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A Conceptual Framework for U.S. EPA's National Exposure Research Laboratory

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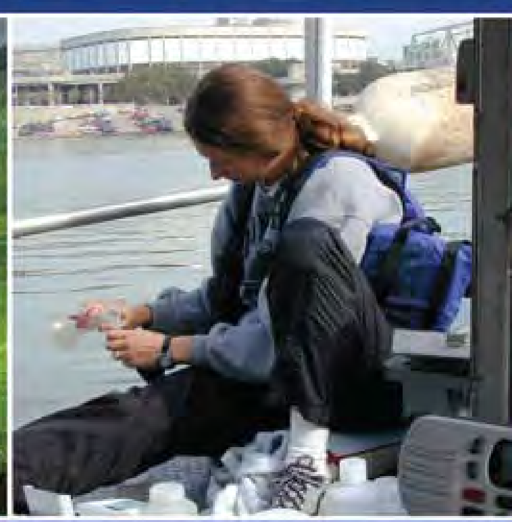

Office of
Research and Development
National Exposure
Research Laboratory

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Notice

Abstract

The Conceptual Framework for the U.S. EPA's National Exposure Research Laboratory (NERL) provides a foundation for addressing NERL's research mission and its scientific leadership goals. The document defines the domain of exposure science; describes the uses for exposure science within the EPA; and provides the principles for developing and implementing NERL research.

NERL's mission is to conduct human health and ecological exposure research that provides the pertinent databases, predictive models, and analytical tools necessary for the EPA to carry out its mission. Fulfilling the EPA's mission to protect human health and the environment carries with it the challenge of understanding exposures for tens of thousands of chemical contaminants, a wide range of biological stressors, and many physical stressors. Exposure science provides the Agency with the fundamental knowledge and tools necessary to assess potential exposures for emerging environmental threats and to mitigate exposures to known contaminants and stressors.

The Conceptual Framework articulates the importance of exposure science in both assessing and managing risks. Internally, the document creates our identity as the National Exposure Research Laboratory and provides a common understanding and a common language for exposure research and its applications. The document also communicates NERL's mission; organizational goals; and processes for strategic planning, communication and organizational development. Externally, the document is intended to define and advance the field of exposure science for both the EPA and the broader scientific community.

Letter from the Director

I am pleased to present this framework document. The goals for the document are to provide a clear and concise conceptual framework for exposure science and an outline for the role of exposure science at the EPA. It also describes the principles for how we move forward as a national laboratory committed to providing scientific understanding, knowledge, and assessment tools that inform Agency policy decisions and aid in implementing Agency regulatory programs.

As such, the concepts presented in this framework are the foundation for NERL's future. This document is a product of considerable discussion and input from across the laboratory. I would like to particularly acknowledge Linda Sheldon and Rochelle Araujo — the primary authors of the document — as well as NERL's division directors, who took a leadership role in developing the framework. Additionally, I would like to thank the NERL BOSC Subcommittee for their constructive comments, which have been incorporated into the document.

NERL is uniquely positioned to address the Nation's most challenging environmental exposure questions. I am confident that this framework will serve us well as we move exposure science into the 21st century.

Lawrence W. Reiter, Ph.D.
Director, National Exposure Research Laboratory
Office of Research and Development
Research Triangle Park, North Carolina

Foreword

The exposure framework document was written with the goal of defining the domain of exposure science, the uses for exposure science within the EPA, and the principles for developing and implementing NERL research. In creating this framework, the laboratory's Associate Directors and Division Directors gathered to reflect, discuss, and define exposure science and their vision for developing and maintaining a strategy-focused organization that provides exposure science leadership at national and international levels.

We wish to thank the following individuals for their time spent crafting this framework: Rochelle Araujo, Robert Dyer, Roy Fortmann, Florence Fulk, Fred Hauchman, Daniel Heggem, S.T. Rao, Mark Rodgers, Linda Sheldon, and Eric Weber.

Table of Contents

List of Figures

Introduction

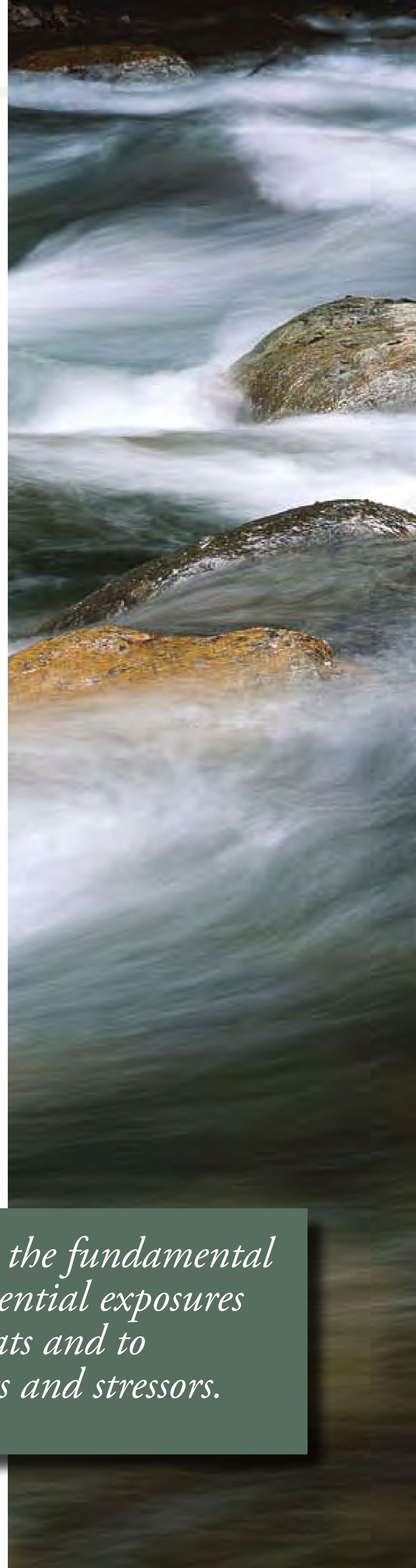
1.0 Introduction

The challenges of environmental protection range from understanding the potential risk associated with exposure of humans and ecosystems to a newly manufactured chemical, to minimizing human exposure to pathogens at public beaches, to linking human activities on the landscape with physical alterations of ecosystems.

In the United States, there are more than 75,000 industrial chemicals currently tracked by the U.S. Environmental Protection Agency (EPA), with an estimated 2,200 new chemicals manufactured or imported each year. Since 2001, the list of environmental chemicals reported in the Centers for Disease Control and Prevention's First, Second, and Third National Report on Human Exposure to Environmental Chemicals has grown from 27 to 148 (NRC, 2006) — evidence of both the need and ability to monitor the public for exposure to contaminants of concern. The popular media routinely reports concerns about contaminants in drinking water supplies, at public beaches, and in the Nation's surface waters. A June 2007 *Newsweek* article (Underwood, 2007) highlighted a growing public awareness of potential risks associated with "emerging contaminants," including pharmaceuticals, cosmetics, and antibacterial soaps. Cited in the article was a 2002 survey by the U.S. Geological Survey which detected a number of these compounds in 80 percent of the 139 streams it examined (Koplin, 2002). While each of the compounds was generally present in small quantities, findings like these raise an overarching question: "What happens when a person is exposed to a whole cocktail of them (Underwood, 2007)?"

Other contaminants are not chemicals manufactured for product use; rather they are byproducts of modern society. As an example, particulates in air come from power plants, automobile emissions, and emissions from natural sources. In addition, many other contaminants can be formed when emissions from biogenic and anthropogenic sources interact in the environment.

For ecosystems, environmental protection goes beyond minimizing exposures to chemical contaminants and includes the restoration and maintenance of the physical and biological integrity of ecosystems. Understanding the relationships between land use, such as urban development and



Exposure science provides the Agency with the fundamental knowledge and tools necessary to assess potential exposures and risks to emerging environmental threats and to mitigate exposures to known contaminants and stressors.

agricultural activities, and how these activities can physically alter ecosystems is a critical component of environmental protection. In the EPA's 2006 report on the condition of wadeable streams in the United States, stream bed sediments and river bank disturbance were identified as two of the most widespread stressors degrading stream condition for fish and other aquatic life. Both of these stressors represent physical alteration of stream systems and are typically associated with human activity alongside streams.

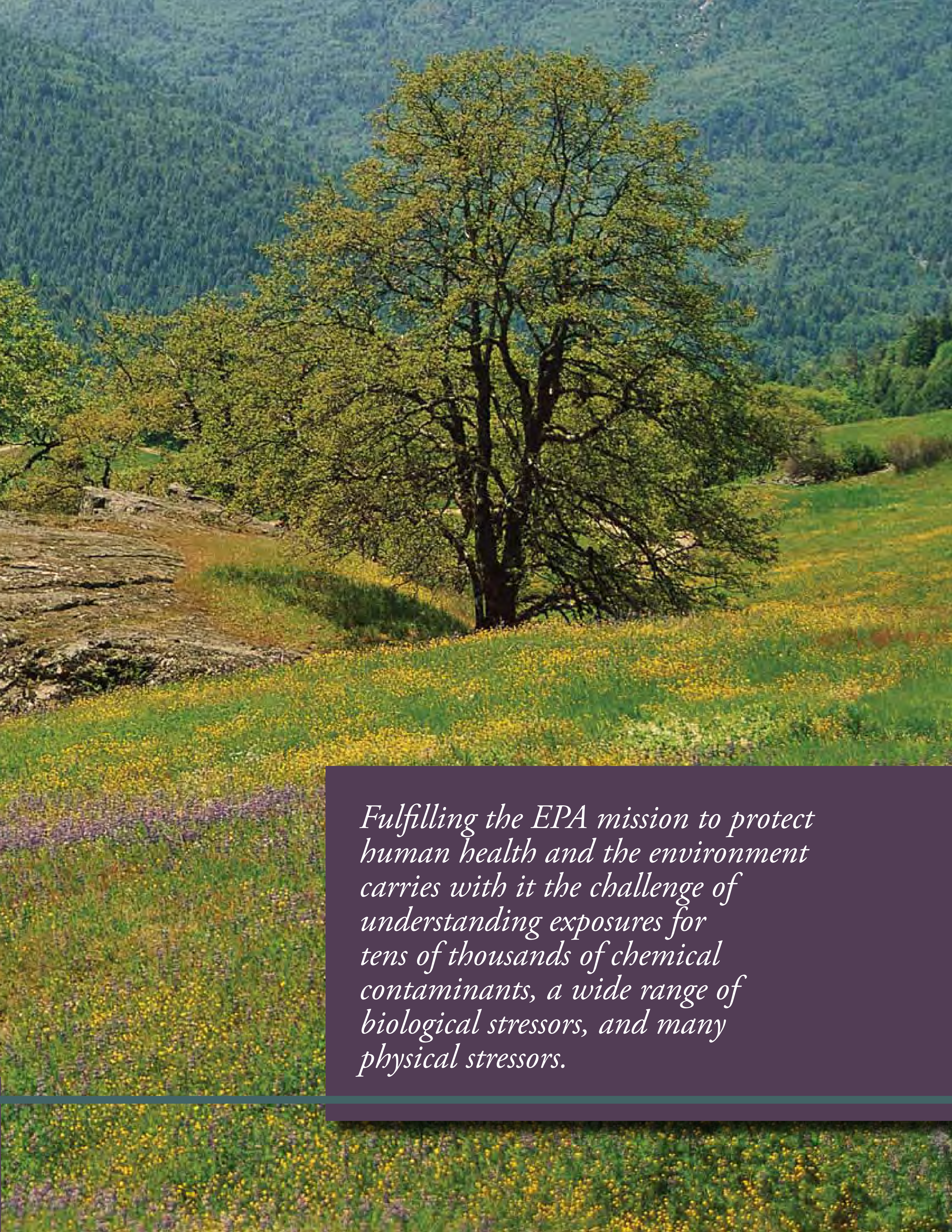
Fulfilling the EPA mission to protect human health and the environment carries with it the challenge of understanding exposures for tens of thousands of chemical contaminants, a wide range of biological stressors, and many physical stressors. The EPA's National Exposure Research Laboratory (NERL) is uniquely positioned to address the Nation's most challenging environmental exposure questions. Exposure science provides the Agency with the fundamental knowledge and tools necessary to assess potential exposures and risks to emerging environmental threats and to mitigate exposures to known contaminants and stressors. NERL's combined expertise in modeling, chemistry, physics, meteorology, statistics, computational science, microbiology, ecology, molecular biology, geographic information systems, and remote sensing enables the Laboratory to bring cutting-edge research and technology to the field of exposure science.

NERL's mission is to conduct human health and ecological exposure research that provides the pertinent databases and predictive modeling and analytical tools necessary for the EPA to carry out its mission. NERL produces research to reduce critical exposure uncertainties associated with the Agency's policy decisions and provides international leadership in exposure science. This document is a conceptual framework for addressing NERL's research mission and achieving its goal of scientific leadership. In the following sections, the document will:

> *NERL's mission is to conduct human health and ecological exposure research for the EPA to carry out its mission. NERL produces research to reduce critical exposure uncertainties associated with the Agency's policy decisions and provides international leadership in exposure science.*

- ❖ define the domain of exposure science (Section 2.0);
- ❖ describe the uses for exposure science within the EPA (Section 3.0); and
- ❖ provide the principles for developing and implementing NERL research within the context of the conceptual framework (Section 4.0).

The primary audience for this document is the NERL research community. Internally, the document creates our identity as the National Exposure Research Laboratory. It provides a common understanding and a common language for exposure research and its applications. As an internal resource, it also communicates our mission, our organizational goals, and the processes for strategic planning, communication, and organizational development. Externally, the document is intended to define and advance the field of exposure science for both EPA and the broader scientific community. Very importantly, it articulates the importance of exposure science in both assessing and managing risks. Finally, the document communicates our mission and our goals to our partners and collaborators both within and outside of EPA.



Fulfilling the EPA mission to protect human health and the environment carries with it the challenge of understanding exposures for tens of thousands of chemical contaminants, a wide range of biological stressors, and many physical stressors.


Exposure Science

2.0 Exposure Science

Exposure is the contact of a stressor with a receptor for a specific duration of time (Zartarian, et.al, 2005). A stressor is any biological, physical, or chemical agent that can potentially lead to an adverse impact. This is a very general concept and includes those stressors that lead to exposure through direct contact as well as those stressors that act indirectly through a series of environmental processes. A receptor is a living organism or group of organisms. In human health research, the individual or population of individuals is the receptor. In ecological research, the receptor can be individual plants or animals, communities of plants or animals, or groups of communities organized into an ecosystem.

For exposure to occur the stressor and the receptor must intersect in both space and time, as illustrated in Figure 2-1 (below). Exposure science characterizes and predicts this intersection. This fundamental definition is consistent with EPA's Guidelines for Risk Assessment (USEPA, 1992) and its Guidelines for Ecological Risk Assessment (USEPA, 1998).

