who manage the Agency's Risk Assessment Forum. The work of the Forum has significantly fostered improved integration and coordination on cross-cutting priority issues. The Forum's colloquia and reports on science policy issues are of high interest in the environmental science community. EPA science policy positions developed through Forum efforts often become the *de facto* national standard.

National Assessments - NCEA has had significant influence on ORD-wide initiatives on dioxins, PM, mercury, children's risk, water microbes and disinfection issues that are of high interest to scientists and researchers

The above four activity areas provide NCEA with opportunities to develop improved methods, conduct precedent-setting assessments, and transfer approaches and information on these important issues with researchers and research organizations around the world.

NCEA also plays other lead roles in ORD-wide strategic planning and program development efforts that have been important communication opportunities. These efforts include: (a) the critical role that NCEA's Associate Director for Ecology has had in the overall ecological strategic plan and his lead role in the initiation, development, and successful completion of the first Agency-wide "EcoCamp," (b) ORD's high-profile global climate change program managed in NCEA (this program has successfully created an ORD-wide "global team", as well as impacting the rest of the Agency, and is recognized as having a credible and important role on the national and international level), and (c) the NCEA Associate Director for Health's role as the one of the primary leads on the development, across ORD, of the human health research strategy.

NCEA has tried to enhance its ability to communicate its mission, capabilities, focus, strengths, and value, all within the framework of the overall ORD Strategic Plan, to its internal EPA partners, clients, and customers. The limiting factor in developing a proactive and vigorous outreach program to various user groups has been scarce resources available to devote to these types of activities. There are many activities in this area and many opportunities to communicate to the Programs, Regions, and ORD about NCEA. Of particular note is the continued large presence of NCEA senior managers and scientists at the annual EPA Regional Risk Assessors meeting. We view this meeting as very important to NCEA because it brings together most of the key EPA Program and Regional health and ecological risk assessors, as well as state participants, and provides an excellent opportunity to communicate to NCEA's clients. NCEA managers and scientists often avail themselves of a variety of other communication opportunities, such as scientist-to-scientist meetings, annual strategic planning meetings, program reviews, and weekly Research Coordination Team (RCT) meetings.

Another example of interactions in this area is NCEA's role with the Office of Water in managing and developing research partnerships with major water customers outside of the Agency to fund university-based research. These outside organizations include the American Water Works Association Research Foundation (AWWARF) and the Microbial and Disinfection By-Products Research Council. Also, in addition to the relationships that each of the NCEA Divisions (Cincinnati, Washington, Research Triangle Park) have with local universities, NCEA has two Memoranda of Understanding (MOU) in place with non-local organizations; one with the State of California EPA's *Office of Environmental Health Hazard Assessment* and the other with the University of Virginia's *Center for Risk Management of Engineering Systems.* The purpose of both MOUs is to provide opportunities to collaborate on some projects of mutual interest and value.

Also, there are two other activities that demonstrate NCEA's outreach and involvement with other environmental health organizations. The first is an upcoming conference, September 16-19, entitled, "A National Conference on Biological Variability in Children and Implications for Environmental Risk Assessment: New Perspectives on the Roles of Ethnicity, Race and Gender." This event is being sponsored by NCEA and the University of Maryland. The purpose of the conference is to convene a group of experts together for the purpose of presenting, discussing and evaluating environmental health issues as they relate to biological diversity between children. The conference will focus on the emerging body of evidence showing biological variability and susceptibility between children from different ethnic, racial and gender groups and its impact on environmental risk

assessment.

Another activity of interest is the Longitudinal Cohort Study of Environmental Effects on Child Health and Development (LCS), a federal interagency study led by the National Institute of Child Health and Human Development, the Centers for Disease Control and Prevention, and EPA. NCEA has the Agency lead on this important activity. The Longitudinal Cohort Study will identify about 100,000 children across the United States as early in pregnancy as possible and follow them to adulthood. The LCS provides an unparalleled opportunity to study the relationships between exposure to environmental agents and adverse health outcomes in children. In this context, "environment" is broadly defined to include chemical, physical, and social/behavioral influences on children. Data will be collected on exposure to environmental toxicants; factors such as nutrition, general health and safety, and socio-economic status; and health outcomes including asthma and immunological disorders, neurobehavioral endpoints, birth defects, injuries, general growth and development, and infectious disease.

An example of collaboration with both other federal agencies and states is the *Interagency Mixed Exposures Research Group*, that is co-chaired by NCEA and NIOSH. The group presently includes representatives from 12 Federal and 4 State agencies. Its purpose is to coordinate mixture risk research plans and facilitate interagency collaboration. In May 1998 the group held its first meeting at EPA in Cincinnati and shared information regarding projects. A second meeting was held in September 2000 at NIOSH to discuss potential collaboration and initiation of reviews of ATSDR and NIOSH mixture risk research plans. The group has initiated the development of consensus glossary that is scheduled for completion in 2002.

Finally, NCEA also collaborates on research activities at the international level. They include:

NCEA International Activities - CATEGORIES

- Political (UN POPs Treaty)
- Situational/Expert Contribution
  - *Exposure/Study Population (Respiratory Health in China)*
  - *Chemical/Compound Specific (As, Cr)*
  - *Emergency Response (Indonesia Biomass Fires)*
  - *Ecological Risk Assessment in New Zealand*
- Methods Development (Harmonization Project)

United Nations Persistent Organic Pollutants (POPs) Treaty

NCEA Role: Participation in and negotiation of research and monitoring of POPs
Ongoing preparation of technical support documents during ratification process

Ambient Particulate Matter (PM) Exposure and Respiratory Health in 4 Chinese Cities

NCEA Role: Situational/Internal ORD Grant
Exposure assessment and data collection opportunity

Health Effects of Arsenic - Chile Study, Exposure situation in India

NCEA Role: Situational/Exposure and Study Population
Exposure assessment and data collection opportunity

Harmonization of Approaches to Risk Assessment (WHO)

NCEA Role: Leadership of International Programme on Chemical Safety (IPCS) Harmonization Project
Expert Contribution and Collaboration

Arctic Assessment/Research Program

NCEA Role: On-site NCEA staff
Coordination role with other Arctic Council countries

Global Environmental Security Issues

NCEA Role: Expert support to the Administrator

F. *Specifically, how have you incorporated social and behavioral science into your research program?*

Social and behavioral science considerations have been incorporated into NCEA's health risk assessments for a long time. Whether they were called out as such, is another question. However, considerations of exposures to the most vulnerable in the general population have been historically addressed in NCEA's work. These include:

> Elderly, children, subsistence fishers/farmers, pregnant women, or women of child-bearing, nursing infants, individuals with unique diets, occupationally exposed individuals, cigarette smokers, and individuals who live near significant sources.

Some examples of these considerations are in the dioxin reassessment, the Mercury Study Report to Congress, and environmental tobacco smoke health assessment report. NCEA also published and continually updates the *Exposure Factors Handbook*, a widely used reference document that analyzes studies quantifying factors related to exposures, and provide recommendations for values and distributions for use in EPA exposure assessments. These factors include time-activity patters data and other behavioral data that bring individuals into contact with environmental agents. Exposure factors for particular segments of the populations, such as various age groups have also been developed.

In addition, our research in ecological risk methods and our assessments of Global Change, the Arctic, and place-based assessments (e.g.,watersheds) have begun to incorporate the social and behavioral sciences into their design and execution. The classic work of Paul Slovic, an internationally recognized expert on risk perceptions, typifies the nature of this work. He describes how cognitive psychology can be used to characterize risk perceptions; the psychometric paradigm uses psycho-physical scaling and multi-variate analysis to quantify and map risk perceptions. Psychometric studies have shown that perceived risk is quantifiable and predictable, and that psychometric techniques seem well suited for identifying similarities and differences among groups with regard to perceptions and attitudes. Recent research on perceived health risk has provided insight into key social aspects of health risk management including the determinants of value judgments underlying health risk tradeoffs.

There are a number of key demographic and socioeconomic factors that have been shown to correlate with risk perception including factors such as gender, race, political worldviews, and affiliation. As such, these factors potentially confound observed expert-lay differences that have been attributed to expertise. The most widely demonstrated demographic factor related to risk perception is that of gender, with men tending to judge risks as smaller or less problematic than do women. Apart from gender, there are other potential confounding factors that need to be considered in expert-lay studies of risk perceptions. Studies have found that racial differences were related to risk perceptions, with white males giving lower ratings than non-white males, more so than white females, and non-white females. Perceived risk tends to be inversely related to income and educational level. Hence, white males with the lowest risk perception scores tend to be more highly educated, have higher household

incomes, and are politically more conservative. Some studies have found evidence of income being related to risk perception, but not to educational level with age correlated to risk perceptions. In general, however, NCEA has given relatively little attention to social science questions regarding the human perception, mental characterization, value assessment, and world views regarding ecological risks.

Examples of incorporation of behavioral and social science into risk assessment include:

Trichloroethylene (TCE) Health Assessment

One innovative new approach to addressing social and behavioral science is illustrated in the draft TCE Assessment which will soon go to the Science Advisory Board for external peer review. The TCE assessment identifies several potential risk factors for TCE toxicity including disease (e.g., diabetes), lifestyle factors (e.g., alcohol consumption), and concurrent exposures to other chlorinated solvents or disinfection byproducts. Children are also identified as a potentially susceptible population. The TCE assessment is the first to identify several potentially susceptible populations based on genetic and acquired factors that can alter metabolic rates.

