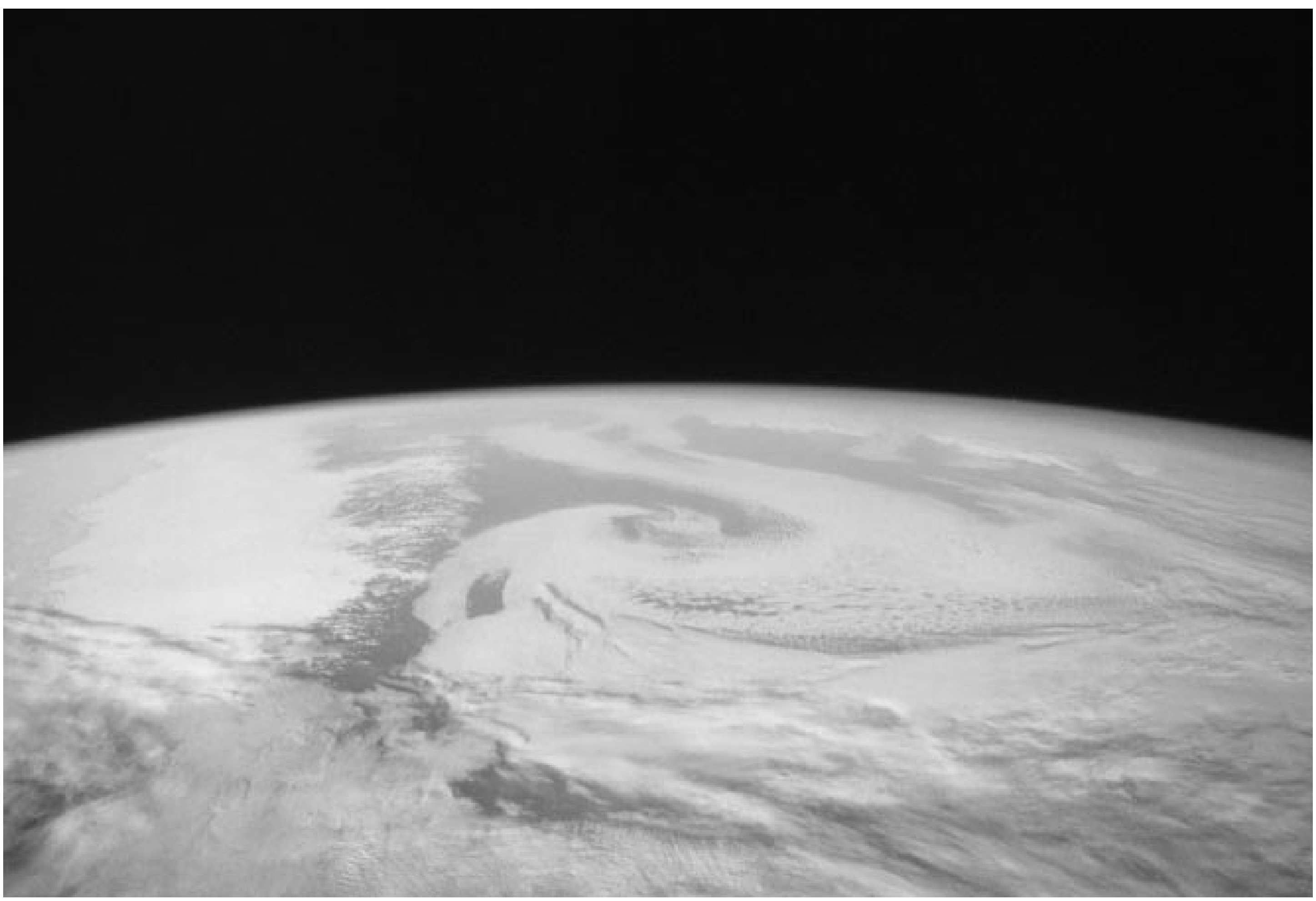
United States
Environmental Protection
Agency

Research and
Development
(8101)

EPA/600/R-96/059
May 1996

Strategic Plan for the Office of Research and Development



Printed on paper that contains at least 20% postconsumer fiber.

ORD's Strategic Plan

Office of Research and Development

U.S. Environmental Protection Agency
Washington, DC 20460

May 1996

Foreword

I am very pleased to present this new Strategic Plan for environmental research at the U.S. Environmental Protection Agency's (EPA's) Office of Research and Development (ORD). In recent years, many important groups—including EPA's Science Advisory Board and blue ribbon panels convened by the National Academy of Public Administration and the National Research Council—have made many excellent suggestions for improving science at EPA. This plan incorporates and builds on these ideas to provide a blueprint for charting a course of strong, credible science at EPA into the next century.

This plan is the culmination of a number of strategic changes to institute a more effective, risk-based research program at ORD. For example, we reorganized our nationwide system of laboratories to conform to the fundamental components of the widely used risk assessment and risk management processes. With this Strategic Plan, we have instituted a new system for determining research priorities based on risk assessment and risk management principles. We will use this system to sharpen the focus of our research by directing our resources where we can contribute most effectively to understanding and solving environmental problems, while also fully supporting EPA in fulfilling its mandates.

By providing clear mechanisms and opportunities for stakeholder involvement, this plan promotes greater partnership between ORD and its primary clients—EPA's Program and Regional Offices—as well as the external scientific community. And, by clearly delineating ORD's research planning process, goals, and objectives, this plan is a tool our stakeholders can use to measure our success in providing practical, credible, and timely information and tools for risk-based decision-making. To ensure the utmost transparency, this plan also includes a detailed description of how ORD translates its research priorities into a research program, as well as a discussion of our commitment to providing the infrastructure needed to conduct high quality research.

This plan is a foundation for the future. We have designed this Strategic Plan to endure and yet be dynamic in the face of continually advancing scientific knowledge and understanding. That is why we have selected time-tested risk-based organizing and decision-making principles that transcend economic and political changes. At the same time, we have designed the plan to be flexible, providing capacity for our planning mechanisms to constructively adapt to changing EPA and national priorities over time.

We invited other EPA offices and Regions as well as numerous external organizations to peer review a draft of this plan. This final version of the plan now incorporates many of their useful suggestions. We will periodically revisit and, as necessary, modify this Strategic Plan to ensure the continued productivity of ORD's research and development efforts to meet EPA and national environmental goals.

I firmly believe that this Strategic Plan, coupled with the other strategic changes we have instituted at ORD (listed on the back inside cover), offer unparalleled opportunities for ORD to improve the overall quality and relevancy of EPA research and development. I am confident that, in the coming years, these changes will serve as essential catalysts for moving EPA into the highest echelon of leadership in environmental science.

Robert J. Huggett
Assistant Administrator, Office of Research and Development

Contents

List of Acronyms

CRADA	Cooperative Research and Development Agreement
EPA	U.S. Environmental Protection Agency
IRIS	Integrated Risk Information System
NAE	National Academy of Engineering
NAPA	National Academy of Public Administration
NAS	National Academy of Sciences
NCEA	National Center for Environmental Assessment
NCERQA	National Center for Environmental Research and Quality Assurance
NERL	National Exposure Research Laboratory
NHEERL	National Health and Environmental Effects Research Laboratory
NRC	National Research Council
NRMRL	National Risk Management Research Laboratory
ORD	Office of Research and Development
ORMA	Office of Resources Management and Administration
ORSI	Office of Research and Science Integration
OSP	Office of Science Policy
RCC	Research Coordination Council
RCT	Research Coordination Team
R&D	research and development
RFA	Request for Application
ROPE	Research Opportunities and Priorities for EPA
SAB	Science Advisory Board
STAR	Science to Achieve Results

Executive Summary

The U.S. Environmental Protection Agency's Office of Research and Development (ORD) has undertaken some of the most dramatic changes in its organizational history, setting the vision and direction for the research that will provide the scientific foundation to support EPA's mission:

- ORD ***realigned its organizational structure*** to use risk assessment and risk management as organizing principles for its nationwide laboratory system.
- ORD ***strengthened its interaction with the larger scientific community*** by expanding its competitive extramural grants and graduate fellowship programs. These programs stimulate research in areas vital to EPA by involving universities and other not-for-profit institutions.
- ORD ***intensified its peer review process*** to ensure that all science meets our standards for excellence.
- And, most importantly, ORD ***instituted a new strategic planning and management process*** by which we identify and select our research priorities. This new process sets us on a course that will allow us to more clearly define the next generation of environmental needs and identify the research to address those needs.

Describing this strategic planning and management process, and providing the framework for research priorities, is the ORD Strategic Plan.

Strategic Principles

The ORD Strategic Plan is based on nine strategic operating principles, summarized below, which draw on the many recommendations ORD has received from outside groups in recent years:

- Focus research and development on the greatest risks to people and the environment.
- Focus research on reducing uncertainty in risk assessment.
- Balance human health and ecological research.
- Infuse ORD's work with a customer/client ethic.
- Give priority to maintaining strong and viable core capabilities.
- Nurture and support the development of outstanding scientists, engineers, and other environmental professionals.
- Increase competitively awarded research grants.
- Require the highest level of independent peer review and quality assurance.
- Provide the infrastructure to achieve and maintain an outstanding R&D program.

Most important of these principles is the explicit use of the risk paradigm to shape and focus our organizational structure and research agenda.

ORD's Vision, Mission, and Long-Term Goals

ORD's commitment to develop a risk-based research agenda has required us to rethink our vision, mission, and goals and to develop a risk-based process for selecting and ranking those research areas of primary importance to EPA. ORD's vision and mission for the future arise from a consideration of the key role that ORD science plays within EPA and in the broader context of our nation's environmental research agenda. Our vision is that ORD will provide the scientific foundation to support EPA's mission. Our new mission statement is divided into four main components: research and development, technical support, integration of scientific information, and anticipatory research. This translates into six long-term, overarching goals—broad areas of research and development where we believe ORD can and must make important contributions to

EPA's mission and mandates and to our nation's overall environmental research agenda.

Setting ORD Research Priorities

Essential to meeting our long-term goals is a process we will use to set priorities within the universe of possible research, and to focus our efforts on those areas of primary importance to EPA's mission. Our new priority-setting process involves the following steps:

- First, ***we involve all parts of EPA, including ORD's own researchers and staff, in helping us set research priorities.*** The Research Coordination Council, the Science Council, Research Coordination Teams consisting of senior representatives from ORD's new National Laboratories and Centers and EPA's Program and Regional Offices identify the most important and relevant areas for our research efforts. We also work with EPA's Science Advisory Board, the National Research Council, and the private sector early in the planning process to ***obtain recommendations from the external scientific community*** regarding the major scientific directions and priorities for our research program. Based on this input, we identify potential research topics.
- We then narrow the pool of potential topics by ***selecting areas that clearly will contribute to fulfilling Agency mandates.***
- To these remaining areas falling within ORD's mission and goals, ***we apply a series of human health, ecological health, and risk management criteria to set priorities according to their potential to support effective risk assessment and enhance risk reduction***—for example by reducing the uncertainties in risk assessment. We use comparative risk analyses, as needed, to ascertain the most pressing problems. We also consider whether the research would develop broadly applicable methods and models needed by EPA programs. We then ascertain whether ORD can make a significant contribution. Through this screening process, we set priorities among the research topics.
- We then define our specific R&D projects by ***considering each topic area in totality.*** For each topic area, we systematically examine the research needs within each component of the risk paradigm: effects, exposure, assessment, and risk management. Based on this analysis, we define a series of high-priority research activities across the risk paradigm that will produce a comprehensive set of useful risk-based results.
- Once we have identified our high-priority topics, we ***develop and implement a research program*** with specified roles for intramural and extramural participants, identifiable products, and provisions for accountability and visibility regarding progress on our commitments.

High-Priority Research

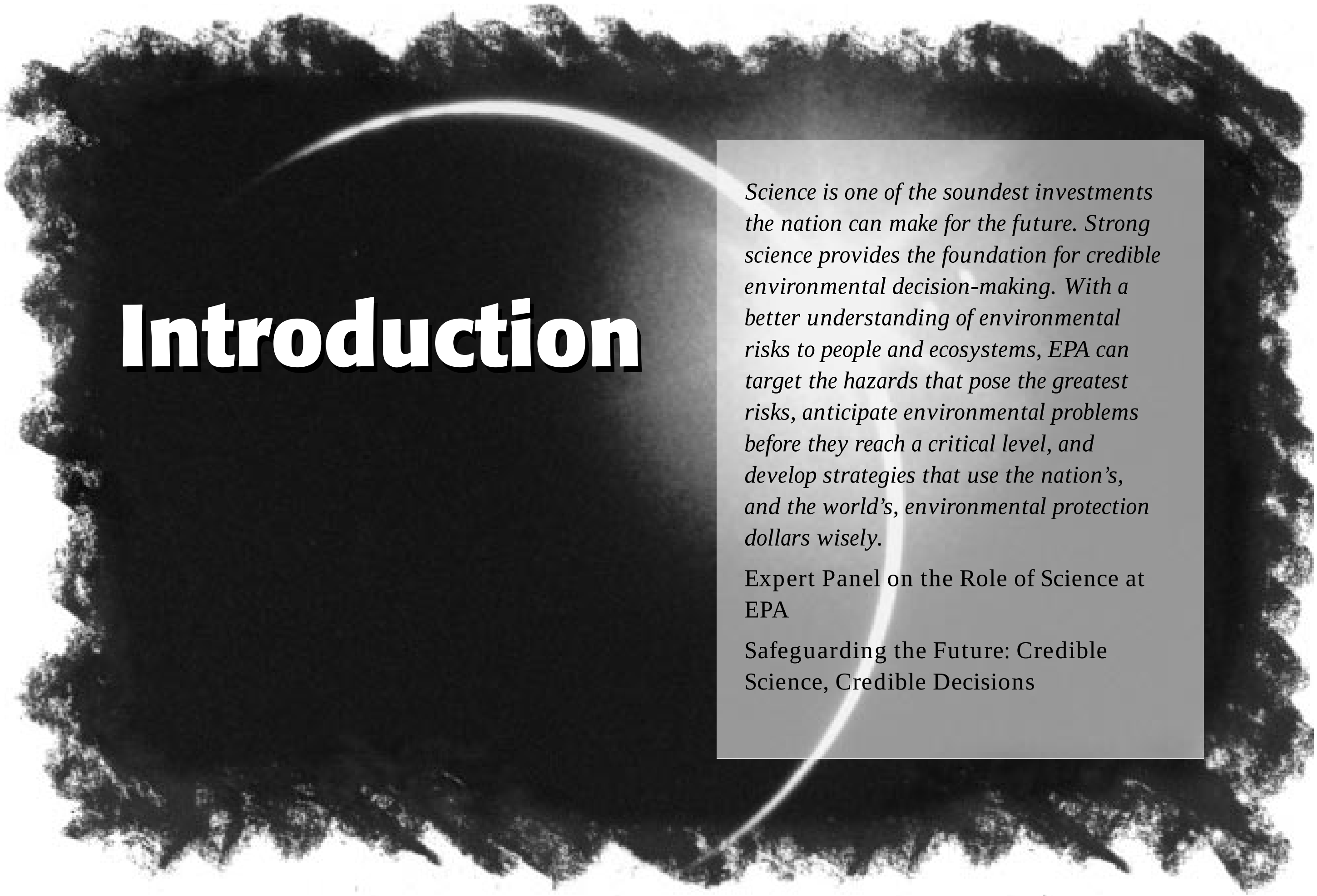
ORD has used the process described above to establish our research priorities for the next few years. Using our new risk-based planning process and criteria, ORD has identified six high priorities that will receive special, expanded attention within the broader ORD program. These high priorities include three discrete research topics and three broad-based areas that can incorporate many additional specific topics:

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

Looking Ahead

The Strategic Plan provides a blueprint for designing and implementing a research program to produce the sound science needed to support EPA's mission. In the years to come, ORD will place a continuing priority on providing the communication, infrastructure, and support necessary for successful implementation of the plan.

For ORD's stakeholders, including the EPA Program and Regional Offices, academia, the private sector, and other government agencies, the plan serves as a roadmap that explains ORD's research planning and implementation process, defines how our stakeholders contribute to this process, and specifies the goals, objectives, and products they can use to hold us accountable for our progress in environmental research. This plan is intended to serve as a practical tool for ensuring the constructive involvement of our stakeholders in establishing and executing ORD's research agenda during the coming years.



Introduction

Science is one of the soundest investments the nation can make for the future. Strong science provides the foundation for credible environmental decision-making. With a better understanding of environmental risks to people and ecosystems, EPA can target the hazards that pose the greatest risks, anticipate environmental problems before they reach a critical level, and develop strategies that use the nation's, and the world's, environmental protection dollars wisely.

Expert Panel on the Role of Science at EPA

Safeguarding the Future: Credible Science, Credible Decisions

In recent years, a convergence of thinking has occurred about science at the U.S. Environmental Protection Agency (EPA). The Agency's own Science Advisory Board (an independent group of engineering and science advisors to EPA) and expert blue-ribbon panels convened by the National Academy of Sciences (NAS)[1] and the National Academy of Public Administration (NAPA)[2] all have emphasized the importance of science at EPA and made many recommendations concerning its role and direction.

As these groups affirmed, science provides the foundation for credible environmental decision-making. It is vital to achieving a healthy population, thriving environment, and robust economy. Only through adequate knowledge about the risks to human health and ecosystems, and innovative solutions to prevent pollution and reduce risk, can we continue to enjoy a high quality of life. In July 1994, EPA published a *Five-Year Strategic Plan*[3] that adopts strong science and credible data as one of seven guiding principles to fulfill the Agency's mission to protect human health and environmental quality. While all of EPA uses science for policy and regulatory decision-making, and various EPA offices perform research, the responsibility for leadership in science at EPA and for the bulk of EPA's research and development work resides in EPA's Office of Research and Development (ORD).

ORD's Reinvention Around the Risk Paradigm

In the past two years, we at ORD have substantially changed our organization and operation so that we

---

[1] *Interim Report of the Committee on Research and Peer Review at EPA*. National Academy of Sciences Board on Environmental Studies and Toxicology. 1995. National Academy Press.

[2] *Setting Priorities, Getting Results. A New Direction for EPA*. National Academy of Public Administration. 1995. Washington, DC.

[3] *The New Generation of Environmental Protection. A Summary of EPA's Five-Year Strategic Plan*. U.S. Environmental Protection Agency. 1994. EPA200-2-94-001. Washington, DC.

can strengthen EPA's science base and improve the Agency's and our nation's ability to effectively respond to the complex environmental challenges of the future. These changes represent a significant departure from the past. They are based on a set of strategic principles we have developed (Table 1) that draw upon the many recommendations we have received from outside groups in recent years. The most important of these principles is the explicit use of the risk paradigm to shape and focus our organizational structure and research agenda.

The risk assessment paradigm has been defined many times over the years, most notably in 1983 by the NAS (Figure 1), which consolidated and gave context to terms that had been defined in different ways up to that point. ***Risk assessment*** is the process that scientists use to understand and evaluate the magnitude and probability of risk posed to human health and ecosystems by environmental stressors, such as pollution or habitat loss or change. The resulting risk characterization, together with other public health, statutory, legal, social, economic, political, and technical factors, provides the critical input for deciding whether and how to manage the risk associated with a particular stressor. Risk management options may include both regulatory programs and voluntary activities (e.g., recycling) to reduce or eliminate production of the stressor.