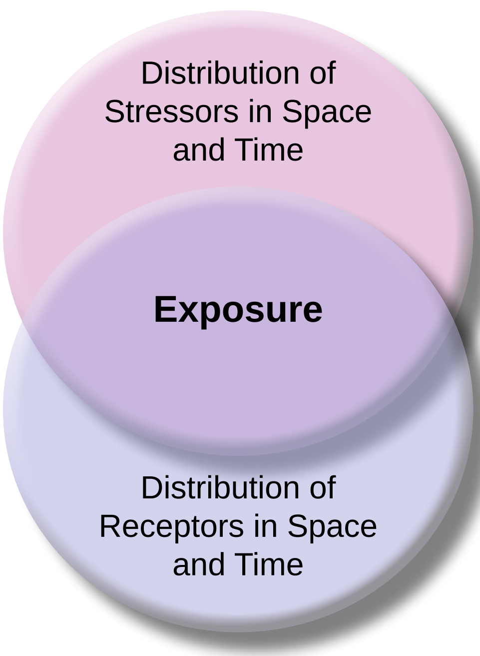
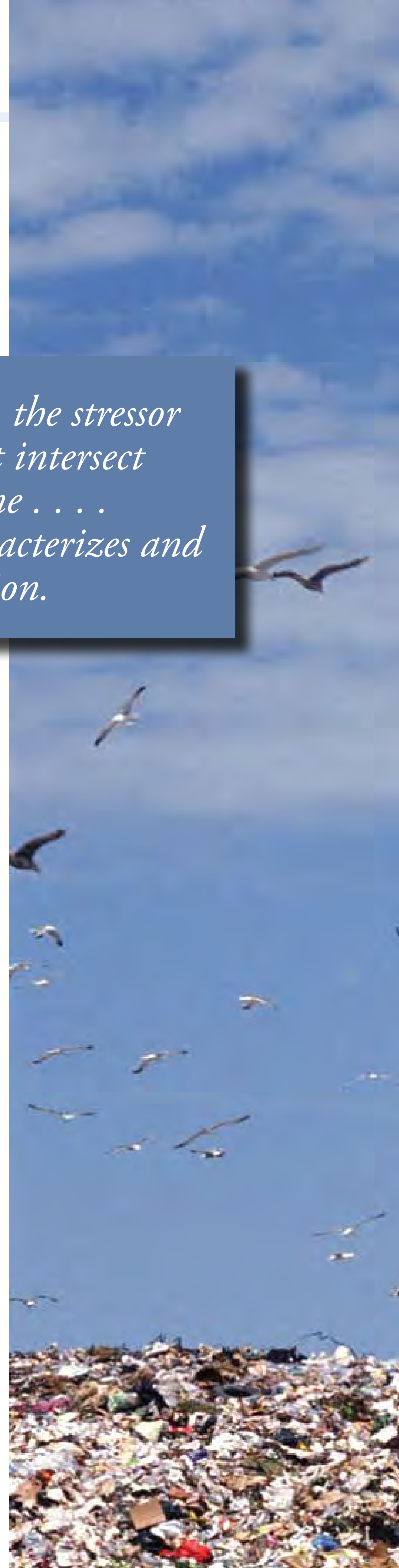


Figure 2-1. Conceptual diagram of exposure

For exposure to occur, the stressor and the receptor must intersect in both space and time . . . . Exposure science characterizes and predicts this intersection.

Exposure is described in terms of the magnitude, frequency, and duration of contact. For most stressors, the magnitude of exposure to a receptor is a critical characteristic in determining adverse effects. Likewise, both the frequency and the timing of exposures can have an important impact. Exposure can be either continuous or intermittent depending upon the source of the stressor, its persistence in the environment, and receptor activities that lead to contact with the stressor. Exposure durations can range from short-term or acute (i.e., minutes to hours) to long-term or persistent (i.e., years). For example, exposure to an accidental chemical release would be short-term and intermittent. While at the other end of the spectrum, chemicals such as lead, dioxins, polychlorinated biphenyls (PCBs), and organochlorine pesticides are persistent in the environment and can be found in environmental media where humans and wildlife have frequent contact. Because of this, exposures to these chemicals



are generally continuous and persistent. Additionally, for some stressors, there are very specific receptor life stages (such as fetal development) where specific and characteristic exposure routes may predominate and where exposure will lead to an enhanced adverse outcome.

Exposure assessment is the process for identifying potentially exposed populations and pathways of exposure, as well as quantifying the magnitude, frequency, duration, and time-pattern of exposure. The adverse impact of exposure depends upon the characteristics of the exposure, the potency of the stressor, and the susceptibility of the receptor. The greatest adverse impact of any given stressor will be to those individuals, populations, communities, or ecosystems that are most exposed and/or most susceptible to the exposure. This concept is illustrated in Figure 2-2 (right), which expands upon the simplified illustration in Figure 2-1.

Within the exposure research framework, vulnerability refers to characteristics of a receptor (e.g., an individual, population or ecosystem) that places them at increased risk of an adverse effect (USEPA, 2005). The text box above shows some of the ways that a receptor may be more vulnerable. Included are factors that can lead to increased susceptibility or higher exposure. Susceptibility refers to characteristics that lead to a greater response for the same exposure. The concepts of differential exposure and susceptibility are crucial given the EPA's mandate to protect not only the general population, but also those populations at greatest risk. Exposure assessments, therefore, should identify and understand those conditions that lead to the highest stressor intensities and resulting exposures, as well as those situations that lead to exposure for the most susceptible receptors.

Vulnerability Factors (Exposure/Activity)

- Age or life stage
- Culture and lifestyle
- Activities and occupation
- Geographic locations/ distributions
- Socioeconomic status

Susceptibility Factors (Biological)

- Age or life stage
- Gender
- Genetic differences
- Health status
- Previous exposures

Figure 2-2 suggests that both stressors and receptors vary in time and space; however, there is an important distinction between human and ecological exposure research in this regard. The human receptor is essentially the same in all locations; only stressor intensity, population characteristics (e.g., density), and susceptibility will vary in space. For ecological exposures, location determines not only the stressors present and their intensities, but also which receptors might be present, and the circumstances under which they encounter the stressor. That is, the organisms that are present vary as a function of location, as well.

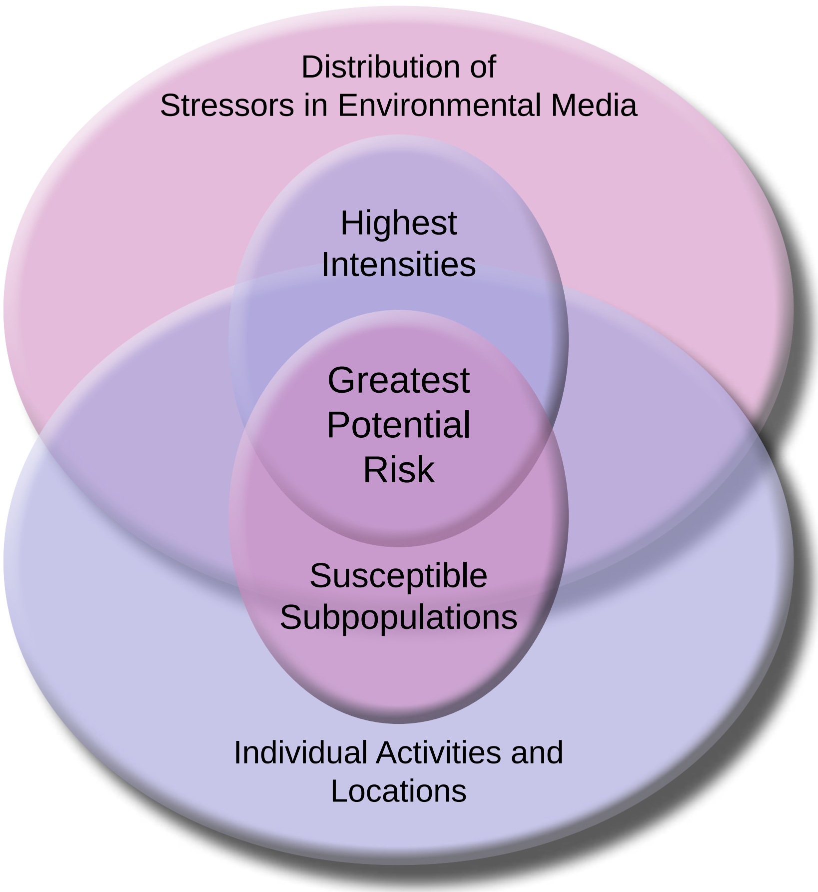


Figure 2-2. The highest concentrations and the most susceptible populations create the greatest potential risk.

There are many commonalities between human and ecological exposure science and these commonalities serve as the basis for this framework document. There are also differences that must be recognized in order to have a complete understanding of the science. For example, our understanding of the concepts of human and ecological exposure science is influenced by the EPA's responsibilities in the two areas. The EPA is responsible for human health outcomes solely related to environmental stressors (primarily chemical or biological agents). In contrast, the Agency is responsible for protecting the condition or state of entire ecosystems from multiple stressors, including physical, chemical, and biological agents. Important differences between the human health and ecological disciplines are shown in the table below.

The goal of exposure science is to characterize, forecast, hindcast, and manage exposures. In addition to identifying and characterizing stressors and receptors, exposure research also characterizes and links the processes that impact the movement and interactions of stressors from their sources through the environment, and their intersection with receptors. This includes understanding and describing the interactions of multiple stressors, with diverse environments, and multiple receptors. In very simple terms, the elements of exposure science can be illustrated within a "source-to-outcome" framework (Figures 2-3 and 2-4 on following pages), in both forward and reverse directions, providing the critical link between sources of environmental stressors and associated impacts.

Differences Between Human Health and Ecological Research Disciplines

Human Health Research	***Ecological Research***
• Agency is responsible for human health outcomes solely related to environmental stressors	• Agency is responsible for health of the entire ecosystem
• Chemical and biological agents are primary stressors of concern	• Physical condition along with chemical and biological agents are primary stressors of concern
• Single Receptor - human at individual or population level	• Multiple Receptors – individual plant or animal species, communities of plants and animals, or entire ecosystems
• Receptors (humans) are the same at all locations – population density, vulnerability, and susceptibility may change across locations	• Receptors will vary across locations – location will determine what receptors are present and the circumstances for contact with the stressor
• Traditionally, risks have been evaluated for a single stressor at a time	• Risks are evaluated for multiple stressors, using a systems approach
• Exposures and outcomes stop with consideration of the human receptor	• Exposures and outcomes can cascade when the outcome in one receptor serves as the stressor for another
	• Exposure and outcomes are of interest at additional levels of biological organization

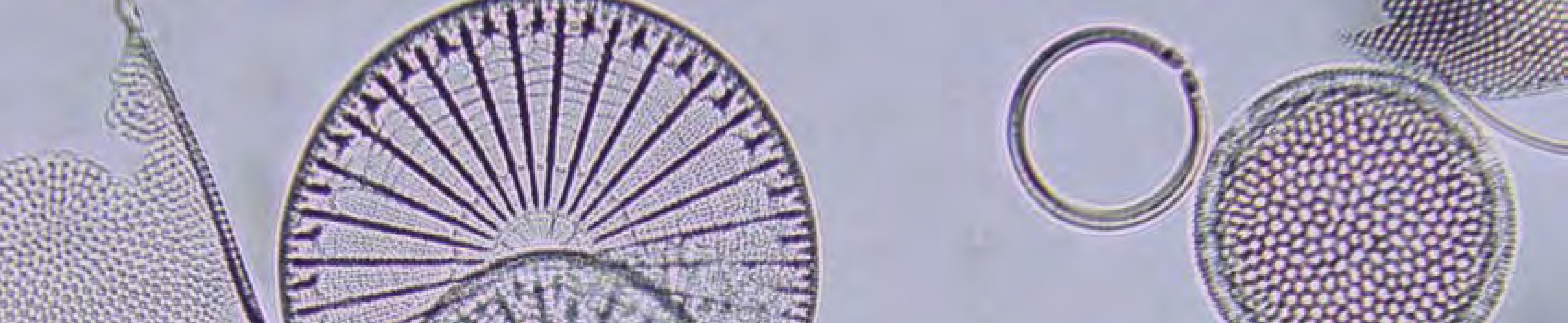


Figure 2-3 (below) is an adaptation of the source-to-outcome framework developed by the National Research Council (NRC, 1983, 1998). The processes that are important for exposure science start with a stressor entering the environment and end with dose characterization. Starting in the upper left-hand corner, stressors (primarily chemical or biological) are released into the environment from a source. Many stressors can be transformed through a number of processes, including chemical reactions and biological degradation. Stressors or their transformation products move through the environment and can be found in environmental media including air, water, soil, dust, and food. The intensity of exposure depends upon the stressor concentration in the media, as well as the duration of contact with the receptor. Exposure becomes "dose" when the stressor moves across the receptor's body barrier. The text under each box in Figure 2-3 shows the information that is used to characterize the various processes represented in the boxes. The arrows between the boxes represent models that are used to link the processes.

