Environmental Public Health Outcomes Workshop Proceedings: Research Triangle Park, North Carolina, July 30 – 31, 2002

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Summary Report

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List of Acronyms

ABLES	Adult Blood Lead Epidemiology and Surveillance
ADHD	Attention deficit hyperactivity disorder
AFIP	Armed Forces Institute of Pathology
ALS	Amyotrophic lateral sclerosis
ATSDR	Agency for Toxic Substances and Disease Registry
BRFSS	Behavioral Risk Factor Surveillance System
CBLS	Childhood Blood Lead Surveillance
CDC	Centers for Disease Control and Prevention
CHAD	Consolidated Human Activities Database
CISNET	Cancer Invention and Surveillance Modeling Network
CSTE	Council of State and Territorial Epidemiologists
CTEPP	Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants
DALY	Disability-adjusted life years
DHHS	Department of Health and Human Services
DNA	Deoxyribonucleic acid
DOE	Department of Energy
EBD	Environmental burden of disease
EIMS	Environmental Information Management System
EMAP	Environmental Monitoring and Assessment Program
EPA	Environmental Protection Agency

List of Acronyms (continued)

EPHO	Environmental public health outcome
EPO	Epidemiology Program Office
FFPE	Formalin-fixed, paraffin-embedded
FY	Fiscal year
GIS	Geographic information system
GPRA	Government Performance and Results Act
HEDS	Human Exposure Database System
HEI	Health Effects Institute
HIV	Human immunodeficiency virus
IRB	Institutional review board
JHU	Johns Hopkins University
MOU	Memorandum of Understanding
NAACCR	North American Association of Central Cancer Registries
NCBDDD	National Center on Birth Defects and Developmental Disabilities (CDC)
NCRA	National Cancer Registrars Association
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion (CDC)
NCEH	National Center for Environmental Health
NCER	National Center for Environmental Research
NCHS	National Center for Health Statistics
NCHSTP	National Center for HIV, STD, and TB Prevention
NCI	National Cancer Institute
NCID	National Center for Infectious Diseases

List of Acronyms (continued)

NEDSS	National Electronic Disease Surveillance System
NERL	National Environmental Research Laboratory
NHANES	National Health and Nutrition Examination Survey
NHEERL	National Health and Environmental Effects Research Laboratory
NHEXAS	National Human Exposure Assessment Studies
NIH	National Institutes of Health
NIEHS	National Institute of Environmental Health Sciences
NIHS	National Health Interview Survey
NIOSH	National Institute for Occupational Safety and Health
NMMAPS	National Morbidity, Mortality and Air Pollution Study
NNDSS	National Notifiable Disease Surveillance System
NORA	National Occupational Research Agenda
NPHSS	National Public Health Surveillance System
NRMRL	National Risk Management Research Laboratory
OEI	Office of Environmental Information
OMB	Office of Management and Budget
ORD	Office of Research and Development
OSP	Office of Science Policy
PM	Particulate matter
RFA	Request for Applications
SEER	Surveillance, Epidemiology, and End Results
SENSOR	Sentinel Event Notification System for Occupational Risks
SOER	*State of the Environment Report*

List of Acronyms (continued)

STD	Sexually transmitted disease
TB	Tuberculosis
TMDL	Total maximum daily load
USEPA	United States Environmental Protection Agency
WHO	World Health Organization
WTC	World Trade Center

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Executive Summary

"It is also important that we hold ourselves accountable to the American public and report to them our progress in reaching the goals we have set for ourselves. Therefore, I am directing the Agency to prepare a State of the Environment Report... to describe the condition of critical environmental areas and human health concerns."

This declaration by the USEPA administrator recognizes that for EPA to truly measure the progress in achieving cleaner air, safer water, and better protected land resources, the Agency must go beyond its historic reliance on process indicators (e.g., decreased emissions/discharges, increased facilities in compliance) to measuring actual changes in ecological and human health outcomes. Process indicators served the Agency and Nation well in the first 30 years of EPA's existence, during which large gains were made in achieving cleaner air, safer water and reduction of land-based pollution (e.g., waste sites, pesticides). However, to justify the costs associated with further incremental improvements may require a more direct demonstration of the benefits to ecological and human health. Whereas the Office of Research and Development's (ORD's) programs have traditionally focused on research to better inform the Agency's risk assessments and risk management decisions, a program is presently to be initiated that would assess the environmental public health outcomes (EPHO) of those decisions and directly support the goals presented in the EPA Administrator's message.

In addition, EPA's EPHO initiative complements similar initiatives in the wider public health arena. For example, as a result of the 2000 Pew Charitable Trust report, America's Environmental Health Gap: Why the Country Needs a Nationwide Health Tracking Network, Congress is providing appropriations in Fiscal Year (FY) 2002 and FY 2003 to the Centers for Disease Control and Prevention (CDC) to begin bolstering America's ability to track and prevent health problems caused by environmental conditions. Also, the CDC recently released the National Report on Human Exposure to Environmental Chemicals (March 2001) that provided data on 27 pollutants present in the blood and urine of a small sample of the U.S. population. Its intent is to continue to build this inventory over the next several years.

To better define ORD's EPHO research agenda, a workshop was held July 30-31, 2002 at EPA facilities in Research Triangle Park, North Carolina. The intent of this workshop was to engage federal and other organizations in a dialog that will assist ORD in developing a framework to guide this research program, identifying potential near-term research areas and pursuing opportunities to collaborate with other public health agencies and organizations. A total of 47 attendees met to discuss aspects of near-term research planning that would involve broad collaborations between several federal agencies in assessing environmental public health outcomes. Discussions on the first day focused on topics emanating from the draft ORD Human Health Research Strategy's Chapter three including: one; are the approaches proposed reasonable and realistic first steps in initiating an EPHO Research Program? two; are there other areas/activities to consider in the early stages? three; are there existing data sets/resources that may be useful? and four; are there ongoing/planned activities within your organization or agency that may be appropriate for collaboration?

Discussions during the second session centered on the Supporting Document for the Human Health Chapter of the EPA's Draft State of the Environment Report (Final Draft). The

panelists were also asked to consider the following questions in reading this background material and in preparation for workshop discussions on these topics: one; what are the challenges in merging environmental monitoring data with health surveillance data? two; what data sets/resources exist that can inform the linkages between health outcomes and environmental factors? three; what are the lessons learned in carrying out these programs? and four; what pilot projects could be done to identify opportunities to improve the understanding of environmental public health outcomes?

Workshop Response

Workshop participants agreed that the proposed EPA effort to measure public health outcomes associated with environmental policies and regulations was worthwhile and that the approach to link environmental monitoring data with health surveillance data seems logical. Numerous suggestions for areas or activities to consider in the early stages of formulating and implementing the proposed program were noted, including forms of measurement, types of indicators, other tools, other disciplines, and communication of information. Participants also agreed that it would be helpful to develop an interagency list of data sets, surveillance programs, research efforts, models and other resources that are currently available. It was also determined that a successful program in this area will have to build on EPA's strengths and existing activities and be coordinated with on-going programs at other agencies.

Several possible challenges were noted to developing a program on public health outcomes. These included whether the science is sufficiently developed, whether the necessary data are available, and whether the proposed activities can be accomplished within a reasonable time frame. The need to anticipate limitations to what can be accomplished, as well as the need for a coordinated effort with other agencies and stakeholders, was also identified.

Next Steps

The workshop also identified several steps that could be followed in developing a program on evaluating public health outcomes, including the following:

1. Create an inventory of data sources to determine what is currently available, how they are structured, and how the data can be related:
2. Identify a known environmental hazard (e.g., methylmercury, ultraviolet radiation) and conduct a pilot study by working through existing exposure and effects data to determine data gaps and data needs:
3. Issue an RFA by the Extramural Program of EPA to develop research on the area of public health outcomes. CDC has expressed interest in co-funding such a solicitation: and
4. Attempt to provide EPA *ad hoc* participation in the review of RFAs from other agencies (i.e., CDC, NCEH) related to evaluation of public health outcomes

Section 1
Introduction

> *"It is also important that we hold ourselves accountable to the American public and report to them our progress in reaching the goals we have set for ourselves. Therefore, I am directing the Agency to prepare a State of the Environment Report… to describe the condition of critical environmental areas and human health concerns."*[1]

This declaration by Governor Christine Todd Whitman, the Administrator for the U.S. Environmental Protection Agency (EPA), on November 13, 2001, recognizes that for EPA to truly measure the progress in achieving cleaner air, safer water, and better protected land resources, the Agency must go beyond its historic reliance on process indicators (e.g., decreased emissions/discharges, increased facilities in compliance) to measuring actual changes in ecological and human health outcomes. Process indicators served the Agency and Nation well in the first 30 years of EPA's existence, during which large gains were made in achieving cleaner air, safer water and reduction of land-based pollution (e.g., waste sites, pesticides). However, EPA must now show that the costs associated with further incremental improvements can be balanced with demonstrated benefits in ecological and human health to justify continuation, modification, and/or redirection. Whereas the Office of Research and Development's (ORD's) programs have traditionally focused on research to better inform the Agency's risk assessments and risk management decisions, a program is presently to be initiated that would assess the environmental public health outcomes (EPHO) of those decisions and directly support the goals presented in the EPA Administrator's message.

EPA's EPHO initiative complements similar initiatives in the wider public health arena. For example, as a result of the 2000 Pew Charitable Trust report, *America's Environmental Health Gap: Why the Country Needs a Nationwide Health Tracking Network,* Congress is providing appropriations in Fiscal Year (FY) 2002 and FY 2003 to the Centers for Disease Control and Prevention (CDC) to begin bolstering America's ability to track and prevent health problems caused by environmental conditions. Also, the CDC recently released the *National Report on Human Exposure to Environmental Chemicals* (March 2001) that provided data on 27 pollutants present in the blood and urine of a small sample of the U.S. population. Its intent is to continue to build this inventory over the next several years.

EPA has supported and been intimately involved in both of these efforts and will be a direct beneficiary. It is recognized "up front" that much of the data needed to support EPA's EPHO effort (e.g., health surveillance and human exposure monitoring) is collected by other agencies with which cross-agency cooperation and collaboration will be essential. The challenge for ORD will be to conduct the complementary research to establish the linkages between these exposure and health events. The characterization of such relationships will be of great value in future environmental decision making for two reasons. First, such characterizations will substantially enhance the scientific basis of environmental policy making. Second, this characterization will increase EPA's accountability to the American public.

There are also a number of established research strategies and assessment approaches from other agencies that may serve as useful models for developing the EPA research framework. Examples include the Surveillance Strategic Plan developed by the National Institute for Occupational Safety and Health (NIOSH), the surveillance research program at the National Cancer Institute (NCI), and global assessments of environmental health outcomes conducted by the World Health Organization (WHO). CDC also leads a number of initiatives of interest such as the National Health and Nutrition Examination Survey (NHANES) that are national in scope and multi-purpose in design.

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[1]Text from Governor Whitman's memorandum to EPA Assistant and Regional Administrators, dated November 13, 2001.

To better define ORD's EPHO research agenda, a workshop was held July 30–31, 2002 at EPA facilities in Research Triangle Park, North Carolina. The intent of this workshop was to engage federal and other organizations in a dialog that will assist ORD in developing a framework to guide this research program, identifying potential near-term research areas and pursuing opportunities to collaborate with other public health agencies and organizations.

In anticipation of the workshop, ORD has produced an EPHO white paper as part of its overall *Draft Human Health Research Strategy*, which outlines a conceptual research program and sets the stage for future activities. ORD also had the lead in producing the human health chapter of EPA's *Draft State of the Environment Report* (SOER), due to be released in the fall of 2002. These two documents provided much of the basis for discussions at the workshop, and participants were asked to read both documents prior to attending the workshop.

On the first day of the workshop, WHO presented its conceptual model for measuring environmental health outcomes and the integrated framework it developed for research in this area. The approach developed by WHO focuses on the environmental burden for disease (EBD) within a harmonized framework for assessment, policy action, and evaluation. The presentation also identified current activities for global- and geographically-focused assessments completed or ongoing, as well as future plans for coupling environmental health assessments to cost-effectiveness of interventions. Through this effort, an extensive list of risk factors has been developed that may be of interest to this EPA initiative.

The first workshop day also included two panel sessions, and each focused on one of these documents. A subset of the participants was assigned to each panel, and specific questions were provided in advance to facilitate discussions. Each panel session included presentations by the assigned panelists, followed by a panel discussion and an open discussion. Included in one panel session was a workshop presentation that provided background information to all participants on the purpose, scope, expectations, and status of the SOER currently in preparation by EPA.

