BOARD OF SCIENTIFIC COUNSELORS (BOSC) OFFICE OF RESEARCH AND DEVELOPMENT (ORD) UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (EPA)

PROGRAM REVIEW OF THE NATIONAL CENTER FOR ENVIRONMENTAL RESEARCH AND QUALITY ASSURANCE (NCERQA)

Final Report of the Ad Hoc Subcommittee on the Review of NCERQA

April 30, 1998

NOTICE

This report has been written as part of the activities of the Board of Scientific Counselors (BOSC), a public advisory group that provides objective and independent counsel to the Assistant Administrator for the Office of Research and Development (ORD) of the Environmental Protection Agency (EPA). The Board is structured to provide a balanced expert assessment of the management and operation of ORD's research programs and its utilization of peer review. This report has not been reviewed for approval by the Agency; and hence, the contents of this report do not necessarily represent the views and policies of the EPA or other agencies in the federal government. Mention of trade names or commercial products does not constitute a recommendation for use.

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PREFACE

The Board of Scientific Counselors (BOSC) provides objective and independent counsel to the Assistant Administrator of the Office of Research and Development (AA/ORD) on the management and operation of ORD's research programs. The primary functions of BOSC are to: (1) 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) evaluate and provide advice concerning the use of peer review within ORD to sustain and enhance the quality of science in EPA.

In fall 1996, Dr. Robert J. Huggett, AA/ORD, requested that BOSC conduct peer reviews of the ORD Laboratories and Centers. Accordingly, BOSC undertook the task of conducting programmatic, as opposed to scientific or technologic, reviews of the Laboratories and Centers and proceeded to establish policies and procedures for conducting such reviews. The scheduled reviews occurred as follows:

- National Exposure Research Laboratory, July 21-22, 1997, at Research Triangle Park, NC
- National Health and Environmental Effects Research Laboratory, August 4-5, 1997, at Research Triangle Park, NC
- National Risk Management Research Laboratory, August 18-19, 1997, at Cincinnati, OH
- ♦ National Center for Environmental Assessment, September 8-9, 1997, at Washington, DC
- National Center for Environmental Research and Quality Assurance, October 20-21, 1997, at Washington, DC

As constructed, the Laboratory and Center reviews are expected to lead to a better understanding of the strategies employed by the respective Directors in accomplishing their missions, and to a better understanding as to how these strategies are implemented. BOSC also expects to develop a clearer perspective on how effective these strategies are in causing the operation of the Laboratories and Centers to come into alignment with the strategic plan of the ORD.

Each Laboratory and Center review consisted of two parts. The first part was a written self-study submitted to the review committee in advance of the date of its review, and the second part was a 2-day site visit conducted by the review committee. In the self-study, Directors were asked to prepare responses to eight questions aimed at a programmatic assessment of the organization. During the first day of the site visit, the Director made a brief presentation about the organization and was then asked to respond to questions from the review committee about the self-study document. Later, case studies were presented that reflected how the organization successfully addressed a specific issue faced by the Agency. The first day concluded with breakout sessions attended by staff scientists and other professionals. On the second day, the committee drafted a report that contained its findings and recommendations. At the end of the day, an exit interview was conducted with the Director.

All review teams were organized as Ad Hoc Subcommittees of the Board of Scientific Counselors and were headed by a chair and vice chair, both members of BOSC. Additional members of the Subcommittee were selected on the basis of an appropriate technical discipline as well as having broad experience in science and research management, planning, and communication. The Chair of BOSC attended all reviews as an ex-officio member.

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1.0 EXECUTIVE SUMMARY

The U.S. EPA Board of Scientific Counselors (BOSC) has conducted a programmatic evaluation of the Office of Research and Development (ORD) National Center for Environmental Research and Quality Assurance (NCERQA). The review was conducted by a Subcommittee of the BOSC (hereinafter referred to as the "Subcommittee"), and included an assessment of a NCERQA Self-Study Report prepared for the review and a site visit at NCERQA offices on October 20-21, 1997. The review focuses upon issues of Center management, staffing, resources, and the quality and coherency of strategic plans and initiatives.

NCERQA plays a central role in the reorganized ORD, responsible for funding extramural research grants, fellowships, and centers. Also, it is responsible for guiding peer review and quality assurance (QA) efforts throughout ORD and EPA. Center management and staff have exhibited extraordinary creativity and hard work in initiating programs to accomplish this mission. NCERQA has grown rapidly in its programs and responsibilities; however, there has not as yet been a commensurate growth in its staff size and internal resources. It is not surprising then that difficulties have arisen in the implementation of some of the Center's initiatives. Further, internal planning as well as ORD and Agency support are needed to ensure that NCERQA can meet its important objectives of providing the EPA and the Nation with the highest quality and most relevant environmental science and engineering, along with effective and consistent programs for peer review and QA.

The report notes the critical need for NCERQA to develop a strategic and management plan to address staff and resource planning issues and processes for managing change in the organization. Particular management issues include workloads, the adequacy of space and infrastructure, and communication within the Center. High workloads and mismatches of skills among grant Project Officers are of particular concern, and they threaten to hinder the ability of NCERQA to provide effective tracking of awarded grants and the promotion of communication among researchers and EPA units in need of the research results.

NCERQA has initiated a number of innovative programs to improve the integration of research efforts and the communication of results to target audiences in the EPA and elsewhere. These include joint solicitations with other federal agencies and organizations; the Adopt-a-Grant program for ORD scientists; RFA-workshop, research-in-progress, and state-of-science reports; an awardwinning Web Site; and an ambitious communication plan. We support these efforts and recommend that the Center continues to expand cooperation and partnerships with other parts of ORD, EPA, and other federal, private, and international research organizations through joint solicitations, Web site links, and the exchange of research results. It is recommended that NCERQA also provide support for a set of pilot "Research Integration" projects designed to track the technical progress of individual grants within a Request for Application (RFA), foster ties with other organizations conducting similar research, and prepare state-of-science reports. This would help to facilitate research integration and the communication of results to others in the Agency. These projects could provide a possible testbed for allowing ORD scientists the opportunity to apply competitively for NCERQA support. Specific recommendations also are provided to the Center to expand RFA workshop proceedings to: include records of workshop discussions; require grant recipients to discuss the relevance of their research to EPA as part of their project summaries; prioritize target audiences for communications; and pretest communication instruments and products.

