Review of the Worker and Public Health Activities Program Administered by the Department of Energy and the Department of Health and Human Services

Committee to Review the Worker and Public Health Activities Program Administered by the Department of Energy and the Department of Health and Human Services, National Research Council

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Nuclear and Radiation Studies Board
Board on Environmental Studies and Toxicology
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Preface

This committee was constituted in the Fall of 2005 at the request of the Department of Energy (DOE) to review the Worker and Public Health Program operated by the Department of Health and Human Services (HHS) at DOE nuclear facilities from 1990 to 2004. The program responsibilities were defined in three Memoranda of Understanding (MOUs) signed at the secretarial level between these departments in 1990, 1996 and 2000. The National Institute of Occupational Safety and Health which carried out a portion of this program, called it the Occupational Energy Research Program. Other HHS organizations that were involved in carrying out parts of this program during this period were the National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry (beginning with the 1996 MOU).

This program represented a change in the worker and public health programs at nuclear facilities that until 1990 had been operated by DOE and included contracts and grants directly managed by the department. Pressure from the public and Congress for a health program with a degree of independence from DOE led to the arrangement under the MOUs in which DOE provided the funding for agencies within HHS that carried out the health studies and some aspects of the communication program. In requesting this study DOE asked the committee to assess whether this program achieved the goals set out for it and to make recommendations on how to improve its effectiveness for the future. The committee report was to be completed within 16 months from the inception of the contract.

The study was launched with the committee's first meeting in November 2005 during which units involved in the program from both DOE and HHS provided briefings relevant to this committee's task. At this meeting, the commit-

tee formulated its approach to the study and identified specific questions and issues which were conveyed to DOE and HHS for response. The committee organized itself around three types of program activities: the technical activities, the public and worker communication activities, and the program governance and management. Using these broad areas of activity, the committee reviewed the HHS agencies' research priorities, research project selection, usefulness of results, and dissemination of completed research. To evaluate the quality of the programs from the viewpoint of science and public policy the committee used a sampling strategy that reviewed selected studies from three DOE sites and, in some cases, multisite studies or products that were not site-specific.

This approach allowed the committee to examine detail, when appropriate, while providing an overall assessment of the program and its achievements. The sampling was initially defined by focusing on program activities involving the Hanford, Oak Ridge, and Los Alamos sites. Activities at these sites were looked at in some detail *although by no means comprehensively*. It became apparent that a number of the activities spanned several sites and such activities were looked at across the appropriate sites.

While this study did not comprehensively evaluate all of the individual studies within the program, it is the committee's judgment that the subset of activities that were examined did provide a sample from which conclusions regarding the effectiveness of the program could be made. It was on the basis of the committee's overview of these programs that recommendations for the future operation of such a program were made.

While this study was nearing completion, the DOE Secretary announced a reorganization that could affect the health and safety programs within DOE. It was not clear to the committee what impact this reorganization, if carried out, will have on DOE's Worker and Public Health Program. The committee was not tasked to comment on the DOE reorganization or the transfer of the Worker and Public Health Program within the agency's structure.

General Acknowledgments

The committee was aided in the consideration of its charge not only by comments from the public but also by formal presentations by experts from a number of fields. The following presentations were made as part of the public portion of the meetings (in order of appearance):

Presentations

Steve Cary
U.S. Department of Energy, Office of Environment, Safety and Health (DOE-EH)

Lewis Wade, V, PhD
National Institute for Occupational Safety and Health (NIOSH)

Mary Schubauer-Berigan, PhD
NIOSH

Tom Sinks, PhD
National Center for Environmental Health (NCEH)/
Agency for Toxic Substances and Disease Registry (ATSDR)

William Cibulas, PhD
ATSDR

Charles W. Miller, PhD
NCEH/Centers for Disease Control and Prevention

Paul Ziemer, PhD
Former Assistant Secretary for Environment, Safety, and Health

David Michaels, PhD
Former Assistant Secretary for Environment, Safety, and Health

F. Owen Hoffman, PhD
SENES Oak Ridge, Inc.
Center for Risk Analysis

We thank these presenters and all other members of the public who spoke on issues related to the Worker and Public Health Activities Program. The committee also wishes to thank the agencies involved in this program for supplying information in response to what must have seemed to them, an endless stream of questions and requests from the committee. From DOE, Steve Cary, Gerry Peterson and Marsha Lawn, and from HHS, Mary Schubauer-Berigan, who fielded not only many questions from the committee but who also prepared an excellent evidence package of information with supplements about the program that was a valuable resource for the committee to help initiate its assessment.

The committee also thanks the National Research Council staff who supported the committee in an active and timely way throughout this study. Studies such as these are long on information and short on time. It is only through the extraordinary efforts of the NRC staff through Program Director Rick Jostes' orchestration that this study was completed on time and budget.

Special thanks to Eileen Abt for her contributions to the study and to Jen Saunders and Naoko Ishibe for their scientific and technical contributions to the report and to Courtney Gibbs for arranging the meetings and preparing the manuscript for publication.

Finally, the chair wishes to thank the individual committee members who gave of their time and expertise in this service to their government. Studies such as this are accomplished under the charter of the National Academies whose role as "advisors to the government" is accomplished through the voluntary efforts of experts such as this committee. As chair of a number of study committees such as this, I am always impressed with the expertise and commitment that committee members bring to these study tasks. This committee was no exception and my thanks go to each of them for their service on this committee.

EDWIN P. PRZYBYLOWICZ, *Chair*

Reviewers

This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purposes of this review are to provide candid and critical comments that will assist the institution in making the published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following for their participation in the review of this report:

Lynn R. Anspaugh, University of Utah School of Medicine, Henderson, NV
Harold L. Beck, Department of Energy Environmental Laboratory (retired), New York City, NY
Jack Cornett, Health Canada, Ottawa, Ontario
Ethel S. Gilbert, National Cancer Institute, Rockville, MD
Thomas Hinton, Savannah River Ecology Laboratory, Aiken, SC
David G. Hoel, Medical University of South Carolina, Charleston
Karl Kelsey, Harvard School of Public Health, Boston, MA
Katherine E. Rowan, George Mason University, Fairfax, VA
Susan Wiltshire, Independent Consultant, South Hamilton, MA

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The

review of this report was overseen by Frank E. Speizer, Harvard School of Public Health, and John C. Bailar III, Professor Emeritus, University of Chicago. Appointed by the National Research Council, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the National Research Council.

Contents

Executive Summary

In 2005, the National Academies convened an expert committee to conduct a review of the Worker and Public Health Activities Program, which is operated by the Department of Health and Human Services (HHS) at Department of Energy (DOE) nuclear facilities under a Memorandum of Understanding (MOU) with DOE. HHS Agencies participating in the MOU included the National Institute for Occupational Safety and Health (NIOSH) and the National Center for Environmental Health (NCEH), both organizational units of the Centers for Disease Control and Prevention (CDC), as well as the Agency for Toxic Substances and Disease Registry (ATSDR), whose administrator is also the CDC Director. The committee's task included assessing and recommending ways to enhance the program's scientific merit, focus, effectiveness, and overall quality; its impact on DOE's policies and decisions; and other program benefits, including the relevance to DOE's mission. The committee's principal conclusions and recommendations are provided in this executive summary; a more detailed summary with findings and recommendations follows.

The committee concluded that positive benefits have accrued to DOE by having occupational epidemiological studies performed through NIOSH by investigators outside its direct control. Research performed under the MOU has directly benefited DOE by providing important information to the Comprehensive Epidemiologic Data Resource, by contributing to the understanding of the risks of protracted low-dose radiation exposure for human health, and by providing advice to several of the worker surveillance activities, including the beryllium sensitization screening program. These activities have provided important scien-

tific support for DOE's Former Worker Medical Surveillance Program. Although the current method to assess beryllium sensitization in workers needs substantial improvement, the committee concludes that the occupational beryllium studies completed by NIOSH have made a significant contribution to the scientific community in general, as well as to DOE's understanding of the potential for beryllium exposure, sensitization, and progression of disease.

The committee concluded that useful research methodologies were developed in the NIOSH program, and also that the work performed by NIOSH under the MOU has been sound. However, there have been serious and not fully explained delays in executing some studies. NIOSH extramural and intramural programs have not been highly productive in terms of contributions to the peer-reviewed literature.

ATSDR has provided DOE-funded products that add value to the program conducted under the MOU and these products are generally of a high quality. The Public Health Assessments (PHAs) and Toxicological Profiles reviewed by the committee generally contribute to enhancing the public's understanding of the potential risks posed to the surrounding communities by the activities at the DOE sites. However, while ATSDR states that it embraces conservative assumptions concerning risks to the community, it is the committee's view that ATSDR's continued use of a threshold for radiation effects in the PHAs reduces both public trust and acceptance of the information provided. In addition, it should be noted that the committee did not review either the completeness or the scientific validity of the responses by ATSDR to the public comments that were included in the final PHAs reviewed.

For many of the DOE facilities, NCEH conducted dose reconstruction studies of historical exposures of the public independent of DOE. NCEH has established a scientifically sound public record of the doses received by members of the communities surrounding these facilities that is of benefit to DOE. The NCEH dose reconstruction methods that have been developed, applied, and refined in the NCEH studies have been accepted widely and are being used in epidemiological studies worldwide. NCEH has made dose reconstruction project findings available on-line via the Radiation Studies Branch web site.[1] In some cases, there are links to the studies from the individual DOE facility's web site, which the committee considers appropriate, since a person seeking information about historical releases from a DOE facility and their potential health effects on the surrounding communities would not necessarily know which organizations would be responsible. The publication of dose reconstruction study findings in the open literature appears to depend on the initiative of the contractors who performed the research.

[1]See *http://www.cdc.gov/nceh/radiation/*. Last accessed August 2006.

The dissemination of information about health risks to the public and workers from HHS agencies, which are more trusted than DOE, also has been of value in the program. The variety of HHS dissemination efforts benefited target audiences by providing them with information about scientific studies and health risk concerns, although the amount and quality of information disseminated varied among the agencies. However, a lack of concerted two-way communication efforts between the agencies and the public might have worked against public acceptance of various HSS messages. The paucity of HHS-sponsored systematic external evaluations of these efforts made it difficult for the committee to assess the impacts or benefits of these dissemination and communication activities.

The majority of the studies conducted under the MOU followed sound research practices and provided results that should be useful for policy decisions. From this perspective the studies had value. The committee finds that the productivity could have been greater with respect to improved coordination between HHS and DOE in the identification and transfer of exposure and outcome records from DOE facilities, in the setting of research priorities, and in NIOSH's peer-reviewed publication record**.** Additional gains in productivity are possible through completion of an ongoing NCEH dose reconstruction and of some ATSDR studies that remain unfinished because of inadequate funding. The dissemination of the results of these studies to workers and the public was extensive and generally made available. However, two-way communication was not common nor were there adequate evaluations of the effectiveness of the dissemination and communication efforts. Continuing and improved dissemination and communication efforts about health risk evaluations are considered by the committee as essential as long as cleanup and remediation activities continue at DOE sites.

The committee concludes that DOE and HHS should sign and implement a new MOU enabling continued work on the Worker and Public Health Activities Research Program. A single advisory committee, with a charter issued jointly by DOE and HHS, should be established to review and comment on the research program. DOE and HHS should establish and maintain oversight and coordination of the program at the Assistant Secretary level in HHS and the equivalent level in DOE, and DOE and the relevant HHS agencies should collaborate to update the research agenda annually. Finally, to enhance communication, DOE and HHS should establish functional feedback mechanisms to each other for all aspects of the research program.

Summary

This committee was constituted in the Fall of 2005 at the request of the Department of Energy (DOE) to review the Worker and Public Health Activities Program operated by the Department of Health and Human Services (HHS) at DOE nuclear facilities from 1990 to 2004. The program responsibilities were defined in three Memoranda of Understanding (MOUs) signed at the secretarial level between these departments in 1990, 1996 and 2000. The National Institute for Occupational Safety and Health (NIOSH), which carried out a portion of this program, called it the Occupational Energy Research Program (OERP). Other HHS organizations that were involved in carrying out parts of this program during this period were the National Center for Environmental Health (NCEH) and the Agency for Toxic Substances and Disease Registry (ATSDR) (beginning with the 1996 MOU).

Funded at approximately $10 million to $20 million annually for more than 20 years, DOE's Worker and Public Health Activities Program was established to study the consequences of exposures to ionizing radiation and other hazardous materials used in DOE operations on workers and the general public in surrounding communities. Initially, the program was managed solely by DOE.

The National Academies' committee was charged both to review the quality of the program and to make recommendations for future improvements. The committee reviewed the HHS agencies' research priorities, research project selection, usefulness of results, and dissemination of completed research. To evaluate the quality of the programs from the viewpoint of science, public policy, and the dissemination and communication of results to workers and the public, the committee used a sampling strategy that reviewed selected studies from three

DOE sites and, in some cases, multisite studies or products that were not site-specific. The Statement of Task and Sampling Strategy follow:

STATEMENT OF TASK

DOE's Office of Health requested that a committee be created by the National Academies to conduct a review of the Worker and Public Health Activities Program to assess and recommend ways to enhance the program's scientific merit, focus, and effectiveness; its impact on the DOE's policies and decisions; and other program benefits, including the relevance to DOE's mission, that are consistent with the objectives of this program. In addition, the National Academies' committee was asked to address the following aspects of the program:

- The congressional mandate in establishing the MOU, and how well its goals have been met through FY 2004;
- Evaluating research priorities for projects from FY 1990 through FY 2004 and for projects included in the agenda;
- Research project selection from FY 1990 through FY 2004 and for projects included in the agenda;
- Usefulness of results and dissemination of completed research through FY 2005; and
- Other aspects to be identified by the committee.

The committee was asked to propose other appropriate measures or indicators to be used in evaluating this program. DOE also requested the committee's assessment, given sufficient information and time, whether or not the individual Centers for Disease Control and Prevention (CDC) agency programs were of the highest quality from the viewpoint of science and public policy.

SAMPLING STRATEGY

In considering the Statement of Task in the context of the size of the program, the number of DOE nuclear sites, and the variety of activities at these various sites, the committee determined that a comprehensive assessment of the entire program was not possible in the time allotted for this study. The committee determined that a sampling strategy would be needed.

Accordingly, the committee discussed various subsets of the total program to review and arrived at a selection rationale that took into account the following factors:

- The range of time over which health studies were initiated.
- The number of workers involved as part of the program.
- A variety of types of dissemination and communication challenges.

- A variety of security challenges.
- Size of the surrounding public community.
- Geographic distribution of the sites.

With these factors in mind, the committee selected three DOE nuclear operations sites, Hanford, Oak Ridge, and Los Alamos, as a subset of the total DOE sites on which it would focus its attention. The committee also recognized that it would have to go beyond these sites to look at certain aspects of the program, such as the technical studies (some of which were multisite studies that included more than these three sites) or the program management process which also reached beyond the three sites.

In addition to this sampling strategy for site-specific aspects of the program, the committee requested and considered detailed information from the agencies on broad aspects of the program. These topics included, for example, identification of project categories and specific studies funded by DOE and produced by the three HHS agencies, information on the DOE/HHS budgeting processes, procedures used in the establishment of project priorities, and program management processes for the overall program.

The committee concludes that HHS agencies have made significant contributions to this program and that their continued participation will contribute to the future success of DOE activities at its facilities. Nevertheless, substantial opportunities exist to make the program even more effective, as shown by the following findings and recommendations.

ASSESSMENT OF PROGRAM MANAGEMENT ISSUES: STRENGTHEN THE MOU TO UTILIZE THE UNIQUE STRENGTHS OF DOE AND HHS TO INCLUDE THE FOLLOWING ELEMENTS

The MOU approach for carrying out the worker and public health programs for DOE through HHS partly solved the problems that were building during the time period prior to 1990 in which DOE managed the program internally. The committee found that the MOUs, while setting up an overall operating structure for the worker and public health program at DOE, stopped short of defining specific operating elements that, if implemented, could have improved results and the effectiveness of the program in addressing the health needs of workers and the public. As of the writing of this report, the latest MOU remains unsigned by HHS.

The committee further concluded that a worker and public health program was needed for the continuing hazardous cleanup and remediation operations at DOE sites that may result in exposures to ionizing radiation and radioactive materials. In addition, the program should continue to be operated by HHS to minimize concerns that it was influenced by DOE. The MOU framework pro-

vides a useful mechanism for an inter-Departmental program such has as the health program.

Findings and Recommendations

1. The Committee has concluded that there remains critical information to be gathered and assessed. A health program is needed at DOE sites as long as hazardous operations (including cleanup and remediation) continue. To that end, a mechanism needs to exist for the purpose of developing the research agenda, providing funding for the research, soliciting input into the design, conduct, and review of such studies, and communication of the results to relevant stakeholders, with clear articulation of the roles and responsibilities of the various parties. In the past, the MOUs between DOE and HHS have served as this vehicle, and could do so in the future. Therefore, the committee recommends that:

> DOE and HHS should sign and implement a new MOU enabling continued work on the Worker and Public Health Activities Research Program. This MOU should document the responsibilities of DOE and HHS as well as provide the framework for managing the process for interaction and collaboration between DOE and HHS. In addition to incorporating the recommendations made here with respect to managing the program, the new MOU should incorporate the recommendations presented elsewhere in this report. As noted above, a health program is needed at DOE sites as long as hazardous operations continue. Studies in progress should be completed and follow-up of exposed workers should continue.

2. One of the biggest challenges affecting the program has been the difficulty researchers have had in obtaining exposure and other relevant data to use in their epidemiological studies. Common data collection protocols and standardized data are needed for epidemiology and public health studies. As a remedy to this, the committee recommends that:

> DOE support the development and integration of a repository for exposure records. The committee recommends that all contractor-assembled data be submitted to DOE's Office of Environment, Safety and Health[1] for compilation, management, and storage in centralized databases, using standardized formats. DOE should consider developing a process that captures current exposure data as well as health outcome data, including external radiation

[1]On August 30, 2006, the DOE announced the creation of a new office, the Office of Health, Safety and Security, which will assume the responsibilities of the previous Offices of Environment, Safety and Health and Security and Safety Performance Assurance. This office is headed by a director and does not report to an Assistant Secretary.

exposure, internal radiation exposure, chemical exposure, medical surveillance (e.g., spirometry, liver function tests, smoker-never smoker), biological monitoring, and social security number and demographic information (e.g., gender, birth date) on a continual basis for DOE employees, contractors, and subcontractors, for placement in a secure centralized repository.

3. The quality and integrity of any research program is improved if it is subjected to expert scientific review during its development stage, as the studies in the research agenda are being conducted, and after the results have been gathered by the investigators. In the past, HHS did convene an advisory committee whose mission included the provision of advice and comment (only) to HHS on the OERP. This committee (the Advisory Committee for Energy-Related Epidemiological Research) did not have authority to formally communicate its findings to DOE. This circumstance, along with others, resulted in a sense of disenfranchisement on the part of DOE, and only sporadic interest on the part of DOE senior management in the outcomes of the HHS investigations. As a measure of improvement in the future, the Committee recommends that:

A single advisory committee, with a charter issued jointly by DOE and HHS, should be established to review and comment on the research program. Management of the program would be made more efficient if the advisory committee charged with reviewing and providing recommendations on the elements of the research program could report directly to all of the agencies charged with its development, funding, implementation, and translation of results into policies and practices.

4. In the federal government, the success of a program, particularly a scientific research program, is dependent upon the level of attention and oversight given by senior management. At the beginning, as the research program was being transferred from DOE to HHS, the Secretaries of each agency were involved. However, over time, management and oversight responsibilities drifted downward through the chain of command until they became virtually invisible to the most senior levels. The committee therefore recommends that:

DOE and HHS should reestablish and maintain oversight and coordination of the program at the Assistant Secretary level.[2] Communication and coordination at a senior level within an organization enhances the probability of

[2]The committee developed and unanimously approved this recommendation prior to a recent reorganization within DOE that merged existing safety and health functions into another unit. Because we believe that occupational and environmental health issues remain critically important to DOE workers and surrounding communities, and because we believe that senior-level management engagement is a pre-requisite for effective safety and health program management, the committee recommends that DOE and HHS should establish and maintain oversight and coordination of the program at the Assistant Secretary level in HHS and the equivalent level in DOE.

success of any program initiative. In this instance, attention given to the program at this level provides greater support to the participating agencies in achieving their mission to protect worker and public health and the environment.

5. It is important that both HHS and DOE understand the human and environmental health impacts of activities conducted on DOE sites which may affect both workers and communities. While the committee supports the concept that HHS currently has, and should continue to have, the lead on developing and carrying out the research agenda, it also believes that DOE has a stake in its success and, therefore, should participate more substantively in the updating of the research agenda as work goes forward. Therefore, the committee recommends that:

DOE and the relevant HHS agencies should collaborate to update the research agenda annually. It is critical that the resources committed to funding the worker and public health research program be spent in the most efficient manner, yielding the most useful information to understand the potential health and environmental impacts of activities at DOE facilities. Both HHS and DOE can provide important perspectives, based on their extensive experiences in this realm. These collective experiences, along with those contributed by technical experts on the external advisory committee, should result in a more relevant, scientifically sound research program.

6. During the 15 years that HHS has had the lead for the research program, communication between HHS and DOE has been intermittent at best, and nonproductive at its worst. To ensure better coordination among the agencies the Committee recommends that:

DOE and HHS should establish functional feedback mechanisms to each other for all aspects of the research program. To ensure the greatest level of success for any program of research, a robust program of communication and dissemination about the design and execution of, and results from, a research program should establish linkages not only between the program's executors and the affected populations, but also between those charged with developing and executing the program. This ensures the probability that the program will be robust, yield useful results, and will be of value in enhancing the scientific basis of our understanding of the potential health and environmental risks associated with DOE facility activities. It also enhances the respective agencies' credibility and accountability in meeting their governmental responsibilities.

The elements recommended above should be incorporated in an MOU that will govern the continuing health program at DOE sites and that should operate as long as hazardous work (including cleanup and remediation) is carried out at these sites.

SCIENTIFIC PROGRAM ASSESSMENT: FOCUS AND EXTEND SELECTED SCIENTIFIC STUDIES

The scientific studies within this program ranged from the development of new knowledge regarding exposure versus health effects to the application of existing and new methodologies for assessing the impact of exposures to hazards resulting from DOE operations on workers and the public living near DOE facilities.

National Institute for Occupational Safety and Health (NIOSH)

Continued research into the health of the past and current DOE workforce benefits DOE in three major ways: (1) it assists DOE in fulfilling its obligations to its employees to provide the best possible information about the health consequences of their employment, (2) it enhances methods to reconstruct past exposures, and (3) it contributes directly to the scientific knowledge base regarding protracted low-dose-rate exposures to radiation that are relevant to the protection of populations both in the United States and elsewhere.

Findings and Recommendations

1. The committee noted in its review of the NIOSH program that several large studies remain unfinished. The committee therefore recommends that:

> NIOSH should complete three major unfinished studies: the multisite leukemia case-control study (in preparation for publication at the time of this report), the K-25 multiple myeloma case-control study, and the chemical workers study. The remaining unfinished studies should be evaluated and prioritized by NIOSH and DOE for future funding decisions.

2. As noted earlier, "one of the biggest challenges affecting the program has been the difficulty researchers have had in obtaining exposure and other relevant data to use in their epidemiological studies." Therefore, the committee further recommends that:

> DOE should consider developing a process that captures current exposure data, including external radiation exposure, internal radiation exposure, chemical exposure, and other demographic information (e.g., gender, age, social security number) on a continual basis for DOE employees, DOE contractors, and DOE subcontractors, for placement in a centralized repository (see recommendation 2 under Assessment of Program Management Issues above).

3. The committee finds that continued research into the health of the past and current DOE workforce benefits DOE by enhancing methods of reconstructing past exposures and that the continued development of such methodology is

important to the evaluation of worker and public health effects at the DOE sites. The committee therefore recommends that:

> Further investigation into the utility of novel methods to reconstruct dose, such as fluorescence in situ hybridization, the glycophorin A somatic mutation assay, in vivo electron paramagnetic resonance of teeth, and other promising biological markers, should be given a high priority. The development of such markers, especially if the sensitivity of the methods can be improved, would be useful, particularly in the validation of estimates of external dose. In addition, NIOSH should continue to support methodological studies that address statistical issues such as the effects of systematic errors in the personal dosimeters, the truncation of dose from badge readings, and the effects of dosimetric uncertainties upon epidemiological studies.

4. The latest published follow-up for any of the DOE cohorts ended in the mid-1990s when considerably more than half of the participants in these studies were still alive. Therefore the committee recommends that:

> There should be follow-up of existing DOE cohorts for cause-specific mortality.

5. Deficiencies in data quality or the percent completeness of radiation dose should be resolved before undertaking further pooled analyses. Therefore, the committee recommends that:

> A phased approach toward further pooling of DOE and international nuclear workers studies should be undertaken. The initial phase would be for NIOSH to provide a justification for pooling particular DOE sites and cohorts based on the completeness and accuracy of radiation exposure data and on the site-specific potential for confounding between measured external radiation exposures and unmeasured (e.g., internal doses, chemical, asbestos) exposures.

6. NIOSH conducted nested case-control studies to better address confounders and to seek to improve information on internal exposures to radiation and other exposures. The committee finds that planning of additional nested case-control studies of solid tumors should include the following:

- The scientific advantages and disadvantages of developing both combined analyses of risk for all solid tumor sites and of separate analyses of specific tumor types should be carefully assessed.
- The quality of the data on smoking that will be available in the case-control studies on a site-by-site basis should be assessed carefully.
- Realistic power calculations should be obtained.
- The likely value of job exposure matrix-based methods for retrospectively assigning exposures to chemicals, asbestos, and other workplace toxicants should realistically be assessed.

7. Starting in 1994, the CDC-supported National Program of Cancer Registries has provided funds and oversight for the development of cancer registries in all 50 states. These registries provide the opportunity to link future follow-up of the DOE cohorts to state cancer registries to identify incident cancers in this population for a follow-up period beginning in the mid- to late 1990s. An intramural NIOSH project examined population-based state cancer registries to determine their feasibility and suitability for occupational studies. Despite limitations in statewide cancer registry systems, the study concluded it was feasible to use many statewide registries for occupational health studies. The committee therefore recommends:

> The establishment of linkages between existing cohorts and the 50 state cancer registries.

8. The committee finds that the NIOSH extramural and intramural programs have not been highly productive in terms of contributions to the peer-reviewed literature. Therefore, the committee recommends that:

> NIOSH should increase substantially the number of intramural scientific research findings that are submitted to high-quality scientific journals.

9. Future studies:

The committee concludes that future studies should represent all categories of workers (e.g., contract cleanup workers and others) on DOE sites with potential exposures. These future studies should also include diseases in addition to cancer. The committee recommends that:

> As these questions surface in the future, NIOSH and DOE explore the possibility of addressing them through studies that utilize DNA from DOE workers diagnosed with cancer and from controls. To facilitate these future studies DOE and NIOSH should consider the following:
>
> - Establishment of a database of workers with appropriate data to facilitate follow-up and to evaluate potential confounders (e.g., see recommendation 2).
> - Development of valid methods to identify non-cancer health outcomes including the use of periodic questionnaires, and specific diagnostic tests (e.g., pulmonary function).
> - Support for the continuance of biorepositories such as that funded by ATSDR that archive specimens such as blood and DNA to support future studies.

National Center for Environmental Health (NCEH)

The NCEH program has provided valuable data to communities about the historic operations of DOE facilities and their consequences in terms of health and environmental impacts. The dose reconstruction methods for radiation and chemicals that have been developed, applied, and refined in the NCEH studies have been accepted widely and are being used in epidemiologic studies worldwide. For example, many of the tools and techniques developed in the Hanford Environmental Dose Reconstruction Project are being used to reconstruct the doses from atmospheric releases from nuclear weapons production activities at the Mayak facility to the residents of the city of Ozersk, Russia.[3]

Findings and Recommendations

1. The Los Alamos Historic Document Retrieval and Assessment project at Los Alamos is the sole remaining dose reconstruction activity of NCEH and the public would benefit from the information derived from this activity. Therefore the committee recommends that:

> NCEH complete this project as expeditiously as possible and provide as much evaluation of the compiled data as feasible to inform the public regarding historical doses and risks.

2. The NCEH program has conducted dose reconstruction studies that are independent of DOE. These studies have provided valuable data to the communities surrounding DOE facilities in particular, and to the public in general, about the historic operations of those facilities, the environmental impacts, and the doses or health risks of individuals exposed to releases from the site. Therefore, the committee recommends that:

> NCEH continue to make the findings of its dose reconstruction studies available to the public on-line, ideally including a direct link to the study results from the facility's web site.

> In the event that any further dose reconstructions at DOE sites are required, the committee recommends that NCEH or some other agency independent of DOE should manage and direct the studies and the funding for the studies should be provided by DOE.

Agency for Toxic Substances and Disease Registry (ATSDR)

ATSDR produced valuable products under the various MOUs. In particular, the Public Health Assessments (PHAs) and Toxicological Profiles have potential

[3] *http://www.eh.doe.gov/health/hstudies/russian_health.html.* Last accessed October 2006.

value to the communities surrounding DOE sites. In 1997, ATSDR began submitting DOE public health assessments for peer review. The committee supports the continued peer review of these documents in the future.

Findings and Recommendations

1. The PHAs are presented in such a way as to have potential value to the communities surrounding DOE sites. Some of this utility has been compromised by the public's reaction to ATSDR's use of a threshold for radiation effects. As a result, the committee recommends the following:

> In light of ATSDR's mandate to adopt and apply conservative assumptions, the committee recommends that ATSDR should reevaluate its use of a radiation risk threshold.

2. ATSDR has completed 20 PHAs addressing 22 DOE sites on the Environmental Protection Agency's National Priority List. ATSDR is currently working on five remaining DOE sites, Hanford, Brookhaven, Los Alamos, Savannah River, and Oak Ridge. The committee concludes that the PHAs have potential value to the communities surrounding DOE sites. As a result, the committee recommends the following:

> DOE funding of ATSDR activities at the five DOE sites should continue.

EVALUATION OF DISSEMINATION AND COMMUNICATION: IMPROVE DISSEMINATION AND COMMUNICATION OF RESULTS TO WORKERS AND THE PUBLIC

In reviewing the dissemination and communication efforts of this program, the committee observed various types of information dissemination but few examples of effective communication with workers and the public at or near DOE sites. For the purposes of this report and consistent with its statement of task, the committee drew a distinction between dissemination and communication in its review. Dissemination is a one-way process—to send information out widely, to publicize or broadcast information. This term was specifically used in the charge to the committee. However, the committee judged that to truly evaluate public understanding of health effects, as described in the MOU, it also had to look closely at the communication efforts of the HHS agencies. Communication implies a two-way process—an interchange of knowledge, thoughts, and opinions. The committee's recommendations result from findings of shortfalls in effective communication to affected citizens and workers.

