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SAB Science Integration for Decision Making Fact-Finding Teleconference
Office of Research and Development, National Center for Environmental Assessment (NCEA)
Call-in Number for SAB subgroup: 866-299-3188, access code 343-9981
February 3, 2009, 2:30 p.m. - 4:00 p.m.

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Draft Agenda

Purpose of Interview: to help SAB Committee members learn about the NCEA'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.

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 National Center for Environmental Assessment (NCEA)
Peter Preuss - Center Director
Becki Clark - Deputy Center Director
Lynn Flowers - Associate Director for Health
Mike Slimak - Associate Director for Ecology
Anne Grambsch - Global Team Lead
Stan Barone - Assistant Center Director
Kacee Deener - Program Support Coordinator
David Bussard - Division Director
Sue Norton - Environmental Scientist
Annette Gatchett - Division Director
Mary Ross - Branch Chief

SAB Committee on Science Integration Committee Members
Dr. Thomas Burke, Johns Hopkins University
Dr. James Bus, Dow Chemical Company
Dr. Terry Daniel, University of Arizona
Dr. Thomas Theis, University of Illinois at Chicago (by telephone)

SAB Staff Office
Dr. Vanessa Vu, Director
Dr. Angela Nugent, Designated Federal Officer

National Center for Environmental Assessment

EPA

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Who We Are & What We Do

EPA's National Center for Environmental Assessment (NCEA) is a leader in the science of human health and ecological risk assessment, a process used to determine how pollutants or other stressors may impact human health and the environment.

NCEA occupies a critical position in EPA's Office of Research and Development (ORD) between researchers in other parts of ORD and outside of EPA who are generating new findings and data and the regulators in EPA's Program Offices and Regions who must make regulatory, enforcement, and remedial action decisions. NCEA prepares technical reports and assessments that integrate and evaluate the most up-to-date research and serve as major elements of the science foundation supporting EPA policies. NCEA also conducts cutting-edge research to develop innovative quantitative risk assessment methods and tools that help extrapolate between experimental data and real-world scenarios, improve our understanding of uncertainties, and facilitate careful weighing of evidence.

NCEA's workforce is our strength—its scientists are recognized internationally for their expertise in toxicology, epidemiology, biology, chemistry, and statistics. NCEA scientists serve on many federal government workgroups that are addressing critical environmental challenges and questions.

Examples of NCEA's major efforts include:

- Conducting human health risk assessments and managing EPA's Integrated Risk Information System (IRIS) (**http://www.epa.gov/iris**)
- Producing Integrated Science Assessments for reviews of the National Ambient Air Quality Standards (NAAQS) (**http://www.epa.gov/ncea/isa**)
- Providing human health and ecological risk assessment research, methods, guidelines, training materials, and technical support to EPA's Program Offices and Regions and the public (**http://www.epa.gov/ncea/risk**)
- Developing methods for integrating, deriving, and synthesizing cause and effect relationships for use in impairment investigations and risk assessments (**http://www.epa.gov/caddis**)
- Providing scientific information and decision tools to resource managers, policy makers, and other stakeholders in order to support them as they decide whether and how to respond to global climate change (**http://www.epa.gov/ncea/global.htm**)
- Preparing EPA's Report on the Environment (**http://www.epa.gov/ncea/roe**)

For more information, see NCEA's Web site at http://www.epa.gov/ncea

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Integrated Science Assessments

EPA

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NCEA Ensures National Air Quality Standards Consider Best and Most Recent Science

Clean air is an important goal in implementing EPA's mission of protecting public health and the environment. NCEA supports this mission by creating the scientific assessments that underlie development of the National Ambient Air Quality Standards (NAAQS). These ambient or outdoor air pollution standards protect public health and the environment from adverse effects caused by six principal air pollutants, including ozone and particulate matter, known as the "criteria" air pollutants (see box). It is essential for the standards to be based on the best and most current scientific information. Scientists worldwide are conducting research and publishing their findings about the health and environmental effects of air pollutants, with about 100 new articles in the published literature each month. As findings emerge, NCEA evaluates this new science and often re-interprets the existing information base to prepare the Integrated Science Assessments (ISAs), to provide the scientific basis for EPA's decisions on retaining or revising the air quality standards. This is an essential part of executing the Clean Air Act (CAA) mandate to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health and the environment which may be expected from the presence of [a] pollutant in ambient air."

NCEA's Integrated Science Assessments for the Six "Criteria" Air Pollutants

- **Ground-level Ozone**—AQCD final in 2006
- **Lead**—AQCD final in 2006
- **Particulate Matter**—ISA-Criteria draft is currently under review in 2009
- **Carbon Monoxide**—AQCD final in 2000, Workshops for next review cycle started in 2008
- **Nitrogen Dioxide**—ISA-Health Criteria final in July 2008 and ISA for Oxides of Nitrogen and Sulfur - Environmental Criteria final in 2008
- **Sulfur Dioxide**—ISA-Health Criteria final in September 2008 and ISA for Oxides of Nitrogen and Sulfur - Environmental Criteria final in 2008

How Do Integrated Science Assessments Use the Latest Science?

NCEA scientists identify, evaluate, integrate, and assess the most up-to-date and policy-relevant science for the criteria air pollutants, documenting their analyses in the ISAs, previously called Air Quality Criteria Documents. Through review of scientific findings from atmospheric chemistry, physics, epidemiology, toxicology, ecology, and exposure research for the six criteria pollutants, NCEA ensures that the basis for decisions on air quality standards reflect the best science available from all of these disciplines. After conducting a literature review, which includes consideration of thousands of multidisciplinary publications, NCEA identifies key information, performs new, focused analyses as needed, and integrates this scientific evidence to address the most policy-relevant questions at EPA. NCEA's goal is to meet the Clean Air Act requirement for a 5-year review cycle for each of the criteria pollutants. All ISAs are subjected to a rigorous and extensive peer review by the Clean Air Scientific Advisory Committee, which consists of noted experts appointed by the EPA Administrator to comment on the technical quality of the NAAQS reviews.