Global Climate Change Research Program

Also, an main emphasis of the Global Program's research and assessment strategy is on understanding the risks and opportunities presented by global change, the interdependent and interactive effects of multiple stresses, the human dimensions of global change (human activities that catalyze as well as those that respond to global change), and adaptation options. Human dimensions encompass "analysis of the human causes of global environmental transformations, the consequences of such changes for societies and economies, and the ways in which people and institutions respond to the changes. They also involve the broader social, political, and economic processes and institutions that frame human interactions with the environment and influence human behavior and decisions" (NRC 1999, p. 295). Research on the environmental effects of human activities is critical for understanding global change. The National Academy of Science's *Pathways* report (1998) and the IPCC have both affirmed that understanding how global change affects and is affected by human society is a crucial element of assessment. The Global Change Program incorporates considerations of human dimensions in both its assessment activities and its research program.

Ecological Risk Assessment Guidelines

NCEA, in conjunction with the Risk Assessment Forum, published the Ecological Risk Assessment Guidelines in 1998 that emphasizes the importance of problem formulation in conducting an ecological risk assessment. Problem formulation is the first step in the assessment and is intended to understand what stakeholders consider to be the items at risk and why. There are additional projects that NCEA has initiated that expand our understanding of perceptions of risk.

One is a Forum project on *Ecological Objectives* (http://epa.gov/ncea/raf/dmo.htm). This

project will provide supplemental guidance to EPA's 1998 Guidelines for Ecological Risk Assessment. The topic was identified as one of high interest to EPA clients in a survey conducted by the Risk Assessment Forum after the Guidelines were released. Ecological risk assessment is a complex process that requires thoughtful planning: Planners must decide what species, ecosystems, or functions to protect. They must also consider species interactions and indirect effects; the significance of non-chemical stressors; and environmental laws implemented by other agencies, states, or local authorities. The guidance first discusses how to frame the decision context, and examines how to articulate the decision to be made and how to describe the fabric of public values; legal, regulatory, and institutional context; risk-management options, and the place and time in which the decision is framed. It also describes the typical players–risk managers, risk assessors, interested parties, and other analysts–and their roles, and suggests a process for reaching consensus.

Project on Personal Values and Ecological Risk Perception

Another project deals with personal values, beliefs and ecological risk perception. In this study, EPA risk managers and risk assessors are being surveyed as to their own personal values and beliefs and their perceptions about ecological risk. The theory is that personal values affect one's perception of risk and understanding the role of these values is important both as a risk manager and a risk assessor.

Risk Management Workshop

In June of 1997, NCEA helped sponsor a Society of Environmental Toxicology and Chemistry (SETAC) workshop on ecological risk management that resulted in a publication in Environmental Toxicology and Chemistry 18(2). The report, *A Multi-Stakeholder Framework for Ecological Risk Management: Summary from a SETAC Technical Workshop*, represents a consensus framework that describes a participative, decision-making, multi-stakeholder process for guiding the substantive nature of interactions between risk assessors and risk managers, both preceding and following an ecological risk assessment. The report recognizes that sound and acceptable risk management decisions are supported by a process that effectively integrates social, political, economic, and technical interests and concerns.

Integration of Economics and Ecological Risk

Ecological risk assessments (ERA) provide important scientific information that risk managers need to consider along with other factors (e.g., social, legal, political, economic) in selecting a course of action. But risk assessments and economic analyses are often poorly integrated. They may assume different management goals or spatial boundaries; they may not use the same factual information; or they may use measures (dollars vs. physical measures) that are fundamentally different. A well integrated ecological-economic analysis, conducted alongside an ecological risk assessment, should appropriately use ecological information while placing the ecological risks in a broader socioeconomic context. The goal of this research program is to improve the utility of ERA in the decision making process. The research is intended to help decision-makers to use ERA results, together with information on stakeholder preferences and

strategies, to explicitly weigh ecosystem management options and ensure that systems are protected in a manner that brings greatest overall public benefit.

Integrated Assessment for a Sustainable Bering Sea

This project will expand the application of risk assessment to integrate across ecological, human health, economic and cultural issues by applying the ecosystem risk assessment process within a large complex region of great regional, national and international significance. The assessment will be done in partnership with the Interagency Arctic Research Policy Committee, with input from the State of Alaska, Tribes, environmental and commercial interests. The planning portion of the assessment will be based on a Bering Sea Summit in April 2002. Different aspects of problem formulation will be completed during 2002 by the interagency working group. Federal and state agencies and Tribes will use the outcome for decisions concerning fisheries, contaminants, habitat protection and other issues relevant to the vast and rapid changes occurring in this valuable ecosystem.

Watershed-scale Ecological Risk Assessments

This work demonstrates the application of ecological risk assessment principles to increase the use of sound science and improve decision-making in watersheds. Four prototype watershed ecological risk assessments are underway, and tools and principles developed from these assessments are being extracted and refined to enhance their utility to the four involved watershed communities and to serve as examples for other watershed assessors to follow. Ultimately, clients are watershed associations, states, counties and tribes performing watershed management and seeking to improve the use of ecological science in decision making. Since these organizations may use scientists in their decision making process, our clients also include scientists seeking guidance on how to conduct better assessments and the academic community seeking materials to improve the science used in their grant proposals and for training developing scientists. Based on these experiences a number of lessons have been learned that are being developed into guidance materials. There is a very strong stakeholder component to this work which emphasizes the socio-demographic and cultural differences among the various stakeholders.

NRC/NAS Public Participation Study

Environmental policy choices in the United States are increasingly being informed by processes that combine scientific analysis with deliberations involving policy makers, scientists, and stakeholders. Little systematic knowledge exists, however, about how best to implement such processes. The National Research Council (NRC) of The National Academies has convened a panel of experts to examine the experience of several government agencies and the relevant theoretical and empirical literatures in order to identify tentative lessons from experience, specify indicators of success, map obstacles to good practice, and propose ways for agencies to learn from experience so as to systematically improve their use of public participation in

environmental assessment and decision making. NCEA is one of the sponsoring organizations and is actively involved in designing the scope of the study.

G. *How have you achieved/maintained a balance between human health research and ecological research?*

Probably the area of the most dramatic visible progress has been in addressing the imbalance between ecological and human health risk assessment in NCEA. The emergence of a strengthened NCEA Ecological Risk Assessment (ERA) Program is the result, in part, of ORD's recognition of ecosystem risk assessment as one of the seven highest priority research areas. Integral to ORD's Ecological Research Strategy, NCEA's ERA program is focused on our customer's needs for methods, guidance, and assessments, and advancing the state-of-the-practice of ERA.

There are a few specific activities that are worth mentioning that directly apply to the goal of improving the balance between ecological and health assessment. First and foremost, the development of the NCEA's ecological strategic plan will be the clear plan recommended by the BOSC. The NCEA draft ERA Strategy establishes specific goals and actions to address these challenges. It will:

- Demonstrate the value of the full ERA process by early and active participation by NCEA in the ERA process (e.g. Western Pilot, Mid-Atlantic Integrated Assessment)
- Provide consultative/referral assistance on a full range of assessments (e.g., site, watershed, regional, terrestrial and aquatic);
- Conduct exemplary and prototype ecological risk assessments emphasizing watershed and regional scales to identify scientific gaps and develop essential methods and guidance;
- Increase the use and quality of ERA by developing user friendly guidance that address critical scientific gaps, and by delivering training to a diverse user group;
- Work with clients to identify and develop efficiencies in the ERA process; and
- Enhance the utility of ERA by developing strategies and methods for fully integrating human health and economics with ecological risks.

Another important step in developing that balance has been the hiring of several key ecological risk assessment personnel representing the scientific disciplines needed to create the critical mass required to develop a credible NCEA ERA program. One of those key hires was the Science Advisor in the Cincinnati Division who is a nationally recognized expert in ecological risk assessment. With the inclusion of post doctorate hires, the total ecological program staff is **27** scientists. This is a substantial increase since the 1997 BOSC review. Also, there has been a substantial increase in overall extramural resources to ecological assessment with a strong commitment to and focus on ecological research in the NCEA internal grants program. Finally, across ORD the working relationships among the Laboratory and Center Associate Directors for Ecology has been very important in developing an integrated program across ORD. Also, the close and collegial working partnership in NCEA between the Associate Director for Ecology and the Associate Director for Health is fostering the necessary and important integration of ecological and human health risk

assessment. In addition, the development of the draft Global Change Research Strategy has resulted in good working partnership between ecological and human health assessors particularly in the area of evaluating the effect of global climate change on vector-borne disease and other health outcomes.

H. *Specifically, how has your research management and research program changed since the last BOSC review?*

The overall theme that NCEA heard at the 1997 BOSC review was that the Center appeared to them to be "a mile wide and an inch deep." As the BOSC correctly noted, NCEA is comparatively small with respect to the three national laboratories. However, NCEA appears to take on a broad and, seemingly, unfocused, set of activities. NCEA is also frequently called upon to take on "over the transom" projects, as well as being involved in many "fire drills" and "crises," most of which are outside of NCEA's control. Nevertheless, the general comment of "a mile wide and an inch deep" resonated with NCEA staff and management. Since the 1997 review, this BOSC concern has been often quoted in the course of NCEA planning activities and at science meetings as a caution to focus, coordinate, collaborate, communicate, and divest.