The risk assessment process is one component of the overall process of risk management. The risk management process begins when a potential new

Table 1. ORD's Strategic Principles

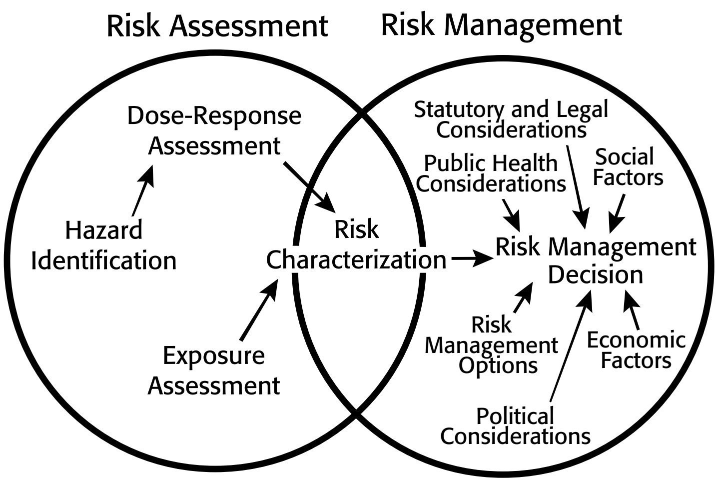
- Focus research and development on the greatest risks to people and the environment, taking into account their potential severity, magnitude, and uncertainty.
- Focus research on reducing uncertainty in risk assessment and on cost-effective approaches for preventing and managing risks.
- Balance human health and ecological research.
- Infuse ORD's work with a customer/client ethic that breaks down organizational barriers and ensures responsiveness to ORD's internal and external customers.
- Give priority to maintaining the strong and viable scientific and engineering core capabilities that allow us to conduct an intramural research and technical support program in areas of highest risk and greatest importance to the Agency.
- Through an innovative and effective human resources development program, nurture and support the development of outstanding scientists, engineers, and other environmental professionals at EPA.
- Take advantage of the creativity of the nation's best research institutions by increasing competitively awarded research grants to further EPA's critical environmental research mission.
- Ensure the quality of the science that underlies our risk assessment and risk reduction efforts by requiring the very highest level of independent peer review and quality assurance for all our science products and programs.
- Provide the infrastructure required for ORD to achieve and maintain an outstanding research and development program in environmental science.

History of This Document

Work on this Strategic Plan began in 1995 by a task force comprised of staff from ORD's National Laboratories and Centers, as well as our headquarters Offices. As we developed the plan, we consulted with our clients in EPA's Program and Regional Offices to ensure that the plan would enable ORD to effectively meet their needs and maintain good customer relations. We also relied heavily on the advice of the National Research Council and EPA's Science Advisory Board. In late 1995, we distributed a review draft of the plan to solicit comments from our external partners and stakeholders. Based on peer reviewer comments, we refined and expanded our plan to produce this final version. Major changes reflected in the final plan include:

- Clarification of our vision, mission, and research goals.
- Better linkage between our research planning process and our criteria for setting research priorities.
- A better balance of health and ecological concerns.
- Clarification of our approach to anticipatory research and emerging environmental problems.
- Discussion of ORD's role in providing enhanced technical support to EPA's Program Offices.
- A more complete discussion of our grants process.
- A brief discussion of "Challenges for the Future" that peer reviewers brought to our attention and to which we plan to devote further study.

Figure 1. The Risk Assessment/Risk Management Paradigm



*Adapted from:

Risk Assessment in the Federal Government: Managing the Process. National Academy of Sciences. 1983.

Science and Judgement in Risk Assessment. National Research Council. 1994.

The risk assessment process consists of four steps:

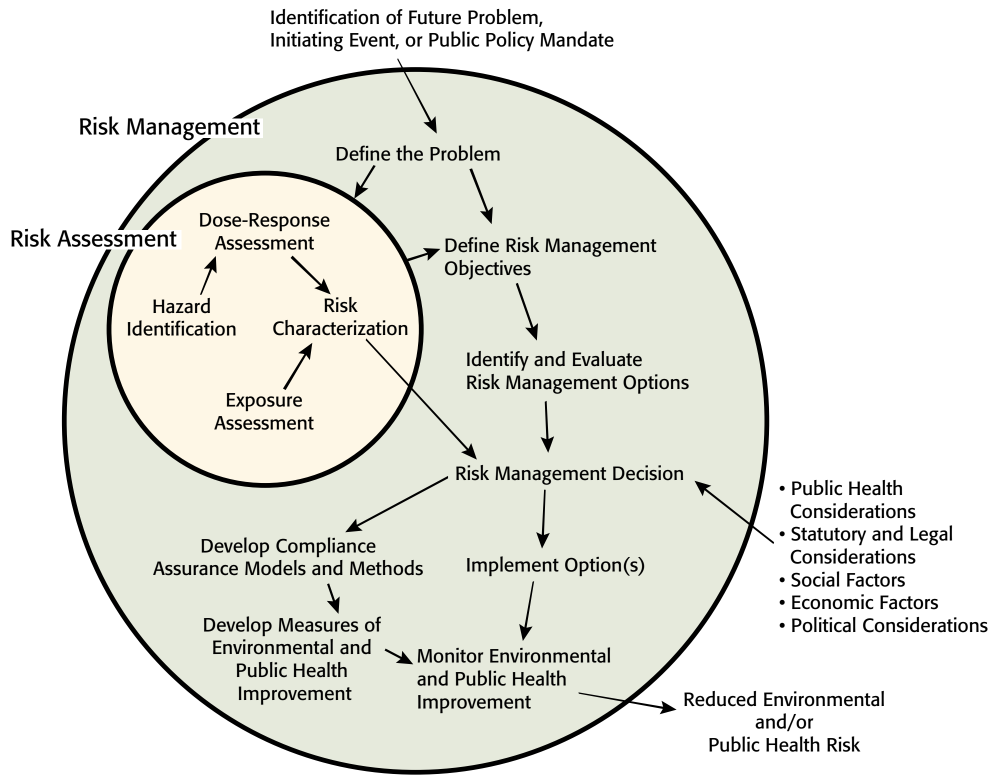
- During ***hazard identification***, scientists describe the adverse effects (e.g., short-term illness, cancer, reproductive effects) that might occur due to exposure to the environmental stressor of concern. To identify potential hazards, scientists use the results of experimental studies on test organisms, reports about accidental exposure, and epidemiologic research.
- During ***dose-response assessment***, scientists determine the toxicity or potency of a stressor. The dose-response assessment describes the quantitative relationship between the amount of exposure to a stressor and the extent of injury or disease.
- During ***exposure assessment***, scientists describe the nature and size of the population(s) or ecosystem(s) exposed to a stressor and the magnitude and duration of exposure. Exposure assessment includes a description of the pathways (e.g., air, food, water) by which the stressor travels through the environment; the changes that a stressor undergoes en route; the environmental concentrations of the stressor relative to time, distance, and direction from its source; potential routes of exposure (oral, dermal, or inhalation); and the distribution of sensitive subgroups, such as pregnant women and children.
- During ***risk characterization***, scientists use the data collected in the three previous steps to predict the effects of human or ecological exposure to the stressor of concern. They estimate the likelihood that a population will experience any of the adverse effects associated with the stressor, under known or expected conditions of exposure. This estimate can be qualitative (e.g., high or low probability) or quantitative (e.g., one in a million probability of occurrence).

The NAS paradigm was developed specifically to define risk assessment and risk management for human health. While ORD recognizes that there are distinctions for ecological risk assessment and that scientific approaches to risk assessment have evolved and expanded since development of the NAS paradigm, the general principles set forth in the NAS paradigm are still useful as an organizing focus for ORD's strategic thinking.

risk comes to light and authorities decide or are mandated to respond to concern about the risk. It involves risk assessment as well as a series of other scientific and technical activities, illustrated in Figure 2, to provide the scientific and technical data for making and implementing a risk management decision. The risk management process ends when the selected risk management option(s) is implemented and the resulting environmental and/or public health improvements are monitored.

Figure 2 expands on the "Risk Management Options" portion of the original NAS paradigm to show the many scientific and technical activities, in addition to risk assessment, that are essential to risk management. These include characterizing the sources of environmental problems; identifying risk management options and evaluating their performance, cost, and effectiveness; and monitoring improvements in environmental quality and public health that result

Figure 2. The Scientific and Technical Contributions to Risk Management



Scientific and technical activities contribute to every stage of the risk management process. Environmental risk management is initiated when a potential new environmental risk comes to light (such as an unusually high disease rate in a particular population) and authorities decide or are mandated to investigate it.

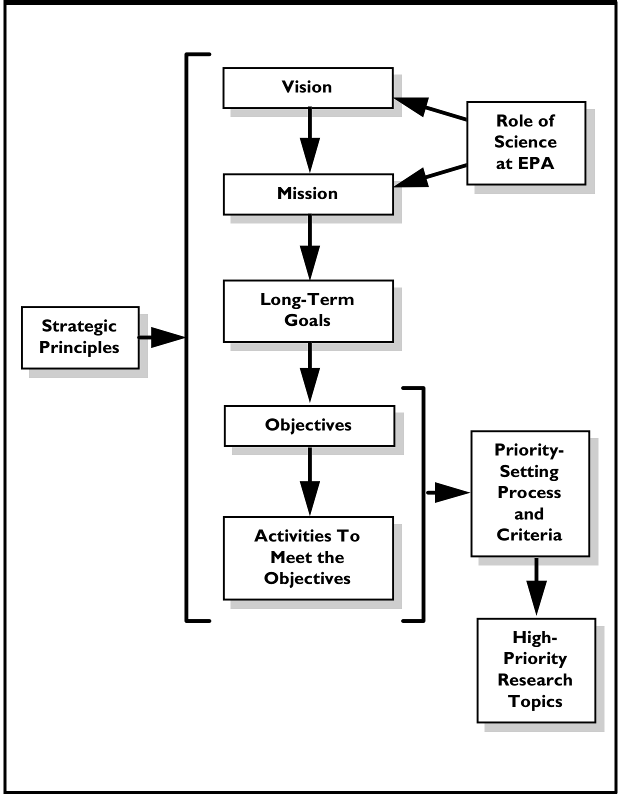
The first step is to ***define the problem***. This involves such activities as determining which stressor(s) (e.g., pollutants, habitat loss) is causing the problem, characterizing the sources of the stressor(s), how these stressors reach target populations, and which human or ecological populations are affected. Once the problem has been sufficiently characterized, the risk assessment process can begin.

If sufficient information is available at this stage, scientists and engineers can also begin to ***define risk management objectives*** (i.e., the degree to which the risk should be managed or reduced) and ***identify risk management options*** that can meet the objectives. Frequently, however, these steps must await further information, provided by the risk assessment, on which populations are at risk and how great that risk is. Once potential options have been identified, scientists and engineers ***evaluate the options*** to determine their performance and cost. Risk management options may include, for example, pollution control technologies, banning or controlling the use of certain chemicals, cleaning up or preventing access to contaminated areas, implementing educational programs to encourage voluntary behavior changes on the part of the public or industry, and redesigning industrial processes to reduce or eliminate toxic waste production.

The resulting information on the feasibility of potential risk management options, together with the risk characterization (and public health, statutory, legal, social, economic, and political factors), is used to make a ***risk management decision***. Typically, this will involve selecting one or more of the potential risk management options and designing a regulatory and/or nonregulatory strategy for implementing the chosen option(s).

Once a risk management strategy has been selected, scientists and engineers then ***develop compliance assurance models and methods*** (if the strategy is regulatory) and ***measures of environmental and public health improvement*** to monitor the success of the strategy in reducing risk to humans or ecosystems. Once the selected option(s) is implemented, scientists and engineers ***monitor the environmental and public health improvement***. Monitoring data provide feedback to the risk management decision-makers about whether the risk management strategy is achieving the desired goals. Decision-makers may then amend the strategy, as necessary, based on these results. The final outcome of a successful risk management process is ***reduced environmental and/or public health risk***.

Figure 3. ORD's Strategic Plan



from risk management activities. ORD contributes to many of the areas depicted in Figure 2. In this way, ORD not only identifies and characterizes environmental problems but also helps to find and implement efficient, cost-effective solutions to these problems.

The first major step in ORD's reinvention was to reorganize ORD so that its new structure mirrors the risk paradigm shown in Figure 1. This new structure is described in Appendix II. ORD's new Strategic Plan—described in this document and illustrated in Figure 3—is the second major step. This Strategic Plan is the blueprint for ORD's risk-based research program.

Audiences for This Document

This Strategic Plan is an important document for many different groups:

- Internally at ORD, the plan provides ***ORD staff*** with a blueprint for designing and implementing ORD's research program in the years to come. Also, it enables ORD staff to relate the individual research projects for which they are responsible to ORD's strategic goals and objectives, as well as to the Agency's environmental goal of "ensuring that the nation's environmental policies are based on the best science and information available."
- For our many ***stakeholders***, including EPA's Program and Regional Offices, academia, the private sector, and other government agencies, the plan serves as a roadmap that:
  - Explains how we plan research and translate our plans into a research program.
  - Defines an explicit role for stakeholders in crafting and reviewing ORD's research agenda.
  - Specifies goals, objectives, and products that can be used to measure and hold us accountable for our progress in environmental research.

Critical Players and Linkages for Implementing ORD's Strategic Plan

The success of ORD's Strategic Plan relies on the contributions of many individuals, institutions, and sectors, as described below.

ORD Staff

First and foremost, ORD staff are crucial to the plan's success. ORD's scientists and engineers, in particular, are the repository of the core scientific and engineering capability in the Agency, as well as a vital conduit for the needs and potential contributions of ORD's research clients and partners.

Successful implementation of the Strategic Plan will depend on the success of ORD managers in communicating the plan to all our staff and in evoking a sense of ownership of the plan and a shared vision of the work to be accomplished. While leadership for communicating this plan must cascade through ORD's management to our scientific, engineering, professional, and support staff, ownership and implementation of the plan will depend on the strength of our work force. ORD will place a continuing priority on internal communication and support to enable and inspire effective implementation of this plan.

EPA Program and Regional Offices

Linkages between ORD and its primary clients—EPA's Program and Regional Offices—are essential to successful implementation of this plan. One important linkage is the day-to-day contact that ORD scientists and engineers have with EPA's Program and Regional Offices. This ongoing informal contact helps ensure that the ORD scientists and engineers involved in our planning process understand our client's needs.

In addition, this Strategic Plan establishes formal areas of linkage to ensure client input during research planning. As Part A of this plan describes, we directly solicit input on priority needs and products from the Program and Regional Offices during the planning process.

ORD's Research Planning Advisors

As described in Part A of this document, our planning process also relies on the contributions of many other groups who provide crucial input for formulating and executing our research program and priorities. These include other federal agencies (both directly and through the National Science and Technology Council and its Committee on Environment and Natural Resources), as well as the National Research Council and EPA's Science Advisory Board.

ORD's Research Partners

Successful plan implementation also relies on ongoing partnerships between ORD and other research organizations in academia, the private sector, and other government agencies. These partnerships benefit all parties. They provide a common sense and cost-effective way for ORD to utilize the special expertise residing outside our organization, while also reducing overlapping and duplicative work. Our partners enrich our research planning process and help ensure that our research products are appropriately targeted to stakeholder needs. ORD accesses and involves partner organizations in implementing our research program through a variety of competitive, grant, and contractual mechanisms.

Shared Leadership

In the context of environmental science, ORD serves both as a team leader for research planning within EPA and as a national leader within the larger scientific community for conducting our nation's environmental science. ORD implicitly shares responsibility for this leadership through our peer review protocols, which ensure both internal and external vetting of each critical step in our research process, from identifying research priorities to evaluating our eventual success.

Looking Ahead

As ORD implements its Strategic Plan in the years to come, we will strengthen our links with our clients and partners. We will work to expand our partnerships with other agencies, universities, and the private sector and to integrate our planning efforts with EPA's overall planning based on the Agency's Strategic Plan. Also, we will strive to forge links with the planning efforts of other federal agencies and other nations as appropriate.

Evolution of the Strategic Plan Over Time

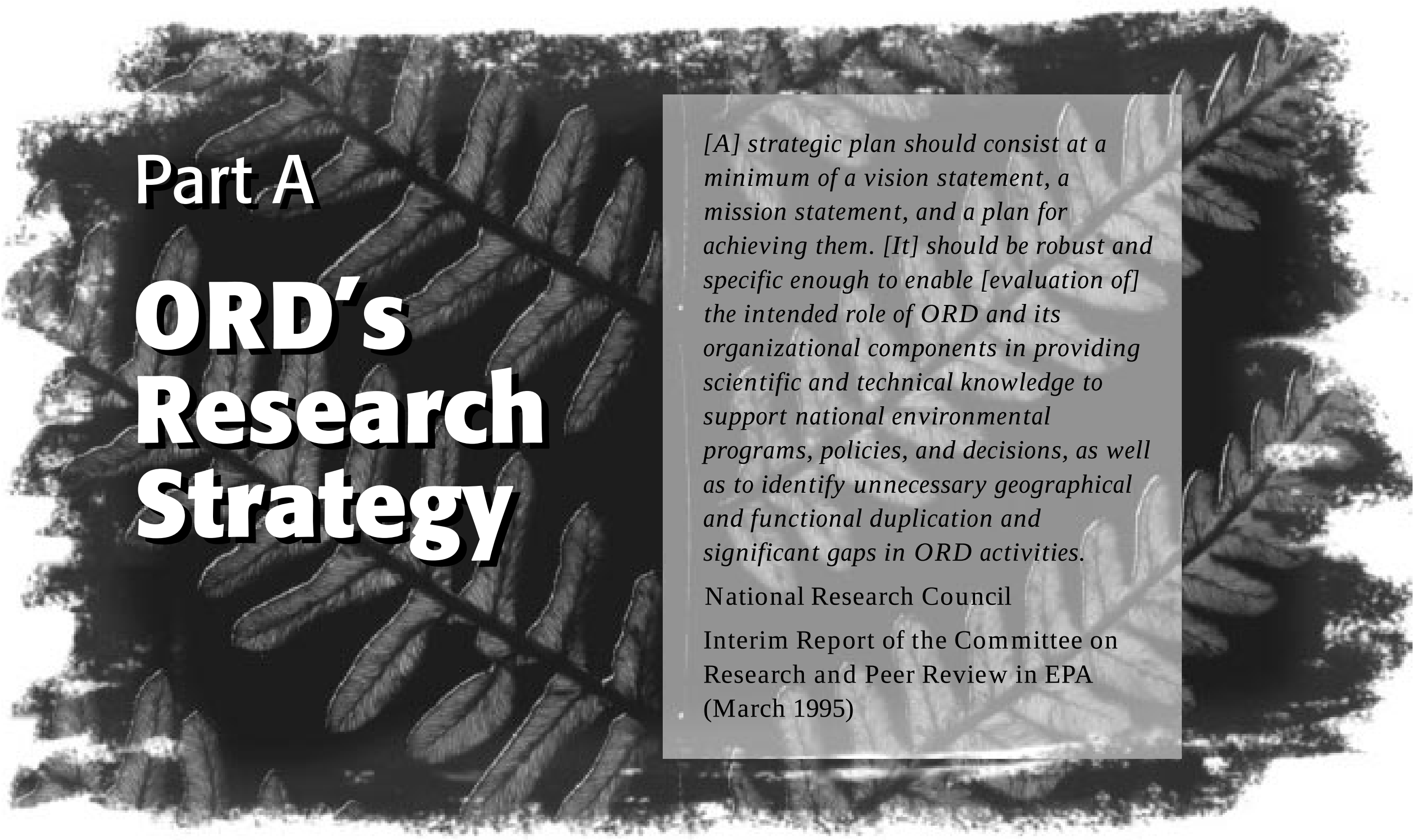
ORD's Strategic Plan is designed to be a robust "living" document. The plan provides a solid underpinning for ORD research that will allow us to maintain continuity and momentum in our work in the coming years, while also constructively adapting to changing EPA and national priorities over time.

We will periodically revisit and, as necessary, modify our Strategic Plan to ensure the continued productivity of ORD's research and development efforts to meet EPA, national, and international environmental goals. At the same time, we will work to ensure that, as the plan evolves, it continues to reflect goals and objectives that are communally derived and universally shared throughout ORD.

A Roadmap for This Document

- ***Part A*** of the plan defines strategic directions (including ORD's vision, mission, and goals) for ORD research; lays out an approach to identifying emerging issues; establishes a risk-based process for determining our research priorities; describes how we translate this Strategic Plan into a specific research program (including research plans, operating plans, laboratory implementation plans, and Requests for Applications); describes how we determine who does the work and when to close it out; describes how we will determine priorities for technical support; presents approaches to measuring success; and describes ORD's commitment to our human resources and infrastructure that are essential to implementing the Strategic Plan. Finally, Part A identifies challenges for future consideration by ORD.

