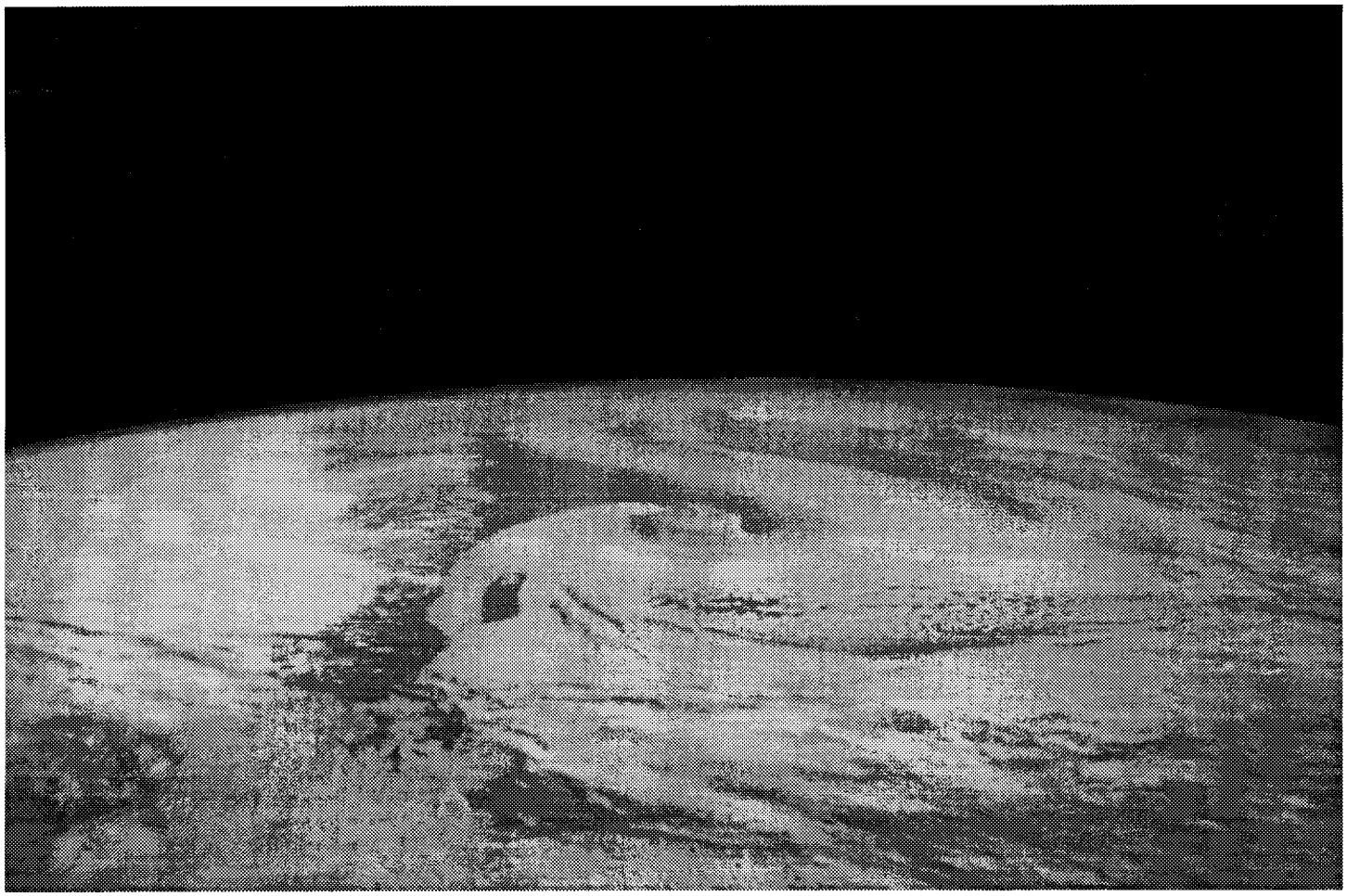
United States
Environmental Protection
Agency

Research and
Development
(8101)

EPA/600/R-97/015
April 1997

EPA

1997 Update to ORD's Strategic Plan



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April 1997

1997 Update to ORD's Strategic Plan

Office of Research and Development

U.S. Environmental Protection Agency
Washington, DC 20460

Foreword

I am pleased to present the 1997 Update to the Strategic Plan for the U.S. Environmental Protection Agency's (EPA's) Office of Research and Development (ORD). This plan summarizes the basis for the actions we have taken to respond to recommendations of numerous expert advisory groups committed to improving science at EPA. The plan serves as a framework for ORD to provide the highest possible quality environmental science to meet today's needs and lead us into the next century.

Central to our strategy is a system for determining research priorities based on risk assessment and risk management principles. We use this system to direct our resources to the nation's most important environmental issues—those areas with the greatest risk to people or the environment, those areas of greatest uncertainty in characterizing risk, and those areas with the greatest need to improve the efficacy of, or reduce the cost of, risk management.

We continue to enhance the quality of ORD's science products through independent peer review of all major aspects of the program, including research plans and proposals, science products, and even our own organization. We augment the efforts of our in-house cadre of experts through our expanding Science to Achieve Results program, which engages the best environmental scientists and technologists from United States universities and laboratories outside EPA. The plan also promotes greater partnership between ORD and our primary clients, EPA's Program and Regional Offices, as well as the external scientific community.

This plan is the foundation for ORD's future. We have designed our strategy to endure and yet be dynamic in the face of advancing scientific knowledge and understanding. While the plan details our current research planning process, long-term research goals and objectives, and near-term priority research topics, these components continue to evolve. Thus, this 1997 Update presents a snapshot of ORD's scientific and management evolution at this point in time. We are continuing to hone our strategic goals and objectives to better focus our work and align ORD's mission and activities with Agency priorities under EPA's new strategic planning process. Also, we have already begun to consider how advances in the state of environmental science and new human health and ecological issues on the horizon provide important perspectives for our 1998 planning efforts.

I take tremendous pride in being part of the team that is keeping ORD a strong and cogent scientific organization. I look forward to achieving ORD's vision for providing the scientific foundation to support EPA's mission guided by the continuing evolution of our Strategic Plan.

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

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List of Acronyms

AMI	Advanced Measurement Initiative
CRADA	Cooperative Research and Development Agreement
DBP	disinfection by-product
DOE	U.S. Department of Energy
EDC	endocrine-disrupting chemical
EPA	U.S. Environmental Protection Agency
GPRA	Government Performance and Results Act
IRIS	Integrated Risk Information System
LCA	life-cycle assessment
NAE	National Academy of Engineering
NAS	National Academy of Sciences
NASA	National Aeronautics and Space Administration
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
NOAA	National Oceanic and Atmospheric Administration
NRC	National Research Council
NRMRL	National Risk Management Research Laboratory
ORD	Office of Research and Development
ORMA	Office of Resources Management and Administration
OSP	Office of Science Policy
PM	particulate matter
R&D	Research and Development
RFA	Request for Applications
SAB	Science Advisory Board
STAR	Science to Achieve Results
USGS	U.S. Geological Survey

Executive Summary

The U.S. Environmental Protection Agency's Office of Research and Development (ORD) has instituted significant changes in its organization and management procedures to provide the vision and direction for the scientific foundation of EPA's mission.

- First, ORD has aligned its organizational structure to comport with risk assessment and risk management principles and has made these principles central to our strategy for determining risk-based research priorities. In this way ORD can assure that science resources are directed to the most pressing environmental problems nationwide—pollution posing the greatest risks to people or the environment; environmental risks most difficult to understand and describe; and areas where we most need to improve the effectiveness and efficiency of managing environmental risk.
- Further, ORD has strengthened interactions with the larger scientific community in two ways:
  - By expanding our competitive extramural grants and graduate fellowship programs, we are working to stimulate research in areas vital to EPA by more broadly involving universities and other not-for-profit institutions.
  - By intensifying our peer review process, we ensure that all major facets of our science program are independently reviewed by experts external to our organization.

  Both of these activities leverage and potentiate our scientific expertise and capabilities.
- Most importantly, ORD's strategic planning and management process for selecting research priorities, instituted in 1995, has set us firmly on course to meet the science needs of today while positioning ourselves to identify and aid in resolving the environmental problems of tomorrow.

EPA's Mission

The mission of the United States Environmental Protection Agency is to protect public health and to safeguard and improve the natural environment—air, water, and land—upon which life depends. EPA's purpose is to ensure that:

- Federal environmental laws are implemented and enforced fairly and effectively.
- Environmental protection is an integral consideration in U.S. policies concerning economic growth, energy, transportation, agriculture, industry, international trade, and natural resources.
- National efforts to reduce environmental risk are based on the best available scientific information.
- All parts of society—business, state, and local government, communities, and citizens—have full access to information so that they can become full participants in preventing pollution and protecting human health and the environment.

May 6, 1996

This 1997 Update to the ORD Strategic Plan describes our revised strategy for research planning, the process for deploying our research plan, and our current research priorities.

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 and ***improving cost-effectiveness*** in risk prevention and management.

- 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.***
- Recruit and ***engage the best scientists from outside EPA*** through competitively awarded grants and fellowships.
- 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 requires us to examine 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 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 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 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, and Research Coordination Teams consisting of senior representatives from ORD's National Laboratories and Centers and EPA's Program and Regional Offices each identify 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 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 areas of research on environmental problems and three broad-based areas of research on methods and approaches that will impact many additional topics:

Environmental Problem Areas

- Safe drinking water (with a near-term focus on microbial pathogens, disinfection by-products, and arsenic)
- High-priority air pollutants (with a near-term focus on particulate matter)
- Emerging environmental issues (with a near-term focus on endocrine disruptors)

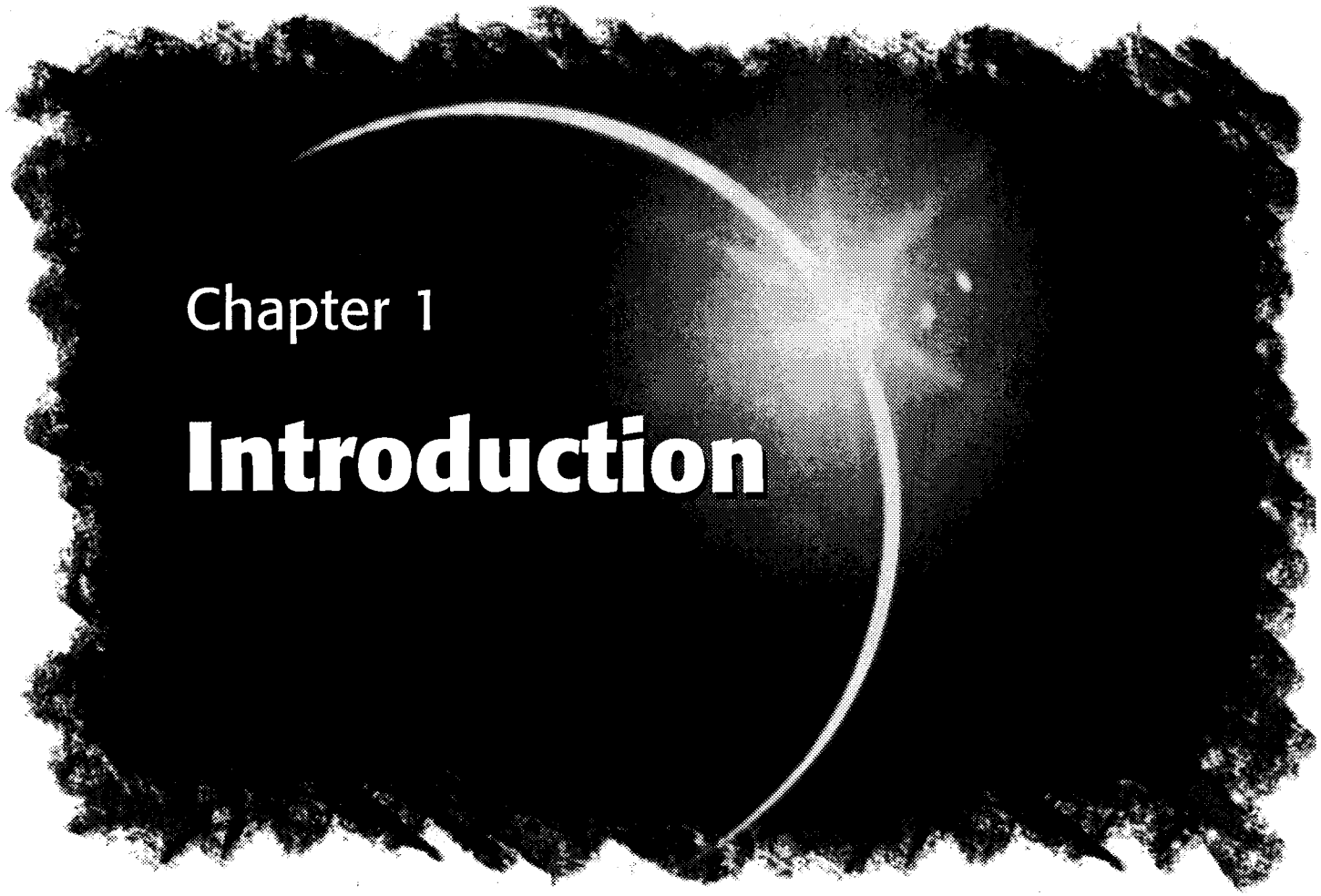
Broad-Based Methods and Approaches Areas

- Research to improve ecosystem risk assessment
- Research to improve health risk assessment
- Pollution prevention and new technologies for environmental protection

Planning for the Future

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.



Chapter 1

Introduction

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. EPA has identified strong science and credible data as one of the 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 contribute to the scientific underpinnings of the Agency's decisions, 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 and the Risk Assessment/Risk Management Paradigm

We at ORD have shaped our organization and research agenda to 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 efforts are based on a set of strategic principles we have developed (Table 1) that draw on the many recommendations we have received from outside groups and our own staff in recent years. The most important of these principles is the explicit use of the risk paradigm.

Risk assessment 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 the stressor or the consequences of subsequent risks.

The risk assessment process is one component of the overall process of risk management. The risk management process involves the recognition of a potential new risk and a decision by authorities to respond to concern about the risk. It includes risk assessment as well as a series of other scientific and technical activities, illustrated in Figure 2, that provide the scientific and technical data for making and implementing a risk management decision. The risk management process concludes with the selected risk management option(s) being implemented and the resulting environmental and/or public health improvements being 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 part of risk management. These

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, variability, 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 supporting 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.