Open communication that involves dialogue among the agencies, workers, advisory bodies, and the public is critically important to improve relationships among management, workers, and communities in which DOE sites are located.

Findings and Recommendations

1. Efforts to disseminate results to citizens and workers at DOE sites by HHS agencies were extensive and benefited the target audiences by giving them needed information about health risk issues. As a result, the committee recommends the following:

- HHS agencies should be the continuing main source of active risk communication and education programs at DOE facilities due to significant evidence of continuing distrust of DOE and its contractors. DOE should work with the HHS agencies, its own contractors, and citizens' advisory boards to try to gain back trust in communities near its facilities with its own open, two-way communication efforts.
- Dissemination and communication efforts should be coordinated among the federal agencies involved as long as such coordination does not affect trust issues for HHS agencies among workers and citizens in and near DOE facilities.

2. While HHS information dissemination was generally laudable, communication activities related to worker and public health were variable in quality and uneven, agency to agency. Guiding principles for effective risk communication and best practices recommended in previous studies of other nuclear and hazardous operations could be applied to improve efforts to communicate the risks involved at DOE sites to both workers and community groups. As a result, the committee recommends the following:

- Both DOE and HHS agencies should develop improved long-term communication plans that incorporate risk communication lessons learned during the past 15 years from scholars and practitioners (including those at these agencies). These improved communication plans should continually be updated and reviewed by outside risk communication experts every few years.
- DOE and the HHS agencies should support their communication activities at DOE facilities with significantly increased organizational, financial, and personnel assistance.

3. While the committee recognizes difficulties inherent in communicating about risk to the public directly or in a public participation process, it believes that open communication involving dialogue among the agencies, workers, advisory bodies, and the public is critically important and needs improvement. As a result, the committee recommends the following:

- DOE and the HHS agencies should specify in their improved risk communication plans how they hope to achieve more effective, open, two-way communication about health risks associated with cleanup activities as

well as continuing or new missions at DOE facilities. Risk communication research on how best to incorporate public participation and work with citizen groups should be applied to these plans, with a reminder that the specific best practices at one site might not necessarily be the best practices at another site. Agendas for public and worker meetings should be developed in concert with citizen and worker representatives to ensure that stakeholders' concerns and opinions are treated with respect and responded to seriously.

- The Hanford Community Health Project directed by ATSDR should be continued to ensure good public health information at that site, particularly during cleanup activities. Similar projects should be established at other DOE sites where serious health effects issues exist.
- DOE Site-Specific Advisory Boards (SSABs) have been an important communication element at DOE sites. These should be continued as long as cleanup work continues at the sites and can be improved by including ex officio representatives from both DOE and HHS agencies.
- Similarly, the Health Effects Subcommittees (HESs) were a very important communication element and should be reconstituted at DOE sites where serious concerns about health effects issues exist.
- All SSABs and any reconstituted HESs should have a subcommittee that reviews and recommends actions on risk communication to workers and the public. This subcommittee should work with DOE and HHS agencies to provide overview, feedback, and advice on communication activities. To further these goals, these subcommittees should add a communication professional as a member, if there is no such person already on the group.

4. There has not been enough outside evaluation of the communication aspects of the HHS programs. Best practices in risk communication require professional evaluation, particularly to meet the needs of different stakeholders. As a result the committee recommends the following:

- HHS agencies and DOE should engage in periodic and systematic evaluations of their communication efforts using the most current risk communication research and practices available. These evaluations should include development of a framework to assess the effectiveness of their communications to stakeholders, and be conducted by both internal and external evaluators.

Evaluations should assess the quality of the communication products, effectiveness of dissemination, and most importantly, how information is interpreted, perceived, and accepted by the affected communities and workers. To ensure that the most current risk communication research and practices are being applied and necessary adjustments are made, internal evaluations should be done yearly and external evaluations should be done at least every 3 years.

1

Introduction

The effects of ionizing radiation on human health and the environment have been a serious public concern since the United States began producing and testing nuclear weapons during World War II. These public concerns emerged in response to the unknown health consequences of exposure to radioactive materials and the potential for extensive environmental contamination. Growing public interest regarding exposures at or near nuclear weapons facilities was a major impetus for many of the early epidemiologic studies that examined the health effects of radioactive material exposures of former and current workers and the public living near the nuclear facilities.

The "nuclear weapons complex" in the United States resulted in one of the earliest occupational research programs to study and monitor worker exposures to ionizing radiation and radioactive materials at nuclear weapons facilities. The Atomic Energy Commission (AEC), established in 1946, was charged with regulating the development of nuclear science and technology in addition to conducting research on health issues related to occupational exposures to radiation at nuclear weapons sites. In the early 1960s, the AEC designed a series of feasibility studies to determine whether personnel records could be used to monitor mortality at the Manhattan Engineering District facilities. Pilot studies were initiated by the AEC in 1964, and a long-term epidemiologic study of former workers (the Worker Health and Mortality Study) was implemented in 1970 (NRC 1990).

In 1977, the Department of Energy (DOE) was created to consolidate energy policy programs from the AEC into the succeeding Energy Research and Development Administration (ERDA) (AEC was reorganized into the U.S. Nuclear Regulatory Commission and ERDA in 1974; ERDA was reorganized along with

other activities into DOE in 1977). DOE was charged with management and oversight relating to radioactive waste disposal programs, energy-related research, the nuclear weapons program, and those epidemiologic studies of workers at nuclear weapons facilities previously administered by AEC. DOE and its predecessors also conducted many animal studies of radiation health effects, partially funds the Radiation Effects Research Foundation (RERF), and administers a low-dose radiation effects program. Currently, most of the research on the health effects of radiation exposure in occupationally exposed populations is managed by DOE's Office of Environment, Safety and Health (ES&H).[1] Management of the program was being reorganized within DOE during the time this report was in review; the program will reside in the Office of Illness and Injury Prevention, Office of Health, Safety and Security, HS-13.

DEPARTMENT OF ENERGY'S OFFICE OF ENVIRONMENT, SAFETY AND HEALTH

In 1981, DOE established ES&H to enhance the performance of the department's environment, safety, and health programs and to advise the Secretary of Energy regarding the health and safety of workers and environmental issues at DOE sites (DOE 2006a). ES&H is responsible for formulating environmental standards; developing directives related to environmental, safety, and health issues; enforcing compliance with nuclear safety regulations; and funding epidemiological studies of workers at nuclear facilities (DOE 2006a). Epidemiological research on worker exposures at the DOE sites is currently housed within the Office of Health (OH) in ES&H.

The OH manages current epidemiologic research and dose reconstruction efforts to understand the health consequences of exposure related to ionizing radiation and selected non-radioactive materials, such as beryllium, that are used in the weapons program. The OH also supports RERF jointly with Japan's Ministry of Health, Labour, and Welfare. Data from the RERF still provide the basis for the radiation risk estimates that are used to estimate risk to workers and others exposed to ionizing radiation. The office also maintains extensive records on data collected during health studies, including the Comprehensive Epidemiologic Data Resource, which is a public use data repository for such information. The Worker and Public Health Activities Program, which is the focus of this report, is one specific worker safety and health program managed by DOE's OH, in collaboration with the Department of Health and Human Services (HHS). At the time this report was in review, the program under the Memorandum of Understanding (MOU) was being reorganized within DOE and will reside in the Office of Health, Safety and Security.

[1]See *http://www.eh.doe.gov/health/orgchart.pdf* and *http://www.eh.doe.gov/ehorganization.pdf.* Last accessed October 2006.

WORKER AND PUBLIC HEALTH ACTIVITIES PROGRAM

Funded at approximately $10 million to $20 million annually for more than 20 years (see Annex 1A), the Worker and Public Health Activities Program was established to study the consequences of exposures to ionizing radiation and other hazardous materials used in DOE operations for workers and the general public in surrounding communities (DOE 2006b). Initially, the program was managed solely by DOE.

Growing public concern about DOE sites and the program provided an impetus for external reviews. In the late 1980s, a number of congressional and media inquiries highlighted environmental and safety violations that had occurred at a number of DOE sites, including accidental spills and radioactive contamination. These problems coupled with other concerns regarding DOE's handling of its epidemiologic research attracted significant public interest. DOE was criticized for a perceived inherent conflict of interest in the department's role in conducting such studies, particularly those studies designed to evaluate the health effects of exposure to low-dose radiation; the credibility of the program was an issue because a majority of the mortality studies were carried out by DOE contractors closely associated with the production efforts. A general distrust of the results of the studies also developed in part from the fact that the data were considered proprietary by DOE and were not made publicly available (NRC 1990). In response to these criticisms, in 1989 DOE Secretary James M. Watkins established an advisory committee, the Secretarial Panel for Evaluation of Epidemiologic Research Activities (SPEERA), to conduct an evaluation of the program.

Reviews of the program by SPEERA (SPEERA 1990) and National Research Council (NRC) committees (NRC 1990, 1994) were ultimately responsible for the restructuring of the program. In its evaluation in 1990, SPEERA recommended, and Congress subsequently requested, that analytic epidemiological research efforts be transferred to HHS because of concerns regarding the independence and objectivity of the DOE program. In addition, SPEERA recommended that DOE be more forthright in its efforts to communicate results of the studies to affected individuals and communities. In 1990, to address issues of credibility and transparency, DOE and two agencies within HHS (the National Institute for Occupational Safety and Health [NIOSH] and the National Center for Environmental Health [NCEH]) entered into an interagency MOU.[2] DOE became the administrator and funding source for the program while HHS conducted the research, thereby improving the independence and objectivity of the program. The MOU between the agencies was renewed in 1996 without substantive changes. (The Agency for Toxic Substances and Disease Registry [ATSDR] signed separate MOUs with DOE in 1990, 1992, and 1997.)

[2]1990 Memorandum of Understanding between the U.S. Department of Energy and the U.S. Department of Health and Human Services. See Appendix A.

Each of the agencies within HHS (i.e., NIOSH, NCEH, and ATSDR) conducts research for the Worker and Public Health Activities Program based on its legislative mandates. This research is conducted both intramurally and extramurally, with NIOSH, NCEH, and ATSDR conducting, respectively, 10, 40, and 10 percent of their portion of the research extramurally. NIOSH is tasked with studying occupational exposures including the epidemiological studies of workers at DOE sites. NCEH evaluates exposures at the sites through historical dose reconstruction projects and community epidemiological studies. ATSDR is responsible for assessing environmental exposures and related health effects in communities surrounding the DOE sites, all of which are considered Superfund sites.

In 2000, the interagency agreement[3] was modified, per congressional request, to direct "DOE to develop a single memorandum of understanding with HHS agencies that would set forth the authority, resources, and responsibility for conduct of HHS public health activities conducted by CDC [the Center for Disease Control and Prevention] and ATSDR at the DOE sites." A draft MOU is currently under negotiation between DOE and HHS. Once signed, this MOU will not be renewed beyond 2009 unless the need for additional significant health research is indicated.

Figure 1-1 illustrates a timeline of selected activities relevant to worker and public health at the DOE sites.

Current Responsibilities Within the Worker and Public Health Activities Program

Since 1990, NIOSH, NCEH, and ATSDR have been involved in a wide range of research activities related to assessing occupational and environmental exposures at or near DOE sites, including epidemiological studies of occupationally exposed workers, community assessments of health issues related to exposures at the sites, dose reconstruction to determine retrospective exposures, and dissemination of information to affected communities.

DOE and HHS documented their priority research efforts in their public health agenda (Agenda for HHS Public Health Activities [for Fiscal Years 2003-2008] at Department of Energy Sites; DOE and HHS 2003). This agenda is intended to guide activities conducted under the 2000 MOU and includes information about past and current activities at each of the DOE sites. Some current efforts are described below.

[3]2000 Memorandum of Understanding between the U.S. Department of Energy and the U.S. Department of Health and Human Services.

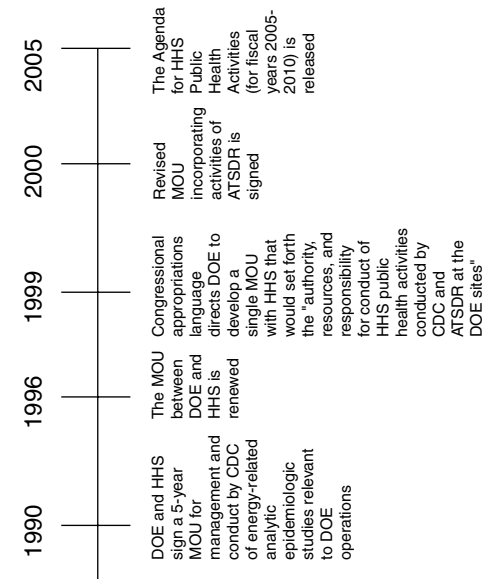

FIGURE 1-1 Timeline of activities relating to the worker and public health program.

CDC's National Institute for Occupational Safety and Health

NIOSH, the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness, has supported the activities of the Worker and Public Health Activities Program through its Occupational Energy Research Branch (NIOSH 2006). The mission of the branch is to conduct a variety of analytic epidemiology studies of the effects of exposure to ionizing radiation and other chemical and physical agents on the health of current and former DOE workers (Schubauer-Berigan 2005).

NIOSH has been involved primarily in conducting hypothesis-based analytic epidemiology through cohort mortality studies of workers at a number of DOE sites including the Idaho National Laboratory, the Los Alamos National Laboratory, the Nevada Test Site, the Portsmouth Gaseous Diffusion Plant, the Rocky Flats Plant, the Feed Materials Production Center (Fernald), the Savannah River Site, the Oak Ridge Plant, and the Hanford site (Schubauer-Berigan 2005). Some of the current research efforts include the Multiple Myeloma Case-Control Study at the Oak Ridge Gaseous Diffusion Plant (K-25), the Cohort Mortality Study of DOE Chemical Laboratory Workers, and the Health Effects of Occupational Exposures in Paducah Gaseous Diffusion Plant Workers (Schubauer-Berigan 2005). Previous research has included a multisite multiple myeloma case-control study at various sites (Wing et al. 2000) and a cohort mortality study of workers at the Portsmouth Gaseous Diffusion Plant (NIOSH 2001).

CDC's National Center for Environmental Health

The NCEH, a division of the CDC, is responsible for conducting public health surveillance, applied research, epidemiological studies, laboratory analyses, and communication and education relating to a variety of environmental health issues (NCEH 2006). The Radiation Studies Branch of NCEH is responsible for conducting dose reconstruction analyses to estimate the level of past exposure to radiation likely received by the communities surrounding DOE sites. Dose reconstruction is a comprehensive multistep process to develop individual estimates of environmental exposures of the public at the sites; it includes collecting data on radiation and chemical releases and determining potential exposure pathways for those living in the vicinity and downwind of the sites (Miller 2005).

The NCEH has completed dose reconstruction analyses for the Hanford, Idaho National Laboratory, Republic of the Marshall Islands, and Fernald sites (Farris et al. 1994a, 1994b; TSP 1994a, 1994b; Meyer et al. 1995; Killough et al. 1998; Till et al. 2001, 2002; Grogan et al. 2002; Apostoaei et al. 2005; Wichner et al. 2005). Some of the dose reconstruction documents for the Hanford, Idaho National Laboratory, Savannah River, Fernald sites, and others, have been peer-reviewed by the NRC (NRC 1995, 1997, 2001). Dose reconstruction activities are being conducted at the Los Alamos and Savannah River sites. NCEH anticipates completing the study at the Savannah River site by the end of September

2006, whereas the dose reconstruction at Los Alamos will continue for at least 3 more years. NCEH has also provided technical support at the Rocky Flats and Oak Ridge sites (Miller 2005).

CDC's Agency for Toxic Substances and Disease Registry

The ATSDR is congressionally mandated to assess health hazards at specific hazardous waste sites, in particular at Superfund sites, and to increase public knowledge about potential health effects resulting from exposure to hazardous substances at these sites (ATSDR 2006). For the Worker and Public Health Activities Program, ATSDR has assessed the public health impact of community exposures to hazardous substances released from DOE facilities and has supported education efforts to inform the community about potential health hazards at or near the sites (Cibulas 2005). ATSDR produces public health assessments to address concerns related to potential exposures to the individuals that make up the communities at these sites. To date, the agency has completed 20 Public Health Assessments at DOE sites and is finalizing or planning to complete 5 additional assessments at the Brookhaven, Los Alamos, Savannah River, Hanford, and Oak Ridge sites (ATSDR 2005a, 2005b, 2006; Cibulas 2005). ASTDR has prepared seven extensive toxicological profiles of radionuclides and ionizing radiation in general that were funded completely or partially by DOE: namely, americium, cesium, cobalt (only the update funded with DOE monies), iodine, ionizing radiation, strontium, and uranium (ATSDR 1999, 2004a, 2004b, 2004c, 2004d). The agency is also involved in community education programs, including a program to inform the community about health issues at the Hanford site (Cibulas 2005).

NRC COMMITTEE TO REVIEW THE WORKER AND PUBLIC HEALTH ACTIVITIES PROGRAM

DOE's OH requested that a committee be created by the National Academies to review the Worker and Public Health Activities Program and to assess and recommend ways to enhance the program's scientific merit, focus, and effectiveness; its impact on DOE's policies and decisions; and other program benefits, including the relevance to DOE's mission, that are consistent with the objectives of this program. In addition, the National Academies' committee was asked to address the following aspects of the program in the committee's Statement of Task:

Statement of Task

A committee of the National Academies, lead by the Nuclear and Radiation Studies Board will conduct a review of the Worker and Public Health Activi-

ties Program sponsored by DOE and conducted by DHHS. The committee will assess and will recommend ways to enhance the program's scientific merit, focus, and effectiveness; its demonstrated impact on the agency's policies and decisions; and other benefits, such as relevance to DOE's missions, that are consistent with the objectives of this program. This assessment will address the following aspects of the program:

- the congressional mandate in establishing the MOU, and how well its goals have been met through FY 2004;
- evaluating research priorities for projects from FY 1990 through FY 2004 and for projects included in the agenda;
- research project selection from FY 1990 through FY 2004 and for projects included in the agenda;
- usefulness of results and dissemination of completed research through FY 2005; and
- other aspects to be identified by the committee.

The committee may also propose other appropriate measures or indicators to be used in evaluating this program. DOE is also interested in the committee's assessment, given sufficient information and time, whether or not the individual agency programs were of the highest quality from the viewpoint of science and public policy.

In response to the request, the National Academies established the Committee to Review the Worker and Public Health Activities Program Administered by the Department of Energy and the Health and Human Services, which prepared this report. Members of the committee were selected for their expertise in biostatistics, epidemiology, radionuclide and chemical risk assessment, occupational health, research program evaluation, risk communication, and toxicology. Committee members come from academia and private industry. The committee's review of available information took place over a 9-month period from November 3, 2005, through August 9, 2006.

The committee organized its efforts to review the effectiveness of the program from the standpoint of (1) the research carried out, (2) the policies and practices developed relative to the workers and communities affected, and (3) the effectiveness of communicating the program's findings to the workers and communities affected. Both DOE and the three agencies of the HHS provided historical data that the committee requested to evaluate these three areas of activity. In addition, other public sources of information were used in the committee's program evaluation and are referenced throughout this report.

To address its task, the NRC committee held two public sessions in which it heard presentations from DOE, NIOSH, NCEH, and ATSDR officials, from former DOE Assistant Secretaries; and from a former member of the Advisory

Committee on Energy-Related Epidemiologic Research (ACERER).[4] The NRC committee requested additional information from each of the agencies to assess budgets, research outcomes, and methods for developing research priorities. In addition to the two public meetings, the committee met six times in closed sessions to discuss the program.

The committee reviewed agency research priorities, research project selection, usefulness of results, and dissemination of completed research. In addition, to evaluate the quality of the programs from the viewpoint of science and public policy, the committee used a sampling strategy that reviewed selected studies, activities, and publications from three DOE sites and, in some cases, products that were not site-specific. The committee additionally targeted a sample of the information dissemination programs for a more detailed look.

Sampling Strategy

In discussing the Statement of Task in the context of the size of the program, the number of DOE nuclear sites and the variety of activities at these various sites, the committee concluded that a comprehensive assessment of the entire program was not possible in the time allotted for this study. Thus there were two options for carrying out this review: (1) a superficial look at the entire program, or (2) a more detailed look at a portion of the program. The committee concluded that a superficial review of the entire program would not lead to meaningful recommendations, but that a more detailed look at a representative portion of the program would be more useful.

Accordingly, the committee discussed various subsets of the total program to review and arrived at a selection rationale that took into account the following factors:

- The range of time over which health studies were initiated.
- The number of workers involved as part of the program.
- A variety of types of dissemination and communication challenges.
- A variety of security challenges.
- Size of the surrounding public community.
- A geographic distribution of the sites.

With these factors in mind, the committee selected three DOE nuclear operations sites, Hanford, Oak Ridge, and Los Alamos, as a subset of the total nuclear sites on which it would focus its attention. The committee also recognized that it

[4]HHS established ACERER in early 1992, with its first meeting occurring in January 1993. ACERER continued to provide advice to the Secretary of HHS regarding the OERP research agenda till 2000.

would have to go beyond these sites to look at certain aspects of the program such as the technical studies (some of which were multisite studies that included more than these three sites) or the program management process which also reached beyond the three sites.

For example, more than 50 percent of the nuclear workers were involved in the combined Oak Ridge and Hanford sites. Health studies were first initiated at the Hanford site and much later at the Los Alamos National Laboratory. The Hanford site had a wider range of stakeholders (i.e., communities with whom the information had to be shared) than did the other two sites. The *level of security* at Los Alamos appeared to be greater than at the other two sites. This selection process resulted in a subset that the committee concluded would be representative of the program activities executed by HHS. Thus the assessment of work from this subset would lead to conclusions and recommendations that would be valid for the program as a whole.

In addition to this sampling strategy for site-specific aspects of the program, the committee considered detailed information from the agencies on broad aspects of the program. These topics included, for example, identification of project categories and specific studies funded by DOE and produced by the three HHS agencies, information on the DOE/HHS budgeting processes, procedures used in the establishment of project priorities, and program management processes for the overall program.

By using a combination of the sampling strategy for review of site-specific activities along with a review of overall management aspects of the program, the committee concluded that its assessment would be representative of the program activities carried out by HHS. Through the use of this review strategy the committee judges that it conducted a balanced assessment of the program and that its conclusions and recommendations are valid for the program as a whole.

Use of the Memorandum of Understanding Mechanism

As noted earlier in this chapter, the recommendations made by SPEERA to have the analytical epidemiological studies carried out by an agency outside of DOE specified in an MOU was the mechanism of choice of DOE and HHS in 1990. The MOUs also appeared to be the mechanism Congress supported to implement cooperation between the two departments. While this mechanism improved the program, it did not solve all the problems, nor did it catalyze seamless collaboration between the departments. Rather than attempting to devise a totally new, untried mechanism to further improve the results from this program, the committee concluded that there were specific weaknesses in the MOU structure, which if modified could provide better results. Subsequent MOUs signed in 1996 and especially in 2000 further modified the working relationship between the Departments as needs changed in the program. Presently, a draft MOU exists which has not been signed off by HHS, presumably due to lack of agreement on the specifications of the proposed MOU renewal.

As this report details in Chapters 2-5, the program operating under these MOUs made some significant advances in the scientific understanding of the hazards that the nuclear workers were exposed to and in communicating this understanding to the workers and communities involved. The committee did consider whether the program should be continued or terminated and concluded, as described in detail in subsequent chapters, that it should be continued as long as DOE engaged in hazardous operations such as cleanup and remediation at the nuclear sites. With the background of accomplishment under the past three MOUs, the charge to consider ways of improving the future program led the committee to accept the MOU as a basic operating framework and consider ways of improving it to address some of the shortcomings of the past program.

There was little evidence reviewed by the committee indicating that DOE had overcome the public concerns about their credibility on health issues that led SPEERA to recommend that an "independent" agency carry out the health studies. This may not be a commentary on DOE specifically, but rather a public distrust of any arrangement in which the primary objective of an operation might be better achieved through a compromise of some of its other objectives, for example, improved productivity at the expense of the health studies of its workers or communities. Thus the committee concluded that a continuing health program should be based on the MOU structure, albeit an improved one. Alternative structures for a continuing health program in which DOE was the sole governmental management group responsible for the health program of its workers were not adopted by the committee since such structures would lack credibility with the workers and the communities in which DOE operations were located and, if different from the previously used management structures, would represent untried and untested structures that might require a larger commitment of scarce resources with no surety of a better result. The present acceptance of the program under the MOU, while not perfect, is improved by DOE's association with HHS. The committee judges that improvement of the present structure would have a better chance of success than changing strategies at this stage.

Budgetary Considerations

The program conducted under the MOU was supported by DOE through funding transfers to HHS. Although the funds transferred under these agreements were relatively small compared to the total budget of either agency, they had a significant impact on the DOE office that had previously been responsible for this work. That office was required to turn over a substantial portion of its funding and staff to HHS to take over and carry out subsequent research. At the time this occurred during the early 1990s, the transfer of staff positions constituted a more serious resource constraint than funding limitations. According to information provided by the three agencies in the HHS, approximately $9.1 million was transferred in FY 1992 to carry out this work (see Table 1A-1, Annex 1A). The

funding and program transfer from DOE to HHS appears to have strained the working relationship between these two agencies from the outset of the work under the MOU. Subsequently, about $210 million was provided from DOE to HHS for this program from FY 1991 through FY 2005.[5] Table 1A-2 in Annex 1A shows the pattern of these expenditures over this period according to information provided by HHS agencies. DOE declined to provide any budgetary information that could be used in confirming these levels and patterns of expenditures.[6]

Although the allocation of these funds among HHS agencies could change substantially from one year to the next, over the entire period the funds were divided relatively evenly among the three agencies. ATSDR received the most (38 percent.) with NIOSH close behind (36 percent.). NCEH received the remaining 28 percent.

Over the 15-year life of the program, about 31 percent. of the total expenditures have been used to support studies by outside researchers (extramural research).[7] NCEH used the largest portion of its funds (78 percent. over 15 years) to support extramural work. NIOSH has used less (34 percent. over the 15 years), and the proportion has decreased in recent years. ATSDR has supported no extramural work in its studies.

As this study got under way, the committee was informed that only a small fraction of the FY 2006 budget requested from DOE by HHS agencies was funded for a continuing health program. NIOSH indicated that it would consider funding some of the continuing work from its internal funds.

ATSDR reportedly closed down operations at some of the DOE sites as a result of these budget cuts. Although the committee is cognizant of the budget limitations that have constrained the program in recent years, it concludes that important work still needs to be done.

This report is organized into three scientific program assessment chapters, followed by one chapter on communication and a final chapter on program management. Chapter 2 evaluates the NIOSH worker epidemiology program; Chap-

[5]The agencies indicated that in some cases, their information on expenditures was only approximate because much of the data for the earlier years had been stored in federal archives and would be difficult to retrieve. It also appears that some of the information provided was information on outlays, and some was information on obligations. Although the differences between these two ways of reporting expenditures argue against adding them together, any errors introduced by combining the data are likely to be relatively small in terms of the information they provide about the general level and pattern of expenditures.

[6]DOE's response to the committee's request for budget information was "the budget is not part of the NAS [National Academies] Statement of Work (SOW) . . . . Refer to HHS for copies of annual requests to DOE for funding."

[7]Extramural work can be paid for through contracts, grants, or cooperative agreements. The committee was less interested in the mechanism for funding outside work than in the comparison between the amount of work done by employees of the agencies and the amount done by external researchers.

ter 3 assesses the DOE-funded ATSDR community health programs; and Chapter 4 evaluates the NCEH dose reconstruction efforts at DOE sites. Chapter 5 reviews HHS dissemination and communication efforts, and Chapter 6 provides a program management assessment.

ANNEX 1A BUDGETARY TABLES

TABLE 1A-1 DOE Analytic Epidemiological Studies and FY 1991 Resources Transferred to HHS

Contractor	Year of Expected Study Update	FY 1991 Funding Level ($)	Program Title
Harvard	1992	$200,000	In vivo mutagenicity and clastogenicity of ionizing radiation
HEHF[a]		$383,000	DOE Hanford Health and Mortality Study
LANL[b]	1991-1992 or open for continuing surveillance	$700,000	Human Health Effects of Plutonium—nine studies
LLNL[c]		DOE funds	Melanoma studies at Lawrence Livermore
ORAU[d]	1991-1993 and one open case-control study	$2.8 million	Health and Mortality Study of workers at Oak Ridge, Fernald, Savannah River, Portsmouth, Paducah, and Mallinkrodt—25 studies
ORO[e]	1992	$6.1 million	CDC Fernald dose reconstruction
PNNL[f]	1992	$295,000	Statistical health effects—three studies
RL[g]	1993	$3.65 million	Hanford dose reconstruction

[a]Hanford Environmental Health Foundation.
[b]Los Alamos National Laboratory.
[c]Lawrence Livermore National Laboratory.
[d]Oak Ridge Associated Universities.
[e]Oak Ridge Operations Office.
[f]Pacific Northwest National Laboratory.
[g]DOE Richland Operations Office.

SOURCE: Appendix A of 1990 MOU.

TABLE 1A-2 Program Expenditures by Agency
(millions of dollars)

		Fiscal Year														
Agency	Ex[a]	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**Total**
NIOSH	X	0.3	1.3	1.1	4.4	4.3	3.6	1.2	2.6	1.7	1.4	1.2	1.5	0.6	0.9	**26.1**
	I	1.4	3.5	3.4	2.6	2.4	4.0	3.3	4.5	4.8	4.3	4.2	3.6	4.6	3.8	**50.4**
	T	**1.7**	**4.9**	**4.5**	**7.0**	**6.7**	**7.6**	**4.5**	**7.1**	**6.5**	**5.7**	**5.4**	**5.1**	**5.2**	**4.7**	**76.5**
NCEH[b]	X	0.4	0.4	2.1	3.0	2.5	2.0	3.1	3.8	5.3	5.1	4.0	3.8	4.1	2.1	**42.0**
	I	8.8	0.0	0.4	0.0	0.9	0.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	**12.0**
	T	**9.2**	**0.4**	**2.5**	**3.0**	**3.3**	**2.5**	**3.1**	**3.8**	**5.3**	**5.1**	**4.0**	**3.8**	**4.1**	**2.1**	**54.0**
ATSDR[c]	**I**	**5.7**	**4.9**	**6.0**	**5.0**	**4.4**	**3.7**	**5.5**	**10.6**	**8.5**	**7.6**	**5.4**	**4.4**	**4.4**	**3.8**	**80.1**
Total	X	0.6	1.7	1.5	6.5	7.3	6.1	3.2	5.7	5.5	6.7	6.3	5.4	4.4	5.0	**68.1**
	I	8.6	17.3	9.4	8.0	6.8	8.6	9.3	15.1	13.3	11.9	9.5	8.0	9.0	7.6	**142.5**
	T	**9.1**	**19.0**	**10.9**	**14.5**	**14.1**	**14.6**	**12.5**	**20.8**	**18.8**	**18.6**	**15.9**	**13.5**	**13.4**	**12.6**	**210.6**

[a]Type of expenditure: X = extramural; I = intramural; T = total.
[b]NCEH also reported spending $1.8 million in FY 1991.
[c]ATSDR also reported spending $0.2 million in FY 1991.

