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EPA Office of Research and Development (ORD) National Health and Environmental
Effects Research Laboratory (NHEERL) and National Exposure Research Laboratory
(NERL)
January 25, 2010

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Schedule and Logistics
Schedule for January 25, 2010
SAB Science Integration for Decision Making Interviews -ORD NHEERL and NERL
109 T.W. Alexander Drive in Research Triangle Park, NC

9:00 - 10:30 a.m.	Meeting with Director and Senior Managers, National Health and Environmental Effects Research Laboratory (NHEERL), Room B301
11:00 a.m. - 12:30 p.m.	Meeting with NHEERL scientists, Room B301
12:30 p.m. - 1:15 p.m.	Lunch
1:15 a.m. - 2:30 p.m.	Meeting with Director and Senior Mangers, National Exposure Research Laboratory (NERL), Room D301
2:45 p.m. - 4:00 p.m.	Meeting with NERL scientists, Room D301

Logistics

SAB members meet at 7:15 for breakfast (Marriott at Research Triangle Park, 4700 Guardian Drive, Durham, NC, 27703, 919-941-6200). Jim Bus will drive to the laboratory and the schedule will allow for transportation and security screening.

SAB Science Integration for Decision Making Fact-Finding Meeting
Meeting with Director and Management Team, EPA Office of Research and Development
(ORD) National Health and Environmental Effects Research Laboratory (NHEERL)
Conference Room B301
109 T.W. Alexander Drive, Durham, NC
Call-in Number for SAB subgroup: 866-299-3188, access code 343-9981 and press the #
sign.
January 12, 2010, 9:00-10:30 a.m.
Draft Agenda

Purpose of Interview: to help SAB Committee members learn about NHEERL current and recent experience with science integration supporting EPA decision making so that the SAB can develop advice to support and/or strengthen Agency science integration efforts.

1. Introductions facilitated by the SAB Staff Office
2. Discussion facilitated by SAB Members
 - Practices for integrating science to support decision making
 - Consideration of public, stakeholder, external scientific, and other input in science assessment
 - Drivers and impediments to implementing past recommendations for science integration
 - Ways program receives feedback on how science is used in decision-making
 - Workforce to support science integration for decision making
3. Identification of any follow-up actions

Planned participants

EPA ORD NHEERL

Hal Zenick, Director
Bob Hetes, Acting Director, Research Planning and Coordination Staff
Steven Hedtke, Associate Director for Ecology
Jennifer Orme-Zavaleta, Acting Director, Environmental Public Health Division
John Rogers, Acting Director, Integrated Systems Toxicology Division
Ram Ramabhadran, Acting Director, Toxicology Assessment Division
Carl Richards, Director, Mid-Continent Ecology Division
Mace Barron, Acting Director, Gulf Ecology Division
Jonathan Garber, Director, Atlantic Ecology Division
Thomas Fontaine, Director, Western Ecology Division

SAB Committee on Science Integration Committee Members

Dr. Deborah Cory-Slechta, University of Rochester
Dr. James Bus, Dow Chemical Company
Dr. Wayne Landis, Western Washington University (by telephone)
Dr. Thomas Theis, University of Illinois at Chicago (by telephone)
Dr. Terry Daniel, University of Arizona (by telephone)

SAB Staff Office

Dr. Vanessa Vu, Director
Dr. Angela Nugent, Designated Federal Officer

**SAB Science Integration for Decision Making Fact-Finding Meeting
Meeting with Scientists, EPA Office of Research and Development (ORD) National Health
and Environmental Effects Research Laboratory (NHEERL) Conference Room B301
Call-in Number for SAB subgroup: 866-299-3188, access code 343-9981 and press the #**

sign.

January 12, 2010, 11:00 a.m. - 12:30 p.m.

Draft Agenda

Purpose of Interview: to help SAB Committee members learn about NHEERL current and recent experience with science integration supporting EPA decision making so that the SAB can develop advice to support and/or strengthen Agency science integration efforts.

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 - Workforce to support science integration for decision making
3. Identification of any follow-up actions

Planned participants

EPA ORD NHEERL

Kevin Crofton

Bob Devlin

Will Boyes

Doug Wolf, ALD for Safet Pesticides/Safe Products MYP, Land MYP, Nantechnology, EDCs

Bill Russo, ALD for Water and Land

Bob Hetes, Acting Director, Research Planning and Coordination Staff

Kevin Summers, AD for Science, GED

Wayne Munns, AD for Science, AED

Janet Keough, AD for Science, MEDSAB

Committee on Science Integration Committee Members

Dr. Deborah Cory-Slechta, University of Rochester

Dr. James Bus, Dow Chemical Company

Dr. Wayne Landis, Western Washington University (by telephone)

Dr. Thomas Theis, University of Illinois at Chicago (by telephone)

Dr. Terry Daniel, University of Arizona (by telephone)

SAB Staff Office

Dr. Vanessa Vu, Director

Dr. Angela Nugent, Designated Federal Officer

Available Biosketches for NHEERL Managers and Scientists

Dr. Harold Zenick is Director, National Health and Environmental Effects Research Laboratory (NHEERL) in the Office of Research and Development in the US Environmental Protection Agency (EPA). Dr. Zenick earned a Ph.D. in Physiological Psychology from the University of Missouri (Columbia). He also completed a Post-Doctoral Fellowship in Toxicology at the University of Cincinnati. Before coming to EPA, Dr. Zenick spent 13 years in academia with the Department of Environmental Health in the University of Cincinnati Medical School, preceded by an appointment at New Mexico Highlands University. Dr. Zenick serves on the Executive Board to the National Toxicology Program and as EPA's liaison to NCER-ATSDR's Board of Scientific Councilors. He co-chairs respectively, two cross-EPA workgroups: one on the Futures of Toxicity Testing; the other on Biomonitoring. He has received numerous awards including being a two-time recipient of the prestigious Presidential Meritorious Executive Rank Award and the ORD Statesmanship and Diversity awards. Dr. Zenick has participated on a number of prominent National and Federal work groups and currently serves as co-chair of federal Pharmaceuticals in the Environment Work Group within the Toxics and Risk Subcommittee under the auspices of the Office of Science, Technology and Policy. Within the Society of Toxicology, he has served as the President of three specialty sections; the most recent being the Occupational and Public Health Specialty Section, and was recently elected to the Awards Committee. Dr. Zenick has over 100 publications. His current interests are in integrating human health and ecological risk assessment, strengthening the linkages between environmental and public health agendas and agencies, and the application of emerging computational, informational and molecule sciences in improving toxicity testing and risk assessment practices.

William K. Boyes, PhD is currently a research scientist at the Neurotoxicology Branch, National Health and Environmental Effects Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency in Research Triangle Park, NC. Previously, he served as the Acting Director of EPA's Neurotoxicology Division and as Chief of the Neurophysiological Toxicology Branch. Dr. Boyes received a PhD in Environmental Health from the University of Cincinnati, College of Medicine in 1981. From 2007-2009, he served as President of the International Neurotoxicology Association. He is currently Associate Editor for the journal *NeuroToxicology*. His research interests include neurotoxicity, visual system toxicity, phototoxic nanomaterials, and toxicity of volatile organic compounds including fuel emission components. Dr. Boyes has published numerous peer-reviewed manuscripts and book chapters dealing with various aspects of environmental neurotoxicity. Dr. Boyes is the recipient of Bronze, Silver and Gold Medal EPA Service awards, as well as multiple EPA Scientific and Technological Achievement Awards. Dr. Boyes holds an Adjunct Faculty appointment at Duke University and lectures periodically at the University of North Carolina in Chapel Hill and North Carolina State University. He also coordinates the scientific reviews of documents submitted to EPA under section 211(b) of the Clean Air Act regarding the potential health effects of fuels and fuel additives, including several gasoline oxygenate compounds and methylcyclopentadienyl manganese tricarbonyl (MMT). In addition, he has authored or co-authored many EPA documents including 870 Health Effects Testing Guidelines and Neurotoxicity Risk Assessment Guidelines.

Dr. Kevin M. Crofton received his Ph.D. in Toxicology from the University of North Carolina at Chapel Hill in 1986. He has been working for the past 20 years as a neurotoxicologist in the Office of Research and Development of the U.S. Environmental Protection Agency, in Research Triangle Park, North Carolina. His research interests include developmental neurotoxicity, with an emphasis on the use of mode-of-action models to improve risk assessments. He is an Adjunct Assistant Professor in the Department of Toxicology at North Carolina State University and the Curriculum in Toxicology, University of North Carolina at Chapel Hill. Dr. Crofton's professional activities include membership in numerous scientific societies and participation on many professional review boards. He currently serves on the WHO/IPCS Programme on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals, Aggregate/Cumulative Risk Assessment Project, and the ILSI Research Foundation Board of Science Advisors. He has presented invited lectures for a variety of government agencies in Europe, Canada, and the U.S., and for numerous professional societies and universities. In addition, he has authored or coauthored at least nine book chapters or reviews and over 125 peer reviewed publications.

Thomas D. Fontaine, Ph.D., Director, Western Ecology Division. After earning his Ph.D. in Environmental Engineering Sciences from the University of Florida in 1978, Dr. Fontaine started his professional career as a scientist at the University of Georgia's Savannah River Ecology Laboratory. In 1983 he joined NOAA's Great Lakes Environmental Research Laboratory as a research program leader and collaborated extensively with the EPA and the International Joint Commission on solving Great Lakes contamination issues. Dr. Fontaine joined the South Florida Water Management District where he served from 1990 to 2001, first as Division Director for Water Quality, then for Everglades Research, and then as senior manager of the Environmental Monitoring and Assessment Department with oversight of three divisions. Dr. Fontaine joined the Federal Government's Senior Executive Service in 2001 when he was appointed Director the USEPA's Western Ecology Division.

Dr. Fontaine specializes in systems ecology and modeling, research program development, and communication at the political and scientific interface. In Florida, he was a member of the Governor's Commission for a Sustainable South Florida Scientific Advisory Panel and received the National Audubon-American Association of Engineering Societies Palladium Medal for his team's efforts to provide the scientific and engineering foundation for Everglades restoration. He has been an invited panelist and speaker both nationally and internationally, has published widely, and is a founding (and current) member of the Editorial Board for the professional journal "Frontiers in Ecology and the Environment".

In his current capacity as Director of EPA's Western Ecology Division he oversees research on ecosystem services in support of human well being; the influence of non-navigable streams and wetlands on navigable waters; the effects of alternate futures (as influenced by population growth, climate change and other factors) on salmon populations, water quality, and water quantity; research and development on monitoring designs and indicators for assessing freshwater and estuarine ecosystem condition and the effectiveness of agency actions; and the temporal and spatial effects of novel technologies (e.g. GM crops, nanomaterials, and pesticides) on terrestrial systems including wildlife.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Photocopy this page or follow this format for each person.

NAME John M. Rogers, Ph.D.	POSITION TITLE Director (acting) Toxicity Assessment Division, NHEERL, EPA
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EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of Miami, Coral Gables, FL	B.S.	1976	Biology
University of Miami, Coral Gables, FL	M.S.	1979	Biology
University of Miami, Coral Gables, FL	Ph.D.	1982	Biology
University of California, Davis, CA	Postdoctoral	1984	Nutrition

RESEARCH AND/OR PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED THREE PAGES** (for a modular grant application)

Professional Experience:

Sept. 1976 - May 1982	Graduate Teaching Assistant, Biology Dept., University of Miami.
May 1982 - July 1982	Lecturer in Biology, Biology Dept., University of Miami
Nov. 1984 - Dec. 1988	Research Biologist, Perinatal Toxicology Branch, Developmental Biology Division, HERL, U.S. EPA
Spring, 1987; Summer, 1990	Visiting Assistant Professor, Department of Zoology, North Carolina State University, Raleigh, NC
Jan. 1989 - Mar. 1991	Chief, Experimental Teratology Section, Perinatal Toxicology Branch, Developmental Toxicology Division, Health Effects Research Laboratory, U.S. EPA
March 1991 – May 2009	Chief, Developmental Biology Branch, Reproductive Toxicology Division, NHEERL, U.S. EPA
October 2007-May 2009	Acting Chief, Gamete and Early Embryo Biology Branch, RTD, NHEERL, USEPA

Professional Societies

Teratology Society; Society of Toxicology; Developmental Origins of Health and Disease (DOHaD) Society	
1997 - 2000	Secretary/Treasurer, SOT Repro./Devel. Tox. Specialty Section
1998 - 2004	Treasurer, Teratology Society
2002- 2005	VP-elect(02), VP(03), President (04), Past-President (05) SOT Reproductive and Developmental Toxicology Specialty Section
2008-2011	VP-elect(08), VP(09), President (10), Past-President (11), Teratology Society

Honors, Awards:

EPA Scientific and Technical Achievement Awards: 1991 Level II, Level III; 1992 Level II; 1993 Level III

(2); 1994 Level I; 1996, Level III; 1998, 2006, Honorable Mention. Lucille S. Hurley Award, U.C.-Davis, 2005; Robert L. Brent Award, Teratology Society. 2006.

Professional Activities (last 5 years)

Editorial Board, Birth Defects Research Part B, Reproductive and Developmental Toxicology, 2003-present

Editorial Board, Journal of the Developmental Origins of Health and Disease, June 2009-present

Co-Chair, SOT Workshop: "Zebrafish – A Model Organism for Assessing Developmental Toxicity in Drug Discovery/Environmental Risk Assessment." Baltimore, MD, SOT, March 24, 2004.

Member, FASEB NIH Federal Funding Committee (representing the Teratology Society), 2005-present.
Co-Chair, SOT Symposium: "Developmental Toxicology of the Lung." New Orleans, LA, SOT, March 6, 2005.

Member, EPA Pregnancy and Environmental Health Campaign, 2005-present.

Member, Center for the Evaluation of Risks to Human Reproduction, Panel on Hydroxyurea, 2006.

Member, ILSI Health and Environmental Sciences Institute's Working Group on Maternal Toxicity. 2007-2009.

Member, ILSI Health and Environmental Sciences Institute's Working Group on Epigenetics. 2007-2009.
Teratology Society, Education Committee, 2007-2008; Program Committee 2008-2009.

Guest Editor, Birth Defects Research, Part C: Embryo Today, Issue on Tobacco and Pregnancy, 2008.

Member, ILSI HESI Working Group on Alternative Tests for Developmental Toxicity 2009-present.

Member, California Tobacco-related Disease Research Program Biomedical Review Panel 2006-present

Invited Presentations: (last 5 years)

The Barker Hypothesis: Implications for Human Health and Well-Being. Mars/MDRU Conference on Epigenetics: Fetal Origins of Health, McLean, VA, June 9, 2004.

Evaluation and Interpretation of Maternal Toxicity in Segment II Studies: Issues, Some Answers and Data Needs. International Union of Toxicologists Meeting, Tampere, Finland, July 14, 2004.

Fetal Skeletal Examinations. Continuing Education Course on Basics of Developmental Toxicology, Society of Toxicology Annual Meeting, New Orleans, LA, March, 2005.

Case Example: Zinc. ILSI Health and Environmental Sciences Institute (HESI) sponsored Continuing Education Course: "Dose-Dependent Transitions in Mechanisms of Toxicity: What Are They? How Are They Applied in Risk Assessment?," Annual Meeting of the American College of Toxicology (ACT), Williamsburg, VA, November 6, 2005.

Everything I Needed to Know I Learned in the Womb: Developmental Origins of Health and Disease. Neurotoxicology Division, NHEERL, ORD, USEPA, Research Triangle Park, NC, November 30, 2005.

Maternal Dietary Folate Intake and Response to Diverse Developmental Toxicants in Rodents. Sixteenth Lucille S. Hurley Distinguished Seminar Speaker, Department of Nutrition and Western Human Nutrition Research Center, University of California, Davis, CA October 17, 2005

Of Men, Mice, Monkeys and Metabolism: An Update on the Developmental Toxicity of Methanol. Robert L. Brent Lecture, Teratology Society Annual Meeting, Tucson, AZ, June 26, 2006.

Case Example: Zinc. Round Table on "Dose-Dependent Transitions in Mechanisms of Toxicity" EUROTOX 2006 Meeting, Cavtat, Croatia, September 22, 2006.

Long Term Effects of the Developmental Environment: Implications for Developmental Toxicity Risk Assessment. University of Louisville, Louisville, KY, November 21, 2006.

Development of the Skeletal and Urogenital Systems, Society of Toxicology Continuing Education Course on Basic Embryology, Seattle, WA, March, 2008.

Malformation of the Axial Skeleton by Environmental Agents in Rodents, and Relevance to Humans. Gordon Research Conference on Musculoskeletal Biology and Engineering, Andover, NH, July 31, 2008.

Developmental Origins of Health and Disease: Effects of Gestational Undernutrition and Chemical Exposure in Rodents. Department of Toxicology, North Carolina State University, Raleigh, NC, October 21, 2008.

Long-term Effects of Maternal Undernutrition or Toxicant Exposure on Adult Health of Offspring in Rodents. Triangle Consortium on Reproductive Biology, NIEHS, Research Triangle Park, NC, January 31, 2009.

Long-term Effects of Maternal Undernutrition or Toxicant Exposure on Adult Health of Offspring in Rodents. Society for the Study of Reproduction Annual Meeting, Pittsburgh, PA, July 21, 2009.

Epigenetic Evaluation and Reproductive/Developmental Toxicity Testing. HESI Workshop on the State of the Science of Epigenetics, October 29, 2009.

Animal Models for Testing the DOHaD Hypothesis, PPTox II Meeting (Prenatal Programming and Toxicity), South Miami Beach, FL, Dec 7, 2009.

Publications: (last 5 years)

Rogers JM, KC Brannen, BD Barbee, RM Zucker, and SJ Degitz (2004) Maternal methanol exposure during gastrulation causes holoprosencephaly, facial dysgenesis and cervical vertebral malformations in C57BL/6J mice. *Birth Defects Research, Part B, Dev Reprod Toxicol* 71:17-25.

Degitz SJ, RM Zucker, CY Kawanishi, GS Massenburg, and JM Rogers (2004) Pathogenesis of methanol-induced craniofacial defects in C57BL/6J mice. *Birth Defects Research, Part A, Clin Mol Teratol* 70:172-178.

Degitz SJ, JM Rogers, RM Zucker, and ES Hunter III (2004) Developmental toxicity of methanol: pathogenesis in CD-1 and C57BL/6J mice exposed in whole embryo culture. In press, *Birth Defects Research, Part A, Clin Mol Teratol* 70:179-184.

Slikker W Jr., ME Andersen, MS Bogdanffy, JS Bus, SD Cohen, RB Conolly, RM David, NG Doerrler, DC Dorman, DW Gaylor, D Hattis, JM Rogers, RW Setzer, JA Swenberg, K Wallace (2004) Dose-dependent transitions in mechanisms of toxicity. *Toxicol Appl Pharmacol* 201:203-225.

Slikker W Jr., ME Andersen, MS Bogdanffy, JS Bus, SD Cohen, RB Conolly, RM David, NG Doerrler, DC Dorman, DW Gaylor, D Hattis, JM Rogers, RW Setzer, JA Swenberg, K Wallace (2004) Dose-dependent transitions in mechanisms of toxicity: case studies. *Toxicol Appl Pharmacol* 201:226-294.

Lau C, JL Butenhoff, and JM Rogers (2004) The developmental toxicity of perfluoroalkyl acids and their derivatives. *Toxicol Appl Pharmacol* 198:231-241.

Chernoff N, and JM Rogers (2004) Supernumerary ribs in developmental toxicity bioassays and in human populations: incidence and biological significance. *J Toxicol Environ Health Part B: Crit Rev* 7:437-450.

Lau C, and JM Rogers (2004) Embryonic and fetal programming of physiological disorders in adulthood. *Birth Defects Research Part C: Embryo Today*, 72:300-312.

Grasty, RC, JA Bjork, KB Wallace, CS Lau, and JM Rogers (2005) Effects of prenatal perfluorooctane sulfonate (PFOS) exposure on lung maturation in the perinatal rat. *Birth Defects Res Part B, Dev Reprod Toxicol* 74:405-416.

Massaro, E.J., and J.M. Rogers (eds). (2005) The Skeleton: Biochemical and Molecular Interactions in Development and Homeostasis, Humana Press, Boca Raton, FL.

Rogers JM, N Chernoff, CL Keen, and GP Daston (2005) Evaluation and interpretation of maternal toxicity in Segment II studies: Issues, some answers and data needs. *Toxicol Appl Pharmacol* 207:S367-S374.

Lau C, Thibodeaux JR, Hanson RG, Narotsky MG, Rogers JM, Lindstrom AB, Strynar MJ. (2006) Effects of perfluorooctanoic acid exposure during pregnancy in the mouse. *Toxicol Sci.* 90:510-518.

Rogers JM (2006) Toxicological Highlight. Casting a broad network: Fishing for mechanisms of retinoid teratogenicity. *Toxicol. Sciences*, in press.

Rogers JM (2006) The Barker Hypothesis: Implications for future directions in developmental toxicology. *Current Opinions in Endocrinology and Diabetes* 13:536-540.

[Rogers JM.](#) (2006) Casting a broad network: fishing for mechanisms of retinoid teratogenicity. *Toxicol Sci.* 94:1-2.

Rogers JM, and R.J. Kavlock (2007) Developmental toxicology. In: Casarett and Doull's Toxicology, Seventh Ed., C.D. Klaassen, ed. McGraw-Hill, New York,

[Tyl RW, N Chernoff, JM Rogers.](#) (2007) Altered axial skeletal development. *Birth Defects Res B Dev Reprod Toxicol.* 80: 451-72.

[Rogers JM.](#) (2008) Tobacco and pregnancy: overview of exposures and effects. *Birth Defects Res C Embryo Today* 84: 1-15.

Ellis-Hutchings R and JM Rogers (2009) Epigenetic mechanisms-role of DNA methylation and histone acetylation. In: Developmental Toxicology-3rd Edition, D. Hansen and B. Abbott, Eds. *In press*.
Rogers, JM, Ellis-Hutchings R, and Christopher Lau (2009) Epigenetics and the Developmental Origins of Health and Disease. In: Comprehensive Toxicology, 2nd ed., GP Daston and TB Knudsen, eds. *In press*.
Rogers, JM (2009) Tobacco and Pregnancy. *Reprod Toxicol*, 2009 Apr 9. [Epub ahead of print].
Rogers, JM (2009) Reproductive and Developmental Toxicity. In: The Toxicology of Methanol, John Clary, ed., Wiley-Blackwell, in preparation.