The QA and peer review activities of NCERQA are critically important for maintaining and improving the quality and credibility of science throughout ORD and EPA. To fulfill this potential, recommendations are provided to the Agency to: track and document the value-added of QA and peer review activities, ensuring that the benefits of particular procedures are commensurate with the cost and effort needed to implement them in the target areas of application; ensure the implementation of QA plans and peer review of research products; and clearly support and communicate the need for consistent policies for QA and peer review in both intramural and extramural research programs.

Recommendations also are provided in Appendix D of Section 5.0, on steps that could be taken to expand and better integrate social science research within NCERQA and ORD programs.

2.0 CENTER REVIEW

2.1 Introduction

The National Center for Environmental Research and Quality Assurance (NCERQA) plays a central role in the reorganized and refocused EPA Office of Research and Development (ORD). Major goals of the reorganization have included the promotion and reinvigoration of the quality of ORD science; ensuring participation by outside scientists of the highest quality based on open and highly publicized competitive opportunities; rigorous and independent peer review for selection among competing proposals; consistent quality assurance (QA) and followup to maintain standards; and greater integration with the rest of the Agency to ensure that the science is both useful and utilized. NCERQA, although smallest among the Laboratories and Centers, is the focal point for many of the new ORD initiatives to achieve these objectives. As the arm of ORD principally responsible for funding extramural research, and with responsibility to guide peer review and QA efforts throughout the ORD and the EPA as a whole, much of the burden for leading ORD in its new strategic direction falls on the Center.

Since its founding in 1995, NCERQA's budget has nearly doubled in size each year. This increase has been primarily within the extramural Science to Achieve Results (STAR) program, which accounts for 85 percent of the NCERQA annual budget. The STAR program supports 230 colleges, universities, and nonprofit centers across the United States. NCERQA administers 500 to 600 research grants and some 300 fellowships. It receives approximately 3,500 to 4,000 proposals each year, including direct proposals in research focus areas through RFAs (Request for Applications), Exploratory Solicitations, and Fellowship Applications. These go through a rigorous peer review process modeled on that of the National Science Foundation (NSF).

Two divisions administer the NCERQA research and development (R&D) programs: the Environmental Science Research Division and the Environmental Engineering Research Division. There is a total of approximately 36 staff in these two divisions. The two remaining divisions of the Center include the Peer Review Division (PRD), which employs approximately 15 staff, and the Quality Assurance Division (QAD), which is staffed by approximately 13 individuals. The PRD organizes and manages the outside, independent reviews necessary to select among the many applications for the grants and fellowships awarded by the Center and also coordinates ongoing peer review of EPA-supported Centers of Excellence, while the QAD is responsible for establishing QA policies and procedures throughout the ORD and the Agency.

2.2 NCERQA Self-Study Report

In preparation for the BOSC review, NCERQA management prepared a Self-Study Report addressing the questions specified in the letter from the BOSC Chair to the Center Director (see Section 5.0, Appendix A). The following summarizes highlights of NCERQA's Self-Study Report, and identifies issues that are emphasized in our subsequent review.

2.2.1 Alignment of Priorities and Directions With the ORD Strategic Plan

As noted in the Self-Study Report, the programs of NCERQA are an integral component of the ORD Strategic Plan. NCERQA has the particular role of providing support for participation by outside scientists and institutions and for leading efforts in peer review and QA. The stated priorities and directions of the Center are fully consistent with the ORD Strategic Plan.

2.2.2 Center Strategic Initiatives

The Self-Study Report lists the following four principal strategic initiatives: (1) the extramural grants, fellowship, and research centers programs; (2) ensuring relevancy of Center research program results to EPA Program Offices and Regions; (3) forming partnerships for joint research solicitations; and (4) providing leadership for cross-Agency peer review and QA. Although these initiatives are important in defining the overall mission of the Center and its relationship with other parts of ORD, EPA, and groups outside the Agency, the report provides less information on the internal roles and interactions among divisions and staff within NCERQA to implement these initiatives. Furthermore, the Center has not yet developed its own strategic plan to address these issues. A strategic plan, to identify staff and management needs and planning processes for determining future priorities and initiatives, is identified as a major need in our report.

2.2.3 Integration of Work Across and Within Divisions and Within ORD

The Self-Study Report describes how NCERQA works with other parts of the Agency and ORD, using their Management and Science Councils and Research Coordination Teams (RCTs) to select and implement RFAs. The Report also describes a number of integration and communication programs recently initiated. We note the critical importance of these programs and provide a number of suggestions to help ensure successful implementation.

2.2.4 Measures of Performance and Awards

The Self-Study Report describes a number of key contributions from ORD extramural research to EPA decisionmaking, including Criteria Documents and staff papers. Also, it discusses alternative ways of tracking the scientific quality of research output, including peer appraisals and awards, and organizational measures of success, including efficiency in grant awarding, the ability to obtain partners for leveraging research funds, and the assessed quality and responsiveness of RFAs to the ORD Strategic Plan (and grant awards to the RFAs). The Report openly acknowledges that finding the right metrics for evaluating the quality and value-added of extramural research in a mission-oriented agency such as EPA is a very difficult task and that the Center management and staff continue to struggle to find good solutions. We support NCERQA's efforts to find performance metrics that combine scientific quality and relevance to the Agency's mission. We also provide guidance to the Center for a similar focus on the value-added of their peer review and QA activities.

2.2.5 Organizational Performance Compared With Others

The Self-Study Report identifies other federal agencies active in environmental research, describes current and pending partnerships with these and private organizations, and compares its process for peer review of proposals to that of the National Science Foundation (NSF) and the National Institutes of Health (NIH). Further comparisons are made to NSF, including the similarity

of procedures for identifying topic areas; similar award-to-application ratios; and a similar emphasis on particular communication channels for completed research. The Report also suggests that EPA QA procedures are more complete than those of many other federal agencies. The Center has defined a somewhat unique role for its extramural research program, blending basic and applied environmental research for problems with a range of time scales and immediacy. We note that the Center also would benefit from consideration of environmental agencies and organizations in other countries, both for the purpose of benchmarking and future partnerships.