Over the intervening years, NCEA has tried, within the framework of the Agency priorities, the MYPs and the ORD Strategic Plan, to address this focus issue. It has been difficult, but progress has been made. Examples of improved focus include: consolidating ecological priorities under the framework of an Ecological Research Strategy, focusing human health research on three priority areas, and strengthening the focus on support for IRIS. The act of focusing has forced NCEA to abandon past practices and investment areas. NCEA has stopped doing routine chemical risk assessments for the program and regional offices, concentrating instead on assessments that are precedent-setting or of national significance. NCEA has also dropped as a priority strategic area research into information management methods, which in prior years was one of three strategic priorities.

In addition, one of the recommendations of the 1997 review was that NCEA should develop an improved process to track cost and effort investment for project conduct so that management can better visualize which activities are consuming resources. NCEA's Cincinnati division is pilot testing a project development and tracking system based on Microsoft Project™ software. When preliminary results are received, staff will brief NCEA's Deputy Director. Assuming positive results, NCEA will hold an internal workshop to discuss applicability.

In addition, the emergence of strong ecological assessment, global change, and IRIS programs has changed the face of NCEA. These are high profile programs of interest to a broad stakeholder community. While NCEA's human health assessment, generally chemical-specific, have always been of high interest inside and outside of EPA, the success of these programs have broadened the "public face" of NCEA.

Another area of change since the 1997 review is in the roles of the Associate Directors (AD) for Ecology and Health within the NCEA and ORD management framework. While the roles of the NCEA ADs have been greatly strengthened, they are still not compatible with the line-management functions of this same position in other ORD components. This area organization design is one where

the Subcommittee could assist the Center. The discrepancies of organization/management framework within ORD has created some working tensions that need to be addressed. Advice in this area would be helpful. Nevertheless, it has been made clear in NCEA planning activities, outreach, communication, and interactions with administrative and scientific staff that these two positions have overall leadership and management function of NCEA's ecological and human health assessment programs, respectively. To a great extent this message has been embraced and the strengthened role accepted throughout the organization, albeit there is still work to do in this area.

2. RESEARCH STRENGTHS AND WEAKNESSES

A. What are your unique research capabilities and strengths to accomplish your objectives?

NCEA's vision is to be a high performing assessment center providing timely and high quality risk information to environmental decision-makers. To accomplish this goal the Center has many significant research capabilities and strengths including:

RISK ASSESSMENT METHODOLOGIES/TOOLS

NCEA has gained a national and international reputation for the development and mastery of risk assessment methodologies and tools that are innovative and on the cutting edge of risk assessment science in both ecological health and human health. These methodologies/tools are developed to meet emerging assessment needs. The use of these methodologies and tools result in improved risk assessment procedures to better characterize risk and to address uncertainty resulting from data gaps in risk assessments. Examples include:

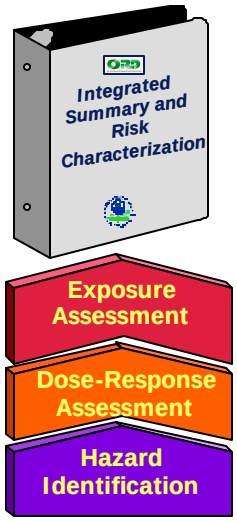
- Benchmark Dose Modeling Guidance and Software
- Stressor Identification
- Physiologically-Based Pharmacokinetics (PBPK)Modeling
- All-Ages Lead Model
- Multi-pathway Exposure Model

CHARACTERIZATION AND SYNTHESIS

Another of NCEA's niches and significant strengths is in the area of risk characterization and synthesis. NCEA is correctly know as an organization that takes on assessments of broad, as well as high, national interest. The ability to take a large, often times significantly large, amount of data and analysis and provide a careful and thorough review that results in an integrated summary and risk characterization is a unique capability of NCEA scientists and staff. These risk assessment documents incorporate and summarize information from the across the risk paradigm to provide support and credible science to Agency decision-makers.

Risk Characterization:

- Summarize all data, strengths and weaknesses
- Integrate information from previous steps
- Discuss uncertainties and assumptions
- Develop estimates of risk for public health and ecological integrity
- Provide tools for risk managers who make decisions.



INTEGRATION and HARMONIZATION

NCEA also has unique capabilities in the area of integration and harmonization of many aspects of risk assessment. Goal 4 of ORD's Strategic Plan calls for the integration of environmental science and technology to solve environmental problems; synthesize the broadest range of cutting-edge science and engineering into a comprehensive set of insights and an understanding of the increasingly complex environmental problems that we face. NCEA has taken a leading role in integration across the risk paradigm on ecological and human health aspects of risk assessment. This includes the integration across the risk assessment and risk management components of risk analysis. Closer ties with ORD's risk management laboratory (NRMRL) have been made and both ORD components are working together to accomplish this integration goal.

Integrated Assessments

- Many different types and levels of integration
- Health focus on chemicals; eco focus on places
- Integration includes health, ecological, economic and cultural risks
- Geographical Information System (GIS) is an integrating tool
- Integration requires good communication
- Develop cross-divisional assessment teams

In addition, NCEA has taken the lead on integration and harmonization activities that address the perceived dichotomy between risk assessment approaches in non-cancer human health assessment and cancer assessment. The Center has also been at the forefront in harmonization of risk assessment approaches taken within EPA, by other federal agencies, and within the international health assessment community, particularly in conjunction with the World Health Organization (WHO). Another area where NCEA is becoming an Agency resource is in the area of integration of risk assessment approaches with other decision-support sciences such as policy analysis and economics.

B. *How does NCEA communicate your results within the organization, within ORD, within EPA, to outside agencies, and to the outside world?*

NCEA recognizes the importance of communicating the results of NCEA's research and projects to a broad range of users, clients, and stakeholders. This task is two-fold and complex. NCEA acknowledges that we must both communicate good information and communicate this good information well. This is the challenge.

Another concern that science organizations need to address is communication on at least two levels (and usually many more); plain language communication to reach the broadest possible audience and technical communication of results to meet the science needs of the environmental health community in NCEA, within ORD, within EPA, to outside agencies, and to the outside world. NCEA does an adequate job of communicating its results with the science community. However, addressing the communication needs of the general public, education institutions grades K-12, etc. has not been a priority. NCEA has not dedicated staff for internal and external communication whose job could include proactively showcasing NCEA's product and illustrating how NCEA's work makes a difference in the health of the communities where people live and work and in the health of the planet. NCEA looks to the BOSC Subcommittee for some guidance in resource issues and approaches for outreach in this area.

Some examples of areas of outreach and communication include:

INTRANET/INTERNET

The primary method of communicating NCEA's results to all of the above user communities is NCEA's Intranet and Internet home pages. The NCEA Intranet website is in the process of being revised and updated to make it more navigable and transparent. However, the NCEA Intranet site does include links to library access for NCEA scientists to 7 university and government libraries and also to *Current Contents*.

The current NCEA Internet site is one of the largest in EPA. The site includes project descriptions, documents, databases, as well as full text of NCEA products whether 70 pages, as in the case of the PCB cancer dose-response assessment document, or the 4000+ page draft dioxin reassessment. The NCEA web site is heavily accessed with approximately 510,000 hits per month.

A new NCEA Internet web site (home page shown) will be available to users soon. The contents of the website is dynamically created from the Environmental Information Management System (EIMS) database. The new website features improved search capability and also allows multiple

NCEA personnel to create web information, while maintaining appropriate management control. The NCEA Science Inventory (products, data, and tools) are continuously loaded into EIMS and thus available via the public website.

Benchmark Dose Software (BMDS) -- One example of an NCEA product on the website that illustrates the success of the Internet as one communication approach, is the Benchmark Dose Software (BMDS) Development, Maintenance, and User Support The primary purpose of the BMDS project is to develop software to support Agency risk assessors in their analysis of the kinds of dose-response data that are used by EPA to assess the health risks of pollutants. BMDS has been used within several EPA program offices to estimate benchmarks such as cancer slope factors, reference doses (RfDs) and reference concentrations (RfCs), which are used along with other scientific information to prioritize Agency efforts, set standards and establish regulations. BMDS can be used for other purposes, however, as illustrated by the fact that its customer base has recently expanded to over 1,200 registered non-EPA users in over 70 countries.

PROFESSIONAL SOCIETIES

NCEA scientists are members of various professional societies, as well as officers in some. These societies have annual meetings, some on a very large scale, such as the Society of Toxicology's conference which is attended by scientists from all of the world. These national meetings, where NCEA scientists are often key note or plenary speakers, leaders of panel discussions, or presenters of several topical papers, are excellent opportunities for showcasing the exceptional work being done in the Center.

PEER REVIEWED JOURNAL ARTICLES

Another method of communication is through articles by NCEA scientists appearing in peer-reviewed journals. NCEA scientists also serve on the editorial boards of prestigious journals. In fact, an NCEA scientist is the current "Area Editor for Ecological and Environmental Risk Assessment" for the journal *Risk Analysis* and another NCEA scientist is an Associate Editor for Ecological Risk Assessment for the journal *Human and Ecological Risk Assessment*.