Carl Richards

Division Director

218-529-5010

richards.carl@epa.gov

Education:

B.S., Biology, University of Southern Mississippi, 1975

M.S., Biology, California State University, Los Angeles, 1978

Ph.D., Biology/Ecology, Idaho State University, 1986

Employment:

2005–Present Division Director, U.S. EPA Mid-Continent Ecology Division, Duluth, MN

1999–2005 Director, Minnesota Sea Grant College Program, University of Minnesota

1999–2005 Professor, Department of Biology, University of Minnesota Duluth

1989–2005 Senior Research Associate, Center for Water and the Environment, Natural Resources Research Institute, University of Minnesota, Duluth

1996–1998 Acting Director, Center for Water and the Environment, Natural Resources Research Institute, University of Minnesota Duluth

1989 Visiting Assistant Professor, Idaho State University, Pocatello, ID

1986–1989 Director, Anadromous Fisheries Program, Shoshone-Bannock Tribes, Fort Hall, ID

Research Interests and Skills:

Fish/habitat relationships; benthic ecology; watershed, stream and lake linkages; landscape ecology; aquatic invasive species; educational and technical outreach

Professional Societies:

American Association for the Advancement of Science

North American Benthological Society

Society of Conservation Biology

Selected Appointments/Honors/Major Awards:

Chair, Natural Resources Peer-review Panel, Legislative Commission on Minnesota Resources, 2007

Member, Lake Superior Binational Task Force, 2005-Present

Graduate Faculty Member, Integrated Biosciences Graduate Program, University of Minnesota Duluth, 2005–Present

Peer Review Panel Chair, NOAA Great Lakes Cooperative Joint Institute, 2005

Core Member, Board of Technical Experts, Great Lakes Fishery Commission, 2004–Present

Executive Board Member, Sea Grant Association, 2001-2005

Graduate Faculty Member, Department of Fisheries, Wildlife, and Conservation Biology, University of Minnesota, St. Paul, 1990–Present

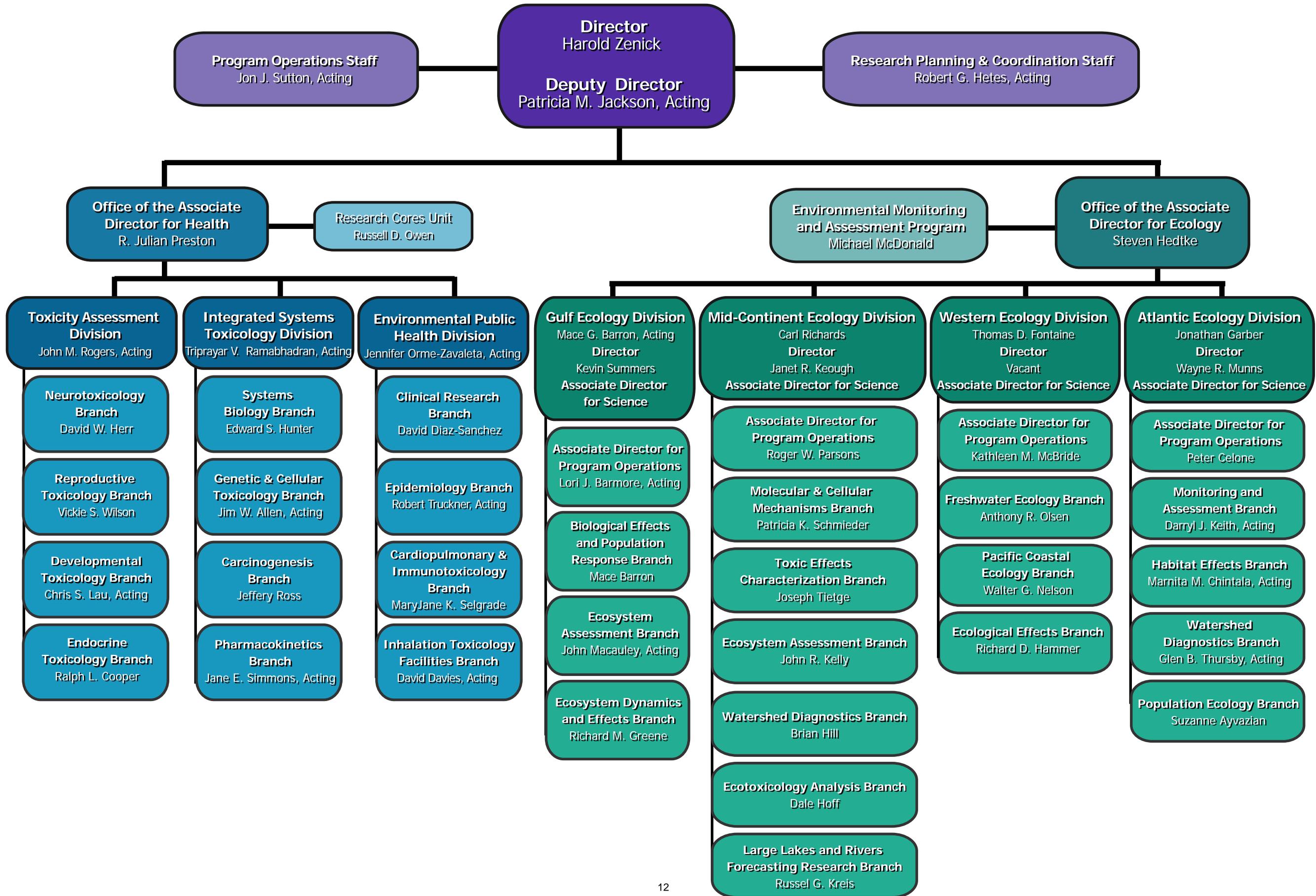
Graduate Faculty Member, Water Resources Program, University of Minnesota, 1995–Present

Program Coordinator, Water Pollution Control Technology and Aquaculture Programs, Natural Resources Research Institute, University of Minnesota Duluth, 1990–1999

Selected Publications:

- Grigorovich, I.A. E.L. Mills, C.B. Richards, D. Breneman, and J.J.H. Ciborowski. 2005. European valve snail *Valvata piscinalis* (Müller) in the Laurentian Great Lakes basin. *Journal of Great Lakes Research* 31(2):135-143.
- Bronte, C.R., M.P. Ebner, D.R. Schriener, D.S. DeVault, M.M. Petzold, D.A. Jensen, C. Richards, S.J. Lozano. 2003. Fish community change in Lake Superior, 1970-2000. *Canadian Journal of Fisheries and Aquatic Sciences* 60: 1552-1574.
- L.B. Johnson, D.H. Breneman, and C. Richards. 2003. Macroinvertebrate community structure and function associated with large wood in low gradient streams. *River Research and Applications* 19:199-218.
- Johnson, C.M., L.B. Johnson, C. Richards, and V. Beasley. 2002. Predicting the occurrence of Amphibians: An assessment of multiple-scale models. pp. 157-170. In M.J. Scott et al. (eds). *Predicting Species Occurrences: Issues of Accuracy and Scale*. Island Press. Washington, DC, USA.
- Richards, C., M. White, R. Axler, A. Hershey, J. Schomberg. 2001. Simulating effects of landscape composition and structure on stream water quality in forested watersheds. *Verh. Internat. Verein. Limnol.* 27:3561-3565.
- Breneman, D., C. Richards, S. Lozano. 2000. Environmental influences on benthic community structure in a Great Lakes embayment. *Journal of Great Lakes Research* 26(3):287-304
- Cholwek, G. J. Bonde, X. Li, C. Richards, K. Yin. 2000. Processing RoxAnn sonar data to improve its categorization of lake bed surficial substrates. *Marine Geophysical Researches* 21(5): 409-42.
- Richards, C. and R. Hollingsworth. 1999. Managing for fish in riparian areas. pp 151-163. In S. Verry (ed). *Riparian Management in Forests of the Continental Eastern U.S.*, Pergamon Press, Oxford, UK.
- Hershey, A.E., G. Gettel, M.E. McDonald, M.C. Miller, H. Mooers, W.J. O'Brien, J. Pastor, C. Richards, and J.A. Schuldt. 1999. A geomorphic-trophic model for landscape control of trophic structure in arctic lakes. *BioScience* 49:887-897.
- Richards, C. and L.B. Johnson. 1998. Landscape perspectives on ecological risk assessment. pp 255-274. In M. Newman (ed). *Risk Assessment: Logic and Measurement*. Ann Arbor Press, Ann Arbor, MI.
- Kutka, F., and C. Richards. 1997. Short-term nutrient influences on algal assemblages in three rivers of the Minnesota Basin. *Journal of Freshwater Ecology* 12:411-419.
- Richards, C., R.J. Haro, L.B. Johnson, and G.E. Host. 1997. Catchment and reach-scale properties as indicators of macroinvertebrate species traits. *Freshwater Biology* 37:219-230.
- Johnson, L.B., C. Richards, G.E. Host, and J.W. Arthur. 1997. Landscape influences on water chemistry in Midwestern stream ecosystems. *Freshwater Biology* 37:193-208.
- Richards, C., L.B. Johnson, and G.E. Host. 1996. Landscape scale influences on stream habitats and biota. *Canadian Journal of Fisheries and Aquatic Sciences*: 53 (Suppl. 1): 295-311.
- Kutka, F. and C. Richards. 1996. Relating diatom assemblage structure to stream habitat quality. *Journal of the North American Benthological Society* 15:469-480.

National Health & Environmental Effects Research Laboratory (NHEERL)



National Health and Environmental Effects Research Laboratory

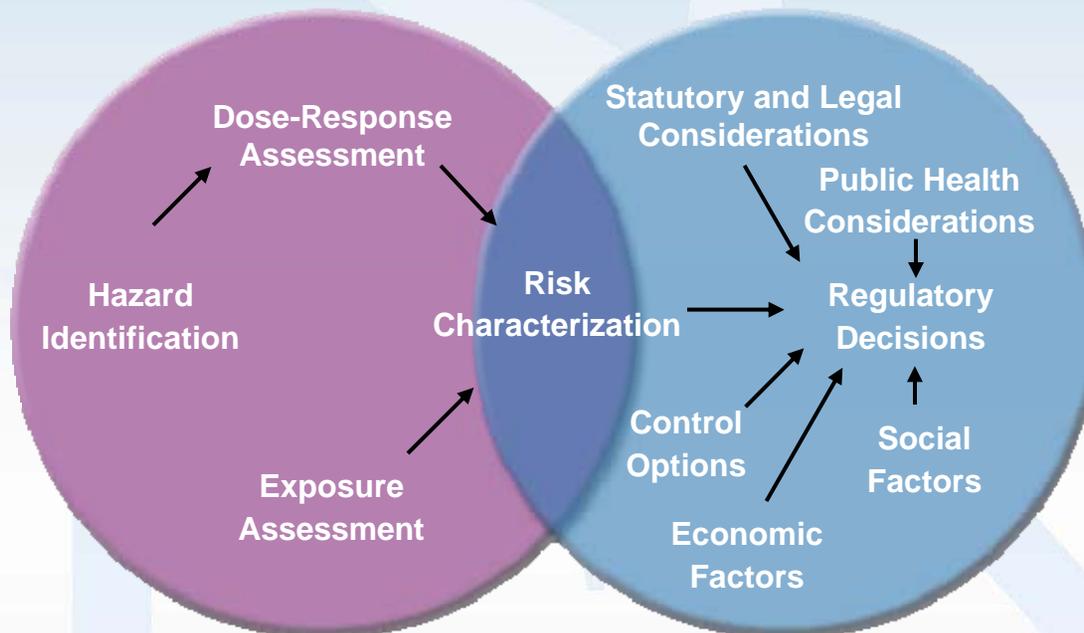
NHEERL at a Glance



January 25, 2010

Risk Assessment/ Risk Management Paradigm

**Risk
Assessment**



**Risk
Management**

National Health and
Environmental Effects
Research Laboratory
Research Triangle Park, NC

National Exposure
Research Laboratory
Research Triangle Park, NC

National
Risk Management
Research Laboratory
Cincinnati, OH

National Center for
Computational
Toxicology
Research Triangle Park, NC

National Center for
Environmental
Assessment
Washington, DC

National Homeland
Security Research
Center
Cincinnati, OH

National Center for
Environmental
Research
Washington, DC

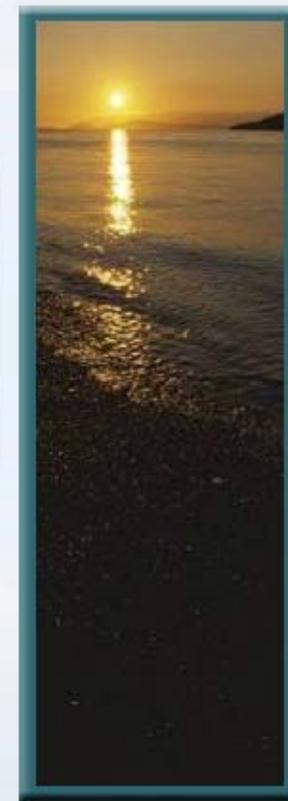
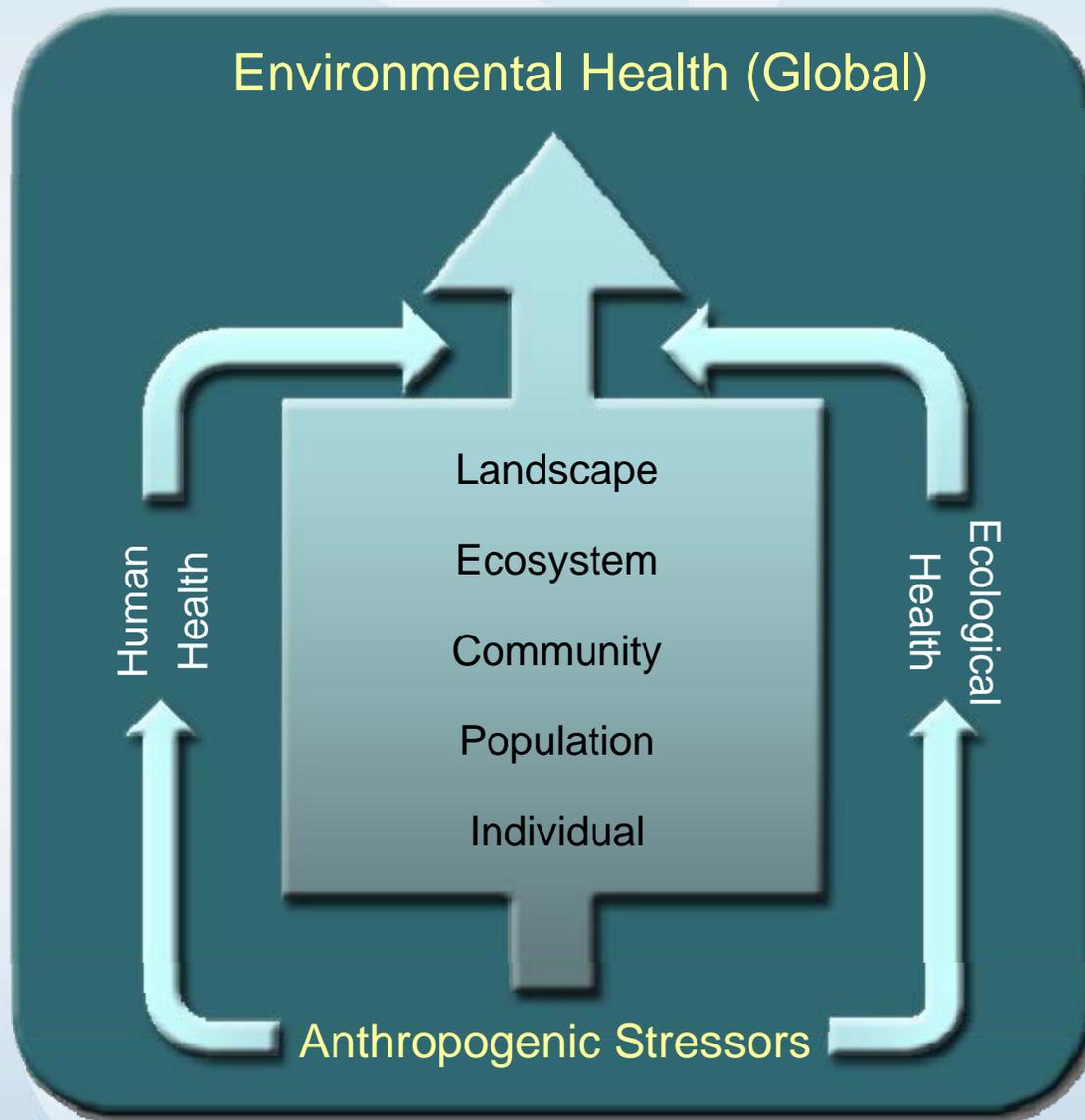
Laboratories

Centers

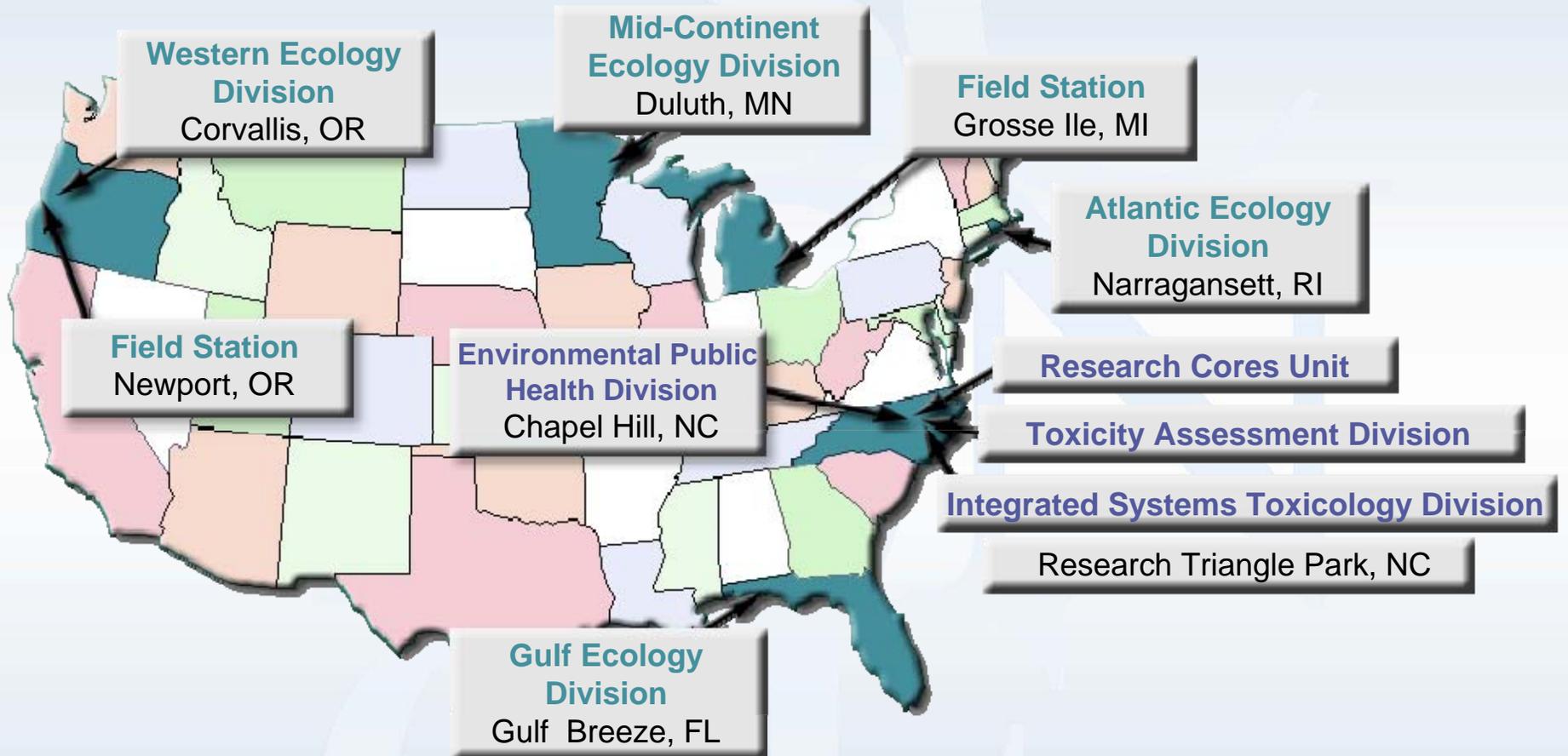
NHEERL's Mission

NHEERL formulates and implements a comprehensive research program that investigates the effects of environmental pollutants and other anthropogenic stresses on human health and the ecosystems in which we live.

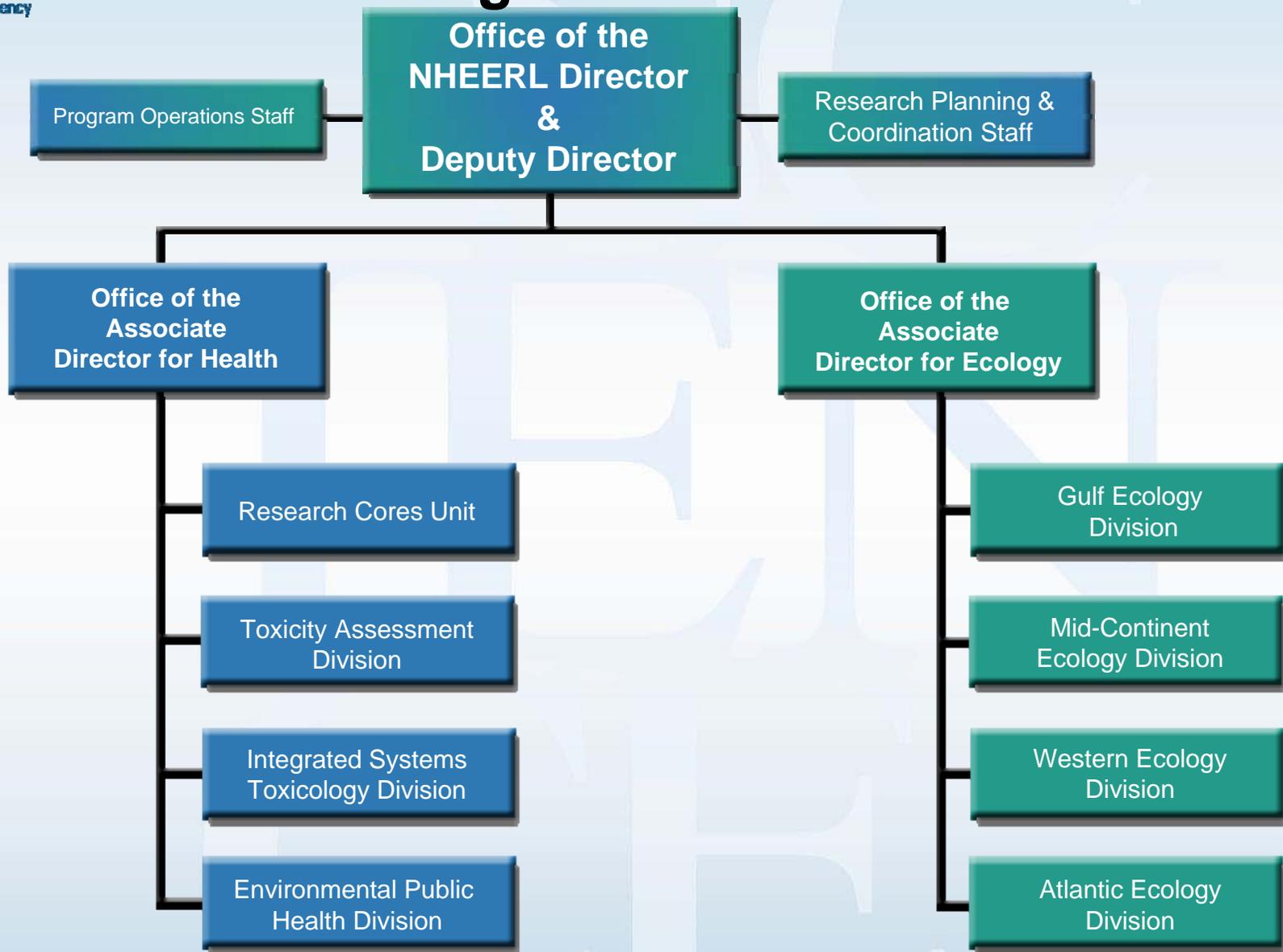
NHEERL Integrates Human Health and Ecological Sciences