- ***Part B*** expands on ORD's goals and lists the specific research objectives and activities ORD will pursue to achieve its goals.
- ***Appendix I*** describes the six high-priority research topics and areas selected when we applied our new priority-setting process (described in Part A) to our long-term objectives and activities (described in Part B).
- ***Appendix II*** describes ORD's new organization around the risk assessment / risk management paradigm.
- ***Appendix III*** describes ORD's management structure for implementing the Strategic Plan.
- ***Appendix IV*** shows how ORD's extramural investments (in the form of Requests for Applications for research grants) relate to the high-priority research described in Appendix I.



Part A

ORD's Research Strategy

[A] strategic plan should consist at a minimum of a vision statement, a mission statement, and a plan for achieving them. [It] should be robust and specific enough to enable [evaluation of] the intended role of ORD and its organizational components in providing scientific and technical knowledge to support national environmental programs, policies, and decisions, as well as to identify unnecessary geographical and functional duplication and significant gaps in ORD activities.

National Research Council

Interim Report of the Committee on Research and Peer Review in EPA (March 1995)

ORD's commitment to develop a risk-based research agenda has required us to rethink our vision, mission, and goals and to develop a risk-based process for selecting and ranking those research topics of primary importance to ORD and EPA.

ORD's vision and mission for the future arise from a consideration of the importance of science at EPA and in the broader context of our nation's environmental research agenda, and of ORD's key role in environmental science. Our vision, described below, represents the overall level of achievement that we will strive for in all our research and development work. Our mission statement, described below, defines the broad areas of research and development where we believe ORD can and must make important contributions to EPA's mission and mandates and to our nation's overall environmental research agenda.

ORD's Vision

ORD will provide the scientific foundation to support EPA's mission.

ORD's Mission

ORD's mission is to:

- ***Perform research and development*** to identify, understand, and solve current and future environmental problems.
- ***Provide responsive technical support*** to EPA's mission.
- ***Integrate the work of ORD's scientific partners*** (other agencies, nations, private sector organizations, and academia).
- ***Provide leadership*** in addressing emerging environmental issues and in advancing the science and technology of risk assessment and risk management.

ORD's Key Role

Public and private sector institutions have long been significant contributors to our nation's environmental and human health research agenda. EPA's Office of Research and Development, however, is unique among scientific institutions in this country in combining research, analysis, and the integration of scientific information across the full spectrum of health and ecological issues and across both risk assessment and risk management. This broad scope has resulted in scientific and engineering expertise, physical facilities, and equipment that permit and encourage integrated multimedia and multidisciplinary research on environmental issues. As part of a regulatory Agency that establishes national priorities and sets national standards, ORD research is conducted to protect human and ecosystem health in a cost-effective manner and to provide a firm scientific and technical foundation for environmental decisions and standards.

ORD's Long-Term Goals and Objectives

ORD's four mission areas translate into six long-term, overarching goals that we will strive to meet in order to fulfill our mission (Table 2). Part B of this plan describes these goals in detail and breaks each goal down into a series of specific research objectives and activities that ORD will pursue to achieve its goals.

Identifying Specific Research Topics

The objectives and activities listed in Part B of this plan provide detail about how ORD will go about meeting its goals. Each objective and activity still represents a relatively broad research area. ORD, therefore, has developed a priority-setting process and criteria, illustrated in Figures 4 and 5 and described below, for identifying specific research topics within the objective and activity areas that are of primary importance to our vision, mission, and goals. Each year, we will use this priority-setting process and criteria to identify high-priority research topics that will help us achieve ORD's goals and objectives.

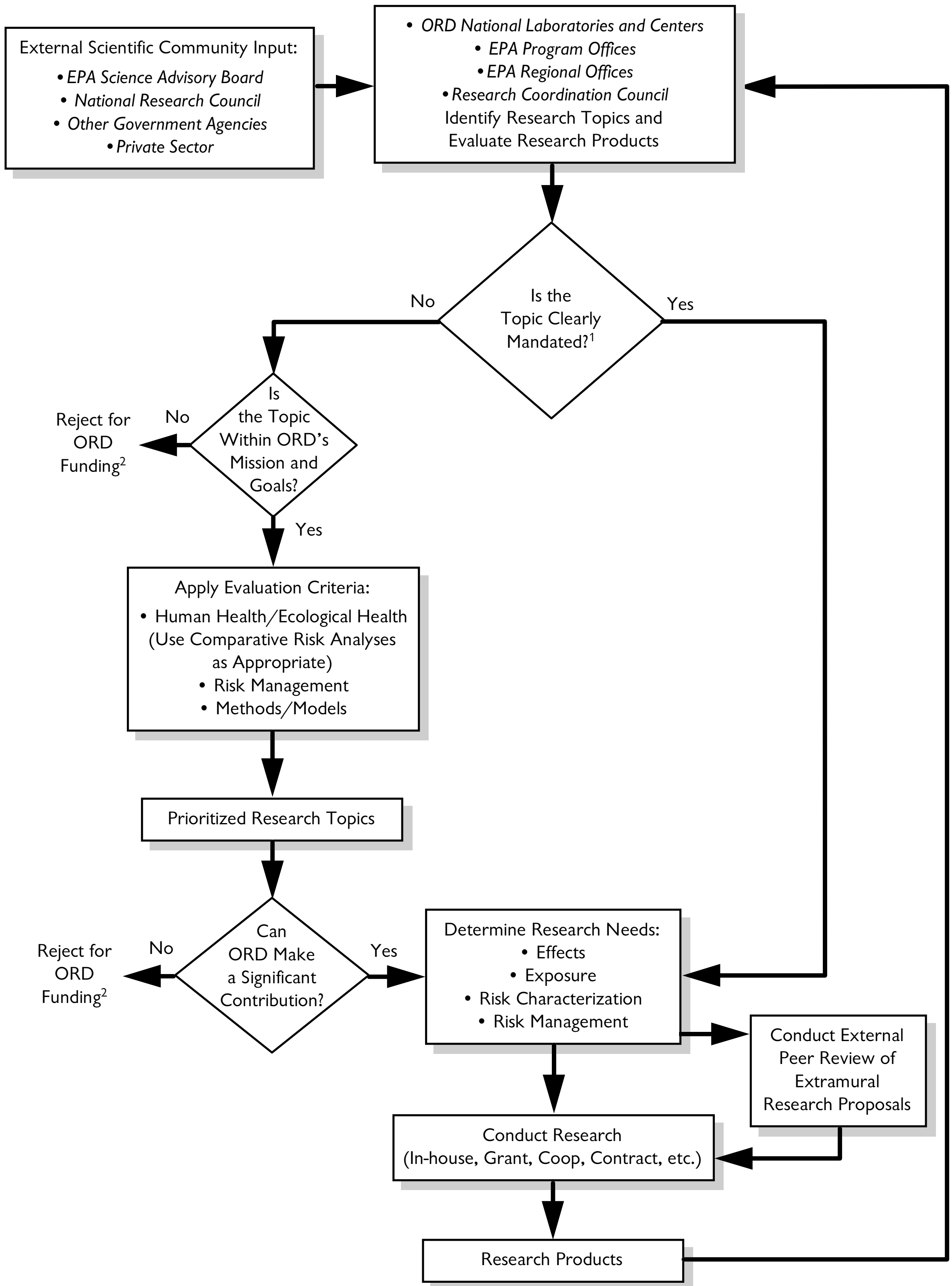
We applied our new priority-setting process and criteria for the first time in 1995, when we used them to reexamine our ongoing research and identify important new initiatives. Based on this first application, we identified six high-priority research topics—some specific and others broad-based—for the next few years. These six topics are described in Appendix I.

Many topics will remain a high priority for several years. Each year, working with our program partners and external advisory bodies, we will examine the previous year's topics to add new topics as appropriate and remove previous topics for which sufficient research has been conducted.

Table 2. ORD's Long-Term Goals

Mission Area	Goals
Perform research and development to identify, understand, and solve current and future environmental problems.	To develop scientifically sound approaches to assessing and characterizing risks to human health and the environment.
	To integrate human health and ecological assessment methods into a comprehensive multimedia assessment methodology.
	To provide common sense and cost-effective approaches for preventing and managing risks.
Provide responsive technical support of EPA's mission.	To provide credible, state-of-the-art risk assessments, methods, models, and guidance.
Integrate the work of ORD's scientific partners.	To exchange reliable scientific, engineering, and risk assessment/risk management information among private and public stakeholders.
Provide leadership in addressing emerging environmental issues and in advancing the science and technology of risk assessment and risk management.	To provide leadership and encourage others to participate in identifying emerging environmental issues, characterizing the risks associated with these issues, and developing ways of preventing or reducing these risks.

Figure 4. Setting Research Priorities



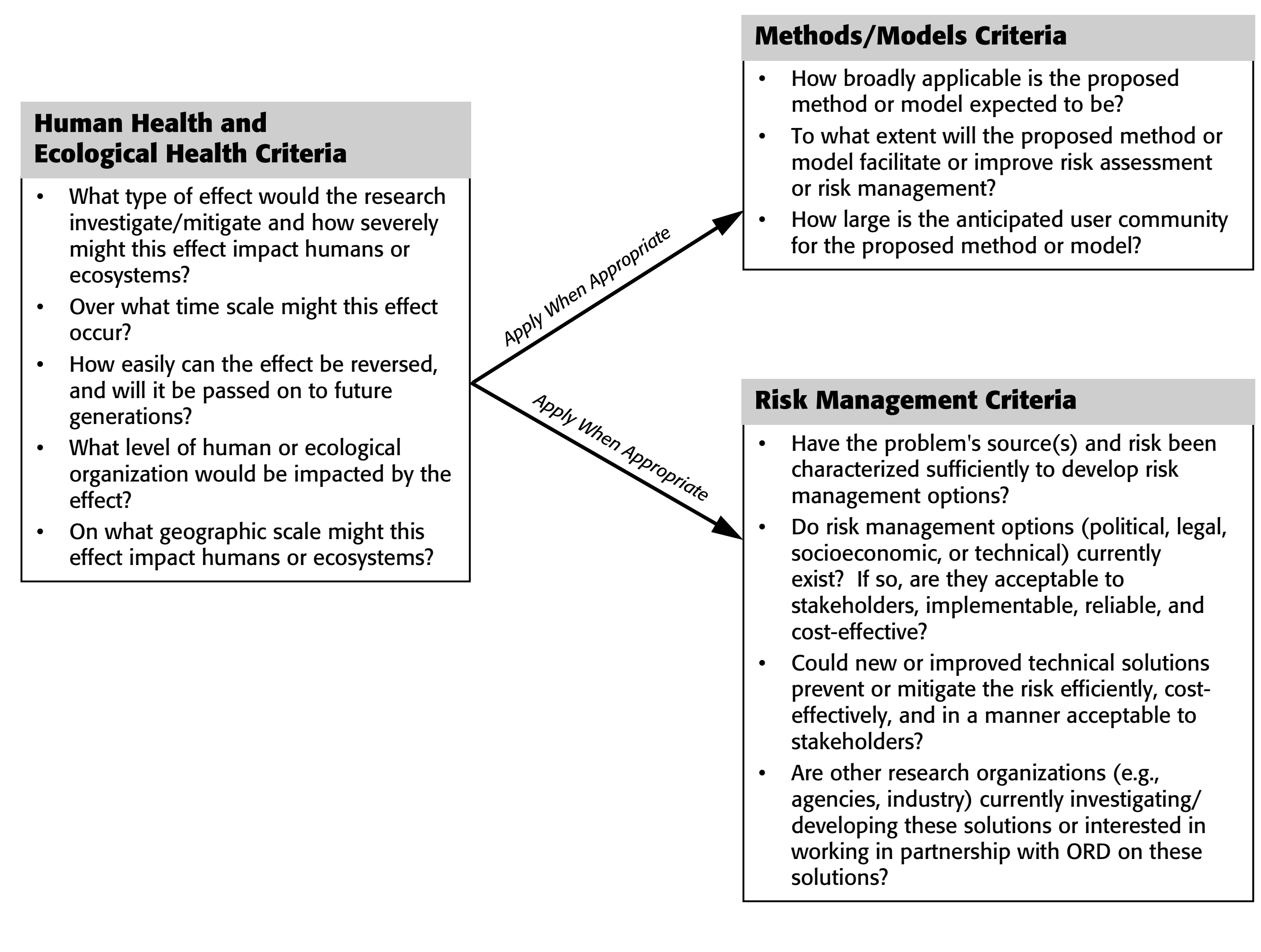
[1]If so, EPA may have no discretion to reject or delay this research.
[2]EPA program offices and regions may still choose to fund, using ORD labs, grants, contracts, etc., or a research source outside of ORD.

Identifying Emerging Issues, Anticipatory Research, and Exploratory Research

In recent years, EPA has begun moving beyond environmental regulation to environmental protection in its broadest sense, including anticipating and preventing problems before they mushroom into major concerns. To support EPA in this endeavor, ORD is evaluating the best means to anticipate tomorrow's environmental problems and provide EPA with the necessary information to evaluate findings, interact with other agencies and organizations, and possibly act on early warnings of emerging environmental issues.

The EPA Science Advisory Board's January 1995 report *Beyond the Horizon: Using Foresight to Protect the Environmental Future* suggests many useful measures we will evaluate for possible implementation. One measure we are currently considering is the creation of "lookout panels" comprised of individuals from inside and outside the federal government to identify, screen, evaluate, and prioritize emerging issues. As a first step in this direction, the National Research Council has established, at ORD's request, a Committee on Research Opportunities and Priorities for EPA (ROPE). This committee is tasked with thinking creatively about ORD's research areas and identifying high-priority research topics key to solving some of our nation's most pressing current and future environmental problems. Such research could spark entirely new approaches to environmental management in the future. Each year, we will consider any high-priority topics related to anticipatory research as we review and revise our research agenda.

Figure 5. ORD Criteria for Evaluating and Ranking Potential Research Topics



ORD's Priority-Setting Process

ORD's new priority-setting process, depicted in Figure 4, involves the following steps:

- First, we seek input from all parts of EPA, including ORD's own researchers and staff. The Research Coordination Council, the Science Council, and Research Coordination Teams (see Appendix III) consisting of senior representatives from ORD's National Laboratories and Centers, the EPA Program Offices, and EPA's Regional Offices identify the most important and relevant areas for our research efforts. (As state and local governments play a larger role in environmental protection, their research needs must also be considered at this stage.) We also work with EPA's Science Advisory Board, the National Research Council, and the private sector early in the planning process to obtain recommendations from the external scientific community regarding the major scientific directions and priorities for our research program. Finally, we consider the status and results of our recent research activities. Based on this information, ORD identifies potential research topics, for both intramural and extramural investments.
- We then separate the pool of potential topics into two categories:
  - Those that are clearly mandated because of statutory requirements or court orders (i.e., EPA may have no discretion to reject or delay the research).
  - All other topics.
- For ***all other topics***, we narrow the pool by retaining only those that are within ORD's mission and goals.
  - We then apply a series of human health, ecological health, and risk management criteria (Figure 5) to compare the mission-related topics according to their potential to support effective risk reduction. We use comparative risk analyses to help ascertain the most pressing environmental problems. We also apply criteria to consider whether the research would develop broadly applicable methods and models needed by EPA programs. Through this screening process, we set priorities among the research topics.
  - We then further narrow this pool of topics by retaining only those areas where ORD can make a ***significant*** contribution to environmental science. Factors we consider at this stage include: Is the work feasible from a scientific and resource perspective? Does ORD have access to the appropriate expertise? What contributions are other research organizations making to this area of research?
- ***For these remaining topics where ORD can make a significant contribution, as well as all nondiscretionary topics,*** we then define specific research and development projects by considering each topic in totality. For each topic, we determine what the research needs are within each component of the risk paradigm: effects (hazard identification and dose-response assessment), exposure assessment, risk characterization, and risk management. At this stage, we give priority to research that will make the greatest contribution to reducing the uncertainty associated with risk characterization, or will improve the effectiveness of risk management.

This approach to strategic planning clearly indicates the following areas where ORD will reduce or eliminate resources:

- Exposure or effects research in areas of low risk.
- Risk reduction research in areas of low risk.
- Routine measurements and monitoring where R&D has been completed or that does not support R&D efforts.

Criteria for Setting ORD Research Priorities

A key component of ORD's new planning process is the criteria we will use to set priorities among research topics. Three sets of criteria are used: human and ecological health criteria, risk management criteria, and methods / models criteria (Figure 5). These criteria, described below, are not set in concrete, nor are they universally applicable to all research areas. We will periodically revisit the criteria, and they likely will evolve with use and experience. Additional or alternative criteria may be used in some cases as appropriate.

Human and Ecological Health Criteria

ORD's human and ecological health criteria are based on five broad categories outlined in the EPA Science Advisory Board's 1990 report, *Reducing Risk: Setting Priorities and Strategies for Environmental*

Table 3. ORD's Human Health and Ecological Health Criteria

	Ecological Health	Human Health
Severity of Response/ Function of Stressor	• Mortality • Morbidity • Degree of physical disruption	• Mortality • Morbidity
Time Scale of Response	• Immediate effects • Effects that will occur in the future	• Acute effects • Subchronic effects • Chronic effects or effects with a long latency period
Permanence of Response	• Irreversible effects • Effects that can be reversed only by human intervention • Temporary effects that reverse naturally over a long time • Temporary effects that reverse naturally over a short time	• Transgenerational effects • Nontransgenerational effects
Level of Organization	• Effects on an entire ecosystem / community • Effects on a single species • Effects on a population within a single species • Effects on individual animals or organisms	• Effects on the general population • Effects on a subpopulation • Effects on individuals
Extent of Response	• Global effects • Ecoregional effects[1] • Effects on several localities • Localized effects	• Global effects • International effects • National effects • Effects on several localities • Localized effects

[1] An ecoregion is a geographic area that has similar topography, climate, and biota across the entire area.

Protection: the severity, time scale, and permanence of the response; the level or organization where the response is expected to occur; and the geographic extent of the response. Table 3 lists the criteria that ORD has developed for each of these five categories.

Risk Management Criteria

Risk management criteria are applied to those research topics that concern risk management. These criteria, listed in Figure 5, are designed to give priority to research that will produce the most effective and useful risk management options. The criteria consider whether sufficient risk characterization information is available to set meaningful objectives for the risk management research; the availability, acceptability to stakeholders, reliability, and cost-effectiveness of existing options; the potential benefits of the proposed research; and whether other research organizations are already conducting or interested in this type of research.

Methods/Models Criteria

The methods / models criteria are applied to research concerning the development or application of methods or models for gathering or analyzing risk-related data. These criteria give priority to research that will likely produce the most useful results. The criteria consider how broadly the method or model would be used, the size of the anticipated user community, and the degree to which the method or model would improve risk assessment or risk management.

Strengths of ORD's Priority-Setting Process and Criteria

Our new process and criteria for setting research priorities have many strengths. They encompass both scientific and stakeholder priorities. They ensure that ORD will continue to fully support EPA in fulfilling its mandates. They focus our resources where we can make the most significant contributions. And, they enable ORD to generate practical, credible information and tools for risk-based decision-making.

Translating ORD's Strategic Plan Into a Research Program

The steps involved in translating ORD's Strategic Plan into a research program are illustrated in Figure 6. Once we have identified our high-priority research topics, we develop and implement a research program based on these topics. This involves:

- Developing science research plans.
- Deciding whether the work will be conducted in-house or extramurally. (ORD's research program is comprised of intramural and extramural research; however, resources for these two areas are kept separate.)
- For intramural research, developing budget operating plans and laboratory implementation plans.
- For extramural research, selecting and implementing the appropriate mechanisms to access the external scientific community.

Developing Science Research Plans

For each selected research topic, Research Coordination Teams composed of ORD scientists and engineers as well as representatives of EPA's Program and Regional Offices develop science research plans that:

- Lay out the major research components and directions we will pursue over the next few years.
- Describe how these components fit into the risk assessment/risk management paradigm.
- Delineate the major outputs to be produced over the next three years.

Research plans are important tools for measuring accountability because they make clear to our clients and stakeholders the rationale for and intended products of our research. They also enable ORD to clearly track its progress toward achieving its goals, as required by the Government Performance and Results Act of 1993.

We consult ORD's main research clients—the EPA Program and Regional Offices—to ensure that the final research plans clearly include the research products they will need to fulfill their responsibilities. In addition, all our research plans are subjected to rigorous external peer review.