SOURCE: Data provided by NIOSH, NCEH, and ATSDR.

REFERENCES

Apostoaei, A.I., B.A. Thomas, D.C. Kocher, and F.O. Hoffman. 2005. Doses to the Public from Atmospheric Releases of Radionuclides from the Idaho Chemical Processing Plant at the Idaho National Engineering Laboratory (1957-1959). Prepared by SC&A, Inc., and Senes Oak Ridge, Inc. Atlanta, GA: Centers for Disease Control and Prevention.

ATSDR (Agency for Toxic Substances and Disease Registry). 1999. Toxicological Profile for Cesium. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2004a. Toxicological Profile for Cobalt. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2004b. Toxicological Profile for Cesium. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2004c. Toxicological Profile for Strontium. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2004d. Toxicological Profile for Iodine. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2005a. Public Health Assessment for Brookhaven National Laboratory. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2005b. Public Health Assessment for Los Alamos National Laboratory. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2006. ATSDR response to NRC committee questions. To the Committee to Review the Worker and Public Health Activities Program, Atlanta, GA, February 10.

Cibulas, W. 2005. Public Health Activities at DOE Facilities. Presentation to the Committee to Review the Worker and Public Health Activities Program, Washington, DC, November 4.

DOE (Department of Energy). 2006a. Office of Environment, Safety, and Health [on-line]. Available: http://www.eh.doe.gov/ [accessed February 2, 2006].

DOE (Department of Energy). 2006b. Worker and Public Health Activities Program [on-line]. Available: http://www.eh.doe.gov/health/hstudies/hhs.html [accessed February 2, 2006].

DOE and HHS (Department of Energy and Department of Health and Human Services). 2003. Agenda for HHS Public Health Activities (for Fiscal Years 2003-2008) at Department of Energy Sites. Washington, DC: U.S. Department of Energy, Office of Health Studies.

Farris, W.T., B.A. Napier, T.A. Ikenberry, J.C. Simpson, and D.B. Shipler. 1994a. Atmospheric Pathway Dosimetry Report, 1944-1992. Hanford Environmental Dose Reconstruction Project. PNWD-2228 HEDR. Richland, WA: Battelle Pacific Northwest Laboratories.

Farris, W.T., B.A. Napier, J.C. Simpson, S.F. Snyder, and D.B. Shipler. 1994b. Columbia River Pathway Dosimetry Report, 1944-1992. Hanford Environmental Dose Reconstruction Project. PNWD-2227 HEDR. Richland, WA: Battelle Pacific Northwest Laboratories.

Grogan, H.A., A.S. Rood, J.W. Aanenson, and E.B. Liebow. 2002. A Risk-Based Screening Analysis for Radionuclides Released to the Columbia River from Past Activities at the U.S. Department of Energy Nuclear Weapons Site in Hanford, Washington. RAC Report No. 3-CDC-Task Order 7-2002-FINAL. Prepared by Risk Assessment Corporation, Neeses, SC. Atlanta, GA: Centers for Disease Control and Prevention.

Killough, G.G., M.J. Case, K.R. Meyer, R.E. Moore, S.K. Rope, D.W. Schmidt, B. Shleien, W.K. Sinclair, P.G. Voillequé, and J.E. Till. 1998. Task 6: Radiation Doses and Risk to Residents from FMPC Operations from 1951-1988, Volumes I and II. Final Report. The Fernald Dosimetry Reconstruction Project. RAC Report No. 1-CDC-Fernal-1998-FINAL. Prepared by Radiological Assessments Corporation, Neeses, SC. Atlanta, GA: Centers for Disease Control and Prevention.

Meyer, K.R., P.D. McGavran, P.G. Voillequé, H.A. Grogan, L.W. Bell, H.R. Meyer, S.K. Rope, and J.E. Till. 1995. Evaluation of Materials Released from the Savannah River Site. Phase I: Data Retrieval and Assessment. RAC Report No. 6 CDC-SRS-95-Final. Prepared by Radiological Assessments Corporation, Neeses, SC. Atlanta, GA: Centers for Disease Control and Prevention.

Miller, C.W. 2005. A Review of Environmental Dose Reconstruction Activities at DOE Nuclear Weapons Production and Testing Facilities. Presentation to the Committee to Review the Worker and Public Health Activities Program, Washington, DC, November, 4.

NCEH (National Center for Environmental Health). 2006. NCEH responses to NAS questions dated March 16, 2006.

NIOSH (National Institute for Occupational Safety and Health). 2001. Mortality Patterns Among Uranium Enrichment Workers at the Portsmouth Gaseous Diffusion Plant, Piketon, Ohio. Final Report. Cincinnati, OH: NIOSH, Division of Surveillance, Hazard Evaluations and Field Studies, Health-Related Energy Research Branch, 179 pp.

NIOSH (National Institute for Occupational Safety and Health). 2006. NIOSH Occupational Energy Research Program [on-line]. Available: http://www.cdc.gov/niosh/oerp/default.html [accessed February 1, 2006].

NRC (National Research Council). 1990. Providing Access to Epidemiological Data. Washington, DC: National Academy Press.

NRC (National Research Council). 1994. Epidemiological Research Programs at the Department of Energy: Looking to the Future. Washington, DC: National Academy Press.

NRC (National Research Council). 1995. A Review of Two Hanford Environmental Dose Reconstruction Project (HEDR) Dosimetry Reports: Columbia River Pathway and Atmospheric Pathway. Washington, DC: National Academy Press.

NRC (National Research Council). 1997. A Review of the Radiological Assessment Corporation's Fernald Dose Reconstruction Report. Washington, DC: National Academy Press.

NRC (National Research Council). 2001. Letter Report to Review Identification and Prioritization of Radionuclide Releases from the Idaho National Engineering and Environmental Laboratory. Washington, DC: National Academy Press.

Schubauer-Berigan, M. 2005. Occupational Energy Research Program: Overview for the National Academies' Review of the Worker and Public Health Activities Program Administered by DOE and HHS. Presentation to the Committee to Review the Worker and Public Health Activities Program, Washington, DC, November 4.

SPEERA (Secretarial Panel for the Evaluation of Epidemiological Research Activities for the Department of Energy). 1990. Report to the Secretary. Washington, DC: U.S. Department of Energy.

Till, J.E., J.W. Aanenson, P.J. Boelter, M.C. Case, M. Dreicer, H.A. Grogan, M.O. Langan, P.D. McGavran, K.R. Meyer, R. Meyer, H.J. Mohler, A.S. Rood, R.C. Rope, S.K. Rope, L.A. Stetar, P.G. Voillequé, T.F. Winsor, and W. Yang. 2001. Evaluation of Materials Released from the Savannah River Site. Savannah River Site Environmental Dose Reconstruction Project. Phase II: Source Term Calculation and Ingestion Pathway Data Retrieval. RAC Report No.1-CDC-SRS-1999-Final. Final Report. Prepared by Radiological Assessment Corporation, Neeses, SC. Atlanta, GA: Centers for Disease Control and Prevention.

Till, J.E., K.R. Meyer, H.J. Mohler, and J.W. Aanenson. 2002. Identification and Prioritization of Radionuclide Releases from the Idaho National Engineering and Environmental Laboratory. Final Report. Prepared by Risk Assessment Corporation, Neeses, SC. Atlanta, GA: Centers for Disease Control and Prevention.

TSP (Technical Steering Panel). 1994a. Summary: Radiation Dose Estimates from Hanford Radioactive Material Releases to the Air and the Columbia River. Revision 1. Olympia, WA: Washington Department of Ecology.

TSP (Technical Steering Panel). 1994b. Representative Hanford Radiation Dose Estimates. Revision 1. Olympia, WA: Washington Department of Ecology.

Wichner, R.P., J.P. Renier, and A.I. Apostoaei. 2005. Atmospheric Source Terms for the Idaho Chemical Processing Plant, 1957-1959. Final Report. Prepared by SC&A, Inc. and Senes Oak Ridge, Inc. Atlanta, GA: Centers for Disease Control and Prevention.

Wing, S., D. Richardson, S. Wolf, G. Mihlan, D. Crawford-Brown, and J. Wood. 2000. A case control study of multiple myeloma at four nuclear facilities. Ann Epidemiol 10:144-153.

2

Scientific Program Assessment: National Institute for Occupational Safety and Health

The committee reviewed the research priorities for the epidemiological projects, research project selection, dissemination of results of completed research, and contribution of research to the Department of Energy (DOE). The output of selected products of the Occupational Energy Research Program (OERP) of the National Institute for Occupational Safety and Health (NIOSH) program as of May 2006 is presented in Annex 2A. The remainder of this chapter presents material relevant to the committee's statement of task as follows: (1) a review of selected but representative components of NIOSH's research program for quality; (2) an evaluation of the research priorities to date; (3) a summary of the usefulness of the results of the NIOSH program and its impact on DOE policies and decisions; and (4) recommendations for enhancements of the NIOSH research program for the future.

To evaluate whether the research programs were of high scientific quality (i.e., methodologically sound, relevant, reasonable interpretation of results), the committee sampled research products at three DOE sites: Hanford, Oak Ridge National Laboratory (ORNL), and Los Alamos National Laboratory (LANL). The committee also reviewed selected multisite studies that included data from these three locations. These studies were judged by the committee to represent relevant combined analyses of occupational health DOE-wide and to be representative of the types of studies carried out across the program. In addition, because beryllium has been used extensively in various components and processes in the U.S. nuclear weapons industry since the 1940s, the committee reviewed the beryllium-related research performed under the Memorandum of Understanding (MOU).

Specifically, the committee reviewed the following NIOSH research:

1. Publications examining exposures at Hanford and ORNL in relation to cancer and non-cancer mortality—the committee also discusses the one single-site publication that used the LANL mortality data in a risk analysis;
2. The U.S.-based multisite studies that include Hanford and ORNL data (the Childhood Leukemia Case-Control Study and the Female Nuclear Workers Study);
3. The multisite case-control study of multiple myeloma and the ongoing multisite case-control study of leukemia;
4. Non-radiologic health studies focused primarily on beryllium-related issues; and
5. The contribution of DOE sites to international studies of cancer mortality among nuclear workers.

COMPLEXITIES AND LIMITATIONS INVOLVED IN THE EPIDEMIOLOGICAL STUDIES

One of the most contentious issues in the fields of radiation protection and radiation epidemiology relating to cancer causation is that of the linearity of the dose response and the related question of dose-rate effects, i.e., whether the same dose delivered over an extended period has different effects than *a dose delivered instantaneously*. High-dose studies, particularly the A-bomb survivor study, show unequivocally that radiation can cause cancer, including most leukemias and most solid tumors. Interpolation of the high-dose studies down to the levels of exposure that are experienced in today's occupational settings indicates that workers exposed near the maximum levels (2 rem/year) allowed by DOE will experience perhaps a ½ percent to 1 percent increase in the relative hazard of all tumors (for each year of such exposure). Current radiation protection standards and compensation programs are based upon the results of this extrapolation of high-dose effects down to low dose. The considerable uncertainty, however, in this high-dose extrapolation provides the fundamental rationale for conducting epidemiological studies of occupational radiation.

Direct studies of low-dose effects are desirable because there are scientific questions concerning the theoretical basis for extrapolation of human epidemiological data from acute radiation exposures in excess of about 200 mSv to lower doses delivered at the long-term chronic exposure rates experienced by most radiation workers. However, in direct studies of workers, the relatively low degree of excess risk poses enormous difficulties for epidemiological studies of current exposure levels, since even a perfect epidemiological study, where dose is known precisely and the chance for confounding is very limited, would require many decades of follow-up of hundreds of thousands of workers in order to accrue enough cases of cancer to have adequate statistical power to detect such relatively small increases. For example, to study the relationship between a spe-

cific outcome (disease of interest, e.g., overall or cause-specific cancer mortality) and radiation, if 20 percent of workers in the industry were exposed to enough radiation to result in a 10 percent increase in the outcome, it would be necessary to observe over 5,000 cases of disease (in a cohort study) or over 10,000 cases (in a 1-1 matched case-control study) before there would be good statistical power to detect that this level of radiation was harmful. It would be expected that less than 2 percent of all cases would be caused by exposure. Currently the *total* workforce at a large DOE facility is on the order of 10,000 people.

These risks are at the limit of what current epidemiological methods can achieve, especially given that no analytic observational study is free of confounders, and that doses are not perfectly measured. Furthermore, individuals, or even groups of individuals, may differ in their susceptibility to exposures. For certain cancers (e.g., some leukemias), the relative risks due to radiation exposure may be considerably higher, so that far fewer cases of cancer are required in a study. However, even though the fraction of these types of radiogenic cancers is correspondingly higher, the cancers are often quite rare requiring a lengthy surveillance of large numbers of workers.

Going beyond the expected small excesses of radiation-caused cancers, other important issues increase the difficulty of the epidemiological studies performed under the MOU. For example, the extraordinary history of the weapons plants, including the speed at which the processes and weapons were first developed, the rate at which the DOE workforces grew in the early years, the urgency of their mission, the complexity of the research and industrial processes, the many decades that this work force has been in existence, and the potentially long-lived effects of exposure on risk, all contribute to the challenges of epidemiological investigations performed under the MOU from the 1990s to the present. Only one exposure of interest, namely external radiation, is demonstrably captured with any degree of completeness, and even for this exposure there are continuing uncertainties, related to the uniformity of monitoring requirements, monitor performance, recording practices, and record retention. The situation for chemical exposures and for internal dose estimation appears to be rather more difficult, with large "documentation" gaps affecting the ability to either directly study these exposures as a cause of disease, or to correct for them in the analysis of radiation effects. The same applies to lifestyle-related exposures, especially to tobacco, a known cause of some of the same diseases (e.g., lung cancer) that are also of interest as an effect of radiation exposure. In addition, the socioeconomic status of various types of workers (known to affect health and mortality) has a complex interplay with exposure as well, with most exposures at most sites being received by lower-status workers. Over these studies as a whole, therefore, the committee notes enormous challenges in the evaluation of existing records of exposure, especially chemical and internal radiation exposures, but also in many cases (generally for the early years) to external penetrating radiation.

DOE SINGLE-SITE MORTALITY STUDIES

Oak Ridge National Laboratory, Hanford, and Los Alamos National Laboratory Epidemiological Studies

There are three major DOE sites in the Oak Ridge area: ORNL (formerly the site of the X-10 reactor), the K-25 gaseous diffusion plant, and the Y-12/TEC site (formally the site of the electromagnetic separator and later of specialized research projects). According to Frome et al. (1997), only workers at the ORNL site and a fraction of the workers at Y-12 had individualized external dosimetry data that could be used in dose-response analyses. Data from one ongoing case-control study of multiple myeloma at the K-25 facility, which began in 1995, have yet to be analyzed. Much of the work has focused on ORNL (X-10). Data from Y-12 has apparently been used in only one published dose-response analysis (Frome et al. 1997); Y-12 has not been chosen for inclusion in the multisite leukemia study described below, having not met that study's requirement that the potential for internal exposure be minimized. For similar reasons Y-12 workers have not been included in the international pooled studies (Cardis et al. 1995, 2005). Work began at the Oak Ridge and Hanford sites quite early, so many of the publications on Oak Ridge and Hanford are reports of work that were started under contract to DOE and were later transferred to NIOSH after the MOUs were initiated.

The Hanford operations were larger than those at ORNL. More workers were monitored for radiation exposure, and the average dose of workers who were exposed to radiation was higher at Hanford (26 versus 22 mSv), although the general dose distribution was similar (Gilbert et al. 1993a). The fraction of subjects exposed to greater than 100 mSv is also similar at the two sites. Early studies included workers initially employed at Hanford between 1944 and 1978 and at ORNL between 1943 and 1972. Several analyses and reanalyses of the data have been undertaken. These have involved (1) updating the follow-up from the mid-1980s (Wing et al. 1991; Gilbert et al. 1993a) to the early 1990s; (2) expanding the ORNL cohort to include women and non-white workers as well as others not included in some earlier studies; and (3) working to improve the dosimetry data, partly through efforts to capture additional historical records and partly through improvements in the statistical treatment of missing doses (Gilbert et al. 1996; Xue et al. 2004; Daniels and Schubauer-Berigan 2005; Daniels et al. 2006; Richardson et al. 1999). In addition some work on internal plutonium exposure has been performed for the Hanford cohort (Wing et al. 2004) although no formal dose-response analysis has been possible since internal measurements are available only for small numbers of potentially exposed workers. In general, however, the cohort of workers studied at ORNL and Hanford has been fixed, with no new subjects entering the studies after the middle to late 1970s.

Overall there is limited evidence from these sites of an ionizing radiation dose-response relationship for all cancers. For example Gilbert et al. (1993b)

found non-significant negative dose-response relationships between external penetrating dose and either solid tumor or leukemia mortality in the Hanford cohort (follow-up through 1986). A few specific tumor sites (multiple myeloma, cancer of the pancreas, and non-Hodgkin's lymphoma) appeared to be positively related to exposure at a marginally statistically significant level. The estimated excess relative risks (ERRs)[1] per unit exposure were found early on (Gilbert et al. 1993a) to be much greater in the ORNL data than in either the Hanford data or the data for A-bomb survivors (Gilbert et al. 1993a). However, because the ORNL cohort was considerably smaller than the Hanford cohort, 95 percent confidence intervals for ORNL still overlap the values for Hanford and include the null value indicating that no association was found between an increase in cancer risk and protracted low-level exposures.

Some reports (Mancuso et al. 1977; Wing and Richardson 2005) have found that exposures received by workers at older ages were more strongly related to cancer occurrence than exposures received at younger ages, which runs counter to certain other epidemiological data such as for thyroid exposure to ^{131}I from Chernobyl, as well as high-dose exposures among the A-bomb survivors and all solid tumor cancer incidence and mortality, where age at exposure has been found to be inversely related to ERR (NRC 2006a).

As described below, even the most recent international pooled study of Cardis et al. (2005) did not take into account all available follow-up data from these two sites only follow-up data for ORNL and Hanford through 1984 and 1986, respectively, were made available to the International Agency for Research on Cancer (IARC) for the international study.

Although the cohorts at LANL and ORNL are approximately the same size, fewer findings have been published from the LANL cohort than either ORNL or Hanford because dosimetry data were unavailable until recently. Data from this cohort were not included in the international pooled studies (Cardis et al. 2005), but this site has been chosen for inclusion in the multisite leukemia case-control study. The one published report that the committee reviewed (Wiggs et al. 1994) analyzed cause-specific mortality for approximately 15,000 white male workers who were hired between 1943 and 1977 and followed through 1990. The study found limited evidence of any dose-response relationships for radiogenic cancers. As with the other DOE sites, investigators were not able to control for potential confounding with lifestyle factors or occupational exposures other than ionizing radiation.

[1]The ERR is the rate of disease in an exposed population divided by the rate of disease in an unexposed population minus 1.0.

MULTISITE EPIDEMIOLOGICAL STUDIES

In the 1980s the need for joint analyses of occupational groups was recognized and studies were underway. IARC began the three country study (Cardis et al. 1995) and Gilbert in the United States (Gilbert et al. 1989), and investigators in the United Kingdom (Carpenter et al. 1998) had initiated joint analyses of occupational groups. A key criticism made by the "Dead Reckoning" monograph (PSR 1992) of pre-MOU occupational radiation exposure studies at DOE sites was their reliance on small sample sizes at single facilities rather than on an overall evaluation of hazards to the entire DOE workforce. Pooling efforts therefore have been given priority, both under the MOU and in the study of nuclear workers in general (Cardis et al. 1995, 2005). A key issue impeding pooling has been the degree of heterogeneity of the types of radiation exposures considered. Generally, data from sites where internal radiation exposures are expected to predominate, such as Fernald, have not been pooled with data from cohorts exposed primarily to external penetrating radiation. In addition, the Portsmouth Navy Shipyard (PNS), a non-DOE site that services nuclear submarines and their components, where workers are exposed exclusively to external radiation, has been included in NIOSH's work under the MOU. There were efforts even before the MOU to conduct combined analyses, such as in combining Hanford, ORNL, and Rocky Flats (Gilbert et al. 1989, 1993a); the goal of combining homogeneous DOE data has not yet been fully realized, however (see recommendations). In this section the committee reviews two different types of multisite studies conducted under the MOU:

1. Multisite studies aimed at either incorporating additional sites beyond Hanford and ORNL into the analyses and/or addressing questions regarding dose estimation and confounding whether by lifestyle or other occupational exposures; and
2. Special multisite studies addressing specific questions that have arisen in relation to exposures and health of the DOE workforce or their families, but not specifically directed at improving or extending the understanding of radiation health effects on the workforce as a whole (e.g., female workers study, study of childhood leukemia).

Multisite Leukemia Case-Control Study

The ongoing multisite leukemia case-control study is important both with respect to the findings it may report and as a pilot study for future proposed NIOSH studies of solid tumors. The proposed studies would use similar methods but would require considerably larger numbers of cases and controls because of the lower risks caused by radiation.

Leukemia is the most radiogenic of all cancers, although this differs by leukemia subtype, with chronic lymphocytic leukemia (CLL) generally consid-

ered to be unrelated to radiation exposure (for an exception, see the recent study by Rericha et al. 2006). Excesses of leukemia have been observed at one DOE site, Savannah River (Cragle et al. 1988). Currently, the epidemiological evidence for effects of protracted exposure to low doses in elevating leukemia risk is somewhat equivocal. The 1995 international study (Cardis et al. 1995) found a significantly higher ERR estimate, but this weakened to borderline statistical significance in the 2005 update (Cardis et al. 2005).

The committee's evaluation of the multisite leukemia study is based on a protocol received from NIOSH, several published papers on methodology (Daniels and Schubauer-Berigan 2005; Daniels and Yiin 2006; Daniels et al. 2006), and a 2006 presentation by Mary Schubauer-Berigan (NIOSH) at the American Statistical Association's 2006 radiation meeting. There have been important methodological findings from the multisite leukemia study. First, very little external dose was found to be "missed" because of either recording practices (e.g., round-off methods, detection limits) or missing records. For example, Daniels and Yiin (2006) presented a convincing case that only a few percent of total collective external dose was likely lost because of detection limit issues. Second, an intensive search for records on internal dose revealed a relatively small contribution (Daniels et al. 2006) to bone marrow dose from internal sources, although this contribution did appear to be positively correlated with external doses, leaving the possibility of some confounding of the effects of the two types of exposure. Finally, from the American Statistical Association presentation noted above, the investigators were successful in building a job exposure matrix to estimate exposure to carbon tetrachloride and benzene for cases and controls.

These findings have relevance for evaluating the likelihood of success of proposed future work by NIOSH DOE sites (see recommendations). Furthermore, when properly combined with the IARC pooled analysis, this study could provide important information regarding leukemia risk as a function of protracted exposure to low-dose-rate radiation.[2]

Multisite Multiple Myeloma Study

This study was undertaken by investigators at the University of North Carolina. The nested case-control method was used to assess exposure to radiation and chemicals, including benzene, among 98 cases with multiple myeloma and 391 controls. One published report (Wing et al. 2000) and an extensive final report[3]

[2]About 30 percent of the cases in the multisite leukemia study are included in the IARC 2005 publication (NIOSH 1996, 2006). The multisite leukemia study had approximately 10 years more of follow-up from Hanford and ORNL and included four other sites (LANL, PNS, SRS, Zia) not included in the IARC publication. IARC analyzed 196 leukemia cases. This would be increased to approximately 340 in the combined analyses.

[3]See *http://www.cdc.gov/niosh/oerp/completed.html*. Last accessed August 2006.

were reviewed by the committee. The multisite multiple myeloma study found no overall excess risk due to exposure to external radiation. However, the investigators noted that doses received at older ages were positively related to risk, while doses received at younger ages were inversely associated with risk. The interpretation of this unexpected finding is not something about which the committee can make a judgment, but it could be a chance finding as a result of multiple comparisons. However, in light of findings in the ORNL and Hanford studies of positive associations for doses received at older ages and null associations at younger ages, this result does suggest that the issue of age interactions with exposure needs further investigation, possibly through pooling of studies, including DOE and international nuclear worker studies. One study that could potentially add valuable information to address this question is the multiple myeloma study being conducted at the K-25 (the Oak Ridge Gaseous Diffusion Plant) facility. This separate single-site study has a large number of cases of multiple myeloma for a rare cancer (63, according to the Agency for Toxic Substances and Disease Registry [ATSDR][4]), but it has been considerably delayed from its original expected completion date of 2002.

Multisite Female Nuclear Workers Mortality Study

The pooled female worker study surveyed the mortality of approximately 68,000 female workers at 12 DOE sites (Wilkinson et al. 2000).[5] The mean cumulative doses (external) for those monitored ranged from 0.6 mSv at Fernald to approximately 10 mSv at Savannah and the maximum lifetime dose for any monitored female worker ranged from 51 mSv at Fernald to 420 mSv at Los Alamos (Table 16). There was a total of 88 person Sv (Table 17) collective exposure in total for all monitored female workers at the facilities included in the study. The multisite female worker study sought in two ways to determine whether some lethal radiation effects may be unique to, or more common in, females: first, by an overall survey of death certificates, and second, as a follow-up on the one positive finding from the mortality survey, by a case-control study of mental disorders. Since approximately two-thirds of the women in the mortality survey did not have records of external radiation exposure, a "yes-no" surrogate for radiation exposure between badged and unbadged workers was used in many analyses. Overall mortality and overall cancer mortality, especially from lung cancer, were higher in the unbadged than the badged workers. In addition, a few positive associations between the yes-no surrogate and the risk of cancer or other diseases were noted, and death due to so-called mental disorders was elevated in the badged group. The general tendency for unbadged workers to have higher

[4]See *http://www.atsdr.cdc.gov/HAC/oakridge/phact/c_1.html#213*. Last accessed August 2006.
[5]See *http://www.cdc.gov/niosh/oerp/pdfs/2001-133g17.pdf*. Last accessed October 2006.

cancer mortality than badged workers is likely due to differences in lifestyle factors, particularly smoking, that could not be controlled for in this analysis. The significant finding for mental disorders was followed up in a case-control study in which individual dose estimates were obtained (Sibley et al. 2003). While a marginally significant dose response for this outcome was observed, the biological basis of such an effect if it is confirmed is unclear. However, since many outcomes were surveyed, multiple comparisons may have produced a chance finding. Among approximately 21,000 women with external monitoring data, statistically significant positive dose responses, based on a total of 11 deaths, were observed for leukemia and suggestive results were obtained for all cancer mortality and breast cancer mortality.

To increase sample size, female workers from 12 DOE sites were considered in the analysis. As noted by the authors, workers received both internal and external radiation exposures. Therefore the exposures may have been both more heterogeneous and less well measured by radiation badges than in studies such as the multicenter leukemia case-control study, which concentrated on DOE sites where external exposures were expected to predominate. In addition, lack of control for confounding and lack of any quantitative dosimetry for most workers limit the contribution of this study to understanding worker-related adverse health outcomes or sex-specific response to radiation.

Multisite Offspring Leukemia Study

The committee reviewed one case-control study of childhood leukemia in relation to pre-conception parental exposure among children living in locations near three DOE nuclear facilities (Idaho, Oak Ridge, and Hanford) (Sever et al. 1997). This study was designed to follow-up on the well-known Sellafield study (Gardner et al. 1990) that found an association between pre-conception paternal radiation exposure at the Sellafield nuclear plant in the United Kingdom and risk of childhood leukemia. A total of 233 cases of childhood cancer with either parent employed at any one of three DOE sites were identified from hospitals, cancer registries, and death certificates, and 4 controls were chosen for each case from among parents of children without cancer working at the same DOE sites. The comparison of cases and controls gave no indication of a positive association between childhood leukemia and parental dose, since for all three worksites the mean dose to the fathers of cases prior to conception was lower than the mean dose to the fathers of controls prior to conception. This study made a significant contribution to a topic of interest. While limited in statistical power, the results of the study were consistent with subsequent similar studies that also did not support the findings at Sellafield.

International Collaborative Study of Nuclear Industry Workers

This study conducted by IARC was partially funded by NIOSH through the OERP extramural research program. The study updated the earlier IARC study (Cardis et al. 1995) of mortality data from nuclear workers in 3 countries, expanding it to include data for worker cohorts from a total of 15 countries (Cardis et al. 2005). The stated goals of the study were to include data from existing cohorts with individual monitoring data for external penetrating exposures and with follow-up for mortality for all cohort members. This study included data from three DOE sites: Idaho National Laboratory (INL), Hanford, and ORNL. IARC and its collaborators conducted a series of studies of dosimetry practices (Gilbert et al. 1996) exposure conditions, and dosimeter response (Thierry-Chef et al. 2002) in support of the efforts to meaningfully combine radiation dosimetry data from all 15 countries and the various facilities therein. While this study of approximately 600,000 workers (which included approximately 5,000 deaths from cancer in the main analyses) is the largest study in existence of low-dose external penetrating exposure to workers, it does necessarily suffer from many of the same drawbacks as do the DOE studies. While facilities where internal radiation doses were the predominant source of exposure were likely excluded from study, the potential for confounding by chemical and tobacco exposure and other workplace exposures remains a serious concern. Overall, a positive dose response for solid tumors was reported, amounting to approximately a 1 percent increase in the relative risk of solid tumor mortality for each 10 mSv of cumulative exposure. The confidence intervals for this estimate remained wide, however, and thus the estimated risk is not inconsistent with the (lower) risk estimates from the A-bomb survivors. It is especially notable that approximately 43 percent of cancers were at tumor sites considered to be smoking-related. Since risk estimates for these tumor sites may be seriously biased if tobacco use and radiation exposure are correlated, additional analyses were conducted restricted to solid tumor sites unrelated to smoking. These showed somewhat smaller risk estimates and were not statistically significant. For leukemia, not including CLL, a non-significant positive slope was estimated. In the committee's overall appraisal, the IARC study is regarded as important, but as described below, there are important gaps related to the contribution or exclusion of data from specific DOE cohorts, and the length of mortality follow-up used for Hanford and ORNL.