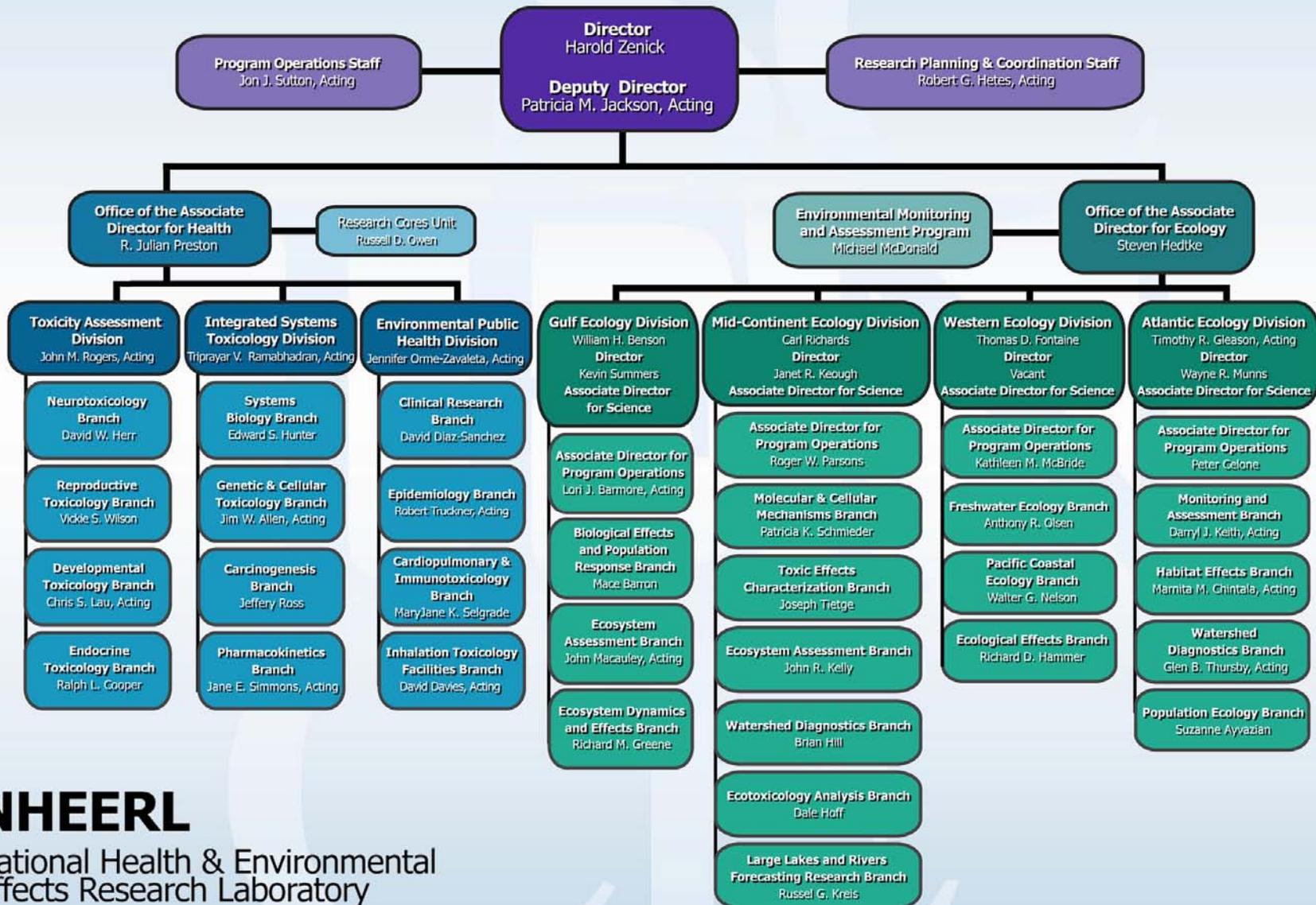
NHEERL Locations



Current Organization Chart



Current Organization



NHEERL

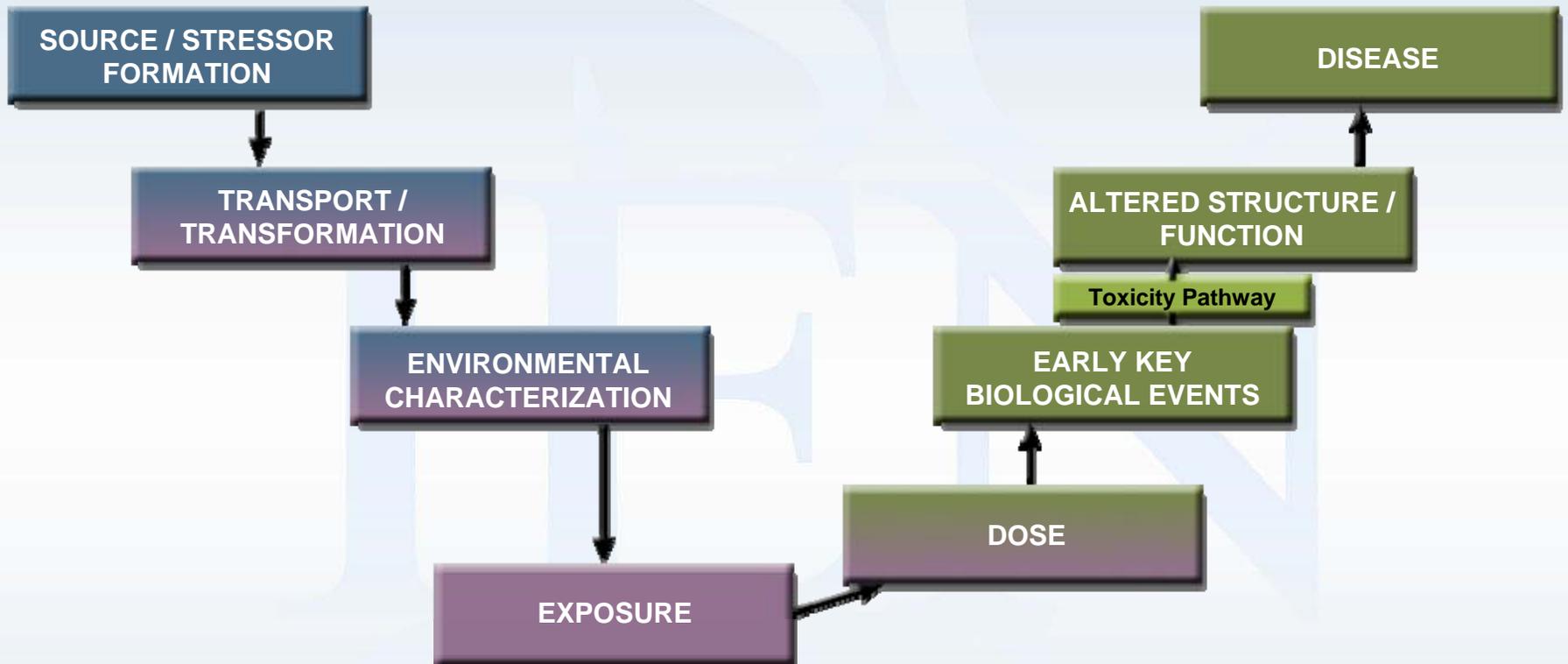
National Health & Environmental
Effects Research Laboratory

Multi-pronged Approach to Research Emphasizing Lab-Field Interface

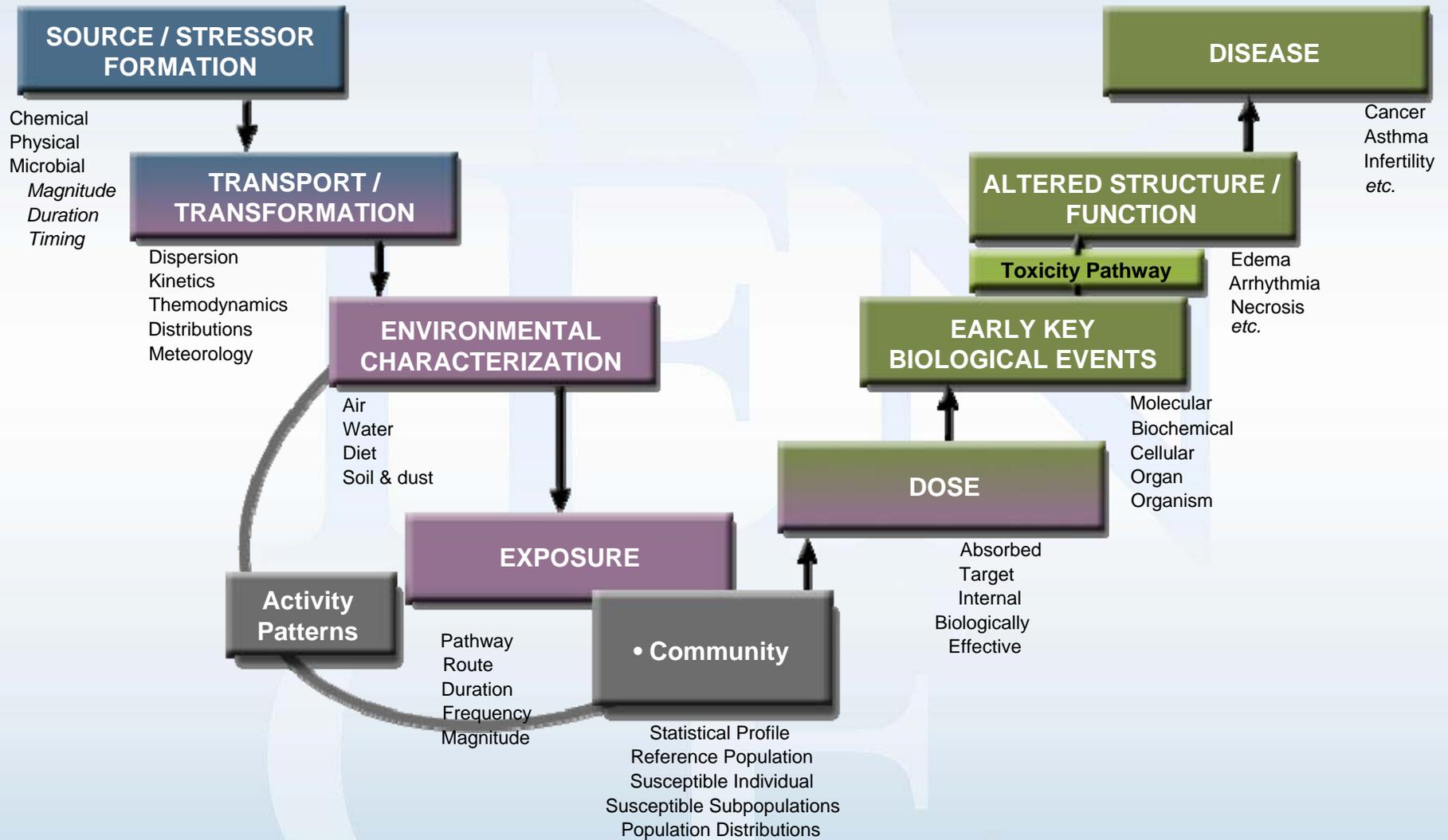
Research



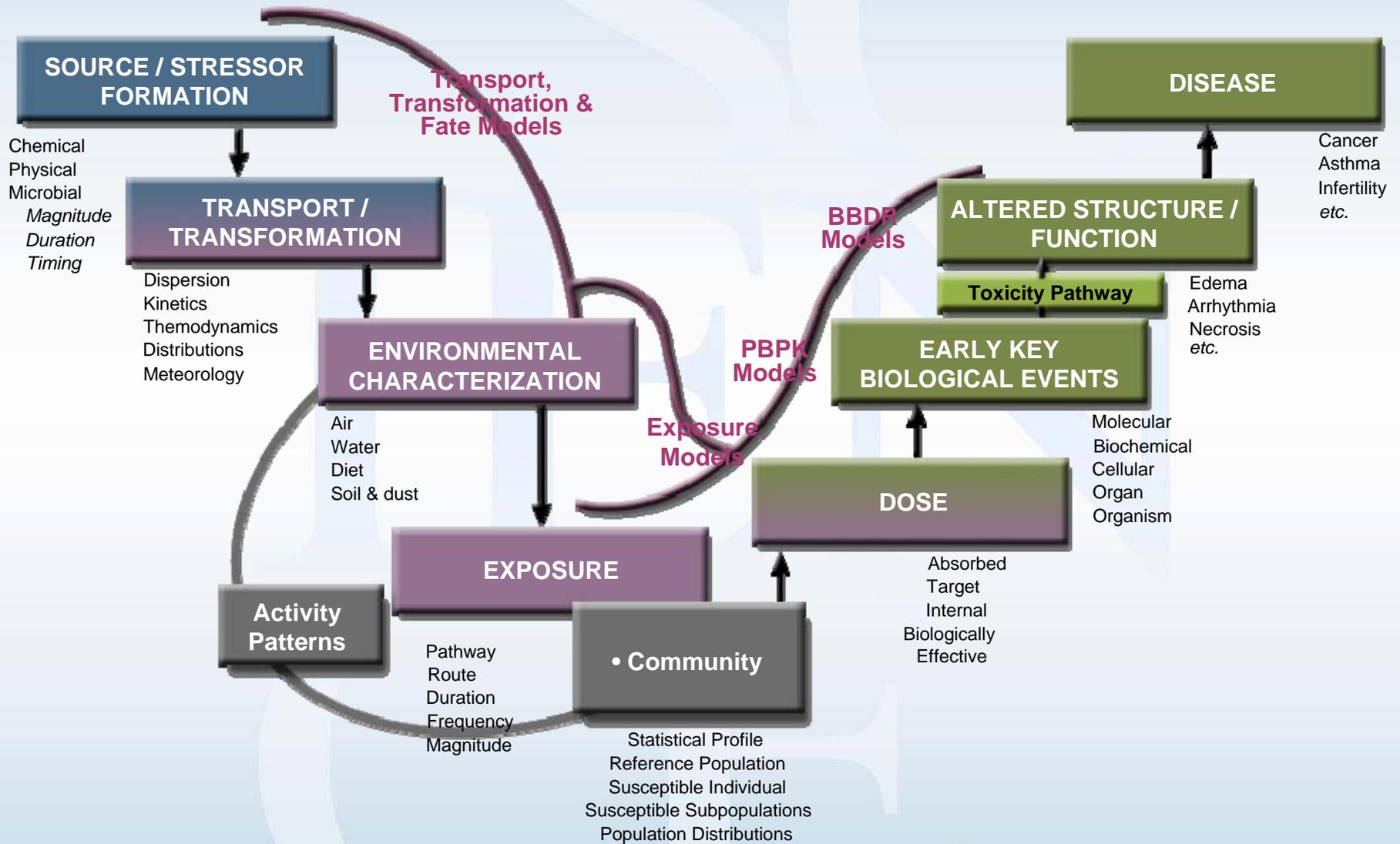
Source-Exposure-Dose-Effects Continuum



Source-Exposure-Dose-Effects Continuum



Source-Exposure-Dose-Effects Continuum



ORD Research Areas – NHEERL Engagement

Program-Targeted Research

- Air
- Drinking Water
- Water Quality
- Land Preservation and Restoration
- Safe Pesticides and Products
- Homeland Security

Cross-Program Research

- Human Health
- Ecosystem Services
- Human Health Risk Assessment
- Global Change
- Mercury
- Endocrine Disrupting Chemicals
- Computational Toxicology
- Nanotechnology
- Science and Technology for Sustainability
- Fellowships

ORD Research Areas – NHEERL Engagement

Program-Targeted Research

- Air
 - Reduce uncertainty in standard setting
 - Source-to-Health Linkages
- Drinking Water
 - Characterize Risks
 - Manage Risks
- Water Quality
 - Criteria
 - Watershed management
- Land Preservation / Restoration
 - Asbestos
 - Nanomaterials
- Safe Pesticides and Products
 - Predictive tools and data for risk assessment
 - Wildlife Risk Reduction
 - Biotechnology

Cross-Program Research

- Human Health
 - Mode of action
 - Cumulative / community risk
 - Susceptible populations
 - Risk mgmt. effectiveness
- Ecosystem Services
 - Effective decision support
 - Mapping, monitoring, modeling
 - Nitrogen assessment
 - Ecosystem projects
 - Place-based demonstrations
- Global Change
 - Protect water quality and aquatic ecosystems
- Endocrine Disrupting Chemicals
 - Effects, exposure, assessment, and management
 - Extent of impacts of EDCs
 - Screening and testing
- Computational Toxicology
- Nanotechnology

SAB Science Integration for Decision Making Fact-Finding Meeting
Meeting with Director and Management Team, EPA Office of Research and Development
(ORD) National Exposure Research Laboratory (NERL) Conference Room D301
109 T.W. Alexander Drive, Durham, NC
Call-in Number for SAB subgroup: 866-299-3188, access code 343-9981 and press the #
sign.
January 12, 2010, 1:15 a.m. to 2:30 p.m.
Draft Agenda

Purpose of Interview: to help SAB Committee members learn about NERL current and recent experience with science integration supporting EPA decision making so that the SAB can develop advice to support and/or strengthen Agency science integration efforts.

1. Introductions facilitated by the SAB Staff Office
2. Discussion facilitated by SAB Members
 - Practices for integrating science to support decision making
 - Consideration of public, stakeholder, external scientific, and other input in science assessment
 - Drivers and impediments to implementing past recommendations for science integration
 - Ways program receives feedback on how science is used in decision-making
 - Workforce to support science integration for decision making
3. Identification of any follow-up actions

Planned participants

EPA ORD NERL

Larry Reiter – Director, National Exposure Research Laboratory (NERL)
Jewel F. Morris – Deputy Director, NERL
William H. Benson – Acting Associate Directory for Ecology
Linda S. Sheldon – Associate Director for Human Health
Robert S. Dyer – Director, Research Planning and Coordination Staff

SAB Committee on Science Integration Committee Members

Dr. Deborah Cory-Slechta, University of Rochester
Dr. James Bus, Dow Chemical Company
Dr. Wayne Landis, Western Washington University (by telephone)
Dr. Thomas Theis, University of Illinois at Chicago (by telephone)
Dr. Terry Daniel, University of Arizona (by telephone)

SAB Staff Office

Dr. Vanessa Vu, Director
Dr. Angela Nugent, Designated Federal Officer

**SAB Science Integration for Decision Making Fact-Finding Meeting
Meeting with Scientists, EPA Office of Research and Development (ORD) National
Exposure Research Laboratory (NERL) Conference Room D301
Call-in Number for SAB subgroup: 866-299-3188, access code 343-9981 and press the #
sign.**

**January 12, 2010, 2:45 p.m. - 4:00 p.m.
Draft Agenda**

Purpose of Interview: to help SAB Committee members learn about NERL current and recent experience with science integration supporting EPA decision making so that the SAB can develop advice to support and/or strengthen Agency science integration efforts.

1. Introductions facilitated by the SAB Staff Office
2. Discussion facilitated by SAB Members
 - Practices for integrating science to support decision making
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3. Identification of any follow-up actions

Planned participants

EPA ORD NERL

Rochelle Araujo – Senior Research Ecologist, Immediate Office
Rogelio Tornero-Velez – Research Scientist
Kenneth Schere – Research Scientist
Ken Fritz – Research Scientist
Timothy Watkins – Deputy Director, Human Exposure and Atmospheric Sciences Division
Alan Vette – Research Scientist
Meghan Mehaffey – Research Scientist
Valerie Zartarian – Research Scientist
Brad Autrey – Research Scientist

Committee on Science Integration Committee Members

Dr. Deborah Cory-Slechta, University of Rochester
Dr. James Bus, Dow Chemical Company
Dr. Wayne Landis, Western Washington University (by telephone)
Dr. Thomas Theis, University of Illinois at Chicago (by telephone)
Dr. Terry Daniel, University of Arizona (by telephone)

SAB Staff Office

Dr. Vanessa Vu, Director
Dr. Angela Nugent, Designated Federal Officer

Available NERL Interviewee Biosketches

Lawrence Reiter, Ph.D., is the Director of the National Exposure Research Laboratory (NERL), one of three national laboratories within the EPA. Dr. Reiter joined the EPA Health Effects Research Laboratory (HERL) in 1973. From 1978 through 1988 he served as the first Director of EPA's Neurotoxicology Division, establishing a major research program in neurotoxicology. In 1988, he was appointed as Director of HERL with responsibility for EPA's health research program. From 1995 to 2005, Dr. Reiter was the Director of the National Health and Environmental Effects Research Laboratory (NHEERL). Dr. Reiter serves on the advisory panels of numerous organizations, both within EPA as well as in the scientific community, including the World Health Organization and the National Academy of Sciences. He is the recipient of a number of awards, including the Presidential Distinguished Executive Award for leadership in defining and strengthening the vital role of science at EPA, as well as the Presidential Meritorious Executive Award, both presented by the White House in recognition of outstanding achievement in public service. Dr. Reiter received a B.S. in Chemistry from Rockhurst College in Kansas City, MO in 1965 and a Ph.D. in Neuropharmacology from the University of Kansas Medical Center Department of Pharmacology in 1970. Prior to joining EPA, he completed a three-year postdoctoral fellowship in the Environmental Toxicology Department at the University of California/Davis.

Jewel F. Morris has been the Deputy Director for the NERL since March 2003. Jewel began her career as a Research Chemist with Burroughs Wellcome in 1972 and left to join ORD as an Industrial Hygienist in 1977. During this time, Jewel created an environmental program for the EPA-RTP facilities which provided technical oversight for programs such as; hazardous wastes, wastewater discharge, air, and a variety of others. In 1993, Jewel became the Director of the ORD Safety, Health, and Environmental Management office. After serving in that role for approximately 4 years, Jewel became the Director of NERL's Program Operations Staff. As Director, she was responsible for the oversight of NERL's budget, management policies and procedures, human resource management, communication issues, and many other areas while supervising a staff of 32 employees. Jewel is a native North Carolinian. She received her Bachelors of Science degree from Meredith College, Raleigh, NC in 1972. Jewel continued her education at the University of North Carolina, Chapel Hill, NC, receiving her Master of Science degree in 1982. Jewel is very active in different organizations outside of EPA, which includes maintaining a position on the Board of Directors for the Research Triangle Park Credit Union and being a member and past President of the RTP Rotary Club.

William H. Benson, Ph.D., currently serves as Acting Associate Director for Ecology of the National Exposure Research Laboratory (NERL) within the U.S. Environmental Protection Agency's Office of Research and Development. Dr. Benson's permanent assignment is as Director of the National Health and Environmental Effects Research Laboratory's Gulf Ecology Division. As Associate Director for Ecology of NERL, Dr. Benson is responsible for directing the Laboratory's ecological exposure research focused on reducing critical exposure uncertainties associated with the Agency's policy decisions and provide leadership in exposure science. Dr. Benson's research activities have been directed towards assessing the influence of environmental stressors on health and ecological integrity. He has conducted research in the areas of metal and pesticide bioavailability, reproductive and developmental effects in aquatic organisms, endocrine disrupting chemicals, and use of indicators in assessing health and ecological integrity. In addition, he has published over 100 scientific publications focusing on environmental toxicology and chemistry. Dr. Benson obtained a Bachelor of Science degree in Biology from Florida Institute of Technology and his M.S. and Ph.D. degrees in Toxicology were obtained from the University of Kentucky. Dr. Benson is a Past President of the Society of Environmental Toxicology and Chemistry (SETAC) and has served on the International Council of SETAC. Dr. Benson was elected as a Fellow of the American Association for the Advancement of Science, and is active in several other professional societies, including the Society of Toxicology.

Linda S. Sheldon, Ph.D. Dr. Sheldon earned a Ph.D. in Environmental Chemistry from the University of Michigan. She also completed two years of post Doctoral training at the Massachusetts Institute of Technology. Over the past 30 years, Dr. Sheldon work has focused on understanding and predicting human exposures to environmental chemicals

Dr. Sheldon has been at EPA in the National Exposure Research Laboratory (NERL) for the past 12 years. She is currently the Associate Director for Human Health within the laboratory. In the position, she has led the effort to develop the exposure framework for NERL, developed the exposure research component for the ORD Strategic plan

for Toxicity Testing in the 21st Century, served as the Long Term Goal Lead for Cumulative Risk Assessment for the Human Health Research Program, and led NERL's research effort in biomonitoring and exposure reconstruction. Dr. Sheldon has also served as both the Division Director and the Associate Division Director for the Human Exposure and Atmospheric Science Division in NERL. During that time, she developed and led a comprehensive measurements and modeling program to understand and predict human exposure to chemicals for children and other susceptible populations. Dr. Sheldon served on Science Advisory Boards and Research Steering Committees for nine national and international research centers in the area of exposure assessment. She has also been a member of two World Health Organization workgroups that developed Environmental Health Criteria for exposure assessments and for health risk for children.