Deciding Who Will Do the Work

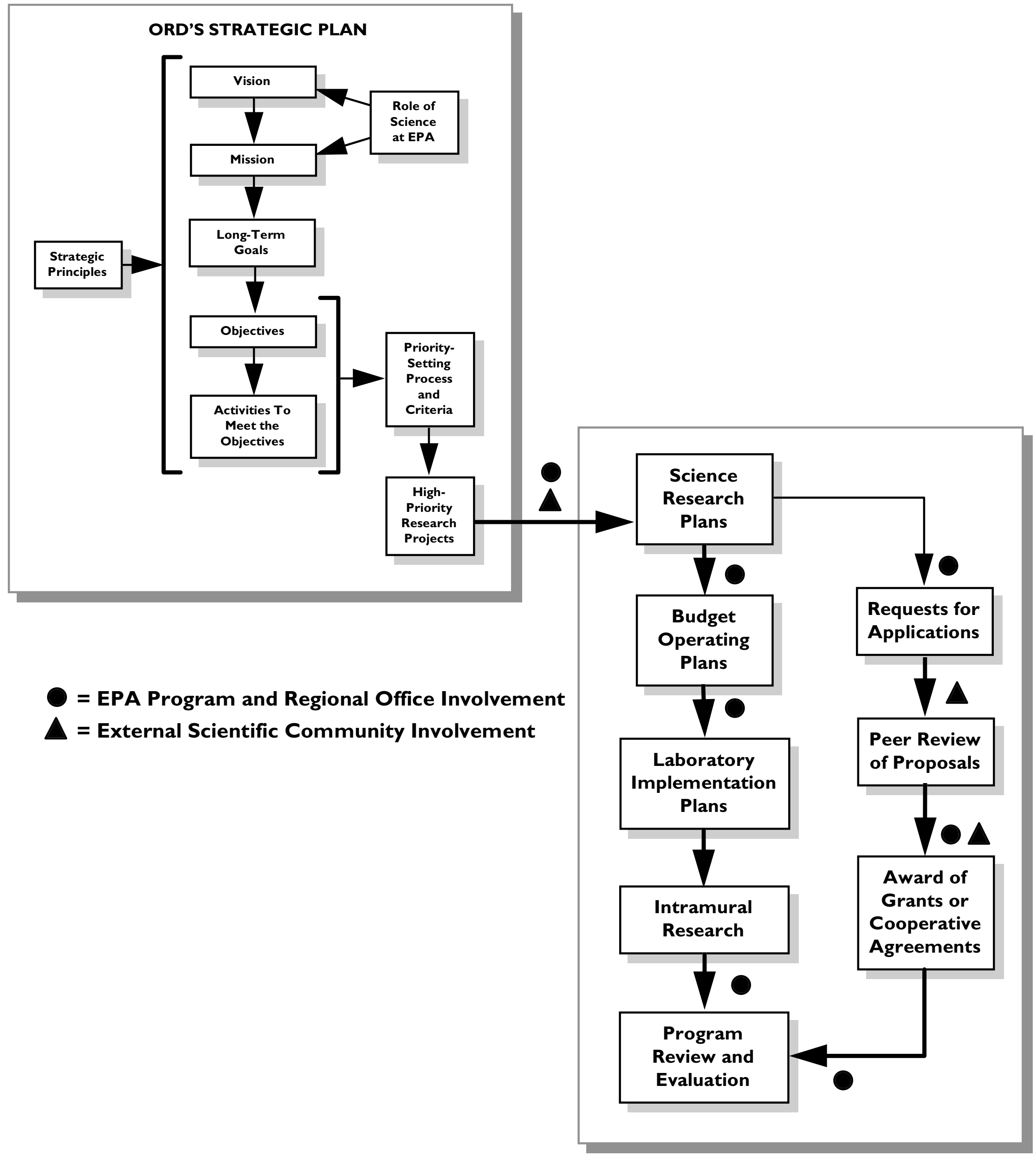
After modifying the science research plans in response to peer reviewer comments, ORD then decides whether the work would best be accomplished internally at ORD or externally through one of several mechanisms: grants to universities or nonprofit centers; Cooperative Research and Development Agreements (CRADAs) with the private sector; cooperative agreements with another government agency or universities; or by contract. Many factors influence this decision, including:

- Which organization has the most appropriate expertise?
- What type of work is called for (risk assessment and regulatory support work are generally retained in-house, whereas research work may be done externally)?
- How urgently are the research products needed (since some mechanisms are faster than others)?
- Would there be value in involving multiple institutions?
- To what extent can we specify what is needed (contracts)? To what extent must we rely on the creativity and insight of the researcher (grants)?
- What is our available in-house capacity?
- What are the opportunities for leverage?

Internal Research

Development of budget operating plans. For internal research, ORD integrates the science research plans with budgetary decisions in order to allocate resources to the selected research topics by laboratory program and research component. This helps ensure that our priority-setting decisions (guided by science) also reflect budgetary realities.

Figure 6. Translating ORD's Strategic Plan Into a Research Program



Development of laboratory implementation plans. Based on the science research plans and budgetary decisions, ORD's Laboratories and Centers develop detailed plans for implementing each area of research to be undertaken internally. These laboratory implementation plans provide a blueprint for Laboratory and Center work and form the basis for managerial oversight and guidance.

Extramural Research

Extramural research is conducted via grants, cooperative agreements, CRADAs, or contracts. Rigorous external peer review is a key mechanism we use to evaluate both the proposals for and results of external research.

One of ORD's primary mechanisms for involving external scientists is the Science to Achieve Results

(STAR) program. STAR targets the best scientists from universities and nonprofit centers because they are an integral and important part of the environmental research community. STAR consists of focused Requests for Applications (RFAs), investigator-initiated exploratory research grants, graduate fellowships, and several "critical mass" environmental research centers.

The bulk of the STAR program derives from RFAs that focus on specific research needs to support the Agency. Working with EPA's Program and Regional Offices, Research Coordination Teams write these RFAs to be consistent with ORD's Strategic Plan and science research plans, and complementary to ORD's in-house work. The RFAs are announced annually to scientists at U.S. academic and nonprofit institutions. Proposals from the external scientific community are peer-reviewed and projects are then selected for funding through grants or cooperative agreements. ORD leverages the STAR program resources by jointly funding research with other federal agencies. Appendix IV shows how the fiscal year 1996 RFA topic areas relate to ORD's high-priority research topics.

Measures of Success

In general, the success of a research organization can be measured in several ways: by the number of articles published in prestigious scientific journals, by the number of times that articles written by the organization's scientists are cited in other journal articles, and so on. However, for a mission-oriented organization like ORD, measures of the extent that we help and support EPA in meeting its goals are equally crucial. In measuring the success of this Strategic Plan, the quality of ORD's work, and the usefulness of our research products, we will use the following measures of success.

Significance: Is ORD Working on the Right Issues?

This is a measure that the EPA Program Offices and Regions and the broad scientific community can help us judge. For our research, development, and support efforts to be useful, we must work on the most important environmental issues and target areas for research that will significantly improve risk assessment and/or risk management in the Agency and elsewhere. Peer review by scientists in the external scientific community will assist us in judging significance.

Relevance: Is ORD Providing Data That the Agency Can Use?

This question can best be answered by the rest of the Agency and is best judged by the degree to which ORD's contributions support EPA decisions. ORD will strive to ensure that its work is useful to the Agency and has a positive impact on advancing EPA's mission.

Credibility: Is ORD Doing Research of the Highest Quality?

ORD's credibility can best be judged by the external scientific community through such mechanisms as peer review of ORD products, reviews of programs at the ORD Laboratories, peer-reviewed journal articles, scientific citations, and external recognition of both ORD and its people.

Timeliness: Is ORD Meeting EPA's Expert Consultation and Assessment Needs in a Timely Manner, Providing Research Products According to Schedule, and Addressing Long-Term Issues With Adequate Forethought and Preparation?

The first part of this question can best be answered by EPA's Program Offices and Regions as they determine whether ORD consultations and assessments are being provided in time to be optimally useful for Agency decisions. The middle part of this question can be answered by ORD managers and EPA's Program Offices and Regions through annual program reviews and other activities. The final aspect of timeliness is more subjective and therefore more difficult to assess. ORD has accepted the challenge of anticipating important environmental issues that are just emerging and may not become critical problems until well into the next century. The U.S. public is the ultimate judge of how successful ORD has been in this effort. ORD will strive to regularly gather the public's view on this issue.

Mechanisms for Evaluation and Accountability

ORD has implemented, or plans to implement, several mechanisms for evaluating its performance, communicating progress and results, and measuring success. These include:

- ***Annual research program reviews,*** jointly organized by ORD's Research Coordination Teams and EPA's Program and Regional Offices, that present to EPA senior managers the entire EPA research portfolio in a given area. These joint reviews focus on the status and accomplishments of the ORD research program to ensure that ORD's research continues to meet ORD and client objectives. They also present the ongoing research being conducted by the Program Offices and Regions so that the total research agenda can be viewed. The objectives of these reviews are to evaluate progress in completing planned research projects, to track and evaluate research results, and to generally obtain feedback on ORD's work and any adjustments that may be needed to help us better meet our clients' needs. These reviews complement, rather than supplant, external peer reviews (see below).
- ***Annual ORD review of its science research plans.*** ORD examines its research plans annually and adjusts them if warranted by our research results, by changes in EPA or national priorities, or by emerging issues and concerns.
- ***External peer reviews of ORD science research plans and products*** and overall progress in meeting our goals and objectives. These reviews are conducted at key steps in our research planning and implementation process.
- ***External peer reviews of research proposals*** received from extramural research scientists in response to the Requests for Applications.
- ***External peer reviews of ORD Laboratories and of ORD's use of peer review*** through our Board of Scientific Councilors under the Federal Advisory Committee Act.
- ***Annual science workshops*** designed to make the progress and results of all ORD research (including the external grants program) accessible to EPA's Program Offices and Regions.
- ***A data tracking system,*** part of ORD's Management Information System, which tracks resources and progress.

Through these mechanisms, ORD will strive to develop and conduct the most responsive, scientifically justifiable research program possible within the constraints of our available resources.

Closing Out Completed Work

Through the continuing involvement of the Research Coordination Teams and the annual program reviews mentioned above, ORD will assess ongoing research to evaluate:

- Whether the research is on track for meeting its goals and schedule.
- When the research should be concluded.

Prudent management of evolving priorities and declining resources requires that we clearly define our research and conclude it within an appropriate timeframe, so we can begin work on new priorities without delay.

Technical Support

ORD is refining its process for providing technical support to EPA's Program Offices. Using an Interoffice Management Work Group and the Environmental Monitoring Management Council, we are working to:

- Define technical support / assistance.
- Create a plan for new and existing technical assistance.
- Create transition and exit strategies for some technical assistance areas where appropriate.

Areas where technical support will continue include development of new methods, models, and measures or approaches; litigation; regulatory support; and scientific advice. ORD will not continue to conduct routine monitoring and quality assurance / quality control for studies other than its own, but will design transition and exit strategies so that the Program Offices and Regions are prepared to assume these responsibilities.

Human Resources and Infrastructure

The success of ORD's Strategic Plan depends on an adequately funded and well-managed infrastructure, including ORD's work force, systems, and equipment. ORD's recognition of the importance of our infrastructure is reflected in our strategic principles (Table 1), which highlight the critical role of infrastructure "to achieve and maintain an outstanding research and development program in environmental science."

Because we recognize that scientific excellence must be built on a strong foundation, we are committed to constant improvement of our organization and infrastructure. As we implement this Strategic Plan, we will continue to devote leadership and resources to developing and fostering our work force, modelling effective management, and creating a supportive work environment.

ORD's Work Force

By far the most important component of ORD's infrastructure is our work force of scientists, engineers, managers, other environmental professionals, and support staff. ORD can achieve its vision of providing the scientific foundation to support EPA's mission only if we can attract, nurture, and support a productive work force. ORD's strategic principles (Table 1) emphasize the importance of nurturing and supporting "the development of outstanding scientists, engineers, and other environmental professionals at EPA."

The cutting edge nature of research and development at ORD places great demands on our scientists and engineers to continually upgrade their skills and knowledge in response to and anticipation of new scientific developments. Therefore, our work force support must include an effective human resources program that encourages an increasingly diverse cadre of employees to continuously learn new skills and a career development program that promotes career development in directions congruent with ORD's mission. In addition, we must anticipate work force needs and recruit new, culturally diverse employees with the appropriate skills and experience to support ORD's mission.

ORD's recent reorganization has introduced a new organizational structure (see Appendix II) and staffing pattern into ORD. For example, our new organization eliminates certain mid-level management positions and broadens the control span of many supervisors. This flattened organizational structure will require a team-based, matrix-management approach to replace our former, more hierarchical approach to management.

ORD is addressing these needs and challenges by taking several steps to ensure a productive, effective work force. These include:

- Developing and implementing innovative, effective management approaches to accomplishing ORD's mission, such as matrix management and team-based operation.
- Supporting senior managers, via training and other mechanisms, in implementing these new management approaches.
- Developing tools to accurately assess current job effectiveness and determine development needs.
- Providing training and development programs to advance the knowledge and skills of ORD's staff.
- Providing effective career management support with an emphasis on self-directed career planning (e.g., through mentoring, in-placement and out-placement services, and career counseling and development services).
- Creating opportunities for professional and personal growth.
- Taking measures to maintain and enhance the scientific and technical competence and quality of ORD staff.
- Building and maintaining solid linkages to the external scientific community, with an emphasis on scientist-to-scientist interactions (e.g., through ORD-sponsored scientific workshops).
- Providing opportunities for ORD scientists and engineers to contribute, as respected members of the scientific community and leaders in the environmental sciences, to the general scientific literature and community (e.g., through publication of scientific articles in peer-reviewed journals and participation in national and international scientific conferences).

Systems and Equipment

For our work force to successfully implement the Strategic Plan, we must provide them with:

- Safe, environmentally sound, well-maintained, state-of-the-art laboratories, equipment, and supplies.
- Environmental data management systems and advanced communications systems.
- Upgraded technical and fiscal information systems to support the conduct of research,

management, planning, budgeting, and accountability functions.

- A host of other management, administrative, and systems support.

As we implement our Strategic Plan, we will monitor work force needs and strive to provide other programs, mechanisms, and support as necessary to ensure that our work force has the tools and equipment it needs to achieve ORD's vision and goals.

Challenges for the Future

The 1995 peer review of the Strategic Plan produced many useful recommendations that ORD incorporated in this final version of the plan (see *History of This Document* on page 2). ORD is continuing to study other peer reviewer recommendations for possible use in future updates of our Strategic Plan. Recommendations we are considering include:

- ***Periodic reexamination of the plan in light of changes in the risk assessment/risk management framework.*** Reviewers recommended that ORD periodically re-examine the basis for the Strategic Plan to accommodate ongoing changes in risk assessment concepts generally, and in the risk assessment / risk management framework in particular. Such reexamination is a central feature of the process envisioned by this plan, and ORD is committed to the concept that its risk-based priority-setting system will evolve with evolving risk assessment and risk management concepts.

  Reviewers also commented that the risk assessment paradigm has limited applicability for some EPA programs, thus limiting the utility of a plan based on the paradigm. ORD recognizes the validity of this comment in particular cases. As we implement this Strategic Plan, we will be working in close collaboration with EPA's Program and Regional Offices to ensure that our research agenda is tailored to the particular programs and priorities of each EPA office. Based on this experience, we will consider modifications to the plan over time to accommodate these special circumstances, as necessary.

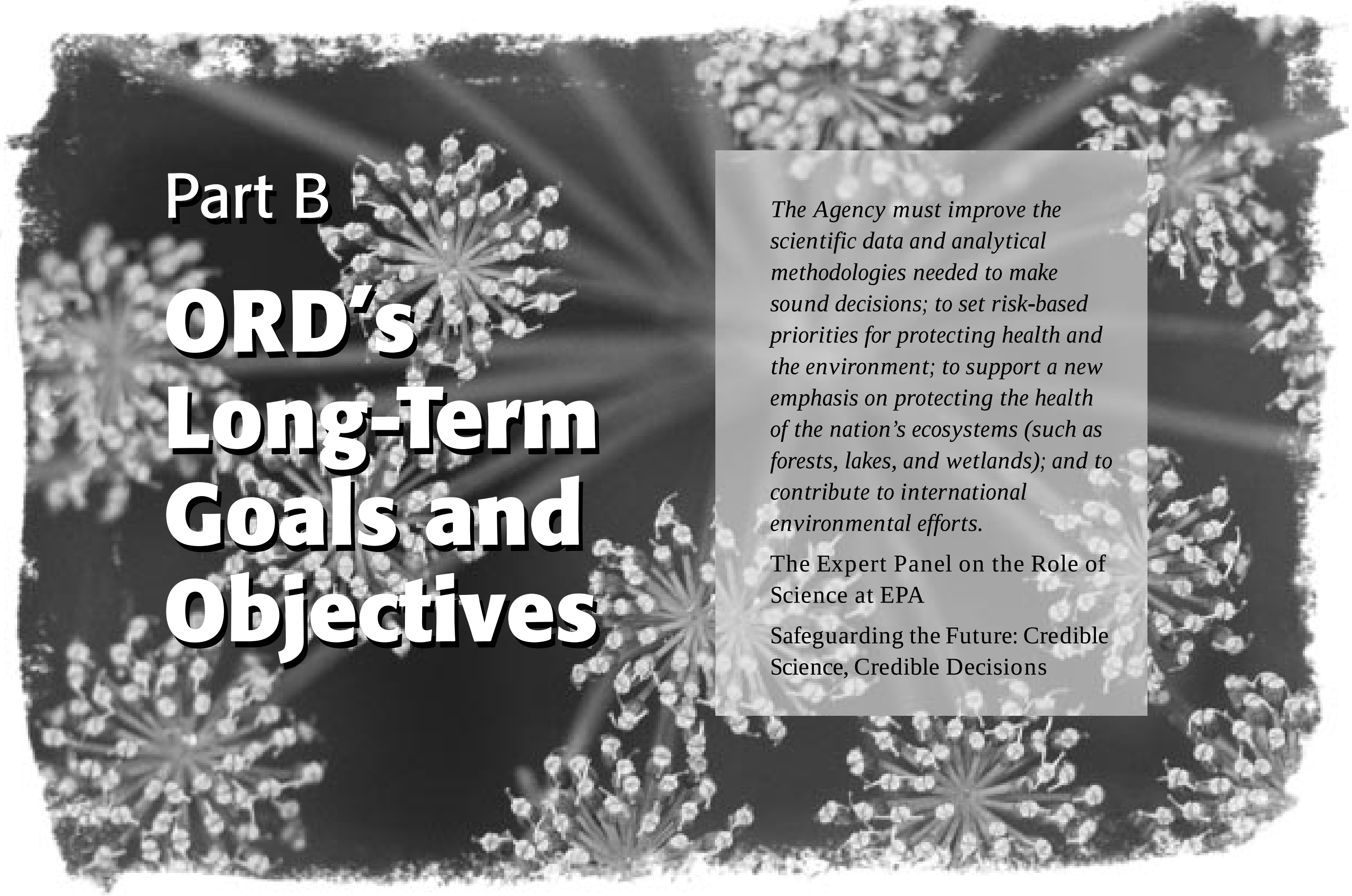
- ***Attention to cost-benefit considerations.*** Reviewers recommended that ORD give more attention to using information on economics and potential costs and benefits in its research prioritization process.

- ***Value of information analysis.*** Reviewers recommended that EPA undertake a "value of information" analysis and conduct a pilot project on a selected research topic to determine where to make our best time and resource investments, and to identify potential customers.

- ***Expansion of strategic goals.*** Reviewers recommended that ORD expand its strategic goals to give additional attention to economics, cost-benefit analyses (including incentives), community-based environmental protection, cumulative risk, environmental justice, and multi-pathway analyses.

- ***Capacity and incentives for long-term research.*** Reviewers recommended that ORD give more attention to building capacity and incentives for long-term environmental research.

Each of these areas warrants special attention and study.