2.2.6 Interactions With the Outside Scientific Community

The Self-Study Report describes meetings and workshops that involve a significant number of outside organizations and individuals for planning research and reviewing and disseminating research results. We focus on the need to ensure that the outside scientists conducting NCERQA research are well connected to and focused on the needs of others within EPA.

2.2.7 Unique Capabilities and Their Uses

This section of the Self-Study Report focuses on the potential contributions of the PRD and the QAD to other parts of ORD and EPA. We concur with the Report, emphasizing the need for peer review and QA procedures specifically tailored to, and meaningful for, the particular application.

2.2.8 Appropriate Mix of Workforce, Facilities, and Infrastructure

The Self-Study Report identifies current problems with the mismatch of skills in certain sections of the grants program and the need for more staff to meet the growing responsibilities of the Center. The Subcommittee finds that staff and resource limitations are such that it is difficult to maintain even current workloads, and provides a number of suggestions for enlisting further support for Center activities. Ultimately, these issues must be addressed as part of the NCERQA Strategic Plan.

2.2.9 Help Needed From the Agency To Support Its Mission

NCERQA's response to this question detailed important issues that the Center wishes to address, including ways to enhance the value and impact of extramural research within the Agency; the role and orientation of socioeconomic research in ORD; and ways to encourage more rapid and effective diffusion of QA and peer review practices throughout EPA. We note that many of the current difficulties in implementing NCERQA programs are to be expected given the rapid growth, shift in focus, and responsibilities of the Center. The Subcommittee encourages ORD and the Agency to support NCERQA in its efforts to define higher standards of excellence and relevance for EPA research. In the findings, conclusions, and recommendations that follow, we highlight the plans and accomplishments of NCERQA to date, as well as those areas where changes or new initiatives are needed to allow the Center to better fulfill its mission. Many of these needs are clearly recognized by NCERQA management and staff. Our goal is to provide suggestions and encour-agement to NCERQA, ORD, and EPA in support of the Center and its important objectives.

3.0 REVIEW FINDINGS

3.1 The Need for a NCERQA Strategic and Management Plan

NCERQA does not currently have either a strategic or a management plan. This is somewhat ironic because the Center management has played a key role in the development of the ORD Strategic Plan and more recently, the overall strategic plan for EPA. Indeed, the Center Director has continued to fulfill his responsibilities at NCERQA while leading the EPA effort to develop and write the Agency-wide strategic plan. As a result, it is not surprising that the expressed goals of the Center are closely aligned with those of ORD, and furthermore, that the Center plays a critical role in ORD's strategic plan and its reorientation to improve the quality of science available for environmental decisionmaking.

The Center does have eight clearly defined aims, as listed in its Self-Study Report:

- 1. To achieve excellence in research by supporting only the highest quality research through national research competitions and independent peer review of proposals.
- 2. To focus on the highest priority environmental science and engineering needs to assist EPA in its mission of protecting human health and the environment . . . by working with EPA's Program and Regional Offices, ORD scientists, the EPA Science Advisory Board, the ORD BOSC, and federal partners and private partners.
- 3. To achieve high levels of accountability and integrity by having an entirely open, transparent, and competitive process; by ensuring that procedures and schedules for solicitations, reviews, and awards are clearly established; and by publishing and broadly disseminating research results.
- 4. To leverage resources and form partnerships on common federal and private sector research agendas through coordination with research partners and joint issuance of solicitations.
- 5. To communicate and integrate research results through workshops and seminars to summarize results of research; state-of-the-science papers that assimilate research results; and a technical liaison program in ORD Laboratories and Program Offices.
- 6. To develop the next generation of environmental scientists through graduate and undergraduate fellowship programs.
- 7. To provide Agency-wide policy development and implementation oversight of the EPA QA program.
- 8. To provide review and oversight of the Agency peer review process.

These aims, along with the NCERQA programs and its strategic initiatives, are closely aligned and wholly consistent with the ORD Strategic Plan. However, they are principally outward in nature, defining NCERQA' s role and contribution to the ORD and EPA. This is clearly the first step of any strategic planning effort, and it is not surprising that, during its less than 3 years of existence, NCERQA has put initial emphasis on defining its broader mission and goals and developing programs to accomplish these. However, commensurate time does not appear to have been available for addressing the inward-looking aspects of strategic planning (i.e., how the Center should be constituted, staffed, and operated to accomplish its goals). As such, the fit between the Center's strategic initiatives and its staff and other resources is less clear. Development of a strategic and management plan is needed to assess and promote this fit and to provide a systematic process for developing strategic actions to support the Center's aims.

It is recommended that NCERQA develop a strategic and management plan. The process for development of this plan should include an assessment of the Center's strengths, weaknesses, opportunities, threats, and resources. The process also should provide a mechanism for fostering and ensuring strong staff participation in the planning process. It is suggested that the plan include both strategic and management issues.

Some of the key strategic issues to be addressed in the strategic plan are described below.

Priorities and Strategic Directions

This should address the following:

- What are high-priority R&D topics for future grant solicitations?
- How can NCERQA play a leadership role as key issues emerge?
- What mechanisms are available for taking advantage of possible synergies from closer program coordination (e.g., between the exploratory and applied research programs, between the Center's core programs and its other program components such as its Centers of Excellence, Small Business Innovation Research Program, and Experimental Program to Stimulate Competitive Research)?
- What should be the role of social science R&D, both for stand-alone, targeted research and as supportive research coordinated with other R&D targeted areas?

Processes for Managing Change

This should identify decisionmaking processes that will help NCERQA manage change and address critical issues on an ongoing basis. (Such a process could be pilot tested by tackling the excellent list of key issues noted by NCERQA in response to Question 9 in the Self-Study Report.)

QA and Peer Review

This should be prominently featured in the strategic and management plan.