Robert S. Dyer, Ph.D. Director, Research Planning and Coordination Staff in the National Exposure Research Laboratory (NERL). In this role Dr Dyer is responsible for leading the NERL (1) planning process (including interfacing NERL with the ORD planning processes); (2) divisional peer review process; (3) accountability processes associated with the Government Performance and Results Act; and (4) regulatory support process. Previously Dr. Dyer has served EPA as a bench scientist, branch chief and division director in the Neurotoxicology Division, Assistant Laboratory Director, and Director of Research Planning and Coordination in the National Health and Environmental Effects Research Laboratory. Dr. Dyer's research focus was development and evaluation of neurophysiological methods for detection and characterization of neurotoxicity. He has published over 100 peer reviewed scientific papers. Dr. Dyer received his Bachelor's Degree in psychology from Grinnell College, his Ph.D. in psychology from the State University of New York at Buffalo, and performed postdoctoral research in neurophysiology at both the University of Michigan and the Johns Hopkins University.

Dr. Rochelle Araujo currently serves as the Senior Research Ecologist in the Immediate Office of the National Exposure Research Laboratory within EPA's Office of Research and Development, located in Research Triangle Park, North Carolina. Dr. Araujo received her BS in Biology from Cornell University, an MS in Marine Sciences from the Marine Science Research Center at SUNY Stony Brook, and a PhD in Environmental Toxicology (with concentrations in ecology and environmental engineering) from Cornell University. During her twenty years with EPA, she has conducted research on ecosystems and water quality, with an emphasis on systems approaches and microbial processes, ranging from oil spill degradation in Alaska to mercury cycling in the Everglades. Dr. Araujo has served as the Associate Director and the Assistant Laboratory Director for Ecology in NERL, as the Acting National Program Director for Water Quality for ORD, and as the co-chair of the CENR Subcommittee on Water Availability and Quality. She is currently focusing on integrating the science of ecosystems and human well-being in the areas of Sustainable Water and Sustainable Communities.

Dr. Rogelio Tornero-Velez is a scientist in the Human Exposure and Atmospheric Studies Division. His main research topic involves developing an exposure-dose modeling framework to assess aggregate exposures to congeneric series of chemicals to assess cumulative risk, using stochastic exposure models linked to physiologically-based pharmacokinetic/ pharmacodynamic (PBPK/PD) models. Other areas of research include the novel application of approaches derived from the field of community ecology to understand the structuring processes that lead to environmental mixtures. Dr. Tornero received his Bachelor of Science (1989) in Chemistry from University of North Carolina at Chapel Hill his Ph.D. in Environmental Sciences and Engineering (2001) from the University of North Carolina School of Public Health. His professional organization memberships include the Society for Risk Analysis and the International Society of Exposure Science.

Kenneth Schere received a B.S. degree from Cornell University in 1973 and an M.S. degree from Penn State University in 1975 in atmospheric science. He worked for the National Oceanic and Atmospheric Administration at U.S. EPA's air quality research and development laboratories in Research Triangle Park, NC from 1975 to 2008 before transferring to the National Exposure Research Laboratory of EPA/ORD. His current position is the Senior Science Advisor in NERL's Atmospheric Modeling and Analysis Division (AMAD), in which capacity he is responsible for strategic and tactical research planning and implementation of Division programs. His research specialty has been the development and evaluation of urban and regional scale photochemical air quality simulation models. From 1988 through 1993, Mr. Schere served as EPA's manager for the regional oxidant modeling research program, and guided the research applications of the Regional Oxidant Model. From 1994 to 2000, he was the Program Manager of EPA's integrated ozone research program, linking the research efforts in chemistry, modeling, monitoring/field studies, methods development, and emissions. He co-chaired a NARSTO Team that produced a major state-of-science assessment document (2000) of tropospheric ozone pollution in North America. Mr. Schere

was the Chief of AMAD's Atmospheric Model Development Branch from 1998 to 2007 where he directed a group of 20 scientists in the development, application, and evaluation of the Community Multiscale Air Quality (CMAQ) modeling system. He also has served on the Committee on Meteorological Aspects of Air Pollution of the American Meteorological Society, and the Committee on Mesoscale Meteorological Modeling Capabilities for Air Pollution and Dispersion Applications of the European Science Foundation.

Ken M. Fritz, Ph.D., currently serves as Research Ecologist in the Ecological Exposure Research Division, National Exposure Research Laboratory (NERL) within the U.S. Environmental Protection Agency's Office of Research and Development. Dr. Fritz received a Bachelor of Science degree in Zoology from Southern Illinois University, and his M.S. and Ph.D. degrees in Biological Sciences from Kansas State University and Auburn University, respectively. Dr. Fritz has been an associate editor for the Journal of the North American Benthological Society for five years. Dr. Fritz's expertise is stream ecology. Some areas of his research include community and ecosystem responses to forestry practices and mountaintop removal mining, the role of habitat modifiers or ecosystem engineers in the community structure and ecosystem processes, how biological systems mediate exposure of contaminants through time and space, and the development of indicators for hydrological permanence and ecological condition. Since joining NERL, Dr. Fritz has been the principal investigator on a nationwide study to characterize headwater stream physical and biological features across a gradient of flow permanence. The intent of this research is to provide scientific information that may inform policy decisions regarding the scope of jurisdictional waters under the Clean Water Act. Additionally, this research lays the foundation for critically assessing the ecological integrity of temporary streams, which represent a significant proportion of U.S. stream miles. Another area of research in which Dr. Fritz is a principal investigator is the measurement of downstream exposure related to the mountaintop removal and valley fill coal mining in the Central Appalachians.

Timothy (Tim) H. Watkins is currently the deputy director of the Human Exposure and Atmospheric Sciences Division (HEASD) in the EPA Office of Research and Development's National Exposure Research Laboratory (NERL). Research conducted in HEASD supports EPA's Air and Human Health research programs by providing methods, measurements, and models to characterize and identify relationships between source emissions, environmental concentrations, human exposures, and target-tissue dose. While Tim supports all of HEASD's scientists, he has the specific responsibility for providing guidance and strategic direction for the air-related research activities within HEASD, which include atmospheric chemistry, atmospheric measurement and modeling, source apportionment, and human exposure methods, measurements, and modeling. Prior to his current position, Tim served as an Assistant Laboratory Director in NERL, where he was responsible for planning, coordination, and communication of NERL's Air and Mercury research programs. Tim has worked with the EPA since 1990. He received his MS in Economics from the University of North Carolina at Chapel Hill and his BA in Economics and Mathematics from Rollins College.

Dr. Alan F. Vette is a research scientist with the U.S. Environmental Protection Agency's National Exposure Research Laboratory (NERL). Dr. Vette's research is focused on source-related human exposures to air pollutants. He has participated in and led the design and conduct of research studies to determine the impact of air pollution sources on inhalation exposures at the personal, residential and community scales. Most recently, he has been a co-lead in EPA's Office of Research and Development designing and implementing a research program to assess the impact of mobile sources on near-road air quality, human exposures and health effects. Dr. Vette received a B.A. in Chemistry from West Virginia University and a M.S. and Ph.D. in Environmental Health Sciences from the University of Michigan.

Megan Mehaffey, Ph.D. currently serves as a Research Ecologist in the Environmental Sciences Division with the National Exposure Research Laboratory (NERL) within the U.S. Environmental Protection Agency's Office of Research and Development. Dr. Mehaffey received a B.S. in Agricultural Sciences from Murray State University, a M.S. in Crop Science from North Carolina State University, and a Ph.D. in Ecology from the University of Kansas. Since joining EPA, Dr. Mehaffey has applied her expertise in ecosystem ecology and landscape assessment to examining the relationships between land use patterns and indicators of water, air, habitat, and quality of life. For her work as Principal Investigator of EPA's New York City Water Supply Landscape Study, Dr. Mehaffey received an ORD Bronze Medal and a Science and Technology Achievement (STAA) Level II Award. She also received a Bronze Medal for the ReVA-SEQL Charlotte study for research that integrated existing and future projections of spatial data of stressor/resource distributions into measures of relative vulnerability (threats) across a geographic area. In addition to her current role as the assistant director of ORD's Regional

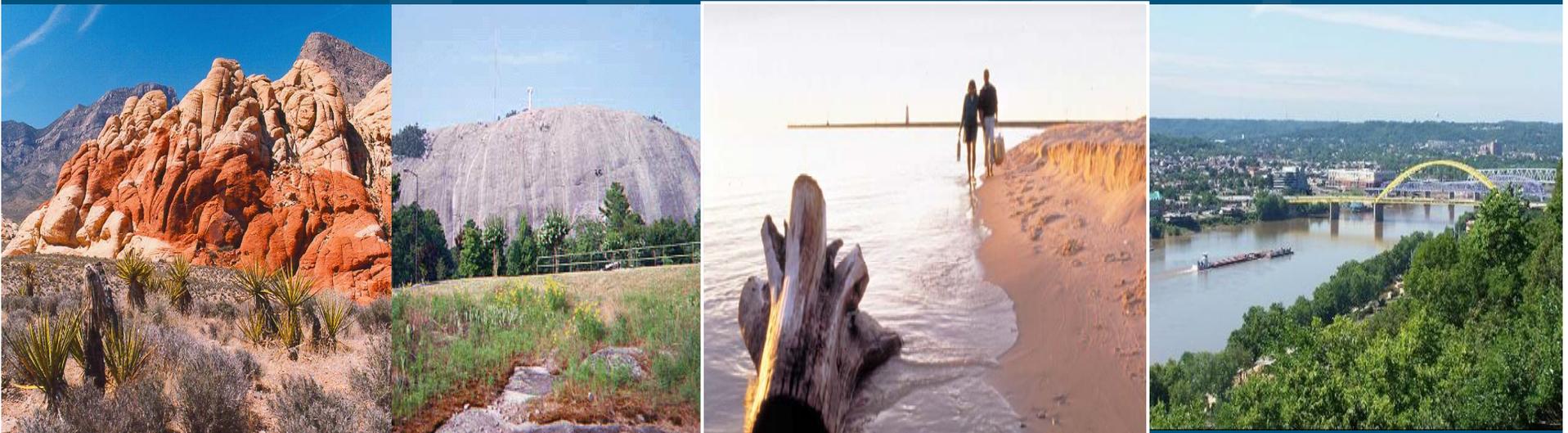
Vulnerability (ReVA) program, Dr. Mehaffey is engaged with the Future Midwest Landscapes study, developing the EISA biofuels target scenario and evaluating changes in ecosystem inputs, functions, and services as a result of shifting land use as a result of ethanol demands, and is contributing to the development of a National Atlas of ecosystem services, focusing on evaluating the relationships between the landscape and human health.

Dr. Valerie Zartarian is an environmental engineer with EPA's Office of Research and Development, National Exposure Research Laboratory, Human Exposure and Atmospheric Sciences Division, Exposure Modeling Research Branch. Prior to joining EPA in 1998, she was a Postdoctoral Research Affiliate and Research Assistant in the Department of Civil Engineering, Stanford, CA, and a water resources engineering consultant with Camp, Dresser, & McKee, Inc., Cambridge, MA. Dr. Zartarian holds Ph.D. and Masters degrees in environmental engineering from Stanford University, and a B.S. in civil engineering from Princeton University. Dr. Zartarian's primary areas of expertise are the development and application of EPA/ORD's probabilistic human exposure model for multimedia chemicals, and exposure tools to assess cumulative health risks from environmental stressors in communities. Her emphasis has involved providing EPA/ORD, EPA Program Offices, EPA Regions, and the scientific community with practical research tools to support both regulatory and voluntary programs. Dr. Zartarian has published over 20 peer-reviewed journal articles, briefed high level EPA officials, and received awards including EPA's Gold Medal for Exceptional Service, the Children's Environmental Health Excellence Award, and the Scientific and Technological Achievement Award .

Bradley C. Autrey, J.D. - Biologist, Ecosystems Exposure Branch, Ecological Exposure Research Division, National Exposure Research Laboratory (NERL) Cincinnati, Ohio.

Mr. Autrey's primary area of research has been in the development of remote sensing and GIS tools to help assess aquatic ecosystems. In addition, he is also interested in the legislative, statutory, and administrative aspects of environmental law. Mr. Autrey received his Bachelor of Science in Biology from the University of North Texas in 1994, his Master of Science in Biology from Stephen F. Austin State University in 1997, and his J.D. from Chase College of Law in 2008.

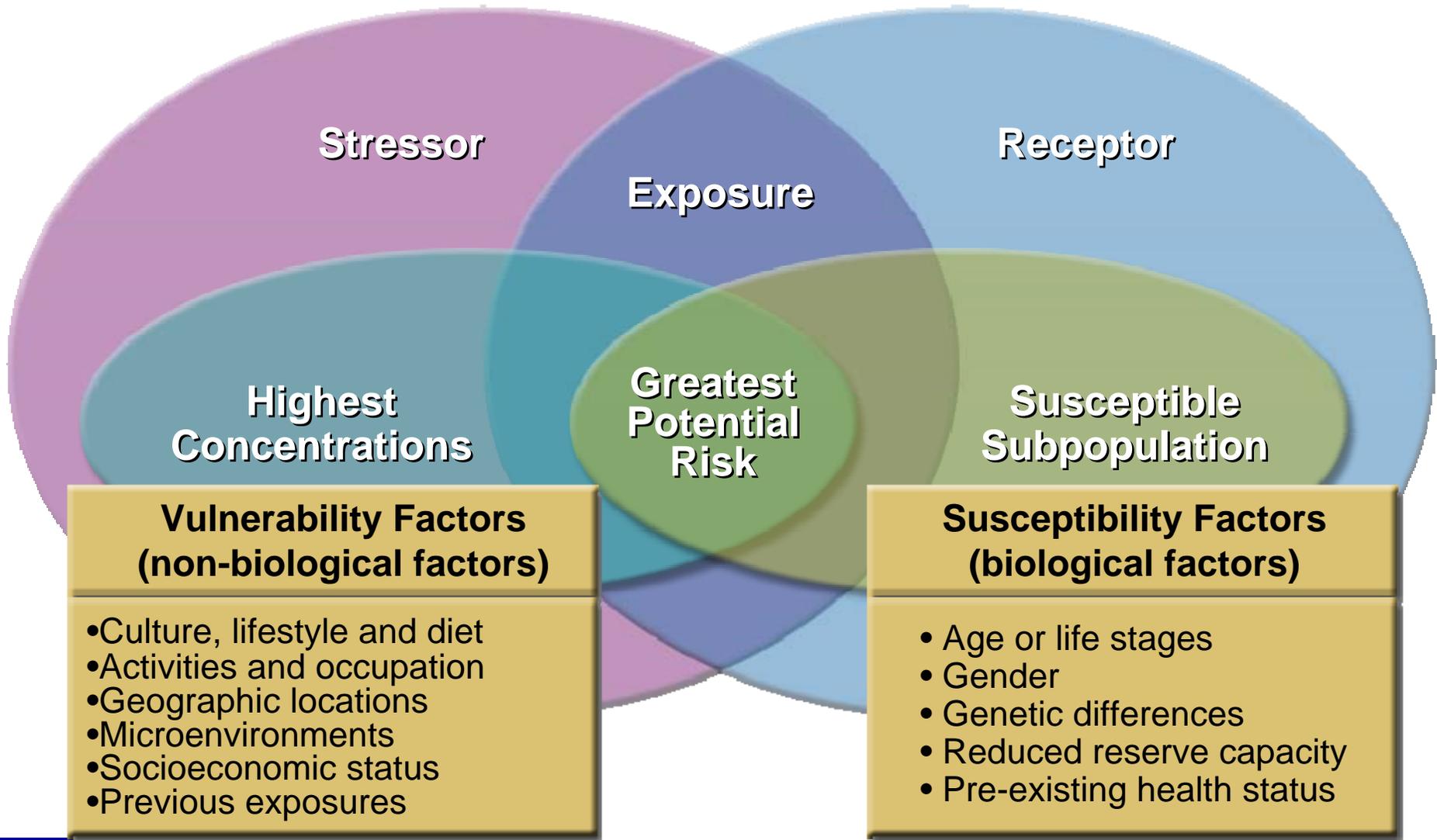
National Exposure Research Laboratory



Outline

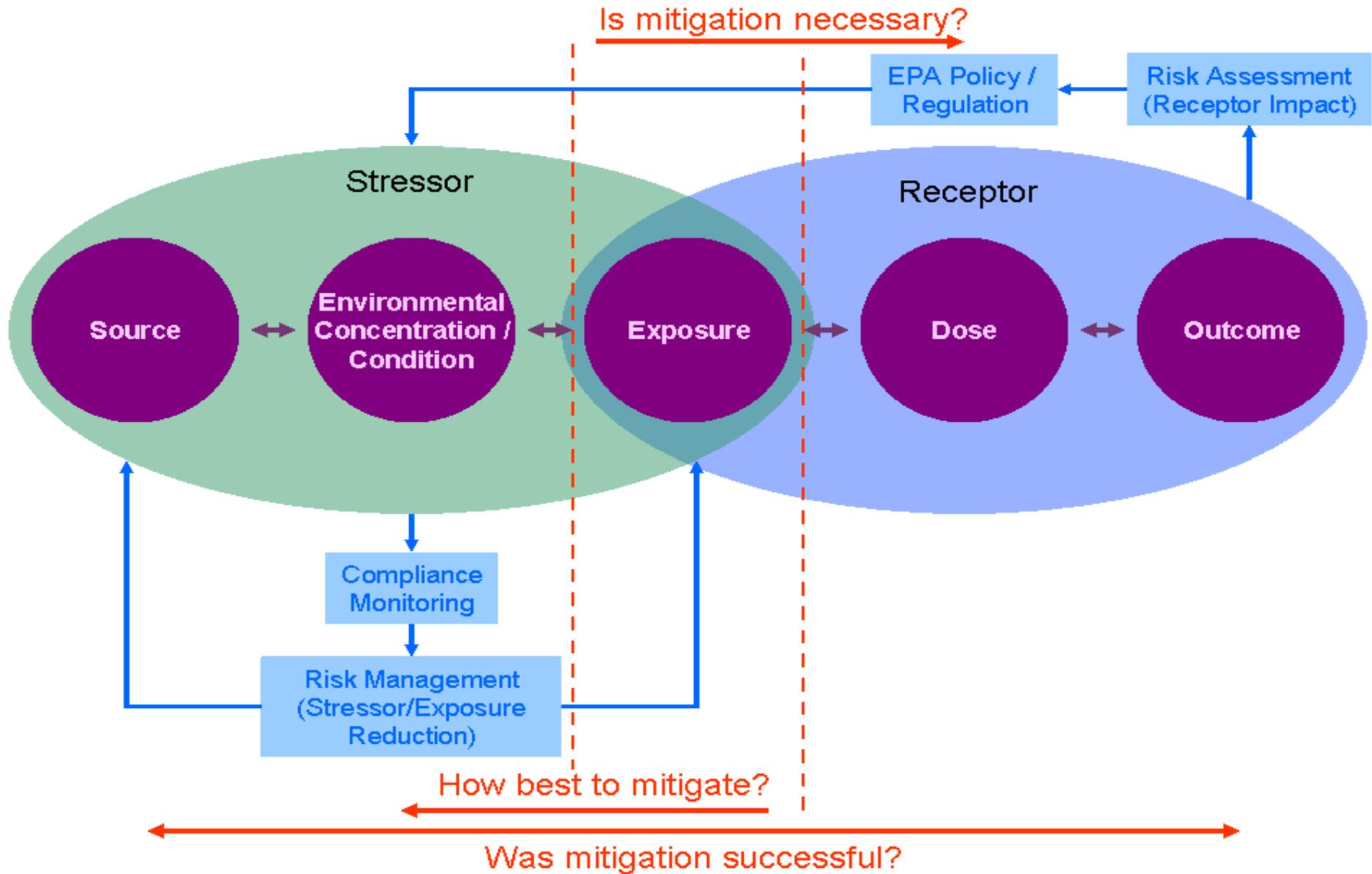
- Exposure – Definition & Significance
- NERL: Mission & Structure
- Exposure Science Framework
- Integrating program & regional priorities

Defining Exposure





Exposure concepts: key to Agency science decisions



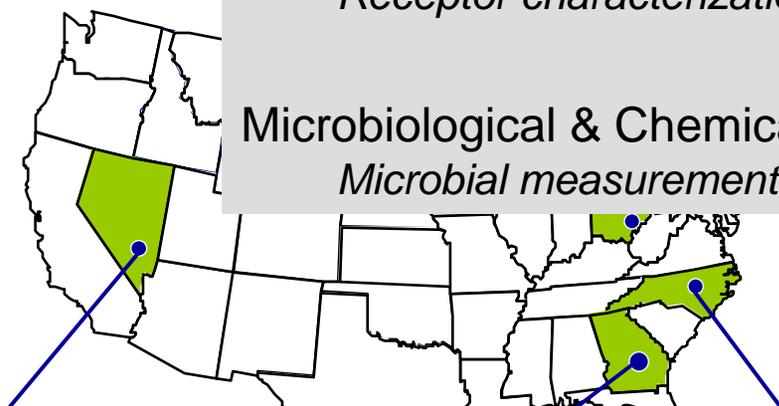
NERL's Mission

Conduct human health and ecological exposure research that provides the pertinent databases, predictive modeling and analytical tools necessary for the EPA to carry out its mission

- **Research:** to reduce critical exposure uncertainties associated with the Agency's policy decisions.
- **Technical support** and recommendations for the evaluation, management and restoration of exposure within environmental systems
- **Leadership** across the international research community to develop and apply state-of-the-science integrated multimedia exposure models



NERL at a Glance



Ecological Exposure Research Division
Receptor characterization

Microbiological & Chemical Exposure Assessment Division
Microbial measurement, characterization & prediction

Environmental Sciences Division
Landscape characterization

Atmospheric Modeling and Assessment Division
Atmospheric pollutant fate and transport models

Human Exposure and Atmospheric Sciences Division
Human exposure characterization (all sources)
Emission & movement of atmospheric pollutants

Ecosystems Research Division
Stressor fate and transport

FY 2010 Budget: \$82.8M

FY2010 NERL Work Force: 664

- EPA Staff **404**
 - scientists* 339
 - managers & administrative* 65
- On-site contractors **>150**
- Postdocs / graduate students **29**
- SEE employees **81**



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

SCIENCE



Evaluation Criteria for Selection of Research Problems

**Does the research support
the Agency's mission?**



Is it exposure research?