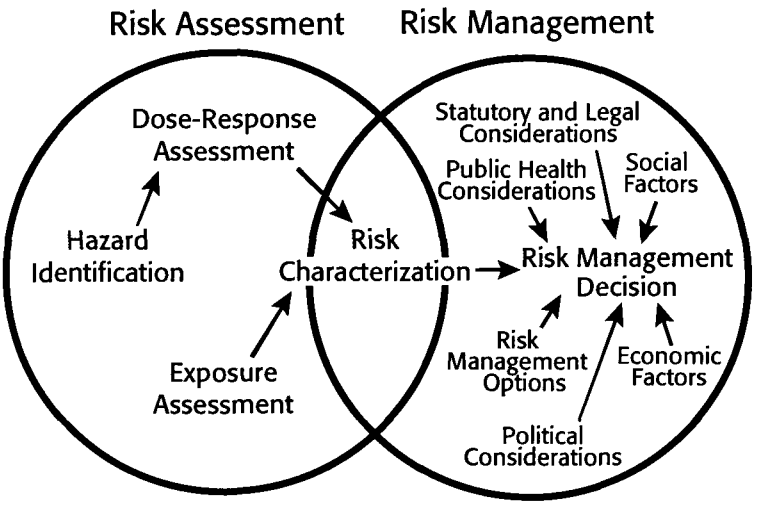
History of This Document

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, and external stakeholders, 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 May 1996, we finalized our Strategic Plan and it has guided our program for a year. The plan has been fully peer-reviewed and reflects ORD's maturing process for evaluating and setting research priorities. The basic principles and priorities outlined in the 1996 plan remain unchanged, and substantial portions of the original text are intact. We are continually improving this process, based on our interactions with outside stakeholders and our own internal deliberations. For example, ORD staff identified several organizational improvements at our *First Annual Workshop on Managing Change.* This revision to our Strategic Plan reflects ORD's continuing evolution, as we address these recommendations. Major changes appearing in the 1997 plan include:

- Elaboration on the evaluation criteria for determining research priorities.
- Clarification of high-priority research topics/areas.
- Inclusion of information on and commitments from ORD's *First Annual Workshop on Managing Change* in Williamsburg, Virginia, December 1996.
- Expansion of the plan's discussion of technical support to EPA Program and Regional Offices.
- Information on ORD's new Information Management Plan.

Figure 1. The Risk Assessment/Risk Management Paradigm



*Adapted from:

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

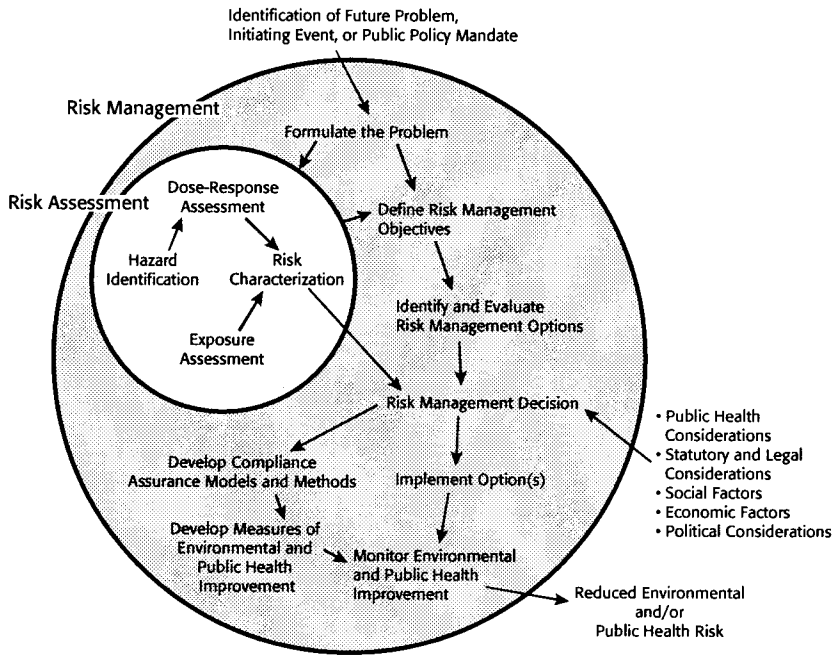
Science and Judgement in Risk Assessment. National Research Council. 1994.

The risk assessment process consists of four kinds of analyses:

- ***Hazard identification*** involves the description by scientists of 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.
- As part of the ***dose-response assessment,*** scientists determine the toxicity or potency of a stressor. The dose-response assessment describes the quantitative relationship between the exposure to a stressor and the extent of injury or disease.
- ***Exposure assessment*** involves scientists describing the nature and size of the population(s) or ecosystem(s) exposed to a stressor and the magnitude, duration, and spatial extent of exposure. It 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.
- In ***risk characterization,*** assessors use the data collected in the three previous analyses 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 mainly in terms of principles relating to 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 useful as an organizing focus for ORD's strategic thinking, and they have been supplemented by new guidelines relating to ecological risk assessment.

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.

First, the ***problem must be formulated.*** 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 stressor(s) reach target populations, and which human or ecological populations are affected. Once the problem has been sufficiently formulated, the risk assessment process can begin.

If sufficient information is available at this point, 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 activities 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 con-taminated 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).

Upon selecting a risk management strategy, 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.***

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 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.

Audiences for This Document

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

- Within 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.

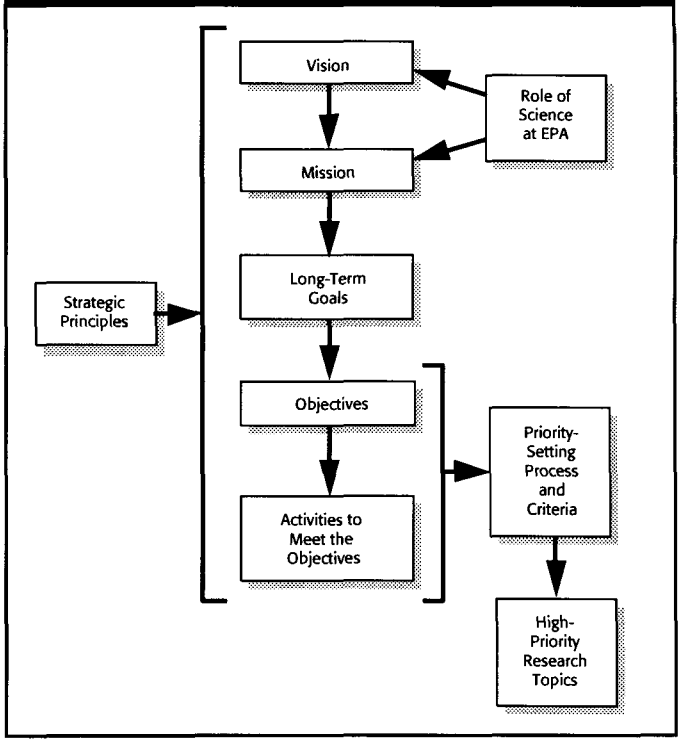
ORD Staff

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 earning 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, managerial, administrative, and clerical staff, ownership and implementation of the plan will depend on the expertise and dedication of our work force. ORD will place a continuing priority on "360-degree" communication and support to enable and inspire effective implementation of this plan.

At its *First Annual Workshop on Managing Change* in December 1996, ORD identified five cross-organizational improvement opportunities to improve our products, processes, and work environment. These five improvement opportunities (described in more detail on page 23 of this document) are: reducing red tape, improving communications, enhancing career development, providing adequate infrastructure to support ORD science, and integrating science with EPA's mission. In summarizing the next steps for implementing these organizational improvement measures, ORD staff

Figure 3. ORD's Strategic Plan



noted that each measure has both a "head" and "heart" component. Each measure simultaneously provides for meeting ***organizational*** (head) needs for time, information, expertise, tools, and strategic direction, as well as ***personal*** (heart) needs for empowerment, access, respect, opportunity, and alignment of each individual's work with Agency and ORD goals.

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 as we plan our research. We directly solicit input on priority needs and products from the Program and Regional Offices during the planning process.

ORD's Research Planning Advisors

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, EPA's Science Advisory Board, and ORD's Board of Scientific Counselors.

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 cooperative arrangements and funding 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 the 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.

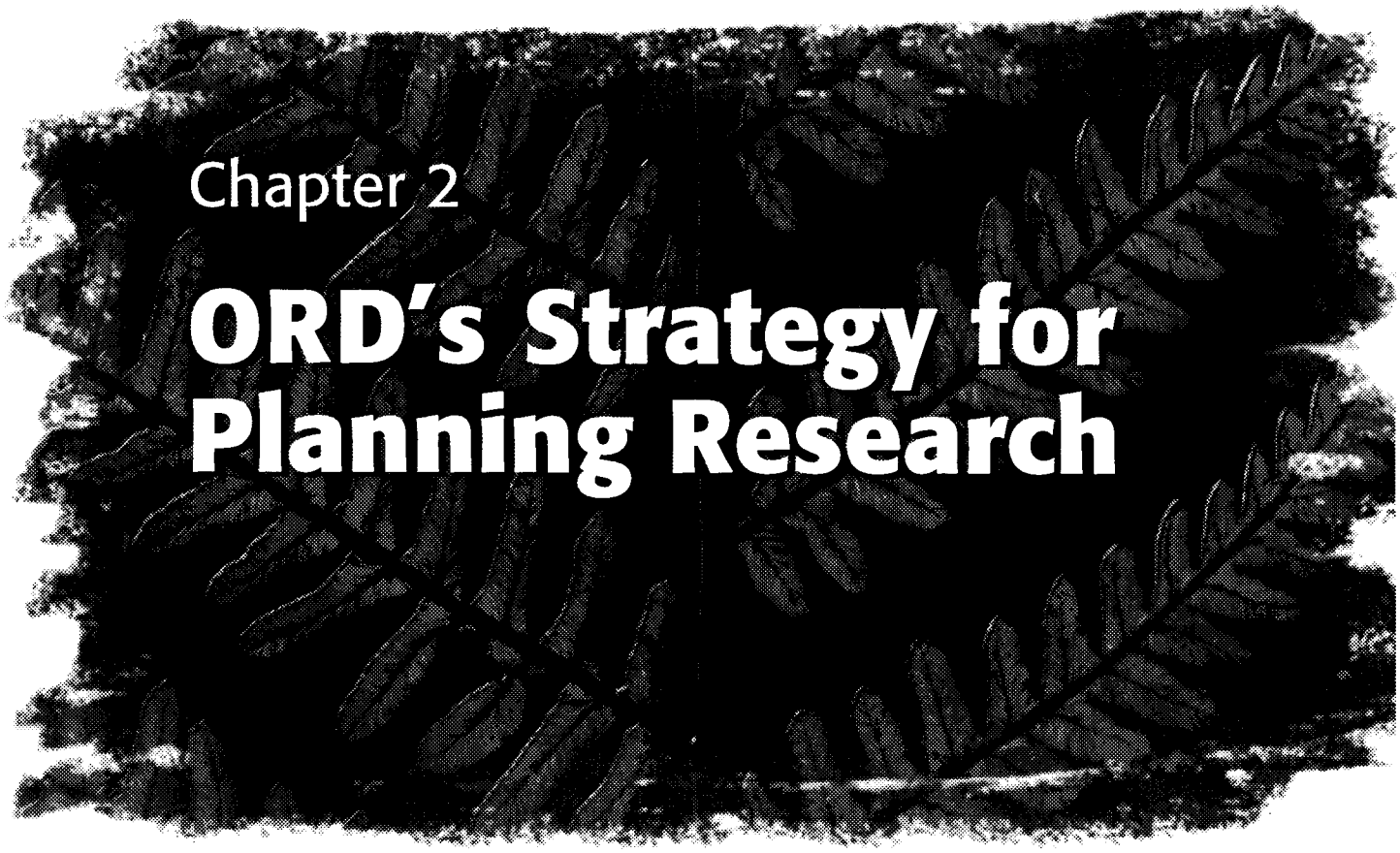
Evolution of the Strategic Plan Over Time

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. EPA is currently developing a new Agency strategic plan. ORD will work with other Agency offices to ensure that science is a strong element of that plan and supports Agency decision-making. We will adapt the ORD Strategic Plan as appropriate to ensure that it supports the Agency's strategy.

Additionally, 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 shared throughout ORD.

A Roadmap for This Document

- *Chapter 2* of this plan defines strategic directions (including ORD's vision, mission, and long-term goals) for ORD research; describes how we identify specific research topics; lays out an approach to identifying emerging issues; establishes a risk-based process for determining our research priorities; and discusses the criteria used in priority setting.
- *Chapter 3* discusses ORD's new plan for information management; describes how we translate our Strategic Plan into a specific research program (including research plans, operating plans, laboratory implementation plans, and Requests for Applications); relates 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, as well as mechanisms for evaluation and accountability; and describes ORD's commitment to our human resources and infrastructure, including commitments to organizational improvement made at our *First Annual Workshop on Managing Change* in ORD. Finally, it identifies challenges for future consideration by ORD.
- *Chapter 4* describes the six high-priority research topics and areas selected when we applied our priority-setting process to the array of science needs identified by the Agency, and in the context of our long-term goals and objectives.
- *Appendix A* expands on ORD's long-term goals and lists the specific research objectives and activities ORD will pursue to achieve its goals.
- *Appendix B* describes ORD's organization built around the risk assessment/risk management paradigm.
- *Appendix C* describes ORD's management structure for implementing the Strategic Plan.
- *Appendix D* shows how ORD's extramural investments (in the form of Requests for Applications for research grants) relate to the high-priority research described in Chapter 4.
- *Appendix E* shows how ORD's fiscal year 1997 and 1998 program enhancements correlate to our high-priority research.



Chapter 2

ORD's Strategy for Planning Research

ORD's commitment to develop a risk-based research agenda undergirds our vision, mission, and long-term goals. This commitment also is embodied in our 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, also 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 (Table 2) that we will strive to meet in order to fulfill our mission. ORD's long-term goals and objectives are detailed in Appendix A. The objectives add another level of detail to our goals that will aid us in organizing and setting more detailed priorities in our annual research planning efforts. Some of the objectives also include a set of specific activities that we will undertake to achieve those objectives. These activities allow both internal and external stakeholders to see how we will conduct our work. Activities are listed under each objective.