Using the Latest Exposure Science for ISAs

Because humans breathe a variable mixture of clean air and pollutants from many outdoor and indoor sources all day, it can sometimes be difficult to separate pollutant sources and isolate specific effects. NCEA's research and state-of-the-science assessments on ambient-level pollutant identification techniques and exposure processes have helped exposure scientists make

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better and more accurate estimates of what groups and individuals actually breathe. NCEA scientists then use these exposure estimates to help epidemiologists interpret data on effects measured in studies conducted throughout the U.S. and the world. These data are then used in analyses and assessments NCEA makes using the measurements of the actual concentrations of outdoor pollutants along with an understanding of the uncertainties in these measurements to assess the strength of causality or association between exposures and effects.

Using the Most Up-to-Date Epidemiology in ISAs

Human epidemiological studies provide the most compelling evidence for the regulation of air pollutants because direct effects on human health can be quantified. Careful integration and interpretation of results from a large number of human studies, while considering the complexity of the information they provide, is needed to assess public health risks. Epidemiological studies can provide direct evidence for or against the need to revise or retain a standard for a criteria air pollutant. During the NAAQS review process, NCEA scientists consider the strengths and limitations, consistency, and robustness of the available evidence to describe the health effects of criteria pollutants, assess the concentrations at which health effects are observed, and identify susceptible populations.

Recent science assessments in which the NCEA review and integration of the evidence from epidemiological studies was critical include:

- Air Quality Criteria for Ozone and Related Photochemical Oxidants (Final 2006)
- Air Quality Criteria for Particulate Matter (Final 2004)
- Air Quality Criteria for Lead (2006)

Interpretation of Clinical Studies in ISAs

The criteria air pollutants (see box above) for which the NAAQS are written benefit from a long series of controlled human exposure studies where ozone, particulate matter, or sulfur dioxide, for example, are given to human subjects in controlled doses. This puts the criteria pollutants at a real advantage over some other environmental pollutants because the interpretation and assessment of human health effects from real ambient exposures can be easier with these controlled exposures, lessening the need for extrapolation from complex animal experiments, or control of possible confounding elements. NCEA scientists evaluate these controlled human studies where they are available and have published results of their reanalyses to better inform the scientific basis for decision-making on the standards.

Improved Understanding through Research and Information Management

In recognition of the tremendous importance of air quality to public health and the environment, EPA has implemented a substantial research program related to air quality. This and other research programs produce research findings that are essential to understand and integrate in the ISAs. To support effective assessments, NCEA has designed and is now implementing a state-of-the-science information management system, the Health and Environmental Research Online (HERO) data base system.

Scientific Integration to Inform Decisions

The great extent and diversity of information available on the criteria air pollutants presents a challenge to risk assessors. Of key importance is to integrate information from clinical, human exposure, epidemiological and animal toxicology studies to provide a coherent and comprehensive understanding of the nature and magnitude of human health effects posed by these pollutants. NCEA has developed and applied a coherent framework to draw conclusions on causality (i.e., the nature and likelihood of adverse effects to be caused by exposure) and to characterize the levels at which such effects may occur. This comprehensive integration provides the internationally recognized fundamental scientific basis for establishing the national ambient air quality standards.

For More Information

EPA's Air Quality Criteria Documents / Integrated Science Assessments Web site: **http://www.epa.gov/ncea/isa**

EPA's NAAQS Web site: **http://www.epa.gov/ttn/naaqs/**

Clean Air Research Program: **http://www.epa.gov/ord/npd/cleanair-research-intro.htm**

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Report on the Environment

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EPA's Report on the Environment: Answering Key Questions about U.S. Health and Environment

EPA's 2008 Report on the Environment (2008 ROE) compiles the most reliable indicators currently available to answer 23 questions of critical importance to EPA's mission and the nation's environment. The questions are divided into five topics: air, water, land, human health, and ecological condition. The report presents 85 indicators— numerical values derived from actual measurements of a stressor, state or ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

With help and data from NOAA, USDA, Department of the Interior, and other agencies and private sector collaborators, NCEA scientists led a team from across EPA's Program and Regional offices that developed the report, reviewed and updated indicators from the 2003 Draft ROE, developed new indicators, and screened them against the new 2008 ROE indicator definition and criteria. Each indicator underwent extensive external peer review and public comment before being incorporated into the 2008 ROE. The report itself was subjected to internal EPA and interagency review, followed by independent peer review by EPA's Science Advisory Board as well as public comment. Following final revisions, EPA's 2008 ROE was released to the public on May 20, 2008.

NCEA also has been working across the Agency to improve the utility of the ROE for Agency planning and decision-making, and with colleagues from European and North American environmental offices to improve environmental reporting and to advance indicator science.

What Are the Findings in the Report on the Environment?

The 2008 ROE compiles the most reliable indicators incorporating the latest available data to help track critical trends in the environment and human health. The report also identifies key limitations of these indicators and gaps where reliable indicators do not yet exist. These gaps and limitations highlight the disparity between the current state of knowledge and the goal of full, reliable, and insightful representation of environmental conditions and trends, and they provide direction for future research and monitoring efforts.

Examples of Key Questions Addressed in EPA's 2008 Report on the Environment

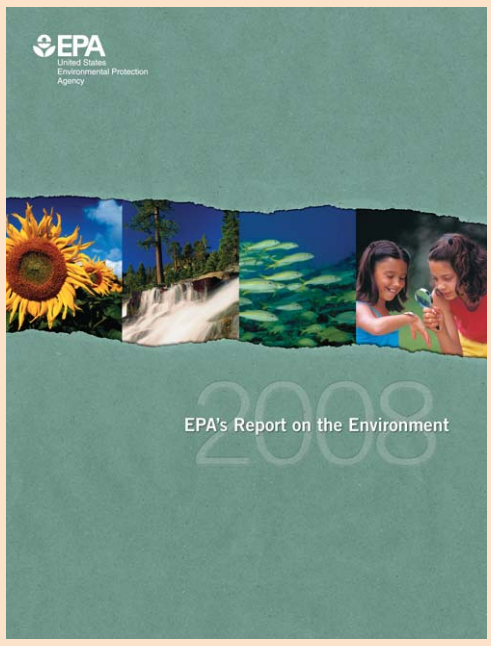
What are the trends in outdoor air quality and their effects on human health and the environment?