Alignment With the ORD Strategic Plan

For the planning of Priorities and Strategic Directions, NCERQA has already given considerable thought to item 1 (prioritization of R&D) and item 2 (identification of emerging R&D topics), as reflected in its Self-Study Report. Addressing item 3 (opportunities for synergy between different parts of the NCERQA grants, centers, and fellowship programs) can allow the Center to

identify strategies for making the total contribution of its various programs more than simply the sum of their parts. In terms of item 4, NCERQA has particularly struggled with the question of how best to address and support social science research related to environmental issues. We address this specific issue of the content of NCERQA research and organizational steps needed to improve EPA's ability to conduct and integrate social science research in Appendix D of Section 5.0, of this report.

Staff planning is key among the management issues that should be covered in the NCERQA strategic and management plan. The need to include a management plan is suggested, in part, by the rapid growth of the Center's budget and responsibilities over the past several years. Rapid growth can create imbalances between actual and needed staff resources. To assess the extent of any current imbalances, while planning for future staff needs, strategic planning and management decisions need to be conducted hand-in-hand. Particular emphasis should be given to identifying existing staff resources; current workloads, including any seasonal fluctuations associated with managing grants programs; staffing requirements of the Center's programs and activities; and current opportunities for skills enhancement.

The adequacy of the facilities and infrastructure available for NCERQA activities also should be addressed in the strategic and management plan. The offices in the new EPA building represent a significant improvement in ambience; however, quality private space is at a premium. Project Officers work alongside each other in cubicles, and there is little opportunity for private discussion or meetings with grantees or colleagues elsewhere in the EPA or in other research organizations. Options for improving this situation need to be generated and considered.

NCERQA management has acknowledged the need for a strategic and management plan, addressing both outward and inward-looking aspects of the Center goals, initiatives, and operations. The Subcommittee believes that the development of such a plan can provide a basis for addressing the problems with focus and facilities raised above as well as the staff and communication issues considered in the following sections.

3.2 Management of Research Grants and Fellowships

The aim of NCERQA is to achieve excellence in research by supporting only the highest quality research through national competitions and independent peer review. The quality and commitment of the Director of NCERQA and the Center's technical Project Officers in the Environmental Science Research Division and the Environmental Engineering Research Division, in this regard, are quite impressive. However, the Director indicated that some of the personnel assigned to grant management during the reorganization do not have the skills needed for their new responsibilities.

Project Officers' responsibilities extend from program initiation and proposal review, through monitoring and QA during the life of the project, to communication and marketing of project results to promote their use following project completion. The responsibilities of the Project Officers have increased significantly since 1995. NCERQA Project Officers expressed a general consensus that their administrative workloads have increased to such a degree that they are now unable to dedicate their desired level of attention to the technical content of the research. Despite the significant increase in program responsibilities, staffing increases have not occurred. Thus, the responsibility placed on each Program Officer has risen significantly.

The Project Officers interviewed during our review expressed particular concern about their ability to stay abreast of progress on awarded grants to promote effective interactions among researchers and Agency personnel. Such followup involves the monitoring of research progress towards the stated goals of the proposal, the marketing of research results to others in the Agency, and the summarization and integration of research results among projects within a given RFA. Some of the Project Officers indicated that their large numbers of projects and associated clerical responsibilities for each preclude them from providing the more thoughtful time and effort needed to accomplish these essential, though less routine, aspects of grant management.

The Adopt-a-Grant program, developed to link ORD Laboratory scientists with the extramural research projects administered by NCERQA, provides an example of an initiative widely recognized as excellent in concept. However, implementing the program has been difficult because of the limited time and administrative support available to Project Officers. The Adopt-A-Grant program was initiated this past year and allows ORD scientists (and EPA Program Office staff) to adopt, informally interface with, and stay abreast of NCERQA projects. However, Project Officers report that this has resulted in additional coordination responsibilities (e.g., the copying and mailing of grant proposals and progress reports to each adopter). Many of the grants have multiple liaisons within a Center or Laboratory, requiring the Project Officers to interface with a large number of individuals on the projects that they monitor. This new responsibility, accompanied by no reduction in the already high expectations of Project Officers, has led some to view the program as another burden, rather than the innovative opportunity to build links between NCERQA and other parts of the Agency, as intended.

Assessment of the support and expectations of Project Officers is a clear priority for ongoing and future management planning. There are indications that an improved computerized system for managing the multiple forms required for grants will be available soon and that this will help to simplify the Program Officer's job. Even with this, there is an apparent need to either focus Project Officers' tasks or to get more resources to support them in their work. More prioritization, and in some cases, streamlining is needed. There is a particular need to ensure that sufficient resources are dedicated to post-award followup. The proposal for pilot "research integration" grants, presented in the following section, provides one option for easing the demands and expectations on Project Officers, while at the same time expanding their ability to monitor, integrate, and market ongoing project results. Other avenues should be explored as part of the recommended Center strategic and management planning process.

3.3 Research Integration and Communication

NCERQA has planned and begun to implement an impressive set of initiatives to promote the integration and communication of research results for potential users within EPA and beyond the Agency. Examples include:

- Partnerships and joint solicitations with other federal agencies and private-sector organizations for targeted research topics.
- Research workshops, where the grantees within an RFA are brought together to present progress reports and exchange ideas.
- The annual STAR Graduate Fellowship Technical Conference.

- STAR Research-in-Progress reports, providing general summaries of recent research results for timely topics (such as the recently completed reports, "Children's Exposure to Pesticides," "Harmful Algal Blooms," and "The Endocrine Disruptor Problem").
- Planned State-of-Science reports for current environmental issues.
- An award-winning Web site that will eventually allow broad and easy access to NCERQA programs and research results.
- ✤ The Adopt-a-Grant program.

In addition, the Center has developed an extensive and ambitious communication plan for a wide range of clients and stakeholders. These research integration and communication initiatives represent creative and forward-looking responses to ensure that research findings are pertinent and available to those who need them. However, many challenges remain in bringing about effective implementation and, in any event, stronger integrating actions would be beneficial.