The following table shows the number of journal articles for NCEA scientists for a six year period. The table also includes other useful information on NCEA products. It should be noted that this table includes only those products/activities reported to NCEA's Technical Information Management Staff. Some of the numbers, particularly the numbers of presentations, may be under-reported. However, the table does illustrate the involvement that NCEA scientists have in outreach to the science community.

Year	criteria docs/ assessments/ tox reviews	journal articles	book chapters/papers/ presentations/ proceedings	other reports (including guidelines/ methods)	computer programs/ software/models/ databases
1995	3	13	3	20	0
1996	2	39	12	13	1
1997	6	37	29	7	1
1998	13	39	18	23	2
1999	3	42	27	30	2
2000	18	60	21	15	3

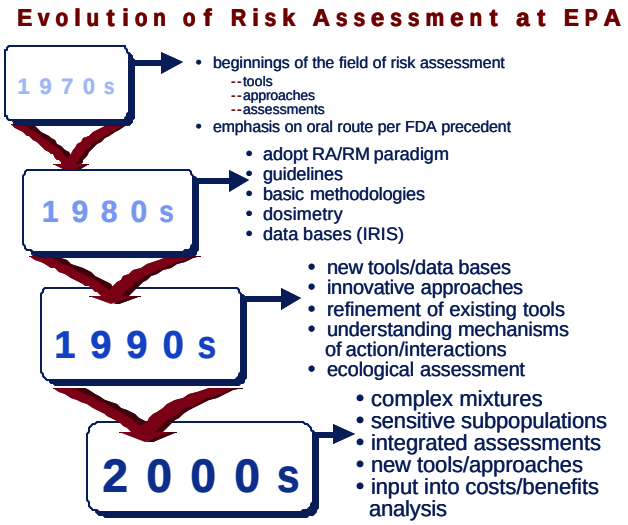
NCEA in the NATIONAL MEDIA

While not an avenue for communications actively sought by NCEA scientists and managers, NCEA does get more than its fair share of local and national media attention. In the Daily Environment Report, in the Risk Policy Report, InsideEPA, and other environmentally- focused medium, NCEA's activities are often the subject of several stories. NCEA's activities are also often the focus of stories in the national media and usually "above-the-fold." These include diesel, dioxin, MTBE, arsenic, perchlorate, lead, and several more.

C. *Where do you need to improve? What are the problems and challenges that you face in the next five years?*

As shown in the illustration, the science of risk assessment has evolved from its earliest days. Even since the publication of the NAS's, "Risk Assessment in the Federal Government: Managing the Process" in 1983, the field has changed greatly. It has even made important strides since the 1994 NAS report. Meeting these challenges in the science of risk assessment and the needs of the Agency, while also addressing the challenges of workforce planning in the coming years, will be an important and difficult task for NCEA management, scientists, and administrative staff.

NCEA's research program and research management has improved since the 1997 BOSC review. However, there are still areas where NCEA specifically needs to improve.



Communication: NCEA recognizes that one of the areas that requires improvement remains client and stakeholder outreach and communication. NCEA knows that it is of great importance but we have not dedicated staff for these activities. NCEA is a small organization, yet reports on NCEA's products and activities frequently appear in the national media. In addition, while NCEA has 10% of ORD's staff and 8% of ORD's budget, NCEA produces over 66% of ORD's category 1 and 2 documents[1]. NCEA is a very productive organization, a message that senior management would like to share by effective and continual outreach to clients, stakeholders, and interested public. NCEA would like to be more proactive about getting information out about its activities and products, rather than simply reacting to national media reports.

Partnerships: NCEA also recognizes the benefits of developing additional research collaborators and partners. To date, we have not invested enough in this area. However, there are potential research collaborators on complex environmental health and ecological issues that NCEA needs to identify. NCEA needs to build partnerships with other research organizations that would leverage existing expertise, provide development opportunities for scientists in both organization, and improve the ability to address all components of a complex environmental or ecological issue. A key issue in developing partnerships is that NCEA needs stable resources so

[1] **Category 1:** Major scientific or technical work products that support important decisions or have special importance in their own right; large scale public peer review with external experts
Category 2: Major work products that are less complex, novel, or controversial or have a lower impact; lower profile peer review such as letter review

ensure that NCEA is able to meet its commitment to a partner. Also, there may be some opportunities for staff training in methods and approaches on how to accomplish this goal.

Integration: As discussed earlier, "integration" is one of ORD's strategic priorities. In the context of ORD-wide activities to improve integration, NCEA's challenges are to clarify the role of risk assessment within the ORD organizational paradigm and to incorporate that role into the multi-year plans (MYPs) now being developed. These MYPs will go a long way towards solving the problems noted in the past concerning forming cohesive and focused objectives. Some of these difficulties can be attributed to the fact that the previous planning process allowed uncoordinated projects across the labs and centers, that did not result in complete and transparent programs. Where NCEA and ORD need to improve is not only in understanding the dependent nature of the risk assessment/risk management paradigm in the context of research planning, but in embracing the full paradigm and developing a planning process that intrinsically links one component of ORD to the other.

For example, a simple scenario can be developed that illustrates the links, although an actual case is always more complicated. The scenario goes as follows.

1. The Agency has a critical research priority.
2. In consultation with clients and, perhaps, with other federal research partners, a research needs/problem formulation is developed.
3. This results in data gathering.
4. The analysis of the data results in a risk assessment that because of the weaknesses/gaps in the available data set, includes the use of standard defaults and many uncertainties.
5. A research needs chapter or separate document is prepared as part of, or closely following, a competed assessment.
6. Based on the information known and the risk characterization analysis, the risk management options are presented to the client.
7. Then, in order to reduce uncertainties and decrease the reliance on standard default assumptions, the research program of the data gathering laboratories is aligned around the research needs delineated in the research needs document.
8. This results in data gathering.
9. The analysis of the data results in a risk assessment that now reduces the Agency reliance on standard defaults and reduces uncertainty, which leads in turn to fulfilling the goals of "credible science."

The cycle would continue, strengthening the science at EPA that is the foundation of agency regulatory decisions and resulting in better supported risk management options. As MYPs are completed and integrated planning becomes routine in ORD, NCEA will be a better performing organization and a better partner with its EPA and federal colleagues.

D. *What are the 3-5 most serious problems identified in the first BOSC review? How have you responded to these problems and the BOSC recommendations related to it?*

1. *BOSC 1997: Place a greater emphasis on understanding the expectations of its clients, including those at the Assistant Administrator level, and then work to ensure that NCEA initiatives are in place to fulfill those needs. To ensure that NCEA is successfully satisfying its various clients, a comprehensive client-based evaluation of both NCEA program support and its Director's leadership should be initiated.*

NCEA Response: Working to enhance its interactions with its clients in ORD and within the Agency has been, and will continue to be, a priority for NCEA. Historically, annual program reviews with the Office of Air, Office of Water, etc. and regularly scheduled general meetings with senior media program managers and with staff at the Assistant Administrator level help to communicate these kind of understandings. However, the BOSC's recommendation to work to enhance these interactions and consultations was appropriate and well-taken. These interactions provide an opportunity for clients to inform NCEA of their long-term priorities and needs, while giving NCEA an important opportunity to inform clients about NCEA's unique capabilities. The NCEA Acting Director has instituted a regular program of face-to-face "check-in" meetings with client offices. These have proven useful and successful as they satisfy the needs of both NCEA and the client office to offer guidance, concerns, and insights into Agency directions and policies sometimes outside of both parties immediate control. As NCEA's strategic plan unfolds, it becomes more important to understand and incorporate client's long-range priorities so that NCEA can plan strategically to meet those needs, particularly regarding personnel and resources.

However, as to the recommendation to conduct a comprehensive client-based evaluation of both NCEA program support and its Director's leadership, NCEA has not yet undertaken the broader and more formalized client-based evaluation that the BOSC recommended. NCEA has been exploring approaches to respond to this recommendation and is committed to developing an approach, perhaps involving input of an extramural expert in the field of organizational benchmarking, in 1999. In addition, NCEA staff have taken "customer satisfaction" training to better assess, as a team, how well NCEA client needs are being met.

2. *BOSC 1997: Set a goal to reach closure for all projects NCEA initiates within preplanned time projections.*

NCEA Response: Many of the chemicals/agents or place-based risk assessments, methodology development, and risk guidance activities underway or planned in NCEA are complex, multi-step, multi-year projects. Most require several major document review steps that may include internal peer review, external peer review, Science Policy Council review, and/or review by the Agency's Science Advisory Board. The BOSC recommended that all projects should be planned with clearly delineated deliverables. This has been an area where NCEA had already begun to make some improvements, and acknowledges the BOSC's recommendation for greater emphasis in this area. In addition, the Government Performance and Results Act (GPRA) has refocused efforts in all organizations in the government towards well-defined goals and milestones in all projects for each fiscal year. The clearly

delineated Annual Performance Goals (APGs) and Annual Performance Measures (APMs) for NCEA assessment activities will go a long way to address this recommendation. Another example of accountability for projects and products is that the design of NCEA's Internal Grants Program also requires linkages of proposed research to APGs and specification of interim milestones and ultimate products useful in characterizing appropriate APMs under GPRA.