What are the trends in extent and condition of fresh waters and their effects on human health and the environment?

What are the trends in land cover and their effects on human health and the environment?

What are the trends in health status in the United States?

What are the trends in the extent and distribution of the nation's ecological systems?



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Examples of Indicators Presented in EPA's Report on the Environment

Air: emissions and ambient concentrations of carbon monoxide, lead, particulate matter, nitrogen oxides, ozone, volatile organic compounds, green house gases, and acid deposition

Water: stream flows, nitrogen and phosphorus, pesticides in streams, wetland extent, hypoxia in the Gulf of Mexico, fish tissue contaminants, and sediment quality

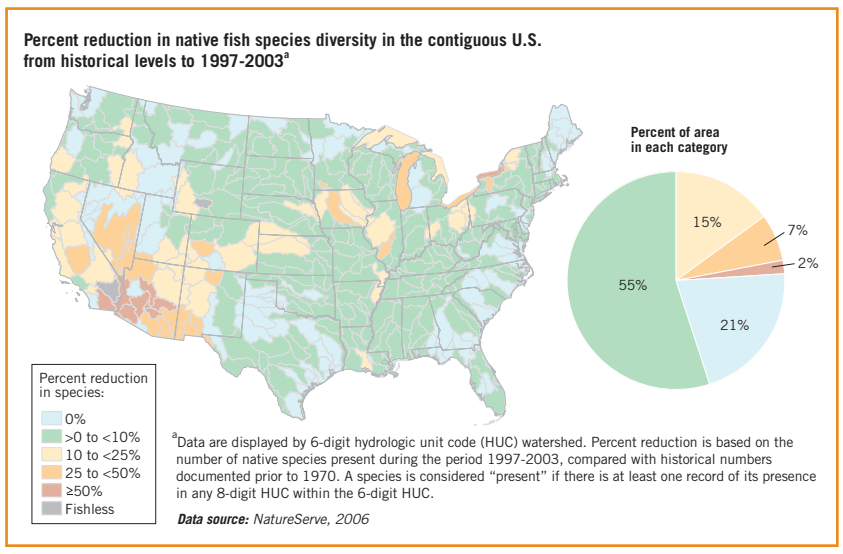
Land: land cover, forest extent and type, quantity of municipal and hazardous solid waste generated, and fertilizer used for agriculture

Human Health: mortality, life expectancy at birth, infant mortality, cancer incidence, asthma prevalence, birth defects, preterm delivery, blood levels for lead, mercury, cadmium, persistent organic pollutants, and cotinine, and urinary levels of pesticides and phthalates

Ecological Condition: land cover, forest extent and type, urbanization and population change, coastal benthic communities, birds, harmful algal bloom outbreaks, U.S. and global mean temperature, sea surface temperature, and sea level

Examples of the findings in the 2008 ROE include:

- Blood lead levels show a steady decline since the 1980s.
- Continuing annual declines have been seen in indicators of hazardous waste generation and all air emissions indicators with the exception of greenhouse gases.
- Moderate or high disturbances of bottom invertebrate communities have been found in approximately 1/3 of benthic coastal communities and 2/3 of wadeable streams.
- Between 2002 and 2007, there has been a 45% decline in the number of high priority clean-up sites with spreading goundwater contamination.



The map of the U.S., from the 2008 Report on the Environment shows the percent reduction in native fish species diversity from 1970 to 1997-2003. These data are part of the Fish Faunal Intactness Indicator in the Report on the Environment. Watershed covering about one-fifth (21 percent) of the area of the contiguous U.S. appear to have fish faunas that are fully intact, retaining the entire complement of fish species that were present before 1970. Watersheds covering nearly a quarter (24 percent) of the area have lost 10 percent or more of their native fish species.

What Are Future Plans for the Report on the Environment?

It is NCEA's goal to utilize the internet in order to provide timely updates for indicators and produce new editions of the ROE every 4 years and to time updates with the Agency's strategic planning process. New editions will reflect revisions or additions to the key questions, updates and revisions of the indicators, and addition of new indicators. An electronic version of the report, the e-ROE, has provided users with the ability to navigate and query the report and additional content. It will be updated on an ongoing basis to keep the ROE content as current as possible.

For More Information

EPA Report on the Environment 2008 Home Page: **http://www.epa.gov/ncea/roe**

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IRIS

IRIS: An Influential and High Quality Source of Health Effects Information for Chemical Risk Assessment

www.epa.gov/ncea

When conducting human health risk assessments that support decisions on air emissions, water discharges, or contaminated site clean-ups, risk assessors need high quality, peer reviewed information about human health effects that may result from exposure to chemical pollutants. More often than not, they use the EPA's Integrated Risk Information System (IRIS), a Web-based database of chemical assessments and quantitative toxicity values that have been developed by EPA and undergone rigorous peer reviews.

NCEA is responsible for preparing the IRIS assessments, managing the peer review process, and maintaining the online database. The main purpose of IRIS is to meet EPA statutory, regulatory, or program implementation needs, with special emphasis on chemicals of high interest to the public or other levels of government. Because of the high quality of its assessments, IRIS is used widely beyond EPA, including internationally.

What is IRIS' Role in Protecting Human Health?

IRIS values are used in combination with site-specific exposure information and, as such, play an essential role in protecting human health. By incorporating available scientific research findings into a comprehensive assessment, IRIS provides information that risk assessors and managers can use to assess risk and make decisions. Information in IRIS is a key part of evaluating the potential for adverse health effects from exposure to chemicals in the environment, and IRIS assessments can have broad impact in the form of regulatory—and other—decisions made by risk managers. IRIS provides data for the human health hazard identification and dose-response assessment phases of chemical risk assessments and includes information about cancer or non-cancer endpoints depending on the availability and quality of toxicological and epidemiological data. This information can be used in combination with exposure information to characterize the public health risks of a particular substance in a given situation. Many environmental stakeholders—EPA programs and regions, state and local governments, federal and international agencies,

"The documents [produced for IRIS] are the gold standard in risk assessments performed by program offices, other federal agencies, states, and even international organizations."