Research should meet one or more of the following criteria:

**Requires NERL's
expertise or
unique facilities**

**Requires integrated
approach only NERL
can provide**

**Exposure and
exposure data are
integral part of
overall research
question**

**Scope and scale of
the research
require NERL's
involvement**

**It is a priority research area
for the Agency**

**It is the right time for
NERL's involvement**

Incorporating Framework into NERL Business

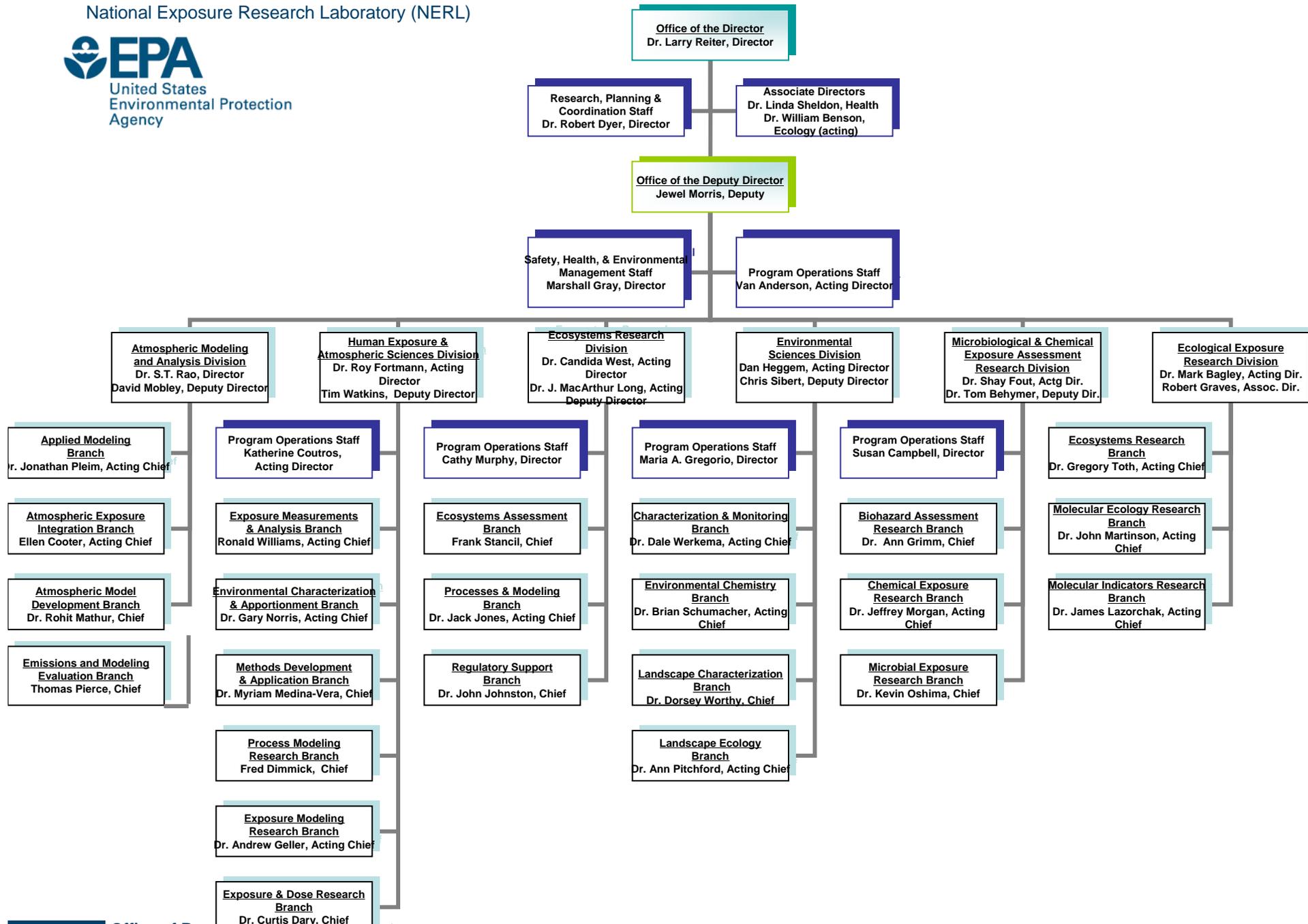
- Act corporately.
- Science comes first.
- Apply integrated multidisciplinary approaches.
- Seek functional solutions first.
- Optimize use of resources.

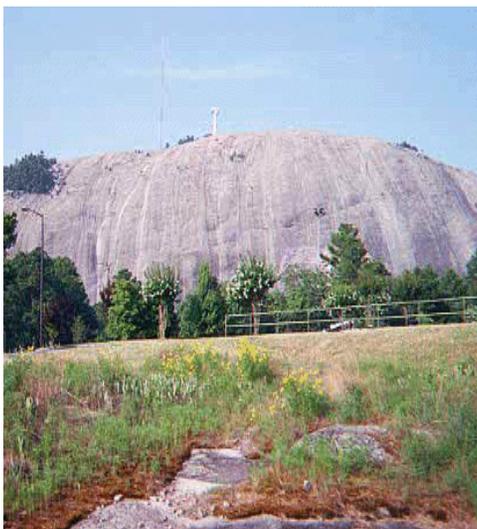
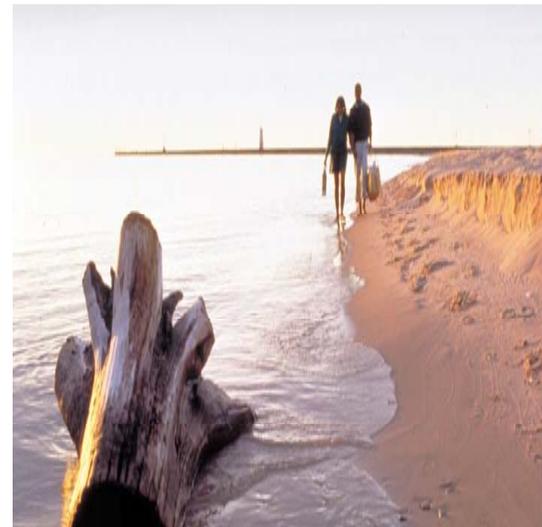
**NERL's Framework is central to a
Strategy Focused Organization.**

Mechanisms to integrate program priorities

- ORD planning process (e.g. MYPs)
- NERL implementation planning process
- Direct interaction with programs & regions (e.g. RARE)
- NERL Senior Managers meetings (strategic discussions)

National Exposure Research Laboratory (NERL)





Research Planning in ORD's National Exposure Research Laboratory (NERL)

Planning

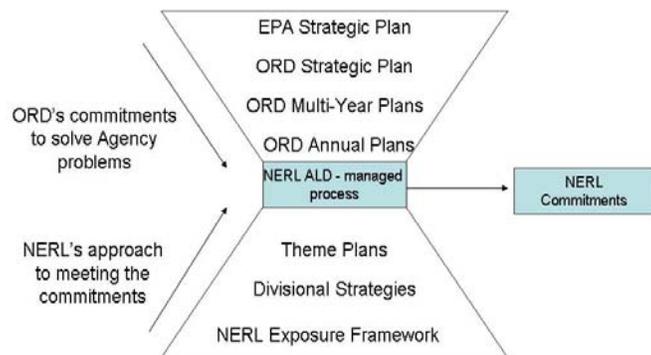
Research planning in NERL is intended to ensure the Lab focuses on the highest priority Agency needs for research, bringing to bear the best available science, while optimizing engagement of the Laboratory workforce. This intent has resulted in a process that combines top down guidance with bottom up input. Partner and stakeholder priorities are considered primarily through the ORD Multi-year plans, which are developed by ORD's National Program Directors (NPDs) with input from the Laboratories. An NPD is responsible for ORD strategic planning in each of ORD's major research programs. NERL interfaces with NPDs for research programs in Air, Drinking Water, Water Quality, Land, Toxics and Pesticides. NERL also interfaces with ORD NPDs for its Human Health research program, and its Ecosystem Services research program. NERL has five Assistant Laboratory Directors (ALDs), who serve as the primary interface between the Laboratory and both the NPDs and the regulatory program offices. ALDs manage the overall NERL planning process, and are responsible for ensuring that priorities are communicated effectively, and translated appropriately into Laboratory research commitments. NERL has developed a conceptual framework to guide selection of research problems. In consultation with their scientific staff, NERL division directors clarify, sharpen the focus of and develop research plans to solve the research problems delivered by the ORD planning process. Specific research commitments are negotiated with the NPDs, partners and stakeholders, division directors, ALDs, scientific staff. The process by which commitments are made and tracked is managed by the NERL Accountability Manager, who ensures that NERL complies with the requirements of the Government Performance and Results Act.

Communication

Responsibility for communication about NERL's research program and progress is shared throughout the organization.

NERL has a communication staff with responsibility for representing NERL programs to the public, both directly and through Agency communication staff. NERL's Assistant Laboratory Directors have a major responsibility to ensure effective, timely and accurate communication with partners and stakeholders regarding NERL programs and progress. NERL's divisions and their scientific staff retain primary responsibility for communicating with the scientific community, and for communicating detailed technical information within the Agency.

Relationship between ORD and NERL Planning



Feedback

Ensuring responsiveness to the needs of partners and stakeholders requires feedback from them. NERL's researchers and planning staff are expected to maintain dialogue with partners and stakeholders during the research process. Dialogue ranges from formal seminars and planning meetings to informal telephone discussions. In addition, NERL has experimented with more

formal means of obtaining feedback on selected products (e.g. feedback forms provided with transmittal of documents).

Headwater Streams and Isolated Waters/Wetlands



Problem: A 2001 Supreme Court decision (SWANCC) that withdrew protection of isolated wetlands based on their lack of “significant nexus” to navigable waters ultimately called into question the jurisdictional status of headwater, intermittent and ephemeral streams. Lack of understanding or agreement about what constituted a “significant nexus” led to divergent outcomes in numerous subsequent rulings. Better scientific understanding of the structure and function of headwater streams was/is necessary to determine if they fall within

Clean Water Act jurisdiction. (Nadeau and Rains, 2007)

Regardless of jurisdictional status, preliminary scientific investigations indicate that the existence and health of headwater streams impact the water quality of downstream waters and the ecological integrity of whole watersheds. Many landuse activities, including the currently contested practice of mountaintop mining/valley fill, threaten headwater streams. The magnitude of impacts on water quality and the thresholds for cumulative losses of headwater streams are still scientific uncertainties with significant policy and management implications.

Process: State and Regional Scientists were finding that the existing stream assessment methods were ill-suited for use in headwater streams, partly due to the lack of hydrologic permanence. EERD assistance was sought through the Regional Methods Initiative (RMI) program. The extension of those methods to mountain top mining/valley fill (MTM/VF) impacts and reconstructed streams was advanced by the Regional Research Partnership with Region 4 and the Universities of Louisville and Kentucky

In addition, the Office of Water’s Office of Wetlands, Oceans, and Watersheds (OW/OWOW) identified the need for better understanding of the role headwater streams and isolated wetlands play in downstream water quality as one of their research priorities, which prompted EERD to expand the scope of the headwater streams project to include function questions.

Approach:

The science-based knowledge that was/is needed to resolve both the legal and management issues of headwater streams includes answers to the following questions:

What constitutes significant nexus? Must nexus be physical (i.e. hydrological – via surface only?) or can it be exchange or export of chemical, biological properties?

What is the WQ impact of HW streams on downstream (regulated water bodies)?

What is the role of headwater streams in maintaining integrity of stream networks/watersheds (e.g. cumulative impacts)?

Over what spatial and temporal scales is hydrological connectivity relevant?

:

NERL scientists have developed tools to assess the quality and permanence of headwaters streams, including geomorphic and biological indicators. To provide guidance in the use of these tools, NERL scientists have published a manual and several peer-reviewed journal articles outlining the methods. The manual, titled *Field Operations Manual for Assessing the Hydrologic Permanence and Ecological Condition of Headwater Streams* (Fritz et al., 2006), provides guidance to regulatory agencies on when to use each method and how to interpret the data the methods generate. To aid in educating regulators in the use of these tools, EPA scientists facilitated six workshops on these methods between 2003 and 2005, attended by over 100 state and regional personnel.

Results/Impact

In their 2003 Advanced Notice of Rulemaking, the EPA and Army Corps of Engineers have received comments from 43 states, numerous tribes and local governments, with greater than 90% of the comments supporting jurisdictional protection for non-navigable tributaries and isolated waters. EPA's Region 3 has issued a white paper to the Huntington and Pittsburgh US Army Corps Districts making regulatory recommendations based on the published findings. Recent judicial rulings increasingly shift responsibilities for protection to states and several states (e.g. Ohio, NC) are already adopting protection measures for HW streams. Moreover, recent guidance from EPA's Office of Water on watershed approaches for protecting aquatic systems and human health incorporate protection for headwater streams.

As direct result of the publications of the field manual and the supporting scientific articles, NERL scientists have been asked to participate on workgroups for developing jurisdictional determination tools for Oregon (with NHEERL/WED) and South Carolina. Numerous requests for the handbook have been received from contractors supporting coal industry in MTM/VF.

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Overview of NERL's Clean Air Research Program

The Clean Air Act requires EPA to develop and implement National Ambient Air Quality Standards (NAAQS) for criteria pollutants and other air quality regulations, including regulations for toxic air pollutants and mobile sources. NERL's Clean Air Research Program supports the development and implementation of these air quality regulations and is aligned with the ORD's Clean Air Research Multiyear Plan (MYP), which has the following two long term goals (LTG):

- LTG 1: reduce uncertainty in standard setting and air quality management decisions
- LTG 2: reduce uncertainties in linking health and environmental outcomes to air pollution sources to support effective air quality strategies

The implementation of the NAAQS requires monitoring and modeling tools to identify problem areas and potential solutions to bring these areas into attainment with the NAAQS. Recent National Research Council reports emphasize a more integrated multi-pollutant approach to air quality management.

The Atmospheric Modeling and Analysis Division (AMAD) and the Human Exposure and Atmospheric Sciences Division (HEASD) work together in conducting NERL's Clean Air Research Program. The AMAD leads the development and evaluation of predictive atmospheric models (such as the Community Multiscale Air Quality [CMAQ] model) on all spatial and temporal scales for assessing changes in air quality and air pollutant exposures, as affected by air quality management decisions and for forecasting the Nation's air quality. The models developed by AMAD are being used by EPA, NOAA, the States, and the air pollution community in understanding and forecasting not only the magnitude of the air pollution problem, but also in developing emission control policies and regulations for air quality improvements. The CMAQ model user community numbers well over 1000 worldwide. The HEASD leads the development and evaluation of exposure and source apportionment measurements and modeling tools (such as the Stochastic Human Exposure and Dose Simulation [SHEDS] model), atmospheric chemistry methods and models, and ambient monitoring methods for implementation of NAAQS. The models and methods developed by HEASD are used by EPA and States to develop and implement air quality management activities. In addition, HEASD atmospheric chemistry research feeds gas-phase chemistry and aerosol mechanisms into the AMAD air quality model development research, while AMADs' air model development research links with HEASD exposure modeling and source apportionment research. Current areas of focus in NERL's Clean Air Research Program include multidisciplinary integrated research related to near-roadway human exposures and risks, urban source apportionment, the formation of secondary aerosols (both organics and nitrate), better quantification of primary PM emissions, the linkage of air quality models with ecosystem exposure and watershed models, and the linkage of air quality and global climate change models to understand regional climate change impacts on local/regional air quality.

The impact of NERL's Clean Air Research is significant. NERL methods (e.g., Federal Reference Methods for NAAQS) and models (e.g., CMAQ air quality model; Positive

Matrix Factorization source-apportionment model) are used domestically and internationally by air quality managers and the science community to develop, evaluate, and implement scientifically sound air quality management policies to protect human and ecosystem health.

Cumulative Risk Assessment of Pyrethroid Insecticides through Linked Human Exposure and Dose Models

Rogelio Tornero-Velez , Valerie Zartarian

Science Issue

The Food Quality Protection Act (FQPA) of 1996 mandates that the U.S. EPA consider both aggregate and cumulative risks. Aggregate assessments account for multiple sources and routes of exposure for a single chemical. FQPA mandated cumulative assessments combine exposures to two or more chemicals that share a common mechanism of toxicity. EPA's Office of Pesticides Programs (OPP) and Office of Research and Development (ORD) are conducting collaborative science to inform the pyrethroid cumulative risk assessment (CRA) anticipated in 2011-2012.

Approach

Previous assessments involving the organophosphate and N-methyl carbamate pesticides combined exposure and hazard data without explicit consideration of intervening ADME processes (absorption, distribution, metabolism, excretion) that modulate the availability of toxicant at the target site. Through a coordinated multi-disciplinary effort, the ORD and OPP scientists have developed new approaches for CRA:

(1) models to estimate longitudinal dietary and residential exposure to pyrethroids; (2) models to estimate tissue burden and urinary concentrations of pyrethroids through class-oriented physiologically-based pharmacokinetic (PBPK) modeling; and, (3) approaches to relate cumulative exposure to risk by application of PBPK models and tissue-based relative potency factors (RPFs)

The overall goal of this task is to develop and link state-of-the-art exposure (Stochastic Human Exposure and Dose Simulation [SHEDS]) and dose (Exposure-Related Dose Estimating Model [ERDEM]) modeling tools to support the pyrethroid CRA. The results from various measurement studies, corresponding data analyses, and exposure modeling (SHEDS) are being used to identify and quantify occurrence, magnitude, critical routes and pathways of pyrethroid exposure. These results are being used to identify the individual and mixtures of pyrethroid pesticides that individuals are exposed to in real-world scenarios. The PBPK models are being used to interpret the exposure data and compute integrated dose metrics related to toxic outcomes for multiple routes of exposures for individual pyrethroids and pyrethroid mixtures. The combined exposure and dose modeled outputs will permit an evaluation of the simultaneous and aggregate of exposures of the targeted pyrethroids. The output from the linked exposure-dose modeling will be integrated with the corresponding effects research to provide the enhanced science and inform the cumulative risk assessment

SHEDS for multimedia, multi-route/ pathway chemicals (SHEDS-Multimedia) was presented to the FIFRA Scientific Advisory Panel (SAP) in August 2007. SHEDS-Multimedia is a state-of-science probabilistic computer model for improving estimates of aggregate and cumulative human exposure and dose. PBPK models for deltamethrin and permethrin have been developed to date for rats, and by utilizing a *family approach*, will be developed for other chemical members in the pesticide class. A *family approach* for

developing physiologically-based pharmacokinetics models of pyrethroid disposition was presented to the FIFRA SAP in August 2007. This approach leverages structure-property relationships within the chemical class to decrease the burden of *in vivo* kinetic data needed to model additional members of its class. Bayesian methods address uncertainties in *chemical extrapolations* and *in vitro* to *in vivo* extrapolations. The SAP indicated that, as a class, pyrethroid pesticides have sufficient structural similarities such that a “generic” model structure with chemical specific parameters as needed is appropriate. Initial linkages of SHEDS and ERDEM have been tested using annual simulations of exposure accounting for aggregate exposure across multiple routes. Further testing of the linkages along with model evaluation against biomonitoring data is underway for a SAP review anticipated in 2010. The methods and models developed under this effort will provide new science and data that will inform a cumulative risk assessment of pyrethroids and aid in future assessments of compounds sharing property relations.

Impact and Outcomes: The enhanced science and products of this research will reduce uncertainty in risk assessment/management by providing ORD, OPP, other Agency, academia, and industry exposure and risk assessors with:

- A peer-reviewed approach for developing and applying probabilistic exposure models of multimedia, multi-route/pathway chemicals
- A peer-reviewed approach for structure-based approaches in PBPK model development
- Linked models for exposure-to-dose analyses, reviewed by the FIFRA SAP, for application to inform the anticipated CRA for pyrethroid pesticides
- An established conceptual model for considering cumulative risk assessment for compounds considered in the future.

Contributors: J. Xue, E. Scollon, J. Starr, J. Johnson, and C. Dary (NERL); M. DeVito and M. Hughes (NHEERL); J. Davis and W. Setzer (NCCT); and A. Lowit (OPP).

Key Products:

Assessing Approaches for the Development of PBPK Models of Pyrethroid Pesticides. Federal Register / Vol. 72, No. 94 / Wednesday, May 16, 2007 FIFRA Scientific Advisory Panel; Notice of Public Meeting [EPA-HQ-OPP-2007-0388; FRL-8131-2]

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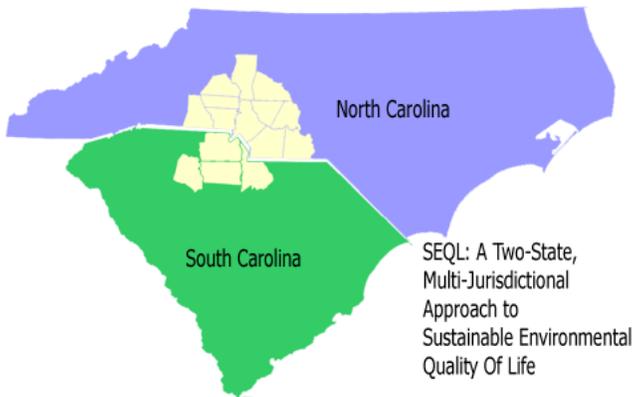
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ReVA SEQL: Regional Vulnerability Assessment (ReVA) Program addresses Sustainable Environment for Quality of Life (SEQL)



Problem: Charlotte-Gastonia-Rock Hill is a rapidly developing greater metropolitan area, whose current population of 2.1 million people is expected to grow by 1.8 million people by 2030. In addition to the region's current ozone non-attainment designation and river basin TMDLs, this projected growth is expected to exacerbate numerous environmental and quality of life issues. Local politicians, planners and citizen's groups sought the science and technology to develop a regional, integrated approach that:

- Allowed local governments the opportunity to work in regional cooperation and collaboration across jurisdictional lines (two states, 15 counties and 117 political jurisdictions) setting a standard for the nation
- Provided implementation assistance to local governments on environmental "commitment action items" developed under the Charlotte/Mecklenburg Sustainability Demonstration Project.
- Analyzed air quality issues including ozone, particulate matter, and air toxins, while also addressing transportation, water, land use, energy use, and economic development

Process

Following on EPA's Sustainability Project, and building on the need to construct population projections and traffic demand models with the Office of Air Quality Protection Standards (OAQPS), Charlotte and Mecklenburg Counties initiated an effort to forge holistic solutions largely outside of regulatory domain. The resulting Federal-State-Local partnership effort (SEQL) led by the Centralina and Catawba Regional Councils of Government (COGs), ultimately engaging over 80 jurisdictions and other stakeholder groups.

ORD engagement was initiated by the Region 4 representative to NC and SC, and a strong partnership between OAQPS and ORD resulted. That partnership was supported by ORD's Ecosystems Research Program (currently The Ecosystems Services Research Program) and built on the science and technology developed by RevA in the Mid-Atlantic Highlands.

Ultimately, EPA supported SEQL through complementary and well-coordinated efforts between OAQPS (grants, technology evaluation) and ORD (ReVA – landuse change modeling; local and regional data inventory and integration)

Approach

NERL scientists brought data and models to the stakeholder-driven “visioning” process carried out by the Councils of Governments (COGs). Population projections and landuse models formed the basis for alternative environmental and development futures, which in turn, served as inputs into models for water quality, and other quality of life outcomes, such as commuting patterns, access to recreational land, etc.

Comprehending and evaluating multiple model outputs and integrating multiple data streams required the construction of a web-accessible, regional data framework and a set of advanced statistical and visualization tools. ReVA collaborated with numerous partners to populate the data framework and to create integration methods that reflected and were responsive to stakeholder preferences and concerns, including multi-dimensional indices and indicators for fiscal impacts and quality of life.

Impact

SEQL has achieved significant results on air quality, water quality, sustainable growth and emissions reductions. The “lessons learned” and a set of “how-to” guidance documents have been developed by the two COGs and are in wide use throughout the Charlotte region and the Southeast. 84 jurisdictions have self-reported implementation of these guidances in the form of 732 actions in four areas:

- Air quality (burning limits, commuter programs, energy use reduction)
- Water quality (water supply plans, buffer construction, upgraded wastewater treatments)
- Sustainable growth (greenways and open space, multi-modal transit, pedestrian and bike transit)
- Emissions reductions and other (diesel retrofit, brownfields redevelopment, green building, pervious pavement)

The data and integration framework developed by ORD-ReVA has been transferred to the Urban Institute at the University of North Carolina – Charlotte for continued use in regional planning and evaluation activities.

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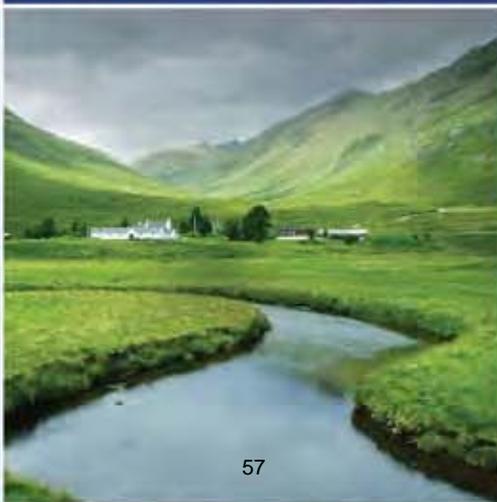
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A Conceptual Framework for U.S. EPA's National Exposure Research Laboratory

SCIENCE





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

SCIENCE



Notice

The information in this document has been funded by the United States Environmental Protection Agency. It has been subjected to the Agency's peer and administrative review and has been approved for publication as an EPA document.