3. *BOSC 1997: A significant BOSC concern was that NCEA is a mile wide and an inch deep. In the Executive Summary of the 1997 BOSC report, the BOSC said,*

> "The NCEA vision is to become recognized within ORD and the Agency as "The Risk Assessment People." Although this vision appears to be bold, it will likely provide significant value to ORD if attained. The Subcommittee offers several recommendations that, if implemented, may promote NCEA as an effective Center supporting the accomplishment of the ORD Strategic Plan.
> NCEA must develop its own strategic plan that provides both focus and balance in support of the ORD Strategic Plan. Of particular importance is the recognition that NCEA is currently under-resourced to support ecological risk assessments, and that at present too much of NCEA*s efforts are directed to "crises," or short-term projects. Given that NCEA is a relatively small resource within ORD, it must develop a plan that reflects its ability to function as an expertise Center, serving ORD and other EPA Offices primarily by acting as a catalyst for generation of scientifically credible risk-assessments. It must develop an operational paradigm that permits it to evolve as a leader for excellent science and service across the spectrum of its Agency clients, and not as a primary "doer" of standard risk assessments."

NCEA response: The above paragraphs from the BOSC's report address the overall recommendation that NCEA should better focus its program and address the general concern by the 1997 panel that NCEA is "a mile wide and an inch deep." Many of the specific BOSC recommendations in the 1997 report were meant to help NCEA begin to remedy the BOSC's concerns and help NCEA meet its goals and the goals outlined in the ORD Strategic Plan.

In fact, major points in the above paragraphs have been effectively addressed since the BOSC's first review.

1) NCEA's 2000 draft Strategic Plan helped NCEA to focus on human health, ecological risk assessment, information management, and administrative management, and divest resources from the area. Since then, NCEA has dropped information management as a focus area to concentrate on science areas of human health, ecological risk.;

2) NCEA's ecological risk assessment program has grown considerably.

3) NCEA has generally divested itself of being the "primary 'doer' of standard risk assessments."

However, NCEA's family of acknowledged experts is still a victim of Agency crises and fire drills. Often NCEA staff and managers get pulled off of their projects of record to work on special projects that get raised to a higher profile because of Congressional interest, an article or story in the

media, or a piece of incoming correspondence. These special projects add to the perception that NCEA is unfocused in its choice of projects and objectives.

Further, the ecological risk program has evolved from a mixed and disassociated collection of small projects to a targeted emphasis on invasive species, global change, and community-based ecosystem protection. Within the health assessment area, NCEA has focused on large-scale assessments of national interest (dioxin, diesel, butadiene, trichloroethylene, and particulate matter) that often times include innovated and precedent setting risk assessment approaches and methods.

In the 1997 BOSC review, NCEA presented itself as "the Risk Assessment People"; we were going to be the Agency's risk assessment office. In part, this vision concept added to NCEA's lack of focus. NCEA has gone a long way in moving towards being known as a *Center of Expertise* that provides the guidance, methods, and approaches that allow others to do the standard assessments and for NCEA to tackle the cross-Agency, high-profile assessments and issues where these new guidances, the methods, and approaches are developed.

Nevertheless, NCEA realizes that additional work need to be done on focusing NCEA's research portfolio. However, at every opportunity NCEA is trying, through the Research Coordinating Teams, the MYP process, our annual operating plan discussions, and discussions with clients and partner to identify distinct and focused objectives that meet the goals of the ORD Strategic Plan and needs of the Agency.

3. PERFORMANCE

A. *What other research organizations (U.S. or international) are similar in purpose and operation? How does NCEA's performance compare to theirs (bench-marking)?*

The breadth and depth of NCEA's mission makes NCEA a unique organization. No other organization has responsibility for both health and ecological risk assessments, for both developing risk assessment methods and applying them, and for both conducting risk assessments and serving as a consultant and educator for others on the use of science in environmental decision making.

Several statutes that are administered by EPA require EPA to conduct risk assessment. NCEA, through the Risk Assessment Forum, does attempt to foster internal scientific consensus on risk assessment issues within EPA and to be sure that this consensus is incorporated into risk guidance.

In the United States, other federal agencies also conduct risk assessments in furtherance of their missions. Although there is no precise consistency in their approaches, those that do chemical risk assessment generally have adopted procedures of various degrees of consistency and transparency based on the four-step process recommended by NAS. Each agency has adapted the steps to the needs imposed by their interpretation of their regulatory authorities.

Although the recent GAO report on Chemical Risk Assessment (*Chemical Risk Assessment: Selected Federal Agencies' Procedures, Assumptions, and Policies* - GAO-10-810, August, 2001) compares aspects of chemical risk assessment procedure among several agencies, it deals only with the chemical risk assessment aspect of NCEA's operation, and does not establish performance measures or make performance comparisons.

Similar observations about Ecological Risk Assessment would be appropriate. Other federal agencies also conduct ecological risk assessments. The Endangered Species Act, for example, requires probabilistic "likelihood" analyses of species potential for extinction. This has led other agencies (e.g., NMFS, FWS) to develop risk assessment methodologies to address their statutory responsibilities, but their approaches are not necessarily consistent, methodologically compatible or comparable to each other or to EPA.

The topic of ecological risk assessment was most thoroughly addressed by the White House Office of Science and Technology Policy document *Ecological Risk Assessment in the Federal Government* (Committee on Environment and Natural Resources of the National Science and Technology Council, May 1999). Although this document concluded that the EPA ecological risk assessment paradigm constituted a common scientific base for all the agencies, it made no attempts at making performance comparisons or developing performance measures.

Thus, selected elements of NCEA functions exist in various places elsewhere in the federal government, but nowhere else is there an assemblage of these functions. In this role, as a nexus for risk based scientific activity, NCEA is unique.

To date, NCEA has engaged in no formal attempts at articulating such evaluative processes or operations, developing specific performance measures, or benchmarking NCEA performance against that of other organizations.

NCEA believes that such a broad evaluation process, leading to some sort of agreed upon uniform consistent standards or methods of performance measurement would be a salutary effort, in no small measure because the effort itself would be so broadly scrutinized as to effectively yield "self correcting" results. This would, however, be no easy task, given the differences in underlying statutory mandates. Even the Society for Risk Analysis, an independent professional organization, has been unable to generate agreement upon consistent definitions in a field in which semantics are of considerable significance.

Identifying those aspects of NCEA's activities with potential for benchmarking, and then establishing benchmarking criteria, could be a useful, although substantial scientific exercise. Nevertheless, benchmarking opportunities could include the following NCEA functional areas and operations:

1. **Conducting human health risk assessments.** Three organizations that conduct and publish scientific health reports/studies are the National Toxicological Program (NTP), the Agency for Toxic Substances and Disease Registry (ATSDR), and Toxicology Excellence for Risk Assessment (TERA). Within EPA, human health risk assessments are conducted by the program and regional offices (following Agency guidelines that NCEA had a major role in completing). Other federal agencies conducting human health risk assessments include the Occupational Safety and Health Administration and its research arm, the National Institute of Occupational Safety and Health (OSHA/NIOSH) and the National Institutes of Health (NIH).

2. **Conducting ecological risk assessments.** EPA's program and regional offices conduct ecological risk assessments using Agency guidelines that NCEA had a major role in completing. These guidelines are also used extensively by other agencies and organizations.

3. **Developing scientific methods, models and guidelines.** NCEA has played a lead role in development of numerous important risk assessment methods and guidelines extensively used by EPA and /or serving as key inputs to analogous methods or guidelines adapted for use by international organizations, e.g. the World Health Organization (WHO). A few important examples include: exposure assessment guidelines/ exposure factors handbook; cancer assessment guidelines; and "RfC" and "RfD" methodologies for assessing non-cancer health effects. Still, NCEA could nevertheless learn from the efforts of other organizations that have analogous functional responsibilities for development of risk assessment methods, models, and guidelines.

4. **Disseminating scientific results (broad external communications).** Communicating results and stimulating application of results is a critical function for any research organization. NCEA could learn from organizations which are particularly effective in these areas.

5. **Consulting with or advising decision makers (risk managers).** NCEA scientific managers and/ or scientific staff are frequently called upon to consult with and/or advise both U.S. EPA and non-EPA decision makers on many different issues addressed by NCEA assessment activities. Some recent important examples include consultation/ advice regarding MTBE and potential alternative oxygenate fuel additives, airborne particle exposure/ health effects: and global climate change issues. Again, NCEA could still learn from other scientific or technical consulting organizations that provide consultation and advice to decision makers.

6. **Identifying and communicating unmet research needs.** ORD's risk paradigm organizational structure implies a role for NCEA in identifying research needed to reduce uncertainties described in specific risk assessments and, indeed, NCEA plays an important role in doing so by a variety of ways. These include, at times, preparation of formal Research Needs Documents, as are done following periodic revision of air quality criteria documents for major air pollutants such as ozone and particulate matter. They also include inputs from NCEA scientific experts on development by NCER of Request for Applications (RFAs) or their conduct of relevancy reviews for extramural grant proposals on topics related to ongoing and/or future NCEA assessment responsibilities. Also, NCEA Assistant Directors for Planning provide important inputs to budget decisions affecting research planning by all ORD laboratories in identifying salient research needs as part of RCT discussions.

7. **General research management** (priority-setting, budgeting, accountability, peer review, training, travel, awards, etc.). Many research organizations could serve as models for NCEA to improve in these areas. NCEA, in addition to carrying out risk assessments, does conduct some limited, highly targeted research efforts aimed at reducing key uncertainties identified in the preparation of risk assessments. Such research addresses a variety of issues across the entire exposure-dose-effects framework for human health and ecological effects. Many research organizations could serve as models for further improvements by NCEA in the planning and conduct of such research.