We are working on refining our research goals and objectives to make them more specific and to enable us to clarify intended outcomes of ORD's science agenda. This refinement will not only better align our program with Agency-wide strategic planning, but will also allow us to track our progress toward achieving our program goals, as required by the Government Performance and Results Act of 1993 (GPRA).

Identifying Specific Research Topics

The objectives and activities listed in Appendix A of this plan provide detail about how ORD will go about meeting its long-term 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 that are of primary importance to our vision, mission, and goals. We will use this priority-setting process and criteria periodically

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 assign and characterize 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.

to identify high-priority research topics that will help us achieve ORD's goals and objectives.

Each year since 1995 we have applied our priority-setting process and criteria to examine our ongoing research and identify important new initiatives. This year we have retained and refined our six priority research topics from 1996. As before, some of our priorities are specific to a particular environmental problem and others are broad-based, since they contribute basic science improvements in both risk assessment and risk management. These six research topics are described in Chapter 4 of this document.

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.

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.

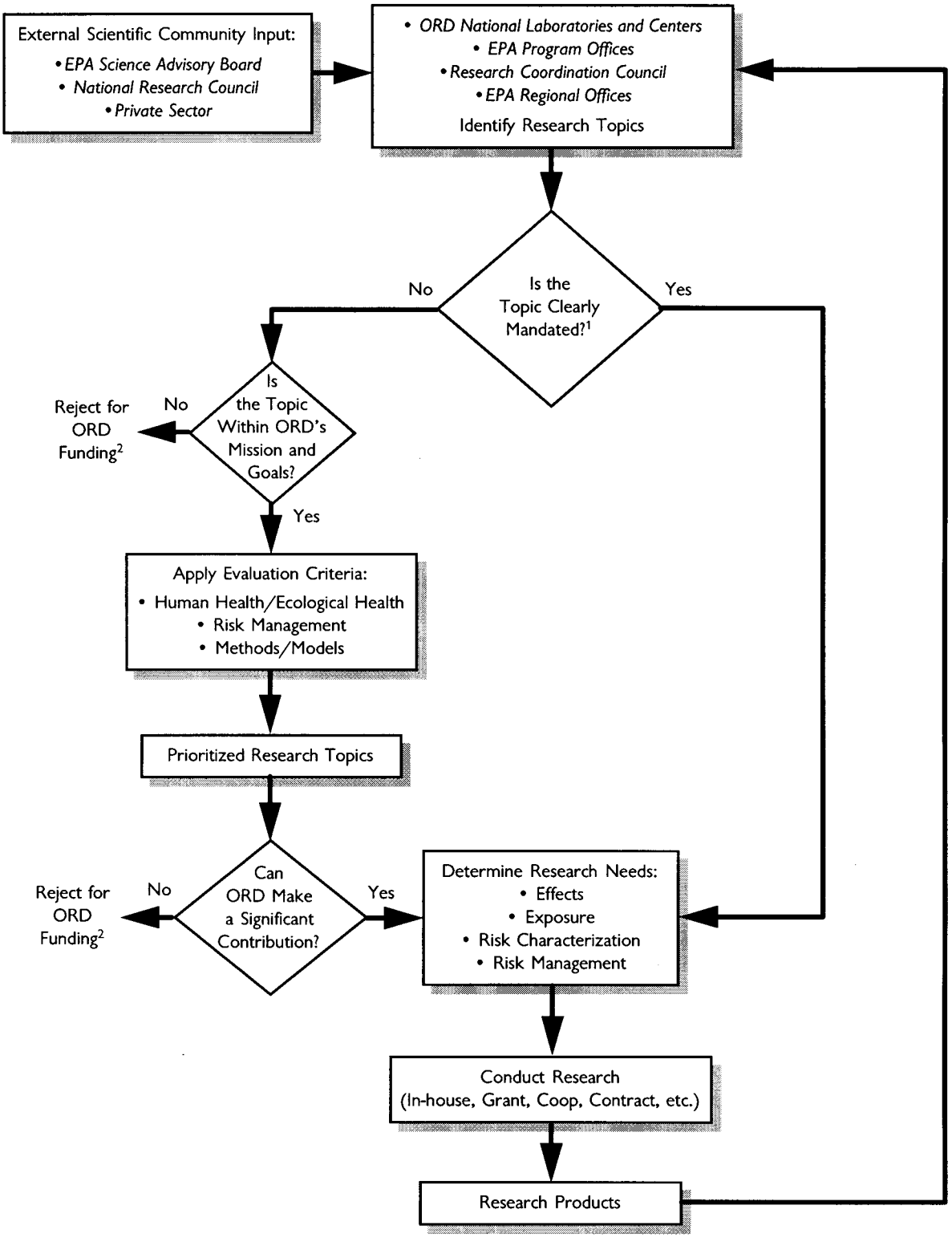
The EPA Science Advisory Board's January 1995 report *Beyond the Horizon: Using Foresight to Protect the Environmental Future* suggests many useful measures we will evaluate for possible implementation. One measure we are currently considering is the creation of "lookout panels" comprised of individuals 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 established, at ORD's request, a Committee on Research Opportunities and Priorities for EPA. This committee was 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 high-priority topics related to anticipatory research as we review and revise our research agenda.

ORD's Priority-Setting Process

ORD's 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 C) 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.

Figure 4. Setting Research Priorities



[1]In other words, ORD has 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.

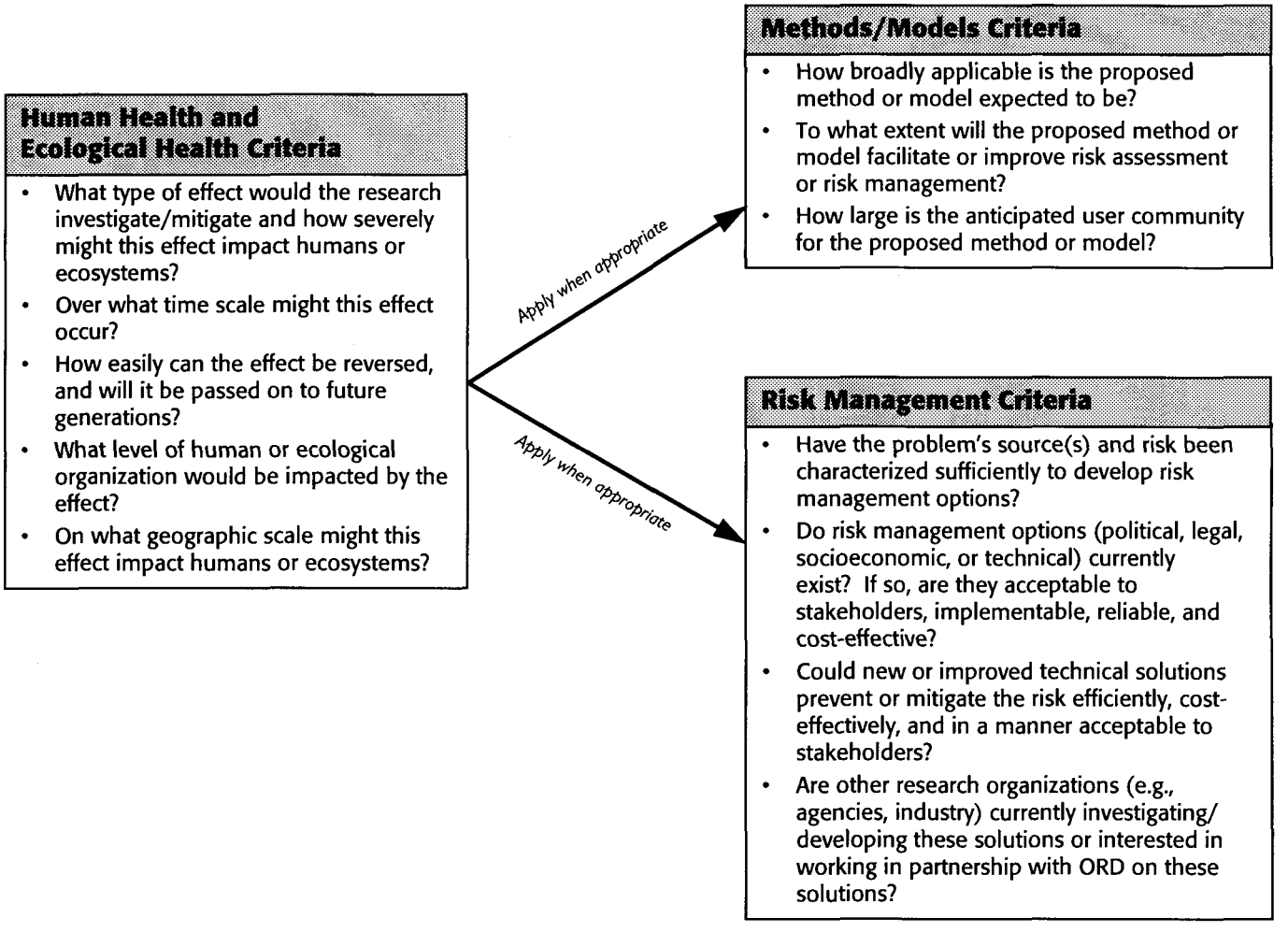
- We then further narrow this pool of topics by retaining only those areas where ORD can make a significant contribution to environmental science. Factors we consider at this stage include: Is the work feasible from a scientific and resource perspective? Does ORD have access to the appropriate expertise? 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 efficacy of or reduce the cost 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 or where the risk is well characterized.
- Risk reduction research in areas of low risk or where cost-effective risk reduction approaches already exist.
- Routine measurements and monitoring where R&D has been completed or that does not support R&D efforts.

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



Criteria for Setting ORD Research Priorities

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

We are continuing to refine these criteria. In particular, the criteria have been undergoing extensive discussion and review during fiscal year 1997 with the twin goals of creating a system that will more directly link ORD's work to the important issues facing the Agency and that will more closely integrate human health and ecological research. We anticipate future modifications to these criteria that will both improve our ability to evaluate the effectiveness of ORD research and help our scientists understand how their research will be used to answer the Agency's most important risk-based questions.

Human and Ecological Health Research Criteria

ORD's human and ecological health criteria are based on five broad categories: 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 criteria ORD has developed in each of these five categories. These factors help us determine the importance of a human or ecological health problem in terms of its magnitude of risk and extent of scientific uncertainty, and thus point to the areas most needing research (Figure 6a). (Conversely, areas of low risk or well-understood risk typically need the least new research.)

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

Risk Management Research 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. Applying these factors directs us toward research investments in areas where risk problems are adequately characterized and where risk management options do not exist, are poorly characterized, are out-dated or inefficient, are too costly, or might be significantly improved (Figure 6b). (Conversely, areas where risk problems are as yet poorly characterized or where management options are already optimized typically need the least new research.)

Methods/Models Development Criteria

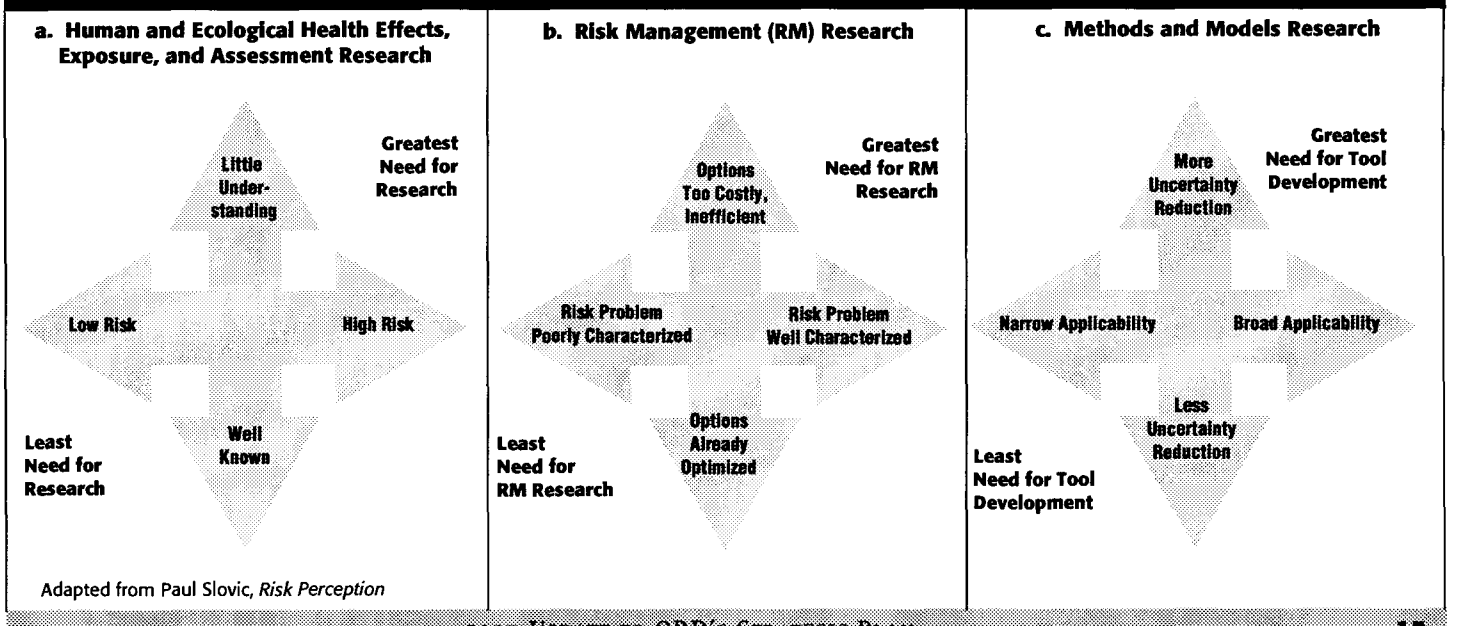
The methods/models development criteria are applied to research concerning the development or application of methods or models for gathering, analyzing, or applying risk-related data. These criteria give priority to research that will likely produce the most useful results. The criteria consider how 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. As a result, ORD can then direct research attention to those areas where tools would be most broadly applicable and where uncertainty in risk assessment or risk management would be most reduced (Figure 6c). (Conversely, tools with narrow applicability or low potential for reducing uncertainty reduced will typically receive the least support.)

