

**Science Integration for Decision Making Fact-Finding Interviews
EPA Office of Research and Development (ORD) National Health and Environmental
Effects Research Laboratory (NHEERL) and National Exposure Research Laboratory
(NERL)
January 25, 2010,**

Five members of the SAB Committee on Science Integration for Decision Making conducted four interviews in Research Triangle Park: Drs. James Bus and Deborah Cory-Slechta in person and Drs. Terry Daniel, Wayne Landis and Thomas Theis by telephone. For each interview, Dr. Vanessa Vu, Director of the SAB Staff Office, provided a brief introduction to the purpose of the interview and the Designated Federal Officer, Dr. Angela Nugent, took notes to develop a summary of the conversation. All interviewees were provided a copy of the committee's Preliminary Study Plan in advance.

Dr. Vu noted in each interview that the purpose of the interview was to help SAB Committee members learn about ORD's 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. Dr. Vu thanked participants for taking time for the interviews.

Meeting with Director and Management Team, EPA Office of Research and Development (ORD) National Health and Environmental Effects Research Laboratory (NHEERL) (9:00-10:30 a.m.)

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

For the National Health and Environmental Effects Research Laboratory (NHEERL), science integration begins with the choice of research to undertake. NHEERL relies heavily on ORD's multi-year plans, developed in coordination with Program Offices, which identify research needs. Assistant laboratory directors interact with National Program Directors to keep research timed to regulatory actions. Reviews from the Board of Scientific Counselors indicate that ORD laboratories have improved their interactions with program offices and their implementation of multi-year plans in recent years.

NHEERL strives to develop an in-depth understanding of environmental problem to be addressed and the decisions to be made, whether they involve a regulatory decision or a voluntary program. NHEERL is always seeking to better understand the match between its

research and to the decisions to be made, rather than generate "fine research with imperfect application."

Program offices often do not clearly identify for ORD the highest priority questions to address. The Office of Air and Radiation, for example, presents four separate agendas for the Office of Transportation and Air Quality, Office of Radiation and Indoor Air, Office of Atmospheric Programs, where the climate change program is housed, and the Office of Air Quality Planning and Standards. It is rare for a senior manager in the Assistant Administrator's Office to meet with ORD lab directors to discuss overall priorities. The Deputy Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances is unique among senior managers in the attention he has devoted to meeting with ORD to discuss priorities for his programs. Occasionally, ORD identifies priority issues that are "natural integrators" (e.g., pesticides of common interest to OPPTS and the Office of Water), but National Program Directors are looking for a more reliable way to identify priorities and to look across research portfolios in different areas to identify common issues, such as complex mixtures, that may be important to several program areas. The Science Policy Council has also begun discussing research priorities that need attention, but that process is only in an early stage.

Once ORD gets lists of research needs from different program offices, a laboratory looks at the capacity of its programs and determines what it is "realistically able to do." An SAB member asked whether there was a process to ensure that other science needs get addressed, so that ORD or a program office may turn to a contractor or use a grant mechanism to generate needed research or be prepared to treat the data gap as an uncertainty. No structured process of this kind exists to address those gaps.

ORD has changed its process for budgeting and funding to focus resources on research identified in multi-year plans. Following those plans, NHEERL is attempting to move to a model wherein resources are allocated to priority projects and related divisions and teams, and no longer to Principal Investigators. Budgets are to be tracked by project.

ORD has introduced human resource practices to encourage scientists to orient their research to support decision making. In grade promotion, ORD managers increasingly give recognition for research, conducted in teams, that has made an impact on decisions, in addition to more traditional factors, such as originality and creativity. Increasingly, ORD is giving less attention to the number of first-authored papers as a primary criterion for promotion. ORD has developed guidance for technical qualification that incorporates this new approach.

ORD managers aim to hire highly qualified experts in technical fields who have flexibility to work on different environmental research problems. Given limited authority to hire new employees, ORD has maximized its use of post-doctoral fellows. There is a need for ORD for strategic workforce planning with a five year horizon for critical hires. It is important to undertake such an effort and get it peer reviewed.

