

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

**PROGRAM REVIEW OF THE
NATIONAL HEALTH AND ENVIRONMENTAL
EFFECTS RESEARCH LABORATORY (NHEERL)**

**Final Report of the Ad Hoc Subcommittee
on the Review of NHEERL**

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 technology, 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 Report. 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 Board of Scientific Counselors (BOSC) to the U.S. Environmental Protection Agency (EPA) Office of Research and Development (ORD) is a Federal Advisory Committee Act (FACA) committee charged with conducting peer reviews of ORD Laboratories as well as ORD's use of peer review, research management practices, and research reports. A six-member Subcommittee of the BOSC (hereinafter referred to as the "Subcommittee") conducted a review of the National Health and Environmental Effects Research Laboratory (NHEERL) in Research Triangle Park, NC, on August 4-5, 1997. The review was programmatic, and not a science or technology review. That is, the review focused on the structure and process of program design, development, and implementation.

Overall, the Subcommittee found NHEERL to be very solid with a high potential for being a national leader in a number of areas, in particular, in linking health and ecological research. NHEERL is one of five research Laboratories or Centers in ORD. Its purpose is to research the health and environmental effects of stressors, and the research is directed primarily toward the regulatory needs of the U.S. EPA. It is the largest ORD Laboratory, and like the other Laboratories, it underwent a massive reorganization in the mid-1990s. NHEERL's current structure, responsibilities, and challenges are unique in combining health and ecological research within one Laboratory.

A principal and overarching finding of the Subcommittee was that incorporating a number of planning processes currently under way within NHEERL into a single plan could produce a useful Laboratory-wide planning process, tying together the rich and varied components of NHEERL. Such a process could provide a framework for integrating the risk assessment paradigm into NHEERL's research, communicating its activities, evaluating performance, and defining core capabilities and future needs. Key aspects of the process also could address the need and opportunity to advance connections between health and ecological research.

Stability of resources and personnel is critical for maintaining a strong research laboratory. This is particularly important given the very recent reorganization. The managers of NHEERL must have enough flexibility to preserve stability while being adaptive to changing demand.

The review consisted of an evaluation of a Self-Study Report submitted by NHEERL to the BOSC Subcommittee on July 10, 1997, followed by a site visit that occurred on August 4-5, 1997. At the site visit, the Director of the Laboratory and staff members made presentations and participated in breakout sessions. The report is organized according to the items that the Laboratory was requested to address as described in a letter from the BOSC Chair to each of the Laboratory Directors (see Section 6.0, Appendix A). This is preceded by a brief introduction to the review process and a description of the Laboratory reviewed.

2.0 INTRODUCTION

The review consisted of an evaluation of a Self-Study Report submitted by NHEERL to the Subcommittee (hereinafter referred to as the "Subcommittee") on July 10, 1997, followed by a site visit that occurred on August 4-5, 1997 (see Section 6.0, Appendix C, for the site visit agenda). At the site visit, the Director of the Laboratory and staff members made presentations and participated in breakout sessions. The report is organized according to the items that the Laboratory was requested to address described in a letter from the BOSC Chair to each of the Laboratory Directors (see Section 6.0, Appendix A). This is preceded by a brief introduction to the review process and a description of the Laboratory reviewed.

NHEERL is ORD's largest Laboratory with approximately 700 employees. The current and proposed organization of NHEERL (as of June 1997) are presented in Appendices E and F, respectively. The current organization figure was provided by NHEERL in the Self-Study Report and the proposed organization was provided during the site visit. NHEERL consists of nine major divisions, of which five are defined in terms of different health effects or approaches and four are geographically defined divisions related to ecology. The organization's current structure reflects a major reorganization that is only 2 years old.

The overall purpose of NHEERL as stated in the latest ORD research accomplishments report (U.S. EPA, ORD, 5/97:1) is the following:

"NHEERL performs laboratory and field research to understand health and ecological effects of exposures to man-made stressors and the likelihood the effects will occur under conditions of environmental exposure."

3.0 LABORATORY REVIEW

3.1 Alignment of Priorities and Directions With the ORD Strategic Plan

The EPA Strategic Plan for ORD sets forth principles, goals, missions, high-priority research areas, and research areas of importance. These plan elements provide a framework for the work of the Laboratories and are used to organize this review, recognizing, however, that not all of the elements are applicable to an individual Laboratory. Highlights of the ORD Strategic Plan, including changes made in the May 1997 update, are summarized in Section 6.0, Appendix D.

The NHEERL Self-Study Report and materials presented during the site visit clearly demonstrated that NHEERL has a solid research foundation, and has made significant efforts to establish priorities and directions consistent with elements applicable to it in the ORD Strategic Plan. This is particularly notable in light of the recent reorganization. These accomplishments are evident in the Laboratory's mission statement, adherence to the strategic principles, high-priority research areas, and research areas of importance.

Mission

The mission of NHEERL reflects three of the stated missions of ORD:

- ❖ Perform high-quality research
- ❖ Provide national leadership
- ❖ Provide technical assistance to the Program Offices.

Principles

1. *Focus Research and Development on the Greatest Risks to People and Environment*

Whether the risks NHEERL addresses are the greatest risks is determined by ORD in a larger prioritization process that involves input from the Laboratory as well as other entities throughout the Agency. No information was available to determine whether or not NHEERL makes an independent assessment of the highest risks, nor whether such an assessment is or should be conducted at the Laboratory level. NHEERL's current structure enables it to encompass studies of risks to both human health and the environment.

2. *Focus Research on Reducing Uncertainty in Risk Assessment* (the 1997 Strategic Plan Update broadened this to include improving cost effectiveness in risk prevention and management)

There is a broad range of sources of uncertainty in risk assessment. Some uncertainties may be reduced by the expansion in knowledge provided by NHEERL research. This appears to be true across the research programs, but the review panel could not evaluate this in detail.