Part B

ORD's Long-Term Goals and Objectives

> *The Agency must improve the scientific data and analytical methodologies needed to make sound decisions; to set risk-based priorities for protecting health and the environment; to support a new emphasis on protecting the health of the nation's ecosystems (such as forests, lakes, and wetlands); and to contribute to international environmental efforts.*
>
> The Expert Panel on the Role of Science at EPA
>
> Safeguarding the Future: Credible Science, Credible Decisions

To help focus selection of research priorities, ORD has defined a set of long-term research objectives within each of the six broad ORD goal areas listed in Table 2. Variations in the specificity of the objectives listed below reflect differences in the maturity and complexity of the science underlying each objective. Many of the objectives include a set of activities (listed under the objective) that ORD intends to undertake to achieve the objective given sufficient resources. This detail allows ORD's internal and external stakeholders to understand specifically how ORD plans to accomplish its objectives.

Designed to be robust and stable, the goals and research objectives described here will guide decisions about research directions for years to come. Each year ORD senior management, working with the Research Coordination Teams, will apply ORD's priority-setting process (described in Part A) to review current topics and identify specific new research topics that best further these objectives. We would not expect to make major changes in priorities every year, but we will evaluate the continuing timeliness and importance of our research topics on an annual basis. The resulting set of research topics will constitute the basis for ORD's research program. Appendix I describes the first set of high-priority research topics that resulted from applying this process.

Goal 1: To Develop Scientifically Sound Approaches to Assessing and Characterizing Risks to Human Health and the Environment

Risk assessments and the associated risk management decisions are often based on limited data obtained in species or under exposure conditions that differ from real-world circumstances. Inevitably, scientists must extrapolate from these data sets to the human or environmental setting of concern to characterize human health or ecological risks. Extrapolation injects uncertainty into risk characterizations, which EPA relies on to develop risk management strategies and research priorities.

Greater certainty in risk assessment would improve the efficiency and effectiveness of EPA's risk management efforts and provide a better foundation for establishing the Agency's research priorities. ORD, therefore, will work to improve existing risk assessment data, methods, and models and to develop new methods for high-risk areas where data currently are inadequate. Already, for example, the science has advanced sufficiently to warrant more refined approaches to risk assessment in several areas, including ecological impacts, effects on vulnerable subpopulations of people or environmental species, and noncancer effects in humans. As ORD develops improved methods, we will work with other parts of the Agency to ensure that these methods are credible and used in ways that are scientifically sound.

In recent years, we have begun to recognize the interdependence of ecosystems and to understand that we must consider the landscape as a whole to maintain the integrity of vital ecosystems into the next century. While continuing to develop and refine scientifically sound approaches to assessing risks to human health, we intend to expand our ecological research. For example, we intend to study concurrent impacts of multiple anthropogenic and natural stressors and to develop techniques to examine nonchemical stressors. The results of this research—including enhanced data on and understanding of ecosystems at multiple levels of organization and geographic and temporal scales—will provide a scientific foundation for developing risk assessment / risk management strategies and techniques for restoring vital ecosystems (see Goal 3).

Objectives

Within this goal area, ORD will work to:

- Replace the current approach to assessing noncancer health risks with more scientifically grounded, biologically plausible approaches and models. This will include:
  - Studying the heightened sensitivity / susceptibility of certain subpopulations (e.g., children).
  - Studying the predictive relationship between toxicologic endpoints and human disease (e.g., to facilitate animal-to-human extrapolation).
  - Developing integrated mechanistic information to support biologically credible health assessments.
- Develop methods and models founded on measurement data and sound theoretical concepts that can be used to better characterize, diagnose, and predict total human exposures to chemical and microbial hazards, to improve and validate exposure models, and to reduce uncertainties in exposure assessments, risk assessments, and risk management decisions. This will include:
  - Determining the relationship between exposure sources and multiple exposure pathways, including characterizing the sources and determining the influence of transport, transformation, and fate on exposure.
  - Developing and evaluating an integrated mass-balance / multimedia / multipathway exposure model that incorporates state-of-the-science pollutant fate and transport process descriptions for use in risk assessment.
  - Developing and applying exposure measurement methods to reduce the uncertainty in exposure-dose relationships, especially analytical methods for identifying and enumerating microbial pathogens and biomarker and chemical marker methods for estimating site-specific exposures.
  - Continuing activity pattern research to reduce uncertainty in models and assessments that predict exposure levels, frequencies, and distributions in populations.
  - Delineating and quantifying the role of exposure in the development of effects in individuals and populations, including susceptible populations.
- Establish approaches to characterizing and understanding risks to ecosystems and, in cooperation with other agencies, develop a national, multiscale, integrated environmental status and trends program. This will include:
  - Developing indicators of the condition of representative ecosystems.
  - Supporting hypothesis-driven, long-term monitoring of important exposure and effects indicators at national reference sites.
  - Characterizing national land-cover / land-use patterns and developing measures of land-

scape condition at multiple scales for specific sites, watersheds, landscapes, and ecoregions.

- Conducting pilot studies in ecologically important regions (e.g., the mid-Atlantic Highlands) to evaluate alternative monitoring designs and to develop techniques to integrate data across geographic scales.

■ Understand and predict ecosystem exposures, responses, and vulnerabilities to high-risk chemical and nonchemical stressors at multiple levels of biological organization and geographic scales. This will require:

- Developing ecological criteria for water (both freshwater and marine), air, soil, and sediment quality (1) as needed for the Agency's risk assessment and risk reduction efforts, and (2) to measure progress toward meeting environmental goals.
- Developing diagnostic tools at all levels of biological organization for retrospective assessments and for characterizing the key sources and stressors in multistressed ecosystems.
- Developing tools for predicting the vulnerability of ecosystems at multiple geographic and temporal scales to ecosystem stressors (e.g., climate change, altered land use, changes in air, soil, or water quality).

Goal 2: To Integrate Human Health and Ecological Assessment Methods Into a Comprehensive Multimedia Assessment Methodology

Human health risk assessments and ecological risk assessments have different histories at EPA and have traditionally been thought of as involving different disciplines. As a result, EPA has developed and used separate methodologies for those assessments. As we have begun to take a more integrated view of risk, however, we have noted that human health and ecological risk assessments actually make use of similar types of data and science. We have realized that we must use a more integrated, multimedia approach to risk assessment if we are to understand and reduce many current and future risks. We will therefore conduct research to develop an accessible, seamless, common methodology for combined human health and ecological risk assessments so that we can provide decision-makers at all levels with the integrated view of risk that they need to make sound decisions.

Objectives

Within this goal area, ORD will work to:

■ Integrate fate and transport modeling techniques with biologically based models needed in human health and ecological risk assessment.

■ Integrate human health and ecological exposure and trends monitoring research.

■ Better understand the relationship between human health and the condition of ecosystems (e.g., to assess the impact of human consumption of contaminated fish or wildlife or the influence of landscape characteristics and climate interactions on disease vectors such as mosquitos, ticks, and rodents).

■ Develop tools and techniques to facilitate the assessment of relative risks to human health and the environment.

■ Harmonize extrapolation methodologies for relating data on toxicity mechanisms for endocrine disruptors, immunotoxins, developmental hazards, and other chemicals with effects in sensitive human subpopulations, wildlife, and aquatic organisms.

■ Improve extrapolation models by integrating toxicologic and mechanistic data obtained in laboratory and field investigations (epidemiology and ecology).

■ Identify and validate wildlife species as sentinels for human health risks.

Goal 3: To Provide Common Sense, Cost-Effective Approaches for Preventing and Managing Risks

To enhance the practicality and cost-effectiveness of the products of ORD's risk management research, we are changing the way we study pollution control and prevention, contaminated site and spill remediation, and technology development. To the extent possible, we are integrating our air, water, and waste-related research, and we are increasingly focusing on emerging, high-risk problems—all so that we can better help regions, communities, and the private sector analyze pollution problems and achieve risk reductions efficiently and cost-effectively. This common sense approach will seek to maximize the health and environmental benefits of risk management by focusing risk management research on those aspects of a process or situation that cause the greatest risks.

To that end, our pollution prevention and control research will now focus on multimedia life-cycle analyses, "green" technologies, and pollution prevention methods that small- and medium-sized companies can use to achieve significant reductions in risk across media. Our maturing site and spill remediation program will concentrate on developing cleanup options for complex risk situations and faster, lower cost natural recovery systems. In addition, we will continue forging partnerships with the private sector to analyze high-risk needs and to develop, evaluate, and verify new pollution prevention and risk reduction technologies.

We have also begun efforts in ecosystem restoration and cost-benefit assessment. Our ecosystem restoration research (connected to that described under Goal 1 above) will focus on developing and demonstrating principles, technologies, and guidance materials that regions and communities can use to help restore local ecosystems. Our cost-benefit assessment research will focus on developing a systematic approach to identifying and reporting the benefits and costs of risk management technologies and alternatives. Such an approach is needed to satisfy the rapidly growing demand for cost-benefit analyses to support environmental decision-making—a demand engendered by the rising cost of environmental protection in an era of limited resources.

Objectives

Within this goal area, ORD will work to:

- Provide cost-effective risk management technologies and approaches for high-risk threats to human health and the environment. This will include:
  - Characterizing sources of fine-particulate emissions, air toxics, and ozone precursors, and identifying, adapting, and developing risk management approaches that control emissions to acceptable levels.
  - Providing cost-effective, reliable technologies and management approaches that reduce drinking water exposures to disinfectant by-products while protecting water supplies from microbial contamination.
  - Providing communities with proven technologies for wet weather flow watershed management, wellhead protection, and restoration of contaminated areas.
- Provide pollution prevention approaches and analytical tools to the private sector. This will include:
  - Providing risk-based systems and tools to analyze options for multimedia pollution prevention for major industrial sectors.
  - Identifying and evaluating the performance and costs for pollution prevention options for small- and medium-sized businesses.
- Develop advanced air quality simulation models that relate sources, emissions, and receptors. This will include:
  - Developing models based on high-performance computing systems to predict the fate of pollutants through the multimedia pathways leading to human and ecosystem exposure to these pollutants.
- Catalyze the development and use of cost-effective risk management approaches for the most difficult and costly environmental management problems. This will include:
  - Developing cost-effective techniques for remediating soils and ground water contaminated with nonaqueous-phase liquids, chlorinated and other hazardous organics, and toxic metals.
  - Developing cost-effective techniques for remediating contaminated sediments.
  - Verifying the performance of innovative risk reduction technologies and accelerating their commercial use.
- Provide cost-estimating / engineering assessment tools and methods for more accurate and meaningful cost-benefit analyses. This will include:
  - Developing data standards and cost reporting protocols.
  - Developing methods and cost analyses for emerging, high-risk environmental problems (e.g., fine particulates, drinking water, wet weather flow controls).

- Develop and provide risk management alternatives to maintain and / or restore ecosystems. This will include:
  - Developing diagnostic and characterization methods and protocols for use in determining appropriate ecosystem restoration goals and requirements for specific sites, watersheds, landscapes, and ecoregions.
  - Identifying, testing, and providing risk management approaches and technical guidance for restoring riparian zones, remediating contaminated soils and sediments, and applying best management practices to restore or maintain ecosystems in urban, suburban, and urbanizing areas.
  - Developing methods to restore and maintain soil ecosystems.

Goal 4: To Provide Credible, State-of-the-Science Risk Assessments, Methods, Models, and Guidance

ORD continues to be a national leader in the field of risk analysis of human health and ecological effects and will continue to serve as a catalyst for advances in the science of risk assessment. ORD will achieve this goal by working to facilitate cooperation and the exchange of ideas between and among federal, state, and local scientists as well as scientists in the environmental, industrial, and academic communities. In addition, ORD will focus on three primary activities:

- Using an open and participatory process, ORD will conduct timely, state-of-the-art risk assessments. These assessments either will serve as prototypes demonstrating new approaches to risk assessment or will respond to Agency needs by assessing multimedia, multiprogram, or contentious or sensitive issues.
- ORD will support other risk assessment efforts by providing guidance, consultation, training, and information products to assist colleagues, both inside and outside EPA, in conducting their own risk assessments. These efforts will respond directly to the needs of the risk assessment community and will target areas of uncertainty in the science and conduct of risk assessment.
- ORD will improve the state-of-the-science of risk assessment by developing scientifically sound and defensible approaches for incorporating and integrating data and models developed by ORD and the general scientific community into risk assessment efforts.

ORD will integrate human health and ecological concerns into all these activities.

Objectives

Within this goal area, ORD will work to:

- Prepare risk assessments for those stressors currently considered of high risk to humans and the environment. This will include:
  - Assessing ubiquitous pollutants in the air that affect human health (e.g., fine particles, ozone).
  - Assessing the risks associated with highly toxic and persistent environmental contaminants (e.g., chlorinated dioxins, mercury).
  - Assessing the risks to ecosystems from non-chemical stressors (e.g., habitat loss and UvB due to stratospheric ozone depletion).
  - Conducting comparative risk assessment of competing risks (e.g., those posed by microorganisms in drinking water versus those posed by disinfection by-products).
- Complete development of new cancer risk guidelines and other guidelines and provide support to the Program Offices and Regions to facilitate their implementation. This will include:
  - Developing and supporting the implementation of guidelines for assessing the ecological impacts of environmental stressors.
  - Supporting the implementation of new guidelines for cancer, neurotoxicity, and reproductive risks.
- Provide expert advice and technical support to EPA staff, other agencies, and EPA stakeholders. This effort will include:
  - Integrating scientific and technical information from ORD Laboratories and other sources to provide a sound scientific base and technical support for Agency decisions and policy.
  - Developing and supporting the implementation of guidelines for assessing the ecological impacts of environmental stressors.
  - Supporting the implementation of new guidelines for cancer, neurotoxicity, and reproductive risks.
  - Supporting chemical- and site-specific risk assessments for criteria air pollutants,

- hazardous air pollutants, waste sites, and drinking water.
- Providing training in risk assessment to state and local stakeholders.
- Continuing to support and improve the Integrated Risk Information System (IRIS) and expert systems such as Risk Assistant.
- Assuring adequate quality assurance for all research, testing, and applications.

■ Develop methods and assess methods developed by others for providing quality-assured data for environmental assessment. This will include:

- Supporting the development of models that can be readily used by Regions and states.

Goal 5: To Exchange Reliable Scientific, Engineering, and Risk Assessment/Risk Management Information Among Private and Public Stakeholders

Effective risk assessments and risk management decisions depend on the availability of accurate sources of scientific and engineering data and information, risk assessments, analytical methods, and guidance. As a leader in the development of such methods and information, we are committed to providing, coordinating, and exchanging expertise and information to decision-makers inside and outside EPA. We will work to identify and fulfill user needs by providing appropriate tools and information through interconnected communication and technical support networks.

Our goal is to facilitate information that is impartial, up-to-date, and relevant to user needs. To that end, we must improve and update existing information systems and develop new systems and information transfer solutions to meet future needs. Working with other EPA offices, we will help to develop an operational communication and information transfer system for on-line scientific, engineering, and risk information that can be accessed by professionals or by members of the public who are involved in community-level analysis and decision-making.

Objectives

Within this goal area, ORD will work to:

■ Provide current and relevant technical information to a broad user community. This will include:

- Developing plain-language guidance and training that adequately and clearly communicate the appropriate use of technical information and that describe limitations and inappropriate applications.
- Developing electronic communication and other information dissemination systems that can be accessed and understood by broad and diverse user communities.

■ Complete the development of the new cancer risk guidelines and provide support to the program offices and regions to facilitate their implementation.

■ Maintain and increase support for existing scientific, engineering, and risk information systems. This will include:

- Ensuring that current information resources are accurate, relevant, and up-to-date.
- Developing electronic and other methods of bringing databases (e.g., IRIS, ECOTOX) to state and local governments and other stakeholders.
- Developing data management systems that make data readily available to all ORD Labs and Centers, EPA Program Offices and Regions, and states.

Goal 6: To Provide Leadership and Encourage Others To Participate in Identifying Emerging Environmental Issues, Characterizing the Risks Associated With These Issues, and Developing Ways of Preventing or Reducing These Risks

With our very broad missions, we in ORD and the Agency as a whole must have some means of evaluating, comparing, and setting priorities for competing needs. We use risk as the common denominator for comparing divergent issues and making decisions. Our focus on relative risks and risk-based decision-making demands that we look beyond the obvious problems of yesterday and today to identify and assess issues just over the horizon; we must determine the potential risks that these issues pose and work to solve them. Often, however, few data exist to support assessments of emerging issues. Thus, we must develop and disseminate data and methods to permit credible decision-making in the face of very high uncertainty. At ORD, we are committed to working with other groups within EPA, the Agency's Science Advisory Board (SAB), the National Academies of Science and Engineering (NAS and NAE), and others to develop new ways of analyzing emerging issues. We recognize that ORD cannot and should not assume leadership in every area of environmental science. Our challenge is to be cognizant of where others are already leading and where ORD should undertake that role.

EPA's general approach to environmental management—assessing risks, evaluating the potential benefits of risk reduction, and devising risk management and risk reduction strategies accordingly—is increasingly being adopted by others in this country and abroad. More than any other organization, ORD has been in the forefront of developing the risk assessment and risk management methods that undergird this risk-based approach to environmental management. More than any other organization, therefore, we should be expected to provide leadership in the development of new, more credible ways of comparing and ranking risks. In providing this leadership, we renew our commitment to encouraging and enabling others in the public and private sectors to participate in identifying, characterizing, and resolving emerging environmental issues.

Objectives

Within this goal area, ORD will work to:

- Collaborate with other parts of the Agency, the SAB, the NAS, and others to develop methods of identifying emerging issues and assessing their potential risks.
- Develop partnerships (via research grants, cooperative agreements, CRADAs, and other mechanisms) with other federal agencies, the White House Committee on Environment and Natural Resources, industry, and academia.
- Provide national and international leadership in risk assessment and its application for risk reduction and risk management.
- Conduct/sponsor workshops and symposia that will provide forums for stimulating interest and discussion on current or emerging environmental issues (e.g., endocrine disruptors), reaching consensus on crucial research needs, and defining the role of ORD and others in addressing those needs.

Appendix I
ORD's High-Priority Research

The goals and objectives listed in Part B of this plan define an ambitious research program for ORD. Within this program, however, the extent of research we can actually perform will be limited by the available resources. Therefore, in consultation with EPA's Program Offices, ORD uses the priority-setting process (described in Part A) to select from its overall program those topics that are of highest priority for research. Priorities to be emphasized for the next few years are (in no particular order):

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

These areas will receive more intense research attention (and resources). Intramural efforts will be supplemented with the talents of extramural scientists through external grants, cooperative agreements, interagency agreements, and contracts.

Proposed research for the six high-priority areas is summarized in Table I-1. Tables I-2 through I-7 provide a breakout, by risk assessment/risk management area, of the strategic issues and proposed research tasks, products, and applications in each of the six topic areas.

Other areas of high importance that will continue to be a major part of ORD's research program include:

- Air pollutants
- Indoor air
- Global change
- Drinking water (in addition to disinfection issues)
- Waste site risk characterization
- Waste management and site remediation

ORD's research agenda also includes additional topics necessary to help the Agency fulfill its nondiscretionary mandates.

Other topics were considered during the planning process but they did not meet the criteria to be included in ORD's research program. In general, these include exposure or effects research in areas of low risk, risk reduction research in areas of low risk, and routine measurements and monitoring where R&D has been completed. In addition, ORD will not pursue research in areas where other research organizations are capable of making a more significant impact.

ORD's entire research program will be captured in more detail in the science research plans being developed by the Research Coordination Teams. These research plans will be finalized after a rigorous peer review. Interested readers should consult these documents.

ORD also uses the principles and priorities of this Strategic Plan as a basis for developing its annual budget requests to fund our research agenda. Our fiscal year 1997 budget request was based on this plan, as will be our fiscal year 1998 budget proposals.

Evolution of ORD Priority Areas Over Time

The six high-priority areas intentionally are a mixture of:

- ***Research targeted at specific pollution problems*** (i.e., drinking water disinfection, particulate matter, and endocrine disruptors).

- ***Broad-based fundamental research*** in risk assessment and risk management (i.e., research to improve ecosystem and health risk assessment, and pollution prevention and new technologies).