On the second-day of the workshop, a subset of participants gathered to review the suggestions, recommendations, and other outcomes of the first-day presentations and discussions. This led to further discussions on setting the overall research framework, as well as next steps for FY 2002 and FY 2003.

This report presents highlights and key points of discussions throughout the two-day EPHO workshop and is organized as follows. Section two summarizes discussions according to the four charge questions identified for the first panel discussion. Section three summarizes discussions according to the four charge questions identified for the second panel discussion. Section four provides other types of feedback received from workshop participants pertinent to the proposed research initiative. Section five presents key highlights of the second-day workshop discussion pertaining to program framework and next steps. The workshop agendas and the lists of workshop attendees are provided in Appendix A and B, respectively. Appendix C provides a list of data resources identified in workshop discussions and presentations.

Section 2
Panel One: Public Health Outcomes White Paper

In preparation for this workshop, panelists were asked to read excerpts from EPA/ORD's *Draft Human Health Research Strategy*, specifically the Executive Summary, Introduction, and Chapter three (*Research to Enable Evaluation of Public Health Outcomes from Risk Management Actions*). The panelists were also asked to consider the following questions while reading this background material in preparation for workshop discussions on these topics:

1. Are the approaches proposed reasonable and realistic first steps in initiating an EPHO Research Program?

2. Are there other areas/activities to consider in the early stages?

3. Are there existing data sets/resources that may be useful?

4. Are there ongoing/planned activities within your organization or agency that may be appropriate for collaboration?

In their presentations, panelists provided information specific to these questions and/or provided illustrative examples observed while conducting similar programs.

The following sections summarize the information presented in workshop sessions and discussions relevant to the preceding questions.

2.1 Are the Approaches Proposed Reasonable and Realistic First Steps In Initiating an EPHO Research Program?

Workshop participants agreed that the proposed EPA effort to measure the public health outcomes associated with environmental policies and regulations is worthwhile and that the proposed approach—to link environmental monitoring data with health surveillance data—is attractive. In association with this overall comment, participants offered additional suggestions for EPA consideration in four areas; general program observations, approaches for establishing priorities, potentially applicable approaches and first steps, and potential models for program development. The following sections provide highlights of workshop discussions in each of these areas. The challenges specifically associated with linking environmental and health data are presented in Section 3.1.

2.1.1 General Program Observations

The general consensus that the proposed EPA program is worth pursuing was tempered with a number of cautionary considerations. The concerns expressed generally focused on whether the science is sufficiently developed, whether the necessary data are available, and whether the proposed activities can be accomplished within the time period required. Workshop participants also noted the need to anticipate that there will be limitations to what can be accomplished as well as the need for a coordinated effort with other agencies/stakeholders. (NRMRL)

Workshop participants also noted that there are limitations to science and to risk assessment as well as significant levels of complexity, uncertainty, and unknowns to be filled by research. Explaining to the public the limitations of science in identifying risk factors, assessing risk, designing interventions, and reducing risks can be difficult. Clusters of disease such as cancer may occur that are not statistical anomalies, yet the cause may remain unknown despite the best scientific efforts. Also, currently available techniques and data sets may be inadequate to detect improvements in overall public health as a consequence of environmental policies and regulations. This does not necessarily mean that public health

has not improved since the institution of pollution control regulations, rather that the improvement may not be measurable with currently available tools. Clearly communicating these distinctions to the public will be very important. (NRMRL, CDC/NCEH)

A related concern was that the background documents for this workshop make these very complex and challenging issues seem achievable to those who are not knowledgeable in these scientific fields. Program planners were cautioned about setting standards, goals, or expectations too high for what can be delivered or implying that complex issues will be solved in a brief period of time. (CDC/NCEH, ATSDR) In addition, workshop participants also acknowledged the difficulty of acquiring hard data that no one will criticize or that prove correlations with diseases. (AFIP)

Framing the program into phases may be reasonable and helpful, but this may mislead critics and the public regarding the linkage between individual phases. How individual projects are related to each other and to the accomplishment of the program and each program phase will be important to communicate. (NIOSH)

Is the program intent to reinvent EPA or to add a new direction or definition to existing programs? Reinvention would require the involvement of more disciplines, backgrounds, and interested/affected stakeholders (e.g., state/local). (NIOSH)

Also noted was the importance of showing that this program is meaningful and has potential, because environmental health is not yet considered a core health area. (WHO) NIOSH similarly noted the need to make this program relevant to the public and to the decision makers rather than focus solely on EPA needs. To do this may require reaching out to a broader audience (beyond those in this workshop) and recognizing roles for professional organizations, academic centers, and industry. Of related importance is encouraging academic collaborators to work with public health counterparts at the state/local levels on real-world situations. (NIOSH)

Many of the EPHO mentioned in the reports reviewed for this workshop are not direct measures for assessing impacts. More research may be necessary to determine specific exposure-outcome relationships in order to make such determinations. (ATSDR)

Furthermore, developing an integrated, coordinated national EPHO research agenda will be challenging because of the number of agencies involved in data collection and the overlap of common research interests between agencies. A helpful step may be to identify the types of research that each agency, including EPA, is most suited to conduct (NRMRL). This research initiative also depends on having the capacity to collect the necessary data and the expertise to interpret the data, and fewer suitable data sets are available than many would assume. (CDC/NCEH)

Also noted was the need to consider, for a successful program outcome, a range of indicators beyond just human health. For example, there are environmental changes that cause adverse global effects but may not cause disease directly (e.g., global warming from hydrocarbon emissions increases floods that kill people in another country). Reasons to control such adverse environmental changes may have nothing to do with disease. A potential program pitfall is to focus on public health outcomes as the only priority to the exclusion of other programs that measure environmental influence. (AFIP)

This initiative could serve to strengthen implementation of risk management approaches, delay them, or lead to the evaluation of things that individuals or organizations may not want evaluated. Programs may be adversely affected if the proposed research is unable to measure/document health benefits from actions the Agency has already taken. Thus, EPA must be prepared to address negative outcomes from the proposed initiative. These could include:

- Finding that the wrong thing is being regulated and being prepared to shift efforts in response to such a finding, even if the proposed studies are not finished (Day-two Sum)

- Inability to show that environmental exposures from certain discharges are causing adverse health effects (or that eliminating such exposures reduces adverse health effects) may result in public pressure to drop the controls/restrictions on such discharges, even though such controls/restrictions are known to be desirable for other reasons or from other source information (NCEA, NRMRL, AFIP, NERL)

- Finding that a specific polluting situation is causing adverse health effects, resulting in criticisms for delaying implementation of appropriate controls or restrictions in favor of completing the research (NCEA, NRMRL AFIP, NERL)

Of particular concern is that this effort may be unable to show that the Agency's policies are successful based on public health indicators. Such success may depend on the creation of a national system to track diseases. Inherent to both the proposed program and a national tracking system are questions of which diseases to select, which diseases are of most concern in managing different types of environmental pollutants, and how individual indicators will be picked. (NIEHS)

Other general suggestions included the following:

- Different individuals may choose to live with different levels of risk (AFIP)

- Better explanation is necessary in the EPA documents reviewed for this workshop regarding the need to link exposures to public health outcomes (NIEHS)

- If emphasis is placed on recording and reporting raw data, trends both upward and downward will be apparent, and increasing trends are not well received (NIOSH)

- Plan so opportunities and expectations are realistic. (ASTHO)

2.1.2 Establishing Priorities

EPA queried participants and attendees for suggestions on how to establish priorities for the proposed program and suggestions on recommended first steps in this effort. The background documents for this workshop cast a broad net and participants suggested the need to winnow the ideas down to core elements that are most important to achieving the desired goals. To do this, participants and attendees suggested that EPA consider:

- What end points are being protected or reduced (ATSDR)

- How the information will provide value to better understanding and validation for risk-management decision making (ATSDR)

- What can be achieved with available resources (ASTHO)

- Economic impact and the cost per life saved (ASTHO)

- What information would EPA like to have or needs to have several years from now, such as the data necessary to support tracking or evaluation of success beyond what is currently available with due consideration given to what data are practical to obtain (ASTHO)

- Using burden of disease in the population as a means of selecting which issues to monitor (CDC/NCHS)

- What public health level(s) to address—case (assure appropriate treatment), contact (assure contacts are treated), community (remove source of outbreaks), or program (monitor effectiveness in real time) (ASTHO)

- What EPA wants to meet or achieve, then steer efforts toward what is desired to be accomplished and look at what already exists that can be converted to help. (WHO)

In addition, the environmental burden of disease (EBD) approach used by WHO in global assessments was noted as one of many tools for prioritizing health problems and risk factors because it uses common health units, compares various risk factors and diseases, and compares environmental health to other areas. This approach can help to monitor progress, to provide a basis for evaluation, and to identify vulnerable subpopulations, and can also serve as basis for calculating the cost-effectiveness of interventions. (WHO)

Workshop participants consistently emphasized that initial studies should be conducted in a manner that will yield rapid results. One option was to begin with a contaminant, an existing data set, an exposure scenario, or a health outcome, and to map out a program covering all three areas of interest—exposure, environment, and health effects. (EPA, NCI, ATSDR) Going through such an exercise will help to identify gaps in the data and in the methodology, and will help to clarify exactly what types of data are most useful. For example, using particulate matter or arsenic data, describe the available data sets and how the risk management programs would be evaluated. This in turn would generate a design of the evaluation system and its required elements. (NIEHS) EPA human exposure researchers already use this approach; for example, they start with a specific pesticide and use exposure models to identify the data needs. (NERL)

Workshop participants also suggested approaches that involved the anticipation of future research needs. For example, consider what data are needed to evaluate the public health outcomes of newly implemented interventions and those that are "in the works" but not yet implemented. Consider EPA's 10-year plan for mercury and think about what data would need to be collected to identify changes in public health outcomes over the years. Recent changes in pesticide registrations provide an additional opportunity to track outcomes over the next few years. Baseline data for some interventions can be collected now, before the effects of the interventions become widespread. (ASTHO)

Other suggestions for first steps to help define program approach and focus involved the use of a pilot program (CDC/NCEH), a hypothetical example (NIEHS), or a hypothetical case study. Examples offered for consideration included:

- Developing an example using a specific regulation or guidance that includes an environmental control activity. "Scope out" the effort, and identify all possible measures in the three areas of interest. (exposure, health effects, environment) considering their utility to the EPA program, to the EPA Administrator goals, and the public good (as good stewards of federal dollars). (ATSDR)

- Working backward from a given regulation or standard. (ATSDR)

- Determining the interests of the public and relating program efforts to those areas; for cancer surveillance, these include prevention, early detection, and quality of life. (NCI)

- Building an evaluation into new regulatory strategies or use the new regulatory strategies as exercises if such an approach cannot be added into the current regulatory process. (ASTHO)

- Identifying the best indicators for success in air or water or waste, then picking only two or three core indicators and conducting the best possible analysis using those indicators. To do this, select a suite of indicators or a specific disease focusing on high priority issues that will measure the success of the program, and specifically consider a set of core tracking indicators where the environment can in fact be measured. (ASTHO)

- Mining existing data sets to determine what additional data are needed and how such data should or can be collected. (NERL)

- Identifying regional issues or focuses (e.g., Great Lakes, large cities, specific chemicals) that are important to community health and are of political interest. (ATSDR)

- Evaluating some specific exposure situations for suitability to this initiative. Examples include the Libby asbestos mine that had specific health impacts and data available from extensive residential health examinations. Such an example would need to consider both cancer and noncancer outcomes. (NIEHS, ATSDR)

- Assuming, for a hypothetical case study, that all the information desired can be obtained, then determining what is really needed to carry out an actual study. (Day-two Sum)

Refer also to other sections of this report for related suggestions pertaining to pilot projects (Section 3.4), other potentially applicable approaches (Section 2.1.3), and collaboration opportunities (Section 2.4).