Non-Radiologic Health Studies

As highlighted in NIOSH public information documents, workers at DOE facilities have been exposed to a variety of chemical and physical hazards (e.g., solvents, gases, metals and other toxicants, loud noises, heat, non-ionizing radia-

tion), some of which are unique to specific DOE facilities.[6] In fact, NIOSH points out that "the chemical exposures may actually be the primary concern for certain health outcomes." The stated objectives of NIOSH studies include estimating uncertainties and biases in exposure assessments and conducting more comprehensive exposure assessments of chemicals. Few studies have focused on site-specific non-radiological hazards. The unpublished chemical worker study is an exception; the primary studies that have been performed to date related to chemical and physical hazards have focused primarily on beryllium and to a lesser extent on mercury and excessive heat exposure.

Beryllium

A listing of DOE sites with current or past beryllium work includes Hanford, ORNL, and LANL, as well as the Ames Laboratory, Argonne East, Argonne West, Brookhaven National Laboratory, Energy Technology Engineering Center, East Tennessee Technology Park (K-25), Fermilab, Kansas City, Lawrence Livermore National Laboratory (LLNL), Mound, Nevada Test Site, ORNL, Pantex, Rocky Flats Environmental Technology Site, Sandia National Laboratory (SNL), Savannah River, Stanford Linear Accelerator Center, and Y-12.[7] In a 1996 survey of current beryllium use at DOE facilities, both ORNL and LANL, as well as Allied Signal-Kansas City Plant, Fermilab, LLNL, Pantex, Rocky Flats, SNL, and Y-12, reported potential worker exposures to beryllium. Even short-term exposures to beryllium fumes, dust, or metal oxides can result in beryllium sensitization and subsequently chronic beryllium disease in some workers.[8]

As part of an epidemiological research review provided to DOE in 1989, the National Research Council (NRC 1989) recommended that DOE make efforts to quantify exposures to and effects from agents in addition to ionizing radiation. The NRC also urged DOE to begin cautiously developing and using molecular markers of chemicals in future studies (NRC 1994). The ongoing DOE epidemiological studies that were transferred to NIOSH in 1991 under the first MOU did not include any epidemiological studies focusing on beryllium. However, the participants at a 1991 workshop devoted to developing an energy-related epidemiological research agenda recommended the completion of health studies related to beryllium exposures. At the initial Advisory Committee on Energy-Related Epidemiological Research (ACERER 1993) meeting, the NIOSH

[6]See *http://www.cdc.gov/niosh/2001-133a.html*. Last accessed August 2006.

[7]See *http://www.eh.doe.gov/administration/training/be/BerylliumSites.pdf*. Last accessed August 2006.

[8]DOE (U.S. Department of Energy). 2006. Final Draft. DOE Beryllium Information Survey Report. DOE Facility Experience from 1994 to 1996. [on-line]. Available: *http://www.eh.doe.gov/be/docs/96survey.pdf*. Last accessed October 2006.

Occupational Energy Research Program (OERP) proposed studies examining the health effects of DOE-related occupational exposures to beryllium (CDC 1993). NIOSH reports (NIOSH 2005) in this area were complete by November 2005 (Sanderson et al. 1999; Martyny et al. 2000; Newman et al. 2001, 2005; Kelleher et al. 2001; Rosenman et al. 2001; Newman 2002).

Beryllium-related research performed under the MOU followed several lines of scientific investigation including beryllium exposure-disease relationships; the rate of progression from beryllium sensitization to chronic beryllium disease; use of the blood beryllium lymphocyte proliferation test (BeLPT) for surveillance; results of medical screenings for beryllium sensitization in relation to exposure measures; cellular and molecular responses to beryllium that promote granuloma formation; and the potential for inadvertent movement of residual beryllium off-site from contamination of workers hands and clothing. The majority of these findings (Sanderson et al. 1999; Martyny et al. 2000; Kelleher et al. 2001; Newman et al. 2001, 2005; Rosenman et al. 2001) were reported in the peer-reviewed scientific literature. The scope of the work is congruent with the mission of OERP to conduct relevant, unbiased research to identify and quantify health effects related to occupational exposures. The research adds important information that enhances and helps guide current research on beryllium performed by NIOSH (outside OERP), DOE, the Department of Defense (DOD), and the National Institute of Environmental Health Services as well as other agencies. The OERP beryllium-related research has also provided information that can be used to help interpret the findings from DOE's Former Worker Medical Surveillance Program (FWMSP). As noted elsewhere (NIOSH 2005), OERP maintains the beryllium worker and health outcomes exposure registry and acts in an advisory capacity to the FWMSP.

Beryllium-related research needs have been developed by DOE with input from DOD, the Occupational Safety and Health Administration, and NIOSH.[9] Many of these needs are directly relevant to the OERP mission. Steps that would directly impact both the power of epidemiological studies and the cost of surveillance would be to develop and validate improved screening and diagnostic tests, and to identify genetic factors that affect either sensitization or disease process. "The BeLPT, which is commercially available at only a limited number of institutions, suffers from low sensitivity with a high rate of false negatives, inaccessibility of labs that can perform the test, and significant problems with both inter and intralaboratory reproducibility of abnormal BeLPT results" (Deubner et al. 2001; Stange et al. 2004). The development and validation of an improved test would also enhance the ability of researchers to successfully address many of the other Be-related research opportunities developed by DOE.

[9]See *http://www.eh.doe.gov/be/researchprograms.pdf*. Last accessed July 2006.

Mercury

In addition to the beryllium-related studies, the committee reviewed a single-site NIOSH study of neurologic defects after occupational exposure to elemental mercury (Letz et al. 2000) that involved Y-12 (Oak Ridge). The study suffered from low participation rates so the results, apparent deficits in peripheral nervous system function decades after exposure, remain equivocal.

Epidemiological and Statistical Methods Research

NIOSH, through its extramural and intramural activities, supported a range of epidemiological and statistical methods research. Some of this work was very focused upon problems of direct relevance to the analysis and interpretation of data from the DOE workers cohorts, while other projects (mainly through the extramural activities) were more inclusive, supporting research with relevance to the general analysis and interpretation of radio-epidemiological data or supporting the analysis and interpretation of data from other radiation-exposed cohorts of workers. The general areas of research included:

Research that focused on understanding the effects of measurement error in the analysis and interpretation of the DOE worker studies included the following research subjects:

Substantial efforts to estimate and assess the impact of workers' exposure to doses that were below the limits of detection for radiation monitors in use at various time periods, as well as the impact of various recording practices used historically (e.g., weekly versus quarterly reading of film badge doses).

Assessment of bias factors and other uncertainties inherent in personal monitors historically used to assess external dose.

Incorporation of the uncertainty of dose estimation into dose-response analysis in DOE and occupational radiation epidemiology studies in general.

Assessment of the quality of records for assessing exposure to chemicals, lifestyle-related exposures, and external and internal radiation for the DOE worker cohorts including:

- historical worker exposures,
- current practices (e.g., for cleanup workers),
- research into modeling the effects of exposure using both empirical and "mechanistic" models for cancer occurrence.

Other special issues such as development of computerized occupational exposure databases and research into exposures to Russian nuclear workers or Chernobyl cohorts that may produce informative information regarding DOE worker cohorts radiation-related risks.

Measurement error problems are especially important in epidemiology for two reasons: (1) random measurement errors have an adverse impact on the power of a study to make inferences about the presence of radiation effects, and (2) both random and systematic measurement errors impact the interpretation and comparability of results from one study to another by biasing risk estimates (most often, but not always towards zero effect).

The problem of estimating doses below the minimum detectable limit of contemporary personal dosimeters was treated both by externally funded investigators and by NIOSH researchers. Much of this work focused at least in part on doses to Hanford and ORNL workers, and most studies addressed monitoring of external radiation. The problem of potential exposures below the level of detection is important to the degree that a significant contribution to workers' dose could be hidden by either the limits of sensitivity of the detectors or by recording practices (e.g., weekly versus quarterly reading of film badge doses) in use historically. If a significant amount of radiation dose was hidden beneath the detection limit, this would have the effect both of weakening the power of studies to detect true radiation effects, but also of tending to give an upward bias to risk estimates. A series of journal articles (Xue and Shore 2003; Xue et al. 2004; Daniels and Yiin 2006) or reports (Ostrouchov et al. 1998) discussed this problem, generally in similar terms, by introducing a model for the true dose distribution in relation to distributions of un-truncated data (for doses above the detectible limit), which provided interpolations of the distribution of true dose below the detectable limit. On a related topic, Richardson et al. (1999) addressed the question regarding whether or not all workers with likely exposure (at Hanford) were properly monitored. In general, it appears that the quality of these studies was quite high, although in some cases perhaps over-elaborate methods were recommended to deal with the problem. Nonetheless, it is apparent that useful findings came out of the studies. The recent publication by Daniels and Yiin (2006) estimates that for the PNS workers only about 1 percent or less of the total collective dose was below the detectable limit, which would imply virtually no significant effect of this issue on risk estimation. The relevance of this finding to the DOE sites is not completely clear, but other indications (such as the dose-response analyses performed by Xue and colleagues for the ORNL cohort, Xue et al. 2004), before and after correcting for doses below the detection limits using their own somewhat different modeling approach, also appeared to suggest that the truncation problem had little effect on the risk estimates. For example, in an analysis of all-cause mortality, risk estimates changed by less than 6 percent after adjustment for "missing" doses. Richardson and colleagues (1999) found that about 2 percent of collective external dose at Hanford was imparted to workers not wearing personal radiation monitors. To obtain this estimate, they used a "nearby" analysis in which doses for monitored workers in similar locations or jobs were applied to the unmonitored workers. This degree of missing dose again would appear to have very little impact on risk estimates. Similar results were

also reported by the same investigators for the Savannah River site (Richardson et al. 2006).

The performance of radiation monitoring badges over the range of external doses was addressed in several projects. Gilbert and colleagues (1996) reviewed the types of dosimeters used and the experimental methods used to calibrate the dosimeters over the history of the Hanford site. Summarizing laboratory studies designed to calibrate the dosimeters to known exposures, Gilbert and colleagues (1996) provided bias factors and estimates of the uncertainty of these bias factors for external doses of several energies and by organs of interest. The derivation of bias and uncertainty factors for external dose was extended to the DOE sites considered in the multi-site leukemia study by Daniels and Schubauer-Berrigan (2005). The view of the committee is that the work on biases of radiation dosimeters described by these two groups of investigators is scientifically sound. To date only the biases, and not the uncertainty in the biases of the external dosimeters, have been incorporated into risk estimation for the major studies or cohorts, except in the case of Hanford where Gilbert (1998) did reanalyze the data using the bias factors and uncertainties discussed in Gilbert et al. (1996). However, the committee does not believe that these uncertainties will strongly influence the overall appraisal of whether radiation effects exist at the low doses and dose rates that the workers were exposed to, although uncertainties in bias factors may have an impact on the comparability of results within these studies or to high-dose studies.

More general methodological work has been funded by NIOSH that was designed to either further develop statistical methods for empirically modeling the effect of exposures on disease (cancer) risk, when the exposures are accumulated over time throughout a worker's working lifetime (Richardson et al. 2004), or to relate these exposures to current thinking about some aspects of cancer etiology (via "mechanistic models") (Hazelton et al. 2006). While much of this work is directly relevant to the analysis of real or apparent modifications of risk by such factors as age, dose rate, etc., it does not appear to have added greatly to the existing statistical tools available for analysis this type of data. In addition, no novel techniques in this regard appear to have been developed under the MOU.

As emphasized elsewhere in this report, the problem of identifying and characterizing internal radiation dose (Wing et al. 2004), chemical exposures, and lifestyle exposures is an extremely challenging one, especially for the early time periods at the DOE sites. While efforts have gone into addressing these problems, they appear to the committee in many cases quite intractable. However, documenting both current and future radiologic and non-radiologic exposures deserves much greater attention. An important study by Silver and colleagues (2000) describing the state of exposure assessment for a relatively new class of workers (e.g., the cleanup or remediation workers) indicates that there are considerable gaps in current practices for chemical and other workplace hazard monitoring

that are exacerbated by the decentralized organization of cleanup work. While external radiation exposures for cleanup workers apparently are monitored and the data are centrally retained, chemicals and other hazards that these workers are exposed to as well as the ability to follow these workers prospectively, based on current employment record retention and practice, appear extremely limited. The identification of this gap by NIOSH in current DOE practice is an important contribution. One project funded extramurally, "Sentinel Exposure Event Surveillance/Evaluation at DOE Sites" (LaMontagne et al. 2001), sought to develop prototype databases for future exposure surveillance at DOE sites. Implementation of exposure databases by DOE is strongly recommended by this committee and the committee views this study as adding worthwhile information.

Overall, the committee's evaluation is that useful methodological work was funded. While some problems (e.g., the detection limit problem) may in retrospect seem to have been given more attention than warranted, given the likely quantity of "missed dose" (this is a judgment informed by hindsight), the committee concludes that relevant and useful work was performed.

RESEARCH PRIORITIES, SCIENTIFIC MERIT OF RESEARCH, RESEARCH DISSEMINATION, AND BENEFITS OF RESEARCH TO DOE

In the remainder of this chapter, the committee provides additional comments regarding its overall perspectives on the research priorities embodied in NIOSH research to date, the scientific merit of the studies undertaken by NIOSH, benefits to DOE provided by the research studies, the impact of these studies on DOE policies and decisions, the dissemination of research results, and the overall effectiveness of the MOU in promoting needed DOE-related occupational research. In addition, the committee provides a series of recommendations intended to enhance the effectiveness of NIOSH's DOE-related research and activities.

Research Priorities

Under the MOUs, NIOSH successfully took over and completed DOE studies that were in progress, including studies of cause-specific mortality at the Hanford and ORNL sites. Research agendas during the early years of the OERP appear to be closely aligned with the recommendations of the Secretarial Panel for the Evaluation of Epidemiologic Research Activities. In addition, many of the studies proposed by OERP at the initial meeting of ACERER in 1993 (Table 1-2 of the NIOSH evidence package; see NIOSH 2005) have been completed except for the following:

- A study of plutonium workers across DOE sites, which remains a proposal in the 5-year agenda for Department of Health and Human Services (HHS) Public Health Activities;[10]
- A case-control study of lung cancer mortality at the PNS and a multiple myeloma case-control study at the K-25 uranium enrichment facility;
- A chemical laboratory workers cohort mortality study; and
- Numerous ongoing studies focused on radiation exposure measurements.

Additional studies that NIOSH lists as uncompleted include the following:[11]

Intramural
- Chronic Lymphocytic Leukemia (CLL)
- Cohort Mortality Study of Fernald Environmental Management Plant

Extramural
- Health Effects of Occupational Exposures in Paducah Gaseous Diffusion Plant Workers
- Stochastic Models for Radiation Carcinogenesis: Temporal Factors and Dose-Rate Effects
- Susceptibility and Occupational Radiation Risks
- Radon and Cigarette Smoking Exposure Assessment in Fernald Workers

ACERER continued to provide advice to the Secretary of HHS regarding the OERP research agenda until 2000. NIOSH reports (NIOSH 2005) that since the dissolution of ACERER, the research agenda has been formulated by "the scientific staff and program managers of the OERP through public and stakeholder meetings, as well as consultation with scientific experts on research needed in specific areas."

As part of the overall OERP research agenda, NIOSH occasionally solicits proposals from extramural investigators in specific research areas. Extramural solicitations for proposals in 1994[12] focused on retrospective exposure assessment, radiation measurement issues, non-cancer morbidity and mortality outcomes, meta-analysis and combined analysis methodologies, uncertainty analysis, and effects of measurement error on risk estimates. While the most recent NIOSH extramural solicitations for proposals[13] continued to focus on a number of the above areas of research including retrospective exposure assessment, meta-analysis and combined analysis methodologies, uncertainty analysis, and effects

[10]See *http://www.cdc.gov/niosh/pdfs/hhsdoe_2005-2010-2.pdf*. Last accessed August 2006.
[11]See *http://www.cdc.gov/niosh/oerp/*. Last accessed November 2006.
[12]See *http://grants.nih.gov/grants/guide/rfa-files/RFA-OH-94-001.html*. Last accessed August 2006.
[13]See *http://grants.nih.gov/grants/guide/rfa-files/RFA-OH-02-002.html*. Last accessed August 2006.

of measurement error on risk estimates, two new categories—epidemiological analysis of the health effects of radiation and statistical modeling—were added to the solicitation. Two categories from the 1994 solicitation including non-cancer morbidity and mortality outcomes as well as radiation measurement issues were not included in the 2002 solicitation.

The majority of the areas of research opportunities, both in 1994 and as late as 2002, appropriately sought to develop methods to improve the validity of the occupational epidemiological studies. However, the category "non-cancer morbidity and mortality outcomes," which is listed in 1994 but not in 2002, sought proposals from researchers to perform epidemiological studies examining adverse health effects such as possible effects of radiation on cardiovascular disease and chronic obstructive pulmonary disease, and on the reproductive, neurologic, and immune systems as well as diseases related to beryllium and mercury exposure. The category also requested researchers to submit applications proposing to examine the identification, validation, and use of biomarkers of disease. It is clear that the primary research focus, at least for radiological exposures, is still on cancer incidence and mortality. While there is a high level of interest in the emerging evidence for cardiovascular effects in both the A-bomb survivors and some high-dose medical exposure patients (NRC 2006a), the evidence for these heath effects comes from exposures that are much higher on average than those received by the workers at the DOE sites. In the A-bomb studies the absolute numbers of excess non-cancer deaths (those due to radiation) is somewhat more than half of the excess number of solid cancer deaths (250 versus 440, respectively) and the relative risks (RRs) are even lower for non-cancer mortality, in part because the baseline number of deaths is higher. In the A-bomb study the RR per Sv for all non-cancers is about one-third of the number for all solid tumors. This means that "much" larger case-control studies would be necessary to confirm that low protracted doses also raise risks of all non-cancer mortality. As noted elsewhere in the report, and by the committee's own simplified calculations, as many as 5,000 cases and more controls would likely be required in order to demonstrate an increased risk of overall cancer mortality in relation to extended low-dose-rate worker exposures. Even larger studies will be required if non-cancer outcomes, such as cardiovascular disease, are to be considered. Numbers this large are available from the cohort studies, however important covariates (e.g., cigarette smoking) are missing for many or most cohort members, expanding the nested case-control approach for the non-cancer outcomes clearly is problematical.

Through the combination of extramural and intramural programs, the research that was performed by NIOSH and extramural scientists followed a logical sequence by

1. Extending, updating, and pooling existing cohorts and collaborating in the international studies of mortality of nuclear workers;

2. Undertaking nested case-control studies to better address confounders and to seek to improve information on internal exposures to radiation and other exposures; and

3. Undertaking or supporting special emphasis studies such as that of childhood leukemia in relation to parental occupational exposures, numerous beryllium-related studies, and so forth.

In support of this work, NIOSH investigators and projects that were extramurally funded placed importance on conducting or supporting methodological studies that dealt with statistical issues such as the effects of systematic errors in the personal dosimeters, the truncation of dose from badge readings, and the effects of dosimetric uncertainties upon epidemiological studies.

Scientific Merit of NIOSH Research

As described in other places in this review, the occupational epidemiology conducted or supported by NIOSH faced major obstacles in attempting to ascertain whether working for DOE placed workers at risk to their health, especially for those workers exposed to low dose rates of radiation for extended periods of time. Here the committee examines the question of the overall scientific merit of the studies in terms of (1) whether the overall direction of research by NIOSH and the purpose of the individual studies was meritorious; (2) whether obstacles to particular studies were so intractable that it should have been obvious at the outset that the goals would not be achievable; and (3) for feasible studies, whether NIOSH or its subcontractors conducted the research and analyzed the data appropriately. The committee notes that individual studies need to be viewed within the broader context of the overall goals of the whole program of research.

The committee finds that the scientific problems that the majority of the DOE/NIOSH studies address (e.g., the health consequences of low-dose-rate exposures over extended periods) are meritorious. Specifically, there were important and outstanding scientific issues addressed by the research under the MOU concerning the effect of chronic low dose exposures, especially in comparison to the extrapolations made from high-dose studies that have been used previously to develop radiation protection standards.

It appears to the committee that a major NIOSH effort for improving the epidemiology at DOE sites was to move from cohort mortality studies, relying on the limited amount of data[14] available for all workers in a given cohort, to nested

[14]Generally age, sex, race, and in most cases summaries of employment and external radiation dose history, as well as life status at end of follow-up and cause of death for the deceased.

case-control studies, in which information on other workplace and lifestyle exposures could be collected for the subjects in the study to evaluate possible confounding. Overall, the committee views this transition as meritorious.

Viewed in isolation and in hindsight, some of the NIOSH case-control studies might not be viewed as meritorious or feasible. For example, the multisite multiple myeloma case-control study began with the identification of 98 cases of multiple myeloma from various cohorts, all of which had summaries of external dose available (Wing et al. 1997). That number of cases matched to 4 controls per case would only have the power to detect the influence of a potential confounder that is present in 25 percent of controls and which doubles the risk of multiple myeloma. Based on this limited number of cases and also the fact that no other exposure to this cohort is thought to produce risks this large (leaving aside race, which is already considered in the cohort study), it might be reasonably argued that in isolation this case-control study should not have been initiated, e.g., that everything about multiple myeloma that could be learned in a case-control study had already been learned from the initial examination of the cohort studies. However, in the context of the transition to using a case-control study design, the multiple myeloma study is informative as a pilot study, and shows the degree to which other occupational and smoking exposure histories can or cannot be quantified. Since these same exposures will be of interest for other disease outcomes, for which many more cases are available, the multiple myeloma study has more value when viewed as a part of the whole NIOSH endeavor than in isolation.

In the committee's own simplified calculations, as many as 5,000 cases and more controls would likely be required in order to demonstrate an increased risk of overall cancer mortality in relation to extended low-dose-rate exposures. Even larger studies would be required if non-cancer outcomes, such as cardiovascular disease, were to be considered. The case-control studies that have been done to date can and should be used to evaluate the feasibility of performing case-control studies of this magnitude in the future. The finding, for example, that in the multiple myeloma study, smoking exposure could only be categorized as ever/never, even after viewing occupational medical records and after contact with survivors of the cases, should significantly affect NIOSH decisions about the feasibility of addressing smoking-related cancers or other smoking-related diseases using the case-control design.

The same general issue arises in evaluating other studies; for example, the subjects in the female nuclear workers study had a dose distribution that is lower than the cohorts overall, and therefore, studies of female workers have less power to define radiation effects than would studies of cohorts of male and female workers or a cohort of only male workers. Moreover, on an absolute risk scale, females do not appear to be more sensitive than men to radiation in the high dose studies. However, past and future DOE occupational research includes women and improving the compilation of radiation dose records and the linkage to mortality records for all DOE workers, as done for female workers in that study, is considered to be

important by the committee. Therefore, this study is also more significant in the context of the overall NIOSH research program than when viewed alone.

Regarding whether these studies were conducted properly, the committee finds that the case-control studies that NIOSH undertook appeared to have been well executed given the constraints that they operated under, some of which may have been unique to the DOE setting. There is evidence provided, for example, in the final report from the multisite multiple myeloma investigators, that the history and culture of secrecy that was associated with the weapons plants had an adverse impact upon the ability of NIOSH investigators and grantees to perform their work in a timely and complete fashion. Given the decentralized nature of management at the DOE facilities, it seems likely that any group of investigators, whether from DOE or from NIOSH, would have faced similar problems.

Overall then, while in some cases there have been serious and not fully explained delays in execution of studies (as in the K-25 multiple myeloma study), and while certain confounding exposures (e.g., smoking) appear to have been especially problematic to address in the studies that have been completed, the committee finds that the work performed by NIOSH under the MOU has been sound, especially if each project is viewed as contributing to the whole program.

It is, however, notable and disappointing to the committee that the NIOSH cohort studies have not made their fullest possible contribution to the pooled international (15 countries) studies (Cardis et al. 2005). In particular, data should have been provided to IARC to extend follow-up of the Hanford and ORNL cohorts through 1994 and 1990, respectively, in time to be included in the most recent publications available to the committee. The committee notes the importance of further pooling with international data in the committee's recommendations.

Scientific Research Dissemination

The NIOSH extramural and intramural programs have not been highly productive in terms of contributions to the peer-reviewed literature. Two of the studies reviewed above, the Female Nuclear Workers Study and the Childhood Leukemia Case Control Study, did not result in any peer-reviewed publications. Gaps in the research record include reports from long-delayed studies such the K-25 multiple myeloma case-control study. While the exposure reconstruction for the myeloma study is especially complex (e.g., internal and external radiation exposures, chemical exposures) and appears to have been subject to many administrative and security roadblocks, it is unclear to the committee why such a relatively small study of 63 cases and their age-matched controls should be delayed to such an extent.

In total, NIOSH and colleagues have published more than 88 scientific papers (16 from the intramural program) to date. Many of the NIOSH-funded "completed projects" listed in the NIOSH evidence package or on the OERP web site produced

only a final report and in some cases no report (NIOSH 2005). While the committee recognizes that not every worthwhile project will either need or merit peer-reviewed publication, and many of the unpublished reports are useful and accessible through the OERP web site, the committee expected that an overall program of this size would be more productive, especially the intramural program.

Benefits of Research to DOE

The committee concludes that positive benefits have accrued to DOE as a result of having the occupational epidemiological studies performed by agencies and investigators outside its direct control. While recognizing that a sizable body of good work had been started before the MOUs, and without implying that DOE was incapable of developing appropriate follow-up programs to the studies that were in existence, it is clear to the committee that the acceptance by the scientific community of the DOE-based work performed by NIOSH is high. In addition, the research performed under the MOU has directly benefited DOE in several ways. First, the data that have been generated by NIOSH and its extramural researchers have provided important information to DOE's Comprehensive Epidemiologic Data Resource (CEDR) that can be used in future worker health studies.

Second, and perhaps the most important contribution, is that the worker health studies have made a significant contribution to our understanding of the risks of protracted low-dose radiation exposure for human health, especially in combination with the international workers studies. The results of the 15-country IARC study (Cardis et al. 2005) show significant dose-response relationships for solid tumors and nearly significant dose response for leukemia. In combination with the very recent results from the multisite leukemia case-control study, which has relatively little overlap with the IARC study, the leukemia dose-response to this low-dose-rate, protracted exposure should also be better defined. In all likelihood, these findings will impact DOE policy directly by buttressing the current administrative limits of 2 rem per year for occupational exposure with additional empirical evidence for the effects of protracted low-dose-rate radiation exposures on cancer risk. In addition, these data may be viewed as strengthening the scientific foundations for defining acceptable levels of passive, non-occupational exposures of the larger populations living near current, future, or past (decommissioned) DOE sites. Given that Richardson and Wing (1999) reported more than 460 deaths from all cancers in a follow-up of the ORNL cohort through 1990, it is not clear why these were not utilized in the IARC 15-country study. Similarly, Wing and Richardson (2005) report follow-up of the Hanford cohort through 1994, compared to 1986 for Cardis et al. (2005). The Frome et al. (1997) study, which had 4,673 white male cancer deaths using all of the Oak Ridge workers was also not included but that study included the K-25 and Y-12 Oak Ridge sites where the workers had substantial uranium exposures.

Third, NIOSH acts in an advisory role for several of the worker surveillance

activities, including the beryllium-sensitization screening program, thereby contributing important scientific support for DOE's FWMSP.

Finally, the committee concludes that the occupational beryllium studies completed by NIOSH have made a significant contribution to the scientific community in general, as well as to DOE's understanding of the potential for beryllium exposure, sensitization, and progression of disease. The beryllium-related studies followed earlier NRC recommendations (NRC 1994) of quantifying exposures to and effects from agents in addition to ionizing radiation. The research appropriately explored several important areas of research related to beryllium and followed a logical progression of research. However, the continued poor interlaboratory and intralaboratory agreement for the BeLPT, necessitating costly split samples and compromising the validity of worker screenings, remains a concern (Stange et al. 2004; Borak et al. 2006).

Summary of Benefits to DOE

Continued research into the health of past and current DOE workers benefits DOE in the following ways:

1. It assists DOE in fulfilling obligations to its employees to provide the best possible information about health effects resulting from their employment.
2. It contributes directly to scientific knowledge regarding protracted low-dose-rate exposures to radiation that are relevant to radiation protection of nuclear workforces both in the United States and generally.
3. It enhances methods for reconstructing past exposures. The committee concludes that the continued development of such methodology is important to the evaluation of worker and public health effects at the DOE sites.
4. It adds indirectly to scientific information about the health effects of other low-dose-rate exposures of the American population as a whole to radiation. These other sources of exposure include diagnostic radiation exposures, environmental or residential exposures, or potential radiological exposures resulting from industrial accidents or an act of terrorism.

By having this work continue under the auspices of NIOSH, DOE benefits by enhancing the openness and independence with which the studies are conducted, thereby reducing public perceptions of, or actual potential for, conflicts of interest between DOE's responsibilities to the health of its workers and citizens and its other responsibilities and mandates.

FINDINGS AND RECOMMENDATIONS

1. Completion of Ongoing Projects

The committee noted in its review of the NIOSH program that a number of studies remain unfinished. The committee therefore recommends that:

The multisite leukemia case-control study be completed as soon as possible and the results published. In addition, the scientific value of completing the long-delayed K-25 multiple myeloma study as well as the Chemical Workers study[15] in their entirety or limited to selected specific aims should be critically evaluated prior to any additional funding. The remaining unfinished studies (see Research Priorities section above) should be evaluated and prioritized by NIOSH and DOE for future funding decisions.