NHEERL does not have a formally established external network of experts to supplement NHEERL staff where there new expertise needs or NHEERL encounters a lack of capacity. Some innovative programs, such as the ecological services research program, have used

innovative contract and consultant mechanisms to reach out to social, economic, and behavioral scientists to supplement EPA's expertise. NHEERL however does coordinate with other federal agencies in several ways. It collaborates informally and shares data with other federal research organizations in RTP. It cooperates in inter-agency agreements related to specific issues. It cooperates with states, especially on ecological research, where there is a common interest. NHEERL is hesitant to have researchers compete for grants from other federal agencies, because it does not want to encourage researchers to have independent sources of funding at a time when ORD is seeking to encourage teamwork and collaboration related to priority research identified in multi-year plans. NHEERL does create Cooperative Research and Development Agreements (CRADAs) with industry to advance specific research goals

Barriers to science integration for NHEERL include:

- Federal personnel policies that make it difficult to remove researchers not flexible enough to shift their focus to supporting decision making
- EPA culture that does not explicitly "look at granularity of data needed for the decision to be made." For example, science needs may be different for priority ranking of Superfund sites, compared to a national rule. Research should generate science that links to the data needed and the decision supported.
- Few EPA program offices have invested in scientists with expertise to match NHEERL's. NHEERL needs partners in program offices that can identify "just how far you need to drill down to have sufficient information to make decisions."
- Inertia and unwillingness to changes how EPA uses science. EPA has become comfortable with using Reference Doses and is hesitant to explore new types of science, such as computational toxicology
- Most program offices focus on immediate program needs and emergency "fire fights" and few take the time to think about strategic science needs.
- Inconsistent practices across National Program Directors in engaging regional scientists in multi-year plans.

NHEERL does not have a formal mechanism for coordinating with regional scientists. Relationships may be stronger between the regions and the labs on ecological issues than on human health issues. Regions often contact NHEERL and other parts of ORD for technical support on issues that are "so yesterday," issues no longer a focus for NHEERL and for which NHEERL may no longer have expertise. ORD's Office of Science Policy has the lead for coordination with EPA regions and may provide the SAB with greater detail on this issue. The issue of technical support for regions is a complex one. ORD does not have a clear sense of what kinds of technical support regions need and how much support of each type. Technical support can be as simple as a phone call or can require extensive work that makes it impossible for ORD scientists to conduct their assigned research. Problems often arise after ORD has completed a project with a program office client (e.g., water quality criteria for ammonia). ORD scientists have moved on to other priority issues, but states and regions must deal with the reality of implementation and may have many science issues to be addressed. ORD would provide technical expertise where possible, but often regional needs are not met.

NHEERL sees the value of bringing a wider public into discussion of the science generated by the laboratory at an earlier stage in product development and a need for reporting

back to the public on the progress of research. These needs were identified as part of ORD's integrated multi-disciplinary research transformation. There may be potential in NHEERL's working with the International Life Science Institute or the Health and Environmental Science Institute to convene academics, non-governmental organizations, and industry to work with ORD and program offices to help identify common problems and possible research partners. EPA/ORD has also established a more formal working relationship with SOT to advance environmental health research. The Society for Environmental Toxicology and Chemistry and the Pellston conferences can play a similar role for ecological science issues.

NHEERL does focus management attention on feedback provided by divisional reviews. The laboratory made an effort three years ago to identify common threads across all program reviews.

SAB advice sometimes poses problems for ORD. Many SAB reports include multiple recommendations calling on ORD to expand its research activities. There are so many recommendations, ORD does not know how to respond and often extends itself beyond its resources. It may be more useful for the SAB reviews to focus on the granularity needed for different kinds of decision making. EPA should articulate more clearly to the SAB the particular decisions to be made and the Agency's constraints. One area might be how to advance EPA's limited epidemiological knowledge, since it is unlikely that the Agency will have a large budget for major epidemiology studies. It would be helpful to hear practical ideas about how to leverage the work of others or possibly use biomarkers to support environmental decisions.

Meeting with Scientists, EPA Office of Research and Development (ORD) National Health and Environmental Effects Research Laboratory (NHEERL) (11:00 a.m. - 12:30 p.m.)

Participants

Kevin Crofton, Research Scientist
Bob Devlin, Research Scientist
Will Boyes, Research Scientist
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

NHEERL scientists have developed a process for providing technical support to program offices and some scientists think research and technical support are "intertwined." One NHEERL scientist has spent significant time working with the Office of Transportation and Air Quality (OTAQ) on test rules evaluating fuels and fuel additives and evaluating research plans provided by the American Petroleum Institute that OAR did not have expertise to review. He coordinates through ORD's Office of Science Policy (OSP), which sends the needed technical information to OAR. The Agency's Action Development Process provides a way for ORD to

have input into regulatory decisions. OSP involves the laboratory in review of rules where the laboratory's expertise (e.g., in residual risk or air toxic analyses) would be useful.

On ecological issues, ORD is often asked to play a significant role early in the decision making process (e.g., nutrient criteria, sediment criteria). It also reviews rules after they are developed as well.