EPA Board of Scientific Counselors
ORD Human Health Risk Assessment Research Program Review
April 2008

EPA's IRIS Web site receives over 20,000 hits a day from readers in over 150 countries.

Health Effects Information Available on IRIS

Carcinogenicity information:

A **cancer slope factor** is a plausible upper bound, approximating a 95% confidence limit, on the increased cancer risk from lifetime exposure to an agent by ingestion. This estimate, usually expressed in units of proportion (of a population) affected per mg of substance/kg body weight-day, is generally reserved for use in the low-dose region of the dose-response relationship

An **inhalation unit risk** is a plausible upper-bound, approximating a 95% confidence limit, on the increased lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 $\mu g/m^3$ in air.

Cancer assessments also include a **qualitative weight-of-evidence characterization** which describes the likelihood that a chemical may cause cancer in humans and the conditions where carcinogenic effects might be expressed.

Non-cancer information:

A **reference dose (RfD)** is an estimate of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of harmful effects over a lifetime.

A **reference concentration (RfC)** is an estimate of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of harmful effects during a lifetime.

EPA Board of Scientific Counselors
ORD Human Health Risk Assessment Research Program Review
April 2008

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industry, and non-governmental organizations—use risk assessment to inform decisions to protect public health, such as determining allowable levels of contaminants in drinking water.

The process for developing IRIS assessments is scientifically rigorous and collaborative, involving several rounds of scientific review. Toxicologists, biologists, health scientists, epidemiologists, and statisticians develop the assessments using available scientific findings from the peer-reviewed literature. Biologically based mathematical models and data on mode of action by which chemicals exert their toxic effects are used to answer questions about the human relevance of animal studies, to extrapolate between animals and humans, to identify and assess sensitive subpopulations, and to select appropriate methods to extrapolate from experimental doses to the generally low doses that people may encounter in their environments. Because the assessments must reflect EPA's opinion, they undergo in-depth reviews by scientists throughout the Agency. The draft assessments also receive review by scientists in other federal agencies and by highly-qualified independent external experts whose scientific disciplines are appropriate for the chemical under review. On occasion, an assessment may be reviewed by independent expert panels formed by the National Research Council of the National Academy of Sciences. The public also has opportunities to comment on draft assessments and contribute data.

IRIS contains information on more than 540 chemicals. Each year, EPA publishes in the Federal Register a list of ongoing and new assessments. NCEA solicits nominations for new and updated assessments from the public and within EPA. Assessments are updated as new scientific information or methods evolve that could significantly change IRIS information.

Examples of IRIS Assessments	
Benzene—widely used as an industrial solvent, an intermediate in chemical synthesis, and a component of gasoline	The assessment supported U.S. EPA's Office of Air and Radiation, Office of Mobile Sources' *Final Rule: Control of Hazardous Air Pollutants from Mobile Sources* (2007) which set new standards that establish controls on gasoline, passenger vehicles, and gas cans to reduce emissions of benzene and other mobile source air toxics.
Diesel engine exhaust—mix of gas and particle pollutants emitted from diesel engines	NCEA's *Health Assessment Document for Diesel Engine Exhaust* has informed EPA efforts to reduce pollution from diesel engines. A March 2008 rule set standards to reduce emissions from locomotive and marine diesel engines by up to 90 percent. EPA also requires reductions in pollution from new heavy-duty trucks and buses. Starting in 2006, diesel fuel contains 97 percent less sulfur.
Boron and compounds—boric acid and sodium salts of boron are used for a variety of industrial purposes and as fire retardants, laundry additives, fertilizers, herbicides, and insecticides	First IRIS assessment to use data-derived adjustment factors rather than using default uncertainty factors. Uncertainty factors are used in the derivation of non-cancer toxicity values that account for variation in susceptibility among the human population, uncertainty in extrapolating animal data to humans, and other uncertainties. Data-derived adjustment factors provide better estimates of uncertainty compared to traditional default uncertainty factors.

What Are Future Plans for IRIS?

EPA's NCEA will continue to update IRIS and add new assessments to ensure it continues as a trusted key resource for chemical risk assessors. In addition, NCEA plans to update IRIS assessments that are more than 10 years old, when new studies are available to support a revised toxicity value. NCEA will incorporate new assessment and modeling tools into IRIS as they are adequately developed and peer reviewed.

For more information

Integrated Risk Information System (IRIS) Web site: **http://www.epa.gov/iris**

IRIS Hot line: **http://www.epa.gov/iris/comments.htm**

EPA's Risk Website: **http://www.epa.gov/risk/**

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Global Change

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NCEA's Global Change Research Program: Assessing the Impacts of Climate Change

NCEA's Global Change Research Program provides critical information to improve society's ability to effectively respond to the risks and opportunities presented by global change. The program addresses the potential consequences of global climate change on air and water quality, aquatic ecosystems, human health, and socioeconomic systems in the United States. It also generates decision-support tools for resource managers coping with a changing climate. These products are used by EPA, communities, states, and others in adapting to climate variability and change.

The impacts of global change effects are often unique to a location such as a watershed or municipality. EPA's Global Change Research Program emphasizes a place-based approach to respond to global change issues particular to a given area. As a result, partnerships are established with locally-based decision makers to ensure that the program is responsive to their unique scientific information needs and the socioeconomic realities at their locales. At the same time, NCEA scientists are working to advance assessment science and develop more general approaches to adaptation that can be applied at multiple scales and locations.

What Are NCEA's Major Contributions to Global Change Research?

The Global Change Research Act of 1990, directs agencies to "produce information readily usable by policymakers attempting to formulate effective strategies for preventing, mitigating, and adapting to the effects of global change" and to undertake periodic scientific assessments. The 13 Federal agencies that make up the U.S. Climate Change Science Program are developing a series of 21 synthesis and assessment products (SAPs) in response to the mandate of the U.S. Climate Change Science Program's Strategic Plan (2003). NCEA scientists are lead authors for two of the SAPs.