3. *Balance Human Health and Ecological Research*

NHEERL has a unique capability to link the continuum between ecology and health in housing both areas within its organizational structure. First, based on information supplied by NHEERL for Fiscal Year (FY) 1997, 55 percent of the total budget was allocated to the

ecological divisions and 33 percent to the health divisions, with the remaining amount devoted to administration. This balance also is similar for the distribution of Full-Time Equivalents (FTEs) between the two programs. FTE and annual budgetary comparisons, however, do not fully reflect all of the resources available to the Laboratory. Second, the Laboratory's stated research priorities reflect an attempt to balance the two areas. Third, the issue of integration in general between the two areas and the mechanisms to accomplish such integration have been given considerable attention by senior management in the Laboratory, and is described in detail in Section 3.3 on integration.

4. *Infuse Customer/Client Ethic*

According to presentations made during the site visit, the key client of NHEERL is the regulatory function of EPA, housed primarily in the Agency's Program Offices. NHEERL's management structure interfaces with the Program Offices primarily through Assistant Laboratory Directors (ALDs), who are senior staff within the Laboratory. Their organization and functions are described under a separate section on organizational integration (see Section 3.3). According to management descriptions distributed on August 5, 1997, the Laboratory Director has a major responsibility for representing NHEERL with outside stakeholders (which includes ORD, Program Offices, the Region, Congress, and the scientific community).

5. *Maintain Strong Viable Core Capabilities*

The need for core capabilities was recently underscored by a National Research Council (1997) study, which identified such capabilities as being critical to addressing new environmental issues as they arise. NHEERL has unique niches in health and ecology, which comprise its core capabilities. The health and ecological areas are organized differently. The health effects divisions have discipline or clearly articulated science-based cores, and ecological divisions have geographically defined cores. These should be made more consistent. One way to accomplish this is to have the ecological divisions articulate their scientific or disciplinary cores better. Such disciplines tend to be concentrated in different locations. For example, Corvallis focuses on terrestrial ecology, and Gulf Breeze and Narragansett focus on coastal ecology. A strategic plan would help pull these core capabilities together and articulate them. This issue is addressed more fully in a later section.

6. *Support and Develop Outstanding Professionals*

There is a strong commitment in NHEERL to develop, support, and reward outstanding professionals, which is reflected in its use of a reward system and in its attempt to boost morale. The efforts, described in Section 3.4, appear to have enhanced the morale of the staff. Professionals who spoke with the Subcommittee members in breakout sessions during the site visit seemed to uniformly agree that morale had improved in the Laboratory since the reorganization, and this is an important component of the support and development of professionals. The Subcommittee highly recommends that these incentives continue.

7. *Increase Competitively Awarded Research Grants*

This principle is no longer contained in the 1997 Update to ORD's Strategic Plan, probably because it is being implemented through EPA's Science to Achieve Results (STAR) program, which is the major extramural competitive research program. The ALDs have input into this research, evaluating it in terms of relevancy, once the review for scientific content has been conducted. NHEERL professionals have expressed the need and desire to be more involved in extramurally funded research.

8. *Require the Highest Level of Independent Peer Review and Quality Assurance*

Peer review is a critical part of NHEERL, and occurs at many different levels and in a number of different forms. Research study designs, publications, organizational units (divisions), and the Laboratory are all peer reviewed. In addition, the Laboratory has had two retreats to obtain feedback about Laboratory working conditions. This is discussed more extensively in the Measures of Performance and Awards section (see Section 3.4). Not enough information was provided to determine how well these performance measures are working.

9. *Provide the Infrastructure to Achieve and Maintain an Outstanding R&D Program* (see Section 3.8)

High-Priority Research Areas

The Laboratory's research areas are aligned with the high-priority research areas articulated in the ORD Strategic Plan. The table that follows indicates which of the divisions have primary responsibility for each of the high-priority research areas. The only area not covered is pollution prevention, which NHEERL regards as the responsibility of another Laboratory, although they support it indirectly.

High-Priority Research Areas

NHEERL Division	Drinking Water	Particulate Matter	Endocrine Disruptors	Ecological Risk Assessment	Health Risk Assessment
ECOLOGY					
Atlantic			✓	✓	
Gulf			✓	✓	
Mid-Continental			✓	✓	
Western				✓	
HEALTH					
Environmental Carcinogenesis	✓		✓		✓
Experimental Toxicology	✓	✓	✓		✓
Human Studies	✓	✓	✓		✓
Neurotoxicology	✓		✓		✓
Reproductive Toxicology	✓		✓		✓

Notes:

- ❖ The Neurotoxicology Division has a lesser role in drinking water.
- ❖ The Experimental Toxicology Division focuses on pulmonary aspects. It has more FTEs than Human Studies, but fewer dollars.
- ❖ This table is based on information presented at the meeting held on August 4, 1997.

Other Important Research Areas

The Laboratory has taken the initiative to support other research that it thinks is important. The Environmental Monitoring and Assessment Program (EMAP) is an appropriate example because this program is valued as a key tool for obtaining environmental status and trends as baseline information for research. Other research areas regarded as important include global environmental change, air pollutants, and site remediation.

Measures of Success

ORD's Strategic Plan advocates using the following measures or criteria for success:

- ❖ Significance: Is the Laboratory working on the right issues?
- ❖ Relevance: Will the research provide useful data?
- ❖ Credibility: Is the research of high quality?
- ❖ Timeliness: Is the research produced in a timely manner so that it is of use in decision-making?

NHEERL is incorporating these measures of success into some of its operations. For example, these criteria are used to evaluate proposals for intramural grant funds. Research Plans are required to identify timelines, milestones, and products. Strong emphasis is placed on producing peer-reviewed publications.

The use of peer review as a means of evaluating the success of research is the subject of considerable debate within the scientific research community. The issues pertain to whether or not scientific research performance can be measured and, if so, how it can be measured. Positions on this issue are varied. Some argue that performance cannot be measured at all. Others say it can be measured for a few limited and specific outputs, for research operations and workforce, comparisons against missions, or in terms of often-used measures of peer-reviewed publications and their impact.