8. **General administrative management** (all NCEA "business" functions). NCEA's "Administrative Management Strategy" identifies eight functional areas and establishes processes for evaluating and improving them, including setting service standards and benchmarking.

B. *Identify and discuss five cases where there has been a need for NCEA's research in program offices or regions of EPA. Include 2-3 examples where this need has been met, and 2-3 examples where it has not. Why or why not?*

Case Studies: Particulate Matter Criteria Air Pollutant Hazard Assessment
Diesel Engine Air Emission Hazard Assessment
Cancer Risk Assessment Guidelines
Technical Support Centers
Genomics, and their relationship to risk assessment

There is a constant increase in available studies of hazards and increasing sophistication sought in risk assessment, so at any point in time risk assessment involves judgment balancing the known and the uncertain and trying to help assessors, or users of NCEA assessments, to make informed decisions on their timetables. Because NCEA focuses on the assessment step of environmental research, it is conscious that research 'needs' are never fully 'met' – but in some areas there has been substantial work done to assess the state-of-the-science, and there are others where we have yet to provide that kind of research.

One of NCEA's missions is to provide EPA program offices with risk assessments on substances of high regulatory significance and great scientific complexity. Two examples of this for the EPA Office of Air and Radiation are the particulate matter criteria document and a hazard assessment on diesel engine exhaust emissions.

Particulate Matter Criteria Air Pollutant Hazard Assessment. The air criteria documents are a good example of integrated effort by EPA laboratories with an NCEA assessment as a central integrating point. This is an example of an area in which NCEA's research activities are very successful, although difficult sometimes to complete as the science keeps developing while EPA tries to take a sophisticated snapshot of its status on a fairly fixed schedule. Generally every five years the hazard assessments on the criteria air pollutants are revised because of a statutory requirement and because of the major health significance of these pollutants and the economic significance of actions for their control. After the completion of an assessment (or during its completion), the process involves an identification of further research that could refine our understanding of the hazards of the pollutant, support of that research by EPA laboratories and other entities, the collection of the new science, and then the assimilation of the new scientific studies into a new revision to the criteria pollutant. The particulate matter criteria document has been a recent major focus of NCEA. A draft of the latest assessment of particulate matter was recently reviewed by the Clean Air Science Advisory Committee. Development was complicated by the late publication of several key studies that EPA wanted to rely upon (e.g. the Harvard Six-Cities Study reanalysis). In addition, an extraordinary number of studies on PM have been published since the last update.

Diesel Engine Air Emission Hazard Assessment. The diesel engine exhaust hazard assessment is an example of meeting a need for an EPA regulatory program even while continuing to refine the scientific assessment document to further address comments raised by EPA's Clean Air Scientific Advisory Committee (CASAC). It looks like this will also prove to be an example of a success in providing the health assessment needed by an EPA program office, although there is on-going litigation as to whether the assessment was sufficiently complete for the regulatory action. Diesel engines have for years been regulated based on control technology and economic considerations. It became clear, though, that in order to advance to tighter regulatory levels and be more inclusive of various types of diesel emissions a case would have be made for the public health issue of diesel exhaust exposure. EPA had no such health assessment, and thus EPA's Office of Transportation and Air Quality asked NCEA for such an assessment. As a result of the need NCEA speeded up work on the assessment in such a way that the draft assessment and CASAC review would dove tail with an accelerated regulatory schedule, i.e., December 2000, for heavy duty diesel exhaust regulations. EPA completed a version of the assessment by July 2000, in time for its use in the December rulemaking. At the same time, NCEA agreed to address a number of issues raised at the CASAC review. NCEA is about to release a final assessment document that addresses those issues and is comfortable that this final version will support the regulatory strategy taken. While the immediate needs for EPA have been met, there is considerable interest in EPA's final assessment document at the State and local level.

Cancer Risk Assessment Guidelines. Our efforts to update the cancer assessment guidelines provide an example of a need for science and science policy guidance that has not been fully met to date. The efforts to update the Agency's 1986 cancer assessment guidelines have raised several controversial science and science policy issues. In attempting to resolve these issues, the Agency has sought out recommendations from the external scientific community, stakeholder groups and the Science Advisory Board. Regrettably a consensus has not yet been reached on some issues. A majority of the Science Advisory Board, recognizing this impasse, has recommended that the Agency consolidate progress to date, finalize the guidelines, and thru application of the guidelines continue to further refine the guidance. EPA's Deputy Administrator is directing the Science Policy Council to make decisions on the critical science policy issues and for these decisions to be reflected in the Risk Assessment Forum's final version of the Guidelines. NCEA will play a lead role in this final drafting, with an NCEA senior scientist working full-time on the project and NCEA staff coordinating the Agency-wide effort. Meanwhile, while final guidelines are not yet available, both EPA program offices and NCEA chemical assessment teams have often benefitted from the principles and approaches described in the draft guidelines and have incorporated some of the thinking into assessments that have been done. This experience in applying the draft guidelines will be an invaluable asset for the team completing the guidelines.

Technical Support Centers. The National Center for Environmental Assessment's Cincinnati division manages three technical support centers to assist EPA's Program and Regional Offices at Superfund and RCRA sites. They are:

Superfund Health Risk Technical Support Center (STSC)
ORD Combustion Technical Assistance Center (CTAC)
Ecological Risk Assessment Support Center (ERASC)

The following are examples of their assistance to the Program Offices and Regions:

1. In response to a request from the Superfund Program Office, NCEA verified the scientific validity the Mirex slope factor and provided assurance that the NTP Pathology Report used to develop that slope factor was free of real or perceived conflict of interest. This was a Congressional request to the Superfund Program based on citizens' comments on the Mirex assessment developed for Region V Nease Chemical Superfund site.

2. NCEA's CTAC provided technical assistance and key scientific expertise to the development of the final draft of the U.S. EPA guidance entitled *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* (HHRAP) (EPA530-D-98-001A). This document was prepared by Region VI for use by the EPA, other agencies and stakeholders.

3. In response to a recent request, the STSC and the CTAC worked collaboratively to develop and externally peer review a provisional toxicity value assessment for chlorine. This was done based on a request from Region X for use at Kalama Chemical site. The Office of Solid Waste participated in the review of this assessment.

4. NCEA's ERASC responded to a request regarding the use and application of the Equilibrium Partitioning (EqP) approach in ecological risk assessment. After determining the magnitude of the need for this information, video teleconferencing was selected as the format for providing the information/training. Approximately 112 scientists participated in the video conference and received presentation materials electronically. The video conference represented a collaborative effort between NHEERL and the ERASC. The video conference was taped and will be distributed on a limited basis.

Genomics, and their relationship to risk assessment. Genomics, and more specifically, the incorporation of data from genomics into risk assessment, is an area where one EPA program office has recently expressed a need for research and where NCEA does not yet have an active program. At a recent internal meeting, several NCEA staff obtained a better understanding of the extent to which other EPA laboratories are using genomic techniques in probing issues related to toxicity. This is an evolving area where there are new techniques

potentially useful in probing any number of aspects of the hazard or risk assessment paradigm, and it is perhaps hard to judge at this point whether it will quickly shed useful insight into risk assessment issues or whether there will be many years during which it is a powerful basic research tool but not yet of major significance to risk assessments. In fact, one of the questions raised by an EPA program office is how to determine when a new finding based on genomics is in fact a significant new risk assessment finding. NCEA does not yet have a good understanding or a set of assessment practices for judging and incorporating the kind of information that may arise as the result of researchers using the evolving tools in this area. It is an area NCEA recognizes it needs to start learning more about, and needs to ascertain to what extent it should be a specific research interest for NCEA and/or a tool that all its researchers need to understand as it generates information of interest to the individual disciplines that go into a complex risk assessment. NCEA does have some senior scientists starting to learn about this area and in dialogue with other federal regulatory agencies who also need to understand this evolving area of scientific inquiry.

C. *Identify and discuss five cases where there has been a need for NCEA's research by stakeholders outside of EPA (e.g. other Federal agencies, state agencies, business, citizen groups, or other organization).*

Case Studies: Hazard Assessments under IRIS (Integrated Risk Information System)
Risk Assessment Research and Technical Assistance to States on Lead
Watershed assessments and lessons learned from them
Global Climate Change Assessment of the Great Lakes
International Risk Assessment Assistance

Hazard Assessments under IRIS. There has been considerable external interest in EPA keeping up to date its centralized assessment of the toxicity of chemicals of significant interest, the Integrated Risk Information System, or "IRIS". This is a repository for chemical hazard assessments that have been done by various parts of EPA which have undergone a consensus review such that all the EPA program offices have agreed that the assessment in IRIS is the hazard assessment upon which all the program offices will rely. External parties are interested in seeing this system maintained and current for several reasons. One is that various State environmental agencies (and EPA Regional offices) use the IRIS assessments as a convenient reference source for chemical hazard assessments both for state rulemakings and for a range of site-specific state decisions such as permit decisions or site cleanup decisions. Because of the important role of these chemical hazard assessments for EPA and state environmental decisions, other stakeholders, such as industry and environmental groups, have often expressed strong interest in seeing that EPA incorporate new data or new science policy or general scientific understandings into the assessment available on the system. NCEA has had success in revising and updating some of these assessments and in general finds high praise for the value of this system. At the same time, NCEA has found that the complexity of the assessments and the evolving sophistication of the risk assessment discussions has slowed the pace at which NCEA and other contributing offices can revise, update, and add to the system. Some program offices with programs that address a large number of toxic chemicals either in site-specific decisions, such as the hazardous waste remediation programs, or in large rulemakings, such as the hazardous waste regulatory program, can find it difficult to address comments raised on toxicity issues on specific chemicals, yet can find that some of the IRIS entries are not sufficiently up-to-date that they already provide a clear response to more recent studies relevant, or claimed to be relevant, to the toxicity of a chemical at issue.