Of final note was a recommendation to avoid giving states complete discretion for setting priorities. A NIOSH program developed in the 1980s was offered as an example for setting national priorities while including mechanisms to address some state-specific aspects. This NIOSH program prescribed a list of conditions to address, yet retained the option for states to submit alternative proposals. (NIOSH)

2.1.3 Potentially Applicable Approaches and First Steps

Workshop discussions addressed the use of both prospective and retrospective approaches. A prospective approach requires the process to be thought out in advance in order to formulate hypotheses. (NERL) However, retrospective approaches using existing data may still yield useful results. (ATSDR) Existing data as well as dose/response and other models can help to develop retrospective and prospective questions to get at the larger issue of "Can or do we affect public health?" (NERL)

Workshop participants also noted the importance of conducting hypothesis-driven studies, even if they are retrospective. (NCEA) Such approaches would involve developing hypotheses for the end points then looking for the environmental conditions that are thought to be contributing or to develop hypotheses of linkages that must then be tested. (NERL)

Additional, more specific suggestions to consider in developing an approach to linking environmental and public health data and measuring health outcomes included the following:

- Measure impacts and endpoints rather than compliance. (ATSDR)

- Choose one parameter from the WHO efforts and apply it in a manner that best fits the needs of the United States. (WHO)

- Select a few high-priority issues to measure success and determine the best indicators for success, then pick a suite of indicators or a specific disease and look at what others are doing in that area. For example, if asthma is a core indicator for air, look into what research is being conducted on asthma and air quality. (ASTHO)

- Use a case control approach to study a high exposure area as compared to low exposure areas, such as air pollution impacts in Los Angeles or another urban center vs. rural areas. (ASTHO)

- Focus on areas that appear to have moderately high or high rates of disease because these represent greater opportunity to observe disease reduction than in areas that have only sporadic disease occurrences. (NIEHS)

- Re-analyze specimens collected under previous studies for new parameters of interest. (ASTHO)

- Make the most of the data that already exist; start with what is available and try to make the data better. (NCI)

- Take advantage of relevant measurement opportunities that may occur such as the study of the relationship between health effects and particulate matter (PM) exposure changes resulting from short-term closure of a plant in Utah or applications of pollution controls on diesel engines in urban areas. (HEI)

- Consider applicability of approach used by the Agency for Toxic Substances and Disease Registry (ATSDR) to evaluate specific remediation activities (removal of lead-contaminated soil) and how this was linked to findings that this intervention decreased blood lead levels in children in nearby households.

- Examine consequences of compliance and noncompliance as well as different levels of noncompliance (grades of noncompliance) to see what the effects are and to look for gradation of effects requiring adjustments for different areas. (ATSDR)

- Involve public health officers to help identify specific local venues/situations for study. (NIOSH)

- Integrate decision making with science and regulations by integrating the principles of surveillance, risk management, and prevention and through more dialog among researchers, risk managers, and policymakers. (NIOSH)

- Acquire and use anecdotal information in addition to case-based surveillance data. (NIOSH, ASTHO)

- Consider different levels of indicators such as core (what are practical nationwide), optional (not applicable nationwide), and developmental (have promise but are not ready for implementation). (ASTHO)

- Leverage the EPA asset of having significant amounts of exposure data rather than reinventing the Agency because this will represent an enhancement or growth area. (NCI)

- Host a conference with representatives from all states and identify several (perhaps five) good venues to pursue. Both science and diplomacy must be considered since few venues may be advantageous to program needs, which may have negative repercussions among the states not selected to participate. (NCEA)

- Consider a two-track system involving data rich/poor areas as well as high/low problem areas. (WHO)

2.1.4 Potential Models for Program Development

There are a number of established research strategies and assessment approaches that might serve as models for framework development. Participants also presented illustrative examples as guidance based on their program experience. These include WHO's conceptual framework for EBD assessments, the NIOSH Surveillance Strategic Plan, CDC prioritization efforts, and the framework for the NCI surveillance research program.

In developing global EBD estimates, WHO is using disability-adjusted life years (DALYs) as a summary measure of population health that spans both diseases and risk factors. Each DALY corresponds to 1 year of healthy life lost. Disease burden is a calculation that considers incidence, mortality, and DALYs. WHO noted that DALYs are a common metric, but the power of their use dissipates when focusing on smaller geographic areas.

NIOSH offered the approach presented in its Surveillance Strategic Plan (available on the NIOSH website) as a useful method for approaching these types of initiatives. Also suggested was applying other NIOSH lessons learned to this process for environmental health evaluation. In developing surveillance programs, NIOSH teamed with academia, federal/state authorities, labor, professional organizations, and academic centers. NIOSH also brought in the insurance industry, which operates at the state level and is an important data resource in the health arena.

In addition, NIOSH created partnerships to develop data resources such as the Sentinel Event Notification System for Occupational Risks (SENSOR, which addresses occupational asthma and pesticides among other factors), the Adult Blood Lead Epidemiology and Surveillance (ABLES), and occupational mortality.

CDC programs are establishing their priorities based on those defined by the Department of Health and Human Services (DHHS) in *Healthy People 2010* and the recommendations from the Pew Charitable Trust report. In this effort, CDC is first arranging for state participation, in order to consider their priorities before actually establishing or setting out CDC programs, for two reasons: (1) the states have specific state/local priorities that need to be considered, and (2) CDC must consider whether these state/local priorities may be national priorities as well.

As another example, setting priorities for each NHANES is a challenge because this is a multi-purpose survey that considers nutrition, disease, and environment. To address this challenge, NHANES planners conducted a significant amount of outreach to the professional community that uses the data collected and held many stakeholder meetings to address priorities. (CDC/NCEH)

NCI has a national framework of cancer registries (SEER), yet the core of the work is through data linkage and ecologic analyses. NCI also draws on modeling and analytical tools applied at many levels. Much of what is accomplished is through a peer review program and grants. NCI also worked with the partners to develop a national framework for cancer surveillance. This considered treatment of cancer, living with cancer, and dying with cancer; primary, secondary, and tertiary prevention; and information/measurement needs for describing the cancer burden by social, economic, racial/ethnic, and geographic subpopulations. (NCI)

The mission of the National Institute of Environmental Health Sciences (NIEHS) is to reduce the burden of environmentally-associated diseases, to define susceptibilities, and how these change over time. The research encompasses the diseases mentioned in the EPA reports reviewed for this workshop including the emerging diseases such as autism, Parkinson's disease, diabetes, and others that may be environmentally-based. Basic and applied research is conducted in all of these areas extramurally and intramurally. Much of the funding goes to various universities and for prevention/intervention programs.

Other frameworks to consider include the following:

- ORD's development of better water quality indicators, which help state TMDL monitoring programs, may be a good model of state-EPA cooperation.

- Many remediation actions are accomplished by combined federal, state, and local efforts and might serve as models of interagency, multilevel cooperation. (NIEHS, ATSDR)

2.2 Are There Other Areas/Activities To Consider In the Early Stages?

Workshop discussions presented numerous suggestions to EPA for other areas or activities to consider in the early stages of formulating and implementing the proposed program. These suggestions involved five general areas: forms of measurement, types of indicators, other tools, other disciplines, and communication of information. The following sections address key points raised in workshop discussions in each of these areas.

2.2.1 Forms of Measurement

EPA program planners were encouraged to think about existing and new forms of measurement to understand the environmental contributions to exposure and health (ATSDR). Examples offered by workshop participants included:

- Identifying biomarkers or biologic measures of exposure that are easier to measure rather than waiting for disease to become clinically apparent in order to measure disease endpoints (ASTHO)

- Use of the DALY metric or other existing summary measures of health to measure across diseases and conditions (WHO)

- Collection and evaluation of both rates of occurrence (frequency) and counts (number of occurrences) (NCI)

- Finding positive as well as negative measures of performance (NIOSH)

- Coupling assessments for risk factors to cost-effectiveness of interventions using the same measurement units. (WHO)

Suggestions for <u>environmental</u> parameters to measure included the following (ATSDR):

- Releases, emissions, and storage

- Ecosystem impacts

- Contamination levels—air, water, food, soil

- Levels of compliance with standards and regulations

- Contaminant levels in workplace, home, school, day care—where people spend large amounts of time

- Usability or sustainability of natural resources.

Suggestions for <u>exposure</u> parameters to measure included the following (ATSDR):

- Level by pathway—air, water, food, soil.

- Re-education and intervention monitoring.
- Biomarkers of exposure—150 contaminants are measurable, some biomarkers have been identified.
- Behavior and knowledge, including perceptions of exposure/risk and compliance behaviors.
- Exposure-dose relationship in humans, including body burdens and excretion.

Suggestions for human health parameters to measure included the following (ATSDR):

- Morbidity, mortality, incidence/prevalence
- Biomarkers of effect—early and late biomarkers of effect and reversibility
- Acute health effects—significant to communities and the general public
- Occupational disease or injury
- Contributions of nonenvironmental factors—lifestyle, demographics, genetics, etc.
- Behavior and knowledge—perceptions of health, knowledge of health outcomes/risks.

2.2.2 Types of Indicators

Environmental public health indicators need to be developed. An example is the initial core list of indicators adopted by the Council of State and Territorial Epidemiologists (CSTE) in July 2001 (ASTHO). This list includes environmental public health indicators needed to monitor the following:

- Air—indoor, outdoor
- Water—drinking and recreational
- Agents/sentinel events—chemicals (e.g., pesticides, metals), physical (e.g., ultraviolet radiation, noise, disasters).

The core list also includes various types of environmental public health indicators such as:

- Hazard—toxic releases from industries, etc.
- Exposure—levels in blood, urine, hair
- Health effect—unusual occurrences of diseases such as asthma (many factors may contribute to a decrease in mortality)
- Intervention.

Workshop participant recommendations also included the need to develop both additional indicators and more precise indicators of human behavior (bottled water use, fish advisory compliance, etc.) as well as the need to create action-oriented indicator(s) tied to a public health objective. (ATSDR, ASTHO)

2.2.3 Other Tools

Integrating national surveillance data systems or making existing data systems compatible was identified as an important tool in many workshop discussions. Similar recommendations involved increasing the

compatibility of state-level data systems with national systems, which would also help to give state/local agencies an opportunity to participate in national surveillance activities and data policies. Some state systems may already be undergoing upgrades to address recent bioterrorism concerns. (ASTHO)

Modeling was identified as another potentially useful tool. Before/after health outcome data can be used in models to try to predict risks; the predictions can then be compared to the actual before/after information to help validate the models. Once validated, the models can be used to predict the effect of environmental policies and regulations on public health. (NERL) In cancer risk management, modeling has been used to link screening, treatment, and prevention goals to mortality goals (NCI). Models, mathematical calculations, and other tools can also be used to predict trends, then measure actual occurrences against those trends. (NCI) Inverse modeling tools are available and may aid in working backward from an effect to the source. (NERL) There may also be the need to develop models that show the entire exposure-effect process. (NERL) In addition, research may be needed to back-up or validate the models, which has been a past criticism of some efforts. (ATSDR)

Another important concern was to geocode the collected data and to either use or plan for the future use of Geographic Information System (GIS) technology. This tool will help with risk communication, especially in regional or national presentation of findings. GIS data layering capabilities are very useful, but depend on the quality of data entered. (ATSDR)

Newly emerging technologies, such as genomics techniques, may aid in identifying susceptible populations that were previously unrecognized, which may be a more appropriate level of consideration. (ASTHO) These new genomic tools and other new technologies would serve in addition to (not instead of) traditional mortality and morbidity data to better evaluate risk management programs. (NIEHS)

For example, toxicogenomics (which elucidates the genomic response of organisms exposed to environmental toxicants), proteomics, and metabonomics have the potential to provide environmental public health indicators in the form of biomarkers of early disease, exposure, and susceptibility. Biomarkers of early stages of disease will enable earlier detection of health effects from pollutants. These technologies may allow scientists to identify the cellular networks of response to environmental toxicants. (NIEHS)

Other suggestions included the following:

- Identify what can be done with the data and tools that are currently available. Identify what tools (modeling and otherwise) and data need to be developed (NERL)

- Use probability/decision analysis tools to identify the likely influences on a desired outcome then test these possibilities; many such tools already exist (NIEHS, NRMRL)

- Evaluate and develop, as needed, techniques for exposure-dose reconstruction noting that data quality is very important to this effort (ATSDR)

- Develop prevention-effectiveness assessment (cost-effectiveness) techniques; an example is the collaboration between the Agency for Toxic Substances and Disease Registry (ATSDR) and EPA for disinfection models (NCEA)

- Recruit tissue donors to create tissue banks for future analysis for parameters that cannot be measured with current techniques (ASTHO); the Army explored creating such a tissue bank, yet cost was a significant factor in the decision not to pursue it. (AFIP)

2.2.4 Other Disciplines

Economics, social science, and behavioral science were identified as additional disciplines that may be important in developing and conducting the proposed program. Economists have different analytical tools and insights that may be useful.