Strengths of ORD's Research Planning Process

Our planning approach has many strengths:

- It encompasses both scientific and stakeholder priorities.
- It ensures that ORD will continue to fully support EPA in fulfilling its mandates.
- It focuses our resources where we can make our most significant contributions.
- It reinforces our sense of direction and accomplishment as we see our objectives met and goals realized.
- It establishes a structure linking us to Agency-wide strategic planning and the GPRA.
- It enables us to generate practical, credible information and tools for risk-based decision-making.

Figure 6. Setting Research Priorities



Adapted from Paul Slovic, *Risk Perception*

Chapter 3

Translating ORD's Strategy Into a Research Program

The steps involved in translating ORD's Strategic Plan into a research program are illustrated in Figure 7. Once we have identified our high-priority research topics, we develop and implement a research program based on these topics. This involves:

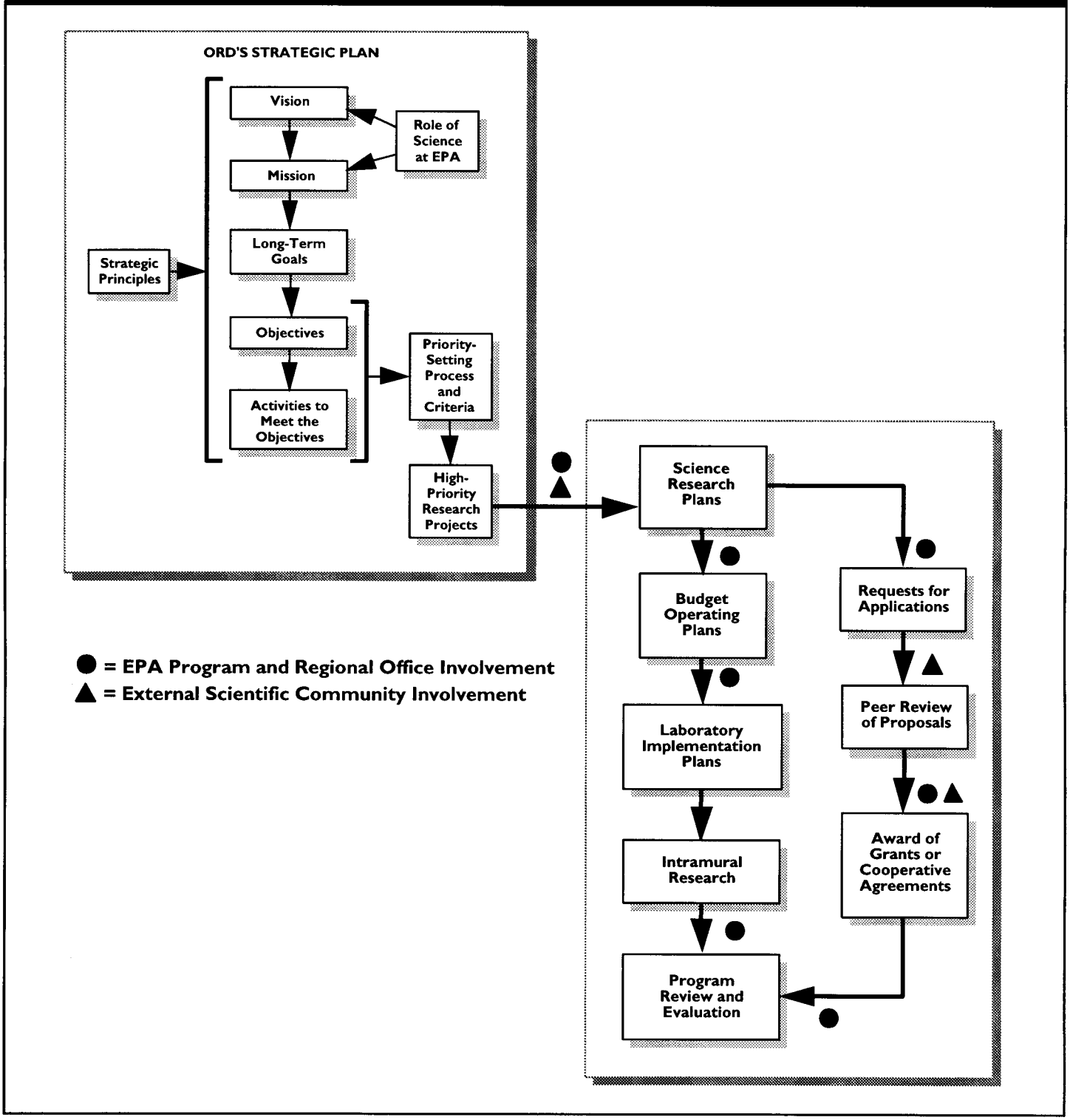
- Developing science research strategies and plans.
- Deciding whether the work will be conducted in-house or extramurally. (ORD's research program is comprised of intramural and extramural research.)
  - For intramural research, developing budget operating plans and laboratory implementation plans.
  - For extramural research, selecting and implementing the appropriate mechanisms to access the external scientific community.
- Integrating information management into research planning.

Developing Science Research Strategies and Plans

Once ORD has identified its high-priority research topics using the process described in pages 11 to 13, teams composed of ORD scientists and engineers as well as representatives of EPA's Program and Regional Offices develop science research strategies and plans for each topic. These plans:

- 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.
- Describe how the data and information to be generated by the research will be used and managed.
- Delineate the major outputs to be produced over the next several years.

Figure 7. Translating ORD's Strategic Plan Into a Research Program



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. And, by explicitly specifying up-front how we will manage our scientific data and information products, we ensure that the results of ORD research will be effectively communicated to our clients and stakeholders. Research plans also enable ORD to clearly track its progress toward achieving its goals, as required by the 1993 Government Performance and Results Act.

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

This is the point of ORD's planning process where we decide whether the work would best be accomplished internally at ORD or externally through one of several mechanisms: grants to universities or nonprofit centers; cooperative agreements with another government agency or with 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, including assessment methods research work, may be done externally).
- How urgently the research products are needed (since some mechanisms are faster than others).
- If there would be value in involving multiple institutions.
- The extent to which we can specify what is needed (contracts). The extent to which we must 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.

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, 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 supports RFAs that focus on specific research needs to support the mission of the Agency. Working with EPA's Program and Regional Offices, we 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, in consultation with EPA's Program Offices and Regions, through grants or cooperative agreements. ORD leverages the STAR program resources by jointly funding research with other federal agencies. Appendix D shows how the fiscal year 1997 RFA topic areas relate to ORD's high-priority research topics.

Integrating Information Management Planning Into the Process

To further enhance the quality and value of our work, we have been developing a plan for managing data and information in ORD. The plan is based on coordinating and enhancing existing ORD and EPA systems and resources. It is built on four fundamental tenets of successful information management:

- Planning and incorporating policies for information management.
- Making potential users aware that information exists.
- Making the information accessible to users.
- Making the information usable.

The plan sets forth an approach to managing all levels and types of ORD information—from the scientific data and information that result from ORD's in-house or extramural research (e.g., raw data collected at field sites, health or ecological risk assessments, aggregated data sets) to the administrative information needed to manage ORD research (e.g., resource data, grant award information, and laboratory implementation plans).

ORD's information management plan will provide a consistent, ORD-wide approach to efficiently planning for, collecting, documenting, manipulating, exchanging, archiving, and distributing science data and information. It will address the full spectrum of ORD's information management needs, including data management; policies and standards; management, staffing, and budget issues; and electronic information technologies.

Information management planning for specific research projects will commence as soon as ORD has identified its specific project needs. For each research project, ORD management and budget decisions will be made considering the entire project, from data collection through long-term archiving of data sets. Information management planning will, to differing degrees, encompass all ORD research projects—including in-house research as well as the extramural research that ORD funds with contracts, cooperative agreements, and grants.

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. ORD's new information management plan seeks to ensure that we make our stakeholders aware of and able to access ORD's science data and information products.

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. Further, we will be judged by the external scientific community on the extent to which we advance the state of environmental science.

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 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.
- *ORD review of its science research plans.* ORD examines its research plans periodically 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 intervals 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.
- *Yearly evaluations* under the Government Performance and Results Act.

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 time frame, so we can begin work on new priorities without delay.

Technical Support

One of ORD's most important functions is to provide technical support to EPA Program Offices and Regions and states. ORD is committed to a strong and sustained technical support program.

In 1996, the EPA Program Offices, ORD, and the EPA Regions initiated the first comprehensive assessment of all technical support activities within EPA, with particular emphasis on ORD's roles and responsibilities for technical support. The purpose of this evaluation was to ensure that ORD:

- Provides the types and quantities of technical support most needed by the Program and Regional Offices, states, and others.

- Focuses its technical support efforts in areas where ORD has unique capability or where the support is not readily available outside EPA.
- Fosters greater involvement of the EPA Program Offices and Regions in guiding ORD's technical support activities.
- Promptly develops exit or entrance strategies for activities that are being phased out or newly introduced.

As an outgrowth of this initial effort, ORD comprehensively assessed its technical support function. We defined the term *technical support,* developed criteria for setting support priorities, inventoried the current distribution of our technical support resources, and developed a process for making technical support decisions.

As defined by our assessment, ORD *technical support* comprises activities ORD conducts in response to specific requests by the Program Offices, Regions, or states to address well-defined needs that are not covered by ORD's research program. For example, ORD's current technical support activities include maintaining the Integrated Risk Information System for the Agency and consulting with the Office of Water on sediment quality criteria guidelines.

The criteria ORD will now use to set its technical support priorities are the extent to which:

- The proposed technical support will provide fundamental support for regulatory programs.
- ORD has unique scientific and or technical capabilities to address the problem.
- Environmental quality and human health will directly benefit from the activity, relative to the resource requirements of the technical support.
- ORD can help solve the problem.

ORD technical support decisions for fiscal year 1998 were made during fiscal years 1996 and 1997 using a process that involved the Research Coordination Teams, the Research Coordination Council, the Environmental Monitoring Management Council, and others. This allowed participants to resolve long-standing issues and develop a common reference point for making future decisions. In the future, decisions about the type and quantity of ORD technical support will be made as part of ORD's overall research planning process.

ORD Customer Focus

ORD is committed to providing excellent service to all external and internal customers. To this end, we will support our employees in applying the Agency's customer service standards, and our senior executives will provide leadership in advocating high quality customer service.

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 in achieving and maintaining 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, modeling 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. ORD maintains its commitment to 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). In addition, we will provide opportunities for ORD scientists and engineers to increase their contribution, 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).

Further, 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 organizational structure (see Appendix B) relies on a relatively small headquarters staff and places program management responsibilities in the hands of ORD's field Laboratories and Centers. This flattened organizational structure requires a team-based, matrix-management approach in place of the traditional, more hierarchical approach to management.

ORD's Organizational Improvement Activities

ORD held its *First Annual Workshop on Managing Change* in Williamsburg, Virginia, on December 2-5, 1996. This meeting marked the beginning a long-term process for managing change within ORD. The overarching purpose of the workshop was to improve the delivery of high-quality science in EPA by:

- Understanding the new directions in ORD.
- Building the ORD team and improving communications.
- Sharing ideas and listening to all participants' views.
- Developing action plans and identifying change agents to achieve specific organizational improvements.
- Strengthening strategic management of ORD's research program.

The workshop was the first of its kind for ORD in terms of its scope, design, and breadth of participation. Participants included a cross-section of staff from ORD Laboratories, Centers, and Offices. ORD's Strategic Plan provided the overall framework for the deliberations.

Participants identified 564 issues and then consolidated and prioritized them to specify five focal areas for improvement:

- Reduce red tape—Empower staff by reducing unnecessary paperwork.
- Communications—Develop and implement a comprehensive communications plan to improve two-way communication and make electronic communications more effective within ORD.
- Career advancement and development—Provide career enhancement opportunities for all employees.
- Resources and infrastructure—Define "infrastructure" and provide adequate resources to support science.
- Integrate science with EPA's mission—Take action to put science first at EPA and to better integrate science with EPA's mission.

Follow-on activities to address these five improvement opportunities include: "local" initiatives to keep commitments made at the workshop; Laboratory/Center/Office groups to identify additional specific actions; the development and administration of the second ORD Organizational Climate Survey to assess progress in implementing improvement in the five areas of concentration; and establishing an ORD-wide Improvement Network that enhances the communications among and between the various ORD Laboratories, Centers, and Offices.

Common problems identified through the Network will be addressed utilizing the Executive, Management, Science, and Human Resource Councils. The Network will also assist in the annual organizational survey and the next annual workshop.

In addition to supporting the innovative actions taken within each ORD Laboratory, Center, and Office, the Network showcases new ideas as models for replication, thereby keeping alive the "spirit" of Williamsburg. Key to this "spirit" is the participation of all levels of employees, an ORD atmosphere of openness, and a commitment to action by a management team that listens.

Systems and Equipment

To promote successful implementation of this Strategic Plan by our work force, ORD is committed to providing safe, environmentally sound, well-maintained, state-of-the art laboratories, equipment, and supplies. Further, by implementing our information management plan described on pages 19 and 20, we will provide ORD staff with data management, technical, and fiscal information systems to support the conduct of research, as well as the management, planning, budgeting, and

accountability functions.

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, work environment, and equipment it needs to achieve ORD's vision and goals.