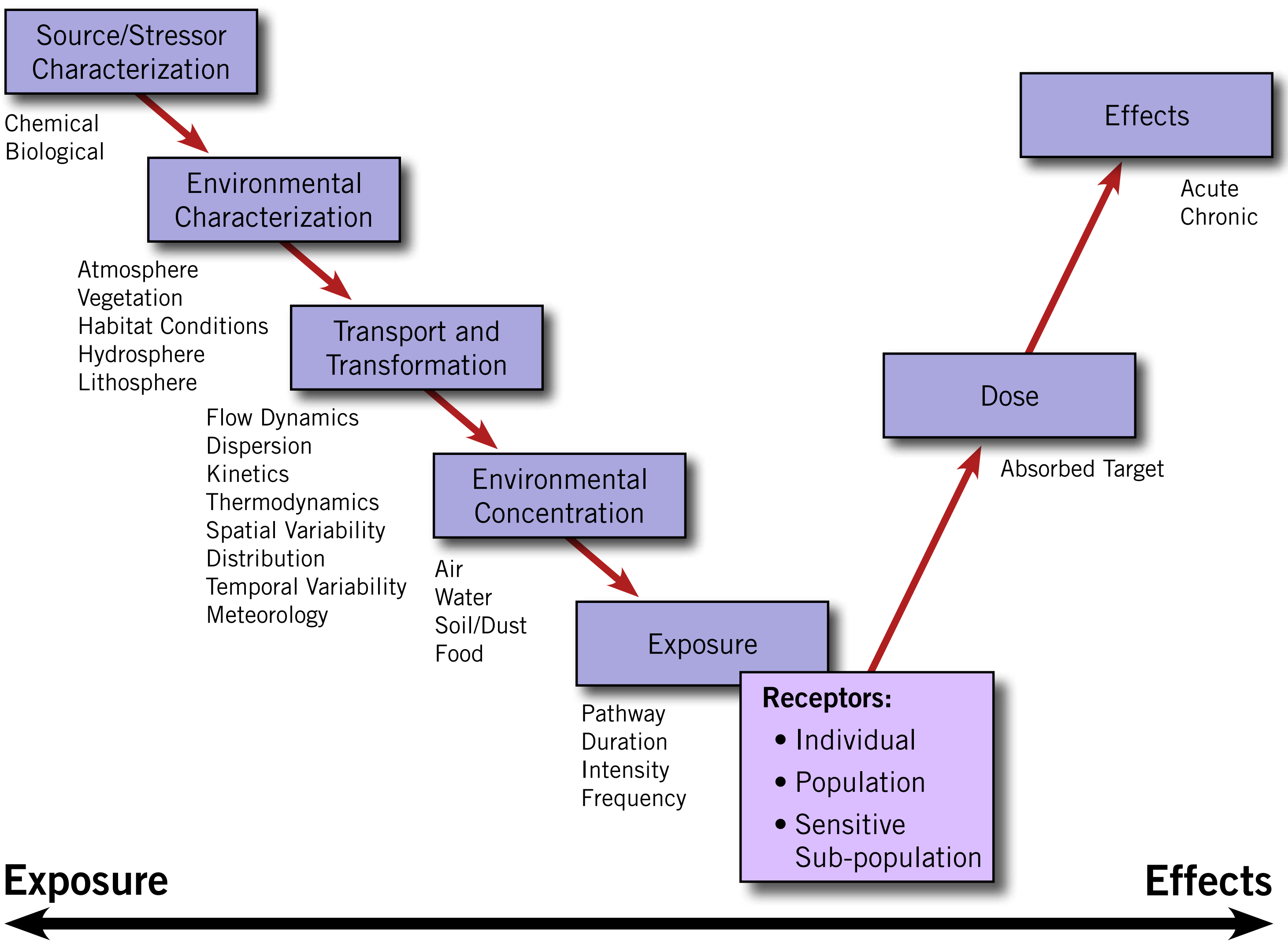


Figure 2-3. Source-to-outcome framework for human health exposure research

Figure 2-4 (below) shows that with several modifications, the same framework can be used to describe the interaction of environmental factors that contribute to ecological exposures. For example, "source" may also refer to activities that give rise to non-chemical stressors, such as changes to habitat from expanding human populations. "Environmental characterization" includes the full suite of ecological conditions, as well as those that affect pollutant/stressor concentrations. For ecological research, "dose" is replaced by an equivalent measure of the stressor's impact on the receptor, that is, stressor intensity within the domain of the receptor. An example of a quantity equivalent to dose, where the receptor is a stream's fish community, might be the turbidity in a stream, caused by excessive sediments, that prevents a fish from finding its food. The figure below illustrates the concept that the receptor is determined by the location and environmental characteristics. Finally, the multiple arrows from the effects box illustrate a sequence of feedbacks that can lead to cascading impacts. For example, the response of an ecosystem to a stressor might include shifts in vegetation, which would feed back to the exposure pathway via environmental characterization. Similarly, an ecosystem response that includes a change in microbial communities could alter the biogeochemical processes that affect transport and transformation. In the ultimate case of cascading exposures, an affected organism may become the prey/food for another organism, thus entering the exposure continuum directly as the immediate source of exposure (environmental concentration). Although there are some circumstances (secondary infection spread) in human exposure research where exposures and outcomes can loop back to serve as stressors, this is not as common and, thus, has not been illustrated in Figure 2-3.

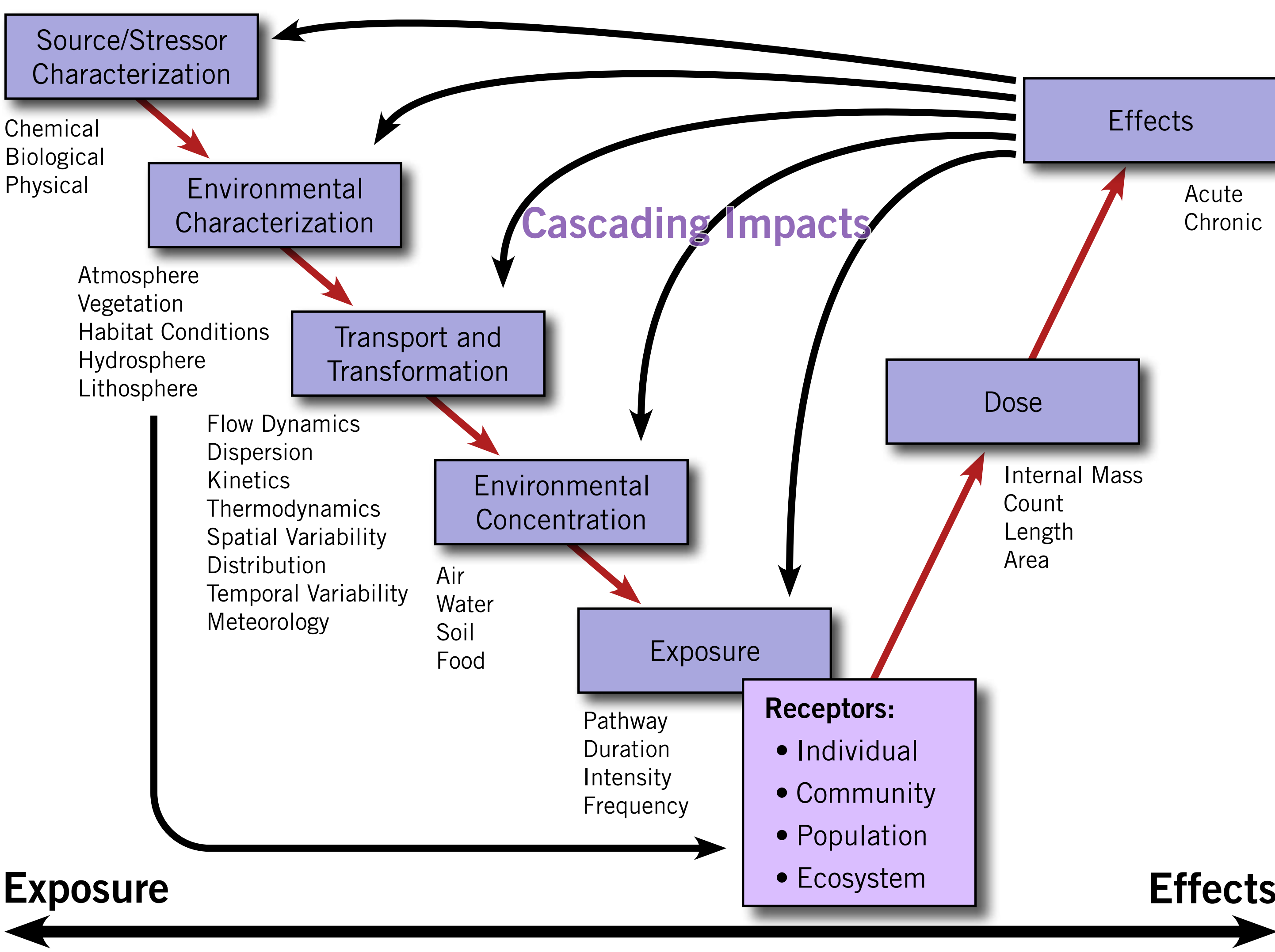


Figure 2-4. Source-to-outcome framework for ecological exposure research

Although the source-to-outcome framework for human health and the framework for ecological research have been diagramed separately in this document, it is important to recognize that the two are closely intertwined and should be considered together. Healthy ecosystems are required for human well-being; they provide clean air, water, and protection from disease. In turn, humans are part of these ecosystems and can positively or negatively impact the state of ecosystems through their actions and management practices.

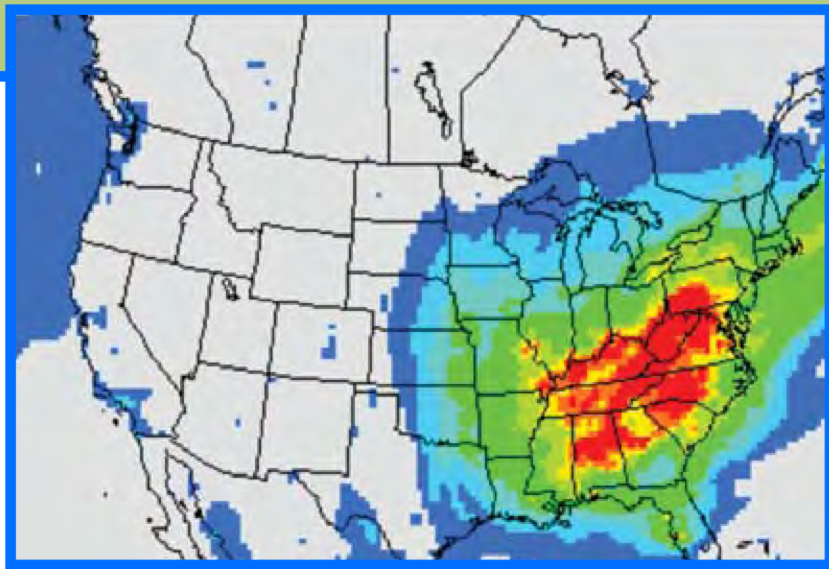
Exposure to environmental stressors is considerably more complex than illustrated in Figure 2-4. Multiple stressors enter the environment at the same time from many different sources. Stressors can remain unchanged or they can be transformed by physical, chemical, or biological processes to become different agents. These stressors or their transformation products can partition and move through many different environmental media (i.e., air, water, soil, sediment, and the plant and animal life of a particular region). Stressors or their transformation products can take many different pathways to reach the receptor. In the simplest case, exposure to a given stressor would be in a single media through a single pathway, although multimedia, multipathway exposures are the more common case. Definitions for concepts associated with multimedia, multipathway exposure are given in the text box below. Aggregate exposure is the sum of exposures to a single stressor from all sources and pathway(s) over a given time period. Cumulative risks are those that result from aggregate exposures to a single stressor over multiple time periods, or from concurrent and/or synergistic exposures to multiple stressors.

Exposure science must describe the complexity of stressors, the environment, and the receptors as they interact. As examples, when stressors from multiple sources reach the receptor by the same pathway, it may be necessary to determine relative source

Exposure media:
environment or media in which stressor exists as it interacts with the receptor.

Exposure pathway:
the course that the chemical takes from its source to the receptor.

Aggregate exposure:
sum of exposure to a single stressor from all sources and pathways.



contributions. Likewise, when a stressor comes in contact with a receptor by multiple pathways, dosimetry must be used to integrate the exposures as they would lead to a health outcome. Although the concepts of aggregate exposures and cumulative risk are relatively new for human health exposure science, understanding impacts of multiple stressors from many different sources has been a fundamental aspect of ecological exposure science that should be extended to both disciplines.

Models are the underpinnings of understanding and controlling environmental health risks within this basic framework for exposure science. Exposure science characterizes the movement, chemical transformations, removal, distribution, and interaction of stressors and receptors in time and space, at different locations and on multiple scales. With such a broad scope, it is necessary to go beyond the simple measurement of conditions for each component of the source-to-outcome framework and focus on the processes that control movement along the framework. Models provide the ability to summarize and link our knowledge of exposure processes and to mathematically quantify and predict concentrations of chemicals, biological and physical conditions, exposures, and dose. Process models enable us to be both prospective and retrospective in describing exposures and outcomes. Moreover, the assessment of cumulative and aggregate exposures requires the use of integrated multimedia models. The use of models is central to Agency decision-making processes (NRC, 2007). The EPA uses models to inform the exposure assessment process (distributions, uncertainty, and variability), assess compliance, and evaluate alternate regulations. As shown in the text box below, there are many uses for exposure models. Both conceptual and computational models also allow us to systematically evaluate our state of knowledge as well as identify data gaps and research needs. The importance of models in exposure science will continue to increase as computational methods advance.

Uses of Exposure Models

Research Uses:

- Provide exposure hypotheses
- Synthesize data collected on the state of a system
- Provide explanations of factors impacting exposure

Management Uses:

- Assess exposure/dose to stressors
- Project future conditions or trends
- Extrapolate to situations where observations are not available
- Assess the contribution of individual sources
- Evaluate the impacts of different policies or future scenarios
- Evaluate post-implementation impact of regulations

Throughout this framework, it is important to distinguish between exposure science and exposure research.

Exposure science is applied in the practice of assessing and managing environmental health risk; whereas exposure research is conducted to address critical gaps that will limit the application of exposure science and in this manner serves to improve the quality of exposure science. Specifically, exposure research provides the scientific understanding of the processes involved in exposure science, develops the tools (methods and models) for conducting the science, provides the data that are used to understand environmental and exposure conditions, and provides inputs to the models.

A complete exposure research program in NERL must include model development, observational measurement research and methods development. As already discussed, modeling research provides the underpinning for exposure science. Observational measurement studies provide a fundamental understanding of model processes, along with inputs for models, and data for model evaluation. Methods research provides the tools that allow observational measurements to be made and interpreted. These measurement tools also have direct application for compliance monitoring.

This document describes NERL's exposure research program. NERL recognizes that full understanding of an environmental issue from source to outcome can only be achieved by conducting integrated, cross-disciplinary, and focused research and by applying the outputs of this research to inform policy.

This can be achieved by NERL exposure researchers working in full coordination with toxicologists, epidemiologists, engineers, risk assessors, and decision makers both within and outside of EPA. Research responsibilities within ORD (EPA's Office of Research and Development) are organized around the source-to-outcome framework. The engineering laboratory (NRMRL) is responsible for research that characterizes sources; NERL is responsible for research associated with fate and transport, environmental concentrations, exposure and dose; and the health laboratory (NHEERL) is responsible for characterizing health outcomes associated with exposures. The engineering laboratory is also responsible for developing and evaluating methods for source reduction. Conducting integrated multidisciplinary research with scientists in these sister laboratories is crucial to addressing the nation's most important environmental health issues, however developing relationships with scientists in academia, other governmental organizations and nongovernmental organizations is also needed to fully develop integrated multidisciplinary research programs.

Exposure science is applied in the practice of assessing and managing environmental health risk; whereas exposure research is conducted to address critical gaps that will limit the application of exposure science and in this manner serves to improve the quality of exposure science.

Exposure Science at U.S. EPA

3.0 Exposure Science at U.S. EPA

3.1 Role of Exposure Science in the Risk Assessment/Risk Management Context

The mission of the EPA is to safeguard public health and the environment from environmental stressors. The mechanism for environmental protection is to minimize human and ecosystem exposures to stressors of concern as part of risk-based assessments. The EPA sets its priorities, targets its actions, and measures its outcomes based on assessing and managing risk. Regardless of the Agency program or regional office that raises the issue, there are three broad questions related to environmental decisions (see text box below).

Broad Questions Related to Agency Problems:

- **Is mitigation necessary? (impact on the receptor)**
- **How best to mitigate? (impact on the stressor)**
- **Was mitigation successful? (accountability)**

The mission of the EPA is to safeguard public health and the environment from environmental stressors.

Figure 3.1 (below) overlays the concepts of stressor and receptor on the source-to-outcome framework. The figure then incorporates the processes associated with environmental management practices, including risk assessment, development of environmental policies and regulations, compliance monitoring, and risk management. Finally, the three questions that face the EPA are overlaid in the figure. As highlighted in the figure and discussed below, exposure is uniquely positioned at the intersection of the stressor and the receptor, and plays a pivotal role in addressing each of the broad Agency questions.

Is mitigation necessary?