The Global Change Research Program has three major areas of emphasis: air quality, water quality/aquatic ecosystems, and human health impacts from global change. NCEA scientists are involved in a multi-lab collaboration that assesses the consequences of global change for U.S. air quality. NCEA also evaluates the sensitivity to climate change of water quality goals and the opportunities available within the provisions of the Clean Water Act and the Safe Drinking Water Act to address anticipated impacts. For example, NCEA scientists are engaged in assessments covering a range of aquatic ecosystems and issues including coral reefs, watersheds, estuaries, biocriteria and aquatic invasive species. These efforts are done in collaboration with the Office of Air and Radiation and the Office of Water.

NCEA Scientists Are Lead Authors on Synthesis and Assessment Products (SAPs)

SAP 4.4: Preliminary Review of Adaptation Options for Climate-sensitive Ecosystems and Resources

The report explains seven "adaptation approaches" for six resource areas: national parks, national forests, national wildlife refuges, wild and scenic rivers, estuaries, and marine protected areas, which can be used to maintain or increase the resilience of ecological systems to climate change.

SAP 4.6: Analyses of the Effects of Global Change on Human Health and Welfare and Human Systems

The report focuses on impacts of global climate change on three broad dimensions of the human condition: human health, human settlements, and human welfare. The report examines potential impacts of climate change on human society, opportunities for adaptation, and associated recommendations for addressing data gaps and near- and long-term research goals.

Health impacts that stem from climate change and associated changes in air and water quality also are evaluated by NCEA. For example, NCEA participated in the Health Sector Assessment of the Global Change Research Program's Climate Change

Impacts on the United States. As a result, NCEA scientists evaluated direct heat effects with respect to mortality, morbidity, violence, and hospital visits and climate impacts on aeroallergens.

In addition to assessments, NCEA develops interactive decision-support tools that support informed discussion of climate variability and change. For example, the Climate Assessment Tool provides users of EPA's BASINS 4.0—a multi-purpose environmental analysis system that integrates a geographical information system (GIS), national watershed data, and modeling tools—the capability to examine climate sensitivities and impacts. NCEA also is developing a set of GIS-based population and land use projections. This project, Integrated Climate and Land Use Scenarios (ICLUS) provides scientists and decision makers a national data base of county-level population and land use changes through 2100 which are designed to be consistent with the Intergovernmental Panel on Climate Change's Special Report on Emission Scenarios. Combined with information on changing climate and environmental conditions, these projections allow users to assess future impacts of climate change.

What Are Future Plans for the Global Change Research Program?

NCEA will continue to be actively involved in the Interagency Climate Change Science Program. NCEA will also continue to advance assessment science by developing innovative interactive tools for understanding local scale systems and their sensitivities. The long-term goal of NCEA's efforts is to provide the approaches, methods, and models to quantitatively evaluate the effects of global change on air and water quality, associated impacts on aquatic ecosystems and human health and adaptive responses to ameliorate adverse consequences of these changes.

For More Information

NCEA's Global Change Program:
http://www.epa.gov/ncea/global.htm

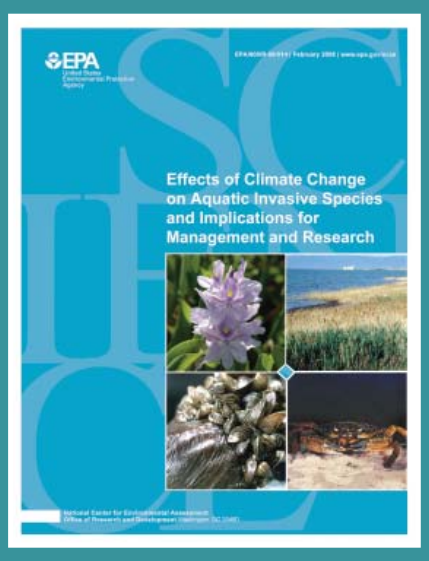
EPA's Climate Change Program: **http://www.epa.gov/climatechange/**

EPA Global Change Research Program:
http://www.epa.gov/ord/npd/globalresearch-intro.htm

U.S. Climate Change Science Program:
http://www.usgcrp.gov/usgcrp/

NCEA's Global Change-Related Water Quality and Aquatic Ecosystems Reports

- A Screening Assessment of the Potential Impacts of Climate Change on Combined Sewer Overflow (CSO) Mitigation in the Great Lakes and New England Regions
- Climate and Land Use Change Effects on Ecological Resources in Three Watersheds: A Synthesis Report
- Climate Change Effects on Stream and River Biological Indicators: A Preliminary Analysis
- Climate Change and Interacting Stressors: Implications for Coral Reef Management in American Samoa
- Effects of Climate Change on Aquatic Invasive Species and Implications for Management and Research



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Risk Assessment Tools

NCEA Methods, Models, and Databases Provide the Scientific Basis for Improved Health and Ecological Risk Assessments

www.epa.gov/ncea

What types of human health problems are caused by substances in the environment? How likely is it that ecological resources, such as watersheds, will experience degradation when exposed to different amounts of a pollutant? How severe is the potential harm likely to be? These are examples of key questions addressed in risk assessments conducted by scientists at the U.S. EPA. Risk assessments provide decision makers with the scientific information they need to make informed decisions about actions that may be taken to protect human health and the environment.

Scientists at NCEA conduct cutting edge research to develop innovative and quantitative risk assessment tools that combine knowledge about biology, physiology, toxicology, ecology and statistics. They are continually working to create and enhance methods, models, and databases that inform EPA risk assessments. State-of-the-art tools and data help risk assessors extrapolate between experimental data and real-world scenarios, characterize uncertainties, and facilitate careful weighing of evidence.

NCEA's dose-response assessment tools help characterize the risk of an adverse effect in humans at a specified dose. Exposure assessment tools help determine the potential sources of a chemical, pathways (e.g., inhalation vs. ingestion) leading to exposure, and the magnitude and duration of contact with the substance. Ecological risk assessment tools support decision making to address ecological concerns such as degradation of surface waters due to pollution. The guidance and tools highlighted here represent only a few of the entire library that are available on NCEA's Web site, www.epa.gov/ncea.