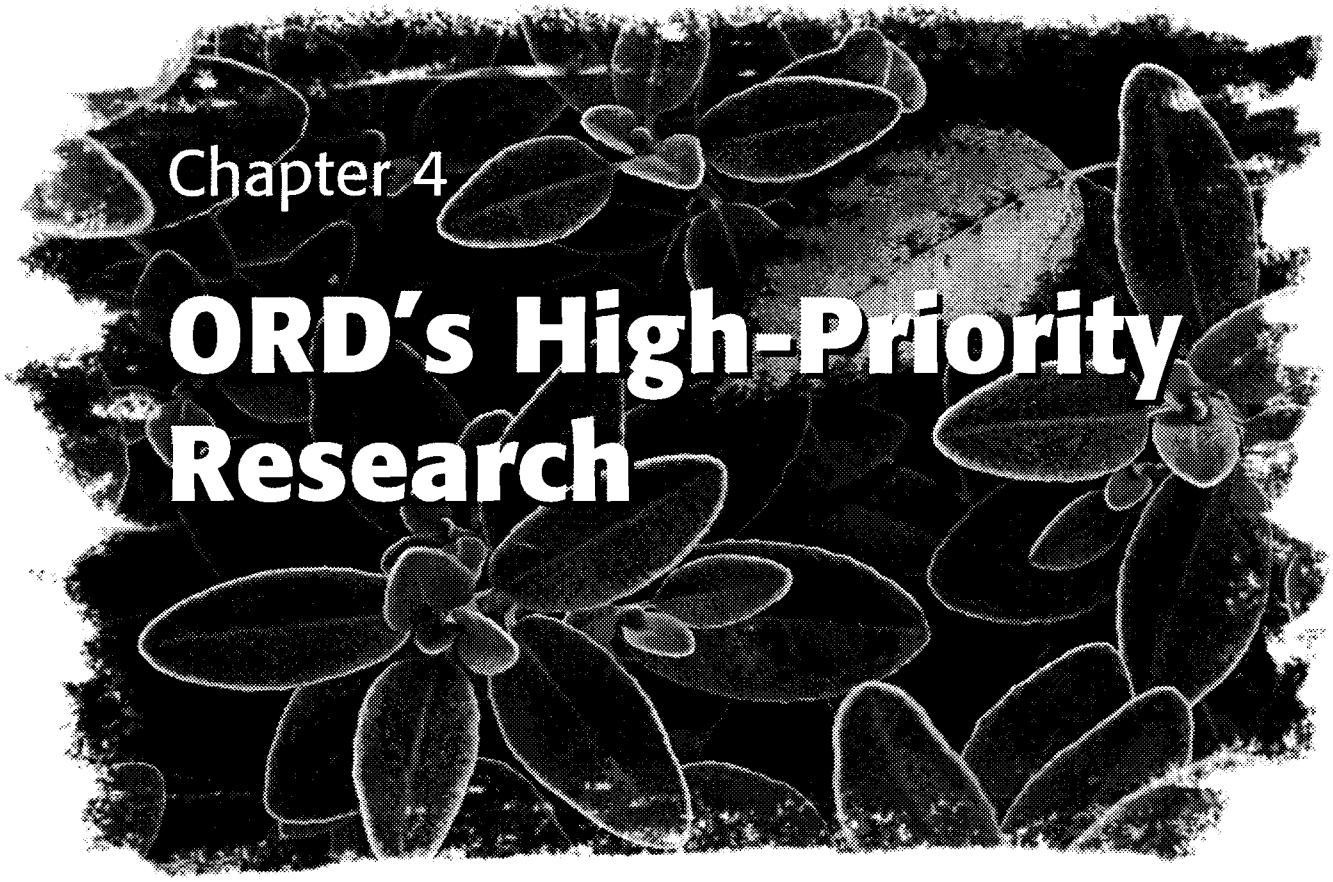
Challenges for the Future

ORD is continuing to study peer reviewer and internal staff recommendations for use in future updates of our Strategic Plan. Comments we are considering include the following:

- Reviewers recommended that ORD periodically reexamine the basis for its 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 their particular programs and priorities. Based on this experience, we will consider modifications to the plan over time to accommodate these special circumstances, as necessary.

In addition, ORD is currently involved in several activities that will impact future updates of this plan:

- We will continue our work to refine the evaluation criteria for determining research priorities.
- In cooperation with the EPA Program Offices, we will continue to merge ORD's goals and objectives into EPA's strategic planning process and GPRA activities.
- Finally, and most importantly, we will examine emerging environmental issues and new scientific information to determine whether we need to adjust our major scientific directions, goals, or objectives in light of new knowledge and developments.



Chapter 4

ORD's High-Priority Research

The goals and objectives listed in Appendix A 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 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):

- Safe drinking water (with a near-term focus on microbial pathogens, disinfection by-products, and arsenic)
- High-priority air pollutants (with a near-term focus on particulate matter)
- Emerging environmental issues (with a near-term focus on endocrine disruptors)
- Research to improve ecosystem risk assessment
- Research to improve health risk assessment
- Pollution prevention and new technologies for environmental protection

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 4. Tables 5 through 10 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. Tables 4 through 10 can be found at the end of this chapter on pages 31 through 54.

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

- Tropospheric ozone
- Global change
- Environmental monitoring
- Contaminated sites—ground water, soils, and sediments
- Exposures to pesticides and toxic substances

- Ecosystem water quality
- Air toxics

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 general, ORD will not pursue major research programs 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 and 1998 requests were based on this plan, as will be our fiscal year 1999 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., safe drinking water, high-priority air pollutants, and emerging issues).
- ***Broad-based research in methods and approaches*** to advance the fields of risk assessment and risk management (i.e., research to improve ecosystem and health risk assessment, and pollution prevention and new technologies for environmental protection).

We will evaluate progress on all ***research targeted at specific pollution problems*** periodically 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 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 methods, measurement, and models development research*** annually. These cross-media 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 Research Topics

The following summaries illustrate how application of the selection criteria described in Chapter 2 gave rise to the six high-priority research topics.

Safe Drinking Water (Microbial Pathogens, Disinfection By-Products, and Arsenic)

The 1996 Safe Drinking Water Act Amendments reemphasized the importance of EPA research on disinfectants, disinfection by-products, and pathogens in drinking water. The Amendments also stressed the need for research on arsenic, sulfates, and radon; risk assessment in sensitive subpopulations (e.g., children); mixtures; and estimating the risk-reduction benefits of drinking water regulations. ORD's near-term focus in this research will be to address uncertainties in drinking water disinfection and arsenic.

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, many hundreds of thousands of people have become ill and some have died 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 pose serious risks of infection.

We still lack methods to measure many known pathogens in water and are uncertain about their infectivity

doses and risks. There is also 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 the highest priority to EPA's Office of Water and ORD's water research agenda.

The current U.S. standard for arsenic in drinking water is based on policy recommendations developed in 1942 that predate modern cancer and other health-related data. Even today, regulation of arsenic in drinking water is controversial because of the health risk uncertainties and the costs of removing arsenic from drinking water. However, legislation now requires EPA to issue a revised standard for arsenic by 2001. Reports of hundreds of thousands of people being poisoned by arsenic in their drinking water in other countries (Taiwan, China, India, Bangladesh, and Chile)—as well as the fact that people in the U.S. on public and private water supplies are exposed to arsenic, particularly in the Southwest—have also heightened the need to address these health uncertainties. Accordingly, this issue is also of high priority to EPA's Office of Water and ORD's water research agenda.

High-Priority Air Pollutants (Particulate Matter)

Recent publications in the scientific literature indicate that exposure to particulate matter (PM) poses a ***high potential human health risk***. These studies suggest exposures to PM alone, and in combination with other priority pollutants such as ozone, may shorten the human life span of susceptible subpopulations (e.g., the elderly) and cause illness in these and other susceptible groups such as children. There is, however, 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 nature of the concentration-response relationship across a wide range of concentrations and conditions. In addition, ***control costs are potentially very high***. For all these reasons, this area is of very high priority to EPA's Office of Air and Radiation and of high priority to ORD's research agenda.

Emerging Environmental Issues (Endocrine Disruptors)

Through the 1990s, concern has grown that humans and wildlife have suffered adverse health effects from exposure to environmental chemicals that interact with the endocrine system. Collectively these substances are known as endocrine-disrupting chemicals (EDCs). The endocrine system as the central mediator of toxicity may explain effects ranging from increased incidence of some birth defects in humans and wildlife, to diminished semen quality in adult males, to increases in certain cancers (breast, prostate, testes). For example, we have clear evidence of a cause-and-effect relationship in the nearly complete mortality of Lake Ontario lake trout in the sac-fry stage, presumably from exposure to dioxin-like EDCs.

Despite these reports, we still know relatively little about the causes of many of the adverse health outcomes in humans of endocrine disruption. However, we do know that endocrine factors regulate the normal functions of all organ systems. Even small disturbances in endocrine function, especially during certain stages of the life cycle, can lead to profound and lasting effects. Developing offspring are likely to be the most sensitive to EDC exposure.

ORD is already committed to explicitly considering health risks to children when assessing environmental risks. EDC issues only heighten our concern that this special population be provided adequate levels of protection from environmental exposures.

Based on the ***potential scope*** of the EDC problem, the ***possibility of serious effects*** on the health of populations, and the ***persistence of some endocrine-disrupting chemicals*** in the environment, this area has been designated as a high priority for ORD research. Consistent with ORD's long-term goals and objectives, particularly pollution prevention, ORD leads international efforts to define the scope of the EDC problem, identify the areas of scientific uncertainty, and develop recommendations for research. Working via an Endocrine Disruptor Work Group under the Committee on the Environment and Natural Resources of the National Science and Technology Council, we have helped develop a

government-wide framework to coordinate research that specifically targets improving the risk assessment process for EDCs. Primary endocrine-disruptor questions include:

- What are the effects of EDCs in exposed human and wildlife populations?
- What are the chemical classes of interest and their potencies?
- What are the dose-response characteristics in the low-dose region?
- Do ORD's testing guidelines adequately evaluate potential endocrine-mediated effects?
- What extrapolation tools are needed?
- What are the effects of exposure to multiple EDCs and will a Toxicity Equivalence Factor approach be applicable?
- How and to what degree are human and wildlife populations exposed to EDCs?
- What are the major sources and environmental fates of EDCs?
- What is needed to assess risks to humans and ecological systems?
- How can unreasonable risks be managed?

Answering these questions will require a coordinated effort by the international research community.

At present, EDC research focuses heavily on developing methods for characterizing the hazards and risks of EDCs, quantifying exposure levels, determining the fate and transport of EDCs in the environment, and developing extrapolation tools. If future research concludes that humans and/or ecosystems are at significant risk due to EDC exposure, research on how best to lower the risks will be needed. At present, EDC sources are poorly characterized and we know little about how effectively current controls reduce EDC emissions. For some EDCs, current controls may be inadequate or too costly; for others, new approaches may be needed that minimize generation and use of EDCs. As the EDC research program matures, we anticipate increasing attention on risk management activities.

Research to Improve Ecosystem Risk Assessment

Ecosystems provide valuable renewable resources and services such as food, water storage and flood control, wood for construction, biodegradation and removal of contaminants from air and water, pest and disease control, and moderation of climatic extremes. If these benefits are impaired by man-made environmental stresses, they must be replaced at great expense by civil works, man-made chemicals, and increased use of nonrenewable energy supplies. In addition, healthy ecosystems contribute to our quality of life through recreational opportunities and scenic beauty.

We have made considerable progress in reducing the most egregious forms of ecological harm from pollution, such as areas of devastation around industrial plants and burning rivers devoid of fish. However, much remains to be understood if we are to avoid future disasters, such as vector-borne epidemic disease, global climate change, forest decline, widespread epidemics of toxic microorganisms in estuaries, reproductive failure of wildlife, and destruction of critical habitat. In particular, we need to better understand the vulnerability and sustainability of our ecological resources within the context of multiple stresses affecting multiple endpoints at multiple scales. And, we need to develop the scientific understanding and tools to better measure, model, and maintain or restore the integrity and sustainability of ecosystems at local, regional, and national scales now and in the future. Specific research needs include:

- Monitoring research to identify and characterize those ecosystems most sensitive to anthropogenic stresses.
- Processes and modeling research to predict future stressor exposures and ecological effects at multiple scales.
- Risk assessment research to define the relative risk posed by multiple stressors on the vulnerability and sustainability of ecosystems.
- Risk management and risk reduction research to provide efficient options to manage and reduce the risk of ecosystem degradation.
- Research to maintain or restore the integrity and sustainability of ecosystems.

This research is essential to significantly reduce the uncertainty surrounding the difficult decisions we must make to protect our ecological resources at local, regional, and national levels. Because of the ***broad applicability of this research*** (particularly its potential to help local communities avoid costly environmental management failures by better understanding the exposures to, effects on, and restoration of our nation's ecological resources)

and the ***significant potential for enhancing ecological risk assessment and risk management,*** ORD has selected research to improve ecosystem risk assessment as a high-priority topic 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 exposure or effects.
- Determining how individuals vary in their response to toxic insults, so that EPA can better identify sensitive subpopulations, such as children and the infirm.

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 for Environmental Protection

Pollution prevention, or anticipating and stopping problems before they occur, is a powerful 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, actually reduces or eliminates the need for legal actions and regulatory standards, which can be costly and difficult to implement. It also offers an opportunity for meaningful stakeholder input and participation as part of the risk management research and development process.

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 its 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 is a high priority for ORD's research agenda. This research builds on ORD's commitment to support and respond to the needs of EPA's Program and Regional Offices for prevention options and information on how best to implement them.

ORD's intramural and extramural research programs support cutting-edge research and development of new tools, techniques, and processes for preventing pollution. This includes analysis tools, such as Life Cycle Assessment, and fundamental precompetitive research on cleaner processes through competitive extramural research solicitations, such as Technology for a Sustainable Environment (a joint program with the National Science Foundation). In addition, the Small Business Innovation Research Program accesses the expertise of private innovators for pollution prevention and other environmental technologies.

The accelerating development of new environmental technologies (e.g., remote sensing, information systems, and computer technologies) has created growing opportunities for managing environmental threats to public health and natural resources. To capitalize on these opportunities, EPA and several other agencies (e.g., the National Aeronautics and Space Administration [NASA], U.S. Department of Energy [DOE], U.S. Geological Survey, and National Oceanic and

Atmospheric Administration) are working cooperatively to identify, evaluate, and develop new advanced technology solutions.

Specifically, ORD has initiated a program—the Advanced Measurement Initiative (AMI)—to guide the identification, research, and application of advanced monitoring tools and enabling technologies in support of EPA's mission. Examples of the kinds of technologies to be evaluated include:

- Thermal infrared sensing of water and watersheds
- Light Detection and Ranging (LIDAR) measurements of air pollutants
- Very high-resolution, visible and infrared wavelength imaging of polluted land areas

AMI's initial emphasis has been applications for remotely sensed information, with NASA and DOE as primary partners. We will progress to investigating other (e.g., in situ) monitoring approaches and will expand to include other agencies and nonfederal developers.

In addition to AMI, the application of high-performance computing to environmental science can improve our ability to access and use data, environmental models, and graphical/analytical tools for informed, risk-based decision-making. Further, the demonstration of new technologies through activities such as the Environmental Technology Verification Program will accelerate development by independently and objectively verifying and reporting technology performance under real-world conditions.