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.

A handwritten signature in black ink that reads "Lawrence W. Reiter". The signature is fluid and cursive, with the first name being the most prominent.

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.

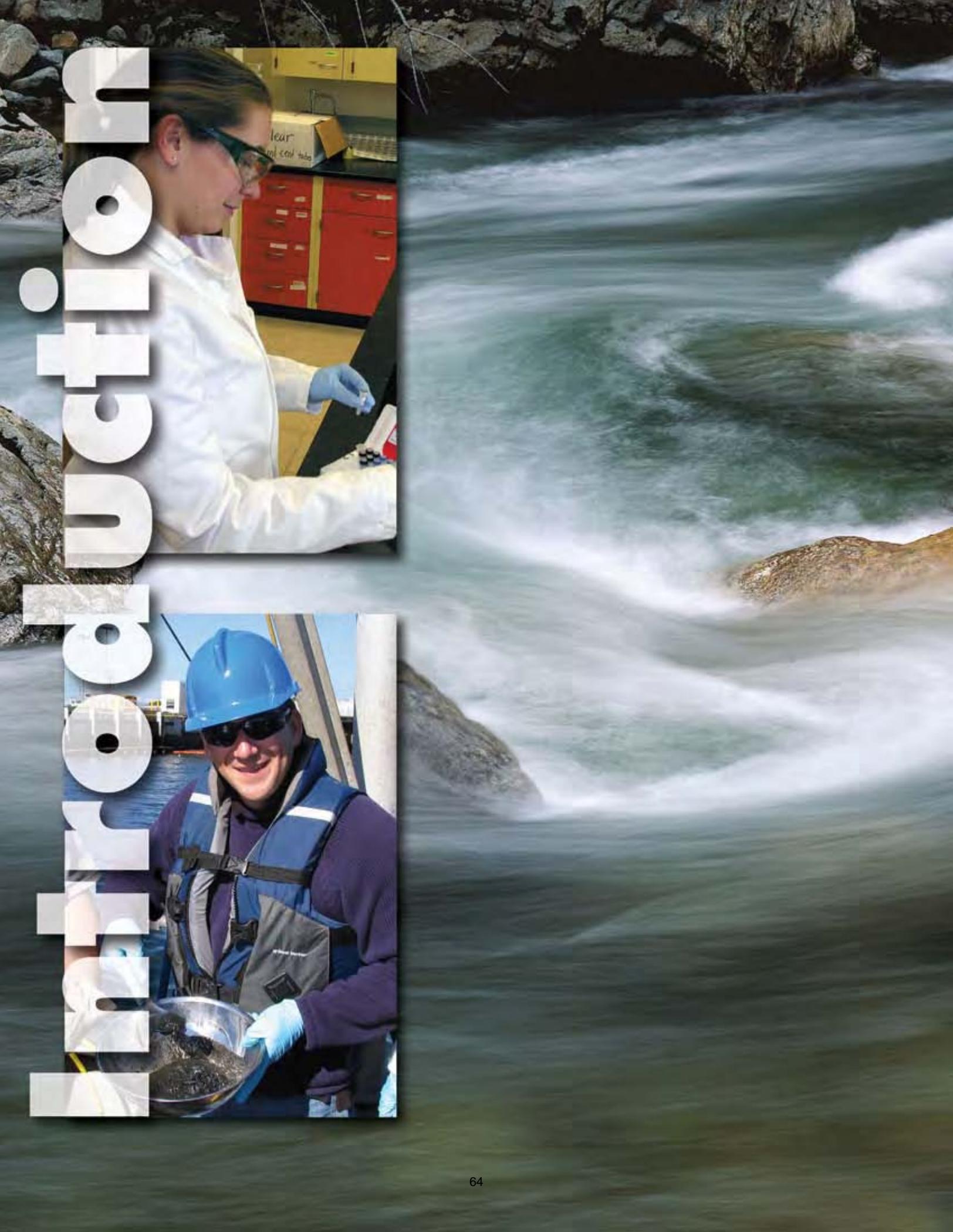
We wish to thank the following individuals for their time spent crafting this framework: Rochelle Araujo, Robert Dyer, Roy Fortmann, Florence Fulk, Fred Hauchman, Daniel Heggem, S.T. Rao, Mark Rodgers, Linda Sheldon, and Eric Weber.

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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

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.

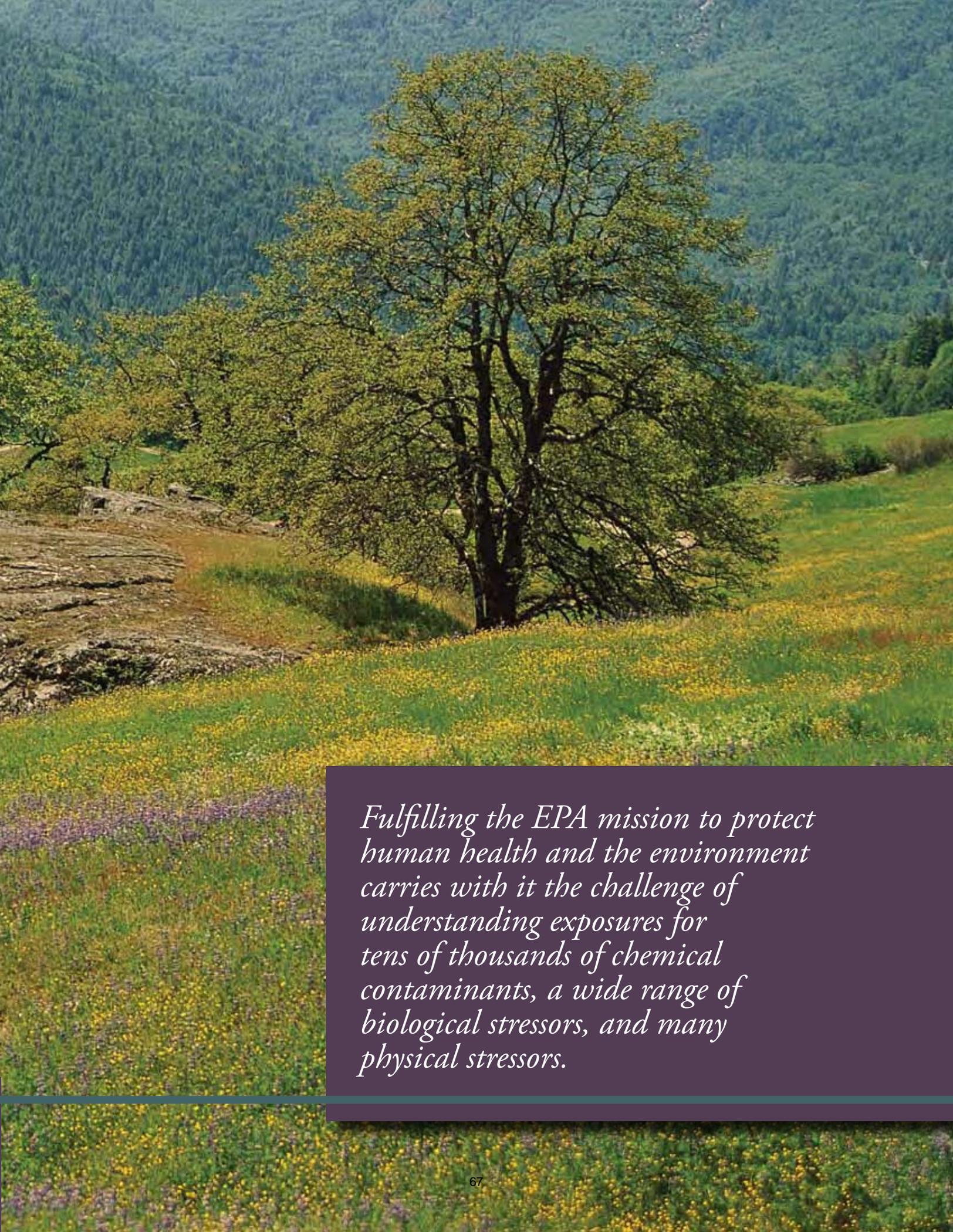
uncertainties associated with the Agency's policy decisions and provides international leadership in exposure science. This document is a conceptual framework for addressing NERL's research

mission and achieving its goal of scientific leadership. In the following sections, the document will:

- ❖ 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).

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

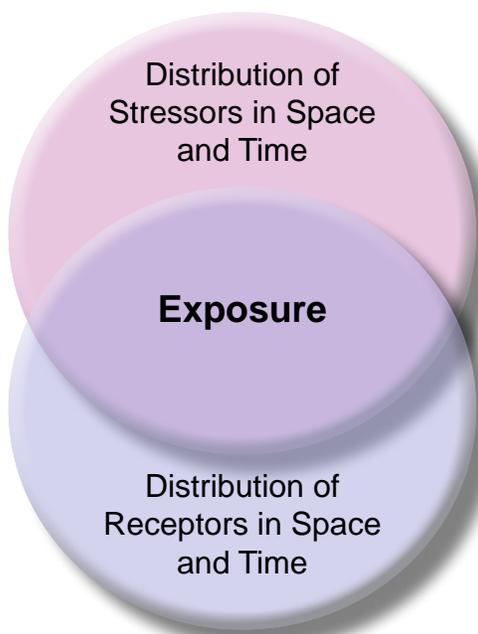


Figure 2-1. Conceptual diagram of exposure



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

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

and resulting exposures, as well as those situations that lead to exposure for the most susceptible receptors.

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.

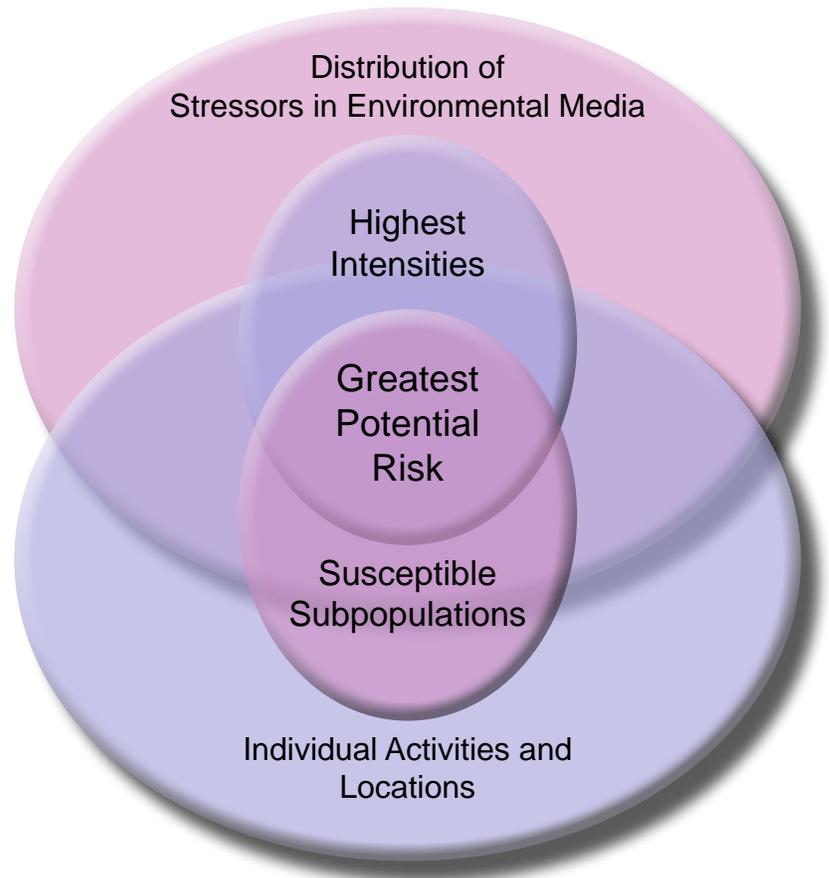


Figure 2-2. The highest concentrations and the most susceptible populations create the greatest potential risk.

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	
<i>Human Health Research</i>	<i>Ecological Research</i>
<ul style="list-style-type: none"> • Agency is responsible for human health outcomes solely related to environmental stressors 	<ul style="list-style-type: none"> • Agency is responsible for health of the entire ecosystem
<ul style="list-style-type: none"> • Chemical and biological agents are primary stressors of concern 	<ul style="list-style-type: none"> • Physical condition along with chemical and biological agents are primary stressors of concern
<ul style="list-style-type: none"> • Single Receptor - human at individual or population level 	<ul style="list-style-type: none"> • Multiple Receptors – individual plant or animal species, communities of plants and animals, or entire ecosystems
<ul style="list-style-type: none"> • Receptors (humans) are the same at all locations – population density, vulnerability, and susceptibility may change across locations 	<ul style="list-style-type: none"> • Receptors will vary across locations – location will determine what receptors are present and the circumstances for contact with the stressor
<ul style="list-style-type: none"> • Traditionally, risks have been evaluated for a single stressor at a time 	<ul style="list-style-type: none"> • Risks are evaluated for multiple stressors, using a systems approach
<ul style="list-style-type: none"> • Exposures and outcomes stop with consideration of the human receptor 	<ul style="list-style-type: none"> • Exposures and outcomes can cascade when the outcome in one receptor serves as the stressor for another
	<ul style="list-style-type: none"> • Exposure and outcomes are of interest at additional levels of biological organization



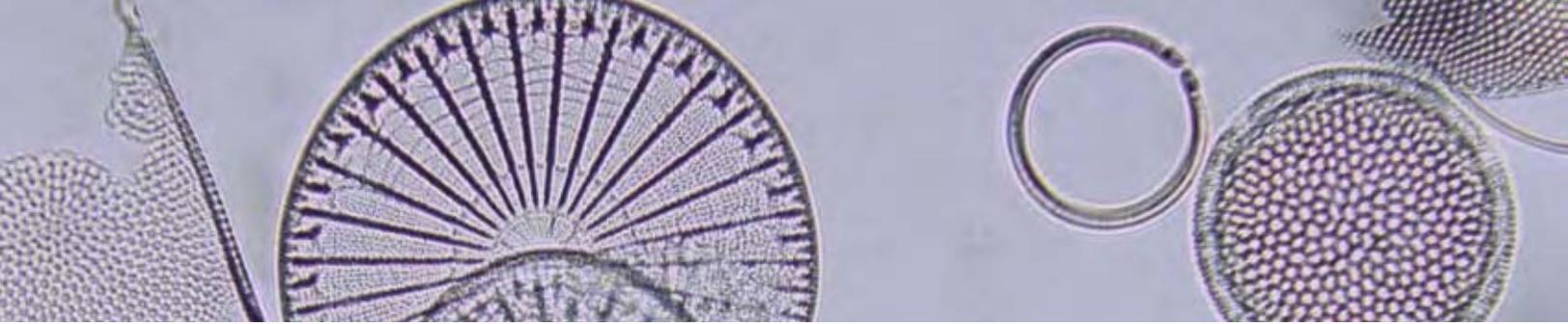


Figure 2-3 (below) is an adaptation of the source-to-outcome framework developed by the National Research Council (NRC, 1983, 1998). The processes that are important for exposure science start with a stressor entering the environment and end with dose characterization. Starting in the upper left-hand 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.

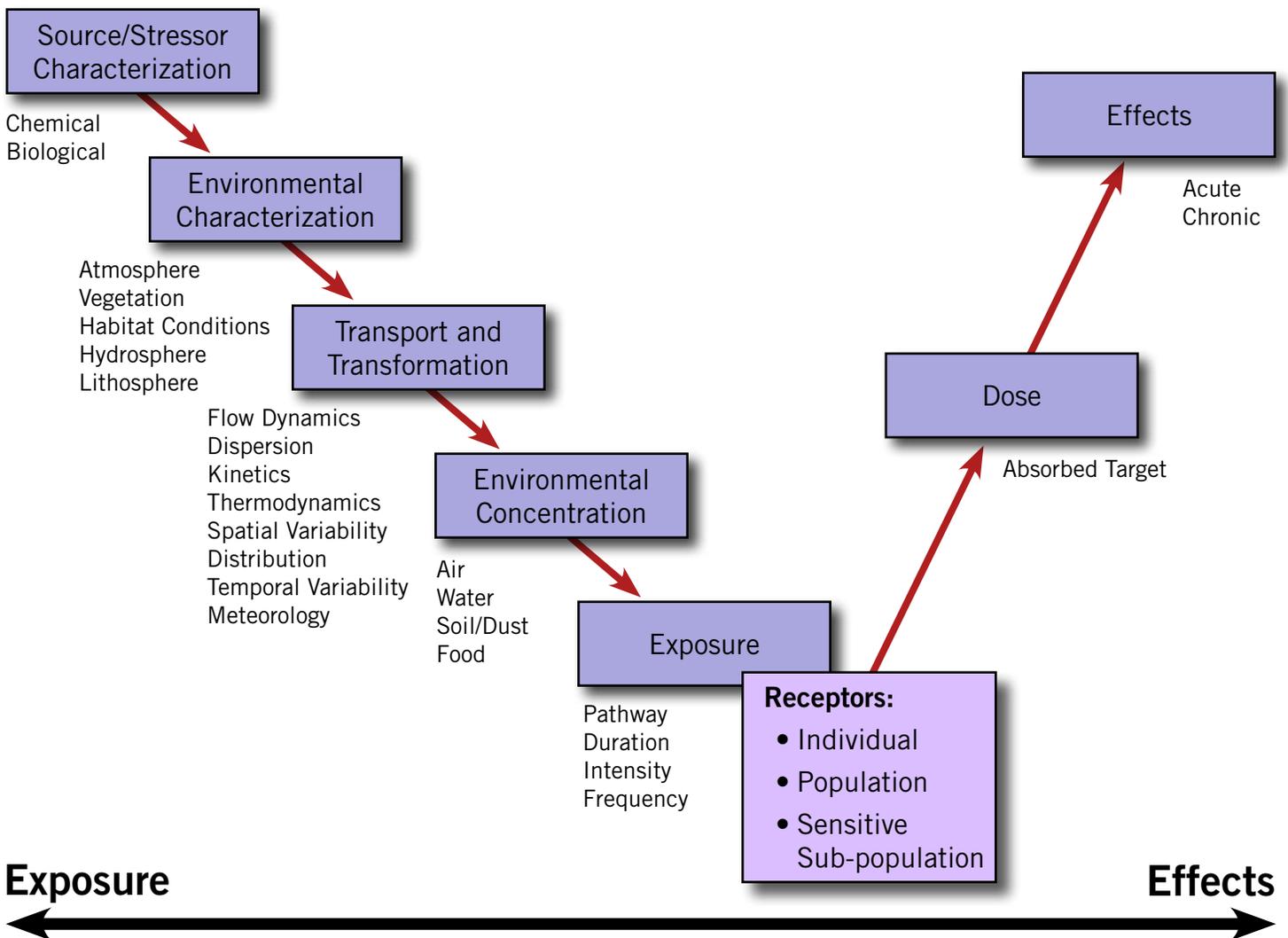


Figure 2-3. Source-to-outcome framework for human health exposure research

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.

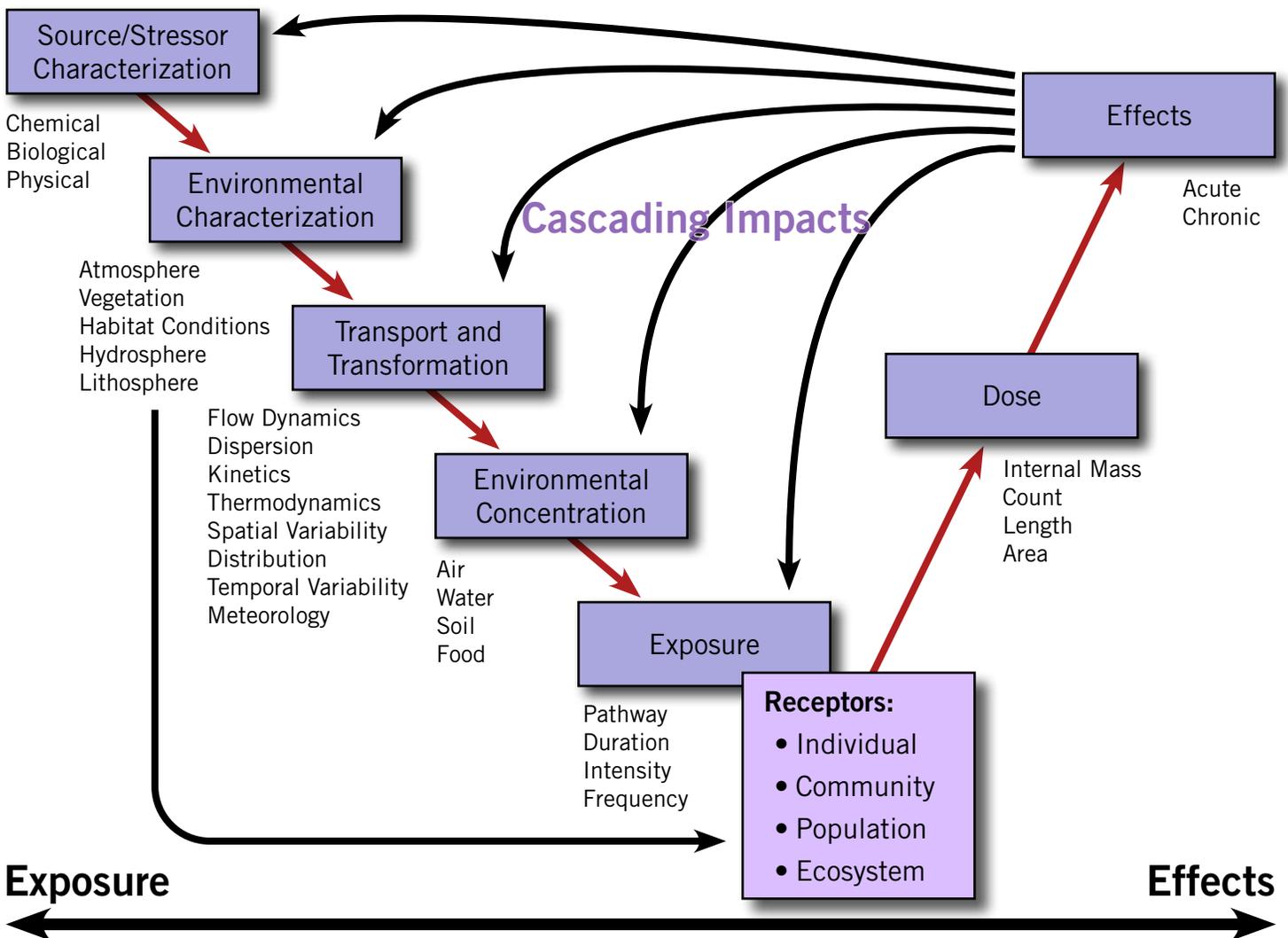


Figure 2-4. Source-to-outcome framework for ecological exposure research

Although the source-to-outcome framework for human health and the framework for ecological research have been diagrammed 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:

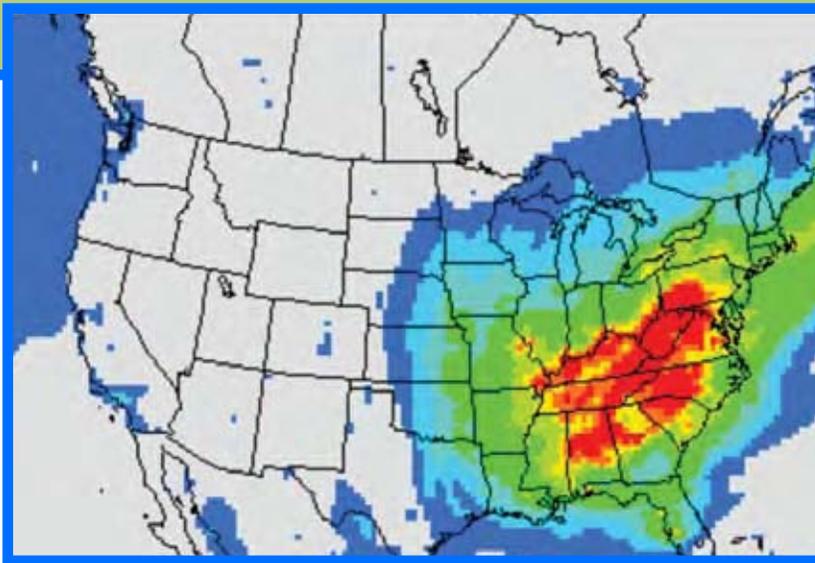
the course that the chemical takes from its source to the receptor.