The tables in this appendix reflect the differences in these two areas of research. Tables I-2 through I-4, which describe the more specific research areas, tend to have more details than Tables I-5 through I-7, which describe the broad-based, fundamental areas.

We will evaluate progress on all ***research targeted at specific pollution problems*** annually to ensure that our research program continues to focus on the most significant problems. As work on problem-specific topics progresses and moves toward closure, we will redirect our research focus and resources to emerging high-priority areas. For example, as we successfully completed work in one of our former priority areas (the health risks of ozone), we shifted resources to particulate matter, one of our current high-priority topics. In the future, the particulate matter research likely will give way to other topics of emerging priority.

We will also evaluate progress on our ***broad-based fundamental research*** annually. These broad-based areas, which reflect ORD's fundamental risk assessment and risk management research programs, will remain high-priority topics. However, the individual projects within these areas will change to reflect research progress and emerging concerns. As the individual projects change, we will revisit and revise research plans for these areas.

Selection of the Six High-Priority Topics

The following summaries illustrate how application of the selection criteria described in Part A gave rise to the six high-priority research topics.

Drinking Water Disinfection

Disinfection of drinking water has been one of the greatest public health success stories of the twentieth century. Nevertheless, some public health concerns still remain. For example, hundreds of people have died and many hundreds of thousands have become ill during recent outbreaks of exposure to the protozoan *Cryptosporidium* in drinking water. Recent studies demonstrate that there is a low threshold of infectivity for *Cryptosporidium* and that people with compromised immune systems—such as the elderly, HIV-positive individuals, and persons receiving chemotherapy—may be at greater risk. In addition, other microorganisms exist in drinking water that may also have serious adverse effects.

There still is a high degree of uncertainty about how to measure microorganisms in water and what their infectivity level is. Additionally, there is a high degree of uncertainty about whether disinfection by-products—the chemical by-products that result when disinfectants react with organic matter in drinking water—pose a significant human health threat. Because of the ***high uncertainty***, the ***widespread human exposure to drinking water***, the ***severity of the known effects from certain microbes***, and the ***potentially high costs of further regulation of drinking water***, this issue is of high priority to EPA's Office of Water and to ORD's research agenda.

Particulate Matter

Recent publications in the scientific literature indicate that exposure to particulate matter poses a ***high potential human health risk***. At the same time, however, there is a ***high degree of uncertainty*** about the size and composition of the particles that may be responsible for these effects, the biological mechanisms of action, and the dose-response relationships at low levels of exposure. In addition, ***control costs are potentially very high.*** For all these reasons, this area is of high priority to EPA's Office of Air and Radiation and of high priority for ORD's research agenda.

Endocrine Disruptors

Evidence has been accumulating that humans and wildlife have suffered adverse health consequences resulting from exposure to environmental chemicals that interact with the endocrine system. Several reports of declines in the quality and quantity of sperm production in humans over the last four decades, and reported increases in the incidence of certain cancers that may have an endocrine-related basis, have led to speculation about environmental causes.

There is considerable scientific uncertainty regarding the causes of these reported effects. However, we do know that endocrine factors regulate the normal functions of all organ systems and that small disturbances in endocrine function—especially during certain stages of the life cycle such as development, pregnancy, and lactation—can lead to profound and lasting effects. The critical issue is whether there are sufficiently high levels of endocrine-disrupting chemicals in the ambient environment to exert effects in the general population.

Given the potential ***scope of the problem***, the possibility of ***serious effects on the health of populations***, and the ***broad occurrence and persistence of some endocrine-disrupting agents in the environment***, this area is of high priority for ORD's research agenda. Research will focus on the most critical gaps in our knowledge base to promote more informed decisions on public health, ecosystem effects, and related management options.

Research To Improve Ecosystem Risk Assessment

We have made considerable progress in reducing the most egregious harm to our environment from air and water pollution and from areas of devastation around industrial plants. Much remains to be done, however, if we are to avoid potential disasters on a tragic scale—such as forest decline, widespread epidemics of toxic microorganisms in estuaries, reproductive failure of wildlife because of global pollutant transport or destruction of critical habitat, the reappearance of vector-borne epidemic diseases, and global climate change.

Ecological research has the potential to significantly reduce many of the uncertainties associated with our understanding of ecosystems. In particular, it is critical that EPA develop:

- Techniques for quantitative risk assessments so that decisions about where to focus ecological research and what solutions are most appropriate can be based on sound science.
- Risk management strategies that take maximum advantage of pollution prevention and the self-purifying potential of natural systems.

To accomplish these goals, research in ecosystem monitoring, processes, modelling, risk assessment, risk management, and restoration is needed for chemical and nonchemical stressors, multiple scales of effects and exposures, and multiple levels of biological organization. Because of the ***broad applicability of these methods*** and their ***significant potential for enhancing ecological risk assessment and risk management,*** ORD has selected research to improve ecosystem risk assessment as a high priority for its research agenda.

Research To Improve Health Risk Assessment

Health risk assessment is the process EPA uses to identify and characterize environmental health problems. The results of health risk assessment are crucial to decisions on health protection measures. ORD's research to improve health risk assessment addresses major deficiencies and uncertainties in health risk assessment (including both problem- or agent-specific risk assessment, as well as cross-cutting or generic risk assessment). For example, ORD's research to improve health risk assessment includes:

- Developing state-of-the-art testing approaches for noncancer and cancer endpoints.
- Conducting mechanistic and toxicokinetic research to improve the exposure and dose-response steps in the risk assessment process.
- Identifying biomarkers that can be used to measure genetic and other biological events.
- Determining how individuals vary in their response to toxic insults, so that EPA can better identify sensitive groups.

Research to improve health risk assessment provides the essential foundation for reliable and scientifically strong risk assessments based on new science and state-of-the-art methods. In addition, this research area supports the development of:

- Computer-based tools to assist risk assessors at the federal, state, and local levels.
- Information management databases that EPA uses to effectively communicate risk information to stakeholders.

Ultimately, the results of this research will enhance risk assessments to support national environmental goals, such as safe drinking water, safe indoor environments, clean air, and safe food. Because of the ***broad applicability*** of improved methods for health risk assessment to ***many user communities***, research to improve health risk assessment is a high priority for ORD's research agenda.

Pollution Prevention and New Technologies

Pollution prevention, or anticipating and stopping problems before they occur, is a valuable risk management tool because it is far more cost-effective and protective of the environment than solving environmental problems after they have been created. Pollution prevention, supported by objective scientific and technical data, can actually reduce or eliminate the need for legal actions and regulatory standards, which can be costly and difficult to implement.

Pollution prevention will be the first strategy considered for all EPA programs and EPA will lead the nation in efforts to reduce and eliminate pollution at the source. Because of the ***broad applicability*** of pollution prevention strategies and the ***potentially large economic and environmental benefits*** of this approach to risk management, pollution prevention and new technologies are of high priority for ORD's research agenda. This research builds on ORD's commitment to support and respond to EPA's Program Offices' and Regions' needs for prevention options and information on how to best implement them.

Table I-1. Summary of EPA/ORD Research Program for Six High-Priority Research Topics

Research Topics	Strategic Focus	Tasks	Products	Uses
Drinking Water Disinfection	What is the comparative risk between waterborne microbial disease and the disinfection byproducts (DBPs) formed during drinking water disinfection? How can both be simultaneously controlled?	Develop methods for measuring pathogen / DBP exposure from drinking water, determine effects and dose-response for them, develop / apply a microbial risk assessment framework, improve DBP risk assessments, and evaluate alternative treatment processes for DBP / microbial control.	Data on effects, dose-response, exposure, comparative risk, and treatment for pathogens / DBPs.	To support DBP / microbial risk assessment / risk reduction rulemaking and compliance monitoring.
Particulate Matter	What morbidity / mortality is associated with low ambient levels of particulate matter (PM), and what cost-effective methods are available to reduce PM emissions to an acceptable level?	Conduct clinical / epidemiology studies of PM effects; reanalyze past epidemiology studies; conduct pharmacokinetic and biological studies; characterize the size / species of PM; conduct a human exposure study; and evaluate, develop, and demonstrate technologies to reduce PM emissions.	Morbidity / mortality, dose-response, and mechanistic data; dosimetric model; methods for measuring PM mass / species; improved human exposure estimates; data on emissions composition; improved risk estimates; and data on cost-effectiveness of PM control strategies.	To improve criteria documents and risk assessments in support of PM National Ambient Air Quality Standards review; to provide information for evaluating alternative PM control strategies.
Endocrine Disruptors	What is known about endocrine disruptor (EDC) exposure, human / eco-effects, and risk assessment? What research still needs to be done?	Review existing literature on EDCs, conduct workshops on research needs, develop QSAR / PBPK / BBDR[a] methods / models, conduct field measurements of EDCs, and assess effects on highly exposed cohorts.	Reports on research needs, analytical methods, risk assessment methods, data from field measurements, and cause-effect data.	To prioritize research needs, review test guidelines, and conduct hazard / effect and preliminary exposure / risk assessments.
Research To Improve Ecosystem Risk Assessment	How can we determine ecosystem risk and capacity to tolerate stress? What are the chemical and nonchemical exposures to the most sensitive systems? Which ecosystems are vulnerable? Where? How can we reduce risk in a cost-effective manner?	Study ecosystem vulnerability and stressor-response relationships; identify eco-effect measures; characterize habitat distribution and chemical exposures; develop / apply eco-risk assessment methods; and study eco-risk reduction.	Ecosystem criteria, models to predict ecosystem effects / risks, national land-cover map, baseline data for documenting future changes, ecosystem exposure profiles, and information on risk reduction approaches for ecosystems.	To inform stakeholders about ecosystem protection, ecosystem assessment, environmental planning, and ecosystem risk reduction / restoration.

(Continued)

Table I-1. Summary of EPA/ORD Research Program for Six High-Priority Research Topics (Continued)

Research Topics	Strategic Focus	Tasks	Products	Uses
Research To Improve Health Risk Assessment	How can we better define / predict hazards, improve dose extrapolation, and better understand mixture toxicity?	Develop or improve methods for screening hazard data, collecting toxicity data, and interpreting hazard data; develop models to estimate target tissue dose and responses to those doses; and develop methods / models for assessing mixtures toxicity.	Hazard screening / testing protocols, models for predicting chemical disposition in the body, and test protocols / models for mixtures toxicity.	To rank / screen chemicals, develop test guidelines, provide guidance for risk assessment, and identify mixtures toxicity.
	What is the population distribution of total exposure? What are the source-exposure-dose relationships?	Determine how exposure is influenced by age, lifestyle, behavior, and socioeconomic factors. Develop total human exposure models, which include source / pathway contributions to total exposure.	Improved exposure measurement and assessment methods, models, and data.	To support exposure assessment during risk-based decision-making
Pollution Prevention and New Technologies	How can pollution prevention be integrated into environmental decision-making?	Study engineering / performance costs for pollution prevention; develop technologies; identify audiences needing technical assistance; develop life-cycle analysis / audit tools; and assist in disseminating technologies to the commercial sector.	Pollution prevention cost accounting protocols, cost data, technology transfer products, life-cycle analysis tools, audit procedures, pollution prevention technologies, and performance data.	To evaluate and implement pollution prevention approaches.

[a]QSAR = quantitative structure-activity relationships.
PBPK = physiologically based pharmacokinetic.
BBDR = biologically based dose-response.

Table I-2. Drinking Water Disinfection

Subtopic	Strategic Focus	Tasks	Products	Uses
Health Effects	What dose levels of pathogens cause illness in exposed populations?	Conduct dose-response studies on waterborne pathogens.	Data for risk assessment models to predict disease incidence.	To provide health effects data for risk assessment to support upcoming surface water and ground-water treatment rules.
	What are endemic and epidemic illness rates for waterborne microbial disease?	Conduct epidemiology studies for pathogen-caused disease.	Indication of magnitude of risks and verification of risk models.	To provide health effects data for risk assessment to support upcoming surface water and ground-water treatment rules.
	What are the relative risks of disinfection byproducts (DBPs) from different disinfection processes?	Conduct epidemiology studies on reproductive / developmental effects and, if feasible, on cancer.	Qualitative / quantitative data on cancer, reproductive effects, and other effects.	To assess the risks of different disinfection processes, combining epidemiology, toxicity, and mixtures information, to support DBP rules.
		Conduct toxicity studies on individual DBPs and mixtures if feasible.	Risk assessments for individual DBPs.	
Exposure	What levels of pathogens are people exposed to?	Develop analytical methods that detect viable / infective organisms.	Practical analytical methods for pathogens.	Survey tool for developing occurrence data; basis for compliance methods for water utilities.
		Identify sources of pathogens and factors affecting occurrence levels in surface and ground waters.	Analyses of pathogen occurrence in source waters. Information on pathogen exposures in drinking water.	To support exposure assessments to predict pathogen occurrence in drinking water under different treatment processes.
	What levels of DBPs are people exposed to?	Develop methods for measuring occurrence of DBPs in drinking water.	Improved practical field and research methods for DBPs in drinking water.	To support exposure assessments for DBPs from different treatment processes; provide basis for compliance methods for water utilities.
		Study the level of DBPs in drinking water supplies.	Identity of new DBPs under different disinfection practices. Data on DBP exposure from drinking water.	
Risk Assessment	What are the comparative risks from DBPs and microbes?	Develop appropriate risk assessment paradigm for microbes, including dose-response models.	Improved risk assessment procedures and risk estimates for microbes.	To provide a comparative risk framework for risk assessments for surface water treatment rules and DBP rules.
		Apply advances in cancer and noncancer risk assessment to individual DBPs and mixtures of DBPs.	Improved risk assessment procedures and risk estimates for DBPs.	

(Continued)

Table I-2. Drinking Water Disinfection (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Risk Management	Which technologies can simultaneously control pathogens and DBPs?	Evaluate treatment processes for pathogen control, including identification of surrogate measures of treatment effectiveness, technologies for small systems, and control of bacterial growth in distribution systems. Simultaneously evaluate processes for controlling DBPs (including chlorine vs. alternative disinfectants) and practices for removing DBP precursors (granular activated carbon, membrane filtration).	Data on the effectiveness of different processes.	To evaluate different treatment options and regulatory strategies for reducing DBP and microbial risks. To provide guidance for operation of treatment plants and distribution systems.

Table I-3. Particulate Matter

Subtopic	Strategic Focus	Tasks	Products	Uses
Health Effects	What health effects are caused by particulate matter (PM) and its components?	Conduct epidemiologic studies of mortality and morbidity coupled with improved exposure characterization. Conduct clinical studies of respiratory effects in controlled human studies.	Qualitative and quantitative data on mortality and / or respiratory diseases.	To provide health effects data for risk assessment (Criteria Document) to support PM National Ambient Air Quality Standards (NAAQS).
	What are the causal mechanisms / particles that explain / support epidemiologic observations?	Conduct animal and clinical studies of biochemical and physiologic events initiated by PM and its components.	Dose-response data describing biochemical and physiologic events induced by PM and their relationship to disease.	To provide health effects data for risk assessment (Criteria Document) to support PM NAAQS.
	What is the relationship between PM exposure and dose? What is the role of dose for effects in sensitive subpopulations?	Develop dosimetric model of particle deposition in the lungs under various exposure and population conditions.	Dosimetric model linking animals to humans and normal humans to sensitive subpopulations (e.g., children, individuals with preexisting disease).	To provide health effects data for risk assessment (Criteria Document) to support PM NAAQS.
Exposure	What PM species and concentration levels are present in ambient air?	Develop ambient PM measurement methodology capable of discriminating particles by size and species.	Methods for measuring fine-particle mass and characterizing species (e.g., acid aerosols, inorganic and organic species).	To serve as a Federal Reference Method for new fine-particle NAAQS. To provide PM methodology for atmospheric chemistry research and total exposure research.
		Conduct PM size and species characterization studies.	PM characterization data.	To assess PM size and concentration levels for regulatory development and epidemiologic study design. To identify sources of PM and address PM formation, transport, and fate. To help develop control strategies for implementing PM regulation(s).

(Continued)

Table I-3. Particulate Matter (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Exposure (Continued)	What PM species and concentration levels are people exposed to?	Conduct prospective epidemiologic and human exposure studies.	Verification of current epidemiologic observations. Improved estimates of human exposure to PM. Reduced uncertainty regarding the size and physical properties of PM that may cause health effects.	To determine the effects of ambient fine and coarse PM on adults' lung function and daily mortality. To evaluate and extend findings on size-specific PM exposure and daily mortality.
Risk Assessment	How can we reduce uncertainties associated with estimates of the PM mortality / morbidity risks at low ambient levels?	Conduct statistical reanalyses of existing epidemiologic databases to further characterize: –The shape of exposure-response relationships (possible 'thresholds'). –The influence of synoptic weather patterns. –The size / chemical composition of key PM components.	Quantitative data analyses providing reduced uncertainties in PM risk estimates.	To provide health effects data for risk assessment (Criteria Document) to support PM NAAQS.
Risk Management	What are the emission rates and physical and chemical characteristics of fine particles from sources that pose the greatest risk to public health?	Characterize fine-particle emissions from sources of concern (e.g., heavy duty diesel trucks, fugitive sources, combustion systems, other stationary sources).	Technical reports and data on the size distribution, chemical composition, and quantity of fine-particle emissions from key mobile and stationary sources.	To provide emissions data to focus regulatory strategies on the most critical sources. To provide methods and models for states to develop fine-particle emissions inventories.

(Continued)

Table I-3. Particulate Matter (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Risk Management (Continued)	What options (e.g., process changes, upgrades of existing controls, application of new technologies) are available that both reduce fine-particle emissions to acceptable levels and are cost-effective?	Investigate options for reducing fine-particle emissions: –Demonstrate the extent to which improved operation and maintenance of existing control equipment for combustion systems can further reduce emissions. –Develop advanced, more cost-effective technologies (e.g., improved electrostatic precipitators and fabric filters) to control fine particles from stationary sources. –Determine the effectiveness of indoor air cleaners for reducing personal exposure to fine particles. Compare the costs of these and other approaches.	Technical reports and data on the performance and cost-effectiveness of competing risk management approaches. User-friendly computer models and other technical assistance tools that transfer risk management information to key users.	To support evaluations of competing regulatory strategies, cost / benefit analyses, and development of guidance documents. To provide guidance to states and the regulated community on the performance and cost of competing fine-particle risk management approaches.

Table I-4. Endocrine Disruptors

Subtopic	Strategic Focus	Tasks	Products	Uses
Identify Research Needs	What do we know about the sources, chemical and physical properties, transport pathways, ecological and human effects of EDCs,[a] and where are the major gaps in our knowledge base?	Conduct workshops involving principal stakeholders in developing consensus on the research needs for exposure, and health and environmental effects.	Reports on the research needs for (1) reproductive, neurologic, immunologic, and carcinogenic effects of EDCs, (2) ecological risk, and (3) exposure assessment.	To develop prioritized research needs.
Effects	What are the important chemical classes for interaction with the endocrine system, and what is their range of potency?	Develop QSAR[b] models for hormone receptor-ligand binding and transcriptional activation.	QSAR models to identify and prioritize in vivo research to define dose-response effects.	As first-tier computer models to predict hazard.
	Do our current testing and monitoring approaches adequately evaluate and assess effects on the endocrine system?	Develop in vivo and in vitro test procedures and biomarkers to detect the action of EDCs and to identify critical life stages at multiple phylogenetic levels.	Recommendations for modifying the testing guidelines for potential adverse ecological and human health effects. Field and laboratory tools to better quantitate effects of putative EDCs.	To revise testing guidelines and improve data interpretation.
	What are the shapes of the dose-response curves for EDCs at relevant exposures, and what tissue levels are responsible for inducing adverse effects?	Develop PBPK[c] and BBDR[d] models that include relevant species-specific parameters. Define potency of EDCs in target species.	Increased understanding of the comparative exposure levels associated with risks. Reduced uncertainty in extrapolating effects.	To reduce uncertainty in chemical-specific risk assessments and relative potency comparisons.
	What is the normal endocrine profile in target wildlife species on a seasonal and regional basis?	Study populations and determine normal profiles for endocrine function during various life stages, seasons, and regions.	Database on endocrine function in wildlife exposed to potential EDCs.	To improve interpretation of endocrine data from field studies and to improve understanding of the magnitude of the EDC problem in wildlife populations.
	What are health outcomes experienced by populations receiving high-level exposure to EDCs?	Assess spectrum of effects in highly exposed cohorts, particularly those with developmental exposures.	Delineation of causes and effects that can set the bounds on effects in less highly exposed populations.	To conduct preliminary risk assessments. To develop remedial actions where adverse effects of EDCs in the environment have been confirmed.