Risk Assessment Research and Technical Assistance to States on Lead. Another research area of significant interest to State programs and other external clients (in addition to EPA clients) is work and technical assistance on assessing the risks of lead exposure. Staff in all three NCEA Divisions and the NCEA Immediate Office are actively contributing to the development, validation, and application of risk assessment tools for lead exposures for children and adults. As with many other NCEA projects, both internal EPA and external (particularly State) clients are very interested in these efforts and make requests for NCEA support. A principal mechanism for these efforts is NCEA's participation in the Technical Review Workgroup for lead (TRW), an inter-office scientific workgroup, convened by

OSWER and relying heavily on four members from NCEA. The TRW is responsible developing technical guidance on lead risk assessment matters for EPA Regions and Programs as well as for use by State Governments. The TRW also is responsible for review of site specific risk assessments for lead contaminated sites (developed and/or referred by EPA offices and States). State clients, requesting assistance with particular lead assessment issues have included, for example, Utah, Ohio, and Texas. Lead contaminated sites often include substantial residential communities (e. g., neighboring smelters or other facilities) where both risks to health and cleanup costs may be very substantial. NCEA scientists had leading roles in the development of the IEUBK Model, the Agency's principal tool for lead risk assessment (per guidance memoranda issued by the Assistant Administrator for OSWER). See the TRW's web site www.epa.gov/superfund/programs/lead/index.htm for further information on risk assessment tools and guidance provided by the group. The IEUBK model also was a principal tool utilized in developing the Title 10 hazard standards for lead in paint, dust and soil (issued by OPPTS in 2000). Currently NCEA is working to develop an extended modeling tool for lead risk assessment, the All Ages Lead Model, that will allow a "birth to death" integration of lead exposures and support a broader set of lead risk assessment concerns.

Watershed and causal assessments. Watershed ecological assessments, and lessons from conducting those assessments, has been another area of research of strong external interest. EPA issued guidelines on ecological risk assessment in 1998. NCEA has also been working with partners to complete ecological assessments of several US watersheds (the Clinch and Powell Rivers in Tennessee and the Big Darby River in Ohio). These assessments and the lessons learned from them are of interest to the EPA, and can both provide the basis for EPA decisions on these watersheds and case studies to educate EPA personnel about watershed assessments in general or to test and develop methodologies. But, they are also of strong interest to other external parties. Protecting and restoring our nations streams and rivers requires coordinated action from many groups ranging from federal, state and local agencies to non governmental groups such as the Nature Conservancy to individual citizens. These groups can manage sources of stress such as runoff from fields or urban areas, or construction of roads and bridges. In addition, many groups can influence the management and installation of factors that can mitigate stress such as planting riparian vegetation or installing storm water ponds. By moving to more comprehensive assessments of all stressors impacting valued ecological resources, EPA can help ensure that money and effort are directed at the most important sources and stressors, and increase confidence that our actions will result in environmental improvement. By improving our understanding of how the economic, social, and regulatory contexts influence risk management choices, we can increase the efficiency and efficacy of these complex decisions.

In a recent effort, NCEA helped produce the Stressor Identification Guidance Document (published in January 2001), which was developed specifically to be used by the states to determine the causes of biological impairments in the TMDL process. In its short existence, it has already begun to be used for that purpose by states including Connecticut and Maine. In addition, because the inferential methodology is applicable to any assessment of the cause of

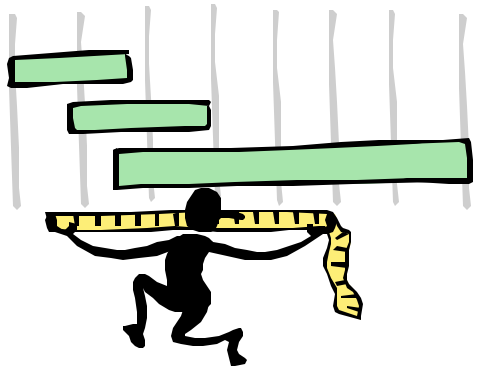
any observed ecological impairment, it is finding wider uses. The authors have learned informally that it is being used by environmental consulting firms for assessments of contaminated sites in the U.S. and Canada. In addition, at least one consultant is using it to help determine whether fish population declines are caused by power plant entrainment and impingement.

Global Climate Change Assessment of the Great Lakes Region. The Great Lakes Regional Assessment of the Potential Impacts of Climate Change has generated considerable outside interest. The Great Lakes assessment, like all of the regional assessments conducted in the global program, is conducted through a public-private partnership that engages researchers from the academic community, decision makers, resource managers, and other stakeholders in the assessment process. This assessment examined the potential consequences of changes in climate and climate variability for the region's agriculture, water resources, ecology, economy, and quality of life. The results are of interest to state and local governments, businesses, and individuals. For example, the report investigated the impacts of recent low lake levels on commercial shipping and recreational boating and examined the ameliorative or exacerbating effects of climate change. The availability of the lakes for commerce and recreation is of tremendous importance to the region, as evidenced by the participation at a workshop on the topic hosted by EPA/ORD and EPA/Region 5. The participants included marina owners, academics, private citizens, and representatives from the marine transport industry, environmental organizations, shipping associations, state and local environmental agencies, and federal agencies, all of whom came together to discuss how changes in the lakes were affecting them and to begin to think about how they might respond. Examples of regional legislative responses include bills to create a climate change damages fund in Wisconsin and efforts by U.S. states and Canadian provinces to tighten rules on the export of Lakes water to other parts of the United States.

International Risk Assessment Assistance. Finally, NCEA provides support to various international entities. NCEA experts support work in risk assessment harmonization for the International Program on Chemical Safety (IPCS). NCEA also develops and reviews Concise International Chemical Assessment Documents and Environmental Health Criteria Documents for IPCS. NCEA supports work of the World Health Organization through cooperative agreement in areas such as the environmental burden of disease, air quality guidelines, and health effects of global climate change. Experts in NCEA also provide direct help to foreign governments in several areas such as understanding air quality and drinking water risks for the development of regulatory programs in those countries. NCEA scientists provided information in support of U.S. delegations to international treaty negotiations, such as the POPs Convention.

4. MEASURES OF SUCCESS AND FUTURE NEEDS

A. *How do you measure the efficacy and results of NCEA's performance? Target indicators? Metrics of success? Show quantitative measures of performance.*



NCEA collects few direct measures of staff and organizational performance. However, NCEA does recognize that it should do a better job of measuring and quantifying its client's and user's successes and difficulties with NCEA's products and measuring performance and the ability of NCEA "to make a difference." (Also see Chapter 3, Response to Question A). This is an area with which we welcome specific suggestions from BOSC members.

1. **Evaluation of Results, Products, and Services.** All NCEA products receive thorough peer review following established Agency guidelines. Peer review is an effective mechanism to evaluate overall quality and potential usefulness; however, peer review is typically not used to evaluate the efficacy, effectiveness, or impact of a research or assessment product. Appendix III is a listing of NCEA's cleared products for FY 2000 which includes identification of each product's review category.

   In striving to be a high performing organization, NCEA uses various qualitative measures of the efficacy and impact of research products. Most effective is the direct feedback and comment we receive from various clients. The Office of Air and Radiation (OAR), for example, typically provides very positive comment on the air quality criteria documents produced by NCEA. We also receive feedback on research products as part of our activities in the ORD planning process through the research coordination teams (RCT) and multi-year planning (MYP) teams. For example, as ORD managers and planners deliberate on those ORD-wide projects that will receive funding for each fiscal year, NCEA's proposed activities are almost always placed high in the final ORD priority ranking scheme.

   Few quantitative measures are currently employed to evaluate the efficacy, effectiveness or impact of NCEA research results or products. One measure of usefulness is the various metrics for our Internet web site at *www.epa.gov/ncea*. This site is one of the most often accessed Agency sites. Current statistics (August 2001) indicate that the web site supports an average of over 16,000 page requests per day, resulting in a transfer of an average of 990 Mbytes per day.

   We have learned about additional metrics that might be used to evaluate the efficacy and impact of NCEA research products. These include various bibliographic metrics (citation frequency, impact on field, etc.) to evaluate NCEA publications. We welcome suggestions from BOSC

members concerning additional metrics we might employ.

2. **Organizational Performance.** Organizational performance for NCEA and other ORD organizations is measured annually through the use of the ORD Organizational Climate Survey. The Climate Survey provides various measures of organizational performance such as: trust, responsiveness of management, respect and collegiality in the workplace, available resources, etc. Generally, NCEA compares favorably with other ORD Centers, laboratories, and offices. The most recent survey revealed serious issues in several NCEA subcomponents that will be addressed in NCEA's FY02 improvement plan.