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:

$$\text{Risk} = \text{Exposure} \times \text{Hazard}$$

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,

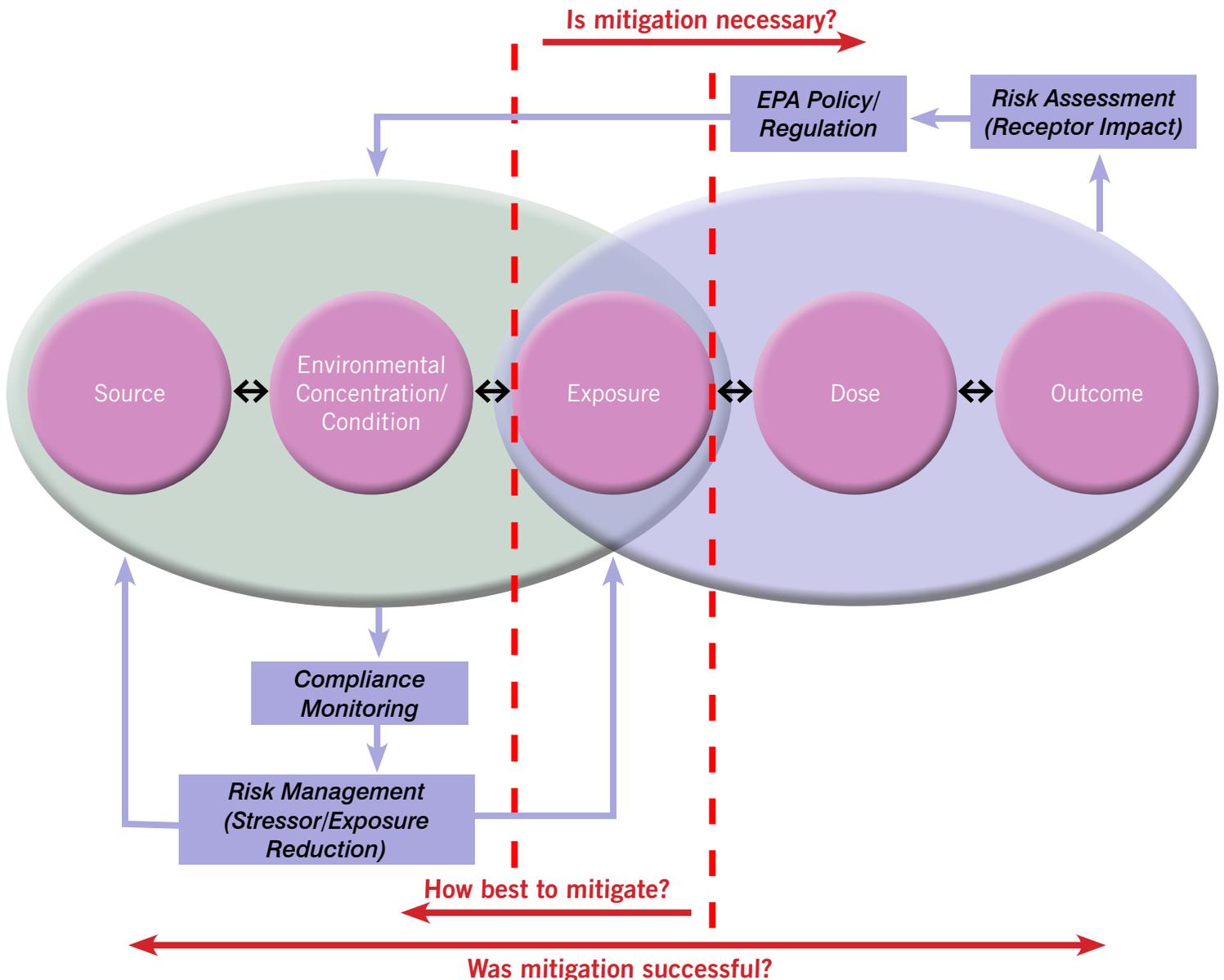


Figure 3-1. Framework for protecting human health and the environment

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.

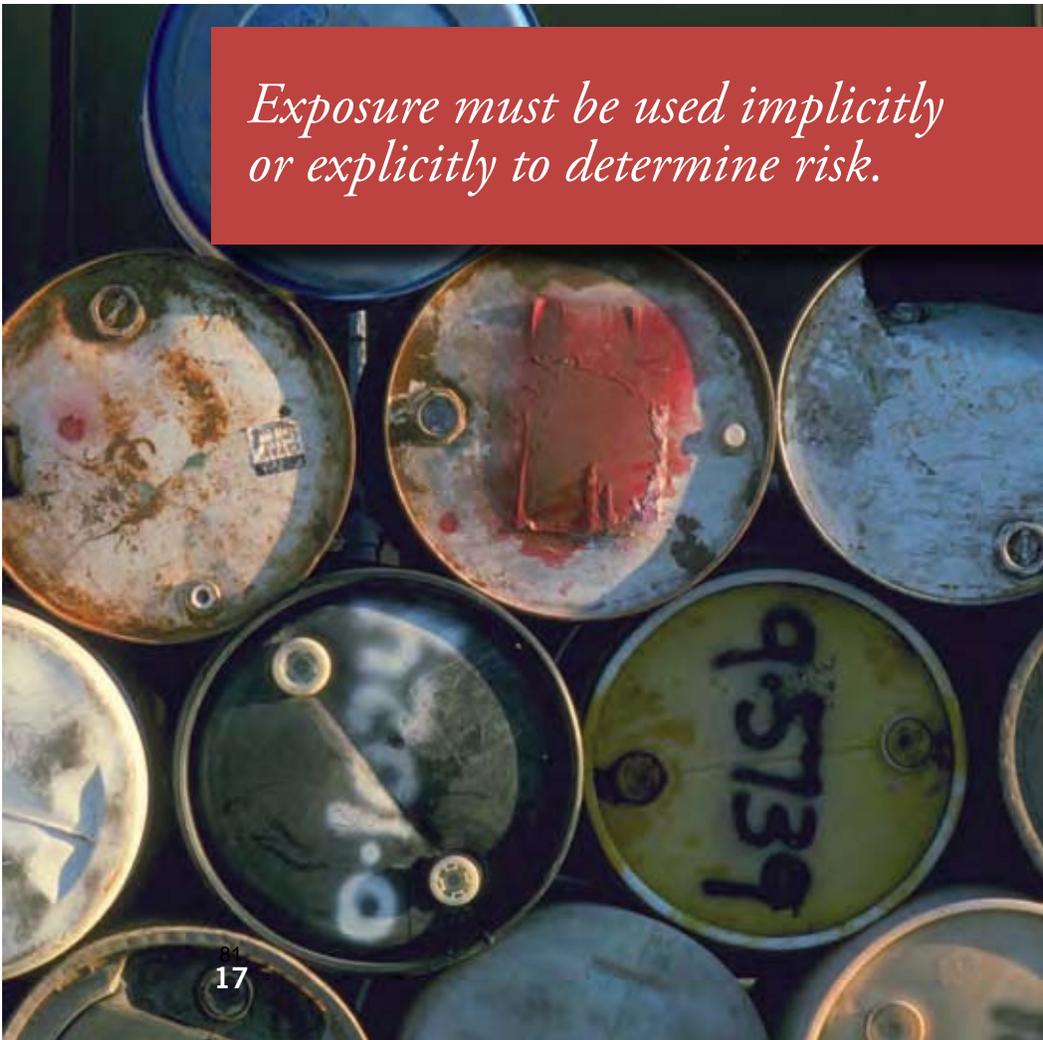
How best to mitigate?

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).

A top-down view of several petri dishes containing various microbial cultures. One dish in the center shows a bright red, solid growth. Another dish to the right has the number '95739' written on it in black marker. The dishes are arranged in a grid-like pattern.

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.

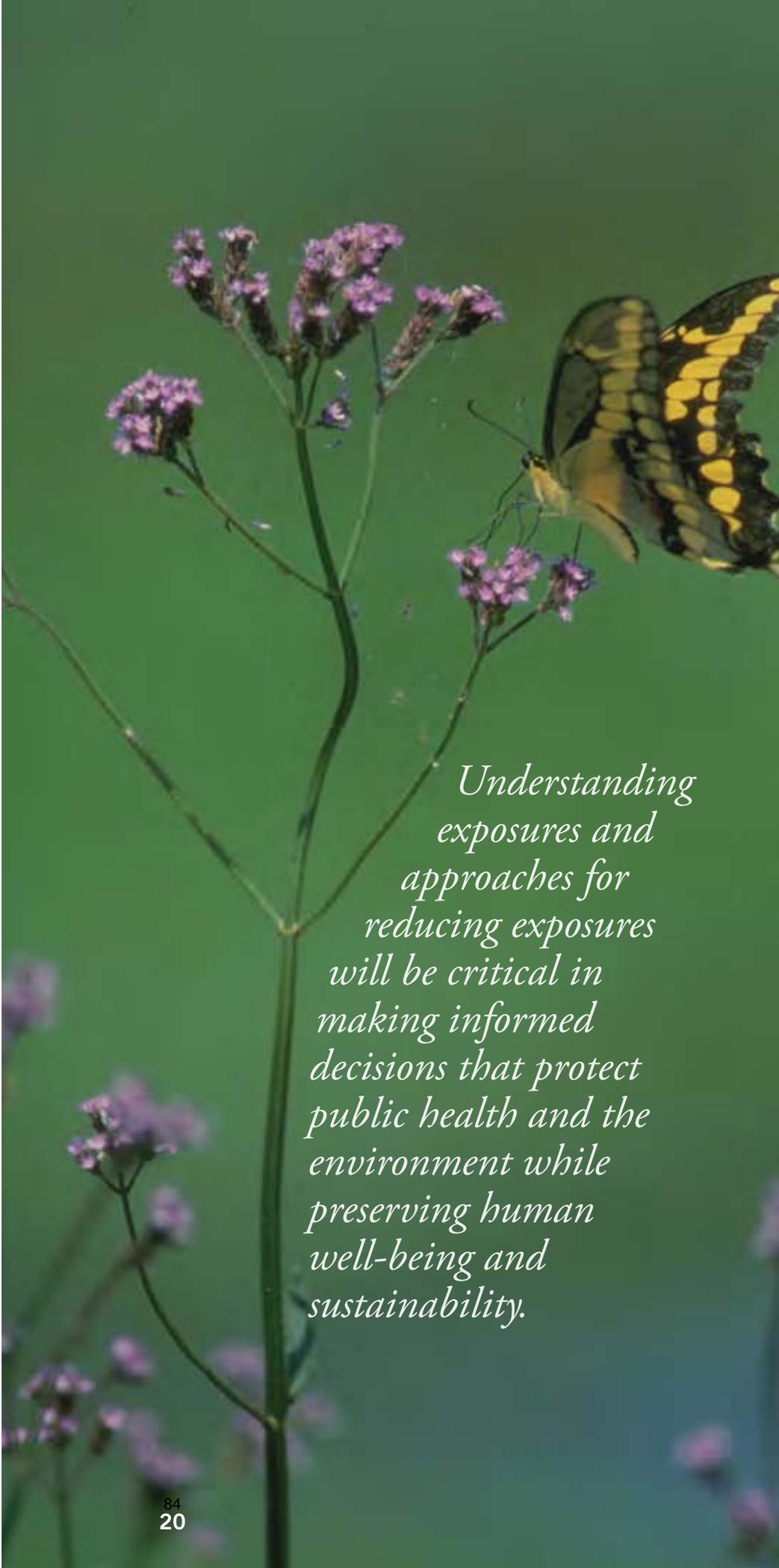


The text box on page 21 identifies the major exposure elements of the EPA's enabling legislation. Identifying and understanding those elements are critical to strengthening and expanding the Agency's use of exposure science.

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**

HAZARDOUS WASTE

FEDERAL LAW PROHIBITS IMPROPER DISPOSAL
IF FOUND, CONTACT THE NEAREST POLICE, OR
PUBLIC SAFETY AUTHORITY OR THE
U.S. ENVIRONMENTAL PROTECTION AGENCY



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.

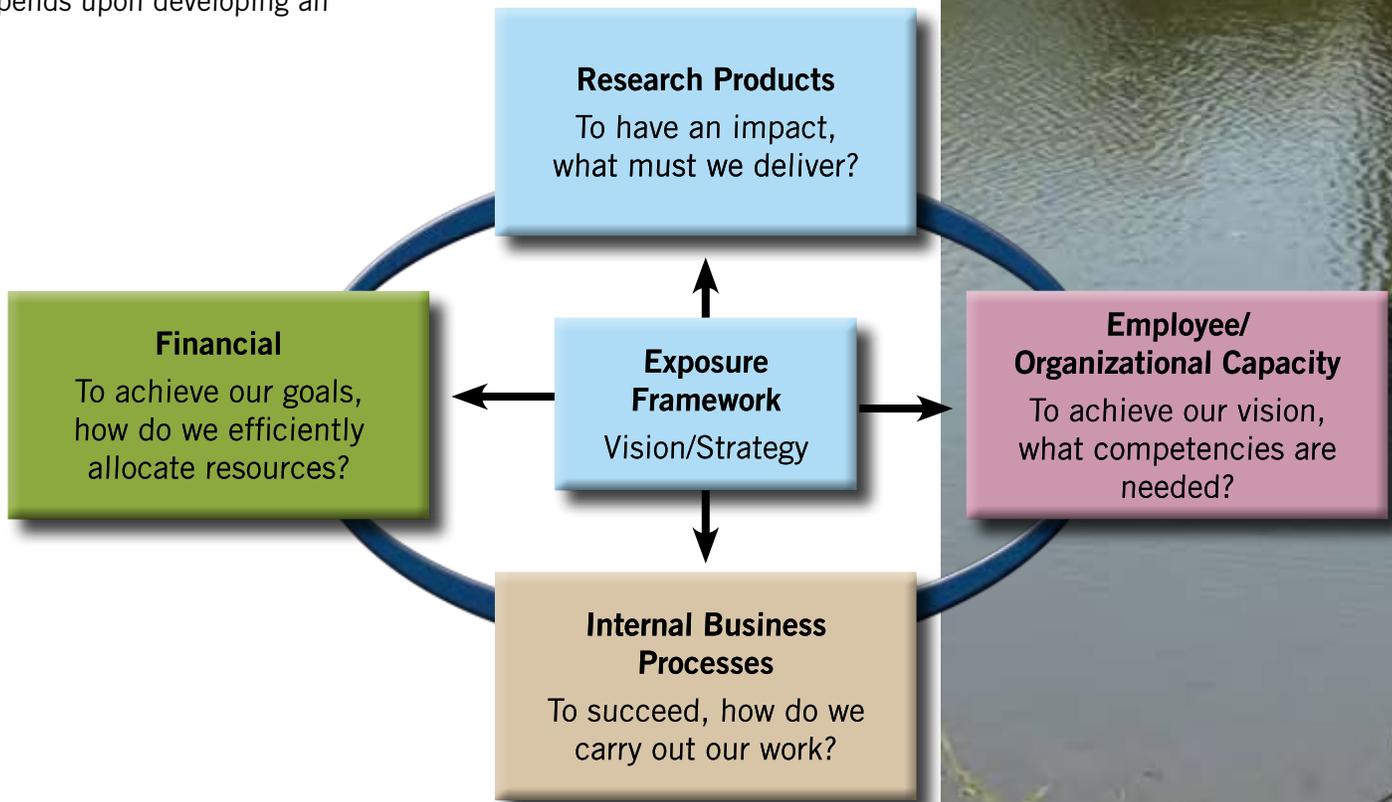


Figure 4-1. Aligning NERL's business as a Strategy-Focused Organization (Adapted from Kaplan and Norton, 2001)



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 through 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 through 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



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? | |

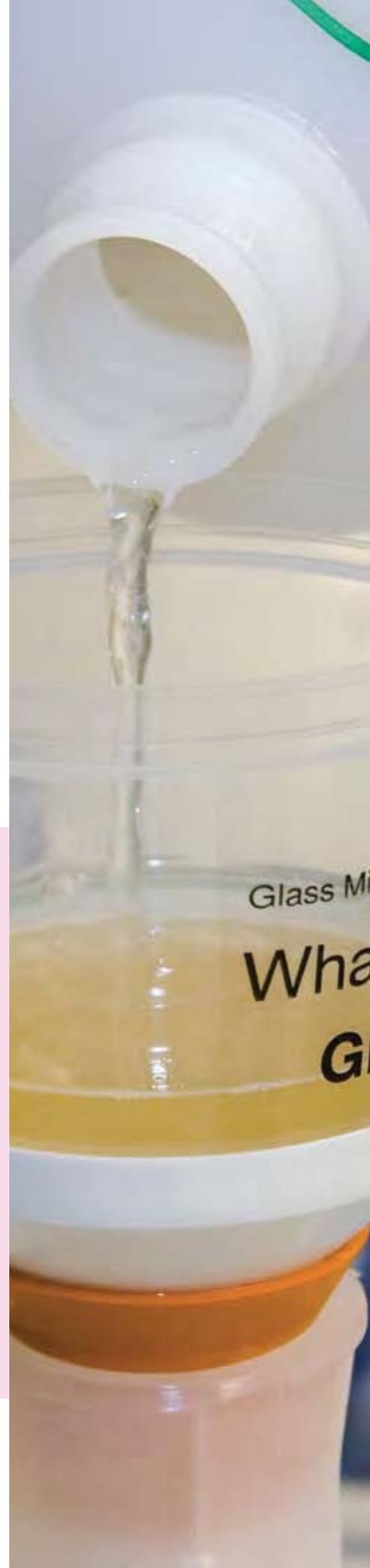


Figure 4-2. Evaluation filters and criteria for assessing potential research areas



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.

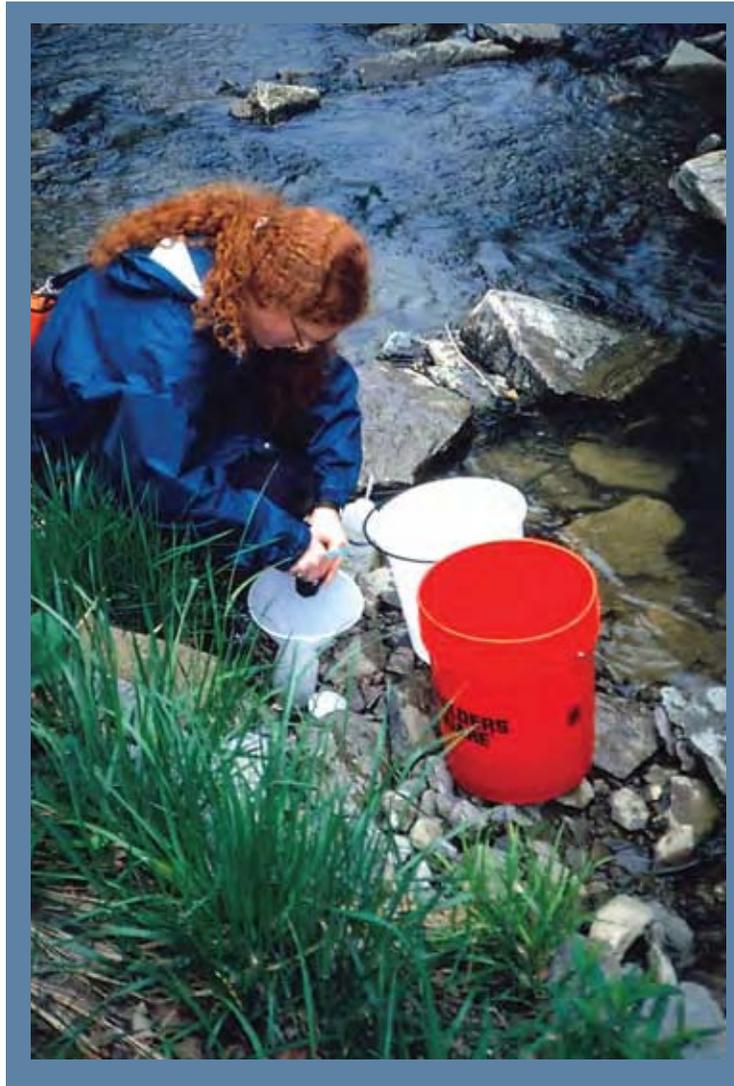
❖ We are the National Exposure Research Laboratory.

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

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



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).

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

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

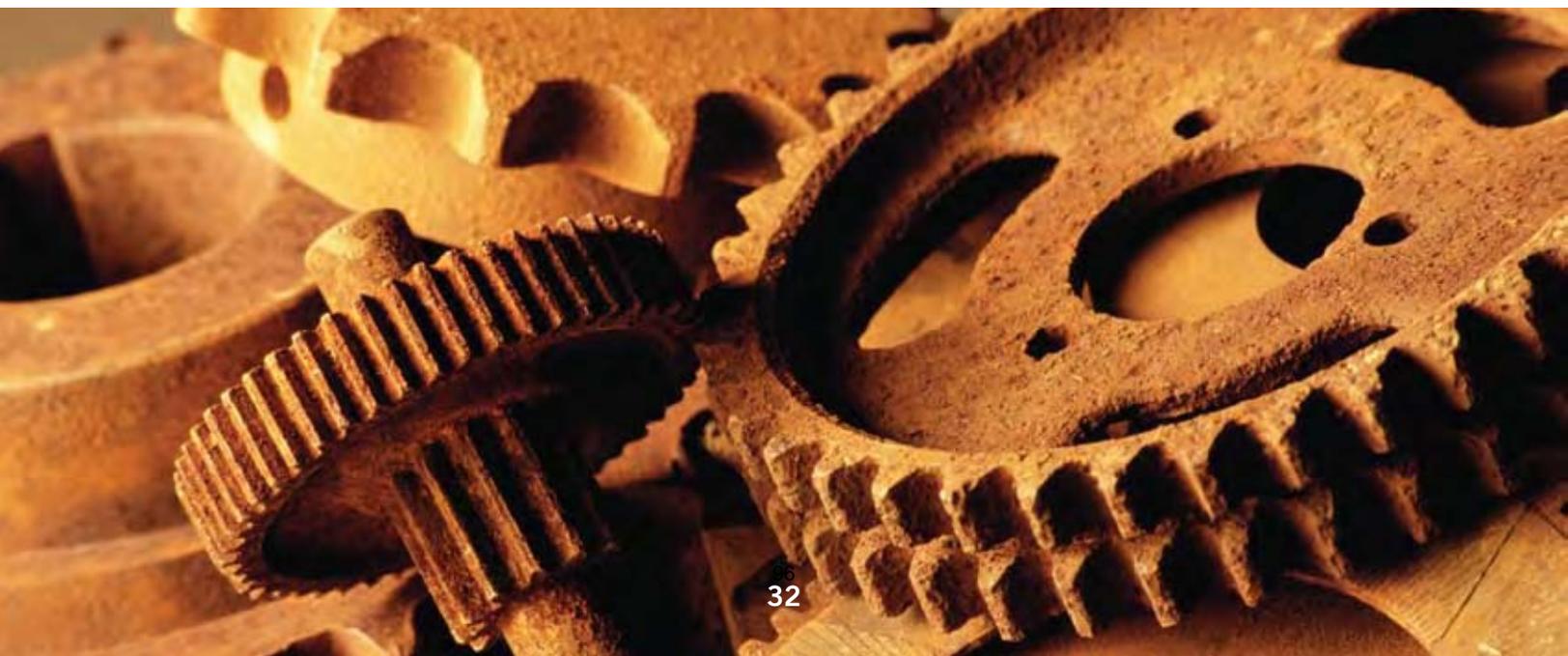
collaboration and integration, such as virtual teams and Web-based communications. As NERL moves forward, it is important to identify and implement proven and time-tested best management and organizational practices; to seek the counsel of organizational leaders and consultants to guide the process; and to commit to adopting management systems that simplify rather than complicate laboratory operations.