The Laboratory seems to be integrating measures of success articulated in ORD's Strategic Plan into some of its programs to the extent that those measures are clearly defined and made applicable to NHEERL's work. Not enough information was reviewed to determine how widely the Laboratory uses these measures. Another measure that is important to consider is impact, (i.e., Has the work advanced the science or impacted policy?). The Subcommittee encourages the Laboratory to have a proactive program to identify and communicate examples of how products of its research have met these criteria and have assisted the agency and others in resolving environmental problems. More specific measures are presented in Section 3.4 on measures of performance.

The Use of the Risk Paradigm

Introduction

The ORD Strategic Plan notes that "Most important of these principles is the explicit use of the risk paradigm to shape and focus our organizational structure and research agenda." The ORD 1997 Strategic Plan Update identifies the risk assessment/risk management paradigm as the critical

strategic tool for implementing ORD's research mission. The paradigm, as articulated in the Plan and earlier documents, defines risk assessment as comprised of four essential components. The first step, hazard identification, identifies the potential that an agent or collection of agents or changing circumstances may cause an adverse impact on human or ecological systems. The second step, dose-response, establishes the dose-response relationships that relate potential toxicity of a stressor to the incidence of potential injury or disease. The third step, exposure assessment, seeks to evaluate past, current, or potential exposures to stressors in the environment and define the level of exposure through different pathways to receptors. The fourth step, risk characterization, summarizes from the hazard identification step the likelihood that a particular stressor in the environment may be associated with an adverse effect. The risk characterization includes the quantitative expressions of the degree of harm by combining information from both the dose-response assessment and the exposure assessment, on the assumption that the agent is capable of inducing harm. Thus, the risk characterization includes both hazard identification, or the likelihood for potential for harm to be induced, and a quantitative characterization of that potential. Risk characterization also is increasingly including expressions of uncertainty associated with the overall risk assessment process.

Risk management is a separate analysis, which seeks to control or reduce sources that contribute to the risk of harm for various receptors, (i.e., humans and ecological systems). The risk management process includes a definition of management alternatives as well as considerations of social and economic impacts as prescribed under EPA's various enabling statutes.

The NHEERL program focuses on the first two steps of the risk assessment process, hazard identification and dose-response assessment, which are an integral part of NHEERL's Statement of Objectives, Mission, and Measures of Success. NHEERL programs aim at providing better methods and models for hazard assessment to predict what agents or stressors are likely to impact human health or ecological systems. Within these two areas, NHEERL programs also provide better tools for defining methods and models for evaluating dose-response relationships. The exposure assessment and risk characterization steps of the process are assigned to other ORD Laboratories or Centers with which NHEERL coordinates to link the various components of the paradigm.

Strengths and Weaknesses

NHEERL uses the risk assessment/risk management paradigm as a framework for tying the ORD programs to the overall EPA mission. It has made major progress in articulating its programs in terms of this paradigm. This is clear from a number of examples, including the case study on drinking water that was presented to the Subcommittee. The Subcommittee recognizes that this is work in progress and that continued progress should be nurtured and encouraged.

In several instances, ORD has been able to plan within the risk assessment and risk management paradigm for anticipated real-world problems that allow for long-term planning to respond to a particular regulatory mandate or risk issue. The ozone research program is an example provided by NHEERL of early problem definition allowing time for a research program to be planned and conducted in the regulatory timeframe so that research results can significantly impact the decision.

A Laboratory-wide comprehensive plan could include a number of elements to expedite the integration of the paradigm more fully into the objectives and missions of the Laboratory, and enable NHEERL to promote accountability and develop measures to assess its performance in light of the

paradigm. One element is the definition of linkages between the health research and the ecological research programs in terms of the risk paradigm. Fruitful areas of collaboration between these two areas that reflect the risk assessment/risk management paradigm include broader issues of mechanisms of action, food chain bioaccumulation that requires addressing toxicity to humans and ecological systems, and assessment methods to predict potential impacts on human or ecological systems.

Another element could be the integration of the hazard identification step (one of NHEERL's areas of concentration) into other steps of the risk paradigm, as well as making fuller use of the hazard identification work. NHEERL's current health research program is addressing methods and models related to hazard identification, but is engaged in only a limited way in actually evaluating the hazard associated with various agents, which is primarily the responsibility of other Laboratories. Thus, the hazard identification step is often completed by other groups.

In summary, NHEERL efforts to align its program according to the risk assessment/risk management paradigm have strengthened its ability to provide research support to the Agency's mission. These efforts have only just commenced, and many challenges lie ahead to fully implement the approach. When the paradigm is fully incorporated into the identification of core capabilities and the design of a comprehensive strategic plan for NHEERL's programs, the whole program, as a consequence, will be brought into closer alignment with the Agency's mission to promote the paradigm. The Subcommittee recommends that NHEERL should formalize linkages with potential users of its methods and models. This would ensure that the user community—the other Laboratories and Program Offices—is knowledgeable of the utility of NHEERL's work to hazard identification and also dose-response evaluation as a part of the risk assessment process. The Subcommittee believes that this includes not only the National Center for Environmental Assessment (NCEA) and the regulatory programs within EPA, but also other user communities, (e.g., the National Toxicology Program (NTP) testing program, state risk assessment efforts, private sector groups, and the international community). Publication of research results in peer-reviewed papers is encouraged, but may not be the only vehicle to ensure timely and appropriate use of NHEERL's research results.

3.2 Laboratory Strategic Initiative

A Laboratory-wide strategic plan is an important means of articulating a strategic initiative. NHEERL does not have a Laboratory-wide plan. Such a plan is not suggested nor required in the ORD Strategic Plan. Such a plan would serve many purposes. It would tie together plan elements that already exist; integrate the work of all NHEERL divisions; unify core capabilities; address implementation plans and division- and project-level research and hiring plans; incorporate the bottom-up, top-down planning process; and communicate the Laboratory's activities. Moreover, it would integrate health and ecology. The NHEERL Director indicated that the elements for such a plan already exist, and he intends to pursue the development of such a plan.