Because of the ***broad applicability*** of these new or improved technical solutions to environmental problems, their ***significant potential for enhancing risk assessment and risk management,*** the ***potentially large economic and environmental benefits*** of these approaches, and the ***opportunities to leverage EPA's resources,*** pollution prevention and new technologies are of high priority for ORD's research agenda.

Table 4. Summary of EPA/ORD Research Program for Six High-Priority Research Topics

Research Topics	Strategic Focus	Tasks	Products	Uses
Safe Drinking Water—Disinfection	What is the comparative risk between waterborne microbial disease and the disinfection by-products (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.
Safe Drinking Water—Arsenic	What are the health risks of arsenic at low doses found in U.S. drinking water? What cost-effective technologies will be available for removing arsenic from drinking water?	Develop methods for measuring arsenic species in drinking water and diet, develop improved dose-response and risk assessments for arsenic species, and evaluate cost-effective treatment processes.	Analytical methods for arsenic species, data on effects, dose-response and treatment processes, and improved risk assessment/characterization of arsenic in drinking water.	To improve the risk assessment/characterization of arsenic in drinking water and ultimately for rulemaking and compliance monitoring.
Particulate Matter	What morbidity/mortality is associated with low ambient levels of particulate matter (PM) alone, and in combination with other high-priority air pollutants, and what cost-effective methods are available to reduce PM and copollutants' emissions to an acceptable level?	Conduct clinical/epidemiology/toxicology studies of effects of PM and copollutants, reanalyze past epidemiology studies and develop improved methods; conduct dosimetric and mechanistic studies; characterize the size/species of PM; conduct human exposure studies; and develop, evaluate, and demonstrate methods to identify and characterize emissions of PM and precursors and technologies to reduce these 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.

(Continued)

Table 4. Summary of EPA/ORD Research Program for Six High-Priority Research Topics (Continued)

Research Topics	Strategic Focus	Tasks	Products	Uses
Endocrine Disruptors	Understanding the potential scope of the endocrine disruption in humans and wildlife, including: defining the range of health effects, critical life stages, sensitive species, and exposures relevant to alterations in endocrine function; developing risk management options to reduce or prevent additional adverse effects in populations.	Develop screening methods for endocrine disruptors; construct predictive dose-response and ecological risk models with emphasis on low-dose effects and effects of combined exposure to endocrine disruptors on the reproductive, neuroendocrine, and immunological systems; provide predictive fate, transport, and exposure models; link exposure models to effect models and characterize effects of ambient exposure to demonstrated endocrine disruptors.	Field data and monitoring tools and delineated effects and predictive models that clarify the health and ecological impact of specific endocrine disruptors and related exposure levels for improved risk assessment and risk management activities.	To develop risk management options for reducing exposures; to ensure that present testing guidelines are adequate for detecting hazards and risks posed by endocrine disruptors, and to assist in implementing the FQPA[a] and SDWA[b] of 1996.
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 4. 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-response extrapolation, characterize variation in human susceptibility, and estimate risks from varying exposure scenarios?	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 following exposures of varying pattern, frequency, and magnitude; identify and characterize factors conferring enhanced susceptibility to pollutant exposures.	Hazard screening/testing protocols and models for predicting chemical disposition and biological response.	To rank/screen chemicals, develop test guidelines, and provide guidance and methods for more confident risk assessment.
	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 for Environmental Protection	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.

(Continued)

Table 4. Summary of EPA/ORD Research Program for Six High-Priority Research Topics (Continued)

Research Topics	Strategic Focus	Tasks	Products	Uses
Pollution Prevention and New Technologies for Environmental Protection (Continued)	How can we best identify, develop, and apply advanced measurement tools and enabling technologies to support environmental protection?	Develop working partnerships between technology developers and environmental policy makers and managers to enhance the use of policy drivers in the development and adoption of new technologies. Organize ongoing activities in EPA to focus them on applying and adopting advanced measurement and companion technologies to environmental protection needs. Work with organizations to leverage their investments in advanced technologies.	EPA Program Office and Regional Needs Inventories, NASA Technology Workshops, EPA/DOE Partnerships, internal research on remote sensing applications to environmental measurements, advanced monitoring pilot projects to evaluate currently feasible applications, research to address fundamental concepts of ecosystem rehabilitation, and identification of opportunities for developing domestic and international commercial markets for applying advanced technologies to environmental issues.	To establish partnerships for identifying specific monitoring technology needs and requirements, and subsequent matches with relevant environmental technologies. To sponsor a number of directed technology application projects and demonstrations. To facilitate the commercial adoption of advanced monitoring technologies to meet the needs of EPA, the regulated community, and the public. To facilitate the export of American technologies to international markets.

[a]FQPA = Food Quality Protection Act.
[b]SDWA = Safe Drinking Water Act.

Table 5a. Safe 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 assessments to support upcoming surface water and ground-water treatment rules.
	What are the 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 assessments to support upcoming surface water and ground-water treatment rules.
	What are the relative risks of disinfection by-products (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, transport, and fate in surface and ground waters.	Analyses of pathogen occurrence in source waters. Information on pathogen exposures in drinking water. Information on microbial pathogen survival, fate, and transport in subsurface environments.	To support exposure assessments to predict pathogen occurrence in drinking water under different treatment processes.

(Continued)

Table 5a. Safe Drinking Water—Disinfection (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Exposure (continued)	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.	
Risk Management	What risk management strategies can simultaneously control pathogens and DBPs?	Evaluate treatment processes for pathogen control, including identification of surrogate measures of treatment effectiveness, technologies for small systems, control of bacterial growth in distribution systems, and prevention of pathogen intrusion into the distribution system. Simultaneously evaluate processes for controlling DBPs (including chlorine vs. alternative disinfectants) and practices for removing DBP precursors (granular activated carbon, membrane filtration). Evaluate vulnerability to microbial pathogens of source waters used by public water supplies.	Data on the effectiveness of different processes. Source water protection protocols for public water supplies, including geohydrologic computer modeling and GIS mapping techniques.	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 5b. Safe Drinking Water—Arsenic

Subtopic	Strategic Focus	Tasks	Products	Uses
Health Effects	What are the health effects and dose-response associated with arsenic exposures?	Conduct epidemiologic studies on arsenic health effects. Conduct animal studies on important health endpoints (developmental, reproductive, cardiovascular, neurologic, etc.).	Data on the relationship (linear or nonlinear) between arsenic exposure and adverse health effects.	To provide health effects data for risk assessment/characterization to support the arsenic drinking water rulemaking.
	What are the dose-responses for various effects at low doses?	Develop biomarkers of effect and susceptibility and model systems to assess mechanisms of arsenic toxicity.	Biomarkers to assess effects and susceptibility, data on arsenic mechanisms of toxicity, and an improved PBPK[a] model.	To provide improved understanding of arsenic-induced adverse health effects in humans and to improve the risk assessments.
	What are the modifiers of susceptibility and dose-response?	Determine the factors that affect human susceptibility.	Assessments of the factors that influence arsenic dose-response and susceptibility in humans.	To provide an improved understanding of human susceptibility to arsenic exposure and to support improved risk assessments used in arsenic drinking water rulemaking.
Exposure	What arsenic species and concentrations are present in drinking water, diet, and biological tissues?	Develop validated analytical methods for speciating arsenic in drinking water, diet, and biological tissues. Develop a National Database on arsenic occurrence and concentrations in drinking water, soils, and dietary constituents.	Practical analytical methods for arsenic species in various media. National Database on arsenic.	To support developing occurence data compliance methods for water utilities, methods for mechanistic studies and for exposure risk assessments. To support exposure risk assessments necessary for the arsenic drinking water rulemakings, now and into the future.
	What are the biomarkers of arsenic exposure?	Develop biomarkers of exposure in biological media.	Standardized biomarkers to assess arsenic exposure from various media.	Standardized biomarkers protocols for assessing exposures in epidemiological studies and to improve the precision of risk assessments.
	What is the bioavailability of arsenic species from various media?	Conduct research to determine the bioavailability of arsenic species found in water, soils, and food constituents.	Empirically derived bioavailabililty (oral absorption) factors for each arsenic species in each media.	To support improved risk assessments necessary for the arsenic drinking water rulemaking.

(Continued)

Table 5b. Safe Drinking Water—Arsenic (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Risk Assessment	What additional risk assessment tools and models are needed to assess arsenic risks?	Develop dose-response predictive models for adverse effects and assessing interactions.	Improved risk assessment procedures and risk estimates for arsenic.	To provide the risk basis for arsenic drinking water rulemaking.
	What risk assessment/characterization guidance can be provided for arsenic exposure scenarios?	Develop guidances for states and EPA regions concerning arsenic exposures.	Interim guidances and reports characterizing human exposures.	To support states and EPA regions in developing regulations and permits and for refinement of risk estimates for EPA rulemaking.
Risk Management	What technologies are available for effective arsenic treatment of drinking water?	Conduct and evaluate laboratory and field tests on different arsenic control technologies.	Series of reports describing the technical performance of the different arsenic control technologies.	To demonstrate the capabilities and performance of arsenic control technologies for use in determining Best Available Technologies and in rulemaking.
	What are the technical and economic considerations of arsenic control for small drinking water systems?	Complete cost evaluations for all arsenic control technologies.	Series of reports describing the economic considerations associated with the operation of each arsenic treatment technology.	To provide data on any adverse economic considerations that may impact small systems and that can be taken into consideration during rulemaking and granting variances to compliance.
	How can arsenic-enhanced residuals be effectively managed from drinking water systems?	Conduct studies on the arsenic characterizations of the residual materials generated from different arsenic control technologies.	Series of reports outlining the composition of the residual arsenic and its mobility in treatment wastes.	To provide data on the recycle/disposal options for the residual material generated and for support in rulemaking decisions.

[a]PBPK = physiologically based pharmacokinetic.

Table 6. Particulate Matter

Subtopic	Strategic Focus	Tasks	Products	Uses
Health Effects	What health effects are caused by particulate matter (PM) and its components? What is the role of copollutants in producing PM toxicity?	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 species and concentration levels of PM, and important copollutants, are people exposed to?	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 6. 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 and precursors 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 6. 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 and precursor 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 7. Endocrine Disruptors

Subtopic	Strategic Focus	Tasks	Products	Uses
Biological Effects	Defining the classes of chemicals that act as EDCs[a] and their potencies.	Develop in vitro/in vivo methods and structure-activity models to screen for EDC action.	Methods to describe the hazard potential of EDCs and likely modes of action and potencies.	Hazard characterization to support implementation of the FQPA[b] and the SDWA.[c]
	Evaluating current testing guidelines and monitoring procedures for adequacy of assessment of EDCs.	Enhance ability of existing test methods (e.g., multigenerational studies in mammals and life-cycle tests in fish and wildlife) to evaluate manifestations of endocrine disruption and underlying modes of action.	Revised testing guidelines that are more indicative of the most sensitive lifestage, sex, and target tissue for chemicals that act through the endocrine system.	To improve regulatory testing requirements and data interpretation.
	Determining the shapes of dose-response curves for EDCs at relevant exposures and the tissue levels associated with adverse effects.	Assess effects of EDC exposure on neuroendocrine, immunological, and reproductive function in developing and adult animals in support of pharmacokinetic and biologically based dose-response models, with emphasis on animal models of EDC-induced diseases.	Animal models of EDC-induced health effects that provide increased understanding of the types and magnitudes of risks for exposure to EDCs during various phases of the life cycles.	To provide quantitative dose-response evaluation and reduced uncertainties for human health extrapolations.
	Describing the normal endocrine profiles in wildlife species.	Provide baseline endocrine information for wildlife populations and their laboratory surrogates, with emphasis on comparative endocrinology and developmental control of sex differentiation, especially for species with little historical attention.	Databases of endocrine profiles in species from multiple phylogenetic levels and improved understanding of the role of the endocrine system in sex differentiation.	To assess the impact of EDCs in wildlife populations.

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Table 7. Endocrine Disruptors (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Biological Effects (Continued)	Extrapolating effects at the individual level to populations for fish and wildlife.	Translate results from measurement endpoints at lower levels of biological organization to impacts on populations and communities through use of microcosms and mesocosms. Identify appropriate sentinel species for environmental monitoring.	Models predicting population level effects from studies at lower levels of biological organization.	To facilitate ecological risk assessment based on effects in individuals.
	Characterizing the effects of exposure to multiple EDCs.	Systematically study the interactions of EDCs at low, relevant dose levels to understand potential for synergism.	Assessment of the validity of the additivity principal for EDCs and predictive models for synergistic interactions.	To reduce uncertainties associated with assessment of exposure to multiple EDCs.
Exposure Studies	Developing a framework to characterize and to diagnose and predict ecological and human exposure to EDCs.	Use physicochemical attributes to identify transport, transformation, and environmental fate characteristics associated with exposure scenarios of concern to biological organisms. Construct compartmental models to predict environmental behaviors.	Validated models to predict and assess transport, fate, and exposure to EDCs from source to receptor.	To conduct preliminary environmental exposure assessments and set priorities for additional focused research.
	Providing adequate tools to estimate exposure to EDCs.	Develop new methods and refine existing ones (e.g., analytical chemistry, sample extraction, biomarkers) to acquire data for compartmental models, with emphasis on the transport and transformation in sediments and tools for assessing exposure in individuals.	Field and laboratory tools to better quantitate EDCs in multimedia.	To improve characterization of exposure to EDCs.

(Continued)

Table 7. Endocrine Disruptors (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Exposure Studies (Continued)	Determining total ecosystem and human exposures to EDCs of concern.	Examine multigenerational transfer of EDCs in ecosystems, including biomagnification processes important to higher vertebrates. Provide information on EDC exposure distribution in the general human population.	Exposure assessments for EDCs in key wildlife species and the general human population.	To monitor the environmenal signals of EDC exposure and effects.
Linkage of Effects, Exposure, and Risk Management	Integrating human and ecological effects research with exposure research within the risk assessment paradigm.	Construct framework to identify, characterize, and prioritize potential exposure to EDCs and provide database for preliminary risk characterization.	Coordinated process for identifying exposure and effects of concern for additional intensive characterization of risk.	To conduct preliminary risk assessments and assist research prioritization.
	Determining classes and concentrations of EDCs associated with observations of endocrine disruption.	Develop informational database for EDCs, including biological effects, environmental concentrations, and historical trends from existing monitoring programs. Conduct integrated toxicology and exposure studies in areas or human populations with suspected contamination or exposure to EDCs.	Database on EDC levels in the human environment and various ecosystems associated with biological effects of concern.	Centralized information source for environmental monitoring of EDCs.
	Establishing status and trends of human and wildlife endocrine disruption and EDC exposure.	Identify sites within geographic proximity to ORD laboratories for long-term intensive observation of potential EDC effects. Examine existing exposure and effect registries for indications of EDC effects.	Consolidated databases of status and trends relevant to EDC exposures and effects.	For environmental monitoring and comparison of effects with more intensive exposures.