The partnerships established with other federal agencies for joint research solicitations during the past 3 years, and more recently with private-sector organizations, have been very successful. These partnerships allow coordination of national efforts for research on environmental issues and have allowed NCERQA to leverage its resources for extramural support by more than 20 percent. Key federal partners include the NSF, the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), the National Oceanic and Atmospheric Administration (NOAA), and the National Institute of Environmental Health Science (NIEHS), while small but important links have been established with the American Water Works Association Research Foundation (AWWARF), the Association of California Water Authorities (ACWA), and the Chemical Manufacturers Association (CMA). These links not only leverage resources and avoid the unnecessary overlap of effort, but also ensure that research activities will be better informed by a wider range of stakeholder concerns while facilitating the subsequent exposure to and use of research results by those who need them. As environmental issues and research provide a unifying basis for global cooperation, these links also should be expanded to include international partners such as environmental agencies in other countries.

Research workshops have been summarized by NCERQA through proceedings, which include a compilation of progress reports for individual projects. Although these proceedings provide a useful record of progress on the individual projects, they have not, as yet, included any record of discussion, exchange of ideas, and integration of results across projects (examples include the Proceedings of the 1996 Water and Watersheds Program Review, the 1996 Program Review on Global Climate Change/Regional Integrated Assessment, and the 1997 Workshop on Valuation and Environmental Policy. Assuming these activities do take place at the workshops (and if they do not, they should), these discussions and an overall summary of the state-of-science derived from the workshop, including implications for environmental decisionmaking, should be included in the workshop reports.

The STAR Research-in-Progress reports and planned State-of-Science Reports provide further examples of excellent approaches for the dissemination of research results. However, both require significant investments of time and personnel, and will require the cultivation of support among

target audiences in the Agency and beyond. The NCERQA Web Site, even in its early stage of development, provides a clear and far-reaching gateway to current NCERQA grant programs, centers, and research in progress for those outside EPA and within. As the information on the Web Site grows to include more information on research topics (and as suggested for the RFA workshop proceedings, perhaps going beyond simple summaries of individual projects), the option presents itself to expand the Web Site beyond NCERQA to include all of ORD, and then beyond the EPA to include environmental research in other agencies and organizations. The most likely approach will be to include appropriate linkages to Web sites of other EPA Laboratories and Centers and those of other agencies. In any case, full realization of the benefits of a highly interactive and well-linked Web site on environmental research will require a continued, and most-likely expanded, commitment by the Center (current full-time Web staff include two individuals; more will likely be needed).

The development of a formal communication plan by NCERQA is a noteworthy accomplishment. The plan identifies the potential consumers of NCERQA-supported research in EPA and elsewhere and discusses their information needs. NCERQA's efforts to meet the needs of its clients is laudable, and its development of a communication plan is a critical step that is too often overlooked. However, it is not clear whether formal efforts were made in developing the draft plan to obtain input or feedback from client groups about their needs and concerns. Significant input from target audiences is needed to ensure that they actually use the information. To do so, NCERQA must obtain additional resources for a needs assessment or must undertake a more limited effort that builds on other NCERQA planning processes. For example, consideration of ways to reach Agency audiences could begin in the initial RCT discussions with Program and Regional Offices and other parts of ORD when decisions are made about RFAs and research objectives. In addition, existing routine contacts with target audiences also might elicit input on existing or proposed communications. Key materials generated by NCERQA, including those for the Web site, should undergo some clarity and pertinence review from client audiences, using standard pretesting methods, just as these materials undergo technical review for scientific accuracy. Although the draft communication plan strives for efficiency by developing communication mechanisms that can reach a variety of users, the draft plan currently targets 11 communication audiences, which may be too ambitious to reach with current staffing. NCEROA needs to prioritize, explicitly selecting certain audiences to receive more attention.

It is clear that research integration and communication are a high priority in current NCERQA planning, but more support or new approaches are needed to ensure that these goals are accomplished without stretching the current personnel and resources of the Center beyond limits. One approach is to require more active participation of grant recipients and center investigators. At minimum, research summaries prepared by investigators should explicitly include a section on the relevance of their research to EPA. NCERQA also could require the relevance section of proposals to include ways that investigators will disseminate research findings to audiences other than academic researchers. NCERQA management should take the lead in devising and delivering an effective reward system for its staff, ORD scientists, and Program Office staff who interact in integration and communication activities.

Another approach for promoting research synthesis is to explicitly fund projects for particular RFAs on research integration. These Research Integration projects could involve:

- Developing State-of-Science Reports.
- Establishing connections with other agencies and organizations conducting similar research.
- Tracking technical progress of individual grants in the RFA and their relevance to EPA.

These functions would be similar to that provided by staff to the Health Effects Institute, who prepare "commentaries" on ongoing and completed research projects, and groups of projects sponsored by the Institute.

The investigators participating on Research Integration projects would work together with Project Officers to ensure synthesis and communication of the research program. Alternatively, Research Integration projects could be planned, managed, and stewarded through the Director's office (perhaps through an Assistant Director or Science Advisor), facilitating further interaction and communication between Center management and the Project Officers. The details of this proposal will require further study and subsequent testing and evaluation through pilot efforts (e.g., to determine whether these projects should be defined as grants, or whether the more predetermined nature of the task dictates that the work be defined as a contract; whether ORD scientists should be able to apply competitively for Research Integration projects (the nature of these projects and the need to interact with others in the Agency are such that these projects could provide a good testbed for the option of allowing ORD scientists to apply competitively for NCERQA grants); and whether Research Integration projects should report to Project Officers or directly to the Director's office. However, these are issues that can be resolved. The concept of a Research Integration project is a promising one for elevating the importance of research integration and communication at the Agency, ensuring greater exchange and coordination among investigators, and providing critical support to NCERQA for grant management and followup. This and NCERQA's other communication efforts have the potential to provide models of ways to make research findings relevant to environmental decisionmakers, and NCEROA should be fully supported in these efforts.