3.3 Integration Across and Within Divisions and Within ORD

The wide diversity of research functions, historical organization patterns, resources, and geographic areas all represent significant challenges for NHEERL's science managers. The development of a unified and sustainable research mission requires the support of strong communication links to integrate the internal divisions, other branches of ORD, the EPA Program

Offices, and a wide range of external stakeholders. The current structure of the Laboratory represents an effort to integrate nine separate and distinct research divisions, in addition to the management and administrative branches.

Three integration issues are addressed here, namely, the integration of health and ecological areas within NHEERL, vertical integration within NHEERL, and Laboratory external interactions with the rest of ORD and EPA. The context in which the Laboratory functions has to be fully considered to evaluate the nature of integration. Shifting priorities and funding are inherent to EPA research. The constant tension between regulatory timetables or deadlines and longer term research schedules persists. The requirements outside of EPA for fiscal and political reviews constantly shape even the day-to-day activities of the Laboratory.

Integration of Health and Ecological Effects Research

A key challenge is the effort to integrate health and ecological effects research within NHEERL. The difficulties of doing this extend well beyond NHEERL and go back to the historical roots of the separation between the two disciplines as well as a general emphasis upon health issues in environmental legislation over the past two decades. Health and ecology issues have traditionally been separate and discussed in separate forums. Each of these two areas has had distinctly separate training and professional identities as well. For example, ecology is linked academically to the natural sciences, while health is linked to the medical sciences.

The current organization chart does not reflect the integration of these two concerns. Four ecology divisions stand separately from five health divisions. Moreover, the divisions are not organized in the same way with health being disciplinary and ecology being geographic. Organizing the divisions along geographic lines does not reflect what questions are important, what disciplines within ecology are critical, and how the work of the ecology Laboratories is organized.

There are a number of substantive areas that could provide a basis for organizing the ecological work of NHEERL on other than a geographic basis. An example of one area that has emerged as being very important is the relationship between land use and nutrient enrichment. The Corvallis Laboratory has focused on atmospheric deposition of nutrients, whereas Narragansett has focused on the impact on coastal areas. This kind of concern should be reflected in the management structure.

The Laboratory has made progress in effecting this integration in a couple of ways. First, the risk assessment and risk management paradigm has helped provide a common framework for the two disciplines. The Laboratory takes advantage of the use of the risk paradigm to apply a common conceptual base or framework to both ecology and health. The risk paradigm suggests a scheme that begins with emission sources and proceeds through identifying environmental concentrations, exposure, dose, biological effects, and adverse outcomes applicable to both areas. Second, an organizational mechanism exists, a NHEERL Synergy Workgroup, to promote interactions between the two sets of divisions. The Workgroup meets approximately every 2 weeks, according to the Laboratory Director. Communication mechanisms have been established to allow electronic exchange of information among these units as well. ALDs provide the major vehicle for linking these areas within the time constraints posed by their many other activities.

A next step is for the Laboratory to expand activities that link health and ecology within the context of single projects. A number of examples of such integration already exist, including:

- ❖ Endocrine Disruptors (Synergy teams are working together)
- ❖ Developmental Research
- ❖ Biomarkers (Gulf Breeze)
- ❖ The Dioxin Reassessment (Duluth did the ecological side)
- ❖ Algal Blooms (planning meetings have been held for collaborative research on the health and ecological effects of algal blooms; see the Self-Study Report)
- ❖ The effects of polluted waters on dolphins and their susceptibility to morbillivirus infection (see the Self-Study Report).

The affinity between health and the environment is reflected in the fact that ecosystem work is moving more in the direction of ecotoxicology. Interaction makes sense in the reproductive and developmental areas, and techniques are transferable from health to ecology. It will take time to accomplish this conversion. Structural and cultural barriers are not easy to overcome, but joint projects augmented by joint seminar series are beginning to foster interaction.

The Subcommittee recommends that this activity continue to find ways of overcoming geographic barriers. The Subcommittee further recommends that a formal mechanism be introduced, such as an advisory board, to formulate the questions and issues in ecology. This should then be incorporated into the Laboratory-wide strategic plan.

Vertical Integration

Another integration issue pertains to the vertical integration extending from the researchers to decisionmaking and policymaking. The vertical structure extending from the Laboratory Director, consists primarily of Associate Directors, Division Directors, Branch Chiefs, and Principal Investigators (PIs). PIs indicated to the review team that their research environment has substantially improved over the past few years, although more linkages with top management would be welcome. Being able to influence the level of resources to accomplish their work and the nature of interactions with other researchers in their field continue to be of concern to the PIs.

The Subcommittee recommends that, given the size of NHEERL, vertical integration mechanisms should be explored that strengthen linkages between the Laboratory scientists and those who make decisions and policies based upon their work.

Laboratory Interactions Within ORD and Within EPA

NHEERL interacts on an almost routine basis with several other Laboratories and Centers (primarily with NCEA, the National Exposure Research Laboratory, and the National Risk Management Research Laboratory), and on a formal basis with the rest of the EPA organization through participation on councils. These vehicles also serve as a means of interacting with EPA Program Offices, which is necessary if the Laboratory is to be responsive to regulatory issues.

ALDs are charged with interfacing and coordinating Laboratory activities with the Program Offices in EPA. There are five ALDs organized by media to interface with the organization of the Program Offices. These media are air and radiation, water, pesticides, multimedia programs, and an unspecified area encompassing genetic toxicology and carcinogenicity. The number of ALDs is relatively small given the size and complexity of the NHEERL organization. Although they set priorities, they have no authority over the distribution of resources. They themselves have little if any staff.

ALDs exercise these functions through ORD entities such as the Science and Management Councils. ALDs meet with the Office of Science Policy (OSP) representatives for each media. Final prioritization by media takes place in this setting.