Risk assessments are used to determine whether mitigation is necessary and they focus on impacts to the receptor. All risk assessments are based on the concept that:

Risk = Exposure × Hazard

Exposure must be used implicitly or explicitly to determine risk. Very simply, risk assessment is a four-step process (see text box, right; NRC,1983). Hazard identification determines qualitatively, whether a stressor will cause an adverse outcome. Dose-response assessments establish the quantitative relationship between dose and the incidence of effects. This information is used, in turn, to develop a "safe" exposure level, often referred to as a reference dose (RfD). Exposure assessment determines the route, magnitude,

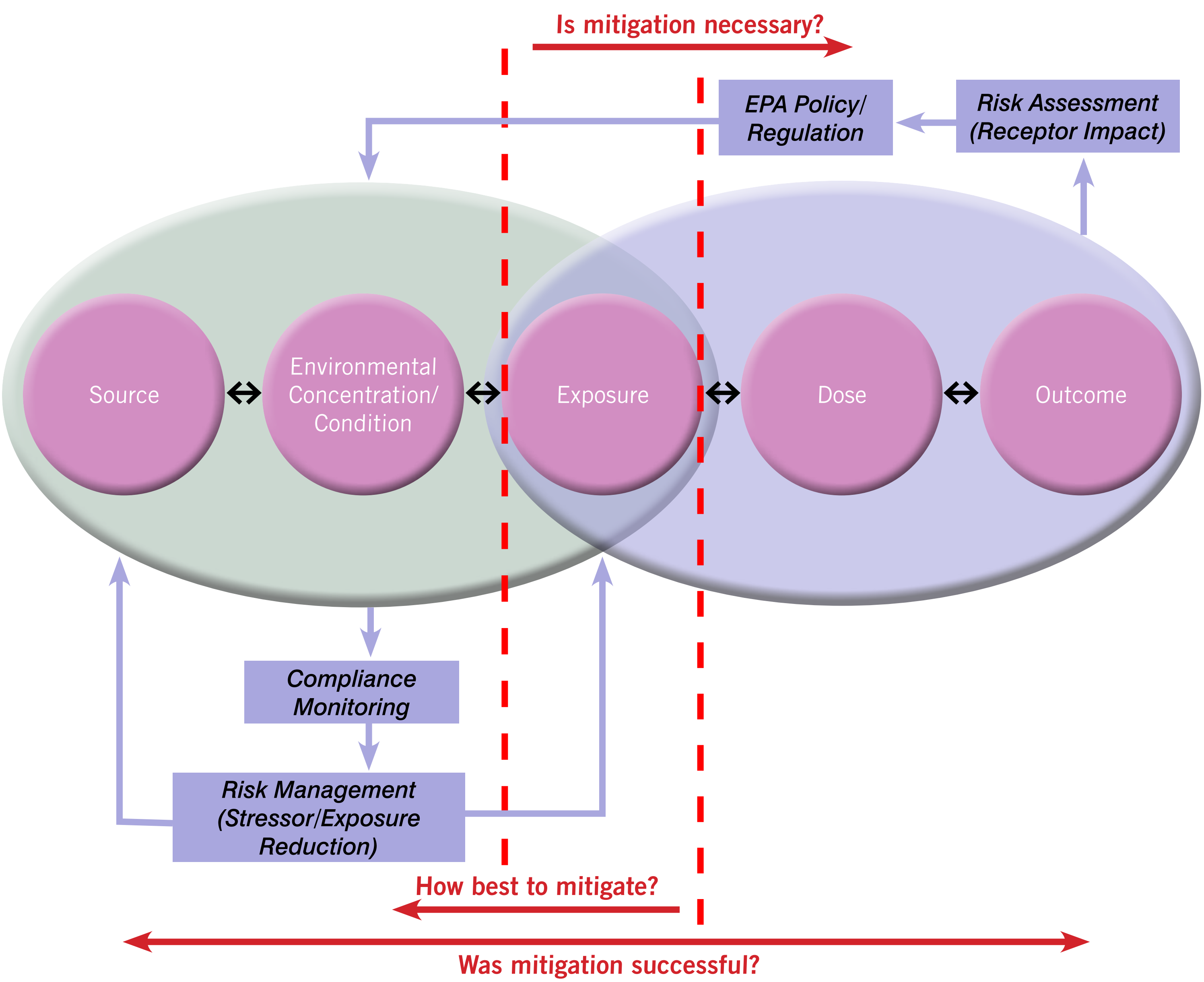


Figure 3-1. Framework for protecting human health and the environment

Steps in Risk Assessment Process

- ❖ **Hazard Identification**
- ❖ **Dose-Response Assessment**
- ❖ **Exposure Assessment**
- ❖ **Risk Characterization**

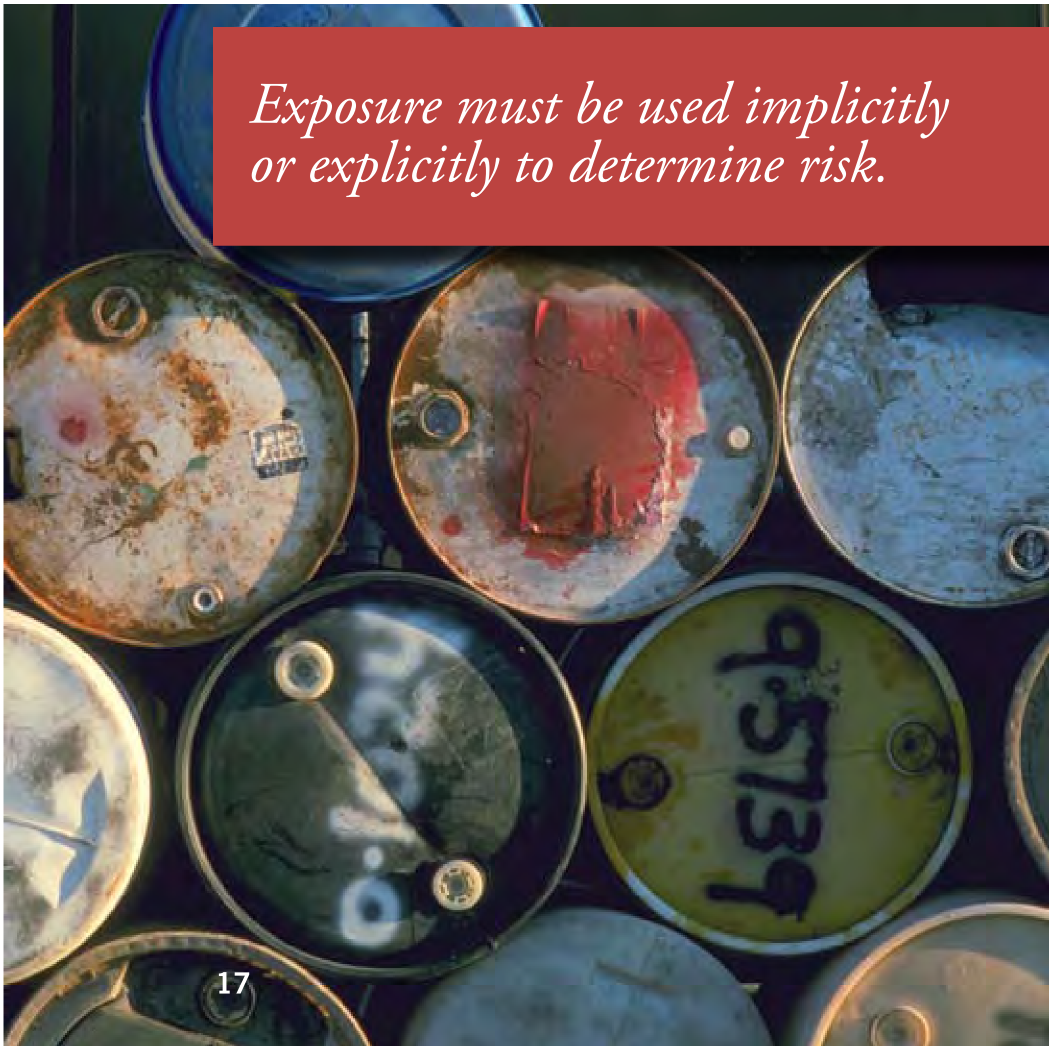
frequency, and distribution of exposure. Risk characterization is conducted by comparing the "safe" exposure level to the distributions of exposure thereby determining the risk of an adverse outcome. Mitigation is required for exposures at or above the "safe" level. Although other information along the continuum (i.e., sources, environmental concentrations, etc.) may provide inputs to the exposure assessment, exposure is the metric that is used to evaluate risk.

Risk assessments can be conducted either by determining dose-response using toxicity studies coupled with an independent exposure assessment or by conducting environmental epidemiology studies where exposure estimates and health outcomes are determined for a specific cohort. Environmental epidemiology is crucially dependent on high-quality exposure estimates. Although epidemiology may not provide evidence of causal associations, it does provide critical information on measurable adverse health effects in real populations associated with exposure to real environmental stressors.

How best to mitigate?

Risk to a receptor is most often lowered by reducing exposure. The "safe" exposure level is determined by the dose response assessment described in the previous section. Activities designed to bring exposures down to that level are developed using information on the sources, pathways, and routes that lead to the exposures. These activities can be directed toward various processes along the source-to-outcome continuum. Standards most often target source controls or environmental concentrations, while some actions, such as fish advisories or ozone alerts, target individual actions in order to reduce exposure. For those standards that target environmental concentrations, environmental monitoring is used to assess compliance. When monitoring results exceed the standard, risk mitigation activities are then directed at the sources of the environmental stressors.

Mitigation activities can be developed without the use of exposure tools and information, however, ensuring the development of activities that are the most protective, with the least burden, requires an understanding of exposure. Exposure science provides information on the levels and processes that control fate and transport, environmental conditions and concentrations, and exposure pathways. Techniques, such as source apportionment and exposure reconstruction, are used to relate exposures or environmental concentrations back to sources. Monitoring methods are developed to evaluate exposures and to assess compliance to standards. Models across the continuum are used to summarize available knowledge needed for regulatory decisions and provide the ability to evaluate alternative regulations, while also offering a framework in which to assess compliance (NRC, 2007).



Exposure must be used implicitly or explicitly to determine risk.

Was mitigation successful?

Over the last several years, there has been an increased interest in assessing the effectiveness of EPA's regulatory and non-regulatory decisions. Research and data across the entirety of Figure 3-1 can be used to address this area. This is a new area of research for the Agency, with the initial emphasis placed on developing and validating indicators along the source-to-outcome continuum (USEPA, 2007). Exposure science is expected to play a very important role in this research area, because it is crucial to linking stressor-based metrics to receptor-based metrics.

3.2 Role of Exposure in EPA Regulations

The EPA's regulations and policies have been formulated to use exposure information according to the general principles outlined on pages 16-18. However, depending on the nature of the contaminant, the environmental medium, and the appropriate treatment of risk, regulations may outline different activities and address exposure in either an explicit or implicit manner. There are four primary areas where the EPA can increase the effectiveness of environmental protection programs by enhancing its emphasis on exposure assessment, and investing in exposure research:

1. Developing current standards/policies

(e.g., developing and evaluating exposure metrics and models that can be used in the risk assessment process, understanding the mitigation or enhancement of exposure by human activity or natural processes, developing and applying reliable exposure indicators for environmental epidemiology);

2. Achieving current standards/policies

(e.g., developing analytical methods to determine compliance, developing and applying models to predict the impact of mitigation strategies, providing information to implement mitigation and simulate alternative scenarios and policies);

3. Evaluating the impact of standards/policies

(e.g., reconstructing exposures to determine environmental concentrations of contaminants relative to exposed populations, developing and applying public health indicators along the source–to-outcome framework, evaluating environmental concentrations against model predictions); and

4. Developing the science for the next generation of standards/policies

(e.g., developing science for assessing cumulative risks, identifying sources of pollution with the greatest risk, determining the potential extent of exposure to emerging contaminants).

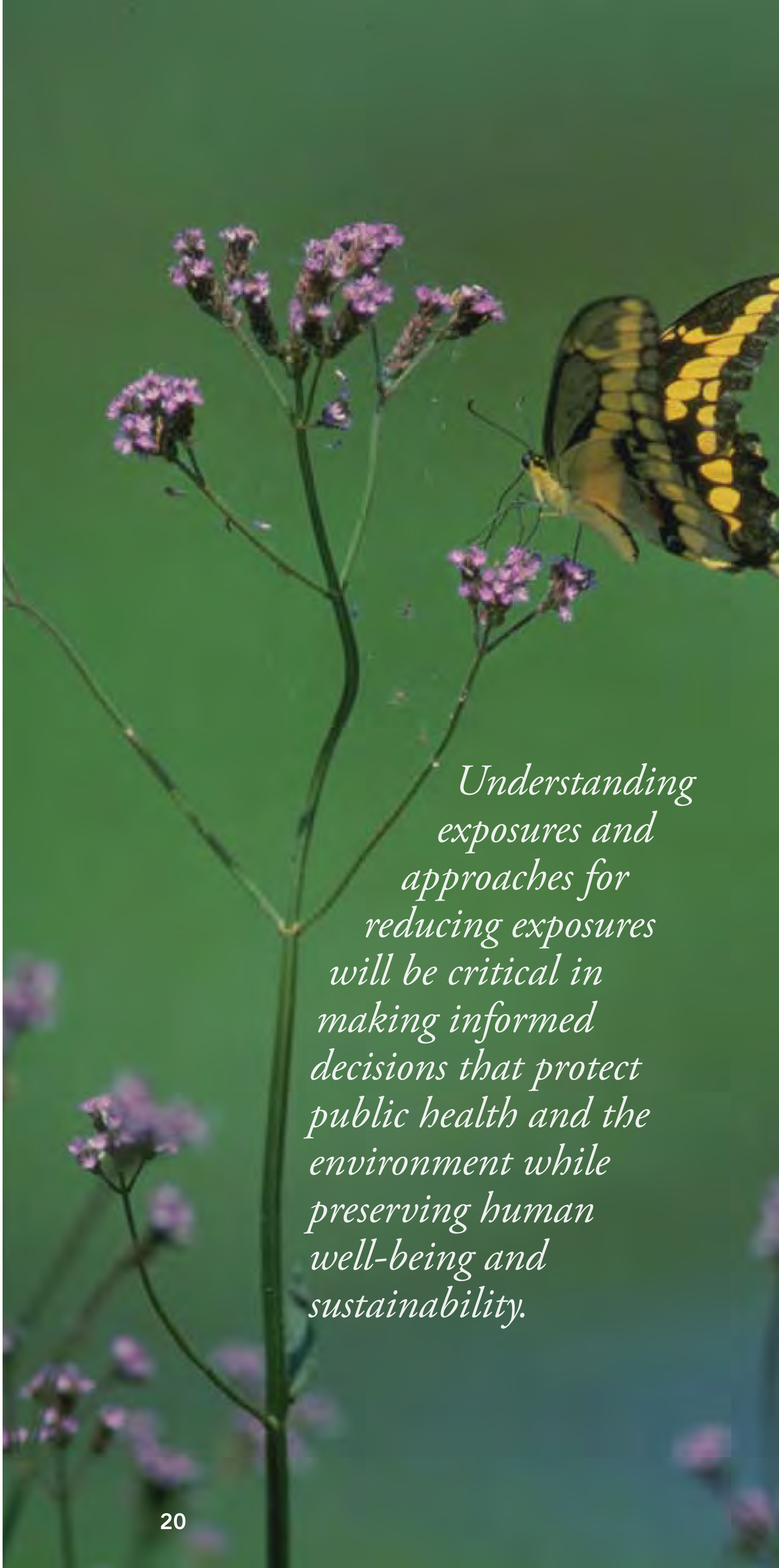
The EPA is facing a number of new challenges for which a one-pollutant, one-medium, one-exposure approach for assessing and managing risk is no longer adequate.