3.4 Peer Review and Quality Assurance

NCERQA is responsible for EPA's QA policies and procedures, review of agency quality management plans, training, and the development of policies and providing oversight for Agency-wide peer review. These responsibilities are essential to ensure the validity of EPA external and internal research. The specific responsibility of NCERQA's QAD is to conduct management assessments of quality system implementation in ORD's Laboratories and Centers to ensure that candidates for extramural research funding have adequately planned for, and recipients of grants have fully complied with, Agency guidelines for the timely delivery of high-quality research. The task of the PRD is to procure expert assessment of the scientific merits of each competitive proposal prior to awarding each grant, and to provide ongoing review of research conducted at EPA-supported Centers of Excellence.

A number of key challenges are ahead before the QA and peer review missions of the Center can be implemented to the fullest benefit of EPA and ORD. These include the need to identify efficient and productive QA and peer review procedures that yield tangible improvements in quality

(and not just more paperwork); the need for consistent and informative metrics to guage the effectiveness and impact of QA and peer review efforts; and the need for a clear recognition across the Agency of the importance of these activities and the specific role of NCERQA in promoting their diffusion and implementation.

Ensuring Real Benefit From QA and Peer Review Activities

An important area of concern when reviewing QA and peer review requirements in any research organization is that they be designed to yield real value-added to the research quality, and not simply result in more paperwork and time diverted from the conduct and dissemination of the work. Despite QAD's advocacy of a graded approach to QA (allowing flexibility in the level of QA data collection and documentation reflecting project needs), a survey of the guidance and implementation materials from QAD suggests that QA might be viewed as burdensome by some Principal Investigators (PIs) and Project Officers. Those on the Executive Committee of the BOSC who have had experience with QA procedures for ORD-funded research also report that these requirements can consume a significant fraction of funds allocated for data collection and analysis. There is a need to benchmark the relative fraction of data-collection budgets spent on QA in EPAsponsored research against those of other research organizations and agencies. NCERQA QA documents state that they have been developed in collaboration with quality management professionals throughout EPA. However, the usefulness of these documents to users, particularly those who are not QA professionals, has not been assessed. In addition, although QAD requires significant paperwork in the form of QA plans and reports, the extent to which this paperwork improves QA implementation has not been documented.

A thorough review (with periodic re-review) should be undertaken to ensure that QA policies, procedures, and documents are as meaningful as possible to both researchers and users of research results. For example, different levels of QA are appropriate for data collection, analysis, and modeling in support of regulatory policy and rulemaking, which must stand up to court challenges, versus exploratory research intended to advance process knowledge and insight. QAD review of QA procedures should involve Agency personnel who are not QA professionals. To accomplish this, QAD may need additional resources and also may need to prioritize tasks differently; for example, reducing the number of documents or policies it develops. Particular consideration should be given to options that allow for a reduction in required paperwork.

To judge the impact and effectiveness of QA and peer review activities in ORD and EPA in general, improved metrics are required. NCERQA has not established quantitative performance measures for their QA or peer review functions. Consequently, objective means are lacking by which either to assess past performance or to identify and prioritize opportunities for improvement. As part of NCERQA's contribution to advancing Agency efforts to comply with the Government Performance and Results Act, NCERQA should develop an explicit set of objectives and quantitative metrics by which progress toward those objectives can be monitored. The objectives, and the metrics by which to track performance, should reflect both program administrative needs (e.g., compliance with contract specifications, timeliness, and completeness of reports, etc.) and scientific quality needs (e.g., excellence in executing the research, publication in the most respected journals, recognition of the research and investigators by professional societies, etc.). Emphasis should be placed on designating criteria/metrics by which the most important value-added contributions from PRD and QAD performance can be recognized, monitored, managed, and rewarded.

Securing Full Recognition for NCERQA's Role in Quality Assurance and Peer Review

A first step in securing NCERQA's role in promoting the importance of QA and peer review in EPA is to clearly delineate these activities as part of the EPA, ORD, and NCERQA strategic plans. Without a strategic plan that explicitly legitimizes the important role of QA and peer review, NCERQA's technical staff are left uncertain about the Agency's commitment to, and support for, their roles. A widely felt sense of diminished legitimacy, plus considerable tension among NCERQA staff, are the results. The EPA, ORD, and NCERQA strategic plans should include explicit and strongly stated commitments to effective QA and peer review. The Center plan should further specify NCERQA's needs for human and financial resources to carry out and evaluate the current programs.

To improve QA and peer review Agency-wide, these processes need higher visibility than NCERQA alone can provide. Unevenness in QA and peer review practices also need to be addressed because it can strain working relations between NCERQA technical staff and the staffs of its sister Laboratories and Centers. The unevenness is most evident when QA and peer review practices applied to research conducted within ORD Laboratories are compared with those practices that are applied to extramural research programs and investigators. Also, although the type and nature of QA and peer review for intramural versus extramural research may legitimately differ, the consistency and vigilance with which standards are applied should be the same for both. Although NCERQA's QAD is empowered to require that an acceptable QA plan be "on-file" before intramural project funding is approved, QAD authority ends at that point. That is, QAD is neither required nor empowered to audit intramural projects to ensure compliance with the previously approved plans. Reward systems for exceptional achievement in QA are essentially absent; neither is outstanding achievement recognized, nor is poor performance aggressively remediated.

NCERQA should develop, and ORD and EPA should fully support, consistent policies and formal implementation guidelines for QA and peer review. These policies and guidelines should be as simple and streamlined as possible, and be tailored specifically to the type of research being conducted and the intended use of the research results. However, once the appropriate type of QA and peer review are determined for each, those procedures should be consistently and even-handedly implemented. The same fundamental elements should be present for both intramural and extramural research, including QA requirements that:

- ✤ A QA plan be submitted and approved by QAD prior to project funding (essentially a continuation of the current practice).
- The plan should include specific and quantitative performance metrics for QA.
- Implementation of the QA strategy (i.e., stewardship of the plan) is the responsibility of the PI(s).
- Assessment and feedback (to PI and NCERQA management) on progress per the plan are monitored.
- Followup occurs to ensure that achievements are recognized, deficiencies corrected, and appropriate communications implemented among NCERQA staff, PIs, and Laboratory management.