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

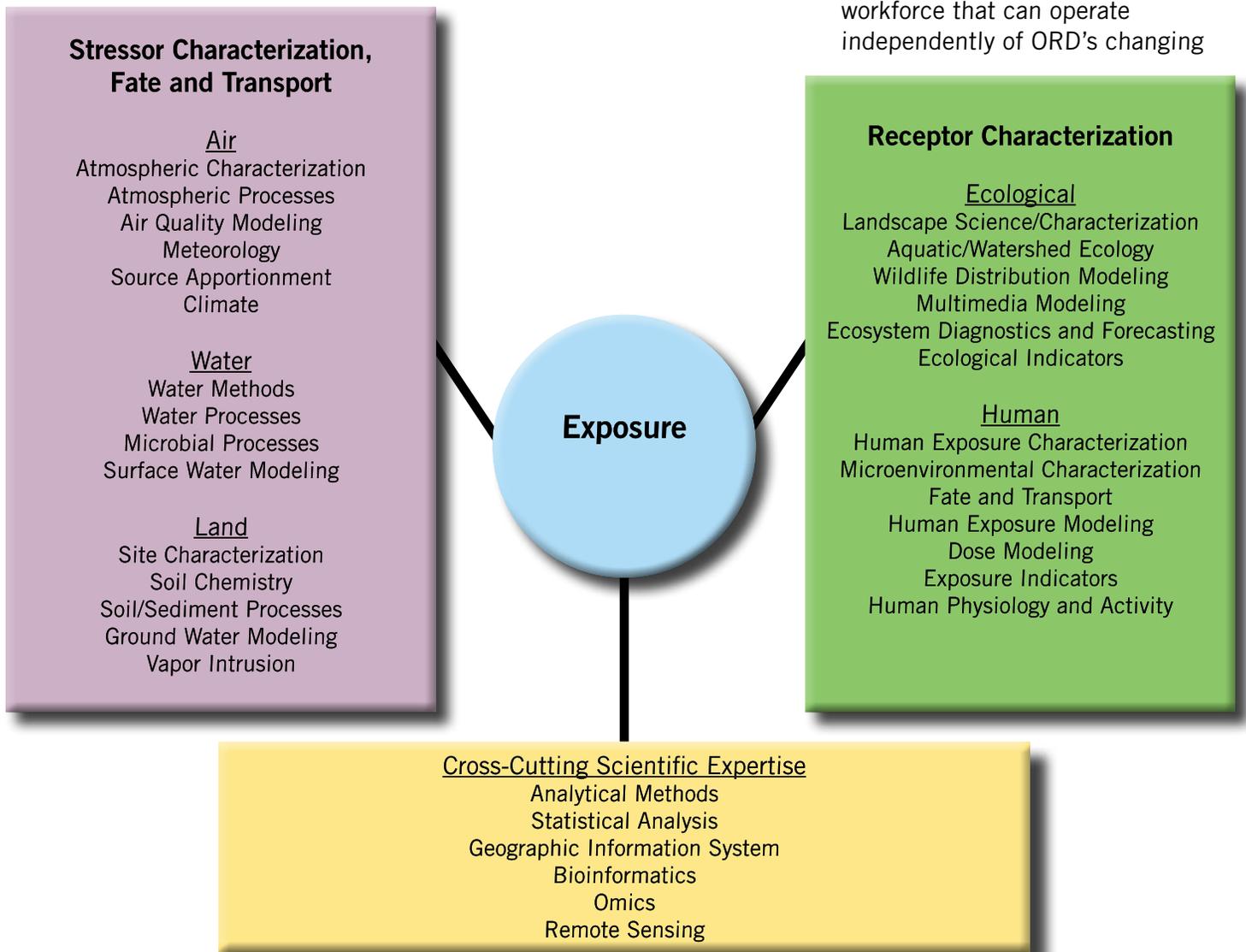
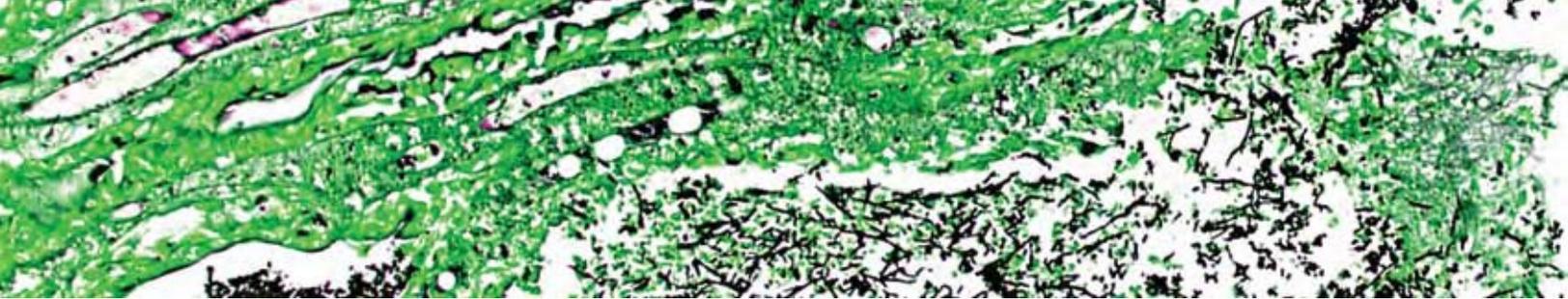


Figure 4-3. Scientific expertise for exposure research



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.



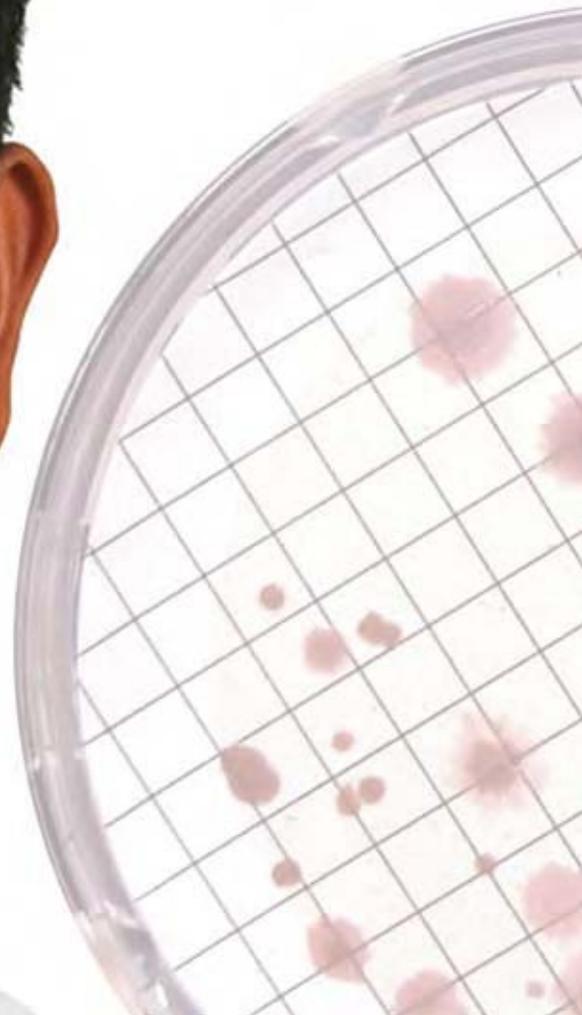
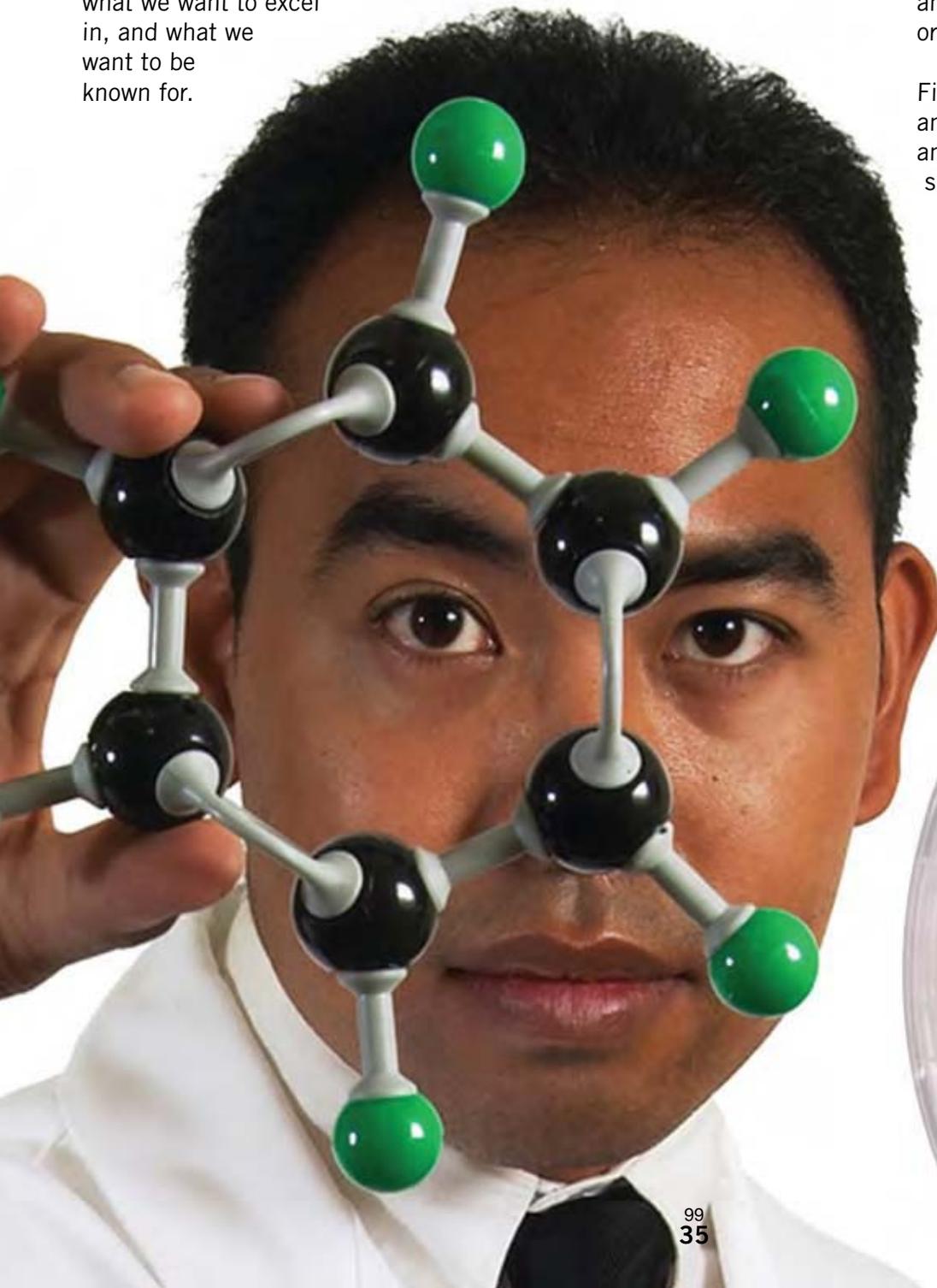
Thus, it is important that we develop individual leadership at all levels throughout the organization. For continued success, we must also promote organizational leadership by developing our next generation of leaders.

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

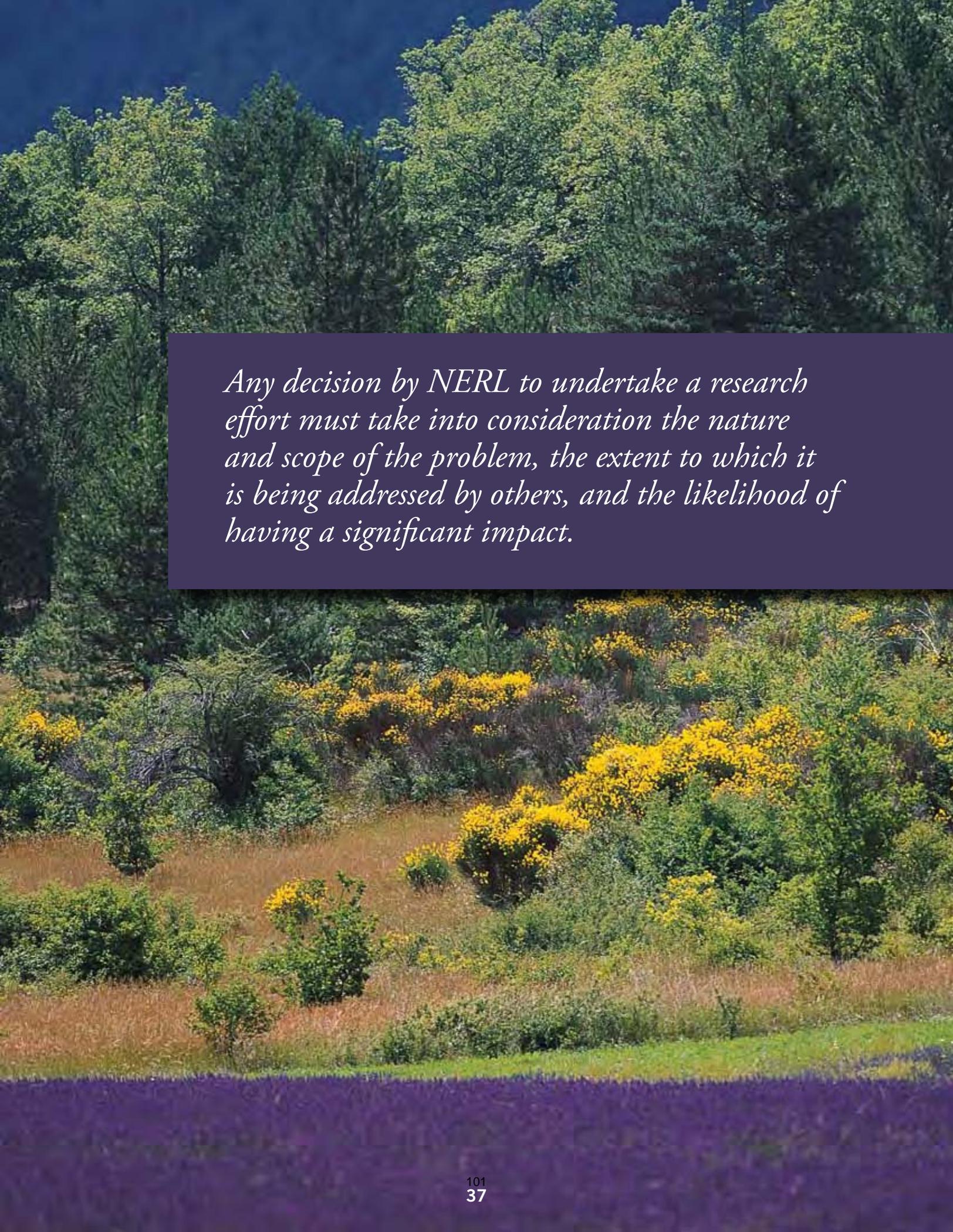
to achieve the NERL objectives of resilience, optimization, and integration.

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. 🌱



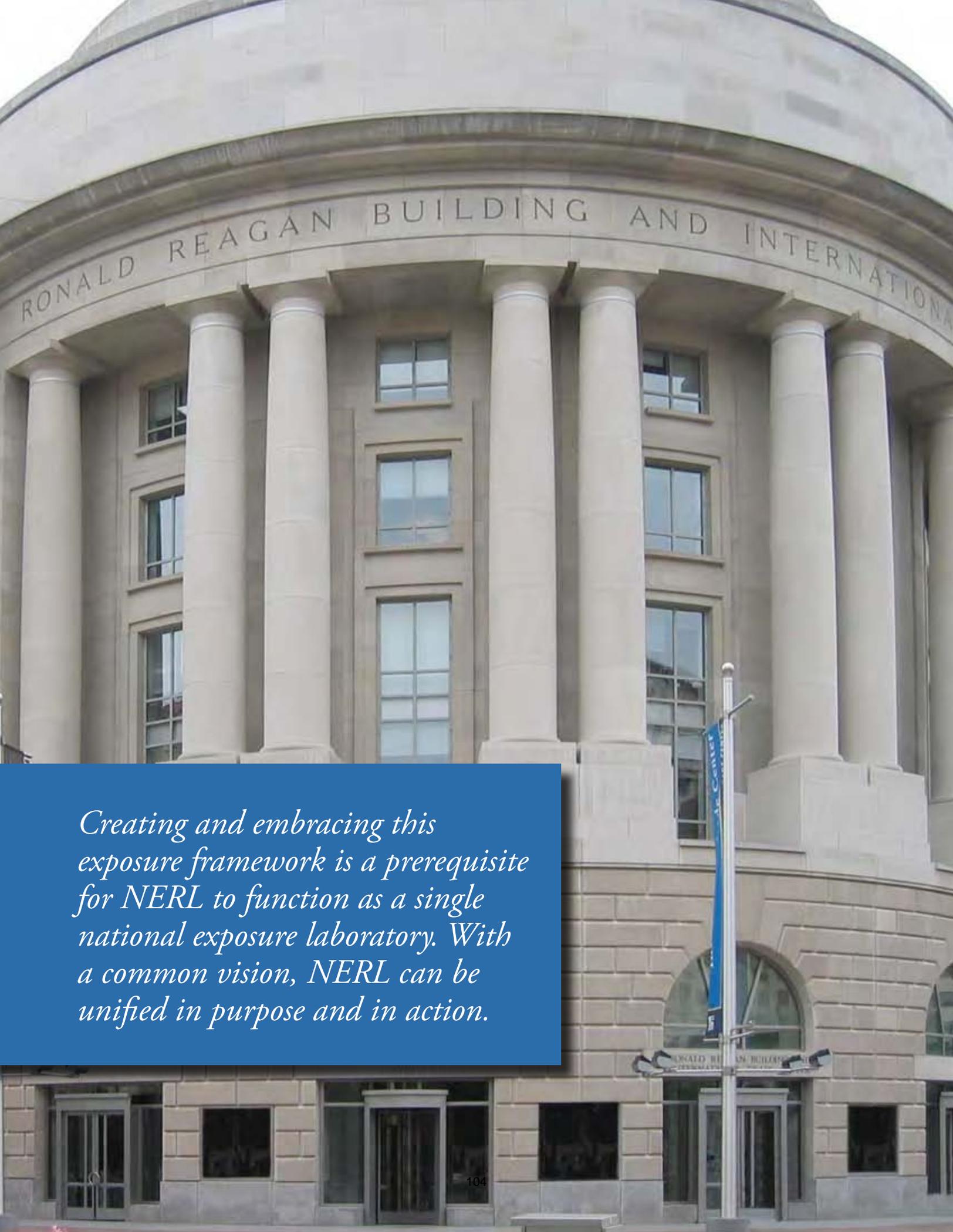
Any decision by NERL to undertake a research effort must take into consideration the nature and scope of the problem, the extent to which it is being addressed by others, and the likelihood of having a significant impact.



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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RONALD REAGAN BUILDING AND INTERNATIONAL TRADE CENTER

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.

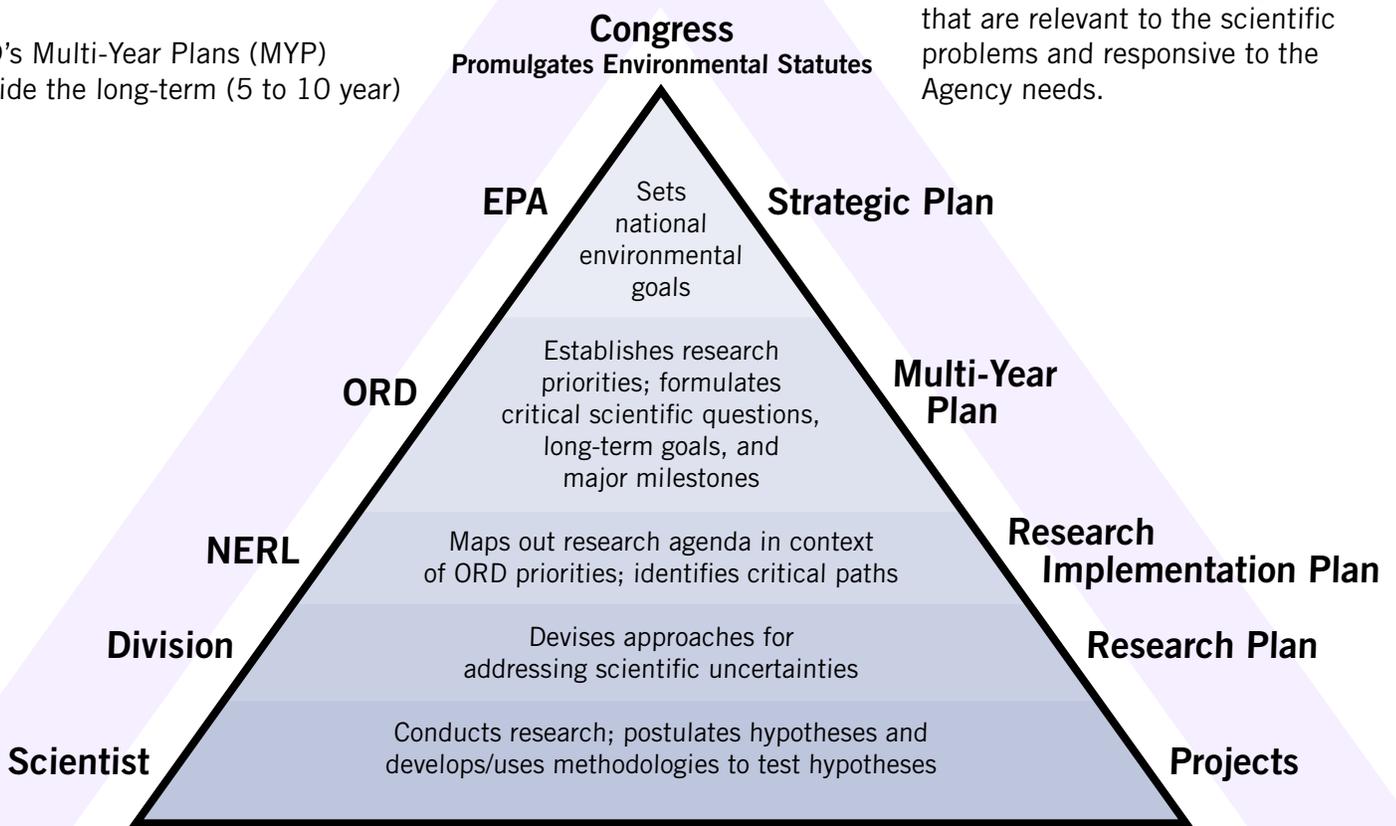
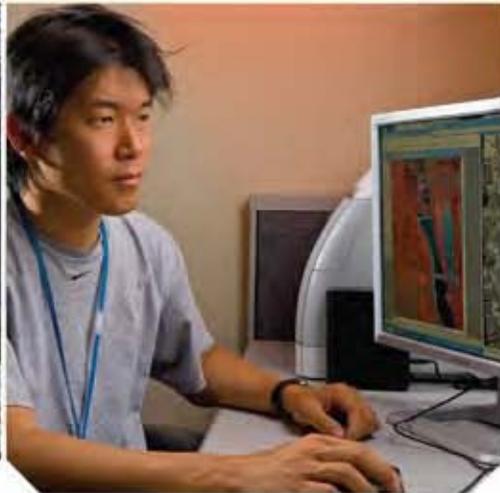


Figure A-1. Research planning in EPA

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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