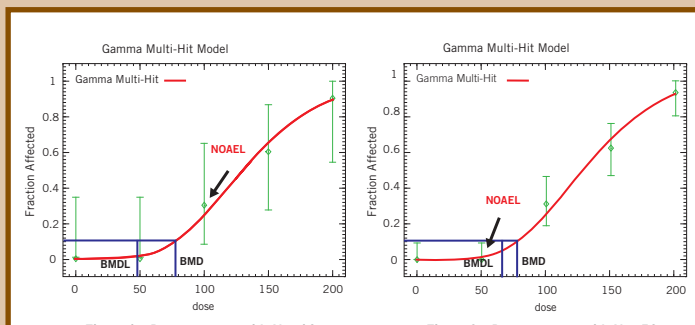

Figure 1—Dose response with N = 10

Figure 2—Dose response with N = 50

This graphic illustrates how the NOAEL is highly dependent on sample size, and how the BMD approach addresses this limitation. In this example, identical dose-response data points from toxicology studies with different sample sizes are shown. Figure 1 shows observed response and statistical confidence limits for response levels in a study that tested 10 animals at each dose level, and Figure 2 shows the same observations for 50 animals tested at each dose level. The NOAEL derived from the study using fewer animals is higher compared to the NOAEL from the study with greater statistical confidence. The BMD approach fits a curve to the data and estimates a response rate that more appropriately reflects the uncertainty due to smaller sample size.

Risk Assessment Methods

NCEA scientists are world leaders in developing and applying novel, state-of-the-art risk assessment methods. They are EPA leaders in methods development, chairing and participating in many cross-agency workgroups. For example they have contributed significantly to framework documents that identify key issues to consider for different types of risk assessments (e.g., for metals, for children) and ways to address those issues. They have also contributed to the development of risk assessment guidelines that offer more specific procedural information (e.g., Guidelines for Carcinogen Risk Assessement, Guidelines for Ecological Risk Assessment). While the guidances do not mandate exactly how assessments should be developed, they provide EPA and other risk assessors with rigorously-vetted approaches that help improve the quality, consistency and use in decision making of their assessments.

Dose-Response Modeling Highlights

Benchmark Dose (BMD) Modeling Software provides data-management tools and a user-friendly interface to support application of different mathematical models to fit a dose-response dataset. This software is extremely important since it is used in all of EPA's Integrated Risk Information System (IRIS) assessments, which provide the scientific basis for many regulatory and public health decisions. The BMD approach can be used for both non-cancer and cancer dose-response assessments.

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It is more informative than the traditional approach of using a no observed adverse effect level (NOAEL) or lowest observed adverse effect level (LOAEL) as the basis for dose-response assessment. In the BMD approach, the risk assessor fits a flexible curve to the dose-response data and uses the results to select a dose level that is associated with a predetermined benchmark response, such as a 10% increase in the incidence of a particular toxic effect. The BMD approach uses more information provided in reports of toxicological studies, and provides more information to risk assessors, than the NOAEL/LOAEL approach, and is preferred when suitable data sets are available. The NCEA BMD web-based modeling tools provide a significant benefit to the international risk assessment community.

Physiologically based pharmacokinetic (PBPK) models use available measured physiological data to more accurately characterize how the body absorbs, metabolizes, distributes, stores, and excretes a chemical and predict the internal dose of the chemical at specific target organs. NCEA scientists published guidance for applying PBPK models in human health risk assessments and quantifying the impact of age-related and other inter-individual differences that may affect health risk. This is an innovative and cutting-edge approach that reduces uncertainty in risk assessments and is now used routinely in IRIS assessments when suitable data are available.

Methods and Guidance for Assessing Chemical Mixtures

In real world scenarios, people are not exposed to one chemical at a time—rather, they experience myriad exposures on a daily basis. To address this fact, NCEA has developed methods and guidance to evaluate exposure to mixtures from environmental media such as drinking water, air and soil. NCEA scientists have conducted research and published methods that address these real world exposure scenarios by quantifying chemical mixture exposures and estimating potential health risks resulting from these exposures.

Exposure Assessment Tools

The Exposure Factors Handbook is an important resource developed by NCEA that provides key information for nearly all exposure assessments conducted by EPA. It contains statistical data on factors such as drinking water consumption, soil ingestion, inhalation rates, dermal factors including skin area and soil adherence factors, consumption of fruits and vegetables, fish, meats, dairy products, homegrown foods, breast milk intake, human activity factors, consumer product use, and residential characteristics. This information is used in risk assessments to calculate human exposure to contaminants. Values are recommended for the general population and for various segments of the population who may have characteristics different from the general population. The Child-Specific Exposure Factors Handbook consolidates child specific data into one resource, and the Example Exposure Scenarios Tool provides outlines of scenarios to demonstrate how to best use the data in the Exposure Factors Handbook. NCEA released a revised and expanded version of the Child-Specific Exposure Factors Handbook in September 2008 and a revised and expanded version of the Exposure Factors Handbook will be available in draft form in 2009.

Ecological Risk Assessment Tools

Two cutting-edge ecological tools include the Causal Analysis/Diagnosis Decision Information System (CADDIS) and the Integrated Climate and Land Use Scenarios (ICLUS). CADDIS allows watershed managers to determine what has caused impairment in a water body with a web-based suite of resources. ICLUS provides scientists with a means to assess future impacts of climate change on different land use scenarios. For more information on CADDIS and ICLUS please see the fact sheets entitled CADDIS and NCEA's Global Change Research Program.