In addition, economic assessments are important because a key issue in any program such as this is the cost associated with environmental regulations. (ASTHO) The economic costs may need to be merged with the health aspects, for example, by assessing the money spent according to some easily identified metric; an illustrative example involved a measure of state dollars spent per highway mile (one million dollars) to enable comparisons of different program costs (e.g., $19 million for bioterrorism equals 19 miles of road construction). Other economic evaluation considerations are the cost of intervention vs. health life years gained or the cost for each life saved as part of a cost-benefit analysis. (WHO, ASTHO)

Social scientists and behavioral scientists also have potential contributions to make in linking exposure and environmental contamination. Specific areas include the identification and assessment of behaviors that lead or contribute to exposure and, subsequently, adverse health effects. Some of these may be age-related or vary by age group, particularly for susceptible populations such as children.

In addition, measurements of social well-being are needed because behavioral aspects affect health (Day2 Sum). Since the risks in many communities result from cumulative stressors, application of a "quality of life" approach also may be useful in developing an index of environmental stressors that could be applied by any community. This type of information may also be more readily collected (e.g., through telephone interviews rather than medical exams). (ASTHO)

2.2.5 Communication of Information

Numerous recommendations emphasized the importance of disseminating findings and communicating with the public and stakeholders. These include:

- Communication of activities and findings to the public is important to overall program success. (NCI, CDC)

- Communication of reasons why certain locales or situations are selected for study, while others are not, is important to maintaining cooperation of state/local agencies. (NCEA)

- Improvement of the dialog among researchers, risk managers, and policymakers to better integrate science and decision making. (NIOSH)

- Language-free communication tools can enhance and improve information dissemination to non-English-speaking and illiterate persons. (NIOSH)

- Risk assessment and other aspects of this program may be difficult to explain to the public. Information must be translated and communicated in terms the recipient audience can understand. Risk communicators can assist in communicating and explaining these concepts to legislative personnel and the general public. (NCI, CDC/NCEH)

- Limitations of science in identifying risk factors, designing interventions, and reducing risks also can be difficult to explain to nonscientists. The reasons for a health occurrence may be beyond current scientific understanding, yet also may be known not to be a statistical anomaly. (CDC/NCEH)

- Effective information dissemination is important for the information to be applied and used because the information will not diffuse on its own. (NCI)

- Communicating information back to a community regarding studies conducted in its area (e.g., cancer cluster-type study) helps to involve the community in the effort and thereby garner its support. (NCEA)

- Conduct outreach to stakeholders as well as to collaborators and potential information sources. (Day2 Sum)

2.3 Are There Existing Data Sets/Resources That May Be Useful?

Participants generally agreed that it would be helpful to develop an interagency list of data sets, surveillance programs, research efforts, models, and other resources that are currently available. Many agencies are involved in collecting data relevant to environmental health, therefore, identifying relevant studies that have been conducted already might also be helpful. Data available from outside the federal government should also be identified.

To start this process, Appendix C provides a tabular listing of the data sets and surveillance systems mentioned in workshop discussions. Other potentially relevant information sources include:

- Lists of indicators, surveys of information sources, and data sets collected for preparation of the SOER; additional data exist beyond what is actually being used in the report

- Lists of indicators developed by the U.S. Forest Service, the Council of State and Territorial Epidemiologists, and EPA programs (e.g., the Environmental Monitoring and Assessment Program, or EMAP)

- A national burden of disease study already prepared by the United States (WHO)

- A round table hosted by WHO on how to address risk factors at a national level.

WHO also offered to share information on its process for assessing disease burden since the entire process is not documented in a specific report.

2.4 Are There Ongoing/Planned Activities Within Your Organization/Agency That May Be Appropriate for Collaboration?

EPA plans for this to be a leveraged program that builds on EPA's strengths and existing activities in coordination with other agencies. Thus, panelists and workshop participants were invited to provide information about ongoing/planned activities in their agencies/organizations that are potentially suited for collaboration with EPA in the EPHO initiative. The following sections present highlights of ongoing and planned activities and initiatives for CDC, ATSDR, NIOSH, NCI, NIEHS, and WHO not otherwise presented in other sections of this report or Appendix C.

2.4.1 CDC

CDC historically has developed programs as they are funded, and these programs are typically disease- or topic-specific. Now CDC programs have an increased interest in standardizing data and integrating existing databases with each other and with new data. CDC also has significant interest in the evaluation/assessment after a risk decision is made (e.g., intervention) regarding effects and the quality of data used. (CDC/NCEH)

CDC is establishing surveillance systems for a number of diseases that are not currently tracked. CDC is willing to discuss disease surveillance methods with interested parties.

CDC is also working to improve exposure databases. The best exposure databases are for childhood lead.

Other CDC activities include:

- Funding up to 15 state/local pilot projects to identify and either improve or initiate surveillance activities on possible environmentally-related diseases as well as to explore the environmental-health linkage

- Creating an inventory of more than 120 existing CDC surveillance systems (see examples in Appendix C)

- Working for 3 or more years with the CSTE focusing on health indicators, including some environmental health indicators.

Two Request for Applications (RFAs) have already been issued for state/local pilot projects. One RFA requires state health and environmental agencies to work together to evaluate existing databases, evaluate existing legislation/regulations, and to develop/enhance data systems. States are classified into tiers based on their capacities in these areas. In states with existing capacities, activities will also include actual linkage projects and examine the feasibility/utility of EPHO indicators in the field. The other RFA will create two or three centers of excellence geared toward schools of public health to bring academic and state programs together to develop statistical algorithms and other approaches.

Specific groups in CDC are developing surveillance systems for new conditions such as autism, learning disabilities, attention deficit hyperactivity disorder (ADHD), and Alzheimer's disease, among others, that may have an environmental contribution. The Developmental Defects Center is looking at autism as an "add on" to the Atlanta birth defects registry effort. CDC also has awarded grants to develop surveillance systems for developmental disorders in other areas.

The following sections summarize ongoing and planned activities within CDC for the National Center for Environmental Health (NCEH) and National Center for Health Statistics (NCHS).

2.4.1.1 NCEH

NCEH is the lead agency developing a nationwide health tracking network for diseases and exposures. This will be an integrated system responsible for data collection, analysis, and dissemination of information. The program goal is to develop and implement comprehensive programs in all 50 states, the District of Columbia, U.S. territories, and tribal nations. (See Appendix C for further information.)

Another NCEH focus is on developing information to be used at the state and local levels, including involvement in the CDC RFAs discussed previously. In addition, NCEH is interested in opportunities to collaborate with NHANES and other national surveys.

CDC/NCEH is also currently involved in discussions with the EPA Office of Environmental Information (OEI) on existing data usage and integration within the constraints of privacy/confidentiality agreements. A small team is being developed (EPA network personnel and others) to look at such issues as how to mesh specific electronic data systems. A Memorandum of Understanding (MOU) is being developed and may provide an opportunity for additional collaboration.

2.4.1.2 NCHS

NCHS collects vital statistics data in partnership with states, and also collects data on health status, health behaviors and the environment, the health system, and treatment and care. The NCHS mandate includes health, environmental, and social aspects. NCHS conducts surveys that include household interviews and

health care providers. NCHS is interested in having these data used as extensively as possible, and noted that links of its data to other data sets are possible, provided confidentiality is protected.

NCHS is also the administrator of the National Health and Nutrition Examination Survey (NHANES). NHANES is an ongoing study with great flexibility to add features that address specific questions of collaborators. The NHANES survey content will change in 2005, and advance planning for this is beginning in September 2002. Opportunities exist at this time to collaborate with NCHS on future survey content and to determine if some of new desired data can be obtained through this survey.

NCHS offered to participate in discussions on use of its data as well as strategization on data access within the confines of the applicable confidentiality agreements. NCHS also offered to collaborate on evaluating the feasibility of proposed data needs and collection techniques and in developing proposals. In addition, NCHS offered partnering opportunities to address the acquisition of geographic information and linkage of geographic information to public health data without violating confidentiality standards.

NCHS also recommended that, when working with an ongoing survey, collaboration should begin in the planning stage so the survey can be adapted to provide the desired data.

2.4.2 ATSDR

ATSDR has expertise in exposure-dose reconstruction and in applications of GIS technology to this field. Priority health conditions being addressed by ATSDR initiatives include:

- Birth defects and reproductive disorders
- Cancer (selected anatomic sites)
- Immune function disorders
- Kidney dysfunction
- Liver dysfunction
- Lung and respiratory diseases
- Neurotoxic disorders.

ATSDR research focus areas for 2002 through 2010 include:

- Exposure assessment
- Chemical mixtures
- Susceptible populations
- Community and tribal concerns
- Evaluation and surveillance of health effects
- Health promotion and intervention.

ATSDR is also working with neurologists and public health agencies to launch pilot surveillance systems for degenerative neurological disorders (e.g., multiple sclerosis, amyotrophic lateral sclerosis, etc.) in four or five states. This will involve the collection of data and assessment of trends.

2.4.3 NIOSH

NIOSH looks at the burden of occupational health and is expanding research at the national and state levels. Ongoing or planned activities include state-based occupational disease surveillance programs (some in place since 1980), and National Occupational Research Agenda (NORA) grant solicitations that leverage NIOSH and partner resources. In collaborative ventures, NIOSH can provide technical assistance, surveillance research expertise, and capacity building.

2.4.4 NCI

Much of what NCI does is conducted through peer review programs and grants. For example, NCI is building a surveillance infrastructure and assembling complex data sets through its Surveillance, Epidemiology and End Results (SEER) program (see Appendix C). In addition, NCI has formed a cooperative group of 17 grantees that are modeling the impact of cancer control interventions on cancer incidence and mortality.

NCI is involved in a partnership via the National Coordinating Council on Cancer Surveillance. This partnership meets voluntarily and includes representatives from the American Cancer Society, American College of Surgeons, North American Association of Central Cancer Registries (NAACCR), CDC, NCI, Armed Forces Institute of Pathology (AFIP), and the National Cancer Registrars Association (NCRA).

2.4.5 NIEHS

NIEHS is working with the National Research Council to develop a committee on emerging issues and data on environmental contaminants. This effort intends to bring together persons in the field of genomics and other emerging technologies with those affected by data coming from such new technologies. This committee will consider technology implications and whether such technologies will support the identification and use of biomarkers for disease or otherwise help with program evaluations.

2.4.6 WHO

The EBD assessment activities that WHO has currently underway include:

- Preparing global assessments for various environmental and other risk factors
- Preparing guides for national and local assessments
- Supporting training in various countries
- Coupling assessments to cost-effectiveness of interventions.

WHO also desires to develop partnerships to look for risk factors relevant to developed countries.

Section 3
Panel 2: *State of the Environment Report* Environmental Health Chapter

In preparation for this workshop, panelists were asked to read the *Supporting Document for the Human Health Chapter of the State of the Environment Report (Final Draft)*. The panelists were also asked to consider the following questions in reading this background material and in preparation for workshop discussions on these topics:

1. What are the challenges in merging environmental monitoring data with health surveillance data?

2. What data sets/resources exist that can inform the linkages between health outcomes and environmental factors?

3. What are the lessons learned in carrying out these programs?

4. What pilot projects could be done to identify opportunities to improve the understanding of environmental public health outcomes?

In their presentations, panelists provided information specific to these questions and/or provided illustrative examples from their experience in conducting similar programs.

The following sections summarize the information presented in workshop sessions and discussions relevant to the preceding questions.

3.1 What Are the Challenges in Merging Environmental Monitoring Data with Health Surveillance Data?

Workshop participants agreed that there are significant challenges to address in linking environmental monitoring data with health surveillance data, yet this is achievable even given that basic research is still needed in order to accomplish this goal. The challenges identified by workshop participants came from their own program experience and were offered to EPA for consideration in developing its own program. These challenges ranged from those specifically related to the scientific and practical aspects of data collection and analysis to data access and overall program framework. All of the presenting agencies expressed their desire to work with EPA in developing and implementing this program as it represents a cross-cutting area of interest and offers the potential to help meet multiple program needs.

Challenges in data linkage identified during the workshop involved the following eight areas:

1. Data availability
2. Data collection capacity
3. Data compatibility
4. Database communication
5. Data access
6. Data and interpretation limitations
7. Overall framework to ask the right questions
8. Common terminology/definitions.

The following sections summarize key points raised in each of these eight areas.

3.1.1 Data Availability

Many federal agencies collect environmental and health data. Because there is little to no coordination between agencies, agencies are often unaware of the past, current, or planned efforts of other agencies that

may be useful to their own efforts. As a result, these workshop sessions generated much interest in inter-agency collaboration as presented in Section 2.4.