(Continued)

Table I-4. Endocrine Disruptors (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Effects (Continued)	For wildlife species, what procedures are available for extrapolating effects of the individual to populations?	Develop models for extrapolating effects measured in individuals to reproductive capacity in wildlife populations.	Models for predicting population-level effects from study at lower levels of biological organization.	To facilitate ecological risk assessment based on effects observed in individuals.
	What are the status and trends of sentinel and keystone species in the various ecological areas?	Identify and periodically conduct censusing of sentinel and keystone species.	Early warning indicators of environmental quality, especially in terms of contamination by EDCs.	For environmental monitoring.
	What are the effects of exposure to multiple EDCs?	Determine potential for synergism or potentiation within and among various modes of action.	Assessment of the potential for non-additivity among EDC health endpoints.	To improve effects assessment for environmentally important multiple exposures to EDCs.
Exposure	What are the pathways of exposure of EDCs?	Develop source-receptor models to assess exposure from specific sources via multimedia pathways.	Validated models to assess exposure to EDCs.	To improve source-receptor relationships determined via hybrid models.
	Do we adequately understand multimedia transport (including phase equilibrium and deposition mechanisms), persistence, bioaccumulation, and biomagnification of EDCs?	Develop methods to monitor exposure to EDCs and methods to characterize exposure half-life, speciation, uptake, and phase equilibrium.	Analytical methods adequate to characterize EDCs in multimedia, to assess transport, fate, and exposure, and to provide input to source-receptor models.	To improve source and receptor models and assessments of EDC exposure.
	Do we have adequate (sensitive, reliable, and inexpensive) tools to monitor populations for exposures to EDCs?	Develop biomarkers for exposure of EDCs applicable to the phylogenetic levels considered to be at greatest risk to EDCs.	Field and laboratory tools to better quantitate the exposures and effects of putative EDCs. Improved algorithms to calculate EDC exposure.	To improve data interpretation.
	What are the environmental concentrations of EDCs in all principal media?	Conduct field studies to measure high-priority EDCs.	Database on EDC levels in the human environment and various ecosystems to assist in designing future exposure strategies.	Preliminary environmental exposure assessments.

(Continued)

Table I-4. Endocrine Disruptors (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Exposure (Continued)	What exposures are experienced by populations affected by EDCs?	Quantitate exposure in populations showing effects of EDCs, particularly those with developmental exposures.	Delineation of causes and effects which can set the bounds on effects in less highly exposed populations.	To conduct preliminary risk assessments. To develop remedial actions where adverse effects of EDCs in the environment have been confirmed.
Assessment	What strengths and weaknesses are present in assessment of existing information on EDCs and related topics?	Convene EPA working group to critically review existing biological effects information.	Report of literature review.	To refine ORD's research strategy. To develop regulatory policy on EDCs.

[a]EDC = endocrine-disrupting chemical.
[b]QSAR = quantitative structure-activity relationship.
[c]PBPK = physiologically based pharmacokinetic.
[d]BBDR = biologically based dose-response.

Table I-5. Research to Improve Ecosystem Risk Assessment

Subtopic	Strategic Focus	Tasks	Products	Uses
Effects	What levels of anthropogenic stress (chemical and nonchemical) can ecosystems tolerate and still be sustained / maintained?	Understand and develop models to predict ecosystem vulnerability to alternative management practices and changing stressors at multiple scales. Develop screening and testing methods to assess viability and sustainability at multiple levels of biological organization.	Quantitative models predicting complex and cascading effects of multiple stressors at multiple geographic and temporal scales. Criteria for maintaining ecosystems.	To inform debate on societal values with respect to ecosystem protection; to provide information to support future community-based ecosystem protection. To provide information to evaluate comparative risks and drive strategic research planning.
	How do ecosystem components respond to changing exposures to stressors?	Conduct research to quantitatively understand stressor-response relationships.	Quantitative models relating levels of exposure to effects for single stressors.	To support ecological effects assessment.
	What are the best measures of ecosystem effects?	Identify indicators (measures) of effect that correspond as closely as possible to assessment endpoints.	Evaluation of indicators of effect.	To provide indicators that can serve as state variables in risk assessment models and as measures of condition for status and trends monitoring. To support objective evaluation of success in risk management decision-making.
Exposure	What are the most significant sources of stressors in various ecoregions of the United States?	Develop methods for characterizing sources of relevant stressors.	Methods for characterizing sources of exposures.	As tools for exposure assessments. As components of expert systems to predict exposure.
	What is the extent and distribution of highly vulnerable systems based on predicted changes in stressors at multiple scales?	Develop methods to efficiently characterize regional landscapes and habitat distribution.	Baseline data for regional assessments. Assessments of highly vulnerable ecosystems, within and among ecoregions. A national land-cover map of the United States.	To support relative risk assessments. To identify vulnerable systems at watershed and regional scales.

(Continued)

Table I-5. Research to Improve Ecosystem Risk Assessment (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Exposure (Continued)	What is the current distribution of exposure to these stressors across vulnerable ecosystems?	Develop models to link transport, transformation, and fate of stressors to exposure to ecosystems at appropriate time and space scales. Support an interagency exposure reference site network. Conduct exposure vulnerability assessments at multiple geographic and temporal scales.	Methods for assessing exposure.	To support relative risk assessments. To identify vulnerable systems at watershed regional and national scales.
	What sources are now causing the most significant exposures?	Develop diagnostic tools for retrospective assessments.	Indicators of source/exposure relationships.	To apportion source strengths. To identify sources for risk reduction technology development.
	How will current patterns of exposure change in 5, 10, 25, and 50 years?	Conduct demographic and economic studies to assist in predicting future sources of stressors. Link landscape and pollutant models to predict future environments.	Documentation of highest priority stressors. Data for predictive models. Predictive models for use by community-based ecosystem protection planners. Predictions of future pollutant and stressor distributions	To support environmental planning at multiple scales. To assist in avoiding the unintended consequences of our current management decisions.
Assessment	What are the assessment endpoints of primary concern to local, watershed, and regional communities?	Develop an ORD-wide ecological data management system.	Data systems to support risk management.	To support ecological risk assessment. To conduct comparative ecological risk assessments to prioritize research and ecological protection efforts.

(Continued)

Table I-5. Research to Improve Ecosystem Risk Assessment (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Assessment (Continued)	What are the comparative risks to populations, communities, and ecosystems from multiple stressors?	Develop risk assessment and characterization methods for single / multiple resources and stressors.	Improved risk assessment methods.	As tools for ecological risk assessment. To conduct comparative ecological risk assessments.
		Assess the risks and their economic implications.	Quantitative / qualitative regional, comparative risk assessments.	To support regional and local community-based ecosystem protection plans. To assist in prioritizing research and ecological protection efforts.
		Develop an expert system for assessing ecological benefits of alternative management strategies at multiple scales. Conduct comparative risk assessments.	Links between human health and ecological risks.	As a tool for environmental management at watershed scales. To assist in environmental management and planning at multiple scales.
Risk Management	What are the most cost-effective and efficient ways to reduce risk to ecosystems?	Identify and evaluate promising options for risk reduction.	Risk management technologies for contaminants, sediments, hazardous wastes, and other stressors. Data on technology effectiveness. Recommendations on optimal ecosystem management approaches.	As tools to select and implement approaches for reducing ecological risk. To avoid an ecological "train-wreck."
	How are degraded ecosystems best restored?	Conduct field restoration projects.	Restoration techniques.	To improve restoration techniques. To restore ecosystems. To provide manuals and guidance on management practices.

Table I-6. Research to Improve Health Risk Assessment

Subtopic	Strategic Focus	Tasks	Products	Uses
Exposure	What is the source-exposure relationship?	Develop verified models that trace the prospective and retrospective relationship between sources and total exposure.	Verified source-exposure models that incorporate fate and transport processes.	To identify the most effective risk management targets.
	What is the population distribution of exposures from all media?	Develop quantitative total human exposure models based on sound theoretical and experimental information.	Improved methods for exposure measurements: - Activity pattern database. - Microenvironmental exposure measurements. - Field studies of populations with a variety of exposure risk factors. - Computer-based exposure model platform.	To support health risk assessments; to measure effectiveness of risk management decisions.
	What are the determinants of exposure?	Determine which behavioral, socioeconomic, or lifestyle factors increase exposure to pollutants; determine the relationship of age (young and old) and preexisting disease to exposure.	Multimedia / pathway exposure data for disadvantaged populations, children, the elderly, and persons living near selected sources (e.g., pesticide use). Exposure models for highly exposed subpopulations.	To identify at-risk subpopulations for risk assessment and to ensure adequacy of rules / regulations.
Dose Estimation	What is the exposure-dose relationship for pollutants from each pathway?	For pollutants having multiple pathways, determine the quantitative contribution of each pathway to total exposure and target-site dose.	Models of relative intakes of persistent chemicals from inhalation, oral, and dermal routes based on measurement data.	To identify the pathways that contribute most to risk and hence require mitigation.
	How can we improve dose estimations across species and exposure scenarios?	Develop methods and models for estimating dose to target tissues (i.e., physiologically based pharmacokinetic models).	Models for predicting disposition of chemicals in the body from all routes.	To improve the scientific basis for cancer and noncancer risk assessments. To reduce uncertainty in risk assessment and risk management decisions.

(Continued)

Table I-6. Research to Improve Health Risk Assessment (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Hazard Identification and Characterization	How can we improve our ability to detect hazards?	Develop screening methods to set testing priorities.	Validated screening protocols using, for example, in vivo, in vitro, and structural activity relationship (SAR) methods.	To identify and rank existing pesticides and industrial chemicals in terms of potential toxicity. To screen new chemicals as they enter the regulatory system; to assess relative toxicity.
		Develop cost-effective methods for toxicity data collection.	New and revised standard toxicity testing protocols.	To develop Agency test guidelines. To support regulatory activities (e.g., TSCA[a] test rules and consent agreements, FIFRA[b] data call-ins).
	How can we better interpret toxicity data to predict and define hazards?	Develop improved methods for data interpretation. For example, identify biomarkers of exposure and effect and validate the use of biomarkers in human populations.	Guidance document on interpretation of toxicity data.	For incorporation into risk assessment guidelines.
Dose-Response Relationship	How can we reduce uncertainty in extrapolations (e.g., from high doses in animals to environmental exposures in humans)?	Develop quantitative models for predicting tissue and organism response to target tissue dose (i.e., biologically based dose-response models).	Models for predicting toxicity due to chemical exposures, which can be modified and applied in chemical-specific risk assessments.	To provide critical examples of development and use of mechanistic models; to evaluate the potential of these models for replacing default approaches for cancer and noncancer risk assessment. To provide a state-of-the-science basis for replacing default, primarily empirical risk assessment approaches.
		Develop improved empirical dose-response models (e.g., benchmark dose models).	Validated benchmark dose models and guidelines for applications.	To improve reference dose concentration procedures and thereby improve the basis for risk management decisions.
Special Problems	What toxicities are associated with mixtures?	Develop methods to assess the toxicity of chemical mixtures.	Validated and standardized testing protocols.	To identify chemical mixtures with potential toxicity that is other than addictive. To assess site-specific relative risk; to support pollution prevention and risk management decisions.
		Develop models to predict the toxicity of chemical mixtures.	Validated and standardized predictive models.	To identify chemical mixtures likely to have synergistic or supra-additive toxic effects. To improve risk management decisions concerning risks posed by mixtures.

[a]TSCA = Toxic Substances Control Act.
[b]FIFRA = Federal Insecticide, Fungicide, and Rodenticide Act.

Table I-7. Pollution Prevention and New Technologies

Subtopic	Strategic Focus	Tasks	Products	Uses
Risk Management	How can pollution prevention strategies be integrated into federal, state, and private sector decision-making?	Develop life-cycle assessment (LCA) tools and models.	LCA tools that include health and ecological impacts.	To demonstrate how LCA can evaluate options for multimedia pollution prevention and risk management that are keyed to the greatest risks. As objective, scientifically credible LCA procedures for regulatory and private sector use.
		Develop pollution prevention modules for industrial plant, product, and process design procedures.	Generic and specific LCA case studies with private and public sector partners. Mathematical models and computer-based simulators for process design.	To establish partnerships to demonstrate risk-based pollution prevention design and process simulation opportunities. For commercial plant and process design methods, models, and procedures. To provide technology transfer to the private sectors through Cooperative Research and Development Agreements and licensing agreements.
		Develop pollution prevention measurement and audit tools for small businesses.	Pollution prevention accounting methods and models. Audit procedures for pollution prevention.	As tools for measuring and estimating "pollution prevented" in small businesses. To provide technical guidance for regulatory programs and private sector needs.
	How can pollution be prevented?	Develop precompetitive and enabling pollution prevention and innovative technologies for major industrial sectors.	Pollution prevention and innovative technologies for Common Sense Initiative-related industrial sectors and high-risk problems, including information on technology costs.	To improve technical and cost data and designs for pollution prevention and innovative technologies keyed on CSI industries and other high-risk needs. To provide a basis for commercially available pollution prevention and innovative technologies for a wide array of U.S. industrial sectors and high-risk problem areas.
		Evaluate and verify these technologies for technical performance and cost-effectiveness.	Technology verification protocols, third-party verification organizations, and outreach to technology enablers and users. Performance and cost data for pollution prevention and innovative technologies.	Enhanced and more credible information to inform decision-makers about pollution prevention and innovative technology options emphasizing both performance and cost. As a basis for developing scientifically credible and commercially available pollution prevention and innovative technologies for both U.S. and foreign markets.

(Continued)

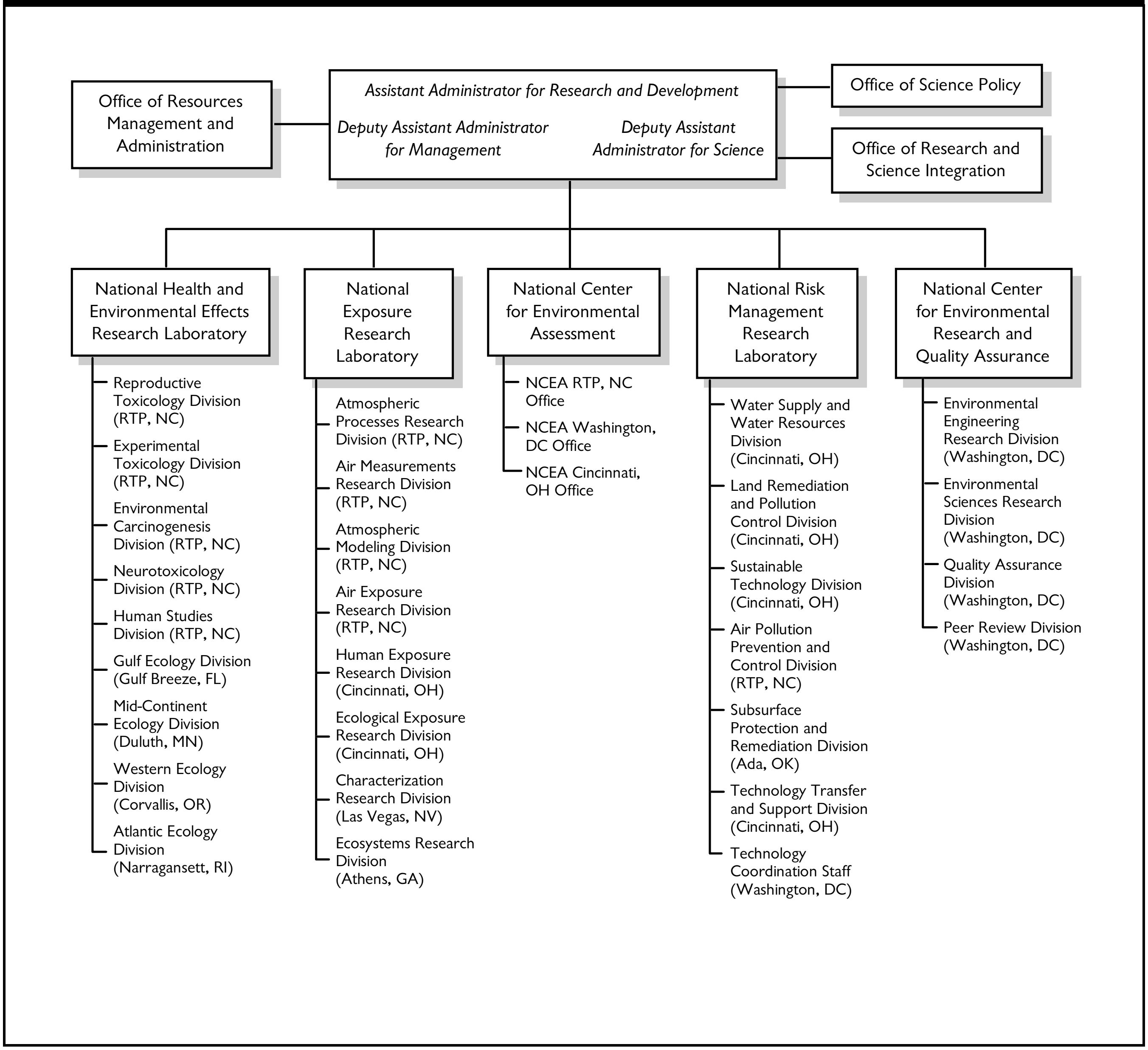
Table I-7. Pollution Prevention and New Technologies (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Risk Management (Continued)	How can reliable and appropriate cost data be generated for pollution prevention and innovative technologies?	Develop process cost models for pollution prevention and innovative technologies. Develop cost data reporting standards and protocols for improved cost comparability.	Cost estimating and reporting protocols and standards.	To improve cost estimating tools for use in cost-effectiveness and cost-benefit methods development. To provide reliable, scientifically credible cost-estimation packages for environmentally preferable approaches and technologies.
		Develop engineering and performance costs for pollution prevention and innovative technologies.	Cost data for pollution prevention and innovative technologies.	For cost-benefit assessments by EPA and other regulatory and nonregulatory decision-makers.
	How can pollution prevention and innovative technologies be disseminated to effect a reduction in environmental risk worldwide?	Identify specific industry and government audiences worldwide, their needs for information, and appropriate products to meet those needs (e.g., seminars, bulletins, demonstrations).	A variety of technology transfer products disseminated via the Internet, teleconferencing, electronic bulletin board, and other more conventional means (e.g., reports, workshops).	To increase the awareness and knowledge of environmental professionals and others about the validity and benefits of pollution prevention and innovative technologies, thereby leading to their increased application and broader use. To improve decision-making among innovative technology users and permitting officials. To support widespread use of applicable pollution prevention and innovative technologies that maximize risk reduction.
			Industry-targeted information dissemination products that will include technical and cost data and performance analyses.	To improve environmental compliance and reduce compliance costs. To encourage the private sector to value and routinely use pollution prevention and innovative technologies as the first or only preference for environmental protection and compliance.

Appendix II
The ORD Organization

ORD's new organization, depicted below, mirrors the risk assessment / risk management paradigm. The functions of ORD's National Laboratories, Centers, and Offices are described on the following pages.

ORD's New Risk-Based Organization



National Health and Environmental Effects Research Laboratory

ORD's National Health and Environmental Effects Research Laboratory (NHEERL) performs laboratory and field research to help EPA answer two fundamental questions:

- What are the health and / or ecological effects of exposures to man-made stressors?
- What is the likelihood that these effects will occur under conditions of environmental exposure?