The National Ambient Air Quality Standards (NAAQS) review process provides the best example of research planning related to decision making. The NAAQS review process is an iterative process that affects intramural and extramural air research. The new NAAQS process begins a NAAQS cycle with an identification of key policy issues and ends with identification of research needs to inform the next NAAQS review round. The process works well because the NAAQS is predictable. Other programs have much more uncertainty around their long-term issues.

ORD's multi-year planning process has experienced a "paradigm shift." ORD now plans more interactively with program offices so that ORD can anticipate most program office needs. Nevertheless, sudden requests for information happen, for example, when a congressman might write a letter about a specific pesticide (e.g., triclosan), and ORD's research is interrupted to respond to this sudden need for information. Both ORD and program offices need to look at strategic science needs to anticipate the questions that can be informed by ORD research and technical assistance.

Even with careful planning, it is difficult to coordinate research and assessment with program needs for information. Sometimes the timing does not work out.

ORD's transformation efforts focuses on program and regional strategic concerns for information for environmental protection (e.g., as for biofuels or nanoparticles) so that these important concerns receive priority attention. Problem formulation, i.e., identification of the research needed to inform decisions is the principal concern of the transformation effort. Once EPA has identified the decisions it will need to make and the information needed to support those decisions, then the Agency can focus on how to develop or access the needed science.

Requests for technical assistance, whether from a region or headquarters, can vary greatly. Sometimes a request just involves a phone call. At other times, an enquiry can have immediate or long-term research responses. Sometimes a specific technical assistance request can fit into a bigger research question, e.g., a triclosan question might relate to a broader issue for the endocrine disruptor program or a broader issue about source water threats. ORD does not have a paradigm or single process for handling such requests, though OSP is working to develop such a process with the Regions.

Problem formulation is an important part of the ORD transformation process, but there is no common approach or structured approach. To date, ORD has not used the six-sigma approach, value of information analysis, or a decision-science approach for problem formulation. In general, problem formulation happens informally, with some involvement of stakeholders on issues like biofuels and nanotechnology. One participant noted the potential value of a lifecycle

"source to outcomes" approach to help ORD examine issues related to fate and transport and target research on the most significant issues.

ORD uses a variety of metrics for assessing its research and is seeking additional useful methods. It currently considers:

- whether the research made a difference in EPA decision making
- whether published literature cites EPA research
- feedback from program offices
- feedback from the BOSC

Challenges and barriers to science integration involve:

- limitation of skills of existing ORD staff
- different languages and assumptions of "regulatory scientists" and ORD scientists. Analysts and scientists in program offices want definitive answers; scientists want to communicate uncertainties
- difficulties collaborating across ORD laboratories (e.g., problems designing a multi-laboratory facility for biofuels that would house both dynamometers and research animals)
- difficulties with grant, cooperative agreement, and procurement processes:
 - it is hard for external scientists collaborating with OAR through a cooperative agreement to work with ORD
 - Grant, cooperative agreement, and procurement processes often move more slowly than the science ORD seeks to develop
- Peer review processes take so long that it is hard "for EPA to stay on the cutting edge"
- Vast majority of current research is targeted to a single client
- Some multi-year plans (e.g., sustainability) have no dedicated FTEs, only extramural dollars.
- Limited resources for expanding multi-year plans that are not legacy programs (such as the drinking water program)

Factors that encourage science integration include:

- Leadership that makes science integration a priority
- ORD Executive Council discussions that encourage science integration across ORD research programs that are the domains of National Program Directors
- External advice from the SAB and others focusing on necessary mechanisms for science integration

Meeting with Director and Management Team, EPA Office of Research and Development (ORD) National Exposure Research Laboratory (NERL)(1:15 a.m. to 2:30 p.m.)

Participants

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

EPA has mechanisms to bring Agency needs for research to ORD, mechanisms for ORD to engage these research needs, and processes to report results of research. ORD's mission is to conduct research, provide technical assistance, and provide scientific leadership to EPA. Communication is a component of all three parts of the mission. ORD's research agenda should be on the critical path to address key scientific questions for decision making. It is important for ORD to engage people representing the regulatory perspective in deciding the research to undertake and for ORD researchers to gain understanding of the context of the research in terms of regulatory decisions and policy implications.

Once research is completed, it is the role of the National Program Directors and Assistant Laboratory Directors to communicate research results. National Exposure Research Laboratory (NERL) also has informal interactions with program offices, such as monthly meetings with program office staff, or ad hoc meetings on individual research areas. There is a particularly well-developed dialogue between OPPTS and NERL and between a division of NERL in Cincinnati focused on drinking water contaminants and the Office of Ground Water and Drinking Water.