As indicated in a proposed organization chart, dated June 25, 1997, and distributed at the site visit, the ALDs report (will report) to the Director of the Research Planning and Coordination Staff, who in turn reports directly to the Director of NHEERL. Thus, they have a direct link to the Laboratory Director. This structure is needed because NHEERL divisions are not organized in a way to interface or correspond with the Program Offices at EPA Headquarters.

The Subcommittee finds that, in general, this structure, which places emphasis upon the ALDs as organizational bridges between the Laboratory and Headquarters, appears to be a good one. However, the Subcommittee recommends that the Laboratory evaluate the sufficiency of resources available to ALDs to enable them to effectively perform their coordination functions. This is especially true of their functions that encompass reaching to other parts of NHEERL (i.e., to the PIs), which may not be within their current scope of responsibility.

3.4 Measures of Performance and Awards

Performance

Measures of performance for scientific research are problematic (Kostoff, 1997; National Research Council, 1994), especially those that exist in a regulatory context (Jasanoff, 1990). Numerical summaries of resources, number of publications, and demographic profiles are useful as collateral information, but are not easily related to the quality and relevance of research. Other approaches to performance have relied on indicators targeted to characteristics of the workforce. An annual accounting of performance of science, engineering, and technology in general, for example, is conducted by the National Science Foundation, using indicators ranging from knowledge of basic scientific concepts to resources and training.

Government Performance and Results Act (GPRA)—At the present time, NHEERL operationalizes performance measures in part by applying measures developed in response to the GPRA of 1993 (Public Law 103-62). The Self-Study Report contains GPRA summary tables that link the activities of the Laboratory with various performance measures. These measures are not quantified nor spelled out enough for a detailed evaluation. Whether GPRA measures can adequately reflect long-term research performance has been open to question (Kostoff, 1997), and the Subcommittee was unable to explore this particular issue in depth.

Case Studies—Two case studies presented during the site visit were illustrative of performance. The cases were on drinking water, illustrative of the use of risk assessment, and the Pacific

Northwest studies, an example of the Laboratory's more integrated and holistic approach to ecosystem research. These offered compelling evidence of performance, and an expanded approach using case studies should be used to gauge performance in the future.

Peer-Reviewed Publications—Based on the documentation provided in the Self-Study Report, publication within the Laboratory seems to be extensive, though it is difficult to know what to measure this against—a problem certainly not unique to NHEERL. A drop in peer-reviewed publications occurred between FY 1995 and FY 1996, which also is difficult to interpret in terms of performance.

Impact Measures—The impact of the Laboratory's work was presented with a rich set of examples. One notable example was the ecosystem concept developed in Corvallis that became the backbone of what the states implemented. They produced a tool that had widespread use. There are numerous examples in the Self-Study Report and in the research compilations that demonstrate how single research projects impacted the direction of regulatory activity. The Laboratory could build a profile over time of these accomplishments and relate this profile to GPRA measures.

A number of recommendations for performance measurement are evident from the review, with the caveat that the performance of research operations is particularly difficult to evaluate. Demographic information about human resources (especially about minorities and women) should be presented. More case studies, similar to the ones presented, would help to illustrate performance.

Awards

Science and Technology Achievement—This is an ORD-wide award. Each Laboratory nominates papers published in the last 3 years. The Science Advisory Board (SAB) ranks the nominees and provides a monetary award to the winners. The Self-Study Report indicated that NHEERL had forwarded 60-80 nominees and has received 39-49 percent of the awards made.

Honor Awards—The Laboratory actively participates in the EPA award system. The Self-Study Report pointed out that in 1995, the only Gold Medals for Exceptional Service were awarded to NHEERL scientists. In 1996, the report indicates that NHEERL scientists again received the EPA Gold Medal. In that same year, six Bronze Medals also were awarded to NHEERL scientists.

Professional Society Awards—Laboratory authors have received annual awards for research papers.

Other examples are given in the Self-Study Report. Whether or not any of these awards was consistent with the Mission of the Laboratory was not evaluated by the Subcommittee.

3.5 Organizational Performance Compared With Others

Discussions with NHEERL regarding this issue indicated that it is difficult for the Laboratory to benchmark or to identify an organization that would be similar enough, given its diversity and size, for adequate comparison. The Subcommittee also believes that such an undertaking is not very fruitful as a means of assessing performance, unless clearly analogous organizations could be identified. In the Self-Study Report, NHEERL did, nevertheless, identify certain organizations against which it could compare itself, namely the U.S. Forest Service and the National Center for

Toxicological Research. Indicators for comparison were very limited, being restricted to staff, travel, publications, and presentations. The comparison did not draw upon the breadth of the performance measures discussed earlier.

3.6 Interactions With the Outside Scientific Community

Interactions between NHEERL and the outside scientific community take a number of different forms. According to NHEERL, these span activities such as the planning and coordination of research findings and the identification of directions for research, collaboration, and participation. NHEERL scientists serve as representatives on various federal committees, have cooperative agreements with universities, and engage in interagency agreements with agencies such as the NTP, the Centers for Disease Control and Prevention (CDC), the U.S. Geological Survey (USGS), and the U.S. Fish and Wildlife Service (described by example in the Self-Study Report on p. 30). Interactions also occur on an individual basis through professional activity. There is a general sense that Laboratory professionals are present in the field through these professional conduits, but it needs to be formalized with outside institutions. A particular concern is that not enough representation of scientists is possible at professional meetings. The Subcommittee recommends that resources be explored to promote such interactions, in particular, to support a plan for the direction and purpose of the interactions, keeping in mind what other activities may be impacted.