NHEERL's research contributes to improving three steps in the risk assessment process:

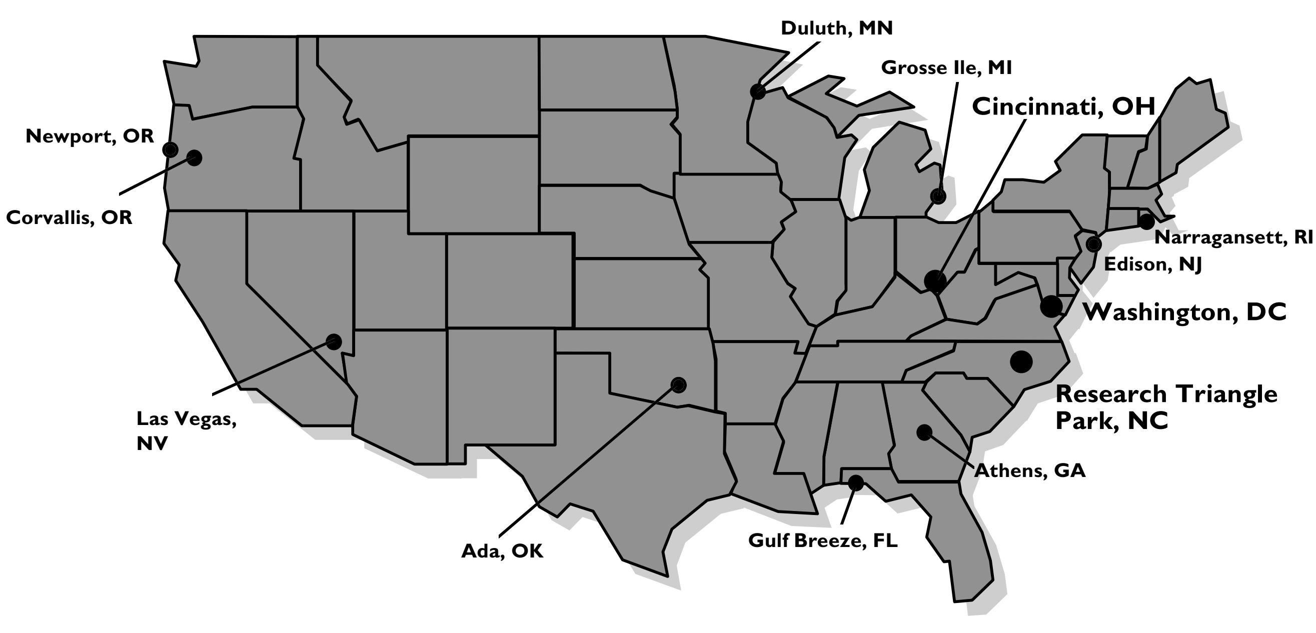
- In the ***hazard identification*** area, NHEERL works to improve both assessment test methods and the interpretation of data developed by these methods (i.e., the relationship of effects measures to health / ecological outcome).
- In the ***dose-response assessment*** area, NHEERL performs mechanistic research to address major uncertainties, as well as research to develop and improve extrapolation and multi-tier models.
- In the ***risk characterization*** area, NHEERL provides data on carefully selected priority problems.

National Exposure Research Laboratory

The work of ORD's National Exposure Research Laboratory (NERL) forms the basis for the ***human and ecosystem exposure assessments*** that are part of the risk assessment process. NERL researchers measure, predict, and apply multimedia data to assess with known certainty the multiple routes by which humans and ecosystems are exposed to environmental stressors. This work includes:

- Characterizing the physical and chemical properties that govern exposure in atmospheric, terrestrial, aquatic, benthic, and aquifer environments in order to identify and quantify phenomena that result in exposure.
- Developing, testing, and demonstrating mathematical and computerized models to:
  - Predict multimedia exposure routes.
  - Describe the status of ecological systems.
  - Evaluate stressor fate and transport mechanisms that affect mitigation, restoration, prevention, and risk management options to minimize exposure.

Location of ORD's National Laboratories and Centers



National Center for Environmental Assessment

ORD's National Center for Environmental Assessment serves as a national resource center for the overall process of risk assessment: integrating hazard, dose-response, and exposure data and models to produce ***risk characterizations***.

National Risk Management Research Laboratory

Research by ORD's National Risk Management Research Laboratory (NRMRL) provides the scientific basis for environmental ***risk management***. Specifically, NRMRL conducts research to reduce the uncertainty associated with making and implementing risk management decisions. This research focusses on two important areas:

- Characterizing pollutant sources that require management.
- Identifying, developing, and evaluating tools and technologies for prevention, control, restoration, and remediation of environmental problems that are high risk, high cost, or that lack effective management alternatives.

NRMRL catalyzes the development and commercial application of some of the more cost-effective risk management alternatives through joint efforts with public and private sector partners, and through programs to verify the performance and cost of innovative technologies. NRMRL also provides technology transfer and technical support to risk management stakeholders to encourage improved risk management decision-making.

National Center for Environmental Research and Quality Assurance

ORD's National Center for Environmental Research and Quality Assurance (NCERQA) represents a major and renewed commitment by ORD to help EPA achieve the highest possible quality of science. In particular, NCERQA has made a major commitment to ensure the high quality of ORD's extramural research by establishing the Science to Achieve Results (STAR) program. The primary purpose of the STAR program is to access the foremost research scientists from universities and nonprofit centers around the country to meet the specific science needs of the Agency. STAR consists of three components—a focused Requests for Applications, an Exploratory Research Grants Program, and a Graduate Fellowships Program—all of which are targeted to issues of importance to EPA. All applications to the STAR program must pass rigorous external peer review by national experts before being considered for funding. A portion of the STAR program is conducted jointly with other federal agencies.

In addition to the STAR program, NCERQA manages the Environmental Research Centers Program and the Hazardous Substance Research Centers and provides managerial oversight of EPA's quality assurance programs.

Office of Resources Management and Administration

The Office of Resources Management and Administration (ORMA) provides support services and leadership to ORD's Laboratories and Centers in many areas: budgeting, finance, human resources, training, information systems and technology, administrative procedures, health and safety, facility operations, and ORD's equipment and laboratory infrastructure. ORMA also serves as the principal staff office to ORD's Senior Resource Official. In this capacity, ORMA oversees all of ORD's contracting and assistance activities and conducts independent reviews of ORD Laboratory and Center management to ensure efficient operations in support of sound science.

Office of Research and Science Integration

ORD's Office of Research and Science Integration (ORSI) is the bridge between ORD and its many constituents:

- ORSI is the key link between ORD science and EPA policies and regulation. ORSI coordinates ORD input into the policy and regulatory development process, as well as ORD feedback on proposed policies and regulations. ORSI also coordinates ORD's support to EPA's Program and Regional Offices.

- ORSI coordinates EPA's research planning process, working closely with ORD's National Laboratories and Centers and EPA's Program and Regional Offices to constructively coordinate their input into ORD's research agenda.

Office of Science Policy

ORD's Office of Science Policy administers the programs of two standing interoffice committees: the Science Policy Council and the Risk Assessment Forum.

- ***The Science Policy Council*** is an EPA organization comprising senior EPA science managers and chaired by EPA's Deputy Administrator. Focusing on selected environmental issues that go beyond program and regional boundaries, the Council develops information and policies to guide EPA decision-makers in their use of scientific and technical information.
- The ***Risk Assessment Forum*** is comprised of senior agency scientists who study and develop guidance on generic risk assessment issues. The Risk Assessment Forum program includes technical analysis and consensus-building on a small set of selected risk science issues, usually controversial or precedent-setting, that relate to evaluating health and ecological risks.

In addition, the Office of Science Policy is responsible for supporting ORD's Assistant Administrator in selected projects.

Appendix III
Management Structure for Implementing ORD's Strategic Plan

Successful implementation of ORD's Strategic Plan requires coordinated input and involvement by all ORD Laboratories, Centers, and Offices as well as EPA's Program and Regional Offices. Several councils and teams, illustrated and described below, provide mechanisms for this participation. Collectively, these groups involve all levels of ORD senior management from ORD's Assistant Administrator through to ORD's Assistant Laboratory Directors (see figure). The Research Coordination Council and ORD's Research Coordination Teams, described below, provide mechanisms for Program and Regional Office involvement. One of the important roles of the councils and teams is to assure "upward" communication from the experts in ORD's Laboratories and Centers.

Executive Council

ORD's Executive Council is chaired by ORD's Assistant Administrator and consists of ORD's Deputy Assistant Administrators for Science and Management and the Directors of ORD's National Laboratories, Centers, and Offices. The Executive Council serves as the primary decision-making body for major planning and management decisions. Based on input from the Management and Science Councils, Research Coordination Council, and Research Coordination Teams, the Executive Council coordinates major policy and budget issues across ORD, including consensus recommendations to ORD's Assistant Administrator.

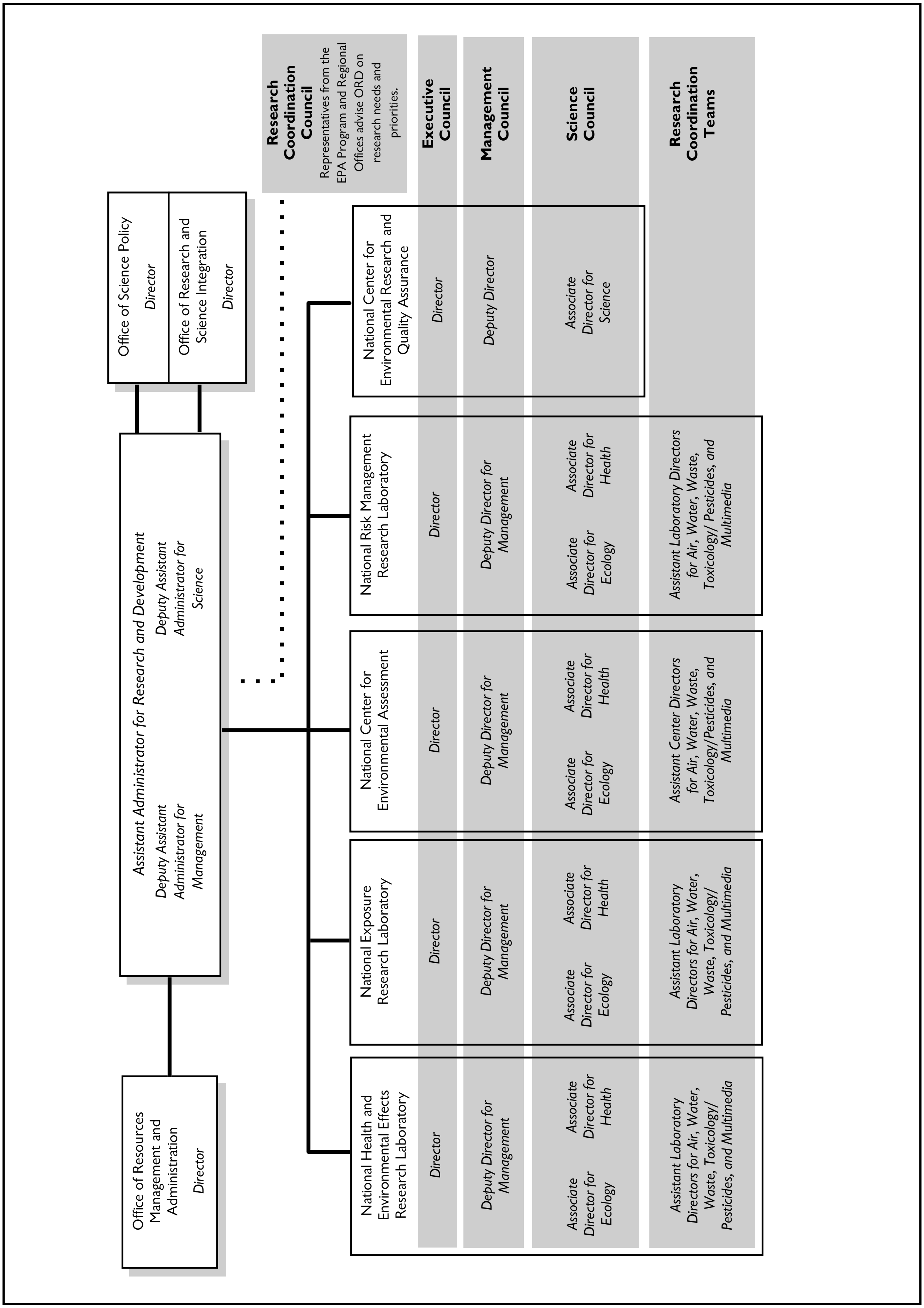
Management Council

ORD's Management Council is chaired by ORD's Deputy Assistant Administrator for Management and includes the Deputy Assistant Administrator for Science as an ex officio member, the Director of ORD's Office of Resources Management and Administration (who serves as the Vice Chair), and the Deputy Directors for Management of ORD's Laboratories and Centers. ORD's Management Council provides senior management leadership for developing and implementing effective management policies, procedures, and systems. For example, the Management Council is leading the development of ORD's Management Information System, a management system to ensure that ORD's resources are efficiently administered. The Management Council also provides input, feedback, and guidance on issues that significantly affect ORD's overall management operations.

Science Council

ORD's Science Council is chaired by ORD's Deputy Assistant Administrator for Science and includes the Deputy Assistant Administrator for Management as an ex officio member. Science Council members provide a balance between health and ecological research. They include the Associate Directors for Health and Ecology of ORD's National Laboratories and Centers, the Associate Director for Science of ORD's National Center for Environmental Research and Quality Assurance, and the Director of ORD's Office of Research and Science Integration.

ORD Management Structure



The Science Council serves as the principal forum for identifying, discussing, and providing advice and recommendations to ORD's Assistant Administrator on scientific and technical issues that significantly affect ORD's overall scientific and technical operations. For example, the Science Council had the lead role in developing ORD's Strategic Plan and will review all research plans.

Research Coordination Council

The Research Coordination Council comprises the Assistant Administrators from key Program Offices and the EPA Regional Administrators, supported on a day-to-day basis by their senior staff. The Research Coordination Council serves as a focal point for integration between ORD and EPA's Program and Regional offices. The Council provides ORD with a cross-agency perspective, participates in ORD's planning process, and recommends potential topics for ORD's research agenda and extramural grants program.

Research Coordination Teams

The Research Coordination Teams coordinate ORD's research program with ORD's clients and across ORD Laboratories and Centers. Organized by environmental media (air, water, waste, toxics/pesticides, and multimedia), the teams assess ORD clients' needs, recommend research priorities, monitor ORD progress toward meeting these priorities, facilitate integration of intramural and extramural research activities, and ensure communication of results to ORD clients. Each Research Coordination Team includes a Team Leader from ORD's Office of Research and Science Integration, the Assistant Laboratory Directors from ORD's Laboratories and Centers, a program analyst from ORD's Office of Resources Management and Administration, a representative from ORD's National Center for Environmental Research and Quality Assurance to provide input on ORD's grants program, and representatives from EPA's Program and Regional Offices. The Research Coordination Teams take the lead in developing ORD's science research plans and in organizing and conducting media-based program reviews of ORD progress and outputs.

Appendix IV

Relationship of Fiscal Year 1996 Requests for Applications (RFA's) to ORD High-Priority Research Topics

	Drinking water disinfection	*Particulate matter in the air*	*Endocrine disruptors*	*Research to improve ecosystem risk assessment*	*Research to improve health risk assessment*	*Pollution prevention and new technologies*
Ecological Assessment, including regional ecosystem protection and restoration and global climate change				✔	✔	
Exposure of Children to Pesticides			✔		✔	
Air Quality, including tropospheric ozone, air toxics, and indoor air		✔			✔	
Analytical and Monitoring Methods, including field analytical methods, continuous measurement methods, and leachability prediction	✔			✔	✔	
Drinking Water, including microbial pathogens and disinfection by-products	✔				✔	

	Drinking water disinfection	*Particulate matter in the air*	*Endocrine disruptors*	*Research to improve ecosystem risk assessment*	*Research to improve health risk assessment*	*Pollution prevention and new technologies*
Environmental Fate and Treatment of Toxics and Hazardous Wastes, including fate and mobility of contaminants in salts and ground water and the assessment of risks of contaminated soils and treatment residuals	✔			✔	✔	
Environmental Statistics	✔			✔	✔	
High Performance Computing		✔		✔	✔	
Risk-based Decisions for Contaminated Sediments			✔	✔	✔	
Endocrine Disruptors			✔	✔	✔	
Role of Interindividual Variability in Human Susceptibility to Cancer					✔	
Water and Watersheds	✔			✔		
Technology for a Sustainable Environment, including green chemistry				✔	✔	✔
Decision-making and Valuation for Environmental Policy						✔
Bioremediation				✔		✔

ORD Response to Blue-Ribbon Panel Recommendations

Recommended Action	ORD Response
EPA should take steps to improve science quality and enhance peer review.[c,i]	We instituted standard operating procedures for peer review in 1994.
	To engage the nation's best research institutions, we expanded our program for extramural research grants selected from competitive, peer-reviewed proposals.
	We created a Peer Review Division in our National Center for Environmental Research and Quality Assurance.
ORD needs a coherent research-planning process, a robust mission statement, and a vision statement.[c,d,i,j]	We developed the ORD Strategic Plan (this document) and distributed it for comment in November 1995.
	We implemented a risk-based research planning process.
	We realigned ORD's organizational structure to use risk assessment and risk management as principal priority-setting criteria.
ORD should enhance environmental education programs for training the next generation of scientists.[a,d,e]	We initiated an expanded graduate fellowship program initiated, with 100 awards in 1995.
ORD should streamline its existing laboratory organization by collapsing the twelve laboratories into four national laboratories.[d,f,h]	We consolidated ORD laboratories into three national laboratories and two centers in 1995 to align laboratories according to risk assessment and risk management components.
ORD should improve its management systems to track planning resources and accomplishments.[g,h]	We are developing the ORD Management Information System to track resources and projects on an ORD-wide basis.
	We established a Management Council, a Science Council, and (together with the program offices and regions) a Research Coordination Council (see Appendix C of this Strategic Plan).
	We will conduct annual research program reviews to evaluate the status and accomplishments of our research.
	We are developing research plans to inform internal and external audiences about the policy relevance, specific objectives, technical approaches, and expected products of our research.
ORD should balance short-term and long-term research.[a,e,g,j]	In 1995, we created the Science To Achieve Results (STAR) Program of peer-reviewed investigator-initiated grants relevant to ORD's mission.
	As described in this Strategic Plan, we give equal consideration to short- and long-term research needs in our priority-setting process.
ORD should balance health and ecological research.[a,c]	We have adopted a balance between ecological risks and human health risks as a major strategic principle (see Table 1 of this Strategic Plan).
	We appointed Laboratory Associate Directors for Health and Ecology for each national laboratory.
EPA should designate ORD's Assistant Administrator (AA / ORD) as the Agency's Chief Scientific Officer.[j]	The EPA Deputy Administrator appointed the AA / ORD as EPA's Scientific and Technical Activities Planner in March 1995.
EPA must improve its capability to anticipate environmental problems.[a-c]	EPA signed an agreement in 1995 with the National Research Council to establish a group to review environmental issues for the next decade and recommend necessary research.

[a] *Future Risk: Research Strategies for the 1990s.* U.S. EPA, Science Advisory Board. 1988.
[b] *Reducing Risks: Setting Priorities and Strategies for Environmental Protection.* U.S. EPA, Science Advisory Board. 1990.
[c] *Safeguarding the Future: Credible Science, Credible Decisions.* Report of the Expert Panel on the Role of Science at EPA. U.S. EPA. 1992.
[d] *Environmental Research and Development: Strengthen the Federal Infrastructure.* The Carnegie Commission. 1992.
[e] *Research to Protect, Restore, and Manage the Environment.* National Research Council. 1993.
[f] *Assessment of the Scientific and Technical Laboratories and Facilities of the U.S. EPA.* MITRE Corporation. May 1994.
[g] *An SAB Report: Review of the MITRE Corp. Draft Report on the EPA Laboratory Study.* U.S. EPA, Science Advisory Board / Research Strategy Advisory Council. May 1994.
[h] *A Review, Evaluation and Critique of a Study of EPA Laboratories by the MITRE Corporation and Additional Commentary on EPA Science and Technology Programs.* National Academy of Public Administration. June 1994.
[i] *Setting Priorities, Getting Results: A New Direction for EPA.* National Academy of Public Administration. April 1995.
[j] *Interim Report of the Committee on Research and Peer Review in EPA.* National Research Council. March 1995.

EPA

United States Environmental Protection Agency
(8101)
Washington, DC 20460