2. Development and Integration of a Repository for Exposure Records

As will be discussed in more detail in chapter 6, "one of the biggest problems affecting the program has been the difficulty researchers have had in obtaining exposure and other relevant data to use in their epidemiological studies. Common data collection protocols and standardized data are needed for epidemiology and public health studies. The fundamental problem was that the worker exposure data had never been collected, processed, or stored with any regard to the possibility that they might be needed in the future for such studies. This situation leads to difficulty in comparing health outcomes with exposure characteristics and in the investigators' ability to combine information from more than one source in order to increase the power of the studies. The committee recommends that:

All contractor-assembled data be submitted to DOE's Office of Environmental Safety and Health for compilation, management, and storage in centralized databases, using standardized formats. DOE should explore the development of a process that captures current exposure data as well as health outcome data for placement in a secure centralized repository: this process should include external radiation exposure, internal radiation exposure, chemical exposure, medical surveillance (e.g., spirometry, liver function tests, smoker versus never smoker), and biological monitoring, as well as social security number and demographic information (e.g., gender, birth date) on a continual basis for all DOE employees, DOE contractors, and DOE subcontractors who may have occupational exposures to radiation or toxic chemicals. The database would have to be integrated with existing data repositories, (e.g., Radiation Exposure Monitoring System, CEDR). However, unlike CEDR, which facilitates public access to data collected for studies regarding the health impacts associated with working at or living near DOE operations, information compiled in the recommended repository

[15]"The chemical workers study addresses hazards outside the DOE complex, including chemical and mixed exposures. The sites selected include Savannah River and three facilities at Oak Ridge (X-10, Y-12, and K-25). To address sample size needs, a fifth site (Hanford) is under evaluation for inclusion." Abstracted from *http://www.cdc.gov/niosh/oerp/ongoing.html.* Last accessed September 2006.

would be available to NIOSH's scientific investigators or to researchers funded extramurally through NIOSH to perform DOE-related health studies. Such a database would be of paramount importance for expanding existing cohort studies or performing nested case-control studies.

3. Improved Techniques to Reconstruct Past Exposure

The committee finds that continued research into the health of the past and current DOE workforce benefits DOE by enhancing methods of reconstructing past exposures and that the continued development of such methodology is important to the evaluation of worker and public health effects at the DOE sites. The committee therefore recommends:

Further investigation into the utility of novel methods to reconstruct dose, such as fluorescence in situ hybridization, the glycophorin A somatic mutation assay (GPA), in vivo electron paramagnetic resonance of teeth, and other promising biologic markers, should be given a high priority.[16] In addition, NIOSH should continue to support methodological studies that address statistical issues such as the effects of systematic errors in the personal dosimeters, the truncation of dose from badge readings, and the effects of dosimetric uncertainties upon epidemiological studies.

As noted repeatedly in the committee's assessment of the quality of the studies performed by NIOSH, the objective of adequately reconstructing retrospective radiation and chemical exposures is paramount. Although biologic materials may not be available for a significant portion of each cohort, these novel methods may be helpful as validation methods for existing dose reconstructions.

In addition, because of the lack of a reliable screening test to detect workers who have been sensitized to beryllium, the committee recommends that any future beryllium-related research focus first on developing a substantially improved screening tool to identify beryllium-sensitized workers.

4. Continued Mortality Follow-up of Existing Cohorts

The latest published follow-up for any of the DOE cohorts ended in the mid-1990s when considerably more than half of the participants in these studies were still alive. The numbers of cause-specific deaths for any particular facility are still relatively small and further follow-up of the study cohorts will provide a larger number of deaths for analyses. Therefore, the committee recommends that:

Follow-up of the existing cohorts be continued for all causes of mortality and possibly for cancer incidence (see recommendation 7) and that analyses of these data be updated on a regular basis. Cardiovascular

[16]The committee recognizes that the uncertainty at low doses is very large for these techniques and that this fact may limit the usefulness of such techniques for the mostly low doses received by the DOE workers.

disease mortality as well as cancer mortality (both known to be related to high-dose radiation) should be specifically addressed in these updated analyses. As much attention should be paid as possible to the influence of other exposures that may confound the radiation relationship while recognizing the limitations of these studies in this regard.

5. Development of an Overall Strategy for Selecting Sites for Pooled Analyses of Cancer Mortality

The committee recommends a phased approach toward further pooling of DOE and international nuclear workers studies. The initial phase would be for NIOSH to provide a justification for pooling particular DOE sites and cohorts based on the completeness and accuracy of radiation exposure data and on the site-specific potential for confounding between measured external radiation exposures and unmeasured (e.g., internal radiation, chemical, asbestos) exposures.

Deficiencies in data quality or the percent completeness of radiation dose should be resolved before undertaking further pooled analyses. For some tumor types (e.g., lung) it is questionable whether further analyses are warranted if potential confounders, particularly tobacco use, cannot be addressed. In addition, consideration should be given to sensitivity analyses that address uncertainty in risk estimates due to incomplete and biased data. These analyses should incorporate reasonable assumptions about correlations between observed radiation dose and the other exposures or confounders that are relevant for major cancer sites.

If further pooling appears justified, then updated data from ORNL and Hanford as well as data from other DOE sites that pass the initial screen should be made available to IARC in the event that updated analyses of the 15-country study are conducted. Until that occurs, statistical methods for combining the updated DOE cohort datasets with the published data from IARC for the non-DOE sites should be considered as an approximation to an updated full pooled analysis.

6. Additional Nested Case-Control Studies

NIOSH provided two short concept plans (identified as FY06 High-LET.pdf and FY06 Low-LET.pdf) that propose to extend the use of the multisite case-control studies for DOE sites (and including Navy sites such as PNS) to the study of solid tumor mortality. Such studies should be carefully justified. NIOSH also conducted nested case-control studies to better address confounders and to seek to improve information on internal exposures to radiation and other exposures. The committee finds that planning of additional nested case-control studies of solid tumors should include the following:

- The scientific advantages and disadvantages of developing combined analyses of risk for all solid tumor sites and the scientific advantages and disad-

vantages of separate analyses of specific tumor types should be carefully assessed.

- The quality of the data on smoking that will be available in the case-control studies on a site-by-site basis should be assessed carefully. Careful assessment of the correlation of unmeasured smoking with radiation dose, and the likely effects of such correlation in biasing risk estimates, will have to be addressed. If the quality of the smoking data is deficient, NIOSH may wish to consider restricting case-control studies to cancers not strongly associated with smoking.
- Realistic power calculations should be obtained.
- The likely value of job exposure matrix-based methods for retrospectively assigning exposures to chemicals, asbestos, and other workplace toxicants should realistically be assessed.

This preliminary phase of the study will be an essential part of an informed decision about whether to proceed with full-scale studies. Such preliminary studies will also have considerable impact on the conduct of pooled analyses of mortality data described above. Sites that do not meet criteria for inclusion in the case-control studies should not be included in the pooled analyses of existing data. Therefore, the committee recommends:

> That NIOSH proceed with the careful planning of additional nested case-control studies of solid tumors. Without implication for past study designs, the planning phase for future studies should include the considerations described in the findings above.

7. Use of the State Cancer Registries to Assess Cancer Incidence

There are some important advantages to studying cancer incidence in addition to cancer mortality in cohort studies. First, the power to detect effects of exposure for non-uniformly fatal cancers is increased. Second, coding of specific sites of cancer, or even documenting cancer as a contributing factor to death, is more precise. For example, death records may not be clear about the origin of metastases and the role of primary versus secondary cancers as a cause of death. Starting in 1994, the Centers for Disease Control and Prevention-supported National Program of Cancer Registries has provided funds and oversight for the development of cancer registries in all 50 states. These registries provide the opportunity to link future follow-up of the DOE cohorts to state cancer registries to identify incident cancers in this population for a follow-up period beginning in the mid- to late 1990s. An intramural NIOSH project (Foster and Espinoza 2000) examined population-based state cancer registries to determine their feasibility and suitability for occupational studies. Information was collected from statewide cancer registries in 16 states, including those that contained DOE sites and adjacent states. Despite limitations in statewide cancer registry systems, the study concluded that it is feasible to use many statewide registries for occupational health studies. By the mid-1990s, more than half of the workers involved in the major DOE occupational

cohorts were still alive, although, because radiation exposures to workers have greatly decreased over time, some of the higher-exposed workers may have died prior to the establishment of the registries. Nonetheless, in many cases the majority of information from these cohorts regarding the risk of both generally fatal cancers with a long latency period and cancers with better survival (e.g., thyroid cancer, chronic lymphocytic leukemia, prostate cancer) may be yet to come. Therefore, the committee recommends:

> Establishing linkages between existing cohorts and the 50 state cancer registries.

8. Increase the number of peer-reviewed publications.

The committee finds that the NIOSH extramural and intramural programs have not been highly productive in terms of contributions to the peer-reviewed literature. Two of the studies reviewed, the Female Nuclear Workers Study and the Childhood Leukemia Case Control Study, did not result in any peer-reviewed publications. Gaps in the research record include reports from long-delayed studies such the K-25 multiple myeloma case-control study. While the exposure reconstruction for the myeloma study is especially complex (e.g., internal and external radiation exposures, chemical exposures) and appears to have been subject to many administrative and security roadblocks, it is unclear to the committee why such a relatively small study of 63 cases and their age-matched controls should be delayed to such an extent. In total, NIOSH and colleagues have published more than 88 scientific papers (16 from the intramural program) to date. Many of the NIOSH-funded "completed projects" listed in the NIOSH evidence package or on the OERP web site produced only a final report and in some cases no report (NIOSH 2005). While the committee recognizes that not every worthwhile project will either need or merit peer-reviewed publication, and many of the unpublished reports are useful and accessible through the OERP web site, the committee expected that an overall program of this size would be more productive, especially the intramural program. The committee finds that the NIOSH extramural and intramural programs have not been highly productive in terms of contributions to the peer-reviewed literature. Therefore, the committee recommends:

> NIOSH should increase substantially the number of intramural scientific research findings that are submitted to high-quality scientific journals.

9. Future Studies

The committee concludes that future studies should represent all categories of workers (e.g., contract cleanup workers and others) on DOE sites with potential exposures. These future studies should also include diseases in addition to cancer. Since non-cancer outcomes may not be accurately ascertained through death certificates, other methods of data collection including questionnaires, physical examinations, and diagnostic tests should be considered. Much is likely to be learned in the future about baseline genetic susceptibility to cancer and other diseases, and it will be of increasing importance to determine whether

individuals with a higher baseline risk of disease, because of inherited variation, also have higher excess risks from exposure. Similarly, genes found to confer sensitivity to high-dose radiation exposures, such as those now being evaluated in studies of second cancers following radiation therapy, should also be studied in people with protracted exposure to radiation at low-dose rates. The committee recommends that:

> As these questions surface in the future, NIOSH and DOE explore the possibility of addressing them through studies that utilize DNA from DOE workers diagnosed with cancer and from controls. To facilitate these future studies DOE and NIOSH should consider the following:
>
> • Establishment of a database of workers with appropriate data to facilitate follow-up and to evaluate potential confounders (e.g., see recommendation 2);
> • Development of valid methods to identify non-cancer health outcomes including the use of periodic questionnaires, and specific diagnostic tests (e.g., pulmonary function); and
> • Support for the continuance of biorepositories such as that funded by ATSDR (Gunter 1997; NRC 2006b) that archive specimens such as blood and DNA to support future studies.

ANNEX 2A NIOSH RESEARCH PUBLICATIONS

NIOSH provided independently (NIOSH 2005), and also in response to committee requests, information detailing the DOE-funded output of the NIOSH OERP program. In addition, the committee accessed the NIOSH OERP website,[17] which is periodically updated with new publications that cite OERP funding. These sources also identified the material as intramural and extramural. That information was updated during the committee's 10-month study period and is included in Table 2A-1 that follows. The table is based on information received from NIOSH May 9, 2006. NIOSH noted in responding to a committee information request that: ". . . the bibliography has been revised and updated to include all known publications that acknowledge whole or partial funding by DOE through the NIOSH Occupational Energy Research Program. This includes those studies funded directly by DOE between 1991 and 1993 but overseen by NIOSH under the OERP. Studies and literature that may relate to the OERP but did not acknowledge either DOE or NIOSH funding were not included. The committee should be aware that, for grants, there is no requirement that grantees report publications to NIOSH; therefore, we have identified many of these publications

[17] http://www.cdc.gov/niosh/oerp/

through literature searches and inspection of the acknowledgments for mention of NIOSH grant numbers." This committee has not included certain categories from the provided list, such as extended abstracts. The committee also notes that the NIOSH Intramural and Extramural catagories are apparently classified as such for NIOSH record-keeping purposes. For example, NIOSH lists the Cardis 15-country publication as "intramural" while the funding for the study came from multiple sources. The complete and current OERP program output can be accessed at http://www.cdc.gov/niosh/oerp/ (last accessed October 2006).

TABLE 2A-1 NIOSH Research Supported by DOE Including Papers Published in Refereed Journals by Intramural and Extramural Investigators

Subject	Site if Applicable	Reference
		Intramural Peer-Reviewed Journal Articles
Evaluation of an unanticipated contaminant		Ahrenholz SH [1996]. Case studies: A mysterious yellow-white paste: evaluation of an unanticipated contaminant. Appll Occup Environ Hyg 11(12)1371-1375.
Radiation exposure from work-related chest X-rays		Cardarelli J, Spitz H, Rice C, Buncher R, Elson H, Succop P [2002]. Significance of radiation exposure from work-related chest X-rays for epidemiological studies of radiation workers. Am J Ind Med 42(6):490-501.
Proposed model for estimating dose to inhabitants of ^{60}Co contaminated buildings	Taiwan	Cardarelli EL, Hornung R, Chang WP [1997]. Proposed model for estimating dose to inhabitants of ^{60}Co-contaminated buildings. Health Phys 72(3):351-360.
Risk of cancer after low doses of ionizing radiation	15 countries	Cardis E, Vrijheid M, Blettner M, Gilbert E, Hakama M, Hill C, Howe G, Kaldor J, Muirhead CR, Schubauer-Berigan MK, Yoshimura T, and the international study group [2005]. Risk of cancer after low doses of ionising radiation—retrospective cohort study in 15 countries. Brit Med J 327:765-768.[a]
Plutonium exposures for an epidemiological study of U.S. nuclear workers	Multisite	Daniels RD, Lodwick CJ, Schubauer-Berigan MK, Spitz HB [2006]. Assessment of plutonium exposures for an epidemiological study of US nuclear workers. Radiat Prot Dosimetry 118(1):43-55.
Bias and uncertainty of penetrating photon dose measured by film dosimeters		Daniels RD, Schubauer-Berigan MK [2005]. Bias and uncertainty of penetrating photon dose measured by film dosemeters in an epidemiological study of US nuclear workers. Radiat Prot Dosimetry 113(3):275-289.

Radiation exposure assessment	Portsmouth Naval Shipyard	Daniels RD, Taulbee TD, Chen P [2004]. Radiation exposure assessment for Portsmouth Naval Shipyard health studies. Radiat Prot Dosimetry 111(2):139-150.
Estimation of less than detectable ionizing radiation exposures		Daniels RD, Yiin J [2006]. Estimation of less than detectable ionizing radiation exposures. Radiat Prot Dosimetry Mar 3; [Epub ahead of print].
Leukemia mortality and ionizing radiation	Portsmouth Naval Shipyard	Kubale TL, Daniels RD, Yiin JH, Couch J, Schubauer-Berigan MK, Kinnes GH, Silver SR, Nowlin SJ, Chen P [2005]. A nested case-control study of leukemia mortality and ionizing radiation at the Portsmouth Naval Shipyard. Radiat Res 164(6):810-819.
Use of historical uranium air sampling data to estimate worker exposure		Methner MM, Feng HA, Utterback DF [2001]. Use of historical uranium air sampling data to estimate worker exposure potential to airborne radioactive particulate in a uranium processing facility. Appl Occup Environ Hyg 16(12):1150-1157.
Identification of potential sources of arsenic exposure		Methner MM [2004]. Identification of potential sources of arsenic exposure during scrapyard work at a former uranium enrichment facility. J Occup Environ Hyg 1(9):D96-D100.
Diagnostic radiation and risk of multiple myeloma		Robinson C, Cardarelli J, Spitz HB, Utterback DF [2002]. Re: Diagnostic radiation and the risk of multiple myeloma (United States). Cancer Causes Control 13(10):975; author reply 977.
Leukemia mortality among radiation-exposed workers		Schubauer-Berigan MK, Wenzl TB [2001]. Leukemia mortality among radiation-exposed workers. Occup Med 16(2):271-287.
Differences in mortality by radiation monitoring status	Portsmouth Naval Shipyard	Silver SR, Daniels RD, Taulbee TD, Zaebst DD, Kinnes GM, Couch JR, Kubale TL, Yiin JH, Schubauer-Berigan MK, Chen PH [2004]. Differences in mortality by radiation monitoring status in an expanded cohort of Portsmouth Naval Shipyard workers. J Occup Environ Med 46(7):677-690.
Magnetic field exposures of rail maintenance workers		Wenzl TB [1997]. Estimating magnetic field exposures of rail maintenance workers. Am Ind Hyg Assoc J 58(9):667-671.

continued

TABLE 2A-1 Continued

Subject	Site if Applicable	Reference
Assessment of magnetic field exposures for a mortality study at a uranium enrichment plant		Wenzl TB [1999]. Assessment of magnetic field exposures for a mortality study at a uranium enrichment plant. Am Ind Hyg Assoc J 60(6):818-824.
Risk of lung cancer and leukemia from exposure to ionizing radiation	Portsmouth Naval Shipyard	Yiin JH, Schubauer-Berigan MK, Silver SR, Daniels RD, Kinnes GM, Zaebst DD, Couch JR, Kubale TL, Chen PH [2005]. Risk of lung cancer and leukemia from exposure to ionizing radiation and potential confounders among workers at the Portsmouth Naval Shipyard. Radiat Res 163(6):603-613.
In Press		
Bone marrow dose estimates		Anderson JL, Daniels RD [in press]. Bone marrow dose estimates from work-related medical X-ray examinations given between 1943 and 1966 for personnel from five U.S. nuclear facilities. Health Phys.
The 15-country collaborative study of cancer risk among radiation workers in the nuclear industry: study of errors in dosimetry	15 countries	Thierry-Chef I, Marshall M, Fix JJ, Bermann F, Gilbert ES, Hacker C, Heinmiller B, Murray W, Pearce MS, Utterback D, Bernar J, Deboodt P, Eklof M, Griciene B, Holan K, Hyvonen H, Kerekes A, Lee M-C, Moser M, Pernicka F, Cardis E [in press]. The 15-country collaborative study of cancer risk among radiation workers in the nuclear industry: study of errors in dosimetry. Radiat Res.
Extramural Peer-Reviewed Journal Articles		
Characteristics of the healthy survivor effect	Hanford	Baillargeon J, Wilkinson GS [1999]. Characteristics of the healthy survivor effect among male and female Hanford workers. Am J Ind Med 35(4):343-347.

Characteristics of the healthy worker effect	Hanford	Baillargeon J, Wilkinson G, Rudkin L, Baillargeon G, Ray L [1998]. Characteristics of the healthy worker effect: a comparison of male and female occupational cohorts. J Occup Environ Med 40(4):368-373.
Biodosimetry of Chernobyl cleanup workers	Chernobyl	Bigbee WL, Jensen RH, Veidebaum T, Tekkel M, Rahu M, Stengrevics A, Auvinen A, Hakulinen T, Servomaa K, Rytomaa T, et al. [1997] Biodosimetry of Chernobyl cleanup workers from Estonia and Latvia using the glycophorin A in vivo somatic cell mutation assay. Radiat Res, 147(2):215-24.
Lung cancer and internal lung doses among plutonium workers	Rocky Flats site	Brown SC, Schonbeck MF, McClure D, Baron AE, Navidi WC, Byers T, Ruttenber AJ [2004]. Lung cancer and internal lung doses among plutonium workers at the Rocky Flats Plant: a case-control study. Am J Epidemiol 15;160(2):163-172.
Lung cancer and plutonium exposure	Rocky Flats site	Brown SC, Ruttenber AJ [2005]. Lung cancer and plutonium exposure in Rocky Flats workers. Radiat Res 163(6):696-697.
Direct estimates of cancer mortality due to low doses of ionizing radiation	3 countries	Cardis E, Gilbert ES, Carpenter L, Howe G, Kato I, Levé EC, Armstrong BK [1994]. Direct estimates of cancer mortality due to low doses of ionising radiation: an international study. IARC Study Group on Cancer Risk Among Nuclear Industry Workers. Lancet 344(8929):1039-1043.
Cancer mortality among nuclear industry workers in three countries	3 countries	Cardis E, Gilbert ES, Carpenter L, Howe G, Kato I, Armstrong BK, Beral V, Cowper G, Douglas A, Fix J, et al. [1995]. Effects of low doses and low dose rates of external ionizing radiation: cancer mortality among nuclear industry workers in three countries. Radiat Res 142(2):117-132.
Chronic health risks from aggregate exposures to ionizing radiation and chemicals		Chen WC, McKone TE [2001]. Chronic health risks from aggregate exposures to ionizing radiation and chemicals: scientific basis for an assessment framework. Risk Anal 21(1):25-42.

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TABLE 2A-1 Continued

Subject	Site if Applicable	Reference
Risk factors associated with the classification of unspecified and/or unexplained causes of death	Oak Ridge	Cragle DL, Fetcher A [1992]. Risk factors associated with the classification of unspecified and/or unexplained causes of death in an occupational cohort. Am J Public Health 82(3):455-457. Comment: Am J Public Health 83(10):1492-1493.
Case-control study of brain tumors and ionizing radiation		Dimarco JH, Wilkinson GS [1995]. Case-control study of brain-tumors and ionizing-radiation nested within a cohort of nuclear workers. Am J Epidemiol 14(11):S30-S30.
Falls in workers during pregnancy		Dunning K, LeMasters G, Levin L, Bhattacharya A, Alterman T, Lordo K [2003]. Falls in workers during pregnancy: risk factors, job hazards, and high risk occupations. Am J Ind Med 44(6):664-672.
Uranium dust exposure and lung cancer risk in four uranium processing operations	Oak Ridge National Laboratory	Dupree EA, Watkins JP, Ingle JN, Wallace PW, West CM, Tankersley WG [1995]. Uranium dust exposure and lung cancer risk in four uranium processing operations. Epidemiology 6(4):370-375.
External radiation exposure and mortality		Dupree-Ellis E, Watkins J, Ingle JN, Phillips J [2000]. External radiation exposure and mortality in a cohort of uranium processing workers. Am J Epidemiol 152(1):91-95.
Mortality study of employees of the nuclear industry	Oak Ridge National Laboratory	Frome EL, Cragle DL, Watkins JP, Wing S, Shy CM, Tankersley WG, West CM [1997]. A mortality study of employees of the nuclear industry in Oak Ridge, Tennessee. Radiat Res 148(1):64-80.
Health and mortality among contractor employees	Multisite	Fry SA, Cragle DL, Crawford-Brown DJ, Dupree EA, Frome EL, Gilbert ES, Petersen GR, Shy CH, Tankersley WG, Voelz GL, Wallace PW, Watkins JP, Watson JE, Wiggs LD [1995]. Health and mortality among contractor employees at US Department of Energy facilities. Radiation and Public Perception; Adv Chem 243:239-258.

Mortality and morbidity among persons occupationally exposed to >50 mSv in a year	Multisite	Fry SA, Dupree EA, Sipe AH, Seiler DL, Wallace PW [1996]. A study of mortality and morbidity among persons occupationally exposed to >50 mSv in a year: phase I, mortality through 1984. Appl Occup Environ Hyg 11(4):3343-3343.
Updated analyses of combined mortality data	Hanford Site, Oak Ridge National Laboratory, and Rocky Flats Plant	Gilbert ES, Cragle DL, Wiggs LD [1993]. Updated analyses of combined mortality data for workers at the Hanford Site, Oak Ridge National Laboratory, and Rocky Flats Weapons Plant. Radiat Res 136(3):408-421.
Accounting for bias in dose estimates		Gilbert ES, Fix JJ [1995]. Accounting for bias in dose estimates in analyses of data from nuclear worker mortality studies. Health Phys 68(5):650-660.
Mortality of workers	Hanford Site	Gilbert ES, Omohundro E, Buchanan JA, Holter NA [1993]. Mortality of workers at the Hanford Site: 1945-1986. Health Phys 64(6):577-590.
Evaluating bias and uncertainty in estimates of external dose	Hanford Site	Gilbert ES, Fix JJ, and Baumgartner WV. 1996. An approach to evaluating bias and uncertainty in estimates of external dose obtained from personal dosimeters. Health Phys 70:336-345.
Accounting for errors in dose estimates	Hanford Site	Gilbert ES. 1998. Accounting for errors in dose estimates used in studies of workers exposed to external radiation. Health Phys 74:22-29.
Glycophorin A as a biological dosimeter (biomarker study)		Jensen RH, Reynolds JC, Robbins J, Bigbee WL, Grant SG, Langlois RG, Pineda JD, Lee T, Barker WC [1997]. Glycophorin A as a biological dosimeter for radiation dose to the bone marrow from iodine-131. Radiat Res 147(6):747-752.
Beryllium particulate exposure and disease relations		Kelleher PC, Martyny JW, Mroz MM, Maier LA, Ruttenber AJ, Young DA, Newman LS [2001]. Beryllium particulate exposure and disease relations in a beryllium machining plant. J Occup Environ Med 43(3):238-249.

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TABLE 2A-1 Continued

Subject	Site if Applicable	Reference
Studies of cancer risk among Chernobyl liquidators	Chernobyl	Kesniiniene A, Cardis E, Tenet V, Ivanov VK, Kurtinaitis J, Malakhova I, Stengrevics A, Tekkel M [2002]. Studies of cancer risk among Chernobyl liquidators: materials and methods. J Radiol Prot 22(3A):A137-A141.
Exposure surveillance for chemical and physical hazards		LaMontagne AD, Ruttenber AJ, Wegman DH [2000]. Exposure surveillance for chemical and physical hazards. In Maizlish N, ed. Workplace Health Surveillance: Principles and Practice. New York: Oxford University Press, 219-234.
Exposure surveillance		LaMontagne AD, Herrick RF, Van Dyke MV, Martyny JW, Ruttenber AJ [2002]. Exposure databases and exposure surveillance: promise and practice. AIHA J 63(2):205-212.
Cleanup worker exposures		LaMontagne AD, Van Dyke MV, Martyny JW, Ruttenber AJ [2001]. Cleanup worker exposures to hazardous chemicals at a former nuclear weapons plant: piloting of an exposure surveillance system. Appl Occup Environ Hyg 16(2):284-290.
Development of an exposure database		LaMontagne AD, Van Dyke MV, Martyny JW, Simpson MW, Holwager LA, Clausen BM, Ruttenber AJ[2002]. Development and piloting of an exposure database and surveillance system for DOE cleanup operations. Department of Energy. AIHA J 63(2):213-224.
Latency analysis in epidemiological studies	Colorado Plateau uranium miners	Langholz B, Thomas D, Xiang A, Stram D [1999]. Latency analysis in epidemiological studies of occupational exposures: application to the Colorado Plateau uranium miners cohort. Am J Ind Med 35(3):246-256.[a]
Residual neurologic deficits after occupational exposure to elemental mercury	Oak Ridge Y-12	Letz R, Gerr F, Cragle D, Green RC, Watkins J, Fidler AT [2000]. Residual neurologic deficits 30 years after occupational exposure to elemental mercury. Neurotoxicology 21(4):459-474.

Mortality of workers at a nuclear materials production plant	Oak Ridge National Laboratory	Loomis DP, Wolf SH [1996]. Mortality of workers at a nuclear materials production plant at Oak Ridge, Tennessee, 1947-1990. Am J Ind Med 29(2):131-141. Comment: Am J Ind Med 1997 31(1):121.
Aerosols generated during beryllium machining		Martyny JW, Hoover MD, Mroz MM, Ellis K, Maier LA, Sheff KL, Newman LS [2000]. Aerosols generated during beryllium machining. J Occup Environ Med 42(1):8-18.
Dose estimation	Oak Ridge National Laboratory	Mitchell TJ, Ostrouchov G, Frome EL, Kerr GD [1997]. A method for estimating occupational radiation dose to individuals, using weekly dosimetry data. Radiat Res 147(2):195-207.
Beryllium		Newman LS, Mroz MM, Balkissoon R, Maier LA [2005]. Beryllium sensitization progresses to chronic beryllium disease: a longitudinal study of disease risk. Am J Respir Crit Care 171(1):54-60.
Beryllium		Newman LS, Mroz MM, Maier LA, Daniloff EM, Balkissoon R [2001]. Efficacy of serial medical surveillance for chronic beryllium disease in a beryllium machining plant. J Occup Environ Med 43(3):231-237.
Lung fibrosis in plutonium workers		Newman LS, Mroz MM, Ruttenber AJ [2005]. Lung fibrosis in plutonium workers. Radiat Res 164(2):123-131.
Downsizing and health at the DOE		Pepper L, Messinger M, Weinberg J, Campbell R [2003]. Downsizing and health at the United States Department of Energy. Am J Ind Med 44(5):481-491.
Lung cancer mortality among workers	Oak Ridge National Laboratory	Richardson D, Wing S [2006]. Lung cancer mortality among workers at a nuclear materials fabrication plant. Am J Ind Med 49(2):102-111.
Healthy worker survivor effect		Richardson D, Wing S, Steenland K, McKelvey W [2004]. Time-related aspects of the healthy worker survivor effect. Ann Epidemiol 14(9):633-639.

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TABLE 2-A-1 Continued

Subject	Site if Applicable	Reference
Evaluation of annual external radiation doses	Hanford	Richardson D, Wing S, Watson J, Wolf S [2000]. Evaluation of annual external radiation doses at values near minimum detection levels of dosimeters at the Hanford nuclear facility. J Expo Anal Environ Epidemiol 10(1):27-35.
Missing radiation dosimetry data	Hanford	Richardson D, Wing S, Watson J, Wolf S [1999]. Missing annual external radiation dosimetry data among Hanford workers. J Expo Anal Environ Epidemiol 9(6):575-585.
Greater sensitivity to ionizing radiation at older age	Oak Ridge National Laboratory	Richardson DB, Wing S [1999]. Greater sensitivity to ionizing radiation at older age: follow-up of workers at Oak Ridge National Laboratory through 1990. Int J Epidemiol 28(3):428-436.
Age differences in the effects of prolonged exposures	Oak Ridge National Laboratory	Richardson DB, Wing S [1998]. Methods for investigating age differences in the effects of prolonged exposures. Am J Ind Med 33(2):123-130.
Radiation and mortality of workers	Oak Ridge National Laboratory	Richardson DB, Wing S [1999]. Radiation and mortality of workers at Oak Ridge National Laboratory: positive associations for doses received at older ages. Environ Health Perspect 107(8):649-656.
Radiation exposure and cancer mortality		Ritz B [1999]. Radiation exposure and cancer mortality in uranium processing workers. Epidemiology 10(5):531-538.
Chronic beryllium disease		Rosenman K, Hertzberg V, Rice C, Reilly MJ, Aronchick J, Parker JE, Regovich J, Rossman M [2005]. Chronic beryllium disease and sensitization at a beryllium processing facility. Environ Health Perspect 113(10):1366-1372.