The text box on page 21 identifies the major exposure elements of the EPA's enabling legislation. Identifying and understanding those elements are critical to strengthening and expanding the Agency's use of exposure science.

Exposure has not often played a large role in the risk assessment and risk mitigation processes. Environmental regulations were often developed to address contamination that was so severe and immediate to its source that ambient monitoring data or source emissions were adequate surrogates for exposure. The National Ambient Air Quality Standards, developed under the Clean Air Act, and the EPA's drinking water standards, developed under the Safe Drinking Water Act, are but a few examples of this approach.

This process worked well for the EPA in the past and will continue to work well for situations, as long as certain conditions are met:

- The standard is not a risk-based standard (e.g., best available technology); therefore, the risk assessment process is not used.
- The surrogate exposure estimate is either much greater or lower than the risk level, thus better, more realistic exposure information will not change the action.
- There is only one source and pathway of exposure, and the relationship between source, environmental concentration, and exposure is well defined.
- There is only one pathway for exposure, and the pollutant concentration is relatively homogenous, so that a single measure of environmental concentration can be used to estimate exposure.



Understanding exposures and approaches for reducing exposures will be critical in making informed decisions that protect public health and the environment while preserving human well-being and sustainability.

Environmental Regulations and Statutes with Exposure Components

Clean Water Act – Establishes the structure for regulating the discharge of pollutants into U.S. waters. Exposure information is used to set standards to achieve uses, determine achievability of uses via technology and total maximum daily load (TMDL) controls (point, nonpoint sources), and establish watershed planning and best management practices.

Safe Drinking Water Act – Establishes safe standards of purity and requires all public water systems to meet primary standards. Exposure research is used to develop methods to improve exposure assessments, improve microbial detection techniques, detect and classify unregulated contaminants.

Clean Air Act – Established National Ambient Air Quality Standards for the protection of public health and the environment; sets limits on how much of a pollutant can be released in the air. Exposure research is used to develop exposure metrics for epidemiological research that evaluates health impacts of criteria pollutants, develop exposure assessments for air toxics, determine impact of atmospheric processes on air quality, and provide models for air quality and exposure analysis and prediction.

Toxic Substances Control Act – Requires reporting and/or testing of industrial chemicals produced or imported into the U.S. that may pose an environmental or human-health hazard. Exposure information is used to develop methods to measure exposures to industrial chemicals, analyze and report exposure levels based on real-world data, and to conduct exposure assessments on a wide array of chemicals.

Federal Insecticide, Fungicide & Rodenticide Act – Establishes federal control of pesticide distribution, sale and use. Exposure research is used to develop methods and models to characterize exposures to pesticides, model the fate and transport of pesticides through ground water.

Endangered Species Act – Prohibits any action that results in a "taking" of a listed species, or adversely affects habitat of a listed species. Exposure information is used to determine (cumulative) risks to individuals of endangered species (including habitat), and register pesticides based on exposure risk to endangered species.

Food Quality Protection Act – Requires EPA to set limits on the amount of pesticides that may remain in or on foods based on risks to infants and children from exposure from all sources. Exposure research is used to develop important exposure scenarios, identify and quantify factors for children's exposure, develop high-quantity, high-quality exposure data, develop models for estimating exposure and dose to pesticides.

Federal Food, Drug & Cosmetic Act – Requires EPA to address risks to infants and children from exposure to pesticides in diets; requires the development and implementation of a screening program for endocrine effects, including estrogenicity. Exposure information is used to study exposures to susceptible populations, analyze exposures to endocrine disrupting compounds, develop generic techniques to model consumer exposure.

Comprehensive Environmental Response, Compensation, and Liability Act – Provides EPA authority to clean up and/or prevent releases of hazardous substances. Exposure science is used to specify testing and monitoring requirements, determine appropriate groundwater remediation, determine the exposit to which contaminated soils and debris must be excavated.

Resource Conservation and Recovery Act – Requires EPA to control the generation, transportation, treatment, storage, and disposal of hazardous waste to protect human health and the environment. Exposure science is used to measure chemicals at hazardous waste sites, assess risks for leaking underground storage tanks, establish operation standards and promulgate monitoring and control regulations, and specify criteria for acceptable location of treatment, storage and disposal of facilities.

The need for good exposure information is highlighted when we consider the potential risks and adverse outcomes associated with underestimating exposures, along with the potential costs to society of overestimating exposures. This is especially true for situations where a simple approach to exposure assessment is not adequate (see text box, right). In these situations, the overall quality of the risk assessment will be limited, to a great extent, by the quality of the exposure assessment. As an example, in risk assessments of waterborne pathogens which have a very large temporal and spatial variability, the uncertainty surrounding the various components of the exposure assessment can easily be up to several orders of magnitude. This level of uncertainty can have a profound impact on the regulatory action that is taken, as well as the confidence in that action.

The EPA is facing a number of new challenges for which a one-pollutant, one-medium, one-exposure approach for assessing and managing risk is no longer adequate. There is growing awareness of potential exposures to new types of contaminants (e.g., nanomaterials), pressures of population growth on natural ecosystems, complex systems that involve multiple stressors, and pollutants with significant spatial and temporal variability (leading to different exposure scenarios for different populations).

Additionally, there is a need to consider how the consequences of a particular risk management action may lead to unintended consequences. For example, a regulation established to reduce exposure to one contaminant may increase exposure to another contaminant (e.g., decreases in nitrogen loading in streams may increase the bioavailability of mercury).

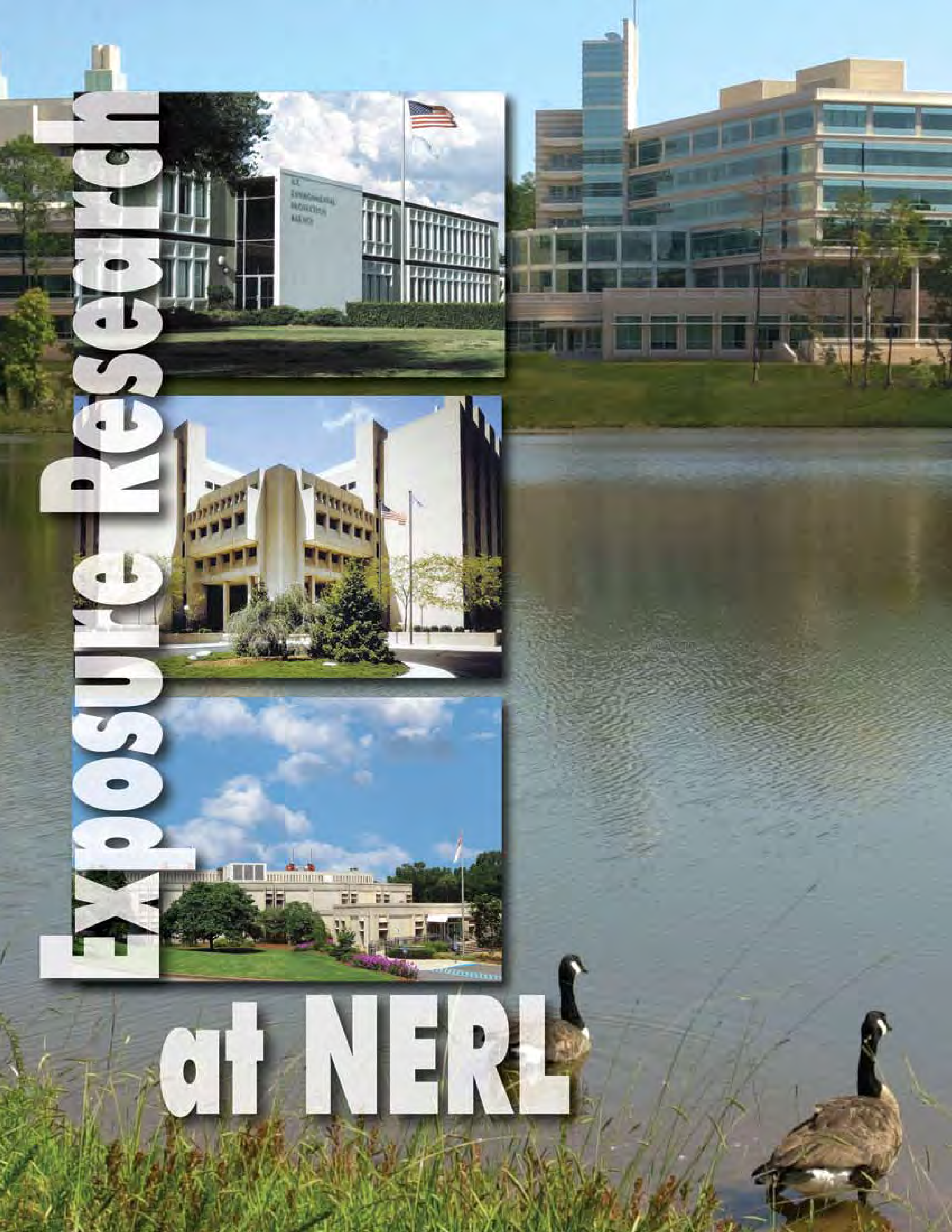
Understanding exposures and approaches for reducing exposures will be critical in meeting these challenges and in making informed decisions that protect public health and the environment while preserving human well-being and sustainability.

Assessments Requiring Refined Exposure Estimates

- **Aggregate exposures from multiple pathways and routes**
- **Cumulative risks from exposures to multiple stressors**
- **Exposures to stressors with significant spatial and temporal variability (e.g., fine particulate sulfate vs. coarse particulate matter in air, chemical contaminants vs. microbes in drinking water, etc.)**
- **Exposures and risks from sources rather than to single pollutants from a source**
- **Total risk associated with regulatory options**

The need for good exposure information is highlighted when we consider the potential risks and adverse outcomes associated with underestimating exposures, along with the potential costs to society of overestimating exposures.

Exposure Research at NERL



4.0 Exposure Research at NERL

As a research organization, NERL has two interrelated goals: to provide leadership in exposure science and to conduct high-quality research to support the EPA's mission. Achieving these goals requires a strategic approach that will inform not only the research we do, but also the processes we use to implement this research. This conceptual framework document is the first crucial step in developing and communicating such an approach by providing a common understanding of exposure science, its role in supporting the EPA's environmental protection agenda, and subsequent implications for the way NERL conducts business.

The consistent delivery of high-quality, high-impact products depends upon developing an organization whose components function to achieve its mission. The first three chapters of this framework describe a vision of exposure science and the role of NERL in achieving the Agency's mission to protect the environment and human health. Figure 4-1 illustrates how the business of NERL — the employees, resources, and practices — must be aligned and in balance with the development, production and communication of research products in order to fulfill that vision. Thus, this final section will discuss how the concepts of exposure science, presented in Sections 2.0 and 3.0 and Figure 3-1, provide the foundation for NERL's research and management practices.

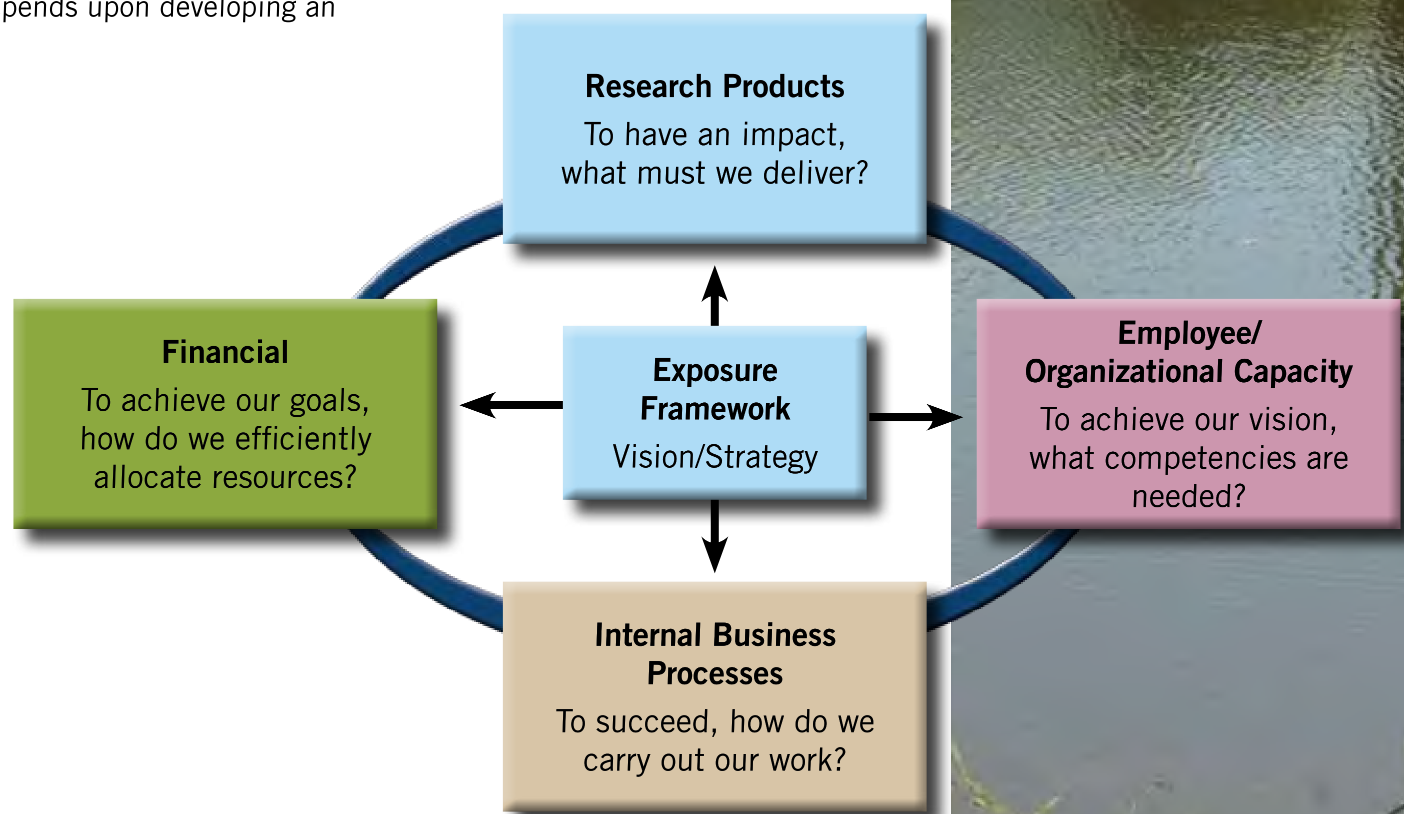


Figure 4-1. Aligning NERL's business as a Strategy-Focused Organization (Adapted from Kaplan and Norton, 2001)

Developing and maintaining a strategy-focused organization at the laboratory level will enable NERL to achieve its science mission.

The four elements of a strategy-focused organization, outlined below, address the direction NERL is taking to achieve its mission.