Specific data availability challenges noted in the workshop include the following:

- Health surveillance data are not as prevalent as many often believe or assume. While there are some excellent registries of disease (NCI) and for blood lead, many gaps exist. (CDC/NCEH)

- Exposure data are believed to be even more difficult to obtain than health surveillance data and that the availability of good exposure databases may be among the weakest links in attempting to relate exposure to environmental disease (CDC/NCEH). Yet, many workshop participants also felt that EPA has extensive exposure information that may be useful to this program and other agencies' efforts. (WHO, NCI)

- Linking public health outcomes and environmental program results may prove difficult without an existing national tracking system. (NIEHS)

- Efforts may be hampered as a result of "under reporting" relevant data, either as a result of missing data or from "under recognition" of the "problem" requiring reporting. (NIOSH)

- Much information may be available (via existing databases and indicator information) that ultimately is not useful to the linkage effort. In developing global risk factors and health assessments, WHO found that, rather than needing more data, it needed less and slightly different data than what was initially collected.

In addition, any approach that relies on state data or state-level assistance with data collection will need the buy-in of the state environmental and/or health agencies. (EPA) The ability of the states to assist in proposed efforts will depend on federal agencies to provide the funding for program implementation, but the potential also exists for there to be legislative hurdles or for resistance because of perceptions that there may be no real need to change their current approaches. Benefits for states to consider in this situation include the usefulness of acquiring locally-correlated data regarding specific health issues as well as to showcase state involvement. (ASTHO) Furthermore, CDC meetings with state personnel indicate significant enthusiasm and interest in the environmental agencies for integrating environmental and health data.

Specific discussions of existing or planned data relevant to EPA efforts are addressed in Section 2.3, Section 3.2, and in Appendix C.

3.1.2 Data Collection Capacity

Development of a program such as EPA envisions must consider both the capacity to collect the data needed and the expertise to interpret the data. Current capacities for both data collection and evaluation may be insufficient to meet current or future needs. (CDC/NCEH)

3.1.3 Data Compatibility

The types of data collected and the manner of their collection reflect the data needs being addressed in the particular study design/protocol, which can limit broader use or applicability of the collected data beyond its intended purpose. For example, environmental data collected by regulatory programs is typically collected from a facility or a geographic location while health data are usually collected from individuals. As another example, most medical data are not collected from a surveillance perspective. (CDC/NCEH)

Also, environmental and health data sets often do not mesh well. As an example, if a specific geographic area is being evaluated, environmental data may not reflect the health data for the same region. People move in/out of the area and some health effects may not be seen for many years after the exposure. Assuming that all people in that geographic area are exposed to a contaminant of interest or that all health effects are counted can be misleading. (ATSDR)

In addition, data quality will vary even among the same study conducted in different years. For example, the quality standards differ in each NHANES. More is learned during each NHANES about how to monitor quality of data and those lessons learned are incorporated into subsequent efforts. This can result in the need to repeat analyses to obtain data that meet the quality standard. (CDC/NCEH, CDC/NCHS)

3.1.4 Database Communication

EPA, CDC, and many federal and state health agencies are developing databases and data repositories without accounting for the possible need for these different data repositories to communicate and share information. These data repositories are often disease- or program-specific. Without such communication, efforts to facilitate data sharing and exchange for multi-purpose data use are and will continue to be hampered. CDC and EPA are both currently exploring how to address such issues as how to integrate databases, how to standardize, and how to get existing systems to communicate as well as consideration of joint future needs. (CDC/NCEH)

3.1.5 Data Access

A major challenge in accessing data, particularly health data, involves conflicts between right-to-know and right-to-privacy. This directly affects the ability to construct a program with a mandate to issue information to stakeholders while also maintaining the privacy of survey respondents. The nature of the commitments to privacy made in confidentiality agreements for surveillance program participants can preclude the reporting of certain types of information, which in turn limits the ability to link these data with other data or to use the data for other, future purposes. As an example, geographic data may be collected in a health survey but may not be able to be released. However, in the future it may be possible to acquire the relevant geographic data from other registries, death certificates, or other sources. (CDC/NCEH, CDC/NCHS)

These disclosure and confidentiality issues may also affect the ability to use older data because the agreements signed at the time of those surveys do not meet the standards in use today. As a result, some of those data may not be reportable for current or future programs. (CDC/NCHS) In addition, current requirements on confidentiality provisions may require specific, focused reasons for data use; broad, open-ended agreements on future access and use may not be allowed.

Access to restricted and/or confidential data may be especially important when trying to link environmental and public health data. Stewards of human health data bases must both provide a public health benefit and protect public health information. Access to this information may require explicit permission of participants. This can prevent the acquisition of pertinent data. (NCI)

One key concern raised by EPA was the need to find appropriate ways to access existing health data given the associated confidentiality/protection requirements and that investigators are often reluctant to release raw data to the EPA. (NHEERL) Workshop participants noted that third-party researchers (via grants) are

often able to access and evaluate confidential/proprietary information that the federal government is unable to easily do so.

Other data access concerns include:

- Maintaining future access to samples collected

- Privacy and proprietary issues for privately held data (e.g., insurance and pharmaceutical companies) similar to those described previously.

3.1.6 Data and Interpretation Limitations

Workshop participants identified a number of limitations with regard to the data needed to form linkages and the ability to identify linkages through the interpretation of such data. These include:

- Reasonable expectations need to be set regarding what current data analysis tools can and cannot measure. Current tools may not be able to measure a health or biological effect, but that does not make the effect nonexistent. Conversely, the need also exists to remain cognizant of the limitations of the data and the science. Concentrated outbreaks of disease, such as cancer clusters, may occur, but current methods may be unable to ascertain the common factor. (HEI, CDC/NCEH, AFIP)

- Environmental measurements may not correlate with health effects in a specific geographic area for many reasons, including latency in appearance of the health effect after exposure, movement of exposed populations out of the area, movement of unexposed populations into the area, etc. (ATSDR)

- Back-calculation of exposure from environmental contamination data is the common, though not preferred, approach. (WHO)

- Monitoring data may show exposure, but may not always show health impacts. (WHO)

- Many public health outcomes do not result solely from exposure. For example, development of cancer involves more than just exposure and depends also on the failure of multiple repair, homeostatic, and immune defense systems. Thus, the exposure damage may not result in cancer for many years until another disease compromises the immune, defense, or repair systems that were otherwise preventing the cancer from occurring. (AFIP)

- Data can be interpreted in different ways and at different levels of stringency, resulting in different conclusions. (AFIP)

- Most public health surveillance is conducted locally regardless of purpose (e.g., health, environmental, enforcement) and the data are collected for a specific point in time. (ASTHO)

- Establishing EBD requires having an indicator for exposure assessment at the population level and the evidence must be applicable to the targeted study population. (WHO)

- Calculation of EBD requires a very strong database to show the relationship between exposure and disease, a strong evidence base to show the relationship between risk factor and disease, and knowledge of the exposure-response relationship. (WHO)

- Exposure distribution in the population needs to be in same format as the exposure-response relationship. (WHO)

- Basis for intervention may be difficult to establish for purposes of regulations as it may not be possible to base interventions only on safe exposure value. Focusing only on health outcomes without evaluating interventions and regulatory response may result in insufficient information for policymaking. (WHO)

In addition, there are also a number of nonenvironmental components that contribute to exposure and health outcomes including age, genetic predisposition, racial genetic inheritance, economic status, demographics, and behavior/lifestyle. (ATSDR)

Significant challenges were also noted for the following types of data analysis:

- Inferring annual or long-term exposure from one-day activity patterns. (NERL)
- Making linkages that elucidate causal relationships. (NERL)
- Proving that the agent of interest is the cause of disease. (AFIP)
- Working backward from an effect to find the source unless a unique, discrete event or a well-defined source are involved; working forward from a source through exposure to effect is easier, but the source may be only one of many factors contributing to the observed effect. (NERL)
- Developing one method to evaluate both short- and long-term outcomes and to enable comparisons. (AFIP)
- Finding a common basis to address cancer and noncancer diseases because of the significant differences in their nature and development. (AFIP)
- Accounting for contributing factors beyond just mortality, such as reduced consumption of contaminated fish. (ASTHO)
- Extrapolating exposure response data across species (e.g., rats to human). (CDC/NCEH)

Other challenges in data analysis include the consideration of different types of risks (e.g., cumulative and aggregate risks), multiple chemical exposures and resulting effects on organ systems, and susceptible populations. Some differences in health effects found in other programs indicate the potential for multiple contributing factors. An example cited was the difference in blood lead levels between African Americans and Caucasian Americans that seems to involve more than just the age of their homes. (CDC/NCEH)

In addition, the proposed efforts will be addressing multi-variable situations without simultaneous controls. As a result, it will be difficult to obtain hard data that no one will criticize; criticisms may involve adequacy of survey design, statistics, and DALY parameter selection, among others. (AFIP)

3.1.7 Program Framework/Asking the Right Questions

The program framework needs to set the focus of the effort through the following specific questions: (1) what do we want to know, and (2) why the data should or need to be linked. Setting specific goals for linking any type of data is very important in order to avoid spending effort on linking data just because it is possible to do so. (CDC/NCEH)

Another program framework question is whether to focus on making linkages or to focus on hypothesis-driven testing of these linkages. In addition, the SOER framework represents a transition from traditional data-driven approaches (e.g., "we can answer this") to a question-driven approach ("what would we like to be able to answer"), so it may also be necessary to identify a primary set of questions to address. Many

workshop participants noted that hypothesis- or question-driven testing may be much more productive than attempting to identify all of the linkages through more traditional framework approaches.

In addition, decisions must be made to determine whether the sampling design will involve a national effort or state-level efforts that are then aggregated nationally. This also requires consideration of the capacity of the state resources to support this. (NHEERL) More detailed discussions on a national vs. state and resource/capacity considerations are found in Sections 4.3 and 4.7, respectively.

Furthermore, workshop participants also suggested that one aspect of any framework is whether the public will see the proposed effort as an appropriate use of its tax dollars. (Day2 Sum)

3.1.8 Common Terminology/Definitions

Many workshop participants noted the need to have a common set of terminology and definitions of terms as these differ among different agencies and between health and environmental programs and disciplines. For example, the definitions of exposure and use of exposure terms may be different for WHO, CDC, and EPA. This affects how problems and abatement of risk are conceptualized as well as the comparability and use of data. (NIOSH) An exposure terminology workgroup organized by WHO examined many glossaries of exposure and health terms, and used this information to develop a short list of terminology to use in its efforts; this resource is available on the Internet. (NERL)

In addition, autism, ADHD, and other related disorders are on the increase and may have environmental linkages. There is a need for common definitions of these disorders as well. CDC activities discussed in Section 2.4 may yield some results in this area.

3.2 What Data Sets/Resources Exist that Can Inform the Linkages Between Health Outcomes and Environmental Factors, to What Level Are the Data Applicable (National, State, etc.), and What Are the Geographic, Temporal, and Demographic Sampling Parameters?

Many data sets and resources exist at both the national and state levels that can assist in linking environmental factors to health outcomes. The range of data encompass:

- One-time and ongoing health surveillance or other data acquisition efforts
- Cross-cutting demographics or over-sampling of specific subpopulations (e.g., age, gender, race, socioeconomic)
- Multiple topic areas such as health, mortality, disease, vital statistics, behavior, exposure, environmental contamination, environmental effects, and burden of disease
- Tissue banks that may serve as surrogates of exposure
- Hard copy data, electronic data, and samples (e.g., tissue, body fluids, environmental).

Appendix C provides a table listing all of the data sets and resources mentioned during the workshop.

3.3 What Are the Lessons Learned in Carrying Out These Programs?

The general consensus of workshop participants was that EPA should move forward and attempt to develop the desired linkages and performance measures, regardless of the concerns regarding the challenges in linking health and environmental data and the potential absence of necessary data or measurement tools. This was a key lesson learned from across many programs—move forward with the effort, describe the

limitations, and recognize that linking the data will be more difficult than anticipated and will take time to accomplish.
More specific lessons learned identified during the workshop involved the following six areas:

1. Planning, collaboration, and innovation
2. Data collection/analysis
3. Use of accepted standards, tools, and systems
4. Information technology
5. Informed consent
6. Program burden on collaborators and respondents.

The following sections summarize key points raised in each of these six areas.