Integrating workplace exposure databases		Ruttenber AJ, McCrea JS, Wade TD, Schonbeck MF, LaMontagne AD, Van Dyke MV, Martyny JW [2001]. Integrating workplace exposure databases for occupational medicine services and epidemiological studies at a former nuclear weapons facility. Appl Occup Environ Hyg 16(2):192-200.
Improving estimates of exposures for epidemiological studies of plutonium workers		Ruttenber AJ, Schonbeck M, McCrea J, McClure D, Martyny J [2001]. Improving estimates of exposures for epidemiological studies of plutonium workers. Occup Med 16(2):239-258.
Structure and function of occupational health services	Multisite	Salazar MK, Takaro TK, Ertell K, Gochfeld M, O'Neill S, Connon C, Barnhart S [1999]. Structure and function of occupational health services within selected Department of Energy sites. J Occup Environ Med 41(12):1072-1078.
Evaluation of factors affecting hazardous waste workers' use of respiratory protective equipment	Hanford	Salazar MK, Connon C, Takaro TK, Beaudet N, Barnhart S [2001]. An evaluation of factors affecting hazardous waste workers' use of respiratory protective equipment. AIHA J 62(2):236-245.
Respiratory protective equipment use	Hanford	Salazar MK, Takaro TK, Connon C, Ertell K, Pappas G, Barnhart S [1999]. A description of factors affecting hazardous waste workers' use of respiratory protective equipment. Appl Occup Environ Hyg 14(7):470-478.
Beryllium contamination		Sanderson WT, Henneberger PK, Martyny J, Ellis K, Mroz MM, Newman LS [1999]. Beryllium contamination inside vehicles of machine shop workers. Appl Occup Environ Hyg 14(4):223-230.
Beryllium contamination		Sanderson WT, Henneberger PK, Martyny J, Ellis K, Mroz MM, Newman LS [1999]. Beryllium contamination inside vehicles of machine shop workers. Am J Ind Med Suppl 1:72-74.
Chronic beryllium disease		Sawyer RT, Maier LA, Kittle LA, Newman LS [2002]. Chronic beryllium disease: a model interaction between innate and acquired immunity. Int Immunopharmacol 2(2-3):249-261.

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TABLE 2A-1 Continued

Subject	Site if Applicable	Reference
Mortality from dementia within a pooled cohort of female nuclear weapons workers	Multisite	Sibley RF, Moscato BS, Wilkinson GS, Natarajan N [2003]. Nested case-control study of external ionizing radiation dose and mortality from dementia within a pooled cohort of female nuclear weapons workers. Am J Ind Med 44(4):351-358.
Correcting for exposure measurement error in uranium miner studies		Stram DO, Huberman M, Langholz B [2000]. Correcting for exposure measurement error in uranium miners studies: impact on inverse dose-rate effects. Radiat Res 154(6):738-739; Discussion 739-740.[b]
Power and uncertainty analysis of epidemiological studies of radiation-related disease risk		Stram DO, Kopecky KJ [2003]. Power and uncertainty analysis of epidemiological studies of radiation-related disease risk in which dose estimates are based on a complex dosimetry system: some observations. Radiat Res 160(4):408-417.[b]
Correcting for exposure measurement error		Stram DO, Langholz B, Huberman M, Thomas DC [1999]. Correcting for exposure measurement error in a reanalysis of lung cancer mortality for the Colorado Plateau uranium miners cohort. Health Phys 77(3):265-275.[b]
Barriers and solutions in implementing occupational health and safety services	Hanford	Takaro TK, Ertell K, Salazar MK, Beaudet N, Stover B, Hagopian A, Omenn G, Barnhart S [2000]. Barriers and solutions in implementing occupational health and safety services at a large nuclear weapons facility. J Healthc Qual 22(6):29-37.
Impact of a worker notification program		Tan-Wilhelm D, Witte K, Liu WY, Newman LS, Janssen A, Ellison C, Yancey A, Sanderson W, Henneberger PK [2000]. Impact of a worker notification program: assessment of attitudinal and behavioral outcomes. Am J Ind Med 37(2):205-213.
A method to assess predominant energies of exposure	Saclay (France)	Thierry-Chef I, Cardis E, Ciampi A, Delacroix D, Marshall M, Amoros E, Bermann F [2001]. A method to assess predominant energies of exposure in a nuclear research centre—Saclay (France). Radiat Prot Dosimetry 94(3):215-225.

Dosimeters		Thierry-Chef I, Pernicka F, Marshall M, Cardis E, Andreo P [2002]. Study of a selection of 10 historical types of dosemeter: variation of the response to Hp(10) with photon energy and geometry of exposure. Radiat Prot Dosimetry 102(2):101-113.
Development of an exposure database		Van Dyke MV, LaMontagne AD, Martyny JW, Ruttenber AJ [2001]. Development of an exposure database and surveillance system for use by practicing OSH professionals. Appl Occup Environ Hyg 16(2):135-143.
Collection, validation, and treatment of data for a mortality study	Oak Ridge National Laboratory	Watkins JP, Cragle, DL, Frome EL, Reagan JL, West CM, Crawford-Brown D, Tankersley WG [1997]. Collection, validation, and treatment of data for a mortality study of nuclear workers. Appl Occup Environ Hyg 12(3):195-205.
Age-based methods to explore time-related variables in occupational epidemiology studies	Oak Ridge National Laboratory	Watkins JP, Frome EL, Cragle DL [2005]. Age-based methods to explore time-related variables in occupational epidemiology studies. Proceedings of the American Statistical Association, Section on Statistics in Epidemiology [CD-ROM], Alexandria, VA.
Estimation of radiation doses	Oak Ridge National Laboratory	Watson JE Jr, Wood JL, Tankersley WG, West CM [1994]. Estimation of radiation doses for workers without monitoring data for retrospective epidemiological studies. Health Phys 67(4):402-405.
Lung dose estimates	Oak Ridge National Laboratory	West CM, Watkins JP, Tankersley WG, Payne DD [1995]. Lung dose estimates from air sampling and bioassay data—a comparison. Health Phys 69(4):481-486.
Mortality among workers monitored for ^{210}Po exposure		Wiggs LD, Cox-DeVore CA, Voelz GL [1991]. Mortality among a cohort of workers monitored for ^{210}Po exposure: 1944-1972. Health Phys 61(1):71-76.
Mortality among workers exposed to external ionizing radiation	Mound Plant, OH	Wiggs LD, Cox-DeVore CA, Wilkinson GS, Reyes M [1991]. Mortality among workers exposed to external ionizing radiation at a nuclear facility in Ohio. J Occup Med 33(5):632-637.

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TABLE 2A-1 Continued

Subject	Site if Applicable	Reference
Mortality through 1990 of white male workers	Los Alamos National Laboratory	Wiggs LD, Johnson ER, Cox-DeVore CA, Voelz GL [1994]. Mortality through 1990 among white male workers at the Los Alamos National Laboratory: considering exposures to plutonium and external ionizing radiation. Health Phys 67(6):577-588.
Risk factors for malignant melanoma		Wilkinson GS [1997]. Invited commentary: are low radiation doses or occupational exposures really risk factors for malignant melanoma? Am J Epidemiol 145(6):532.
Healthy worker effect		Wilkinson GS, Morgenstern H [1995]. Internal comparisons do not always control for the healthy worker effect. Am J Epidemiol 141(11):S58.
Cancer mortality among plutonium and radiation workers		Wilkinson GS, Baillargeon J, Ray L, Baillargeon G, Trieff N [1997]. Cancer mortality among plutonium and radiation workers. Am J Epidemiol 145(11):158.
Relevance of occupational epidemiology to radiation protection standards		Wing S, Richardson D, Stewart S [1999]. The relevance of occupational epidemiology to radiation protection standards. New Solutions 9(2):133-151.
Case-control study of multiple myeloma at four nuclear facilities	Multisite	Wing S, Richardson D, Wolf S, Mihlan G, Crawford-Brown D, Wood J [2000]. A case control study of multiple myeloma at four nuclear facilities. Ann Epidemiol 10(3):144-153.
Plutonium-related work and cause-specific mortality at DOE	Hanford site	Wing S, Richardson D, Wolf S, Mihlan G [2004]. Plutonium-related work and cause-specific mortality at the United States Department of Energy Hanford Site. Am J Ind Med 45(2):153-164.
Age at exposure to ionizing radiation and cancer mortality	Hanford site	Wing S, Richardson DB [2005]. Age at exposure to ionizing radiation and cancer mortality among Hanford workers: follow up through 1994. Occup Environ Med 62(7):465-472.

Mortality among workers	Oak Ridge National Laboratory	Wing S, Shy CM, Wood JL, Wolf S, Cragle DL, Frome EL [1991]. Mortality among workers at Oak Ridge National Laboratory. Evidence of radiation effects in follow-up through 1984. JAMA 265(11):1397-1402. Erratum: JAMA 1991 266(5):657, 1992 268(11):1414. Comment: JAMA 1991 266(5):652-655, JAMA 1992 267(7):929-930.
Job factors, radiation, and cancer mortality	Oak Ridge National Laboratory	Wing S, Shy CM, Wood JL, Wolf S, Cragle DL, Tankersley W, Frome EL [1993]. Job factors, radiation and cancer mortality at Oak Ridge National Laboratory: follow-up through 1984. Am J Ind Med 23(2):265-279. Erratum: Am J Ind Med 23(4):673.
Recording external radiation exposures	Oak Ridge National Laboratory	Wing S, West CM, Wood JL, Tankersley W [1994]. Recording of external radiation exposures at Oak Ridge National Laboratory: implications for epidemiological studies. J Expo Anal Environ Epidemiol 4(1):83-93.
Smoking history		Woo JG, Pinney SM [2002]. Retrospective smoking history data collection for deceased workers: completeness and accuracy of surrogate reports. J Occup Environ Med 44(10):915-923.
Cluster analysis		Wu JD, Milton DK, Hammond SK, Spear RC [1999]. Hierarchical cluster analysis applied to workers' exposures in fiberglass insulation manufacturing. Ann Occup Hyg 43(1):43-55.
Estimating dose-response relationship for occupational radiation exposure	Oak Ridge National Laboratory	Xue X, Shore RE, Ye X, Kim MY [2004]. Estimating the dose response relationship for occupational radiation exposure measured with minimum detection level. Health Phys 87(4):397-404.
Estimating occupational radiation doses	Oak Ridge National Laboratory	Xue X, Shore RE [2003]. A method for estimating occupational radiation doses subject to minimum detection levels. Health Phys 84(1):61-71.
NIOSH Numbered Reports		
Epidemiological use of non-detectable values in radiation exposure measurements		Cardarelli, J, Spitz H, Elliott L [1993]. NIOSH Research Issues Workshop: Epidemiological Use of Nondetectable Values in Radiation Exposure Measurements. Cincinnati, OH: U.S. Department of Health and Human Services, NIOSH Publication No. 224647; 27 pp.

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TABLE 2A-1 Continued

Subject	Site if Applicable	Reference
Study of leukemia and ionizing radiation	Portsmouth Naval Shipyard	Kubale TL, Daniels RD, Yiin JH, Kinnes GM, Couch J, Schubauer-Berigan MK, Silver SR, Nowlin SJ, Chen PH [2004]. A nested case-control study of leukemia and ionizing radiation at the Portsmouth Naval Shipyard. Cincinnati, OH: U.S. Department of Health and Human Services, NIOSH Publication No. 2005-104; 182 pp.
NIOSH Occupational Energy Research Program		NIOSH [2001]. NIOSH Occupational Energy Research Program. Cincinnati, OH: U.S. Department of Health and Human Services, NIOSH Publication No. 2001-133.
Report of public meeting to seek input on gaps in CLL radiogenicity research		NIOSH [2005]. Report of Public Meeting to Seek Input on Gaps in Chronic Lymphocytic Leukemia (CLL) Radiogenicity Research Held July 21, 2004. Cincinnati, OH: U.S. Department of Health and Human Services, NIOSH Publication No. 2006-100; 104 pp.
Mortality and radiation-related risk of cancer among workers	Idaho National Engineering and Environmental Laboratory	Schubauer-Berigan MK, Macievic GV, Utterback DF, Tseng C-Y, Flora JT [2005]. An epidemiological study of mortality and radiation-related risk of cancer among workers at the Idaho National Engineering and Environmental Laboratory, a U.S. Department of Energy Facility. Cincinnati, OH: U.S. Department of Health and Human Services, NIOSH Publication No. 2005-131; 224 pp.
Mortality update	Pantex weapons facility	Silver SR, Anderson-Mahoney P, Burphy J, Hiratzka S, Schubauer-Berigan MK, Waters KM [2005]. Mortality update for the Pantex weapons facility: final report. Cincinnati, OH: U.S. Department of Health and Human Services, NIOSH Publication No. 2005-124; 24 pp.
		Unnumbered Intramural Reports
Cancer incidence and sentinel event registries		Foster S, Espinoza R [2000]. Cancer incidence and sentinel event registries. Cincinnati, OH: NIOSH; 107 pp.

Specificity of the National Death Index and Social Security Administration Death Master File when information on Social Security number is lacking		Foster SO, Schubauer-Berigan MK, Waters KM [2000]. The specificity of the National Death Index and Social Security Administration Death Master File when information on Social Security Number is lacking. Cincinnati, OH: NIOSH.
Adverse reproductive outcomes among females employed at DOE facilities		Massoudi BL [1996]. Adverse reproductive outcomes among females employed at Department of Energy facilities: the feasibility of epidemiological studies. Cincinnati, OH: NIOSH; 18 pp.
Dosimetry data compilation for international radiation workers study		Murray B [1997]. Dosimetry data compilation for international radiation worker study: final report. IARC Collaborative Study; Cincinnati, OH: NIOSH; 52 pp.
Mortality patterns among uranium enrichment workers	Portsmouth Gaseous Diffusion Plant	Rinsky R, Cardarelli J, Ahrenholz S, Wenzl T, Hornung R, Reeder D, Waters K, Dill P [2001]. Final technical report: Mortality patterns among uranium enrichment workers at the Portsmouth Gaseous Diffusion Plant, Piketon, Ohio. Cincinnati, OH: NIOSH; 179 pp.
Feasibility assessment: epidemiological study of personnel involved in the underground nuclear detonation, Cannikin site, Amchitka, Alaska		Rinsky R, Taulbee T [1998]. Report to Deputy Assistant Secretary, U.S. Department of Energy. Feasibility assessment. Epidemiological study of personnel involved in the underground nuclear detonation, Cannikin site, Amchitka, Alaska. Cincinnati, OH: NIOSH; 18 pp.
Evaluation of data for DOE site remediation workers		Silver SR, Robinson CF, Kinnes G, Taulbee T, Ahrenholz S [2000]. Evaluation of data for DOE site remediation workers. Cincinnati, OH: NIOSH; 37 pp.
Depleted uranium: sources, exposure and health effects		Schmid E, Keith S, TenfordeT, Alberth D, Cloeren M, Kramp R, et al. [2001]. Depleted uranium: sources, exposure and health effects. Dept Prot Hum Env Apr:1-209.
Electromagnetic fields and rail maintenance workers		Wenzl TB, Mills P, Murray WE [1996]. Electromagnetic fields [EMF] and rail maintenance workers: final report of an exposure survey and feasibility investigation. Cincinnati, OH: NIOSH; 7 pp.

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TABLE 2A-1 Continued

Subject	Site if Applicable	Reference
		Extramural Reports
Remediation workers' exposure assessment feasibility study	Rocky Flats	Back DA, Stevens GW [1998]. Remediation workers' exposure assessment feasibility study at the Department of Energy's Rocky Flats site—Phase I report.
Glycophorin A biodosimetry in patients treated with iodine-131		Bigbee WL, Brown ML, Burmeister LA, Carty SE, Swanson D, Watson CG [1998]. Final performance report: Glycophorin A (GPA) biodosimetry in I-131 treated patients. Pittsburgh, PA: Center forEnvironmental and Occupational Health and Toxicology, Department of Environmental and Occupationa Health, Graduate School of Public Health, University of Pittsburgh; 36 pp.
Work histories—evaluating new participatory methods		Bingham E, Rice C [1999]. Work histories—evaluating new participatory methods. Cincinnati, OH: Department of Environmental Health, University of Cincinnati; 21 pp.
Surveillance methods for solvent-related hepatotoxicity		Brodkin CA, Checkoway H, Bushley A, Stover B, McDonald G, Lee S, Wang K, Carpenter K, Dubinsky T, Green D [2001]. Surveillance methods for solvent-related hepatotoxicity. Seattle, WA: University of Washington. Available from NIOSH/Health-Related Energy Research Branch (HERB), Cincinnati, OH; 7 pp.
Reconstruction of doses for Chernobyl liquidators	Chernobyl	Cardis E, Krjuchkov VP, Anspaugh L, Bouville A, Chumak VV, Drozdovich V, Gavrilin Y, Golovanov I, Hubert P, Illychev S, Ivanov VK, Kesminiene A, Kurtinaitis J, Maceika E, Malakhova IV, Mirhaidarov AK, Pitkevitch VA, Stengrevics A, Tekkel M, Tenet V, Tsykalo A [2003]. Reconstruction of doses for Chernobyl liquidators (Final performance report). Available from the NIOSH/HERB, Cincinnati, OH; 53 pp.
Cancer risk among radiation workers in the nuclear industry		Cardis E, Martuzzi M, Amoros E [1997]. International Collaborative Study of Cancer Risk Among Radiation Workers in the Nuclear Industry—II. Procedures Document (1997 revision). Lyon, France: International Agency for Research on Cancer, World Health Organization; 102 pp.

Mortality among a cohort of white male workers at a uranium processing plant	Fernald Feed Materials Production Center, 1951-1989	Cragle DL, Watkins JP, Ingle JN, Robertson-Demers K, Tankersley WG, West CM [1995]. Mortality among a cohort of white male workers at a uranium processing plant: Fernald Feed Materials Production Center, 1951-1989. Oak Ridge, TN: Center for Epidemiological Research, Oak Ridge Institute for Science and Education; unpublished; 29 pp.
Study of the health effects of exposure to elemental mercury	Y-12 plant in Oak Ridge	Departments of Behavioral Sciences and Health Education and of Environmental and Occupational Health; Rollins School of Public Health of Emory University, and Center for Epidemiological Research Environmental and Health Sciences Division Oak Ridge Associated Universities [undated]. A study of the health effects of exposure to elemental mercury: a followup of mercury exposed workers at the Y-12 plant in Oak Ridge, Tennessee. Available from the NIOSH/HERB, Cincinnati, OH; 134 pp.
Mortality among workers employed between 1945 and 1984 at a uranium gaseous diffusion facility	Oak Ridge	Dupree EA, Wells SM, Watkins JP, Wallace PW, Davis NC [1994]. Mortality among workers employed between 1945 and 1984 at a uranium gaseous diffusion facility. Oak Ridge, TN: Center for Epidemiological Research Medical Sciences Division. Available from NIOSH/HERB, Cincinnati, OH; 24 pp.
Job task analysis quality assessment	14 sites	Ertell K, Takaro T, Shorter C, Stover B, Beaudet N, Barnhart S, Rabito F, White LE [2000]. Results of employee job task analysis (EJTA) quality assessment: Combined analysis for fourteen Hanford contractors. Seattle, WA: University of Washington; 34 pp.
Occupational magnetic field personal exposures	Seattle metro transit's electric trolley system	EM Factors [1999]. Study of occupational magnetic-field personal exposures associated with Seattle metro transit's electric trolley system. Richland, WA. Available from NIOSH/HERB, Cincinnati, OH; 67 pp.
Evaluation of dosimetry data		Fix JJ [2001]. Interim final report: evaluation of dosimetry data for National Institute for Occupational Safety and Health (NIOSH) Collaboration with the International Agency for Research on Cancer (IARC) Nuclear Worker Study. Richland, WA: Pacific Northwest National Laboratory; 65 pp.

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TABLE 2A-1 Continued

Subject	Site if Applicable	Reference
Dose validation study	Multisite	Fix JJ, Scherpelz RI, Strom DJ, Traub RJ [2005]. Dose validation for NIOSH/HERB multisite leukemia case control study. PNWD-3538. Richland WA: Battelle Pacific Northwest Division, 218 pp.
Mortality in an ethnically diverse radiation-exposed occupational cohort	Los Alamos National Laboratory	Galke GA, Johnson ER, Tietjen GL [1992]. Mortality in an ethnically diverse radiation exposed occupational cohort. Los Alamos, NM: Los Alamos National Laboratory; unpublished; 70 pp.
Occupational magnetic field personal exposures		Kaune WT [1999]. Study of occupational magnetic-field personal exposures of non-flying airline employees. Richland, WA: EM Factors. Available from NIOSH/HERB, Cincinnati, OH; 52 pp.
Method for estimating occupational radiation dose to individuals	Oak Ridge National Laboratory	Mitchell RJ, Ostrouchov G, Frome EL, Kerr GD [1993]. A method for estimating occupational radiation dose to individuals, using weekly dosimetry data. Oak Ridge, TN: Oak Ridge National Laboratory; 46 pp.
		Newman LS [2002]. Final performance report: beryllium disease natural history and exposure-response. Denver, CO: Division of Environmental and Occupational Health Sciences, National Jewish Medical and Research Center; 17 pp.
Lung fibrosis in plutonium workers		Newman LS, Mroz MM, Ruttenber JA [2002]. Lung fibrosis in plutonium workers. Division of Environmental and Occupational Health Sciences, National Jewish Medical and Research Center, Denver, CO. Available from NIOSH/HERB, Cincinnati, OH; 19 pp.
Adequacy of vital status follow-up in the Hanford Worker Mortality Study	Hanford	Omohundro E, Gilbert E [1993]. An evaluation of the adequacy of vital status follow-up in the Hanford Worker Mortality Study. Richland, WA: Hanford Environmental Health Foundation. Available from NTIS, Springfield, VA; DE94005179, 40 pp.

Dose estimation	Oak Ridge National Laboratory	Ostrouchov G, Frome EL, Kerr GD [1998]. Dose estimation from daily and weekly dosimetry data. Oak Ridge, TN: Oak Ridge National Laboratory.
Health effects of downsizing in the nuclear industry	Idaho National Engineering and Environmental Laboratory	Pepper L [2000]. The health effects of downsizing in the nuclear industry: findings at the Idaho National Engineering and Environmental Laboratory. Boston, MA: Boston University School of Public Health. Available from NIOSH/HERB, Cincinnati, OH; 129 pp.
Health effects of downsizing in the nuclear industry	Los Alamos National Laboratory	Pepper L [2000]. The health effects of downsizing in the nuclear industry: findings at the Los Alamos National Laboratory. Boston, MA: Boston University School of Public Health. Available from NIOSH/HERB, Cincinnati, OH; 135 pp.
Health effects of downsizing in the nuclear industry	Nevada Test Site	Pepper L [2000]. The health effects of downsizing in the nuclear industry: findings at the Nevada Test Site. Boston, MA: Boston University School of Public Health. Available from NIOSH/HERB, Cincinnati, OH; 125 pp.
Health effects of downsizing in the nuclear industry	Pantex	Pepper L [2000]. The health effects of downsizing in the nuclear industry: Pantex. Boston, MA: Boston University School of Public Health. Available from NIOSH/HERB, Cincinnati, OH; 133 pp.
Health effects of downsizing in the nuclear industry	Y-12 Plant, Oak Ridge	Pepper L [2000]. The health effects of downsizing in the nuclear industry: findings at the Y-12 Plant, Oak Ridge Reservation. Boston, MA: Boston University School of Public Health. Available from NIOSH/HERB, Cincinnati, OH; 129 pp.
Radon and cigarette smoking	Fernald	Pinney S [2004]. Radon and cigarette smoking assessment in Fernald workers. Cincinnati, OH: University of Cincinnati; 103 pp.
United Brotherhood of Carpenters Health and Safety Fund		Rosenman KD, Gardiner J, Cameron W, Anger KW [2000]. United Brotherhood of Carpenters Health and Safety Fund. Available from NIOSH/HERB, Cincinnati, Ohio; 76 pp.

continued

TABLE 2A-1 Continued

Subject	Site if Applicable	Reference
Chronic beryllium disease among beryllium-exposed workers		Rosenman KD, Hertzberg VS, Rice C, Rossman M. 2001. Final performance report: chronic beryllium disease among beryllium-exposed workers cooperative agreement; 25 pp.
Sentinel exposure event surveillance		Ruttenber AJ, LaMontagne AD, Van Dyke MV, Martyny JW [2004]. Final performance report: sentinel exposure event surveillance and evaluation for DOE sites. Denver, CO: University of Colorado Health Sciences Center; 5 pp.
Epidemiological analyses of Rocky Flats production workers	Rocky Flats	Ruttenber AJ, Schonbeck M, Brown S, Wells T, McClure D, McCrea J, Popken D, Martyny J [2003]. Report of epidemiological analyses performed for Rocky Flats production workers employed between 1952-1989: Available from NIOSH/HERB, Cincinnati, OH; unpublished; 75 pp.
Epidemiological evaluation of childhood leukemia and paternal exposure to ionizing radiation		Sever LE, Gilbert ES, Tucker K, Greaves J, Greaves C, Buchanan J [1997]. Epidemiological evaluation of childhood leukemia and paternal exposure to ionizing radiation. Seattle, WA: Battelle Memorial Institute. Available from NIOSH/HERB, Cincinnati, OH; 51 pp.
Mortality among workers at Oak Ridge National Laboratory: follow-up through 1990	Oak Ridge National Laboratory	Shy C, Wing S [1994]. A report on mortality among workers at Oak Ridge National Laboratory: followup through 1990. Oak Ridge, TN: Oak Ridge Associated Universities, 21 pp.
Exposure assessment	Fernald	Stevens GW, Back DA [1996]. Hazardous waste, decontamination and decommissioning, and clean-up workers exposure assessment feasibility study at the Department of Energy's Fernald site—Phase I: report; 156 pp.
Exposure assessment	Mound Plant	Stevens GW, Back DA [1997]. Remediation workers' exposure assessment feasibility study at the Department of Energy's Mound site—Phase I: report; 218 pp.

Measurement error methods		Stram DO [2001]. Measurement error methods for underground miner studies. Available from NIOSH/HERB, Cincinnati, OH; 4 pp.[b]
Potential exposure profile system users' guide		Tankersley WG [1997]. Potential exposure profile system (PEPS) users guide. Oak Ridge, TN: Oak Ridge Associated Universities; 34 pp.
Exposure assessment feasibility study	Savannah River site	Tankersley WG, West CM, Gray FE [1998]. Hazardous waste, decontamination and decommissioning and clean-up workers exposure assessment feasibility study at the Department of Energy's Savannah River site. Cincinnati OH; 142 pp.
Exposure assessment feasibility study	Oak Ridge	Tankersley WG, West CM, Gray FE [1999]. Hazardous waste, deactivation, dismantlement, and cleanup workers exposure assessment feasibility study at the Department of Energy Oak Ridge reservation; 134 pp.
Mortality of 244 male workers exposed to plutonium	Los Alamos National Laboratory	Voelz GL, Johnson ER, Lawrence JNP [1993]. Mortality of 244 male workers exposed to plutonium. Los Alamos, NM: Los Alamos National Laboratory; unpublished; 16 pp.
Acute radiation syndrome in Russian nuclear workers		Wald N, Day R, Shekhter-Levin S, Vergona R, Aimin Z [2001]. Acute radiation syndrome in Russian nuclear workers. Pittsburgh, PA: University of Pittsburgh. Available from NIOSH/HERB, Cincinnati, OH; 59 pp.
Time-related variables in occupational epidemiology studies		Watkins JP, Frome EL, Cragle DL [2004]. Evaluating time-related variables in occupational epidemiology studies. Final project report. Oak Ridge, TN: Oak Ridge Associated Universities; 57 pp. + 3 appendixes.
. Estimating dose and chemical exposure		West CM, Rutherford BF, Tankersley WG [1997]. Current programs for estimating dose and chemical exposure: Volume I. Oak Ridge, TN: Oak Ridge Associated Universities; 124 pp.

continued

TABLE 2A-1 Continued

Subject	Site if Applicable	Reference
Estimating dose and chemical exposure		West CM, Rutherford BF, Tankersley WG [1997]. Current programs for estimating dose and chemical exposure: Volume II. Oak Ridge, TN: Oak Ridge Associated Universities; 107 pp.
Mortality among female nuclear weapons workers		Wilkinson GS, Trieff, N, Graham, R [2000]. Final report: Study of mortality among female nuclear weapons workers. Buffalo, NY: State University of New York at Buffalo; 447 pp.
Time-related factors in radiation-cancer dose-response		Wing S, Richardson D [1997]. Time-related factors in radiation-cancer dose response. Chapel Hill, NC: University of North Carolina School of Public Health; 226 pp.
Ionizing radiation and mortality	Hanford site	Wing SB [1999]. Ionizing radiation and mortality among Hanford workers. Chapel Hill, NC: University of North Carolina School of Public Health; 1 p.
Case-control study of multiple myeloma among workers exposed to ionizing radiation and other physical and chemical agents		Wing SB, Wolf SH, Crawford-Brown D, Kotecki M, Mihlan GJ, Todd L, Emery J, Pompeii L, Wood JL, Olshan A, Shy CM [1997]. Case-control study of multiple myeloma among workers exposed to ionizing radiation and other physical and chemical agents. Chapel Hill, NC: University of North Carolina, School of Public Health; 203 pp.
Correcting for measurement errors in radiation exposure		Xue X [2002]. Correcting for measurement errors in radiation exposure. Available from NIOSH/HERB, Cincinnati, OH; 16 pp.
Remediation workers exposure assessment feasibility study	Hanford site	Zimmerman TD [1999]. Remediation workers exposure assessment feasibility study at the Department of Energy's Hanford site—Phase I: Report; 204 pp.
Remediation workers exposure assessment feasibility study	INEEL	Zimmerman TD, Moore AM [2000]. Remediation workers exposure assessment feasibility study at the Department of Energy's INEEL Site—Phase I: Report; 217 pp.