3.7 Unique Capabilities and Their Use

The unique capabilities of NHEERL lie in its resources in health and ecological effects, and some of its research initiatives and their use. EMAP is a unique program, and one that the Laboratory tries to sustain in spite of the fact that it is not identified as a high-priority research area in the ORD Strategic Plan. There are a number of other examples. In Corvallis, the concept of ecoregions has been used to identify where one would expect terrestrial and aquatic systems to be similar. The Corvallis Laboratory also has excelled in landscape ecology, a subset of EMAP. This influences how a stream can be regulated to support life. Test methodologies for fresh water and estuarine response to toxicants have been developed at the Duluth facility. In the area of human studies, the Laboratory is unique in having human chamber capability (i.e., putting human subjects into exposure scenarios). The Laboratory also has been unique in expanding its capabilities in the area of non-cancer endpoints. It has well-developed capabilities in neurotoxicology as well as reproductive and developmental toxicology. Certain health projects are unique, such as disinfection byproducts work. Furthermore, NHEERL has expanded the stressors it considers beyond toxic chemical stressors to include other kinds of stressors and their ecological consequences. The Pacific Northwest Forest Management project, which evaluates various development scenarios on watersheds, EMAP, and the Dead Zone in the Gulf of Mexico, are all examples of important NHEERL research programs that address stressors other than chemicals. The Subcommittee encourages NHEERL to continue supporting such initiatives.

3.8 Appropriate Mix of Workforce, Facilities, and Infrastructure

The Laboratory has a total workforce of approximately 700 people, of which about 250 are PIs. A number of the issues with respect to the workforce and its organization were discussed previously in the context of the Laboratory's overall organization.

External Constraints

Like other Laboratories within ORD and the Agency itself, NHEERL has faced considerable downsizing, as stated in the Self-Study Report. Some government-wide and EPA-wide personnel policies provide not only boundaries around what the Laboratory can do, but also provide opportunities. Current hiring and promotion policies for research scientists, development engineers, and other professionals appear soundly based with the use of consistent and specific criteria and the use of peer-review panels. However, scientists in the technician category and support personnel are restricted to classifications that seriously handicap NHEERL's ability to compete. The Laboratory Director is addressing this issue. The Subcommittee recommends that the Laboratory continue to develop the flexibility to compete for quality personnel.

Skill Mix

The match between skills and organizational activities is critical, especially within highly specialized research organizations such as NHEERL. The portrayal of skills in an organization is complex because skills can be defined in any number of ways (e.g., in terms of education, training, experience, or current job descriptions). Any review group would need a lot of time to assess skills. A component that is critical to such an evaluation is the linkage between skills and organizational entities (such as divisions) and research projects. The Self-Study Report and subsequent materials were a start in this direction. A broad tabulation of skills is provided in the Self-Study Report (see Table II on p. 15), which shows ecology (not differentiated) and molecular biology as the dominant skills. The linkage to divisions or research project areas is not provided. A supplement to the Self-Study Report gave biographical sketches of each of the 250 PIs and managers, which shows considerable diversity in the organization.

There are some notable gaps in coverage, given the overall responsibilities of NHEERL. The field of epidemiology plays a critical role in the ability of the Laboratory to accomplish the risk assessment/risk management paradigm, and particularly that portion of the paradigm, described earlier, in which NHEERL specializes—hazard identification and risk characterization. As implementors of the risk assessment/risk management paradigm, epidemiologists play an important role in the interactions with exposure assessment specialists and toxicologists. According to the Self-Study Report, the Laboratory currently employs five epidemiologist/medical personnel, and these are concentrated within one division, the Human Studies Division. Because the category of epidemiologist is combined with medical personnel, it is difficult to determine the specific number of epidemiologists at the Laboratory. The Subcommittee recommends that the representation of this field be expanded to provide greater input and interaction with other fields to fulfill the risk assessment/risk management paradigm.

Infrastructure

Infrastructure is defined by the ORD Laboratories as “The S/T Extramural dollars needed to provide the underlying foundation or basic core capabilities of technical, research, facilities, and administrative support to adequately carry out Laboratory and Center missions.” Infrastructure elements include technical support for PIs; facilities support; predoctoral/ postdoctoral support (one pre- and one postdoctoral fellow is allocated per 10 EPA PIs); research support (e.g., animal care, analytical services); and Senior Environmental Employment (SEE), which includes clerical,

administrative, and technical support (“Infrastructure Concept,” Briefing for ORD Management Council, July 16, 1996, Chapel Hill, NC). These are guaranteed resources needed to conduct research. A second category of resources entitled “Above Infrastructure” is more of the above, (e.g., more postdoctoral professionals, if additional funds become available). The allocation of “above infrastructure” resources tends to be higher in high-priority research areas such as PM₁₀ and drinking water. The availability of infrastructure contributed to the stability and morale of the Laboratory environment. The Subcommittee recommends that above infrastructure funds be aggressively and flexibly used to tie external research to related internal research. The Subcommittee did not believe it had enough information, however, to make any determinations or recommendations about how budgets are designed to provide infrastructure resources, (i.e., as zero-base budgeting or budget set-asides).

4.0 LABORATORY NEEDS TO ACCOMPLISH ITS MISSION

All of the Laboratories reviewed by the BOSC were requested to identify their needs and what the Agency could do to help each organization be more effective in accomplishing its mission. NHEERL identified a number of areas throughout the Self-Study Report, and specifically detailed three issues in Section 5 of the Self-Study Report.

The three issues described in the Self-Study Report were the promotion of: (1) scientific excellence by expanding appointment authority to attract and retain high-quality professionals; (2) the means to foster external collaborations between Laboratory scientists and the external scientific community; and (3) stability within the Laboratory.

4.1 Scientific Excellence

The Laboratory recommends that its ability to attract and retain scientific professionals would be enhanced by encouraging the creation of a mechanism called the Senior Scientific Leadership Corps, which was recently approved by Congress for the Department of Health and Human Services (DHHS). A vehicle more directly under the control of the Laboratory and ORD for directly recruiting postdoctoral professionals as research fellows into the Laboratory also was suggested. Moreover, the Laboratory needs mechanisms to attract good postdoctoral professionals to NHEERL, given the competition. The Subcommittee acknowledged the existence of the problem and the need for EPA to develop an appropriate solution, giving consideration to the proposals made by the Laboratory.