For More Information

EPA NCEA Human Health Guidelines Web Page: **http://www.epa.gov/ncea/healthrisk.htm**

EPA NCEA Ecological Guidelines Web Page: **http://www.epa.gov/ncea/ecorisk.htm**

EPA's Benchmark Dose Software (BMDS) Web Page: **http://www.epa.gov/ncea/bmds**

EPA NCEA Human Health Risk Tools Web Page: **http://www.epa.gov/ncea/risktools.htm**

EPA NCEA Chemical Mixtures Risk Assessment Guidance Web Page:
http://www.epa.gov/ncea/chem

EPA NCEA Physiologically Based Pharmacokinetic (PBPK) Web Page: **http://www.epa.gov/ncea/pbpk**

EPA Exposure Factors Handbook Web Page: **http://www.epa.gov/ncea/efh**

EPA Child-Specific Exposure Factors Handbook Web Page: **http://www.epa.gov/ncea/child**

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Causal Analysis/Diagnosis Decision Information System

www.epa.gov/ncea

CADDIS: A Tool to Help Scientists Identify Causes of Degradation of Streams and Rivers

Watershed management scientists turn into environmental detectives when streams, rivers, or wetlands become so impacted by human activities that there are observable effects on plant and animal life. The scientists need to determine what stressor or stressors are causing harmful effects so that effective solutions can be developed and implemented. To unravel these environmental mysteries, NCEA, working with colleagues from the Agency's Office of Water (OW), Regional offices, and other ORD laboratories created the Causal Analysis/Diagnosis Decision Information System (CADDIS), an online resource that helps scientists find, access, organize, use, and share information to determine what has negatively affected the ecology of the water body.

CADDIS is built upon EPA's Stressor Identification process, which is a formal method for identifying causes of impairments to aquatic ecosystems. The system includes a step-by-step guide to conducting a causal analysis, example worksheets, and informative material on several commonly encountered candidate causes. CADDIS also has a conceptual model library for common stressors, including phosphorus, a nutrient that can lead to harmful algal blooms and other effects when high levels are discharged into aquatic systems. The system features advice on how to use specific data analysis methods and manage data for a causal assessment, downloadable data analysis tools, and other information sources, such as databases of stressor-response information.

In What Situations Would CADDIS Be Helpful and How?

Observations that might prompt the use of CADDIS include:

- kills of fish, invertebrates, plants, or other wildlife or domestic animals
- anomalies in any life form, such as tumors, lesions, parasites, or disease
- altered community structure, such as the absence, reduction, or dominance of a particular species or group
- loss of species or shifts in abundance
- response of indicators designed to monitor or detect biological, community, or ecological condition (e.g., Index of Biotic Integrity or Invertebrate Community Index)
- changes in the reproductive cycle, population structure, or genetic similarity
- alteration of ecosystem function, such as nutrient cycles, respiration, and photosynthetic rates
- alteration of the aerial extent and pattern of different ecosystems (e.g., shrinking wetlands or change in the mosaic of open water, wet meadows, sandbars, and riparian shrubs and trees)

The name CADDIS recognizes the caddis fly's role as a frequently used bioindicator for detecting impacts of aquatic pollutants.

Regarding the benefit of using CADDIS:

"…the Stressor Identification procedure provided a clear, easily understandable format for us to explain and support our conclusions. Our ability to present the results of our analysis in a form that was understandable to both scientists and non-scientists. I believe was critical to the ultimate adoption and approval of the TMDL [Total Maximum Daily Load—the maximum amount of a pollutant that a water body can receive and still meet water quality standards and an allocation of that amount to the pollutants sources]."

Lee Dunbar,
Connecticut TMDL/WQS program

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- CADDIS provides the following basic information on 8 common candidate causes of biological impairment:
  - » what to consider (e.g., sources and site evidence) when deciding whether to include stressors as candidate causes
  - » ways to measure stressors
  - » relevant literature reviews
  - » conceptual model diagrams showing linkages among stressors and their potential sources and effects

CADDIS brings together significant amounts of information in an efficient and effective way. It helps state and local water quality managers develop TMDLs designed to address pollutants contributing to biological impairment in streams. It assists watershed managers with planning and coordination of data collection, best management practices, and technology solutions to address the causes and sources of impairment.

Common Candidate Causes of Biological Impairment in Aquatic Ecosystems

Excess metals

Increased sedimentation

Excess nutrients

Low dissolved oxygen

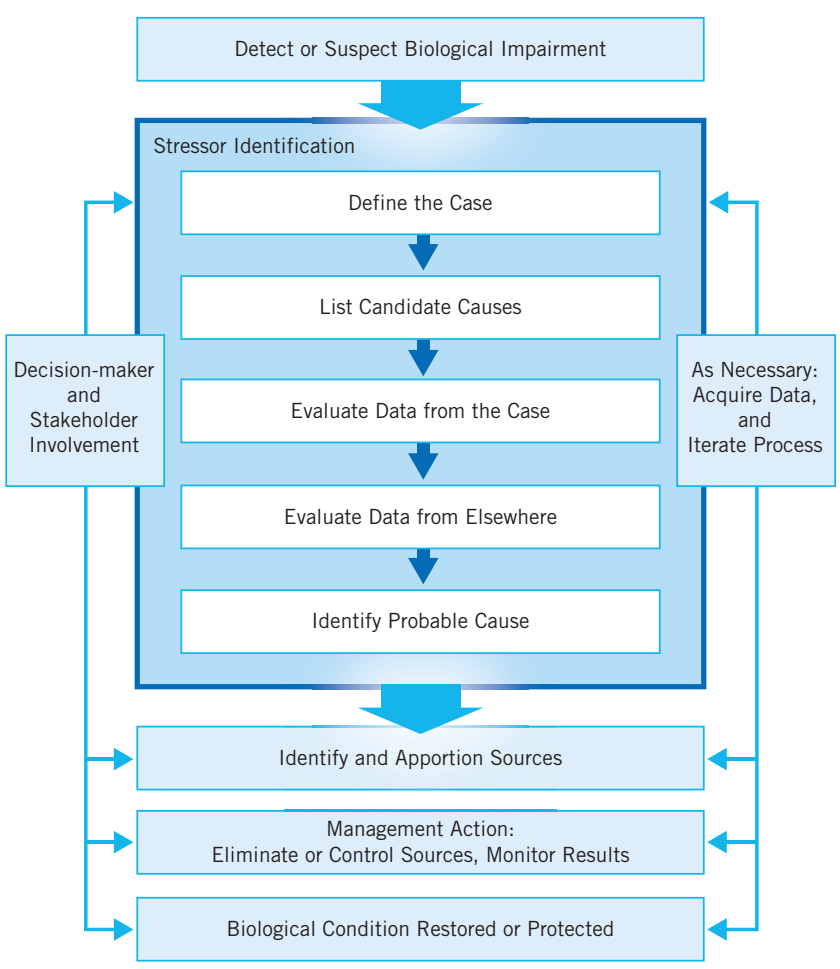
High temperature

Altered ionic strength

Flow alteration

Unspecified toxic chemicals

EPA's Stressor Identification Framework Used in CADDIS



What Are Future Plans for CADDIS?