3.3.1 Planning, Collaboration, and Innovation

Workshop participants generally agreed that planning, collaboration, and innovation are essential to conducting a successful program. Specific lessons learned in these areas included:

- Involve stakeholders in the planning process and throughout the effort. (CDC/NCEH)
- Develop partnerships.
- Talk to candidate collaborators (agencies, organizations) regarding program needs and how they might be accommodated. Explain in detail how the desired data will be used. (CDC/NCHS)
- Be open to new ideas. (CDC/NCEH)
- Be prepared for the process to take time since lots of planning is necessary for effective implementation. (CDC/NCEH)
- Disseminate information, which is the product of interest. (CDC/NCEH)

With regard to the design of a program or survey, workshop participants offered a number of lessons learned from their program experiences, including:

- Set criteria for completeness, timeliness, and quality as well as data transmission. (CDC/NCEH, NCI)
- Remodeling an existing system to meet new needs can be more difficult than developing a new system. (CDC/NCEH)
- A “staged approach” often works best. (CDC/NCEH)
- Keep efforts focused on the environmental public health framework, yet also remain aware throughout all activities that environmental health is part of a bigger picture. (CDC/NCEH)
- Design data collection to serve multiple purposes. (CDC/NCEH)
- Planning in advance for the data needed is easier than incorporating these needs later in the process. (CDC/NCHS, CDC/NCEH)

- Planning and design efforts need to continuously consider the intended usage of the data (CDC/NCEH). Avoid collecting data for the sake of having the data and conducting study after study without the results making a difference. (NRMRL, NCEA)

- Be prepared to use the data that exist even if those data are not perfect, complete, or do not entirely accomplish or address what is really wanted or needed. (ASTHO)

- Use of children in surveys or other studies may require special considerations, such as:

  - Children cannot provide the volume of specimen that adults can provide, which limits the number of analyses.

  - There may be age-related issues in sample collection; for example, urine samples are not usually collected from children under age six. (CDC/NCEH)

  - Interviews/surveys may require completion by parent.

- Low budgets will not support the performance of complicated procedures. (CDC/NCEH)

- Organizational separation of program activities can impede desirable program coordination as well as fragment data collection, analysis, and dissemination efforts. (CDC/NCEH)

- Collaborate with statisticians to properly design the data collection effort. (CDC/NCHS)

3.3.2 Data Collection/Analysis

Workshop discussions noted the following lessons learned pertaining to the collection and analysis of linkage data and the linkage process:

- There is a difference between statistical proof and medical evidence. The same data can be interpreted in different ways and at different levels of stringency, which may result in difficulties in making convincing scientific arguments. (AFIP)

- Older samples may not be useful for the analysis of fat-soluble materials or for other chemical analyses because aging will have affected the matrix. (AFIP)

- Different sample collection/preparation techniques and materials used by pathologists (either over time or by different pathologists) may influence results of interest or their comparability, particularly with regard to use of older samples. (AFIP)

- Consider a broad range of impacts and avoid looking solely at cancer outcomes, which has been a criticism of similar efforts in the past. (NIEHS)

- Find pragmatic ways to integrate or correlate the data available, such as issue by issue. WHO efforts obtained large amounts of data but at first were unable to correlate them due to differences that were ultimately minor aspects.

- Tailor exposure factors to each risk factor to match the exposure-response relationship. A different approach will be needed for each risk factor. (WHO)

3.3.3 Use of Accepted Standards, Tools, and Systems

CDC/NCEH recommended the use of existing national data and information system standards formed by those who develop national standards to develop efficient, integrated, and interoperable surveillance

systems. This garners broader acceptance and may be a more efficient, cost-effective approach than separately developing such standards. Additional workshop commentary expanded this to the use of broadly accepted and applied data analysis tools and information systems as well.

3.3.4 Information Technology

Use of state-of-the-art information technology was strongly recommended as was the need to design surveillance programs in consideration of future potential GIS applications. Acquiring latitude/longitude data at the same time as other data are collected, even if there are no current plans for GIS application, was noted as being easier to accomplish than having to recreate this information from other sources at a future date. (CDC/NCEH)

3.3.5 Informed Consent

A recurring lesson learned was the need to address future sample use in participant consent agreements. Of specific note was to design the informed consent agreements to anticipate future needs or uses for the samples/data collected so that additional approvals or obligations to report results of future studies to the previous participants are not required when archived specimens or data have been used (CDC/NCEH and CDC/NCHS). For example the informed consent for NHANES participants indicates that samples and data collected may be analyzed in the future but is not specific as to what this might be. As a result, CDC has "banked" many tissue samples collected under NHANES. This option is not available in all cases as the current trend by institutional review boards (IRBs) is toward more restricted, rather than broad, consent. For example, starting this year, the Army requires specific permission to be obtained when there is an interest in analyzing a stored sample for another purpose (AFIP).

3.3.6 Program Burden on Collaborators and Respondents

A general cautionary note was raised throughout many workshop sessions regarding the potential for new programs, such as this one, to increase the burden on the limited resources of potential collaborators as well as the potential to affect response rates. Specific lessons learned in this area supporting this cautionary note included the following:

- To avoid adding burden on the limited resources of the health care sector or state/local government, work with existing data in its current form rather than requesting currently reported data be re-reported in a slightly different format (i.e., avoid asking the same data sources for variations of the same data). (CDC/NCEH)

- Individual respondents (from the general public) are often willing to provide substantial amounts of data if they have bought-in to the program, but this willingness to assist will dwindle if the time required to provide these data becomes or appears burdensome. (CDC/NCHS, CDC/NCEH)

3.4 What Pilot Projects Could Be Done To Identify Opportunities To Improve the Understanding of Environmental Public Health Outcomes?

Throughout workshop presentations and discussions, workshop participants offered a number of suggestions for pilot projects. These include:

- Attempt to link existing U.S. data on exposure, exposure risk, and disease, which appear to be extensive, and evaluate these data by risk factor and by disease. This approach may backfire or the data may fail to match up, yet such an effort enables the limitations of the data and the science to be identified and described. (WHO)

- Apply water-ecology indicator efforts as a model for this effort. The Office of Water developed indicators of water quality other than concentration in water body, which gave the states more flexibility in meeting TMDLs. Participants also referenced the EMAP efforts as another model.

Internal resources already exist to support this such as a chart on developing monitoring based on questions. (NHEERL)

- Have a small team examine some specific scenarios and see how the linkage might work. (CDC/NCEH)

- Consider doing an exercise that, if EPA had ideal health and exposure data, how would one go about linking exposure to public health outcome? Consider using PM or arsenic data for such an exercise. Describe the data sets that already exist, and describe how someone would evaluate this for the risk management programs. Such an exercise could help to design the framework and its components as well as determining whether the appropriate focus is local or national. (NIEHS)

- Tap into airport expansion projects, since some modeling is already being done for these projects. (NHEERL)

- Compare areas in compliance with the National Ambient Air Quality Standards to areas that are not in compliance. (Day2 Sum)

- Further examine the link between respiratory effects and motor vehicle use in Atlanta during the Olympic games. (Day2 Sum)

- Consider building on a CDC pilot project in Atlanta (along with some CDC grants) to develop surveillance systems for developmental disorders. (CDC/NCEH)

- Consider pesticides as a topic to set up for tracking changes over next few years. Provisional approvals for pesticides exist but new regulations will be taking effect in the next few years and are anticipated to have large scale impacts. Such an approach would enable creation of a baseline at this time and the ability to track changes resulting from the implementation of new regulations. (ASTHO)

- Evaluate the link between lead levels and learning disabilities in low socioeconomic status areas. (Day2 Sum)

- Consider conducting a community NHANES that would use mobile units to more easily study one community or one area of the country. (CDC/NCHS)

- Attempt to tie CDC-developed environmental health indicators into EPA indicator projects to determine whether there is an association between environmental exposures and disease and whether interventions can have an effect. (CDC/NCEH)

- Attempt to link air emissions data to NHANES data.

- Consider continuing or building upon air pollutant and health studies completed in support of the PM air regulations.

Suggestions and opportunities for collaboration regarding ongoing projects are presented in Section 2.4.

Section 4
Other Feedback

The wide-ranging discussions in each workshop session included numerous examples and suggestions from other program experiences potentially relevant to the planned EPA efforts, but did not fit the specific questions used to focus the two panels on Day 1 as discussed in Sections 2 and 3. The general, overall comment expressed by many participants was the need to move forward using the information currently available while identifying the additional data necessary to achieve the goals expressed in the background documents reviewed for this workshop.

The additional feedback from workshop participants encompassed general observations on exposure assessment and public health frameworks, considerations of state vs. national focus, and resources. The following sections summarize key points raised in each of these four areas.

4.1 General Observations

Several program frameworks, focused on different aspects of exposure, were described during workshop sessions based on different global, federal, and state/local agency approaches and program focuses. These include:

- An environmental public health tracking framework involves a hazard that leads to exposure, which in turn leads to a health effect. Intervention can occur at any of these three steps to have an impact on environmental health (e.g., to change health effects). (CDC/NCEH)

- Central to ORD's public health paradigm is exposure, which is defined as the contact between a contaminant/stressor and a person as a result of that person's activities in the community. This paradigm involves the linkage of health and environmental data. Sound science across the paradigm (from source data to health effects data) is important in deciding whether an action needs to be taken, what action should be taken, and whether the action taken succeeded in addressing the issue. (NERL)

- Exposure is contact between a human and a contaminant at a specific concentration for a specific period of time. This involves a time period over which exposure and concentration (time of contact), personal exposure, and level of exposure (concentration) are integrated, as well as knowledge of how and when a person was exposed. (NERL)

Also offered for consideration was a general vision statement that effective environmental public health surveillance has data driving prevention practices. (NIOSH)

4.2 State vs. National Focus

Much discussion in each workshop session considered whether a national or state/local focus was most appropriate. This focus is an important decision that affects planning and implementation efforts as well as the desired outcome. The discussions encompassed the use of the data to determine which focus is best, the potential need for and benefits of having both a national and a state/local focus, and special considerations regarding a state/local focus. The following sections highlight key discussion points in each of these areas.

4.2.1 Determining the Focus from the Data

One suggestion was to determine the focus by collecting and analyzing the necessary data because the resulting measurements in themselves may determine whether a summary measure or national estimate may

be generated. A related suggestion was to attempt to describe those things that are important to measure, which may be an index (composite of many factors) or a specific value, and to determine whether state/local data must be aggregated to obtain a national summary number. (NCI)

The determination of a national vs. a state/local approach involves consideration of different purposes and methods. At the state/local level, a key purpose is to link immediate control efforts and program evaluations using real-time data on all cases with surveillance linked to control activities. At the national level, a key purpose is to monitor national trends, detect emerging problems, and demonstrate the need for resources; the methods used include aggregation of state/local data and national sample surveys. A related factor to consider is the ability to gather local data to help answer a national question. If this is not possible, then only a national focus on data collection may be possible. (ASTHO)

Another factor affecting selection of the program focus is what information the EPA needs for policy making. WHO assessments involved a global focus, yet individual countries are focusing these assessments on their needs by developing their own severity weights and DALY calculations. Individual countries are developing disease severity weights that are different from those used by WHO and are rethinking the specific parameters that flow into the DALY calculation in order to address country-specific needs.

4.2.2 Potential Need for Both a National and a State/Local Focus

Many workshop participants expressed the belief that both national and state/local data need to be collected. One reason cited was that the public often wants both a national and a state/local emphasis. For example, a criticism of an Hispanic-focused NHANES was that no national data were collected at the same time as the specific data were collected. (CDC/NCHS).