Similarly, greater consistency is needed in the implementation of peer review policies for all aspects of the research process proposal applications, progress reports, and final publicationsacross both intramural and extramural research programs. NCERQA's current practice of formal peer review focuses on evaluating the scientific merit of responses to the RFAs (i.e., the "inputs" to the research program). Although this critical first step has been implemented in a rapid and effective manner by the Center, significant value-added could be realized by applying similarly rigorous peer review to the products of sponsored research. Even though NCERQA staff express their sincere hope (and expectation) that the sponsored research projects will eventually result in publications in peer-reviewed journals, there is no explicit commitment, nor a formal process in place, to test, measure, and ensure the "scientific strength" of research results. For multiyear projects, peer reviews at critical intermediate stages are essential. As a matter of administrative policy and of routine practice, it should be made explicitly clear to all candidate investigators (whether in-house or extramural) that NCERQA regards rigorous peer review as a critically important tool to ensure the soundness of scientific methods, techniques, analyses, and interpretations. Furthermore, the results of that peer review should become part of the research record and be carefully weighed when requests for project continuation/renewal are considered. Finally, the Agency should expect that all efforts be made to ensure that funded research is published in a timely fashion in peer-reviewed scientific journals.

Formalizing the leadership role of NCERQA in EPA QA and peer review activities will require a serious commitment from senior management throughout the Agency, and a further commitment of resources. Currently, NCERQA has responsibility for the diffusion of QA procedures throughout the Agency, but not the authority to ensure implementation. Even so, according to QAD staff, the demands for QA training cannot be met now. For QA training to meet EPA's needs, the Agency could: (1) recruit additional staff, specifically for training in QA; (2) restructure the delivery of training such as through a train-the-trainer program (presently under consideration); and/or (3) outsource part of the QA training function. In addition, it is essential that the full commitment to QA and peer review be expressed and promoted at the highest levels of the Agency.

4.0 CONCLUSIONS AND RECOMMENDATIONS

The Subcommittee's programmatic review of NCERQA suggests an organization of vital importance to ORD, EPA, and the national objective of improving fundamental knowledge for environmental assessment and management. The Center has played a key role in refocusing and shaping the new vision for ORD-to generate the highest quality science, conducted by the highest quality scientists, pertinent and readily transferable to support decisionmaking for the highest priority environmental problems. It has begun to create the infrastructure and programs to accomplish this mission in a remarkably rapid manner, with equal measures of hard work and creativity. This has been accomplished within an environment of rapidly growing budgets for extramural support, but relatively constant budgets for internal staffing and infrastructure; the emergence of new environmental issues along with new ways of conducting research and new technologies for communicating with other scientists, organizations, and citizens; and new Center offices and computer systems, not yet fully operable and supportive of staff needs. It is not surprising then that difficulties have arisen in the implementation of some of NCERQA's new programs, and that more is needed to ensure that the Center can meet its objectives. It is in this spirit that the following conclusions and recommendations are drawn for the Center management, ORD, and EPA.

Strategic and Management Plan

Although the stated mission and objectives of NCERQA are wholly consistent with the ORD Strategic Plan, the Center has not as yet developed a strategic and management plan to address issues of internal planning, operations, staffing, and resources to accomplish these goals.

It is recommended that NCERQA develop a strategic and management plan. The plan should address strategic issues, including: identification of priority issues and directions for research funding; synergies and opportunities for integration among the Center's core programs; processes for managing change within the organization; explicit acknowledgement of the role of QA and peer review for extramural and intramural research; and alignment with the ORD Strategic Plan. Management issues also must be addressed, including: staff resources; workloads; adequacy of space and infrastructure; and communication within the Center.

Management of Research Grants and Fellowships

The responsibilities of NCERQA Project Officers have increased significantly since 1995, and some have skills that are mismatched to the needs and expectations for effective management of the administrative and technical aspects necessary for good scientific research. There is particular concern about whether sufficient time and resources are available to allow Project Officers to keep abreast of progress on awarded grants, facilitate appropriate interactions among researchers, and ensure that research results are communicated to those in the Agency who need them.

It is recommended that the support and expectations of Project Officers be addressed as a priority issue in NCERQA management planning. More prioritization, and in some cases streamlining of grant and fellowship management, appear to be necessary.

Research Integration and Communication

NCERQA has initiated a number of thoughtful and innovative programs to improve the integration of research efforts and the communication of research results. These include the growing program of joint solicitations with federal and private partner organizations, the Adopt-a-Grant program for ORD scientists and EPA staff, research workshops, STAR Research-in-Progress reports, planned State-of-Science Reports, a new and rapidly evolving Web site, and an ambitious communication plan for Center customers and stakeholders. However, current Center resources do not appear to be sufficient to allow for effective, fully beneficial implementation of these many programs. It is clear that more support or new approaches are needed to ensure that these worthwhile objectives are achieved.

- It is recommended that NCERQA continue to expand its cooperation and connections with other federal, private, and international environmental research organizations through joint solicitations, Web site links, and the exchange of ideas and research results.
- It is recommended that RFA workshop proceedings be expanded to include a record of discussions, exchange of ideas, integration across research projects and their relevancy for environmental decisionmaking.
- It is recommended that NCERQA continue to support and expand its Web Site as a central location for information on the Center, ORD, and other organizations performing related research.
- It is recommended that NCERQA prioritize the target audiences identified in its communication plan and that the procedures and products for communication be developed with input from priority customers, including the pretesting of communication instruments and products.
- It is recommended that NCERQA require investigators to discuss the relevance of their research to EPA as part of their project summaries.
- It is recommended that NCERQA fund and evaluate the effectiveness of a set of pilot "Research Integration" projects for selected RFAs. Research Integration projects could be responsible for developing State-of-Science Reports, tracking technical progress on individual grants and their relevance to EPA, and establishing connections with other organizations conducting similar research. These projects could provide a possible testbed to allow ORD scientists the opportunity to apply competitively for NCERQA grants or contracts.

Peer Review and Quality Assurance

The QA and peer review activities of NCERQA provide the potential to markedly improve the quality and credibility of science, and resulting decisions throughout ORD and EPA. To fulfill this potential, additional effort is needed to: ensure that QA and peer review procedures promote substantive improvements in quality without undue burden; document the effectiveness and impact of QA and peer review efforts through the use of informative and consistent metrics of performance; and confirm and legitimize NCERQA leadership in these areas.