NCEA scientists plan to develop improved versions of CADDIS based on user input and feedback. These plans include adding modules for deriving empirical stressor-response relationships, stressor-specific tolerance values and databases, syntheses of relevant literature and statistical methods, candidate cause summaries, and conceptual models. NCEA also plans to add more case studies, including those relevant to terrestrial systems, with links to relevant CADDIS pages and capabilities for user input.

For More Information

EPA's Causal Analysis/Diagnosis Decision Information System (CADDIS) Web Page:
http://www.epa.gov/caddis

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National Emergencies

NCEA Responds: Technical Assistance for Emergency Response and Recovery

www.epa.gov/ncea

Environmental emergencies involve sudden increased threats to public health and the environment from the release or potential release of hazardous materials due to accidents or natural or man-made disaster events. They happen without warning, and the need for environmental assessment is acute. The environmental questions add to the anxiety and loss of the more obvious physical damage. As soon as the dust begins to settle, many scientific questions need to be addressed quickly. How should sampling be conducted to measure exposure levels quickly and accurately? How significant are the risks to public health (e.g. first responders, clean-up personnel, residents) and the environment? Are proposed clean-up and recovery methods effective and when is it safe for re-entry by the public?

Scientists in NCEA help respond to these questions by providing on-call technical support to emergency response and recovery personnel in the EPA's Office of Solid Waste and Emergency Response and EPA regions who are primarily responsible for coordinating EPA's emergency response programs.

Hurricanes Katrina and Rita

NCEA scientists and managers contributed to EPA's environmental and human health impact assessment of the aftermath of Hurricanes Katrina and Rita in the Gulf Coast region in 2005. NCEA scientists participated in an interagency workgroup on guidance and standards for local officials, and they provided critical internal peer reviews of water and sediment sampling and analysis plans and public communication materials. The ability of NCEA scientists to respond quickly to internal EPA requests for scientific expertise helped EPA and other Federal Agencies make better decisions in these crisis situations.

House with Asbestos Cement Shingles

Water Contamination and Debris

Massive Debris Pile for Grinding and Incinerations

Debris Grinder at Empire landfill in Plaquemine parish

Clean up of debris from Hurricane Katrina generated health concerns because debris from older buildings may contain asbestos and lead. ORD scientists developed a methodology to assess risks from the release of these hazardous substances in trial testing of grinding and burning (incineration) technologies that potentially will be used to manage the debris.

Elevated Lead in Washington, DC Drinking Water

In 2004 and 2005, the District of Columbia Water and Sewer Authority detected high levels of lead in numerous samples of residential drinking water. NCEA scientists evaluated the potential impacts on children's blood lead levels and analyzed risks for a "highly exposed" subpopulation of infants who consumed reconstituted formula prepared with tap water. Results from the health assessment helped inform response actions by local officials, such as issuance of public health advisories, replacement of many lead water pipes throughout the city, and corrosion control measures. The assessment results were used by EPA's Office of Water and EPA Region 3 in communicating risk to Washington, DC residents. Due to control treatments that have been

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implemented, DC is now in compliance with safe drinking water act requirements, and risks to children from lead in drinking water have been reduced.

Collapse of the World Trade Center

In the days following the attack on the World Trade Center towers on September 11, 2001, EPA initiated numerous air monitoring activities to better understand the impact of emissions from that disaster. Using these data, NCEA scientists conducted a screening of the potential for risk to the general population associated with off-site inhalation exposure of emissions in the aftermath of the attack. This assessment did not address exposures and potential impacts that could have occurred to rescue workers, firemen, and other site workers nor did it consider indoor exposures. NCEA's work resulted in important analyses that could improve EPA's responses to future national emergencies.

Asbestos Contamination in Libby, Montana

In 1999, an EPA Emergency Response Team went to Libby to investigate local concerns about asbestos-contaminated vermiculite that is mined in the town. Vermiculite is a mineral that, when heated, pops creating pockets of air that make it suitable for use as insulation or as a soil amendment. The asbestos contamination in Libby is a distinct form of asbestos. Since 1999, EPA has been working closely with the community to clean up contamination and reduce risks to human health. EPA conducted a screening level risk assessment in 2001, and NCEA scientists are currently working on a toxicity assessment specific to the unique asbestos in Libby, Montana. This assessment will ensure EPA's site clean-up in Libby, MT, is protective of human health. This work has broad scale implications because 80 percent of the world's vermiculite was produced from the Libby mine and the materials were processed in over 200 locations across the United States.

What Are Future Plans for Incidence Response?

NCEA scientists will continue to provide advice and scientific support to EPA Program Offices, Regions, and the Emergency Response Program when environmental crises arise. By building experience with real-world situations, NCEA scientists are developing innovative approaches for exposure assessments and risk assessments that will be applicable to natural and man-made disasters.

For More Information

EPA Response to 2005 Hurricanes Web Page: **http://www.epa.gov/katrina/**

EPA NCEA World Trade Center Response Web Page:
http://www.epa.gov/ncea/wtc.htm

EPA Region 3 Lead in Drinking Water Web Page: **http://www.epa.gov/dclead/**

EPA Region 8 Libby Asbestos Web page:
http://www.epa.gov/region8//superfund/libby/index.html

Superfund Health Risk Technical Support Center (STSC) Hot Line: 513-569-7300

NCEA's Superfund Health Risk Technical Support Center

This hotline resource is used by EPA regional and program office hazardous waste site managers to obtain the latest information on health risks from toxic substances. There are over 1,500 sites on Superfund's National Priorities List that require site assessment and clean-up. When toxicity values are not available in EPA's Integrated Risk Information System (IRIS) database, NCEA can provide Superfund risk assessors with provisional peer-reviewed toxicity values for specific chemicals as requested. The hotline responds to about 250 calls a year. All assistance is provided on a rapid turn-around basis.

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