1. **Research Products:** We construct and deliver a portfolio of relevant exposure research programs that are responsive to the Agency needs. *(To have an impact, what must we deliver?)*

2. **Internal Business Processes:** We use collaborative, creative, and efficient processes to implement our research. *(To succeed, how do we carry out our work?)*

3. **Employee/Organizational Capacity:** We recruit, retain, and develop a work force with the competencies needed to lead our organization and conduct our research. *(To achieve our vision, what competencies are needed?)*

4. **Financial Resources Management:** We allocate our resources efficiently and effectively. *(To achieve our goals, how do we efficiently allocate our resources?)*

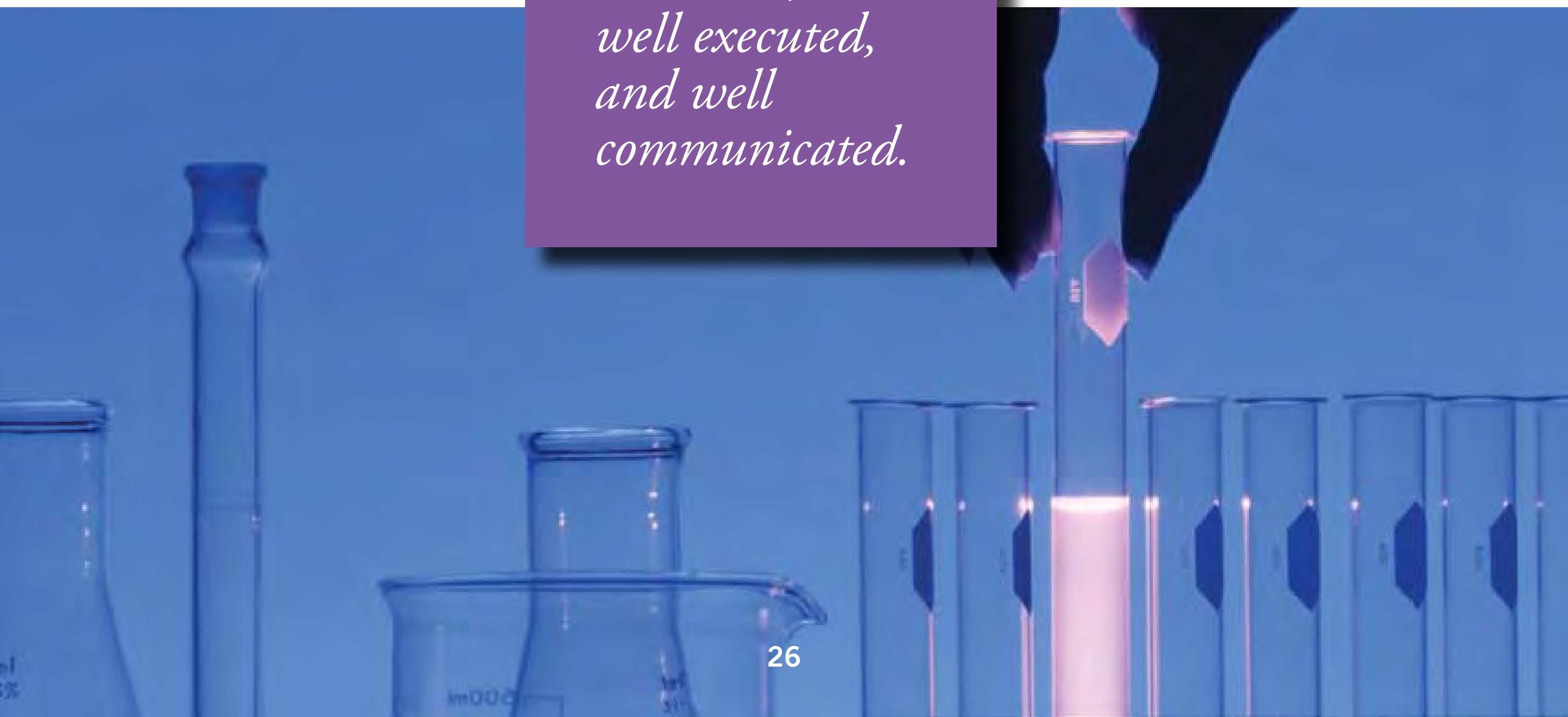
Developing and maintaining a strategy-focused organization at the laboratory level will enable NERL to achieve its science mission, create better solutions though linkages, integration, and synergy, ensure efficiency of research and resources, leverage resources and expertise, and provide a stable environment for conducting and completing research.

NERL's research products must be well conceived, well executed, and well communicated.

4.1 Research Products: To have an impact, what must we deliver?

For NERL to advance exposure research in service to the Agency's mission, the research products must be well conceived, well executed, and well communicated. In this section, we address the processes by which we identify those strategic research directions that will:

- enhance environmental protection through a better understanding of exposure;
- construct and execute a critical path for research implementation, and;
- translate research into tools and communication forms that best serve our clients and partners.



4.1.1 Developing a Research Portfolio

For NERL's science leadership and high-quality responsive research to have an impact on environmental protection, NERL's portfolio must contain a set of programs that address critical exposure science needs directly related to the Agency goals for air, water, and land protection, as well as the health of humans and ecosystems. To that end, NERL's research portfolio should be developed in alignment with ORD's planning process, including the Multi-year Plans (MYPs). Developing NERL's range of research programs is a dynamic process that entails periodically assessing the current programs and identifying future areas of research. Figure 4-2 (below) outlines the factors that are used to evaluate potential programs for inclusion in our research portfolio.

Evaluation factors range from questions about Agency priorities to NERL's ability to advance the state of the science. First and foremost, the area of research must be essential to EPA's and ORD's environmental protection mission. Also, and of great importance to NERL, it must be exposure research as articulated within this document. Areas that pass though these two initial filters are then considered in light of several other criteria.

For the many issues that meet those broad considerations, any decision by NERL to undertake a research effort must take into consideration the nature and scope of the problem, the extent to which it is being addressed by others, and the likelihood of having a significant impact. Does NERL bring a unique capability

Does the research support the Agency's Mission?

↓

Is it exposure research?

↓

The proposed research should meet one or more of the following criteria:

- Does it require NERL's expertise or unique facilities?
- Does it require an integrated approach that only NERL can provide?
- Is exposure and exposure data an integral part of the overall research question?
- Does the scope and scale of the research require NERL's involvement?
- Is it a priority research area for the Agency?
- Is it the right time for NERL's involvement?

Figure 4-2. Evaluation filters and criteria for assessing potential research areas

to the issue, either through the Laboratory's expertise or through unique facilities that are unavailable elsewhere? Does it require an integrated multidisciplinary program? Some research areas are well engaged by other organizations and NERL's incremental contribution would add marginal value. Alternatively, the problems within the area may be so broad in scope or generally intractable that NERL's efforts would make insufficient headway to justify the effort.

Ultimately, a research commitment by NERL must be implemented by its workforce, requiring that NERL have the appropriate workforce size, skill mix, and other resources to address the issue.

4.1.2 Designing a Research Program

Integrated, multidisciplinary, exposure research programs are developed for each program area in NERL's portfolio based on the principles of exposure science and designed to be results-oriented and customer-focused. Programs should have clear priorities, critical paths for meeting each priority, and a set of products and outcomes that demonstrate the research effectiveness.

Appendix A on page 41 provides an overview of how ORD identifies the research outcomes required by a given Multi-year Plan (MYP). This section presents information specifically related to developing and implementing NERL's exposure research programs to address the goals developed in the MYP.

Because EPA is a mission-driven Agency, all of ORD research is applied. The types of research required for environmental protection and conducted by NERL can be thought of as falling into one of two complementary categories: core and problem-driven. Core research seeks to understand the key biological, chemical, and physical processes that underlie environmental systems, and leads to products that may address issues common to many EPA programs. Examples of core research in NERL include efforts to understand exposure and factors responsible for exposure, as well as research to develop predictive models and tools for describing exposure pathways of stressors in human and ecological systems. Problem-driven research is directed at specific Agency needs that arise due to regulatory requirements or court-ordered deadlines. In problem-driven research, NERL brings existing knowledge, tools, models, and data to bear on high-priority Agency problems, augmented by limited, focused research efforts to address gaps and deficiencies in existing knowledge. An important characteristic of problem-driven research is that it be packaged in forms that are most readily communicated to and used by the clients, especially program offices. As an example of problem-driven research, NERL develops analytical methods for identifying and defining unregulated drinking water contaminants, which informs EPA's Office of Water in setting regulatory requirements of the Safe Drinking Water Act. By maintaining a portfolio that balances core and problem-driven research, NERL is best able to address the exposure science research needs of the Agency.

In all circumstances, research programs are initiated by first considering the Agency's environmental protection goals and developing an understanding of exposure issues related to achieving these goals. As described in Chapter 2, the Agency may employ exposure science in deciding whether mitigation is necessary; in determining how best to mitigate; and in establishing the effectiveness of mitigation actions or policies. Below are examples of environmental protection questions faced by the Agency that illustrate each of these perspectives.

- Does exposure to particulate matter 2.5 micrometers or smaller in ambient air cause death and hospitalizations?
- How should the introduction of invasive species through ballast water discharge be regulated?
- Have the efforts to control mercury in combustion sources resulted in a measurable decrease in the levels of mercury in the environment, leading to reduced exposures to humans and ecosystems?

Articulating such questions and translating them into scientific objectives are the first steps in outlining a research implementation plan. Overlaying these questions onto the source-to-outcome conceptual model helps develop the context for the role of exposure, assists in constructing the critical path for the research, and aids in identifying key partners and points in integration. Once a critical path for achieving those scientific objectives is outlined, the current limitations of exposure science and the critical needs for exposure data, methods, and models are determined. Should the science needs exceed NERL's ability to address them, NERL directs its research efforts towards those questions that either have the greatest uncertainty or provide the greatest opportunity for advancing science to support exposure and risk assessment.

4.1.3 Communicating NERL's Research

Conducting cutting-edge research is not enough. To have an impact, the results of our research programs must be communicated to our customers, stakeholders, partners, and to the scientific community. NERL's communication strategy for research will focus on having a high impact in advancing environmental protection and the state of exposure science.

To be recognized as leaders in the research community, NERL scientists must publish in high-impact, peer-reviewed journals. Other activities such as membership in professional societies, participation on editorial review boards and science advisory committees, and development of workshops, workgroups and committees are also required. Communication within the scientific community maximizes the exchange of ideas and approaches to support the Agency's mission. Measures of success in this area include peer-reviewed publications, reports rated as highly-cited and publications rated as having high-impact.

NERL must also ensure that our research is used by the Agency by delivering high-quality, high-impact products to our clients. Working cooperatively, NERL scientists, Division Directors, Associate Directors, and Assistant Laboratory Directors must make certain that NERL research products, which include peer-reviewed software, methods, reports, and journal articles, are strategically provided to its customers for use in their decision-making. NERL should promote implementation of its tools within the Agency by providing workshops, Internet downloads, and user manuals that advance these tools and models. NERL will also demonstrate the intended use of its high-quality methodology through case studies and pilot programs with its partners. Finally, NERL should track its results against metrics for success, including bibliographic analysis, citation indices, and customer use or satisfaction surveys.

4.2 Internal Business Processes: To succeed, how do we carry out our work?

NERL believes that sound science can only come out of a sound organization — that ultimately what we do depends on how we do it. Forging an effective, responsive research organization out of many talented individuals and geographically-separated divisions requires a shared, cohesive vision of ourselves, commitment to a set of working principles, and the development of business practices that integrate and leverage our capabilities.

4.2.1 Management Principles

NERL, as a laboratory, is committed to conducting high-quality, relevant exposure research in an integrated, multidisciplinary, collaborative, and effective manner. Our management processes are crucial to achieving this goal and should promote our core organizational principles. The core principles that underpin NERL's structures and management processes are articulated in the following paragraphs.

❖ We are the National Exposure Research Laboratory.
The title NERL embraces several important principles. We think and act as a single laboratory. We provide leadership at national and international levels in exposure science. Finally, the EPA is the client base, thus NERL must plan and conduct its research based on direct consultation and communication with our clients within the Agency.

❖ Science comes first.
We need to understand where we are going with our science, and then manage ourselves and our resources to get there. As a corollary, NERL will develop and use only those processes that are required to manage its science. NERL will not use processes that are more complex than needed to achieve its science goals.

❖ Apply multidisciplinary approaches where applicable.
The EPA is faced with many large, complex problems that are often best addressed with multidisciplinary research programs that use cutting-edge research tools. Developing an environment that fosters such collaborative, multidisciplinary research will set us above other organizations. This concept applies to research we conduct within NERL as well as research that is conducted across ORD.

Collaborative research allows scientific processes to be used in understanding and managing the impact of stressors as they move from sources to humans and ecosystems. This brings multiple perspectives to a problem for better solutions, and provides opportunities to leverage NERL's state-of-the-science knowledge and skills in multiple areas.

❖ Seek functional solutions first.
Organizations often use structural fixes to deal with functional problems and this usually does not work. NERL should be able to work within the current structure and optimize its implementation processes to achieve the established goals.

❖ Optimize use of existing resources.
NERL has an impressive array of resources to accomplish its mission. Additionally, the Agency has many different high-priority problems to address. NERL will strive to optimally align its existing resources, including staffing, with the highest-priority Agency problems that require exposure science.

4.2.2 Management Processes

Several processes must be in place for NERL to implement an optimized cross-laboratory research program. These processes should allow NERL to fully integrate planning across the laboratory; optimize use of staff, research dollars, and facilities; and efficiently manage resources. If successfully executed, they should serve as a starting point for changing the laboratory culture and moving forward. Importantly, they will allow NERL to work together as a laboratory to produce relevant, high-quality research results.

Implementation Plans and Divisional Business Plans are the documents that fully articulate what we do and translate into how we do it. For those plans to be effective, they must be shaped and informed by the strategic directions as developed above and fully integrated across the laboratory. Currently, Implementation Plans serve as the basis for planning and should provide the mechanism for integration. Each plan is intended to develop a focused, integrated research program that is conducted to solve a complex environmental problem of national significance. The process is designed to consider the Agency's highest priority needs and NERL's resources in addressing key Agency needs.

Developing and conducting a set of well-integrated research programs at the laboratory level is an optimization challenge. Each Implementation Plan must direct NERL resources to address the high-priority exposure associated with an environmental problem. The full set of plans must optimally deploy those resources to move exposure science forward. Thus, prior to developing individual plans, NERL must look across plans to prioritize the research and identify leveraging opportunities (see text box below). It is understood that the highest-priority research should be resourced first. However, as a part of this process, resources (staff and FTEs) must also be balanced across both divisions and plans. The overall goal is to ensure that sufficient resources are available for successfully conducting the most relevant and responsive research in those areas where NERL plans to make a commitment. Understanding the priorities and the distribution of resources will also allow NERL to make informed decisions about redirecting resources, when needing to respond to new initiatives or when faced with reduced resources. Finally, NERL should use the information on science priorities and proposed research to direct workforce planning (as described in section 4.3).

Basis for Prioritizing Research

- **Agency needs**
- **Ability to demonstrate an impact**
- **Ability to make a unique contribution**
- **Appropriate balance between core and problem-driven research**

A number of non-traditional approaches will be needed to staff and implement multidisciplinary research across NERL. The primary goal is to ensure that critical expertise is provided to all programs across the laboratory. Other goals include greater efficiency, increased collaboration, development of new skills and capabilities, advancement of new technologies, and increased scientific leadership. Centers of Excellence (COE) are envisioned as one approach for efficiently using critical technical expertise in integrated laboratory research programs. The general concept for a COE is based on identifying research areas or capabilities of common need that present opportunities for leveraging facilities and experienced staff to optimize technical performance. Potential areas for establishing COEs include the development of analytical methods and technologies, and the application of statistical methods and informatics.