The ideal approach is to derive national measures from an aggregate of local data. Collecting such data at the state/local level is often impractical unless the information is obtained by telephone survey or from death/birth certificates. A key issue is that the sample size to get meaningful results at the state level may be about the same size as that needed for statistically valid national-level assessments. (ASTHO)

In addition, local vital statistics information and national statistics are both critical for comparative purposes. Such information enables states to determine their relative ranking (i.e., high or low) compared to a national average or to determine how good or bad their situation may be. National data are critical for these types of comparisons and can also help in allocating resources to areas with greatest need. (ASTHO)

Also suggested for consideration was the development of a sampling design that allows national inferences and enables the states to buy into the process. (NHEERL)

4.2.3 Special State/Local Focus Considerations

A number of experiences to date indicate that examination of local-level data may be more useful than a national-level emphasis. One example involved blood lead studies that found blood levels in specific housing areas to be much different than the national average. (CDC/NCEH) Another example is understanding of location conditions that link to environmental health effects, such as the decreased driving in Atlanta during the Olympics that led to decreases in emergency room visits for respiratory conditions such as asthma. (CDC/NCEH) Breaking down information into different geographic or socioeconomic regions helps to focus public health programs, yet the potential also exists to identify problems of local concern that do not warrant national-level investigation. (CDC/NCEH, NRMRL)

Extremes are often the most interesting and most useful data. Broad studies such as national surveys help to identify overall trends but often miss the extremes. As a result, they may have a limited ability to reveal the results of EPA policies and interventions. Data of a more local nature may be necessary to make such determinations. Studies that capture anomalies and what causes them (such as local areas with extremes)

may have greater value in assessing the impact of regulations than national averages, particularly in areas such as biomarkers. (NERL, ASTHO)

Political considerations may also favor inclusion of some state/local focus. Congressionally funded programs often must be able to address state/local issues of interest to the public and not just national issues. (ASTHO)

4.3 Resources

EPA has an advantage over many other agencies in that EPA funds both intramural and extramural research. EPA also has both research and regulation in same agency, which is not the case in the federal health arena. (NIOSH) Yet a challenge facing any federal initiative is the Office of Management and Budget (OMB) responsibility for limiting the public cost and burden for collecting information. (CDC/NCHS)

Thus, EPA will need consider ways to support and maintain the data acquisition and interpretation effort, data archives, and the resources (human capital) needed at the national, state, and local levels. Local capacity will be important to success. However, the manpower to acquire and assess the information may not be available to support the needs of the proposed program because agencies are downsizing, budgets are being redirected toward other national priorities such as bioterrorism, there is currently little exposure assessment capacity at state/local level, experienced personnel are retiring, and few programs exist to retrain environmental health officers in areas pertinent to the proposed program efforts. (NIOSH, ORD)

In addition, the public health data system is more tenuous than may be understood. Some data sources are declining, the support for current data coding activities is dwindling as budgets are cut, and the capacity for new initiatives may not be in place. For example, some states no longer code certain vital statistics data on death certificates that have proven useful in the public health area. (ASTHO)

Other suggestions offered for consideration included:

- Developing surveillance capacity with government and academic buy-in along with supportive information systems to maintain all the data. (NIOSH)

- Integrating with what is already available at the local level and building on that to expand capacity. (ASTHO)

- Avoiding the premature inference that funding and positions are available for this effort; otherwise, the academic community may respond to this perceived need by training people for positions that may not exist. (NHEERL)

- Following CDC approach of funding state laboratories to increase their abilities to link up health systems within the states. (CDC/NCEH)

There will also be challenges in focusing the investigative community on measuring health impacts. Integrating public health concepts into EPA research programs and the scientific community will take time. The scientific community may not be positioned to be responsive to the study of opportunistic events (e.g., acute chemical releases, industrial plant shutdowns) as they occur. For example, few responses were received for a recent RFA addressing the health impact of regulations in the context of looking at national databases. Some consideration may need to be given to pre-qualify teams of investigators to address such opportunistic events. (HEI)

Other resource-related observations include the following:

- States may need funds to restructure their databases to meet EPA data needs. (ASTHO)

- A significant number of histological slides exist with researchers and diagnosticians for many diseases, but availability to support this effort may depend on access restrictions. (ASTHO)

- Specimens might be obtained by enlisting local physicians to participate in defining a national survey and then participate in it. A challenge may be to convince them of the utility of this information for more than just the research interest. (ASTHO)

- Consider recruiting individuals to create tissue banks that may be used in the future to look for biomarkers. (ASTHO)

- Universities and clinics already participating in federally-funded grants and other extramural research programs may be potential sources for reporting public health or other pertinent information not already being collected in the funded research efforts. Consider how such programs could be leveraged or restructured to acquire the additional information of interest. (ASTHO)

Section 5
Establishing a Framework for an EPA Intramural/Extramural Public Health Outcomes Research Program

A final workshop session involved wrap-up discussions pertaining to the general framework for proceeding in developing a public health outcomes research program and specific first steps to pursue in government FY 2003. The following sections present highlights of these wrap-up discussions.

5.1 General Framework Discussion

The general framework discussions considered the appropriate focus for the research initiative, the overall planning process and its relationship to Government Performance and Results Act (GPRA) goals, factors to consider in developing a data source list, and interagency partnering and collaboration as presented in the following sections.

5.1.1 Research Initiative Focus

Participants noted that many of the workshop discussions in the first day raised questions among the health-oriented agencies about the intent of the EPA program as presented in the background information. One perception was the potential for EPA to become more involved in the public health arena in a manner that complements activities of the other public health agencies.

EPA is faced with a new need to measure health and ecological improvements as a result of agency programs/actions, which requires defining the health and ecological benefit. This also involves moving the Agency towards a system that measures success more on outcome and end results rather than measures such as the number of permits issued. Thus, the proposed EPA effort is different from the efforts in other agencies, which are tied to meeting specific human health goals and measuring progress toward those goals.

Much public health research and surveillance is underway at other agencies. A suggested approach was to define areas in which EPA can lead and areas in which EPA can be supportive. For example, EPA should focus on developing the underlying science relevant to the public health outcomes initiative rather than conducting public health surveillance and developing such infrastructure in every state.

Similarly, discussions addressed the differences in focus between what ORD is tasked to accomplish and what efforts are more appropriate to other portions of the Agency. For example, an ORD focus is on research issues such as the demonstration of concepts, descriptions of limitations/uncertainties, compilation of federal agency data, issuing RFAs, and similar efforts.

There may be issues or activities relevant to this initiative, such as state/local and private sector involvement or data access, that need to be identified to other EPA organizations to accomplish.

Many participants also favored the development of a framework that included economists, social scientists, and behavioral scientists for the analytical tools and insights they can contribute.

5.1.2 Planning Process and Relationship to GPRA Goals

There was much discussion on whether to keep this effort under Agency GPRA goal 8.2 or to place it under multiple Agency GPRA goals. Specific considerations in these discussions included the following:

- Some elements may be more appropriately addressed under other goals
- Spreading this effort across all goals may dilute ownership of the goal and its accomplishment
- Having a “home” for this effort provides the opportunity to validate specific hypotheses.

All participants noted the cross-cutting nature of the public health outcomes initiative. Much of the research to develop sensitive biomarkers (underlying this initiative) is under the GPRA goals for human health (Agency GPRA goal 8.2), while much of the impetus for ecological side is under GPRA goal 8.1. The focus of this initiative is on the public health outcomes, but the public health and ecological aspects do have to be linked.

As a result of this cross-cutting nature, activities may need to be incorporated across all of the EPA multi-year plans as they come up for revision, as is done for other cross-cutting research areas such as susceptible populations and children's health. Consideration is also being given to developing a separate multi-year plan for this effort, but the question remained as to whether support can be obtained for this initiative in its own right. This research initiative may initially be part of an existing multi-year plan because of funding issues, and, over time, the initiative may develop sufficient impetus to become a separate multi-year plan.

Since this is a core effort applicable to many EPA programs, numerous suggestions were presented for contacting the program/regional offices to explain the proposed plans and how these initiatives will be useful, to garner program/regional office support, and to build a constituency among the multiple beneficiaries within the Agency. For example, biomarkers are of interest to many programs/regional offices within EPA. Other suggestions included contacting the program/regional offices for their suggestions on pilot projects or to develop proposals for such efforts to obtain program/regional office input.

5.1.3 Development of a Data Source List

A potential first step for this initiative would be to develop an interagency compendium of data sources and surveillance systems. Such a compendium will support further determinations of what can be accomplished with the information already available and whether modeling or other tools, data sets, or data collection are necessary.

Such an effort can begin with the compilation of information sources identified during this workshop and documented in this report. This can be expanded through the following additional efforts:

- A list of databases put together by Ken Sexton within EPA during the last 10 years
- Data sources identified during SOER preparation but not used in the SOER
- Compliance programs represent a possible data source and opportunities for study
- Relevant publications (sources of data and how to make the data linkages) such as those from WHO
- WHO discussion group that transmits information on relevant topics, which is open to involvement by others (see WHO website for more information).

Also for consideration is a question as to whether state data can be aggregated to get the types of answers EPA needs, or whether other ongoing surveys may support EPA data collection needs. For example, NHANES may not be designed to answer some of EPA's questions and therefore may not be a relevant information source to pursue.

5.1.4 Interagency Partnering and Collaboration

Other health agencies are already moving forward with their initiatives and RFAs. These may represent particularly relevant opportunities for collaboration and EPA participation. For example, Dr. Zenick (NHEERL) and Dr. Qualters (CDC/NCEH) discussed a CDC RFA that is to undergo peer review in late summer/early fall of this year, and whether EPA could be involved as an ad hoc participant.

Another suggestion was to find ways to continue the dialog begun in this workshop with other agencies. A particular area of interest was to discuss with NIOSH its occupational program experiences that might make a proof of concept project more achievable. Given limited funding in future fiscal years for this initiative, cost-effective efforts may also include followups with CDC and ATSDR for relevant data and program initiatives.

A similar suggestion was to pursue other, more formal interagency arrangements. For example, an MOU currently under development between EPA and DHHS (OEI and CDC) will look at the linkage of existing data sets, particularly, whether information can be taken from the National Exposure Report databases to meet their needs. Such an MOU provides an opportunity to create a related interagency work group, which might serve as a venue to address privacy concerns regarding data sharing.

Few of the other agencies have an intramural research program. Thus, the ability to become involved with EPA to jointly meet different program needs may be attractive to those agencies because many of their efforts mesh well with the EPA public health outcomes initiative.

Similarly, EPA will not do much public health surveillance, but may be able to accomplish a lot in partnership with the agencies that do collect such information. Therefore, understanding their surveillance programs is important to identify areas that EPA can feed into the existing processes such as models, biomarkers, etc., as well as new concepts to include in their surveillance programs. In return, EPA can offer its statistical capability to these other agencies. EPA has conducted a significant amount of statistical work in combining data and interpreting what the results do or do not indicate/support.

Other suggestions included:

- Keep the panelist group from this workshop together as an advisory committee
- Learn more about ongoing surveillance and surveys such as NHANES to better understand how to effectively partner on such efforts to conduct the research
- Enter into Inter-Agency Agreements to fund third-party access to the health data that EPA needs
- A useful model may be how the Department of Energy (DOE) funds other agencies (e.g., CDC/NCEH, NIOSH) to conduct health monitoring useful to DOE programs.

5.2 Next Steps for FY 2003

First steps identified for government FY 2003 as a result of framework discussion included the following:

- Create an inventory of data sources (exposure, health effects, etc.)—look at what is currently available, how the data/database is structured, and how the data can be related.
- Identify and conduct a pilot study. Convene a small group to identify several possible situations that might be amenable to this approach/analysis. Consider also approaching the program/regional offices to see whether they have any case study suggestions to examine in prototypes. Candidate projects offered for consideration included:
    - Identify a focus for an example study (e.g., an exposure worked backward, a chemical, a geographic area) and work that example through with existing information to determine where the real data gaps and data needs are. Suggestions included:

- ✧ Mercury—has known health effects and data are available; ecological programs just as interested/concerned as are air, water, waste, pollution prevention, regional, and program offices as well as United Nations programs; might create a demand for public health outcome efforts.

- ✧ Ultraviolet light—has no direct regulatory program; indirect issue through breakdown of ozone layer with UV exposure as an endpoint of concern; interventions are different than in other EPA programs; multiple potential health effects beyond just skin cancer (e.g., cataracts).

- ✧ Extend or draw on EPA air program studies conducted in establishing the air regulations.

- ▸ Attempt to merge health or NCHS mortality data with air monitoring data.

- ▸ Consider making the hypothesis-driven National Morbidity, Mortality and Air Pollution Study (NMMAPS) study permanent, as was done with NHANES.

- ▸ Conduct a brainstorming session to consider what is needed for retrospective and prospective studies. Use the output of this session to identify candidate projects, define the data needed, and find topics where data are available. Set criteria to focus the potential options on feasible ones (e.g., have readily accessible).

- ▸ Identify geographic opportunities that are prospective. Identify what EPA wants out of those and what might be done.

- ▸ Identify pivotal studies recognized by program/regional offices as important and excellent science to use as models for additional efforts. This could quickly obtain program/regional interest, respect, and buy-in.

- Issue EPA RFA by the National Center for Environmental Research (NCER) in October to January time frame (preferably October) with consideration of the following:

  - ▸ Build in the idea of combining exposure and health data now to see if it can be done, and draw on statisticians to look at the challenges in linking such data.

  - ▸ Pursue short studies, perhaps 2 years in length and focused on statistical analysis with no new data collection.

  - ▸ Combining the data and statistical evaluations may enable funding from different sources to be combined.

  - ▸ Consider 1- to 2-year funding for another group consisting of existing grantees that are collecting data for a different purpose that is also useful to this initiative; however, past experience indicates the potential for significant barriers to modifying or supplementing an existing effort.