4.2 External Interactions

The Laboratory maintains that external interactions with the scientific community could be improved. The Subcommittee recommends that mechanisms should be sought to encourage EPA scientific collaboration with external projects and to overcome whatever barriers currently exist. Moreover, mechanisms to attract national conferences to EPA Laboratory sites or nearby should be sought to reduce the cost of EPA scientists attending professional conferences.

4.3 Stability

Although the Laboratory's key mission is to support EPA's regulatory activity, it operates in a research environment, and as such needs a stable research planning process that acknowledges the timetables within which high-quality research must occur. The Subcommittee strongly supports the need to explore means for promoting such stability through making resources more flexible.

5.0 CONCLUSIONS AND RECOMMENDATIONS

NHEERL has to balance the need for flexibility and stability in addressing a wide range of regulatory issues faced by EPA. A number of specific conclusions and recommendations are noted below.

5.1 Strategic Planning

A considerable amount of planning is already under way within NHEERL. The Subcommittee strongly recommends the development of a Laboratory-wide strategic plan that mirrors the ORD plan, links existing NHEERL planning efforts, and clearly articulates how research priorities are set. A Laboratory strategic plan can be created from the elements that are already in place. A plan is critical to demonstrating the link between health and environmental research. A plan would be an advantage to the Laboratory. It would provide a continuum from policymaking to implementation, and capitalize on what the Laboratory already has in place.

5.2 Risk Assessment/Risk Management Paradigm

The Laboratory has become expert in two components of the risk assessment/risk management paradigm—specifically, hazard identification and risk characterization. The Subcommittee recommends an expansion of this effort in the following ways:

1. Continue the work in progress to identify core programs and write a full strategic plan that incorporates the risk assessment/risk management paradigm as an integral component.
2. Encourage early identification of problems at the highest levels of management in EPA to allow the research program under this paradigm to design its long-term studies, milestones, and anticipated outcomes in a cohesive and coherent way.
3. Use the risk assessment/risk management paradigm as an integral part of the self-evaluation, self-study program for evaluating the status of research programs and commending the researchers who have conducted these efforts.
4. Use the risk assessment/risk management paradigm to identify common problems and collaborative research programs that will necessitate interactions between the health research and ecological research groups within NHEERL. Likewise, the paradigm can be used as a framework for interactions between NHEERL and the exposure assessment components of ORD as well as the risk assessment responsibilities of NCEA. Through these collaborative efforts, NHEERL's program can be expected to be strengthened and more fully supported and appreciated within ORD.
5. Articulate the outcome of the research program more clearly in terms of the risk assessment/risk management paradigm to enable the programs of ORD's regulatory clients and those programs outside ORD, including state, private, and international communities, to use the results of ORD's research for their own particular risk assessment and risk management issues.

6. Match skill mixes to support the risk assessment/risk management paradigm, in particular, increase the role of epidemiology.

5.3 Integration

The interaction between the Laboratory and the Program Offices in Washington, DC, is critical to accomplishing the Laboratory's objective of supporting regulatory decisionmaking. The incorporation of media-specific ALDs at a high level in the organization enables NHEERL to link its work with the Program Offices at EPA. In spite of this, one of the obstacles for effective response by NHEERL is being able to have enough lead time to develop capabilities to respond to current issues. The Subcommittee strongly recommends that NHEERL continue to develop mechanisms to assemble resources to address emerging problems rather than waiting until the problems are upon them.

Another key area of integration is health and ecological effects. The Laboratory has these two capabilities under one Director. A number of initiatives at the project level are already under way, and some organizational capability is being built. The Laboratory should enhance the collaboration and integration of health and ecological effects, and capitalize on what is already there. NHEERL's efforts to date are exemplary. The Subcommittee recommends that these should be expanded, with special emphasis placed on certain directions that are naturally related.

5.4 Organization and Management

The reorganization is moving very successfully within NHEERL, despite its recency. The organization and management of NHEERL has to be viewed in the context of this relatively recent reorganization. The organization, management, and decisionmaking processes also need to be viewed in the context of a complex decisionmaking environment that surrounds the Laboratory pertaining to the division of activities into different media units, the number of RCTs, and the number of budgetary cycles.

The Subcommittee recommends that continued attention be paid to the following three organizational and managerial issues: (1) adequate support for ALDs to accomplish their coordination tasks, (2) continued encouragement of engaging the PIs in the work of the Laboratory, and (3) reevaluation of the current organization structure to enhance the integration of health and ecology.

The Subcommittee further recommends that the organization—in terms of an LD, ALDs, Associate Directors, Division Directors, Branch Chiefs, and PIs—should continue to be clarified and communicated relative to the Laboratory's mission as its organization evolves.

5.5 Sufficiency and Utilization of Resources

NHEERL's resource base, in terms of both personnel and facilities, operates within boundaries created by overall government policies and resource allocations to it. The Laboratory has been very innovative in introducing flexible hiring practices such as having divisions retain FTEs when people leave. It is concerned about its ability to attract and retain high-quality professionals, and in some areas, competition with industry and academia is formidable. It has proposed new mechanisms for doing this, such as a Senior Scientific Leadership Corps, and support of good postdoctoral

professionals, who could work as research fellows in ORD Laboratories. EPA should seriously evaluate these proposals.

The sufficiency of resources depends on what the core capabilities are and the direction of the Laboratory as reflected in a core. A Laboratory-wide strategic plan is the key vehicle for articulating this. The Laboratory also should seek ways of leveraging resources through partnerships with other laboratories and organizations, similar to the partnering that occurs between ORD and NSF on extramural research funding.

NHEERL encourages the involvement of junior scientists and external senior researchers in a number of ways. It accommodates about 100 summer interns at the undergraduate and graduate levels. A major obstacle, however, that has been created by the downsizing is that interns now count against the FTE allotment to the Laboratory when previously they did not. The Laboratory has training cooperative agreements, and its personnel serve on thesis committees. Postdoctoral fellows should be encouraged (even required) to spend substantial time at NHEERL sites working collaboratively with EPA scientists and external mentors.