   We realize that additional measures might be employed to evaluate organizational performance. These might include direct surveys of our collaborators in other parts of ORD or our clients in Agency Program Offices.

B. *How do you use research results to set new research priorities, plan research, and discharge your mission?*

NCEA realizes that research is an evolving process. The research results from current projects are used to stimulate ideas and generate proposals or strategies for future projects. In some cases, this introspection leads us to begin development of new research themes. NCEA's exploration of the integration of human health and ecological risk assessment approaches, and the integration of social and behavioral dimensions into ecological risk assessments, are examples of two evolving new research themes for the Center. A 2001 framework report by the World Health Organization, which includes an NCEA scientist as the lead author, entitled "A framework for the integration of health and ecological risk assessment," is a useful paper on this area. In other cases, the evaluation of the products of current projects leads to plan future projects that expand or enhance.

Two examples are provided of projects that developed from the need to enhance previous projects. Both examples represent components of NCEA's growing ecological risk research efforts.

Ecological Risk Assessment Guidelines, 1998. The first involves NCEA's continued interest in refining and providing example use of our ecological risk assessment guidelines. These guidelines outline and provide guidance for conducting ecological risk assessments. Problem formulation is the first step and includes working with stakeholders to identify the problems and questions of interest and developing a conceptual model to be used in the subsequent step of risk characterization. When originally developed and tested, the guidelines were adequate for site-specific risk assessments. However, with an increased emphasis on regional or watershed scale risk assessments involving multiple stressors, NCEA risk scientists and members of the risk assessment community, thought that existing guidance for problem formulation would need to be expanded. This need lead to the development of an NCEA funded and coordinated workshop, which subsequently lead to the publication of a 1999

workshop report entitled, *Workshop Report on Developing a Problem Formulation Process for Large Spatial Scales*, that provides additional guidance for completing the problem formulation stage of a regional-scale ecological risk assessment.

Aquatic Stressor Identification Research. The second example is related to our ongoing aquatic stressor identification research - a project highlighted in other sections of this report. Our stressor identification research started as a way of providing guidance for how to diagnose the probable causes of aquatic resource degradation. This guidance was then tested with multiple case studies to evaluate the general applicability of the guidance. Support for the guidance from the Office of Water and state aquatic scientists was very positive; however, potential users of the guidance at the state and local levels requested that the stressor diagnostics work be expanded and that the information be packaged in the form of a decision support system. Consequently, NCEA jointly with collaborators in NERL, are moving forward with the development of a decision support system to aid aquatic resource managers with diagnosing the probably cause of aquatic degradation.

C. *Are the human resources at your disposal appropriate for your mission, goals, and objectives?*

Future environmental issues

- GIS/Spatial analysis
- Risk assessment methods
- Microbiology
- Genomics/proteomics
- Systems ecology
- PBPK modeling
- Statistics
- Nanotechnology
- Socio-Economics
- Bioinformatics

Like many other federal organizations, NCEA has many demands placed on a finite staff. In general, NCEA's human resources are commensurate with current expectations. To maintain its historically high level of productivity, NCEA is using various personnel authorities to bring in new talent and to strengthen the effectiveness of operations.

NCEA's ability to expand into new research areas is limited by the low turnover rate of scientific staff and by the impracticality of having distinguished senior scientists with long careers in one discipline or subject area shift into new careers in other disciplines or topical areas. Without new resources or large turnover in staff, it is exceedingly difficult to move into new emphasis areas of likely longer term significance. Examples are microbial risk (drinking water), aggregate and cumulative risks (including mixtures), and genomics and proteomics. The table at right includes some of the research areas that have been identified as growth opportunities.

One factor which is likely to provide a challenge is the large number of NCEA retirements on the near horizon, as shown in the following table. Within the next five years, about 25 per cent of the NCEA workforce will become eligible to retire.

NCEA Associate Directors working with Science Council looking at demand for "new" science capabilities

- ✓ *NCEA's Strategic Vision for Succession Planning:*
- ✓ *Hire strategically (Guidance: ORD and NCEA Strategic Plans)*
- ✓ *Use opportunity to develop centers of expertise*
- ✓ *Focus FTE on strategic priorities*
- ✓ *Continue to build the ecological risk assessment program (from <5 in 1995 to 27 in 2001)*
- ✓ *Look for health and ecological integrators*
- ✓ *Use opportunity to enhance diversity*
- ✓ *Utilize rotational and developmental opportunities*
- ✓ *Emphasize entry-level scientists*
- ✓ *Grow and develop with the organization*

As mentioned above, NCEA has used several flexibilities in the federal personnel system to bring in new talent and expertise. Examples include the Post-Doctoral Program, AAAS Fellows Program, ORISE Fellows Program, EPA Environmental Intern Program, International Visiting Scientist Program, Intergovernmental Personnel Act Program, and various details and rotational assignments.

NCEA's succession plans:

- *Formative study to frame the topic*
- *Strategic workforce planning workshop*
- *Hire strategically to address future environmental issues*
- *Forum's Distance Learning Initiative for Risk Assessment*
  - Significant turnover in risk assessment "brain trust"
  - Need to capture expertise
  - Forum is moving to web-based distance learning
  - Internet pilot to provide self-paced training on the application of the Agency's ecological risk assessment guidelines
- *Risk assessment methods workshops (to pass on to the next generation the expertise developed in NCEA since the 1970s)*

NCEA's Postdoctoral Program

- *FY02 ceiling; 5 FTE*
- *FY2001 Post Doc Program decentralized to NCEA Divisions*
- *NCEA Post Docs Mentoring Program in place*
- *Hiring Plans:*
  - Improve diversity
  - Improve outreach to local universities
  - More aggressive candidate search

NAME	START	EXPERTISE	RESEARCH AREA/LOCATION	STATUS
Janet Gamble	99	Economics	Global Change/IO	Permanent hire
Catriona Rogers	99	Env. Eng	Global Change/IO	Permanent hire
Scott Kegler	00	Statistics	Air/RTP	Left voluntarily (family)
Lester Yuan	01	Env. Eng	Eco Risk/ DC	On Board
Lillian Wolfenbarger	01	Ornithology	Eco Risk/ DC	Left voluntarily (family)
Amy Grady	01	Statistics	Air/RTP	On Board
Matthew Heberling	01	Economics	Eco Risk/Cin	On Board
Michael Griffith	01	Ecology	Eco Risk/Cin	On Board
Kathleen Walker	01	Ecology	Eco Risk/DC	On Board

NCEA's Staff Eligible to Retire*

Of 176 current personnel:	*2001*	*2006*
• Assessors	8	19
• Admin Mgmt. Staff	1	16
• Managers/Execs	1	9
***estimate**	**10**	**44**

Other Mechanisms for Enhancing NCEA's Human Capital

- American Association for the Advancement of Science (AAAS) Program
  - *Begun in 1996-97*
  - *On average 5 Fellows in Washington in any year*
  - *Working to encourage movement of AAAS scientists into the ORD Post Doc Program*
    - 4 Fellows have been hired as Post Docs
    - One former Fellow, Bruce Rodan, is now a senior scientist and program leader
- Rotating Medical Residents
  - *Five participants in last two years*
  - *Current Resident from George Washington University, pediatrician, started September 7, 2001*
  - *Working on Children's risk issues*
- Visiting International Scientist Program
  - *Started in 1998*
  - *Four international scientists have rotated through NCEA (one per year)*
  - *Current scientists; Andrea Gondova, Slovakia (Area: genetically modified organisms)*
- Environmental Intern Program
  - *NCEA is ORD's lead for FY 2001*
  - *Highly qualified graduates or returnees from Peace Corps, Vista, etc.*
  - *Opportunities to enhance diversity*

D. *Do you have the appropriate mix of work force, facilities, and infrastructure to plan, prioritize, implement, and communicate your results?*

NCEA's facilities and infrastructure are adequate. Planning is well underway for new space for the RTP and Cincinnati divisions, and the Washington division and Immediate Office continue to enjoy their 17th Street location. Further, NCEA is justifiably proud of its advanced computer support, including local area networks, servers, GIS capabilities, and computer hardware and software.

Regarding adequacy of its workforce, NCEA takes pride in our productivity and successes. The discussions around this question area should be made in light of the following information:

- NCEA current personnel strength is 176 employees located in three cities (Washington, Research Triangle Park, NC and Cincinnati, Ohio)
- NCEA has 10% of the ~1800 ORD employees or 1% of EPA employees
- NCEA has ~8% of the ORD budget yet produces over **b** of category 1 and 2[1] products

- The potential for employee turnover due to retirements is great.

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[1] **Category 1:** Major scientific or technical work products that support important decisions or have special importance in their own right; large scale public peer review with external experts
Category 2: Major work products that are less complex, novel, or controversial or have a lower impact; lower profile peer review such as letter review

NCEA's efforts to improve the productivity of its workforce include:

- encouraging staff interactions with other offices of ORD and Agency
- acquisition of additional scientific expertise (statistics, genomics, etc.)
- enhanced social skills (team training, conflict management, appreciation for diversity, etc.)
- strengthened internal and external communications (awareness, education and outreach).
- reorganization of immediate office to balance reporting relationships
- reexamine allocation of supervisory positions across NCEA (total number limited by EPA rule)
- continue to clarify staff roles and responsibilities.