  - ▸ Consider drawing on the recently completed particulate matter RFA that combines EPA and other agency health data.

  - ▸ Circulate first draft of proposed RFA to this workgroup as well as the program/regions that were invited but unable to attend this workshop.

- One RFA rather than several, separate, smaller RFAs (e.g., one on air data and one on statistics) is preferable.

- Follow up with CDC/NCEH for EPA ad hoc participation on the review panel for their RFA involving efforts of interest to this initiative. Also follow up on opportunities to collaborate with CDC initiatives involving the creation of centers of excellence, and accessing data from states with the necessary infrastructure to link health outcomes and benefits.

Appendix A
Workshop Agendas

Workshop on Environmental Public Health Outcomes
Research Triangle Park, North Carolina

Day 1 Agenda – July 30, 2002

08:00 - 08:30 am	**Registration**
08:30 - 08:40 am	**Welcome** – William Farland, Ph.D., USEPA ORD
08:40 - 09:00 am	**Introductions and Charge** – Hal Zenick, Ph.D., USEPA ORD/NHEERL and Hugh McKinnon, M.D., USEPA ORD/NRMRL
09:00 - 09:30am	**International Perspective** – Annette Pruess, Ph.D., World Health Organization
9:30 - 9:40 am	**Break**
9:40 - 12:00 pm	**Panel 1: Public Health Outcome White Paper**. Each participant will respond to the charge questions (~20 minutes) followed by panel and then open discussion. **Facilitator: Edward Washburn, USEPA ORD/OSP** Mike McGeehin, Ph.D., M.S.P.H., National Center for Environmental Health, Centers for Disease Control and Prevention Robert Spengler, Sc.D., Agency for Toxic Substances and Disease Registry John Sestito, J.D., M.S., National Institute for Occupational Safety and Health Brenda Edwards, Ph.D., National Cancer Institute, Division of Cancer Prevention and Control Henry Anderson, M.D., Wisconsin Division of Public Health, Association of State and Territorial Health Officers David Brown, M.P.H, National Institute of Environmental Health Sciences
12:00 - 1:00 pm	**Lunch**

1:00 - 3:00 pm **Panel 2: SOER Environmental Health Chapter**.
This session includes brief overviews of the topic, each participant then responding to the charge questions (15-20 minutes) followed by panel and then open discussion.

Facilitator: Herman Gibb, USEPA ORD/NCEA
SOER Introduction – Peter Preuss, Ph.D., USEPA ORD/NCER
Judith Qualters, Ph.D., National Center for Environmental Health, Centers for Disease Control and Prevention
William Fishbein, M.D., Ph.D., Armed Forces Institute of Pathology
Vicki Burt, Sc.M., R.N., National Center for Health Statistics, Centers for Disease Control and Prevention
Larry Cupitt, Ph.D., USEPA ORD/NERL

3:00 - 3:15 pm **Break**

3:15 - 5:00 pm **Resume**

5:00 pm **Adjourn**

Day 2 Agenda – July 31, 2002

(Participants include the EPA workgroup and some of the Day 1 Panelists.)

8:30 am **Reports from Session Chairs from Day 1**– Edward Washburn, USEPA ORD/OSP, and Herman Gibb, USEPA ORD/NCEA

9:50 am **Break**

10:00 am **Establishing a Framework for an EPA Intramural/Extramural Public Health Outcomes Research Program**

Discuss potential design options for the Framework which will provide EPA and collaborating organizations with a mutually beneficial Public Health Outcomes Framework. The Framework will build on existing interagency capacity and infrastructure to provide the structure for an intramural/extramural research program.

Principal Objectives: Discuss potential design options for the Framework which will provide the foundation for building capacity to assess the Public Health Outcomes of EPA risk management activities. Examples of potential benefits include: efficiencies and cost savings; additional support and justification for current health monitoring programs; data comparison studies; data for improved modeling analyses; and multi-media analyses. Explore potential opportunities for collaboration and integration which could be incorporated into a Public Health Outcomes Framework.

11:30 am **Final Comments** – Hal Zenick, Ph.D., USEPA ORD/NHEERL and Hugh McKinnon, M.D., USEPA ORD/NRMRL

Meeting adjourns for outside guests

11:45 am **Public Health Outcomes Workgroup Meeting**

- Working Lunch
- Discussion of Next Steps

1:00 pm **Meeting Adjourns**

Appendix B
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Appendix C
List of Existing Data Sets/Resources

Data Set or Surveillance Study	Brief Description	Agency
Agent Orange (Vietnam) tissue repository	• 4,000 formalin-fixed, paraffin-embedded (FFPE) biopsies • 50 frozen biopsies	AFIP
Arsenic tissue repository	• 170 cases inorganic Arsenic toxicity FFPE blocks and slides • 35 rodents; frozen tissue for speciation • 1,600 matched exposed and control placentas, cord blood, plasma, urine	AFIP
Breast Explant (+ tissue) repository	275 cases	AFIP
Gulf War (Kuwait) tissue repository	• 8,000 FFPE biopsies • 3,000 frozen blood, serum specimens	AFIP
Mutagen, cell culture repository	• 500 frozen fibroblast preps • suspect DNA repair defects	AFIP
Prisoner of War tissue repository (1941 to present)	18,000 FFPE specimens from 12,000 cases	AFIP
Tissue Reactions to Drugs Registry	>12,000 cases, FFPE	AFIP
Children's Cohort Study	longitudinal cohort	ATSDR, CDC, EPA, NIH
Degenerative Neurological Disorder Surveillance	• neurodegenerative diseases (MS, ALS, etc.) • launching in 4-5 states • working with neurologists and public health agencies to gather data and assess trends	ATSDR
Exposure and disease registries (various), including World Trade Center (WTC) and Libby, MT mine	• community cohort registries; some still in development • many follow individuals for subsequent health problems • WTC includes air toxics, >100,000 people • Libby, MT addresses asbestos	ATSDR
Genetic Susceptibility Report	looking for genes to be evaluated in NHANES	ATSDR w/ NCHS
Hazardous Substance Release/Health Effects Database (HazDat)	• site-specific information system • release of hazardous substances from Superfund sites or emergency events • effects of hazardous substances on the health of human populations	ATSDR
Hazardous Substances Emergency Events and Surveillance System	tracks hazardous substance releases, injuries, health issues in 20 or so states	ATSDR
Health tracking and exposure studies	RFA closed July 2002	ATSDR
Poison Control Center Data	studying acute health effects w/ NCEH	ATSDR

Data Set or Surveillance Study	Brief Description	Agency
States Cooperative Agreements Program	30 states, potential mechanism for getting resources to states for assessments/studies	ATSDR
Toxicological profiles	>160 published on CD as a searchable database and includes 5 interaction profiles for common chemical groupings	ATSDR
Inventory of existing CDC surveillance systems	• over 120 surveillance systems • some at state level; updating 1998 inventory	CDC
National Electronic Disease Surveillance System (NEDSS)	data architecture that uses national data and information system standards for development of integrated surveillance systems at the state and local levels	CDC
National Public Health Surveillance System (NPHSS)	• overarching framework to classify all public health surveillance efforts • provides a single point to access PH surveillance data	CDC
Nationwide Health Tracking Network	• integrated system for data tracking, collection, analysis, and dissemination • includes noninfectious diseases and health effects from environment and exposure • to cover all 50 states, DC, US territories, and tribal nations	CDC w/ NCEH lead
National Notifiable Disease Surveillance System (NNDSS)	• states collect and forward to CDC standard, case-level data without identifiers • includes recommended list of conditions for surveillance	CDC EPO
Metropolitan Atlanta Developmental Disabilities Surveillance Program	birth defects surveillance data since 1967	CDC NCBDDD
U.S. Birth Defects Surveillance	cooperative agreements with 18 states to address major problems that hinder the surveillance of birth defects and the use of data for prevention and intervention programs	CDC NCBDDD
National Program of Cancer Registries	helps states and territories improve cancer registries, meet standards for data quality, establish computerized reporting and data processing systems for registries, etc.	CDC NCCDPHP
Autistic Surveillance Program	just beginning	CDC NCEH
Childhood Blood Lead Surveillance (CBLS)	supports state blood lead surveillance programs on the basis of blood lead tests from public and private clinical laboratories	CDC NCEH
National Report on Human Exposure to Environmental Chemicals	updated annually	CDC NCEH
Core Reports (various topic)	• address various health topics • upcoming supplements include Healthy People 2010 and Children With Special Needs	CDC NCHS

Data Set or Surveillance Study	Brief Description	Agency
National Health and Nutrition Examination Survey (NHANES)	• cross-sectional survey with longitudinal ability • estimates prevalence/distribution of health conditions and related risk factors in the population; not designed for regional estimates • oversamples selected groups • collects/analyzes >300 biological and environmental samples • includes 5,000 persons and 15 geographic locations each year	CDC NCHS
National Health Care Surveys	series of surveys on inpatient, ambulatory, and long-term patient care	CDC NCHS
National Health Interview Survey (NHIS)	• annual • personal interviews of 40,000 households and 100,000 persons • uses computer-assisted interviews	CDC NCHS
National Vital Statistics System and Atlas of United States Mortality	• complete reporting on births and deaths along with detailed geographic and demographic information • generates Atlas with national, regional, and local analyses	CDC NCHS
HIV/AIDS Reporting System	U.S. AIDS and HIV case reports, including data by state, metropolitan statistical area, mode of exposure to HIV, and demographic traits	CDC NCHSTP
Foodborne Diseases Active Surveillance Network (FoodNet)	active surveillance for foodborne diseases and related epidemiologic studies	CDC NCID
National West Nile Virus Surveillance System	• 49 states, five cities, and the District of Columbia • wild birds, sentinel chicken flocks, human cases, veterinary cases, and mosquito surveillance	CDC NCID
Behavioral Risk Factor Surveillance System (BRFSS)	state-based activity to help gather human behavior and knowledge data	CDC w/ ATSDR
Adult Blood Lead Epidemiology and Surveillance (ABLES)	state-based surveillance program of laboratory-reported adult blood lead levels	CDC w/ NIOSH
Sentinel Event Notification System for Occupational Risks (SENSOR)	• build and maintain occupational illness and injury surveillance capacity within state health departments • includes pesticides, occupational asthma	CDC w/ NIOSH
Agriculture Health Study (AHS)	identifying exposure factors for pesticide application to relate practices to exposures as measured in urine/blood	EPA
Harvard Six Cities Study	evaluates influence of particulate matter on human health and mortality	EPA

Data Set or Surveillance Study	Brief Description	Agency
National Human Exposure Assessment Studies (NHEXAS)	• environmental and biological samples plus activity patterns • includes EPA Region 5, Arizona, Maryland • available on-line	EPA
National Morbidity, Mortality and Air Pollution Study (NMMAPS)	• addresses 90 cities • links daily mortality data by cause and with air pollution information	EPA w/ HEI, JHU, Harvard
Particulate Matter Panel Studies	• various studies of particulate matter exposure and health effects • includes Baltimore, Fresno, and RTP; to be available on-line soon	EPA
State of the Environment Report	health, exposure, and environmental data in background documents as well as data and reports identified but not used	EPA
Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP)	addresses 260 children; measures activities and exposures at day care centers and at home	EPA ORD NERL
Consolidated Human Activities Database (CHAD)	• data sets from actual exposure • master access to human activity databases in a consistent format • some national, some local data • web accessible • >875,000 records	EPA ORD NERL
Human Exposure Database System (HEDS)	web-accessible repository of data sets, documents, and metadata relating to human exposure studies; directly linked to EPA EIMS	EPA ORD NERL
Cancer Intervention and Surveillance Modeling Network (CISNET)	modeling impact of cancer control interventions on incidence and mortality	NCI
Surveillance, Epidemiology, and End Results (SEER)	• assembles complex data sets on cancer incidence and survival data from 11 population-based cancer registries and three supplemental registries • covers approximately 14 percent of the U.S. population	NCI
American College of Surgeons and other health-related organizations	have collected health data	NCI has used data
Pharmaceutical and insurance companies	variable quality, nonstandard, proprietary health data	NCI has used data
National Toxicology Program	testing program for carcinogenicity and other outcomes	NIEHS
Occupational mortality data	web-accessible counts and rates of death in the United States (1960-1994)	NIOSH w/ CDC
Analytical data from private laboratories	• well water, radon, and other analyses • data may lack specific source location	States

Note: the information presented in this table is drawn from workshop presentations and discussions. Therefore, the descriptions may not be complete.