5.6 Research Environment

Elements of a research environment include stability and the ability to recruit and retain higher level professionals and young postdoctoral fellows into the organization. Rapidly shifting priorities and unstable funding are detrimental to a research environment.

Stability in the research environment is important because of the timeframe of the research environment and it enhances the morale of researchers. It is important to allow new programs the time to develop, that is, new structures and ideas should be given time to play out. Constant change can undermine the environment for the PI and is “out of sync” with timeframes for scientific research. An explicit ongoing and periodic performance system is needed to assess problems in this area.

One element that was described as contributing positively to morale and the research environment was the change in the allocation procedure for FTEs at the division level. Previously, when a person retired or left, the FTE reallocation was made by ORD. Now, the Laboratory Director makes those allocations. The Director has allowed the divisions to retain their FTEs as long as they have a strategic hiring plan that describes what type of hiring will be done to fill the position. PIs have input into the hiring plan. The only drawback is that if a particular postdoctoral professional is not in the hiring plan, then that individual probably will not be able to be hired if a position becomes available. The divisional hiring plans can be fairly flexible. For example, they can be aggregated into summer hirings if opportunities for such hires become available.

5.7 Performance

At the present time, NHEERL takes a number of different approaches to assessing its performance, including the application of GPRA measures, analyzing peer-reviewed publications, and through the use of case studies. An overarching strategic Laboratory-wide plan would provide a good vehicle to identify and articulate its unique niches, define the core, and link stated objectives back to the mission. Once a plan is developed, performance can be gauged more easily against plan elements.

6.0 APPENDICES

A. Letters From Board of Scientific Counselors Chair

B. Self-Study Report

Reiter, Lawrence W., National Health and Environmental Effects Research Laboratory
August 4-5, 1997

C. Meeting Agenda

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

REVIEW OF THE
NATIONAL HEALTH AND ENVIRONMENTAL EFFECTS RESEARCH
LABORATORY (NHEERL)
The Environmental Research Center, Classroom 3
(Intersection of Highway 54 and Alexander Drive)

August 4-5, 1997

PROPOSED SITE VISIT AGENDA

Monday, August 4, 1997

9:00 a.m. - 9:05 a.m.	Welcome and Introduction	Review Team/ Laboratory Director
9:05 a.m. - 9:45 a.m.	Overview of Laboratory—Oral Presentation	Laboratory Director
9:45 a.m. - 12:00 noon	Discussion of NHEERL Self-Study	Review Team/ Laboratory Director
12:00 noon - 1:00 p.m.	LUNCH	
1:00 p.m. - 2:45 p.m.	Presentation of Case Studies	Laboratory Director/ Laboratory Staff
2:45 p.m. - 3:00 p.m.	Public Comments	
3:00 p.m. - 3:15 p.m.	BREAK	
3:15 p.m. - 5:00 p.m.	Breakout Sessions for Detailed Discussions of Selected Topics	Laboratory Management/ Review Team
5:00 p.m.	Adjourn (session may be extended to 6:00 p.m.)	

Tuesday, August 5, 1997

8:00 a.m. - 12:00 noon	Writing Session	Review Team
12:00 noon - 1:00 p.m.	LUNCH	
1:00 p.m. - 5:00 p.m.	Writing Session/Closing Session	Review Team/ Laboratory Management

D. Summary of the ORD Strategic Plan

Strategic Principles (focus for research)

- ❖ Focus on greatest risks to people and the environment
- ❖ Reduce uncertainty in risk assessment [and improving cost-effectiveness in risk prevention and management]
- ❖ Balance human health and ecological research
- ❖ Infuse customer/client ethic
- ❖ Maintain strong and viable core capabilities
- ❖ Nurture and support the development of outstanding scientists, engineers, and other environmental professionals
- ❖ Increase competitively awarded research grants [this is eliminated in the 1997 Update]
- ❖ Require the highest level of independent peer review and quality assurance
- ❖ Provide infrastructure to achieve and maintain an outstanding R&D program.

Reinvention Around the Risk Paradigm—“The most important of these principles is the explicit use of the risk paradigm to shape and focus our organizational structure and research agenda.” Components of the paradigm include effects, exposure, assessment, characterization, and management. ORD Laboratories are aligned along these components of the risk paradigm. (5/97 document, p. 1)

High Priority Research Areas

- ❖ Drinking water disinfection
- ❖ Particulate matter
- ❖ Endocrine disruptors
- ❖ Research to improve ecosystem risk assessment
- ❖ Research to improve health risk assessment
- ❖ Pollution prevention and new technologies

Other Areas of High Importance

- ❖ Air pollutants
- ❖ Indoor air
- ❖ Global change
- ❖ Drinking water (other than disinfection)
- ❖ Waste site characterization
- ❖ Waste management and site remediation

Mission (p. 9, each mission linked to a goal statement, p. 10)

- ❖ Perform R&D for current and future environmental problems
- ❖ Provide responsive technical support for EPA’s mission
- ❖ Integrate the work of ORD’s scientific partners
- ❖ Provide leadership in addressing issues and advancing the science and technology of risk assessment and risk management

Measures of Success (p. 16)

- ❖ Significance—right issues?
- ❖ Relevance—provision of useful data?
- ❖ Credibility—high quality research?
- ❖ Timeliness—performing consultation and assessment function?

NOTE: Bracketed items above are additions or deletions from the 1997 Update.

SOURCES:

U.S. EPA, ORD, *Strategic Plan for the Office of Research and Development*.
Washington, DC: U.S. EPA, ORD, May 1996. EPA/600/R-96/059.

U.S. EPA, ORD. *1997 Update to ORD's Strategic Plan*. Washington, DC: U.S. EPA,
ORD, April 1997. EPA/600/R-97/015.

E. NHEERL Current Organization Chart

F. NHEERL Proposed Organization Chart