NIOSH Health Hazard Evaluations (HHEs) Within the OERP		
Hazard evaluation and technical assistance report	Idaho Falls, Idaho	NIOSH [1994]. Hazard evaluation and technical assistance report: Protection Technology Idaho Inc., Idaho Falls, Idaho. Cincinnati, OH: NIOSH Hazard Evaluation and Technical Assistance (HETA) Report No. 93-0740; 19 pp.
Hazard evaluation and technical assistance report	Lockheed Martin, Piketon, OH	NIOSH [1996]. Hazard evaluation and technical assistance report: Lockheed Martin Utility Services, Inc., Piketon, Ohio. Cincinnati, OH: NIOSH HETA Report No. 94-0077-2568; 41 pp.
Hazard evaluation and technical assistance report	LANL	NIOSH [1998]. Hazard evaluation and technical assistance report: Los Alamos National Laboratory, Los Alamos, NM. Cincinnati, OH: NIOSH HETA Report No. 98-0240; 6 pp.
Hazard evaluation and technical assistance report	Portsmouth Gaseous Diffusion Plant	NIOSH [2000]. Hazard evaluation and technical assistance report: Portsmouth Gaseous Diffusion Plant, Piketon, Ohio. Cincinnati, OH: NIOSH HETA Report No. 96-0198-2651.

[a]While NIOSH lists the 15-country as "Intramural" for NIOSH record-keeping purposes, the funding for the study came from multiple sources.

[b]Dan Stram, a member of the authoring committee of the present report, conducted exposure measurement error analysis in the Colorado Plateau Uranium Miners cohort and the Hanford Thyroid Disease Study with extramural funding from NIOSH. That funding terminated prior to the inception of this study (end date 5/31/2002). Those studies were not a part of this review.

NOTE: Publications that acknowledge whole or partial funding by DOE through the NIOSH Occupational Energy Research Program. From this body of work the committee selected for review publications either directly related to its three sites (Hanford, ORNL, and LANL) or multisite studies that included data from at least one of the three sites. Excludes intramural proceedings, extended abstracts, and submitted publications not in press as of May 2006. Table is current as of information received May 9, 2006.

REFERENCES

ACERER (Advisory Committee for Energy-Related Epidemiological Research). 1993. Minutes of the meeting held January 12 and 13, 1993, at the Centers for Disease Control and Prevention, Chamblee Facility, Building 101. Atlanta, GA: Centers for Disease Control and Prevention.

Borak, J., S.H. Woolf, and C.A. Fields. 2006. Use of beryllium lymphocyte proliferation testing for screening of asymptomatic individuals: an evidence-based assessment. J Occup Environ Med. 48(9): 937-47.

Cardis E., E.S. Gilbert, L. Carpenter, G. Howe, I. Kato, B.K. Armstrong, V. Beral, G. Cowper, A. Douglas, J. Fix, S.A. Fry, J. Kaldor, C. Lave, L. Salmon, P.G. Smith, G.L. Voelz, and L.D. Wiggs. 1995. Effects of low doses and low dose rates of external ionizing radiation: cancer mortality among nuclear industry workers in three countries. Radiat Res 142:117-132.

Cardis, E., M. Vrijheid, M. Blettner, E. Gilbert, M. Hakama, C. Hill, G. Howe, J. Kaldor, C.R. Muirhead, M. Schubauer-Berigan, and T. Yoshimura. 2005. Risk of cancer after low doses of ionising radiation: retrospective cohort study in 15 countries. Br Med J 331(7508):77-80.

Carpenter, L.M., C.D. Higgins, A.J. Douglas, N.E. Maconochie, R.Z. Omar, P. Fraser, V. Beral, and P.G. Smith. 1998. Cancer mortality in relation to monitoring for radionuclide exposure in three UK nuclear industry workforces. Br J Cancer 78:1224-1232.

CDC (Centers for Disease Control and Prevention). 1993. Advisory committee for energy-related epidemiologic research. Minutes of the meeting held January 12 and 13, 1993, at the Centers for Disease Control and Prevention, Chamblee Facility, Building 101. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service, CDC.

Cragle, D.L., R.W. McLain, J.R. Qualters, J.L. Hickey, G.S. Wilkinson, W.G. Tankersley, and C.C. Lushbaugh. 1988. Mortality among workers at a nuclear fuels production facility. Am J Ind Med 14:379-401.

Daniels, R.D., and M.K. Schubauer-Berigan. 2005. Bias and uncertainty of penetrating photon dose measured by film dosimeters in an epidemiological study of US nuclear workers. Radiat Prot Dosimetry 113:275-89.

Daniels, R.D., and J.H. Yiin. 2006. A comparison of statistical methods for estimation of less than detectable ionising radiation exposures [on-line]. Available: http://rpd.oxfordjournals.org/cgi/content/abstract/ncl024v1 [accessed August 25, 2006].

Daniels, R.D., C.J. Lodwick, M.K. Schubauer-Berigan, and H.B. Spitz. 2006. Assessment of plutonium exposures for an epidemiological study of US nuclear workers. Radiat Prot Dosim 118:43-55.

Deubner, D.C., M. Goodman, and J. Iannuzzi. 2001. Variability, predictive value, and uses of the beryllium blood lymphocyte proliferation test (BLPT): preliminary analysis of the ongoing workforce survey. Appl Occ Environ Hyg 16:521-526.

Foster, S., and R. Espinoza. 2000. Cancer incidence and sentinel event registries. Cincinnati, OH: NIOSH; 107 pp.

Frome, E.L., D.L. Cragle, J.P. Watkins, S. Wing, C.M. Shy, W.G. Tankersley, and C.M. West. 1997. A mortality study of employees of the nuclear industry in Oak Ridge, Tennessee. Radiat Res 148:64-80.

Gardner, M.J., M.P. Snee, A.J. Hall, C.A. Powell, S. Downes, and J.D. Terrell. 1990. Results of case-control study of leukaemia and lymphoma among young people near Sellafield nuclear plant in West Cumbria. Br Med J 300(6722):423-429.

Gilbert, E.S. 1998. Accounting for errors in dose estimates used in studies of workers exposed to external radiation. Health Phys 74 (1):22-29.

Gilbert, E.S., S.A. Fry, L.D. Wiggs, G.L. Voelz, D.L. Cragle, and G.R. Petersen. 1989. Analyses of combined mortality data on workers at the Hanford Site, Oak Ridge National Laboratory, and Rocky Flats Nuclear Weapons Plant. Radiat Res 120:19-35.

Gilbert, E.S., D.L. Cragle, and L.D. Wiggs. 1993a. Updated analyses of combined mortality data for workers at the Hanford Site, Oak Ridge National Laboratory, and Rocky Flats Weapons Plant. Radiat Res 136:408-421.

Gilbert, E.S., E. Omohundro, J.A. Buchanan, and N.A. Holter. 1993b. Mortality of workers at the Hanford site: 1945-1986. Health Phys 64:577-590.

Gilbert, E.S., J.J. Fix, and W.V. Baumgartner. 1996. An approach to evaluating bias and uncertainty in estimates of external dose obtained from personal dosimeters. Health Phys 70:336-345.

Gunter, E.W. 1997. Biological and environmental specimen banking at the Centers for Disease Control and Prevention. Chemosphere 34:1945-1953.

Hazelton, W.D., S.H. Moolgavkar, S.B. Curtis, J.M. Zielinski, J.P. Ashmore, and D. Krewski. 2006. Biologically based analysis of lung cancer incidence in a large Canadian occupational cohort with low-dose ionizing radiation exposure, and comparison with Japanese atomic bomb survivors. J Toxicol Environ Health A 69(11):1013-1038.

Kelleher, P.C., J.W. Martyny, M.M. Mroz, L.A. Maier, A.J.Ruttenber, D.A.Young, and L.S. Newman. 2001. Beryllium particulate exposure and disease relations in a beryllium machining plant. J Occup Environ Med 43:238-249.

LaMontagne, A.D., M.V. Van Dyke, J.W. Martyny, and A.J. Ruttenber. 2001. Cleanup worker exposures to hazardous chemicals at a former nuclear weapons plant: piloting of an exposure surveillance system. Appl Occup Environ Hyg 16(2):284-290.

Letz, R., F. Gerr, D. Cragle, R.C. Green, J. Watkins, and A.T. Fidler. 2000. Residual neurologic deficits 30 years after occupational exposure to elemental mercury. Neurotoxicology 21:459-474.

Mancuso, T.F., A. Stewart, and G.W. Kneale. 1977. Radiation exposures of Hanford workers dying from cancer and other causes. Health Phys 33:369-385.

Martyny, J.W., M.D. Hoover, M.M. Mroz, K. Ellis, L.A. Maier, K.L. Sheff, and L.S. Newman. 2000. Aerosols generated during beryllium machining. J Occup Environ Med 42:8-18.

Newman, L.S. 2002. Final Performance Report: Beryllium Disease Natural History and Exposure-Response. Cooperative Agreement # U60/CCU812221-05. Denver, CO: University of Colorado School of Medicine, Department of Medicine and Department of Preventive Medicine and Biometrics.

Newman, L.S., M.M. Mroz, L.A. Maier, E.M. Daniloff, and R. Balkissoon. 2001. Efficacy of serial medical surveillance for chronic beryllium disease in a beryllium machining plant. J Occup Environ Med 43:231-237.

Newman, L.S., M.M. Mroz, R. Balkissoon, and L.A. Maier. 2005. Beryllium sensitization progresses to chronic beryllium disease: a longitudinal study of disease risk. Am J Resp Crit Care Med 171: 54-60.

NIOSH (National Institute for Occupational Safety and Health). 1996. Research Protocol: Multi-site Case-Control of Leukemia and Ionizing Radiation. Atlanta, GA: Centers for Disease Control and Prevention.

NIOSH (National Institute for Occupational Safety and Health). 2005. The NIOSH Occupational Energy Research Program: Evidence for the National Academies' Review of the Worker and Public Health Activities Program Administered by the Department of Energy and the Department of Health and Human Services. Atlanta, GA: Centers for Disease Control and Prevention.

NIOSH (National Institute for Occupational Safety and Health). 2006. ASA Conference on Radiation and Health, Pacific Grove, CA, June 2006. Atlanta, GA: Centers for Disease Control and Prevention.

NRC (National Research Council). 1989. Nuclear Weapons Complex: Management for Health, Safety, and the Environment. Washington, DC: National Academy Press.

NRC (National Research Council). 1994. Epidemiological Research Programs at the Department of Energy: Looking into the Future. Washington, DC: The National Academies Press.

NRC (National Research Council). 2006a. Health Risks from Exposure to Low Levels of Ionizing Radiation. BEIR VII Phase 2. Washington, DC: The National Academies Press.

NRC (National Research Council). 2006b. Human Biomonitoring for Environmental Chemicals. Washington, DC: National Academy Press.

Ostrouchov, G., E.L. Frome, and G.D. Kerr. 1998. Dose estimation from daily and weekly dosimetry data. Oak Ridge, TN: Oak Ridge National Laboratory.

PSR (Physicians for Social Responsibility). 1992. Dead Reckoning: A Critical Review of the Department of Energy's Epidemiological Research. Washington, DC.

Rericha, V., M. Kulich, R. Rericha, D.L. Shore, and D.P. Sandler. 2006. Incidence of leukemia, lymphoma, and multiple myeloma in Czech uranium miners: a case-cohort study. Envir Health Persp 114(6):818-822.

Richardson, D.B., and S. Wing. 1999. Greater sensitivity to ionizing radiation at older age: follow-up of workers at Oak Ridge National Laboratory through 1990. Int J Epidemiol 28(3):428-436.

Richardson, D.B., and S. Wing. 2006. Lung cancer mortality among workers at a nuclear materials fabrication plant. Am J Ind Med 49:102-111.

Richardson, D., S. Wing, J. Watson, and S. Wolf. 1999. Missing annual external radiation dosimetry data among Hanford workers. J Expo Anal Env Epid 9(6):575-585.

Richardson, D., S. Wing, K. Steenland, and W. McKelvey. 2004. Time-related aspects of the healthy worker survivor effect. Ann Epidemiol 14(9):633-639.

Richardson, D.B., S. Wing, and R.D. Daniels. 2006. Evaluation of external radiation dosimetry records at the Savannah River Site. J Expo Sci Environ Epidemiol. 1951-1989.

Rosenman, K.D., V.S. Hertzberg, C. Rice, and M. Rossman. 2001. Final Performance Report: Chronic Beryllium Disease Among Beryllium-Exposed Workers. Cooperative Agreement #UCO CCU512218. East Lansing, MI: Michigan State University.

Sanderson, W.T., P.K. Henneberger, J. Martyny, K. Ellis, M.M. Mroz, and L.S. Newman. 1999. Beryllium contamination inside vehicles of machine shop workers. Am J Ind Med Suppl 1:72-74.

Sever L.E., E.S. Gilbert, K. Tucker, J. Greaves, C. Greaves, and J. Buchanan. 1997. Epidemiological Evaluation of Childhood Leukemia and Paternal Exposure to Ionizing Radiation. Seattle, WA: Battelle Memorial Institute. Available from NIOSH/HERB, Cincinnati, OH.

Sibley, R.F., B.S. Moscato, G.S. Wilkinson, and N. Natarajan. 2003. Nested case-control study of external ionizing radiation dose and mortality from dementia within a pooled cohort of female nuclear weapons workers. Am J Ind Med 44(4):351-358.

Silver, S.R., C.F. Robinson, G. Kinnes, T. Taulbee, and S. Ahrenholz. 2000. Evaluation of Data for DOE Site Remediation Workers. Cincinnati, OH: NIOSH; 37 pp.

Stange, A.W., F.J. Furman, and D.E. Hilmas. 2004. The beryllium lymphocyte proliferation test: relevant issues in beryllium health surveillance. Am J Ind Med 46:453-462.

Thierry-Chef, I., F. Pernicka, M. Marshall, E. Cardis, and P. Andreo. 2002. Study of a selection of 10 historical types of dosemeter: variation of the response to Hp(10) with photon energy and geometry of exposure. Radiat Prot Dosim 102:101-113.

Wiggs, L.D., E.R. Johnson, C.A. Cox-DeVore, and G.L. Voelz. 1994. Mortality through 1990 among white male workers at the Los Alamos National Laboratory: considering exposures to plutonium and external ionizing radiation. Health Phys 67(6):577-588.

Wilkinson, G.S., N. Trieff, and R. Graham. 2000. Final Report: Study of Mortality Among Female Nuclear Weapons Workers. Buffalo, NY: State University of New York at Buffalo.

Wing, S., and D.B. Richardson. 2005. Age at exposure to ionising radiation and cancer mortality among Hanford workers: follow up through 1994. Occup Environ Med 62:465-472.

Wing, S., C.M. Shy, J.L. Wood, S. Wolf, D.L. Cragle, and E.L. Frome. 1991. Mortality among workers at Oak Ridge National Laboratory. Evidence of radiation effects in follow-up through 1984. JAMA 265:1397-1402.

Wing, S.B., S.H. Wolf, D. Crawford-Brown, M. Kotecki, G.T. Mihlan, L. Todd, J. Emery, L. Pompeii, J.L. Wood, A. Olshan, and C.M. Shy. 1997. Case-Control Study of Multiple Myeloma Among Workers Exposed to Ionizing Radiation and Other Physical and Chemical Agents. Chapel Hill, NC: University of North Carolina, School of Public Health; 203 pp.

Wing, S., D. Richardson, S. Wolf, G. Mihlan, D. Crawford-Brown, and J. Wood. 2000. A case control study of multiple myeloma at four nuclear facilities. Ann Epidemiol 10(3):144-153.

Wing, S., D. Richardson, S. Wolf, and G. Mihlan. 2004. Plutonium-related work and cause-specific mortality at the United States Department of Energy Hanford Site. Am J Ind Med 45(2):153-164.

Xue, X., and R.E. Shore. 2003. A method for estimating occupational radiation doses subject to minimum detection levels. Health Phys 84(1):61-71.

Xue, X., R.E. Shore, X. Ye, and M.Y. Kim. 2004. Estimating the dose response relationship for occupational radiation exposure measured with minimum detection level. Health Phys 87:397-404.

3

Scientific Program Assessment: Agency for Toxic Substances and Disease Registry

The Agency for Toxic Substances and Disease Registry (ATSDR) was established and operates under the mandates of the 1986 amendments to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, commonly known as the Superfund law). Memoranda of Understanding (MOUs) between ATSDR and the Department of Energy (DOE) were signed in 1990, 1992, and 1997. In 2000, rather than establishing separate agreements with the three agencies of the Department of Health and Human Services (HHS) involved in the Worker and Public Health Activities Program, ATSDR was added to the MOU that updated the working arrangements between DOE, the National Institute for Occupational Safety and Health (NIOSH), and the National Center for Environmental Health. This MOU expired at the end of FY 2004. A new MOU was proposed in April 2005 and is currently in negotiation between HHS and DOE.

To evaluate the quality of the programs from the viewpoint of science and public policy, the committee used a sampling strategy that reviewed selected studies from three DOE sites and, in some cases, products that were not site-specific (see detailed description of strategy in Chapter 1). Briefly, the selection rationale took into account the following factors:

- The range of time over which health studies were initiated.
- The number of workers involved as part of the program.
- A variety of types of dissemination and communication challenges.
- A variety of security challenges.
- Size of the surrounding public community.
- Geographic distribution of the sites.

With these factors in mind, the committee selected three DOE nuclear operations sites—Hanford, Oak Ridge, and Los Alamos—as a subset of the total DOE sites on which it would focus its attention. In addition to this sampling strategy for site-specific aspects of the program, the committee requested and considered detailed information from the agencies on broad aspects of the program.

In selecting ATSDR products to evaluate, the committee searched through web sites listing ATSDR research products. In addition, all agencies were asked to identify in writing work conducted under the MOU. Further queries were made to determine whether specific studies were conducted under the MOU. In addition to conducting an overview of the types of studies conducted under the MOU, the committee selected certain specific products for closer evaluation.

ATSDR PROGRAM AREAS RELEVANT TO THE MOU

ATSDR produces six principal products as specified in amendments to CERCLA:

1. Public Health Assessments (PHAs)
2. Health Studies
3. Toxicological Profiles
4. Medical Surveillance
5. Exposure and Disease Registries
6. Health Education and Promotion

The committee evaluated the ATSDR DOE-funded program by evaluating ATSDR products listed at the ATSDR web site and through responses to information requests sent to ATSDR (2006) (see Table 3-1). The committee also specifically evaluated selected PHAs at the three committee-selected sites and a health study conducted at one of the sites. Toxicological Profiles developed with DOE funds were also evaluated. The metrics used to evaluate these products included assessment of their appropriateness to the DOE mission and their usefulness in informing the communities surrounding DOE sites of possible health hazards due to past and present activities of DOE.

REVIEW OF SELECTED PUBLIC HEALTH ASSESSMENTS AT THE THREE COMMITTEE-SELECTED SITES

As part of its evaluation of the appropriateness and scientific quality of ATSDR, the committee reviewed selected PHAs at each of the three sites designated in the committee sampling strategy, Hanford, Oak Ridge, and Los Alamos (see sampling strategy in Chapter 1). The ATSDR web site[1] lists one PHA at Los

[1]See *http://www.atsdr.cdc.gov*. Last accessed November 2006

TABLE 3-1 ATSDR Activities Under the MOU[a] (except when noted otherwise)

Name of Product	Type of Product	Comments
Public Health Assessments	Assessments of potential community health hazards at DOE sites. ATSDR notes that PHAs are in-depth evaluations of data and information on the release of hazardous substances into the environment	In 1992, there were 20 DOE sites on ATSDR's work plan (19 DOE NPL sites + 1 petition site). ATSDR has completed 20 PHAs addressing 22 DOE sites
Health studies	Health studies can be divided into two basic types: those that are primarily exploratory in their approach (Type-1 studies), and those that require rigorous scientific methods to evaluate specific exposure-outcome relationships (Type-2 studies).[b] A health study consists of activities that use epidemiological principles to examine the occurrence of health conditions, exposure to harmful substances, or both, by systematically collecting, analyzing, and interpreting data	Under CERCLA and when appropriate, ATSDR on the basis of health assessment results conducts pilot studies of health effects for selected groups of exposed individuals to determine the desirability of conducting a full-scale epidemiological or other health study
Toxicological Profiles	Toxicological Profiles characterize the toxicologic and adverse health effects information for the hazardous substance in question	ATSDR provided the committee seven Toxicological Profiles funded entirely or partially by DOE: americium, cesium, cobalt, iodine, ionizing radiation, strontium, and uranium. ATSDR also noted in its response to the committee that two interaction profiles were funded by DOE
Public Health Statements (PHSs)	PHSs are stand-alone versions of Chapter One of the Toxicological Profiles. PHSs provide more extensive information than is found in the ToxFAQs and are written at an eighth-grade reading level	Spanish versions available
ToxFAQs	Excerpted from the Toxicological Profiles; ToxFAQs are written at about eighth-grade level and are used to educate and inform the public in affected communities	Spanish versions available

Health activities	Health activities may include new studies, ongoing studies, medical screenings, and/or analysis of existing datasets	
Surveillance activities	Surveillance activities are described as the ongoing systematic collection, analysis, and interpretation of health data over time; these are essential to the planning, implementation, and evaluation of public health practice	
Health consultations	Health consultations are very focused and generally address one specific question. Requests come from DOE, EPA, state agencies, or impacted communities	
Exposure investigations	In exposure studies, biological samples such as blood or urine are assessed to see whether exposure to a particular hazardous material can be established	
Exposure and disease registries	A registry is a database that includes information about people with specific exposures or diseases	
Health education and promotion	CERCLA 104 (i)(14) mandates that ATSDR assemble, develop as necessary, and distribute appropriate educational materials on medical surveillance, screening, and methods of diagnosis and treatment of injury or disease related to exposure to hazardous substances	See Chapter 5 for an evaluation of dissemination activities under the MOU

[a]Based on ATSDR responses to committee questions received February 19, 2006.
[b]See *http://www.atsdr.cdc.gov/HS/gd1.html.* Last accessed July 2006.

NOTE: EPA = U.S. Environmental Protection Agency; NPL = National Priorities List.

Alamos (the site itself) and that PHA was selected for review, consistent with the selection strategy. Three of the sites at Hanford were selected for review because the sites span the range from very contaminated (200-Area), to intermediate contamination (300-Area), to very low contamination (1100-Area) and the three PHAs reviewed represented the various stages of the PHA generation process from initial release (200 Area) to final assessment (1100-Area). The ATSDR web site lists a number of PHAs at the Oak Ridge reservation. The Y-12 site was selected because of a wide range of activities at the site over the years of its operation and because of the potential for uranium releases in the past. The TSCA incinerator PHA was selected for review as an assessment that evaluates the potential hazards of a "waste reduction and disposal operation." The copies reviewed represented a range of stages in the PHA generation process including public comment versions and final versions. PDF versions of the reports were accessed on the ATSDR web site and hard copies of the reports were obtained from ATSDR.

Public Health Assessments

ATSDR has indicated to the committee that the criteria used to establish the order of priority for selecting DOE sites for assessment were published in the *Federal Register* (57 FR 37382, August 18, 1992). These criteria included the toxicity of the chemicals present, the site population, exposure pathways, health outcome data, and the plausibility of community concerns. Furthermore, in 1986, amendments to the Superfund law directed ATSDR to conduct a PHA at each of the sites on the Environmental Protection Agency's (EPA's) National Priorities List (NPL; ATSDR 2005a). See Annex 3A for selected language from the CERCLA legislation mandating PHAs at sites on the NPL. Many of the DOE sites evaluated by HHS are on the NPL. A health assessment determines whether people are being exposed to hazardous substances, and if so, the health assessors determine whether that exposure should be stopped or reduced. As the first step, ATSDR scientists review the extent of contamination at a site and how people might come into contact with that contamination. If the initial step indicates that individuals have or will come into contact with a hazardous substance, ATSDR scientists evaluate the risk of harmful effects from these exposures, with a focus on health impacts on the community as a whole. This phase of the assessment usually involves a comparison of the maximum levels of a given substance to which ATSDR estimates the public is exposed with various regulatory standards or non-regulatory guidance values for that substance that estimate what levels of exposure are safe. "Safe" generally is not viewed as an absolute absence of risk; rather, if any risk does exist, it is minimal.

The PHA can also present conclusions about the level of the threat, if any, and can recommend ways to stop or reduce exposure to that threat. In the past,

CERCLA specifically exempted health assessments from peer review, but beginning in 1997, ATSDR began submitting DOE PHAs for peer review (ATSDR 2006). ATSDR notes that the health assessment process is an interactive one, with information solicited from local and federal governments as well as from members of communities during the Public Comment Period. The Public Comment Period allows the community to ask questions about the assessment as well as state concerns they may have with the initial PHA. While many of the questions posed to ATSDR by the public are responded to in writing by ATSDR in the final PHA, the committee is not aware of any independent evaluations performed to assess the objectivity or scientific merit of the responses to the public published in the final PHA. It should be noted that due to the short review period, the committee did not have sufficient time to review either the completeness or the scientific validity of the responses by ATSDR to the public comments that were included in the final PHAs reviewed.

Hanford Site

The committee reviewed PHAs at three sites on the Hanford Nuclear Reservation in southeast Washington State. The Hanford area was the site of plutonium production beginning with the Manhattan Project during the Second World War. The three sites reviewed are designated the 200-Area, which once housed the process that chemically separated uranium from highly radioactive uranium fuel rods produced in the 100-Area reactors; the 5.7-square-mile 300-Area, which once fabricated uranium fuel rods that were irradiated in the 100-Area to produce plutonium; and the 1.2-square-mile 1100-Area that borders the Columbia River and is the closest site to the community of Richland, Washington.

Public Health Assessment for Hanford 200-Area (DOE Initial Release Version July 16, 1997) The 200-Area at Hanford is one of four NPL sites designated at the Hanford Nuclear Reservation (ATSDR 1997b). There are too many toxic substances stored on the 200-Area site to be listed in this short review, but such substances include many radiological and toxic solvent by-products of plutonium production. Radioactive wastes dissolved in chemical solvents have been stored in tanks with varying long-term containment integrities. Soils and water on the site have been contaminated at various times, and air releases of radioactive materials have occurred. Low-level wastes are also stored on the 200-Area, and the site even contains some naval submarine reactor compartments that eventually will be buried. Off-site contamination has also occurred from the 200-Area. The ATSDR assessment includes a thorough description of the history of the site and the types of toxic materials that are distributed throughout the site. The assessment includes a section comparing exposure levels with measures of toxicity such as minimal risk levels and reference doses.

On-site Hazard Evaluation

This ATSDR PHA concludes that the 200-Area of the Hanford site poses a health hazard to workers on the site itself from site-related contaminants released to the air, soils, and groundwater; specifically the PHA notes that on-site soil levels of radiological contaminants present a hazard to workers. Each of the operable units or process areas in the 200 East and West Areas has produced at least one completed exposure pathway with respect to on-site workers. The groundwater is not available to humans, although small amounts of the contaminants might migrate to the Columbia River. The 200-Area is part of lands held in trust for some Native American tribes. Although the area is undergoing remediation, current plans will not release this area for public use.

Off-site Hazard Evaluation

The location and buffer zone around the area have prevented completion of most of the potential exposure pathways extending off-site; the only exceptions are the atmospheric pathway and the Columbia River pathway. The assessment notes that currently available scientific evidence indicates that radiological contaminants released from the 200-Area are not expected to cause adverse health effects for the communities surrounding the sites. While ATSDR believes this area may have posed a public health risk in the past, inadequate data and the lack of documented off-site contamination in the past directly attributable to the 200-Area have not allowed the agency to assess past public health risks. ATSDR also notes that it found the available health outcome data for Washington State and the area around Hanford to be insufficient for this study. In this regard, ATSDR proposed three health-related projects. One of these, the Hanford Fetal Death and Infant Mortality Study, is reviewed later in this chapter as an example of an ATSDR health study.

Public Health Assessment for Hanford 300-Area (DOE Initial Release Version July 16, 1997) The 300-Area is on the NPL because "on-site groundwater is contaminated with uranium and trichloroethelene" (ATSDR 1997a). Soils on-site contain polychlorinated biphenyls (PCBs), trichloroethylene (TCE), cobalt, and uranium. DOE has detected uranium in springs both around the site and in the Columbia River, while strontium and uranium are present in vegetation around the site.

This ATSDR PHA concludes that there is no health hazard to the public because ". . . the public cannot come in contact with the contaminants identified in the [on-site] water and the soil." Although the public is concerned about releases of radioactive materials to publicly available lands and waters, the PHA concludes that such releases have not occurred from the 300-Area. The 300-Area is part of lands held in trust for some Native American tribes, and ATSDR notes

that if the land were returned for tribal use, "ATSDR would need to evaluate the public health implications of contaminants present on site at that time."

Public Health Assessment for Hanford 1100-Area (DOE November 20, 1995) The 1.2-square-mile 1100-Area at Hanford is on the NPL because "on-site wells contain volatile organic compounds that include trichloroethylene" (ATSDR 1995). On-site soils are contaminated with heavy metals and PCBs. Possible exposure routes on-site include direct contact with or accidental ingestion of contaminated groundwater and soil. The Yakima River borders the site and is a main fishing source for the Yakima Indian Reservation (ATSDR 1995). The 1100-Area currently serves as a vehicle maintenance and general support area for DOE's 560-square-mile Hanford Reservation. Because of its proximity to the city of Richland, Washington, good amounts of data on the area have been collected.

This PHA concludes that the 1100-Area poses no apparent public health hazard because no one (off-site) can come in contact with these contaminants; the contaminants identified on-site were not identified off-site. The PHA further concludes that there are no known past or current completed exposure pathways to the local population and that there are unlikely to be completed exposure pathways in the future. ATSDR notes that community health concerns relate mainly to radioactive releases from other areas at Hanford and not to the 1100-Area, where radioactive contamination has not been detected.

Oak Ridge Reservation

ATSDR scientists have conducted or are conducting PHAs on the following releases: Y-12 releases of uranium, Y-12 releases of mercury, X-10 release of iodine-131, X-10 release of radionuclides from White Oak Creek, K-25 releases of uranium and fluoride, and PCBs released from all three facilities. ATSDR's assessment of cancer incidence in counties adjacent to Oak Ridge Reservation shows that higher rates of some cancers and lower rates of other cancers were found in several of the counties for which data were analyzed, although there was no consistent pattern in cancer occurrence. ATSDR concludes that radionuclides released from X-10 via White Oak Creek are not a public health hazard for people who lived near or used the Clinch River or Lower Watts Bar Reservoir in the past or present. ATSDR also found that the TSCA incinerator releases very small amounts of contaminants into the environment, but notes that the amounts are far below levels associated with health effects.[2] The committee reviewed the completed Y-12 uranium PHA at Oak Ridge and the completed Oak Ridge TSCA incinerator PHA.

[2]See *http://www.atsdr.cdc.gov/HAC/oakridge/phact/index.html*. Last accessed July 2006.