ORD in general could do a better job in problem formulation by reaching beyond EPA programs and regions to stakeholders. Such efforts would build on the National Research Council report, *Science and Decisions*.

Providing advice and technical support to EPA programs and regions is the second element of ORD's mission. Programs and regions often have needs for specific data or information and would like ORD to have the flexibility to accommodate their needs. Often the desire is for a regional staff person to be able to reach someone in an ORD laboratory or center. For program offices needs, OSP directs queries for technical advice or scientific review to appropriate ORD organizations. NERL has designated an individual to track incoming program queries and identify a NERL scientist to respond. NERL receives 10 to 15 queries per month. Some requests are quickly dealt with; others may require long-term commitment to an Agency work group. Such requests provide an opportunity for scientists to learn about program needs. NERL has been trying to "train offices to go through OSP," rather than contact laboratory scientists individually.

Regions do not understand how often NERL receives requests and how often requests are addressed, because they are "under the radar." One region recently requested the Athens division of NERL (ERD) to measure environmental samples for PCBs in sludge, not a trivial request.

Once the lab provided the results, the region asked the laboratory to measure ground water samples, which required a different analytical method. "Pretty soon the laboratory had four or five scientists on the regional requests," not pursuing their assigned research.

ORD is now implementing a new process for regional requests to come to OSP and be dealt with more systematically. ORD is trying to develop a culture that supports the regions while avoiding requests to individual divisions or laboratories. It may not always be in the best interest of a region for ORD to simply react to and comply with a regional technical assistance request. Often requests come in without a well-developed problem formulation. In the case of PCBs in caulk, a region requested sampling for certain designated schools. ORD entered into a dialogue with the region and OPPTS with the goal of making a conscious decision about managing chemical risks. It is in the region's interest to think through whether the sample to be analyzed is on a critical path for a decision and it is in ORD's interest to see whether the region's request can be linked to one of ORD's priority research questions. ORD needs regions requesting technical assistance to engage in partnership and dialogue around the request. Sometimes, if a regional request involves a standard scientific analysis, ORD can point regions to contractors who can generate reliable information on a routine basis.

For NERL, improved technical support for regions involves more regional engagement in the ORD transformation process, and regional investment of resources in problem identification, prioritization and selection, and problem formulation.

Impediments to science integration include:

- Lack of a culture and formal experience in problem formulation
- Region calls for expanding the Regional Applied Research Efforts (RARE) grants that leads ORD to lose focus on strategic needs and encourages "job shopping" among ORD scientists
- EPA managers' reluctance to prioritize among research needs (e.g., the Office of Water has a long list of separate needs for water quality, drinking water, and Office of Wetlands Oceans and Watersheds that could "consume all of NERL")
- Regions as a whole don't work together to identify and prioritize their research needs for ORD

As an exposure laboratory, NERL does not have the capacity to evaluate a full range of vulnerability factors that includes socioeconomic and geographic variables. ORD is trying to develop some of this capability in its National Risk Management Research Laboratory and through ORD's extra-mural grant program. NERL has made some "small efforts," using geographic information systems (GIS) to examine multiple exposures. One important example is near-roadway air exposures. The GIS system uses census data in new ways for EPA, but does not look at a variety of social factors important to vulnerability. NERL also does not look at behavior and how behavior influences exposure, other than through the Consolidated Human Activity Database (CHAD), which contains data obtained from pre-existing human activity studies that were collected at city, state, and national levels. CHAD data are used as inputs for exposure/intake dose modeling and/or statistical analysis.

The nature of NERL's mission presents some barriers to science integration. Its long-term goal is to provide scientifically sound, easily accessible tools for regions, programs, and scientists to use. The challenge, however, is that there are no surrogate species for human exposures. NERL scientists cannot go into a laboratory to perform human exposure research; they must either go into the field or use models. Epidemiological and other measurement studies are very expensive and the alternative, predictive models, requires very smart choices and astute predictions about how communities and human behaviors will change, thereby changing exposures.

NERL leadership acknowledged that ORD exposure research is a very small part of federal investment in environmental research. On an ad hoc basis, NERL looks for opportunities to coordinate and collaborate with the National Institutes of Health and Department of Energy. EPA also participates in the formal inter-agency science planning efforts of the Office of Science and Technology Policy and the Committee on Environment and Natural Resources Research (CENR).

Meeting with Scientists, EPA Office of Research and Development (ORD) National Exposure Research Laboratory (NERL) (2:45 p.m. - 4:00 p.m.)