- It is recommended that QA policies, procedures, and documents undergo regular review to ensure that they are meaningful to those who use them, targeting requirements to the purpose of the particular research and data collection program (e.g., with different requirements for research conducted to directly support policy and regulatory development versus exploratory research). QA requirements and the resources to implement QA in sponsored research projects should be compared and benchmarked against those of other organizations and agencies supporting similar research. Particular attention should be given to options that allow reduced paperwork.
- It is recommended that NCERQA develop appoaches and measures to track and evaluate the effectiveness of its QA and peer review functions. These should include administrative measures, such as compliance with contract specifications and timeliness, as well as scientific quality, successful publication, citation and use of the research by others, and successful application to EPA decisionmaking.
- It is recommended that NCERQA authority for QA extend beyond current requirements, to include recommended procedures for implementation by investigators, assessment and feedback, and followup to ensure that achievements are recognized, deficiencies are corrected, and appropriate communications are implemented.
- It is recommended that the emphasis on peer review be extended beyond current practice for external review of proposals to include complementary (external or internal) review of interim and final research products. Results of peer review should become part of the research record and taken into consideration when requests for project continuation/renewal are evaluated. In addition, timely publication of results in peer-reviewed scientific journals should be targeted for all ORD research.
- It is recommended that ORD and EPA fully and visibly support NCERQA's role in developing consistent policies and implementation guidelines for QA and peer review for both intramural and extramural research.

5.0 APPENDICES

A. Letters From Board of Scientific Counselors Chair

B. Self-Study Report

Preuss, Peter W., National Center for Environmental Research and Quality Assurance October 20-21, 1997

C. Meeting Agenda

U.S. Environmental Protection Agency Office of Research and Development Board of Scientific Counselors (BOSC)

REVIEW OF THE NATIONAL CENTER FOR ENVIRONMENTAL RESEARCH AND QUALITY ASSURANCE (NCERQA) U. S. Environmental Protection Agency—Ariel Rios Building, Room 7216 1200 Pennsylvania Avenue, N.W. (On 12th Street between Pennsylvania and Constitution Avenues) Washington, DC

October 20-21, 1997

PROPOSED SITE VISIT AGENDA

Monday, October 20, 1997

8:00 a.m 8:15 a.m.	Welcome and Introduction	Center Director
8:15 a.m 8:30 a.m.	Opening Remarks	BOSC Chair/
		Review Team Chair
8:30 a.m 9:15 a.m.	Overview of NCERQA	Center Director
9:15 a.m 10:30 a.m.	Discussion of NCERQA Self-Study Report	Review Team
10:30 a.m 10:45 a.m.	BREAK	
10:45 a.m 12:00 noon	Discussion of NCERQA Self-Study Report	Review Team
12:00 noon - 1:15 p.m.	LUNCH	
1:15 p.m 2:45 p.m.	Case Study Presentations	Center Staff
2:45 p.m 3:00 p.m.	Public Comment	
3:00 p.m 3:15 p.m.	BREAK	
3:15 p.m 4:30 p.m.	Breakout Sessions (Rooms 6045 & 7216, Ariel Rios Building)	Review Team
4:30 p.m 5:00 p.m.	Wrap-Up and Adjourn	
<u>Tuesday, October 21, 1997</u>		
8:30 a.m 12:00 noon	Writing Session	Review Team
12:00 noon - 1:00 p.m.	LUNCH	
1:00 p.m 2:00 p.m.	Preliminary Feedback to Center Director	Review Team
2:00 p.m 3:30 p.m.	Writing Session	Review Team
3:30 p.m.	Adjourn	

D. Social Science Research in ORD and NCERQA

Current NCERQA funding for the social sciences is largely limited in focus to economic issues such as resource valuation. Furthermore, interdisciplinary RFAs developed with the intent of funding collaborative efforts among physical scientists, engineers, and social scientists have as yet yielded relatively limited and narrow participation by social scientists, and less collaboration than initially envisioned. For example, nearly one-third of the projects discussed in the 1996 Water and Watersheds review had only a single investigator and therefore were unlikely to be truly interdisciplinary.

The development of an effective social science research thrust will require a somewhat different approach than that used for other NCERQA programs, in part because of the dearth of social science researchers (other than economists) in EPA. NCERQA may need to involve staff responsible for public participation, environmental justice, and related topics throughout the Agency, and to draw upon disciplines beyond economics, including human behavioral studies, risk perception and communication, law, history, philosophy, and ethics. Collecting social science research previously funded by the EPA (e.g., through the Office of Policy, Planning, and Evaluation, the Regions, Hazardous Substance Research Centers, etc.), also might be a productive first step. Social science researchers outside the Agency, particularly those who have familiarity with EPA needs, also will be essential to explore how and where social science research would be most beneficial. In addition, we suggest discussing the usefulness of social science research with other agencies that have funded applied research of this type, such as the DOE, the National Cancer Institute (NCI), and the Agency for Toxic Substances and Disease Registry (ATSDR), as well as the NSF, which funds more basic research. A national symposium could facilitate aspects of this process. The development of effective interdisciplinary research also will require the involvement of social scientists in the entire NCERQA decision process, from the initiation of RFAs to final project selection.

Social science research in ORD has been largely limited to the study of economic valuation; however, many other areas of social science are of importance to the understanding and management of the environment, including human behavioral studies, risk perception and communication, law, history, ethics, and philosophy. The approach of integrating the social, physical, and engineering sciences through interdisciplinary RFAs requiring collaborative efforts to address broader environmental problems is a good one; however, it is not clear how successful these efforts have been in generating truly interdisciplinary research.

It is recommended that NCERQA convene a study, perhaps including a national symposium, to identify appropriate topic areas and mechanisms for expanding the current social science research conducted by ORD. This should include participation by EPA staff responsible for public participation, environmental justice, and related topics; social science researchers outside the Agency who have familiarity with EPA needs; and staff from other federal agencies involved in applied social science research, including DOE, NCI, and ATSDR.

E. NCERQA Organization Chart