In addition to the challenges presented by planning and carrying out research in a number of high-priority areas, NERL faces the challenge of creating integrated, multidisciplinary research programs across six divisions in four locations. NERL has traditionally managed much of its research at the level of the individual researcher or branch; however, creating an integrated exposure program will require nontraditional approaches to management.

Creating and embracing this exposure framework is a prerequisite for NERL to function as a single national exposure laboratory. With a common vision, NERL can be unified in purpose and in action. The development of implementation plans by researchers from across NERL, who have been challenged to plan from a NERL-wide perspective, is also essential for creating an integrated exposure program.

Finally, the research, once planned, needs to be executed in an integrated fashion; across disciplines, across the source-to-exposure pathway, and across locations. To that end, NERL is exploring organizational practices and new technologies that promote collaboration and integration, such as virtual teams and Web-based communications. As NERL moves forward, it is important to identify and implement proven and time-tested best management and organizational practices; to seek the counsel of organizational leaders and consultants to guide the process; and to commit to adopting management systems that simplify rather than complicate laboratory operations.

NERL faces the challenge of creating integrated, multidisciplinary research programs across six divisions in four locations.

4.3 Employee/ Organization Capacity: To achieve our vision, what competencies are needed?

Achieving NERL's goals to provide leadership in exposure science and conduct high-quality science to support EPA's mission requires, first and foremost, that we have scientists with the necessary skills to conduct cutting-edge exposure research. We must also have a workforce that embraces the concept of integrated, multidisciplinary research programs and that has the flexibility to adapt to changing technical demands and changing organizational needs. Finally, we must develop leadership throughout the organization to successfully meet today's challenges and the challenges of the future. This section will discuss the concepts for strategic workforce planning and approaches for developing our leaders within NERL.

4.3.1 Strategic Workforce Planning

NERL has a number of challenges when developing a strategic workforce plan. As with all Federal organizations, we have a very stable workforce with little staff turnover;

yet we are a scientific organization that must keep pace with the newest science and changing science needs. Thus our planning must identify those critical areas where we need expertise and the number of staff/researchers needed in each area. We must also develop strategies for providing more flexibility within the workforce. Finally, we want to identify, develop, and reward staff who work across organizational boundaries, who participate in integrated, multidisciplinary research and who can adapt to new technologies and new problems.

NERL is a large research organization with six divisions in four geographical locations. Each division has a unique history that has led to strengths within various scientific disciplines. Nonetheless, the workforce within these divisions and across NERL as a whole should possess a diverse set of skills and expertise that can be used to address complex exposure research questions.

Figure 4-3 (below) depicts the varied expertise that will be required to address the full range of exposure issues for both human health and environmental protection. The box on the left-hand side of the figure shows the scientific expertise needed to assess stressors and their movement throughout the environment. The box on the right-hand side shows the needed expertise to describe the distribution, behaviors, and characteristics of the receptor that will lead to exposure and dose. The box at the bottom of the figure shows the technical expertise that cuts across disciplines and is used to address important exposure issues.

A work force consisting of only principal investigators, even if all of the required disciplines are represented, is not sufficient to carry out a program of exposure research. In order to provide a stable environment for conducting and completing our research, NERL must develop a self-sustaining workforce that can operate independently of ORD's changing

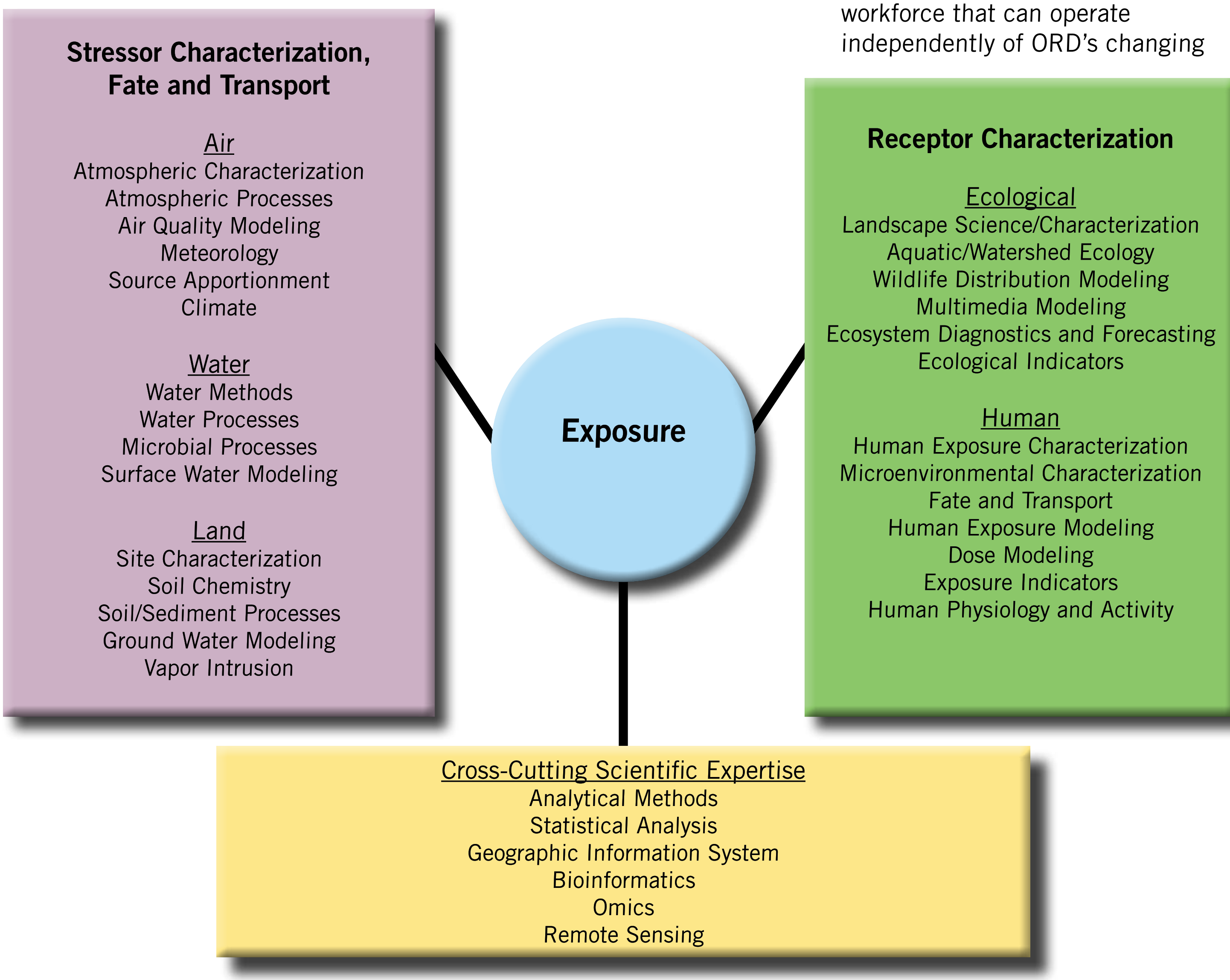
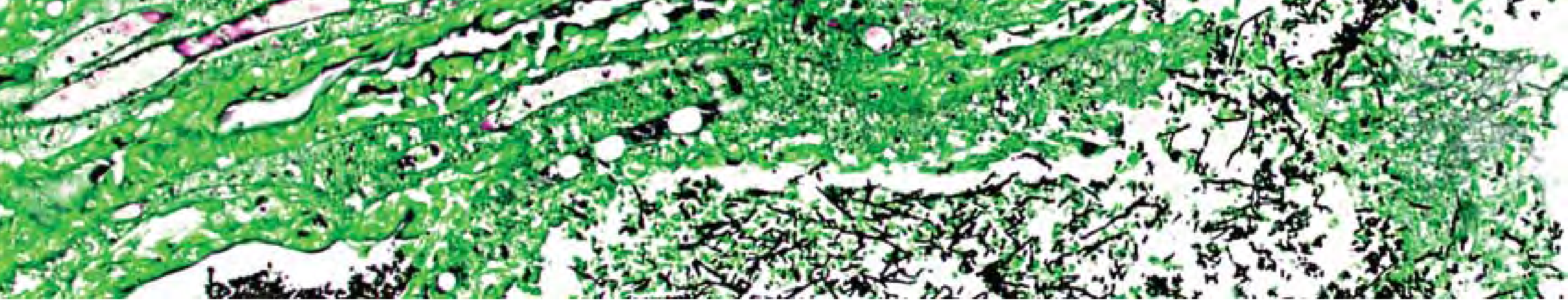


Figure 4-3. Scientific expertise for exposure research



budget. Our staff must include both principal investigators and staff who can provide technical support for these investigators. With this approach, all of our scientists can still maintain critical science programs regardless of funding levels. As funding increases, additional work can be accomplished using extramural mechanisms.

A strategic workforce plan should evaluate the core science that we conduct and the critical expertise and numbers of staff (both PIs and technical support staff) needed to conduct this science. To effectively leverage our resources and to provide the greatest flexibility, this analysis should be done not only at the divisional level but also at the laboratory level. Structures such as the NERL-wide Centers of Excellence can be used to maintain the intellectual base for the expertise that provides technical input to all exposure research across the laboratory (see lower box in figure 4-3). Since the workforce in NERL is very stable, we must be able to anticipate scientific workforce needs five to ten years in advance. It is very important that our planning also include education and training for our current staff to insure that everyone has state-of–the-art skills and understands how these skills can be applied to important exposure issues. We must also devise strategies for obtaining scientific expertise rapidly in new areas as they emerge.

Finally, as we hire new staff, we must ensure that our hiring strategies identify not only the scientific expertise that is required but also the core set of traits and competencies that our staff must possess to be effective contributors in NERL. As examples, traits and competencies that would be consistent with the goals set forth in the framework would include: commitment to NERL's mission, innovative, communicative, professional, flexible, forward-thinking, and collaborative. Individuals with these attributes will enable NERL to advance exposure science and address the Agency's most pressing environmental protection issues through cutting-edge, integrated multidisciplinary research.

4.3.2 Leadership Development within the Workforce

NERL is its people and every individual in the laboratory must feel responsible and work towards its success.

It is important that NERL's planning include education and training for staff to insure that everyone has state-of-the-art skills and understands how these skills can be applied to important exposure issues.

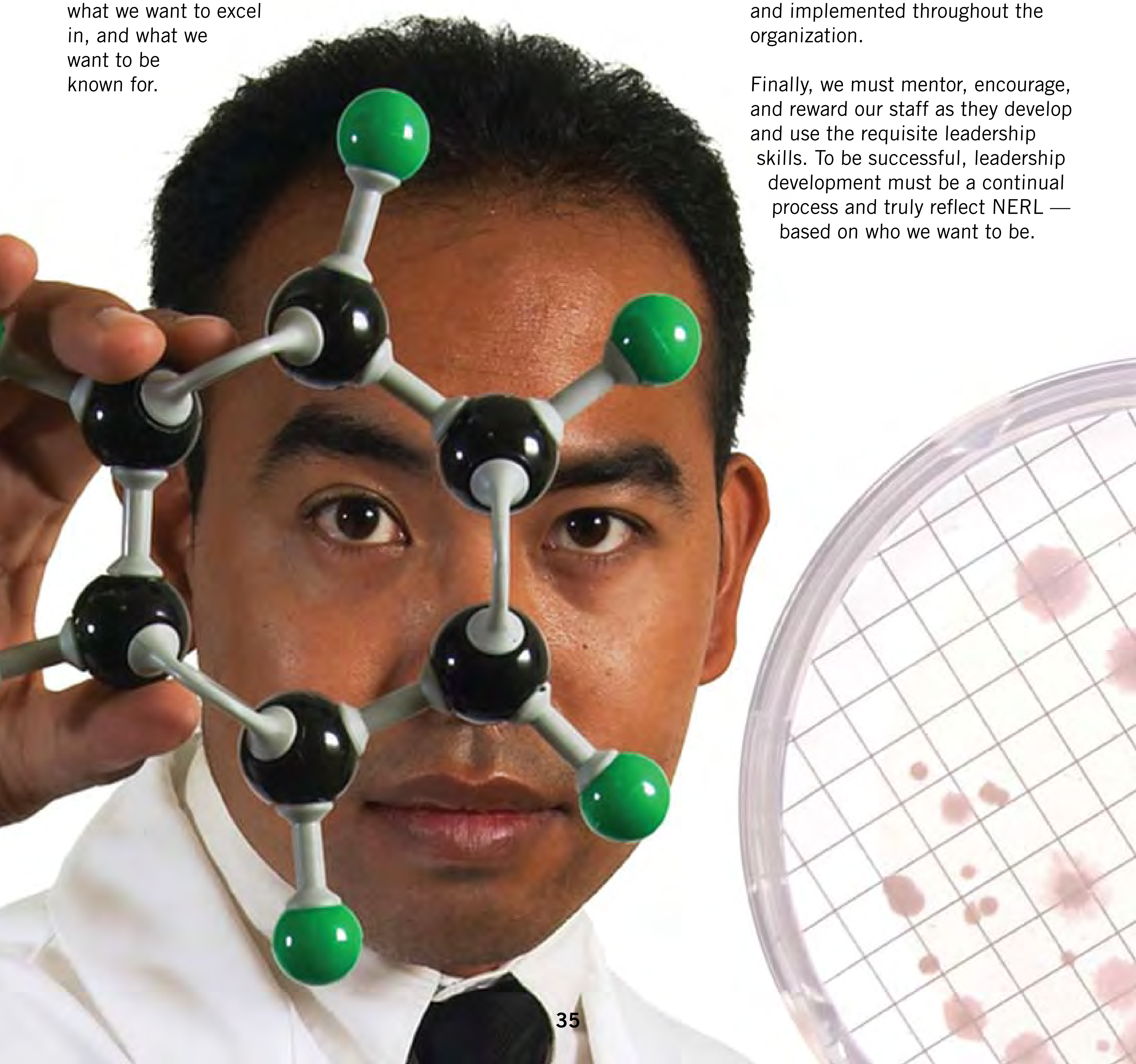
Thus, it is important that we develop individual leadership at all levels throughout the organization. For continued success, we must also promote organizational leadership by developing our next generation of leaders.

Consistent with the principles of a strategy-focused organization, leadership development will be derived based on the concepts set out in the exposure framework, which defines who we are, what we want to excel in, and what we want to be known for.

From this starting point, both the individual and organizational traits and competencies required for leadership throughout the organization can be identified. Individual competencies would address scientific, programmatic, and organizational leadership. Organizational competencies would address the direction of the organization — what we excel in and what we are known for.

Understanding our direction and developing a list of traits and competencies for leadership in the organization is a critical first step toward leadership development in NERL. Our leadership vision and competencies must then be communicated throughout the organization, so every individual knows what they should be striving for in their development efforts. Leadership programs specifically targeted toward essential traits and competencies need to be developed and implemented throughout the organization.

Finally, we must mentor, encourage, and reward our staff as they develop and use the requisite leadership skills. To be successful, leadership development must be a continual process and truly reflect NERL — based on who we want to be.