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Table 7. Endocrine Disruptors (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Linkage of Effects, Exposure, and Risk Management (Continued)	Developing risk management approaches to reduce or eliminate environmental exposure to EDCs.	Identify major sources of EDCs entering the environment. Develop tools for risk management, such as biodegradation processes or pollution prevention strategies.	Risk management tools for elimination or prevention of exposures to significant EDCs.	To develop remedial actions where adverse effects of EDCs have been documented.

[a]EDC = endocrine-disrupting chemical.
[b]FQPA = Food Quality Protection Act.
[c]SDWA = Safe Drinking Water Act.

Table 8. Research to Improve Ecosystem Risk Assessment

Subtopic	Strategic Focus	Tasks	Products	Uses
Exposure and Effects	What is the current condition of the environment?	Develop indicators of ecological condition.	National Land Cover Database for all Regions and indicators of landscape vulnerability and human stress at watershed and larger scales. Suites of new, field applicable biological indicators/criteria for measuring, understanding, and diagnosing ecosystem exposures and effects.	To assist researchers and stakeholders in identifying environmental hazards at multiple scales and evaluating relative condition. To serve as guidance on how to measure regulatory and management success.
	What stressors are most significant in affecting the condition? Where are they? How are they distributed?	Develop multiscale exposure profiles for important stressors.	Multimedia, multistress exposure models for defining the distribution of stresses, alone and in combination, at local, watershed, and larger scales.	To assist researchers and stakeholders in evaluating the magnitude and extent of environmental stressors at local, regional, and national scales. To serve as a tool for predicting the results of alternative source reduction regulations.
	What are the mechanisms of adverse effects? How sensitive are ecosystems to chemical and nonchemical exposures?	Conduct cause/effects research at multiple levels of biological organization.	Ecosystem models for predicting the response of ecosystems to multiple stressors, at multiple scales.	To assist researchers and stakeholders in developing risk management alternatives and predicting ecosystem responses to these alternatives.
Assessment	What is the relative risk posed by stressors, now and in the future? What is the sustainability and/or vulnerability of ecosystems?	Develop multiple scale, multistressor, multi-endpoint relative risk methods.	Assessment techniques and guidelines for defining ecosystem sensitivity, developing associated exposure profiles, and quantifying ecosystem vulnerability and sustainability.	To assist researchers and stakeholders at local, regional, and national scales make cost-effective management decisions on the protection of ecological resources by knowing what the most important problems are, how to get the desired result, how to verify/measure that result, and how to improve conditions now and in the future.

(Continued)

Table 8. Research to Improve Ecosystem Risk Assessment (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Risk Management	What options are available to manage the risk?	Evaluate alternative management options.	Risk managment strategies that take advantage of pollution prevention and the self-purifying potential of natural systems.	To assist researchers and stakeholders in identifying cost-effective risk management options and to provide guidance on how best to maintain or improve conditions now, and in the future.
	How are degraded systems best restored?	Conduct ecosystem restoration studies.	Document techniques for restoring valued ecosystems.	

Table 9. 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.

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Table 9. 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.

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

Table 10. Pollution Prevention and New Technologies for Environmental Protection

Subtopic	Strategic Focus	Tasks	Products	Uses
Exposure	What are the environmental monitoring needs of the EPA Program and Regional Offices?	Develop a monitoring information needs assessment inventory.	Inventory of specific monitoring technology needs and requirements.	To serve as a starting point for discussion with Federal and commercial technology developers to explore possible matches between information needs and technology capabilities.
		Match environmental monitoring needs with relevant environmental technologies.	Inventory of environmental monitoring needs matched with relevant technologies.	To focus research on those technologies that best meet the needs of EPA and the public.
	How can we best leverage the research, technologies, and information of others?	Stage a series of workshops with NASA[a] Mission to Planet Earth.	Joint pilot projects, demonstrations, and collaborative research and development opportunities.	To match the monitoring technolgoy needs of the EPA Program Offices and Regions with the technology capabilities of NASA.
		Sponsor a joint EPA/DOE[b] workshop.	Demonstrations of advanced monitoring technologies and their potential applications.	To identify and showcase new and innovative environmental monitoring technologies that can better meet the nation's needs for ensuring protection of the environment.
	How can we better focus on remote sensing applications research applied to characterizing landscape composition and pattern?	Establish an internal research program.	An interagency (EPA, USGS,[c] NOAA) program (called the Multi-Resolution Landscape Characterization, or MRLC), which is producing land cover information for the United States in accordance with Federal Geographic Data Committee standards for vegetation classification and documentation. (The MRLC has completed mapping of Standard Federal Region 2 and 3. Mapping of Regions 4 and 5 is planned to be completed in 1997.) Assessment tools for analyzing and interpretating landscape composition and pattern at a number of scales, ranging from local communities to Standard Federal Regions.	To provide more comprehensive information about ecological resources to be used for environmental planning purposes. To assess the conditions of watersheds (water quality, terrestrial wildlife habitat suitability and terrestrial ecosystem condition) across the mid-Atlantic region of the U.S., using the landscape tools.

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Table 10. Pollution Prevention and New Technologies for Environmental Protection (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Exposure (Continued)		Initiate pilot projects.	Demonstrations of the use of remote sensing in a range of environmental applications such as air and water quality monitoring, ecosystem evaluation, and site assessment.	To evaluate currently feasible applications leading to broader implemenation involving key stakeholders.
		Establish joint EPA/NASA research program.	Scientific framework to allow the application of remote sensing technologies to diagnose existing ecosystems, establish the basis to prioritize ecosystems that should be restored, describe effectiveness criteria for improvements, and describe desirable endpoints for ecosystem restoration and rehabilitation.	To address fundamental concepts of ecosystem rehabilitation.
	What other advanced measurement technologies are available for real-time monitoring?	Establish an internal research program.	Development of cost-effective, real-time monitoring technologies.	To provide regulators and the public with timely and relevant environmental information.
Risk Assessment	How can we use monitoring information to better assess the risks to human health and ecological resources, and how can we better characterize and communicate these risks?	Develop techniques to characterize monitoring information and communicate this information to the public.	Easily accessible and understandable information about environmental conditions for the public and communities.	To provide better, more consistent environmental information to the public, enabling more informed decision-making.
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 can address high-priority health and environmental problems.	To demonstrate how LCA can evaluate options for multimedia pollution prevention and risk management that are keyed to the greatest risks. To provide objective, scientifically credible LCA procedures for regulatory and private sector use.

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Table 10. Pollution Prevention and New Technologies for Environmental Protection (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Risk Management (Continued)		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 a 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.	To provide 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 using innovative approaches?	Develop precompetitive and enabling pollution prevention approaches for major industrial sectors.	Pollution prevention approaches 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 approaches keyed on Common Sense Initiative industries and other high-risk problems. To encourage the use of pollution prevention approaches for a wide array of U. S. industrial sectors and high-risk problem areas.
		Evaluate and verify these approaches 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 approaches.	To provide credible information that informs decision-makers about pollution prevention options emphasizing both performance and cost. To create a basis for developing scientifically credible and commercially available pollution prevention approaches in both U.S. and foreign markets.

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Table 10. Pollution Prevention and New Technologies for Environmental Protection (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Risk Management (Continued)	How can reliable and appropriate cost data be generated for pollution prevention approaches?	Develop process cost models for pollution prevention approaches. 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 and analysis. To provide reliable, scientifically credible cost-estimation packages for environmentally preferable approaches to preventing pollution.
		Develop engineering and performance costs for pollution prevention approaches.	Cost data for pollution prevention approaches.	To improve cost-benefit assessments by EPA and other regulatory and nonregulatory decision-makers.
	How can pollution prevention results and information be disseminated to affect 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, thereby leading to its increased application and broader use. To improve decision-making among pollution prevention practitioners and permitting officials. To support widespread use of applicable pollution prevention approaches that maximize risk reduction.
			Industry-targeted information dissemination that includes 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 as the first or only preference for environmental protection and compliance.
	How can we encourage private sector development of advanced technologies?	The Small Business Innovative Research Program was established for this purpose.	Private sector development of advanced monitoring sensors, instruments, and data systems.	To support private sector developers of innovative technologies.

(Continued)

Table 10. Pollution Prevention and New Technologies for Environmental Protection (Continued)

Subtopic	Strategic Focus	Tasks	Products	Uses
Risk Management (Continued)	How can the performance of innovative technical solutions to environmental problems that threaten human health or the environment be verified?	Create technology verification entities for high-priority human health and environmental problems.	Performance verification of commercially available advanced environmental technologies and products.	To enhance the diffusion of environmental technologies, both domestically and worldwide. To increase the acceptance of innovative technologies by both regulators and the regulated community.

[a]NASA = National Aeronautics and Space Administration.
[b]DOE = U.S. Department of Energy.
[c]USGS = U. S. Geological Survey.

Appendix A

ORD's Long-Term Goals and Objectives

To help focus selection of research priorities, ORD has defined a set of long-term research objectives within each of the six long-term 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 support the objective.

The goals and research objectives described here will assist 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 to review current topics and identify specific new research topics that best further program goals and 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. ORD is currently refining its strategic goals and objectives to better align with Agency strategic planning and priorities.

The research objectives state, in a more specific and concrete manner than do the goals, what ORD will work to achieve in each of its focal research areas. We intend, after further refinement, to use the objectives and corresponding activities to introduce another level of accountability for results into the ORD planning process, as required by the Government Performance and Results Act (GPRA). Senior management will review the research objectives periodically to ensure that appropriate progress is being made toward their achievement, per GPRA. As necessary, adjustments in focus or approach will be made early on to avoid wasting time or resources. Once ORD has achieved its research objectives, we will devote resources to other high-priority areas. When new high-priority research areas are developed, we will craft new objectives as appropriate.

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 landscape 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 mosquitoes, 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 characterizing and remediating soils and ground water contaminated with nonaqueous-phase liquids, chlorinated and other hazardous organics, and toxic metals.
  - Developing cost-effective techniques for characterizing and remediating contaminated sediments.
  - Verifying the performance of innovative risk reduction and measurement/monitoring 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 nonchemical 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 Laboratories 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

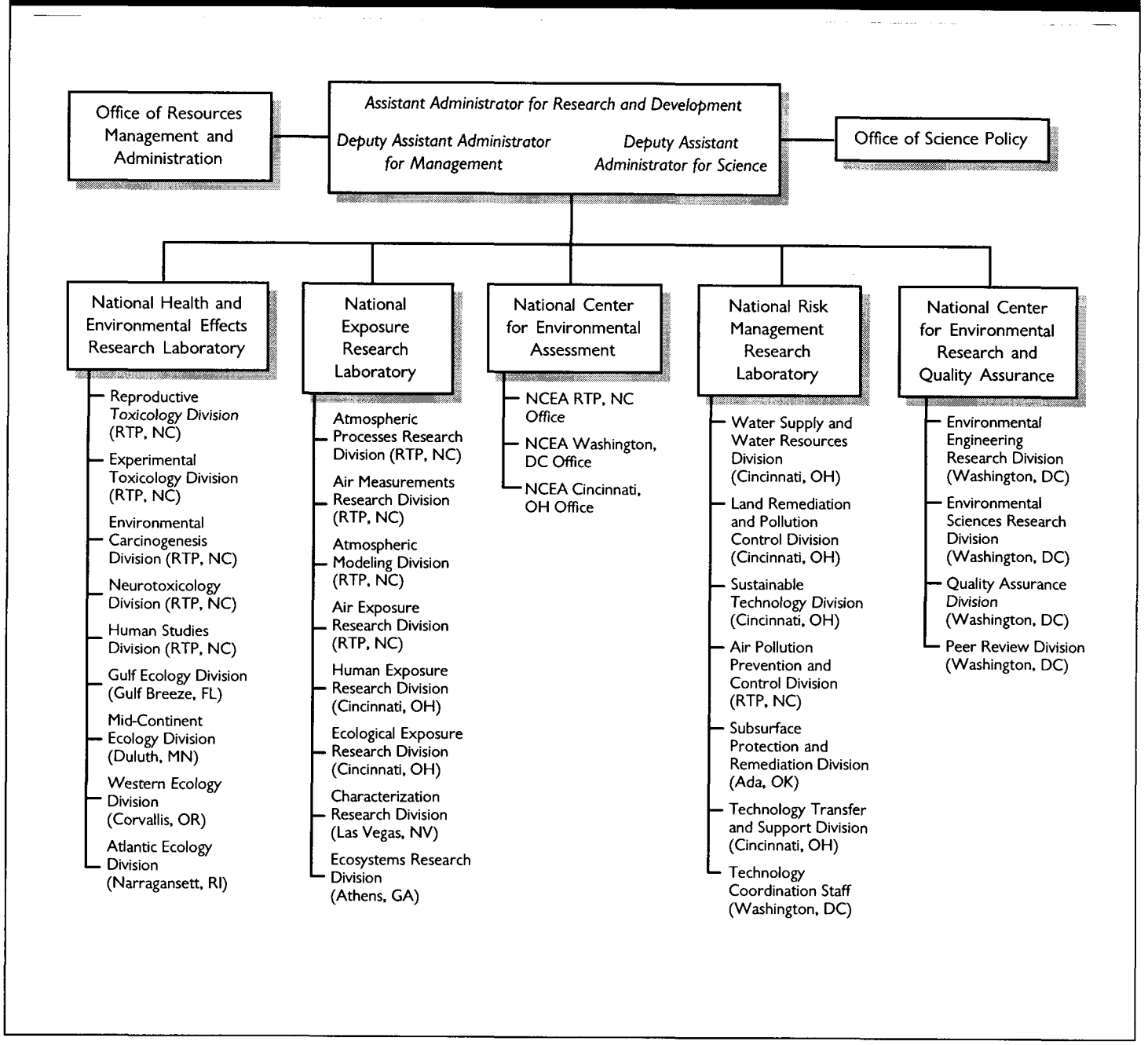
Within this goal area, ORD will work to:

- 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 B
The ORD Organization

ORD's 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 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:

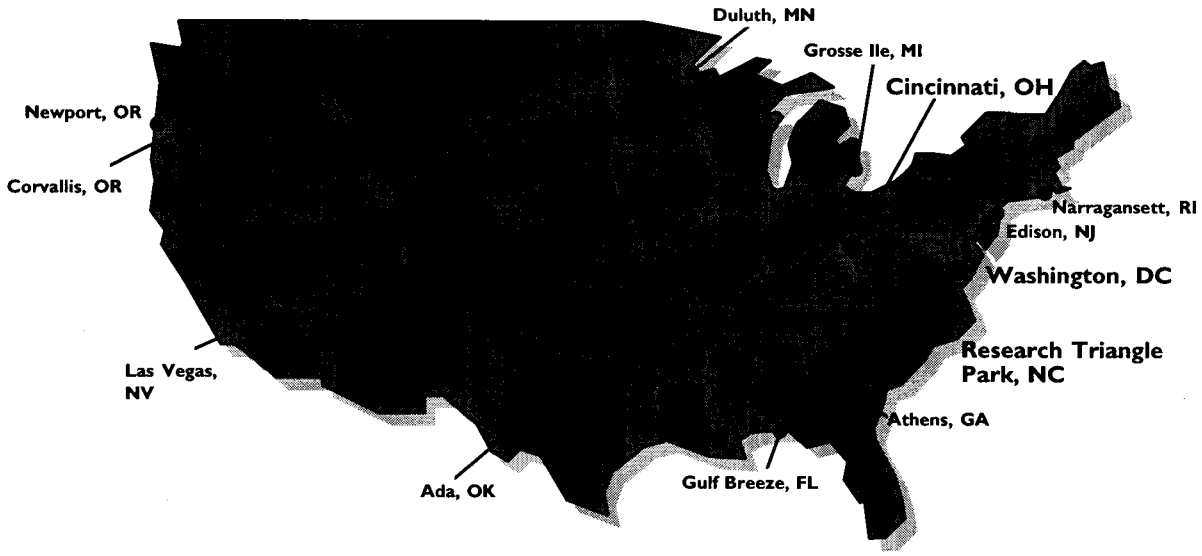
- In the ***hazard identification*** area, NHEERL works to improve both assessment test methods and the interpretation of data developed by these methods (i.e., the relationship of effects measures to health/ecological outcome).
- In the ***dose-response assessment*** area, NHEERL performs mechanistic 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) improves the scientific bases for human and ecosystem exposure assessments that are part of the risk assessment, risk management, and compliance processes. Researchers from NERL conduct methods, measurement, and modeling research to evaluate multimedia and multipathway exposures to a wide variety of physical, chemical, and biological stressors. They also apply their expertise to special problems, as in providing technical consultation to the Program Offices and Regions. The main components of NERL's program are:

- ***Source/Exposure Research*** focuses on investigating the emissions of chemicals from sources. Although most of ORD's research is in this category, NERL has unique expertise and interests here for sources that are part of the pathway of subsequent NERL exposure studies.
- ***Chemical, Physical, and Biological Process Modeling Research*** seeks to understand and predict chemical

Location of ORD's National Laboratories and Centers



and nonchemical stressor distributions. Major programs include fate, transport, and transformation research and advanced multimedia modeling.

- ***Environmental Characterization Research*** focuses on increasing understanding of stressors, receptors, and the related portions of the environment (e.g., ambient air, water, soil, biological quality, and a wide variety of microenvironments). Major program activities include landscape characterization, multimedia-multipathway human exposure measurement, and microbial identification and occurrence.
- ***Exposure Assessment and Analysis Research*** is conducted to estimate current and future exposures to humans and ecosystems. Major programs focus on developing total human exposure models and landscape assessment models.
- ***Exposure/Dose Research*** modeling provides the bridge between the exposures that occur and the dose to the target which ultimately can lead to effects. To improve the bridging and obtain data for the modeling, research collaborations with NHEERL exist.

National Center for Environmental Assessment

ORD's National Center for Environmental Assessment (NCEA) serves as the national resource center for the overall process of human health and ecological risk assessments and the integration of hazard, dose-response, and exposure data and models to produce ***risk characterizations***. Also, NCEA occupies a critical position in ORD between (1) the researchers in other ORD components who are generating new findings and data, and (2) the regulators in the EPA Program Offices and Regions who must make regulatory, enforcement, and remedial action decisions. Thus, NCEA is uniquely positioned to influence ORD's future research agenda to ensure that it addresses research needs identified by risk assessments and to serve as consultants to the Programs and Regions on the use of science in environmental decision-making. In support of these functions, NCEA focuses its work in three major areas:

- Development of methodologies that reduce uncertainties in current approaches:
  - Dose-response models and factors
  - Exposure models and factors
  - Probabilistic models
- Community-based risk assessment
- Assessments of contaminants and sites of national significance
- Guidance and support to risk assessors:
  - Databases
  - Risk assessment guidelines
  - Expert tools
  - Expert consultation and program support
  - Risk assessment training

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

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 focuses 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 include the foremost research scientists from universities and nonprofit centers around the country in the ORD research program to meet the specific science needs of the Agency. STAR consists of four components—focused Requests for Applications, an Exploratory Research Grants Program, a Graduate Fellowships Program, and targeted Environmental Research Centers—all of which address 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. Finally, NCERQA has a major Agency-wide leadership and oversight role in peer review and quality assurance activities.

Office of Resources Management and Administration

The Office of Resources Management and Administration (ORMA) ensures that ORD's management operations promote sound science and efficient operations. Geographically dispersed and encompassing a wide array of scientific and engineering disciplines, ORD poses significant management challenges. ORMA, in partnership with ORD's Management Council, provides the administrative and operational framework integrating ORD's Laboratory and Center activities into a cohesive unit. Serving as the principal staff office to ORD's Senior Resource Official, ORMA provides leadership in budgeting, financial management, procurement, information systems, organizational development, facility operations, and infrastructure. In this capacity, ORMA independently evaluates ORD Laboratory and Center management, bench-marking success against the contribution of administrative processes toward the attainment of ORD's strategic goals.

Office of Science Policy

ORD's Office of Science Policy (OSP) is a bridge between ORD and its many constituents and is a key link between ORD science and EPA policies and regulation. OSP supports ***current*** Agency science needs by participating in ongoing regulatory and science policy activities of EPA's Laboratories, Program and Regional Offices, and the Agency-wide EPA Science Policy Council. OSP provides for ***future*** Agency science needs by leading ORD and Agency research planning activities. Working closely with ORD's National Laboratories and Centers and EPA's Program and Regional Offices, OSP coordinates their input into ORD's research agenda. Further, OSP provides scientific information, counsel, and assistance in policy formulation and other regulatory development activities. These functions all support strategic planning of ORD's research program.

In addition, OSP administers the Science Policy Council, a standing interoffice committee 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.

Appendix C

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

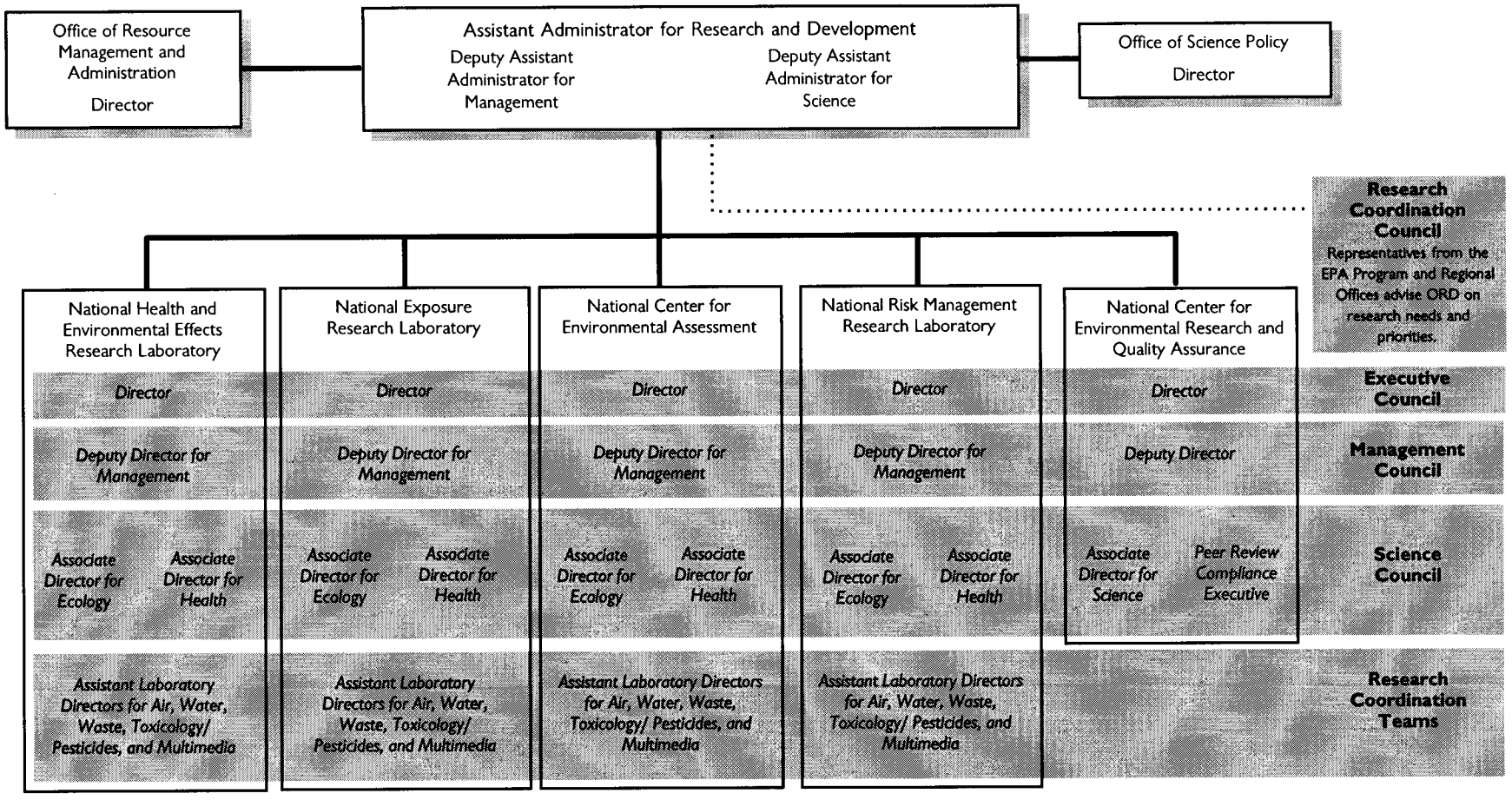
ORD's Management Council is chaired by ORD's Deputy Assistant Administrator for Management and includes the Deputy Assistant Administrator for Science as an ex officio member, the Director of ORD's Office of Resources Management and Administration (who serves as the Vice Chair), and the Deputy Directors 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, the Associate Director for Science of ORD's Office of Science Policy (OSP), and the Director of OSP.

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 first Strategic Plan and will review all research plans.

ORD Management Structure



Human Resources Council

In fiscal year 1996, ORD established a Human Resources Council to provide guidance and direction to ORD management in implementing ORD's Human Resources Program. Chaired by an ORD Laboratory Director as the executive lead, the Council has 25 appointed employees who represent each ORD Office, Laboratory, and Center, with at least one representative from each geographical unit. The representatives reflect ORD's diversity in terms of job types, gender, ethnicity, and grade. In addition, the Council includes representatives from EPA's Human Resources Office; the labor unions who serve ORD Offices, Laboratories, and Centers; and EPA's Office of Civil Rights. ORD's Office of Resources Management and Administration provides staff support and serves as the executive secretary to the Council.

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. The Council is supported by a steering committee made up of senior scientists from their respective EPA offices

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 Science Policy, 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 D

Relationship of Fiscal Year 1997 STAR Focused Requests for Applications (RFAs) to ORD's High-Priority Research

	Safe Drinking Water	High-Priority Air Pollutants	Emerging Issues	Ecosystem Protection	Human Health Risk Assessment	Pollution Prevention and New Technologies for Environmental Protection
Ecosystems Indicators				●		
Issues in Human Health Risk Assessment, including human health effects of complex exposure patterns, variability in human responses to environmental agents, and consumer right-to-know					●	
Endocrine Disruptors			●	●	●	
Ambient Air Quality, including tropospheric ozone and fine particulate matter and urban air toxics		●			●	
Health Effects and Exposures to Particulate Matter and Associated Air Pollutants		●				
Drinking Water, including microbial pathogens in drinking water systems and drinking water disinfection by-products	●				●	
Contaminated Sediments			●	●	●	
Approaches to Multi-scale Ecological Assessment in the Middle Atlantic Region			●	●		●
Ecosystem Restoration				●		●
Ecology and Oceanography of Harmful Algal Blooms				●		
Arsenic	●				●	
Terrestrial Ecology and Global Change				●	●	
Water and Watersheds, including community-based research, and urban/suburban research	●			●	●	
Technology for a Sustainable Environment, including chemistry and engineering for pollution prevention, and measurement, assessment, and feedback techniques				●	●	●
Decision-Making and Valuation for Environment Policy, including benefits and costs of environmental policies and programs, ecosystem valuation and protection, and normative behaviors and environmental decision-making				●	●	●
Bioremediation				●	●	●

Appendix E

Relationship of Fiscal Year 1997 and 1998 Program Enhancements to ORD's High-Priority Research

	Safe Drinking Water	High-Priority Air Pollutants	Emerging Issues	Ecosystem Protection	Human Health Risk Assessment	Pollution Prevention and New Technologies for Environmental Protection
Fiscal Year 1997						
Drinking Water Disinfection and By-Products	●					
Particulate Matter		●				
Endocrine Disruptors			●			
Community-Based Environmental Protection and Ecosystems Research				●	●	
Benefit/Cost Research						●
Fiscal Year 1998						
Particulate Matter and Urban Toxics		●				
Endocrine Disruptors			●			
Global Change			●			
Contaminated Sediments				●		
Children's Health and Food Quality Protection Act					●	
Superfund						●
Advanced Measurement Initiative						●
Environmental Information for Communities						●

United States
Environmental Protection Agency
Center for Environmental Research Information
Cincinnati, OH 45268

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