Participants

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

NERL scientists spoke about science integration issues related to their work. Research on air pollution benefits from a well-defined NAAQS process. ORD scientists play an important role in developing Integrated Science Assessments for criteria pollutants and have opportunities to give the Office of Air and Radiation feedback on their Policy Assessment Document. One area for improvement might be for the Policy Assessment Document to include a formal discussion of where to target research in ORD laboratories for future NAAQS reviews. ORD develops EPA's flagship air quality model, Community Multiscale Air Quality (CMAQ) and participates in monthly meetings about the model with OAR users. The pace of NAAQS reviews requires a high level of communication between OAR and ORD so that ORD assessments support the NAAQS schedules.

ORD only seldom receives questions from regions about the CMAQ model. OAR is the "first line of defense." Some regions use RARE projects to explore use of CMAQ to inform state implementation plans.

A large number of NERL resources are devoted to NAAQS support and resources are stretched tight. Scientists rely on the Clean Air Scientific Advisory Committee for advice on difficult questions, but has few other resources or mechanisms for accessing the external scientific community.

To stay current in their field, members of NERL's modeling division look for young scholars to participate as fellows through the EPA post-doctoral fellowship program, the ORISE program, or National Research Council fellowship program. Interviewees noted a need for NERL and ORD to do more strategic workforce planning to keep abreast of environmental science and environmental issues. They also noted that NERL has been able to hire fewer new employees as budget cut-backs reduce the FTE ceiling for the laboratory.

Interviewees acknowledged changes in their work as a result of the ORD transformation effort. Scientists are involved more often in multi-disciplinary work and team work. They interact more often with program offices and view their research in the context of the environmental decision making needs. The scientists also acknowledged that graduate schools in public health and schools of natural resources increasingly emphasize multi-disciplinary training and new post-docs and new hires bring this orientation.

Participants generally have access to travel funds to interact with a wider scientific community and make use of video, web, and teleconference tools for interacting with other EPA scientists. The only travel restrictions reported were in the Cincinnati NERL laboratory, where field work competes with the travel budget for professional meetings.

External science advice has an impact on NERL's scientific staff. One participant reported that he "finds a lot of review useful and at times painful." Two National Research Council reports (on particulate matter and air quality management in the United States) have been especially insightful and valuable, because it has helped NERL focus on strategic directions. BOSC reviews have also been useful; principal investigators respond to recommendations from BOSC peer reviewers and action items feed into scientists' annual tasks and program development. Another participant spoke of the value of advice from the Scientific Advisory Panel for NERL's collaborative research with the Office of Pesticide Programs.

For ecological research, BOSC and SAB reviews have had major impacts. The goals for the ecological research program shifted five years ago and the program became an ecological services research program. The Ecological Services Research Program has required an "exponential increase" in integration activities across programs and across laboratories.

External review forces scientists to reflect on their programs as they prepare to explain them to outside scientists. BOSC and SAB review call for scientists to engage in the wider scientific community and explain how they serving program offices and meet timelines.

In general, interviewees felt that they had a good balance between long-term research and applied activities. Ideally, there would be no tension and no distinction between the two. Even long-term research for which there is no immediately visible client should be useful to future environmental protection. Participants spoke about the need to allow possibilities for

exploratory research undertaken to prepare for a future need, where there may not be a current client. One example was pharmaceutical research undertaken by a scientist in the National Exposure Research Laboratory before there was a client; now that research is recognized as valuable and the scientist was awarded a gold medal. Similarly, research in sustainability and ecosystem services may be important, but there may be no identified customer at this time and there was no clear client for climate change science in the past administration, so ORD laboratories invested minimal resources in those activities.

Interviewees noted that there is no effective program to enable exploratory research. In the past, ten percent of resources were devoted to exploratory work, but budget cuts have made that a luxury. The multi-year planning process is a top-down planning model. If there are areas for exploratory research within a laboratory, they are generally supported by management, but there are negative consequences for researchers pursuing a risky path.

The last part of the discussion concerned the increased burden of work of ORD scientists who now are expected to stay current with their science, publish meaningful work, coordinate across programs, disciplines, and laboratories, and communicate scientific results to programs and regions. The demands "add to everyone's plate across the board." There are processes, however, that help scientists cope with these demands. Collaboration, for example, with the Office of Pesticide Programs (OPP) relies on processes that help scientists understand OPP's products, needs, and timelines. ORD and OPP scientists work in small workgroups on common projects, hold monthly and bi-weekly meetings, and have assigned clear responsibilities for a common project. OPP's has many cyclical processes that allow ORD to learn OPP's culture and needs. Some other programs have less-well-defined mandates, no review cycle or organizing framework, and as a result do not offer ORD an easy framework for collaboration.