4.4 Financial Resources Management: To achieve our goals, how do we efficiently allocate resources?

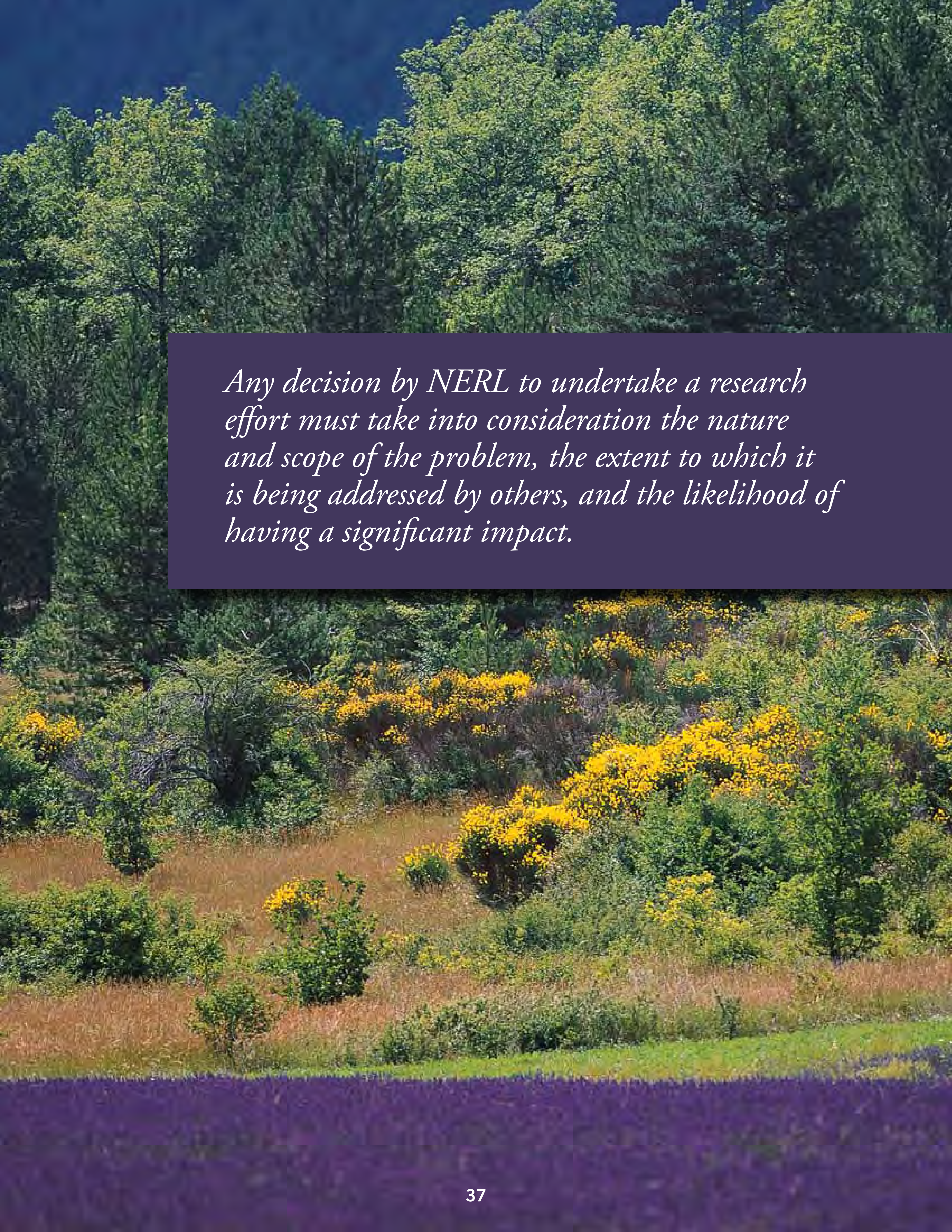
For NERL's researchers and staff to achieve the objectives outlined in this framework, they must be supported by capital and financial resources — buildings and equipment, administrative and technical support, and an adequate budget. This requires the effective and efficient allocation of financial resources. The need to leverage those resources and to promote science integration lead us to perform that allocation with both NERL-wide and division-specific perspectives in mind. The business plans prepared by each division must be developed in concert and with complementary elements, in order to achieve the NERL objectives of resilience, optimization, and integration.

4.4.1 Financial Resilience

Historically, NERL has used its financial resources to enhance its scientific capabilities, employing a number of mechanisms to provide research support to its principal investigators. As uncertainty in budgets has increased and effective funding levels decreased, NERL has been moving to a model of supporting research with in-house staff. During the transition, extramural funds will continue to support in-house research as well as address high-priority acquisition needs. Funds that support in-house research are provided to divisions in a manner that reflects the size, productivity, and discipline-specific demands of its investigator workforce, whereas the priorities for extramural acquisitions are determined as part of the ORD planning process.

4.4.2 Optimization and Integration

The optimal distribution of financial resources across NERL should both sustain the critical scientific capabilities to advance exposure research and promote the integration of organizations and scientific disciplines to that end. Research planning — at both the strategic and implementation levels — lays the critical path for NERL research. Planning collectively promotes the transparent and effective deployment of budgetary resources at each stage of that critical path. Similarly, the acquisition and maintenance of cutting-edge facilities and instrumentation are essential to a high-performing workforce. Planning for large capital investments, then, must align with the highest priority research as well as the potential for collaborative use of the facilities and instruments.



Any decision by NERL to undertake a research effort must take into consideration the nature and scope of the problem, the extent to which it is being addressed by others, and the likelihood of having a significant impact.

Integrated, multidisciplinary, exposure research programs are developed for each program area in NERL's portfolio based on the principles of exposure science and designed to be results-oriented and customer-focused.

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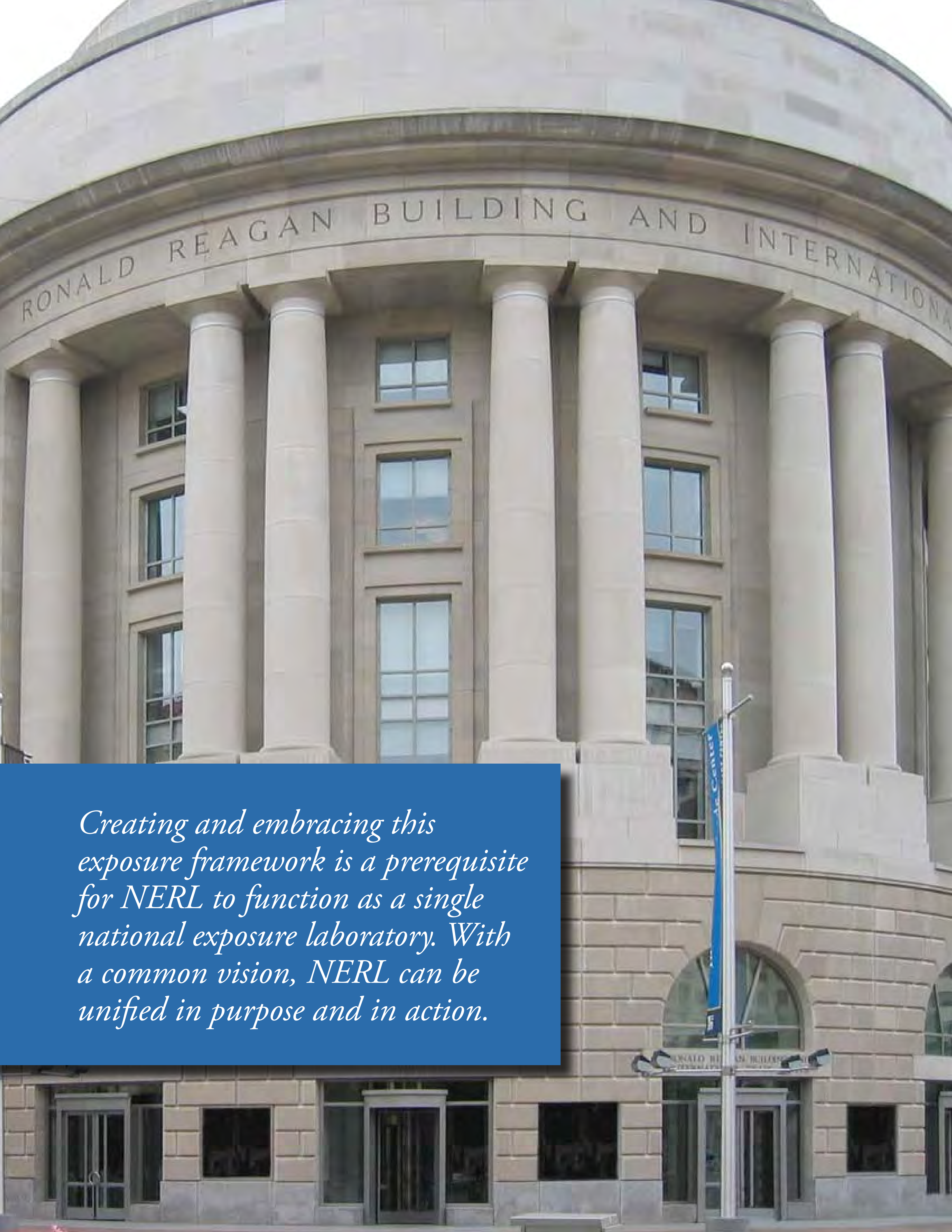

Creating and embracing this exposure framework is a prerequisite for NERL to function as a single national exposure laboratory. With a common vision, NERL can be unified in purpose and in action.

Appendix A
NERL's Research Within the Context of ORD

The EPA's research agenda is determined by means of a research planning process involving every organizational level within the Agency. Figure A-1 is a simplified diagram for this process. ORD's research is driven by the five Agency goals described in the U.S. EPA's Strategic Plan (www.epa.gov/ocfo/plan/plan.htm). Within each goal, ORD works in partnership with numerous stakeholders to identify the highest priority research topics. The objective is to focus on environmental problems that pose the greatest risk to people and the environment; to reduce uncertainties which will improve our ability to identify risks; and to clearly help the Agency fulfill its regulatory mandate. For each goal, ORD commits to reaching certain milestones and delivering specific products within a given time period.

ORD's Multi-Year Plans (MYP) provide the long-term (5 to 10 year) focus for a given area of research, integrating efforts across all of ORD's Labs and Centers. For each MYP, an ORD team conceptualizes a framework for the research with long-term goals that will be addressed across ORD. NERL plays a vital role in the development of the MYPs. All of NERL's research is included in these plans, and the Laboratory is held accountable for meeting commitments contained in MYPs.

NERL develops research Implementation Plans, using ORD's MYPs as roadmaps. The Implementation Plans bring the planning process to the operational level within the Laboratory. Separate plans are developed for each of ORD's MYPs and are intended to develop focused and integrated programs. For each Implementation Plan, steering committees made up of scientists, Associate Laboratory Directors, and Managers within NERL and across the Agency are charged with identifying the important programmatic research questions. Scientists across the Laboratory are then tasked with developing specific research programs to address these questions.

In summary, while the problems NERL is tasked to solve are defined by the Agency's planning process, the research agenda for solving those problems is determined by NERL and its staff. Although the relative emphasis in topic areas may change as ORD priorities and budgets shift, substantial efforts are made by NERL to build and maintain research programs that are relevant to the scientific problems and responsive to the Agency needs.

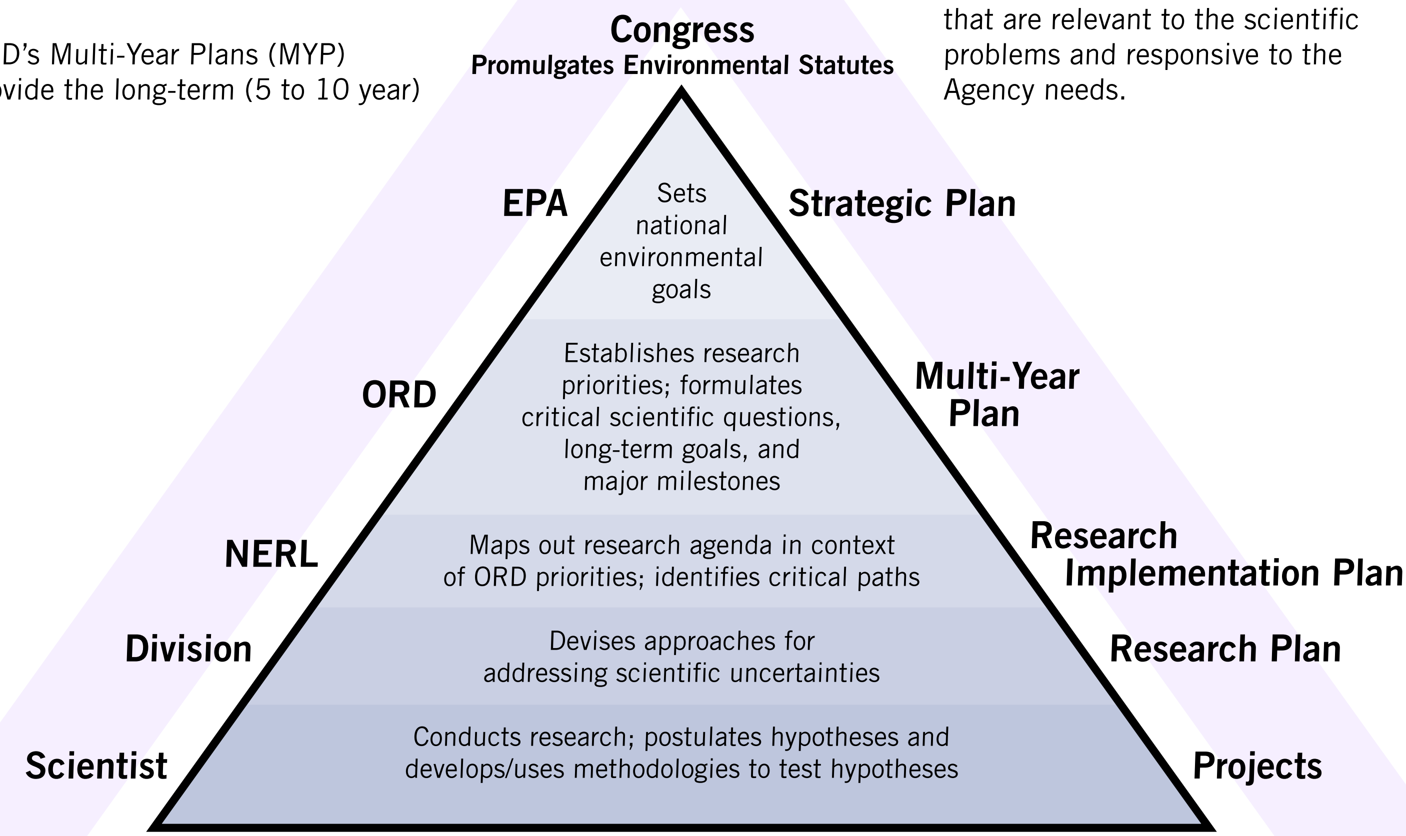

Figure A-1. Research planning in EPA

Acronyms

BOSC .... Board of Scientific Counselors

COE ....Centers of Excellence

EPA... Environmental Protection Agency

FTE .... Full Time Employee

MYP ....Multi-year Plan

NERL .... National Exposure Research Laboratory

NHEERL.. National Health and Environmental Effects Research Laboratory

NRC ....National Research Council

NRMRL ....National Risk Management Research Laboratory

ORD .... Office of Research and Development

PI .... Principal Investigator

RfD .... Reference Dose

TMDL ....Total Maximum Daily Load

USEPA ....United States Environmental Protection Agency

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