Public Health Assessment for Oak Ridge Reservation: Y-12 Uranium Releases (January 30, 2004) In 1942, the federal government established the Oak Ridge Reservation (ORR) in Tennessee as part of the Manhattan Project to produce special nuclear materials for weapons. ORR was added to the EPA's NPL in 1989 due to the presence of radioactive and non-radioactive wastes on the site. Three of the four facilities built in 1942 were created to enrich uranium. One such facility, designated Y-12, is the subject of this extensive PHA.

The 825-acre Y-12 plant, about 2 miles south of downtown Oak Ridge, was used initially to electromagnetically enrich uranium, then to enrich lithium-6 using column-exchange technology, and then to fabricate components for thermonuclear weapons. After the Cold War the mission shifted to weapons disassembly and renovation. The site is a primary storage site for enriched uranium. The town of Oak Ridge, which peaked in population at 75,000 in 1945, has stabilized at about 27,000 people.

This PHA considered detailed pathways of exposure to uranium that could result in inhalation or ingestion of uranium off-site. Exposure values for a reference location, the Scarboro Community, that would have received the highest uranium concentrations in past exposures, were also evaluated. In some past exposures involving ingestion pathway, minimal risk levels (MRLs) were exceeded for some age groups.[3] When MRLs were exceeded, the ATSDR conducted further evaluations of toxicological end points to reach a conclusion regarding the potential for human health hazard at those exposure levels. An overall conclusion of ATSDR's evaluation of both past and current exposures to uranium released from the Y-12 plant was that off-site exposures to uranium were too low to be a health hazard for either radiation or chemical health effects.

Public Health Assessment for TSCA Incinerator at Oak Ridge Reservation (December 2005 Version). This PHA evaluates environmental exposures to contaminants released from the TSCA incinerator at the ORR in Roane County, Tennessee. DOE contractors currently operate the incinerator at the facility currently known as the K-25 site. The TSCA incinerator, which began operation in 1991, destroys organic chemicals in waste and reduces the volumes of waste materials that contain low-level radioactive contamination. This PHA focuses on direct inhalation of airborne contamination, the most likely pathway of exposure. The authors note that a separate PHA will consider the possibility of contamination in other media, such as surface water, soils, and food items (ATSDR 2005b).

This PHA considered the incinerator design and operation, the wastes treated, and the air emissions from the plant. Stack tests were evaluated to identify and measure materials that were released to the environment. A conclusion was that

[3]An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure.

measured emission rates were lower than limits established in health-protective environmental permits. Dispersion models developed by Tennessee, ATSDR, and DOE were considered; ATSDR concludes that the incinerator does not emit contaminants at levels that would cause health problems. ATSDR also considered air sampling data since 1991 and concluded that emissions have minimal air quality impacts beyond the ORR boundary. The assessment further concludes that exposures to contaminants are possible but not at levels of public health concern.

The completed TSCA PHA incorporates a thorough analysis of contaminants released from the incinerator and considers the pathways by which these contaminants might affect the surrounding communities. The demographics of the population living in the vicinity of ORR are also carefully considered. The PHA evaluated was a final version and key findings are highlighted in text boxes in understandable language. Graphics are user friendly and an appendix is included with responses to public comments.

Los Alamos National Laboratory

The committee reviewed one PHA for Los Alamos National Laboratory.

Public Health Assessment for Los Alamos National Laboratory (DOE Public Comment Version April 26, 2005) Los Alamos National Laboratory (LANL) is a 28,000-acre active facility owned by DOE and operated by Los Alamos National Security, LLC, a consortium involving the University of California and three companies (ATSDR 2005a). Approximately 22,000 persons live within a 10-mile radius of LANL. Past activities have released chemical and radioactive wastes into the soil, air, and water around LANL. LANL is investigating the contamination as a first step to monitor hazardous materials and to restore the environment and mitigate past releases.

ATSDR has reviewed past, current, and potential future exposures at LANL. For exposures before 1980, ATSDR has made no determination regarding potential health effects because data on pre-1980 LANL exposures were not yet available for evaluation. ATSDR's review of information since 1980 resulted in a determination that no harmful exposures to the public are presently occurring, and they are not expected to occur in the future due to chemical or radioactive contamination in the groundwater, surface water, soil, air, or biota around LANL. All levels of radioactive and non-radioactive substances that were found to exist at maximum concentrations greater than ATSDR health-based comparison values were judged by ATSDR to be insufficient to result in adverse human health effects.

General Evaluation of PHAs Reviewed

ATSDR has completed 20 PHAs addressing 22 DOE sites on EPA's NPL. ATSDR is currently working on five remaining DOE sites, Hanford, Brookhaven

(document released for public comment), Los Alamos (document released for public comment), Savannah River, and Oak Ridge. (Because Oak Ridge is complex, ATSDR is preparing public health assessments for each exposure concern: one assessment is completed [Y-12], three are at public comment [TSCA incinerator, White Oak Creek, and Off-Site groundwater], and five others were in the draft process but stopped due to funding limitations [ATSDR 2006]).

These assessments evaluate the levels of toxic substances on the sites and possible pathways that might expose the community to the toxic substance. The focus of ATSDR's PHAs is the evaluation of possible off-site health effects on communities rather than individuals. Based on the PHAs reviewed by the committee, these assessments appear to provide good detail on concentrations of potentially toxic substances on the sites and potential pathways for exposure of communities surrounding the sites to these toxicants. The off-site exposures from hazardous substances present on the sites are usually extremely low or non-existent.

In general, maximum estimated exposures of the communities are compared to guidance values and standards such as ATSDR MRLs; EPA maximum contaminant levels and reference doses; toxicology-based lowest-observed-adverse-effect levels; no-observed-adverse-effect levels; and similar values (see abbreviations and acronyms). If a range of exposures is indicated, the PHAs often will use the highest estimated dose as a "conservative" measure when making comparisons with toxicology values. The PHAs, however, are not in themselves quantitative studies of exposure and health effects. In general, the maximum exposures of the communities adjacent to a site are so low that a finding of no adverse human health effect is likely.

One aspect of the PHAs worth noting is that if maximal exposures to the community are below a certain level, a judgment is made that no risk to the community is likely to exist. This may be true of many non-radiological exposures. However, if one accepts a linear-no-threshold (LNT) model for radiation exposure risk, then there is no level of radiation exposure that does not present some risk, although that risk may be very small (NRC 2006). This committee takes no position on whether the extrapolation of human cancer risks from established data to lower doses (where radiation health effects are not detectable by epidemiological methods) should be LNT, supralinear (a greater health risk than would be predicted by the LNT), or sublinear with a threshold below which there is no effect. The committee notes, however, that ATSDR states that conservative (meaning protective) assumptions are made in the development of PHAs. The use of a threshold for radiation risk appears to be a departure from this conservative stance.

Using the Oak Ridge Y-12 Uranium Releases PHA as an example, ATSDR concludes ". . . that doses below the radiogenic cancer comparison value of 5,000 mrem over 70 years are not expected to result in adverse health effects at Oak Ridge (ATSDR 2004a). 5,000 mRem corresponds to 50 mSv. This conclusion is inconsistent with the principles of the conservative approach to the protection of

public health that the agency asserts it applies in the evaluation of radioactive agents and ignores a fundamental epidemiological concept that small relative risks can yield significant adverse health outcomes if the population exposed is large. Recent epidemiological studies of long-term exposure to high-LET (linear energy transfer) radiation (Field et al. 2000; Darby et al. 2005; Krewski et al. 2005, 2006), occupational health analyses utilizing the data available from 15 countries (Cardis et al. 2005), National Academies reports (NRC 1990, 1999, 2006), and an evaluation of the LNT for ionizing radiation by the National Council on Radiation Protection and Measurements (NCRP 2001) and use of the LNT by the Biological Effects of Ionizing Radiation (BEIR) VII committee provide contemporary and continuing support for a conservative assumption of no threshold. In addition, most government agencies, including those with regulatory responsibilities, use this principle.

HEALTH STUDIES

ATSDR has also conducted "health studies" when the initial findings of a PHA indicated that further follow-up was needed. A health study consists of activities that use epidemiological principles to examine the occurrence of health conditions, exposure to harmful substances, or both, by systematically collecting, analyzing, and interpreting data (ATSDR 2006).

In response to committee inquiries about projects completed since 1990, ATSDR listed the following Health studies:

- Hanford CAPI locating—completed March 1998.
- Hanford Mortality—completed August 1997; Final Report dated November 2000; International Journal of Hygiene and Environmental Health article dated 2001. Tatham, L.M., F.J. Bove, W.E. Kaye, and R.F. Spengler. 2002. Population exposures to I-131 releases from Hanford Nuclear Reservation and preterm birth, infant mortality, and fetal deaths. Int J Hyg Environ Health 205:41-48.
- Hanford Area School Follow-Up—Locating persons born in Adams, Benton ,and Franklin Counties between the years 1940 and 1951. Completed July 1998.
- Hanford Medical Monitoring—name was changed to Hanford Community Health Project (HCHP). The HCHP was completed September 2005. A journal article is currently being edited. See http://www.atsdr.cdc.gov/hanford/healthcare/.
- Hanford Cohort—Final Report is being edited; journal article should be complete by July 2006.
- Hazardous Waste Workers—completed. Reports dated February 2000 and July 2002 Not site-specific.
- Fernald—University of Cincinnati—Final Report dated August 2001.

The committee reviewed a health study conducted at one of the three committee-selected sites: the Hanford Infant Mortality and Fetal Death Analysis (Tatham et al. 2002). The study met the criteria of being a study at one of the three sites represented in the committee's selection strategy and was published in sufficient detail for committee evaluation.

A preliminary, unpublished investigation of infant, neonatal, and fetal death rates in eastern Washington State found an increased rate of infant mortality in 1945 for counties exposed to "high" levels of iodine-131 (I-131) released from the Hanford facility compared to counties with "low" exposure. Populations living near the Hanford facility are known to have been exposed to I-131, with the highest releases occurring between December 1944 and December 1947.

A subsequently published ATSDR health study (Tatham et al. 2002) was conducted to investigate the earlier finding of increased infant mortality. Estimates of I-131 dose levels at maternal residential address, defined by zip code, for an eight-county area surrounding the Hanford facility at the time of birth in 1945 and 1946 were assessed for possible associations with infant mortality, fetal death, and preterm birth. In addition, trends and causes of death between 1940 and 1952 were examined. The analysis included 72,154 births, 1,957 infant deaths, and 1,045 fetal deaths over the 13-year study period, and each birth and death record was assigned to one of four exposure groupings. This study found an increased risk of preterm birth in women who lived in counties that had relatively high estimated I-131 exposure in 1945 (OR = 1.6; 95% CI = 1.0-2.6).[4] The association was stronger when the exposure occurred during the latter part of the pregnancy (OR = 1.9; 95% CI = 1.2-3.0). Infant mortality rates for areas further from the facility were higher than those for areas closest to the facility for most of the 13-year period, with the exception of 1945 and 1946 (high-exposure years). The report concludes that "I-131 exposure may be associated with preterm birth." Furthermore, a modest increase in infant mortality was observed, supporting findings from the earlier investigation in 14 counties. Finally, the report concludes that further research on more contemporary populations may be warranted.

There is limited information in the literature on I-131 exposure and pregnancy outcomes, and this study has the potential to provide valuable information. A major strength of the study is the nearly complete ascertainment of outcome data (i.e., births and deaths). However, there are a number of study limitations including possible misclassification of exposure as a result of uncertainties in the dose estimates that were derived from the Hanford Environmental Dose Recon-

[4]OR = odds ratio. The odds of being exposed among diseased persons divided by the odds of being exposed among non-diseased persons. CI = confidence interval; an interval estimate of an unknown parameter, such as a risk.

struction Project (see Chapter 4); change in residence during the pregnancy; inadequate control of potential confounders (e.g., body mass index, mother's education); and the use of multiple comparisons.

General Evaluation

ATSDR's use of health studies when PHAs or other initial indicators suggest that a health hazard may exist is a logical transition to the use of standard epidemiological techniques to quantitatively evaluate potential hazards. The use of such studies also provides a bridge between the methodologies used by ATSDR and those used by NIOSH. The committee encourages the use of epidemiological methods, such as in study design and analytical approaches, similar to those employed by NIOSH while recognizing that the exposures of communities surrounding DOE sites (the ATSDR focus) must be estimated, while exposures of workers at the sites (the population studied by NIOSH) can sometimes be determined by radiation external and internal personal dosimetry measurements.

ATSDR TOXICOLOGY PROFILES

ATSDR also produces toxicological profiles of chemicals or radiological substances. The criteria for selecting toxicological profiles for development were published in the *Federal Register* in 1993 (58 FR 27286-27287, May 7, 1993). This publication also describes the approach that ATSDR uses to develop or update profiles.

Between August and December 1996, ATSDR developed and finalized a list of the top 12 radioactive substances at DOE sites with input from DOE. ATSDR identified seven radiation ToxProfiles™ as being funded or partially funded by DOE. These profiles included six radiological substances that one might expect would be present at some DOE sites and one profile of ionizing radiation itself. Americium, cesium, cobalt, iodine, strontium, and ionizing radiation profiles were funded by DOE. The uranium profile was developed using CERCLA funds but updated in FY 1999 using DOE funding.

In general, the toxicological profiles address community needs and concerns. Many of the profiles have a "Quick Reference for Health Care Providers" section immediately following the preface and preceding the table of contents. This section is intended to attract the attention of health care providers and to guide them to selected chapters and sections of the report that should be of interest and value to the health care professional. In addition, contact and referral information is provided for use by health care professionals.

Chapter 1 of the reviewed toxicology profiles is a public health statement. This chapter is written in such a way as to be of value to the lay reader. Using the cesium toxicology profile as an example, headings include "What is Cesium?"

"How Might I Be Exposed to Cesium?" "How Can Cesium Affect My Health?" (ATSDR 2004b).

Chapter 2, which discusses relevance to public health, is also written for the lay reader and "evaluates, interprets, and assesses the significance of toxicity data to human health" (in the case of the Ionizing Radiation Toxicological Profile, Chapter 2 departs from this structure and is about the "principles of ionizing radiation") (ATSDR 1999).

Chapter 3, on health effects, is more technical, and specific health effects are reported by type of health effect, route of exposure, and length of exposure; both human and animal studies are reported when available. Toxicological profiles undergo internal and external review and are made available for public comment prior to completion.

General Evaluation

The committee concludes that the seven DOE-funded ATSDR radiation toxicological profiles are relevant to DOE's mission and provide in-depth evaluations of the characteristics of the radiological material profiled. The profiles of specific radiological substances, in general, provide an overview of the knowledge base on the potential radiological hazards present at some DOE sites. The profile on the toxicology of ionizing radiation in general, a potential hazard at many DOE sites, is a useful supplement to many reports on this subject, such as the National Research Council's BEIR series and the United Nations Scientific Committee on the Effects of Atomic Radiation series, and International Agency for Research on Cancer publications 75 and 78. Extensive information is presented in the technical chapters from the biological and epidemiological literature. The physics and dosimetry nomenclature are described thoroughly.

The format of the first two chapters is designed to be understandable by both the public and health care providers in communities surrounding the sites, and the committee considers this to be of value to DOE and the public. The committee includes more detail on the origin and intent of toxicological profiles (ATSDR 2006) in Annex 3B.

OTHER ATSDR PRODUCTS

For a tabulation of the range of ATSDR products see Table 3-1. General descriptions of selected additional products are provided below.

Medical Surveillance

CERCLA mandates, when appropriate, the testing of exposed individuals, epidemiological studies, periodic survey and screening programs, or other assistance to determine relationships between exposure to toxic substances and illness. In addition to the PHA and health studies already mentioned, ATSDR also

provides health consultations (HCs). HCs are very focused and generally only one specific question. Requests for consultations come from DOE, EPA, state agencies, or impacted communities. Consultations can address exposure issues as they arise after PHAs are completed. Examples include Paducah, Kentucky—consult on nickel and metal exposures from historic smelter operations; Maywood, New Jersey—consult on each residential property for elevated lead levels; W.R. Grace/Wayne, New Jersey—soil in children's' sand boxes. ATSDR consultations can also address questions for non-NPL sites: Alba Craft Lab, Ohio (Formerly Utilized Sites Remedial Action Program [FUSRAP])—residential soil cleanup levels; Cape Thompson, Alaska (FUSRAP)—cancer incidence rates; West Valley Demonstration Project, New York—reviewed Environmental Impact Statement at request of local tribe; Lawrence-Berkeley, California—confirmed and concurred with overall tritium risk assessment done by DOE (ATSDR 2006).

Exposure Investigations

In exposure investigations, biological samples such as blood or urine are assessed to see whether exposure to a particular hazardous material can be established. As an example, ATSDR has conducted an exposure investigation at Oak Ridge, one of the three committee-selected sites, assessing levels of PCBs and mercury in blood. In 1997, ATSDR screened more than 500 persons and obtained blood samples from 116 persons who were consuming fish from Watts Bar Reservoir. Of the 116 persons, 5 (4 percent) tested had PCB levels greater than 20 μg/L, which is considered elevated. In addition, one participant had a total blood mercury level greater than 10 μg/L, which is also considered elevated (ATSDR 2006).

Exposure and Disease Registries

CERCLA mandates that ATSDR, in cooperation with the states, establish and maintain a national registry of serious diseases and illnesses and a national registry of persons exposed to toxic substances.

As an example, ATSDR maintains the National Exposure Registry (NER), which is a long-term effort that meets the need for collecting information concerning the potential impact of hazardous substances on human health. The registry is a listing of persons exposed to hazardous substances. It contains subregistries for specific substances. There are currently four active subregistries—TCE, trichloroethane, benzene, and dioxin. This exposure registry could be expanded to include other substances, One purpose of the NER is to help scientists understand how long-term exposure to hazardous substances may affect human health. Another purpose of the registry is to have a mechanism through which participants can be notified of the results of research related to their expo-

sure. The registry program carries out its mandate by creating a large database of similarly exposed persons. This database is used to facilitate epidemiological research in ascertaining any adverse health effects of persons exposed to low levels of chemicals over a long period. All data collected are confidential. Names and addresses are protected under the Privacy Act and are not released without written permission of the registrant."[5]

Health Education and Promotion

CERCLA mandates that ATSDR assemble, develop as necessary, and distribute appropriate educational materials on medical surveillance, screening, and methods of diagnosis and treatment of injury or disease related to exposure to hazardous substances through such means as the administrator of ATSDR deems appropriate. The committee evaluates communication efforts in Chapter 5 of this report.

SUMMARY

ATSDR is the source of a number of products, some of which are funded or partially funded by DOE, that have value for the program conducted under the MOU and are generally of a high quality. The PHAs and toxicological profiles are presented in such a way as to have potential value to the communities surrounding DOE sites. Some of this utility has been compromised by the public's reaction to ATSDR's use of a threshold for radiation effects in some of the PHAs. In 1997, ATSDR began submitting DOE PHAs for peer review. The committee supports the continued peer review of these documents in the future. An overview of ATSDR's DOE-funded activities suggests that research priorities and project selection are appropriate, with the understanding that many of the priorities are mandated by CERCLA

FINDINGS AND RECOMMENDATIONS

1. The PHAs are presented in such a way as to have potential value to the communities surrounding DOE sites. Some of this utility has been compromised by the public's reaction to ATSDR's use of a threshold for radiation effects. As a result, the committee recommends the following:

> In light of ATSDR's mandate to adopt and apply conservative assumptions, the committee recommends that ATSDR reevaluate its use of a radiation risk threshold.

[5]See *http://www.atsdr.cdc.gov/NER/index.html*. Last accessed July 2006.

2. ATSDR has completed 20 PHAs addressing 22 DOE sites on EPA's NPL. ATSDR is currently working on five remaining DOE sites, Hanford, Brookhaven, Los Alamos, Savannah River, and Oak Ridge. The committee concludes that the PHAs have potential value to the communities surrounding DOE sites and that the PHAs at the five sites that have already been initiated should be completed. As a result, the committee recommends the following:

DOE funding of ATSDR activities at the five DOE sites should continue.

ANNEX 3A CERCLA DIRECTIVE REGARDING PUBLIC HEALTH ASSESSMENTS

SUBCHAPTER I—HAZARDOUS SUBSTANCES RELEASES, LIABILITY, COMPENSATION. . . .
9604. [CERCLA 104] Response authorities. . . .
(i) Agency for Toxic Substances and Disease Registry; establishment, functions, etc. . . .
(6)
(A) The Administrator of ATSDR shall perform a health assessment for each facility on the National Priorities List established under section 9605 of this title.
. . .
(F) For the purposes of this subsection and section 9611 (c)(4) of this title, the term "health assessments" shall include preliminary assessments of the potential risk to human health posed by individual sites and facilities, based on such factors as the nature and extent of contamination, the existence of potential pathways of human exposure (including ground- or surface-water contamination, air emissions, and food chain contamination), the size and potential susceptibility of the community within the likely pathways of exposure, the comparison of expected human exposure levels to the short-term and long-term health effects associated with identified hazardous substances and any available recommended exposure or tolerance limits for such hazardous substances, and the comparison of existing morbidity and mortality data on diseases that may be associated with the observed levels of exposure. . . .

ANNEX 3B ATSDR DESCRIPTION OF TOXICOLOGICAL PROFILES

Information Provided to the Committee by ATSDR Regarding Toxicological Profiles

• Provide an examination, summary, and interpretation of a hazardous substance to determine its human health impact. Profiles also include guidance values known as MRLs, which are defined as estimates of daily human exposure to

a hazardous substance that are likely to be without appreciable risk of adverse, non-cancer health effects. MRLs are used as screening levels by health assessors to assist in decision making at hazardous waste sites.

- Succinctly characterize the toxicological and adverse health effects information.
- Determine levels of exposure that present a significant risk to human health.
- Identify research needed to fill data gaps.
- Undergo independent peer review.
- Make available for public comment.
- ATSDR's approach to toxicological profiles was published in the *Federal Register* on May 11, 1993.
- Toxicological profiles are developed pursuant to Section 104(i)(3) and (5) of CERCLA for hazardous substances found at DOE waste sites. CERCLA directs ATSDR to develop profiles on substances most commonly found at NPL sites that pose a significant potential threat to human health, as determined by ATSDR and EPA.
- Section 104(i)(5) of CERCLA, as amended, directs ATSDR (in consultation with EPA) to assess whether adequate information on the health effects of a profiled substance is available.
- CERCLA directs ATSDR, in conjunction with EPA, to prepare a list, in order of priority, of at least 100 hazardous substances that are most commonly found at facilities on the NPL and, in their sole discretion, are determined to pose the most significant potential threats to human health (52 FR 12866, April 17, 1987). The "Priority List of Hazardous Substances at Department of Energy National Priorities List Sites and Support Document" was released as final in November 1996 (61 FR 38451, July 24, 1996).

REFERENCES

ATSDR (Agency for Toxic Substances and Disease Registry). 1995. Hanford 1100-Area (US DOE), Richland, Benton County, Washington. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 1997a. Hanford 300-Area (DOE), Richland, Benton County, Washington. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 1997b. Hanford 200-Area (DOE), Richland, Benton County, Washington. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 1999. Toxicological Profile for Ionizing Radiation. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2004a. Y-12 Uranium Releases: U.S. Department of Energy Oak Ridge Reservation Oak Ridge, Anderson County, Tennessee. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2004b. Toxicological Profile for Cesium. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2005a. Public Health Assessment for Los Alamos National Laboratory (USDOE Public Comment version April 26, 2005). Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2005b. TSCA Incinerator: U.S. Department of Energy Oak Ridge Reservation Oak Ridge, Anderson County, Tennessee. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2006. ATSDR response to committee questions. To the Committee to Review the Worker and Public Health Activities Program, Atlanta, GA, February 10.

Cardis, E., M. Vrijheid, M. Blettner, E. Gilbert, M. Hakama, C. Hill, G. Howe, J. Kaldor, C.R. Muirhead, M. Schubauer-Berigan, and T. Yoshimura. 2005. Risk of cancer after low doses of ionising radiation: retrospective cohort study in 15 countries. Br Med J 331(7508):77-80.

Darby. S., D. Hill, A. Auvinen, J.M. Barros-Dios, H. Baysson, F. Bochicchio, H. Deo, R. Falk, F. Forastiere, M. Hakama, I. Heid, L. Kreienbrock, M. Kreuzer, F. Lagarde, I. Makelainen, C. Muirhead, W. Oberaigner, G. Pershagen, A. Ruano-Ravina, E. Ruosteenoja, A.S. Rosario, M. Tirmarche, L. Tomasek, E. Whitley, H.E. Wichmann, and R. Doll. 2005. Radon in homes and risk of lung cancer: collaborative analysis of individual data from 13 European case-control studies. Brit Med J 330(7485):223.

Field, R.W., D.J. Steck, B.J. Smith, C.P. Brus, E.L. Fisher, J.S. Neuberger, C.E. Platz, R.A. Robinson, R.F. Woolson, C.F. Lynch. 2000. Residential radon gas exposure and lung cancer: the Iowa Radon Lung Cancer Study. Amer J Epi 151(11):1091-1102.

Krewski, D., J.H. Lubin, J.M. Zielinski, M. Alavanja, V.S. Catalan, R.W. Field, J.B. Klotz, E.G. Letourneau, C.F. Lynch, J.I. Lyon, D.P. Sandler, J.B. Schoenberg, D.J. Steck, J.A. Stolwijk, C. Weinberg, and H.B. Wilcox. 2005. Residential radon and risk of lung cancer: a combined analysis of 7 North American case-control studies. Epidemiology 16(2):137-145.

Krewski, D., J.H. Lubin, J.M. Zielinski, M. Alavanja, V.S. Catalan, R.W. Field, J.B. Klotz, E.G. Letourneau, C.F. Lynch, J.L. Lyon, D.P. Sandler, J.B. Schoenberg, D.J. Steck, J.A. Stolwijk, C. Weinberg, and H.B. Wilcox. 2006. A combined analysis of North American case-control studies of residential radon and lung cancer. J Toxicol Environ Health A 69(7):533-597.

NCRP (National Council on Radiation Protection and Measurements). 2001. Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation, NCRP Report No. 136. Bethesda, MD.

NRC (National Research Council). 1990. Health Effects of Exposure to Low Levels of Ionzing Radiation (BEIR V). Washington, DC: National Academy Press.

NRC (National Research Council). 1999. Health Risks of Radon (BEIR VI Report). Washington, DC: National Academy Press.

NRC (National Research Council). 2006. Health Risks from Exposure to Low Levels of Ionizing Radiation. BEIR VII Phase 2. Washington, DC: National Academy Press.

Tatham, L.M., F.J. Bove, W.E. Kaye, and R.F. Spengler. 2002. Population exposures to I-131 releases from Hanford Nuclear Reservation and preterm birth, infant mortality, and fetal deaths. Int J Hyg Environ Health 205:41-48.

4

Scientific Program Assessment: Dose Reconstruction Projects Supported by the National Center for Environmental Health

The focus of the research and public health activities under the Memorandum of Understanding (MOU) is on health effects that may have resulted from Department of Energy (DOE) operations, including development and production of nuclear weapons and materials and other nuclear energy-related research and development activities. Under the MOU, the National Center for Environmental Health (NCEH) is responsible for conducting research related to ionizing radiation in the environment. In this context, the Radiation Studies Branch of NCEH has undertaken a series of studies to evaluate the historical exposures of members of the public to contaminants released into the environment from nuclear weapons facilities in the United States. These federally funded studies are referred to as "dose reconstructions" and arose primarily from public concern about the health risks associated with the facilities that had operated in a climate of secrecy during World War II and the ensuing Cold War era. These studies have played an important role in unveiling the details of those operations, quantifying the magnitude of exposures and doses to the surrounding populations, and assessing the potential health impacts.

There had been earlier dose reconstruction efforts in the United States, in particular to reconstruct the doses to members of the public in regions near the Nevada Test Site (NTS) who were exposed to fallout from the atmospheric testing of nuclear weapons (Anspaugh and Church 1986; Anspaugh et al. 1990). The exposure dosimetry was developed under the DOE-funded Offsite Radiation Exposure Review Project (ORERP) (Church et al. 1990). The NTS dose reconstruction effort was important for establishing a methodology to quantify individual exposures. The NTS work was expanded into a more robust and flexible method-

ology to estimate doses for a large number of individuals in a thyroid cohort study and a leukemia case-control epidemiological study conducted at the University of Utah for the National Cancer Institute (Lloyd et al. 1990a, 1990b). More recently, the dosimetry system for the thyroid cohort study was restored and updated to calculate doses in the 1980s (Simon et al. 2006).

When the Radiation Studies Branch of NCEH first became involved in dose reconstruction studies after the signing of the MOU, it used the National Academy of Sciences (NAS)-National Research Council (NRC) to provide scientific advice on dose reconstructions and to help NCEH establish research priorities (NRC 1995). The NAS-NRC organized a committee whose charge was the following:

- Review and comment on the design, methods, analysis, statistical reliability, and scientific interpretation of dose reconstruction and related epidemiological follow-up studies.
- Recommend ways to strengthen study protocols and analyses to enhance the quality of these studies.

To accomplish its task, the 1995 NRC committee not only reviewed NCEH's dose reconstruction efforts at Fernald and Hanford, but also drew on the collective knowledge of 47 scientists from around the world with experience and expertise relevant to reconstructing radiation exposures of human populations. The scientists participated in a 3-day workshop in October 1993 and were asked to assist the committee in identifying criteria to be considered when undertaking radiation dose reconstruction studies, to examine the pitfalls encountered in previous studies, and to recommend areas of needed research. The committee's findings were reported to NCEH and published in a report (NRC 1995). NCEH took account of this information as it initiated new dose reconstruction studies.

To a large extent, however, selection of the dose reconstruction studies arose out of public concern and pressure. NCEH assumed responsibility for the Hanford Environmental Dose Reconstruction (HEDR) Project following the signing of the MOU. A dose reconstruction project at Fernald was mandated by Congress, a study at Los Alamos was requested by the governor of New Mexico, and similarly, a dose reconstruction at Idaho National Laboratory was requested by the governor of Idaho. For selection of the remaining studies, NCEH stated that they also relied on the early Advisory Committee for Energy-related Epidemiological Research (ACERER)[1] recommendations (see Chapter 1).

Table 4-1 provides an overview of the DOE sites at which NCEH has been responsible for dose reconstruction activities. It is apparent from the table that the

[1]The Department of Health and Human Services (HHS) established ACERER in early 1992, with its first meeting occurring in January 1993. ACERER continued to provide advice to the Secretary of HHS regarding the OERP research agenda until 2000.

TABLE 4-1 Overview of NCEH Dose Reconstruction Activities

Facility	Dominant Environmental Releases	Approach to Dose Reconstruction (time frame)
Hanford *1944-1990* Plutonium production	Releases of I-131 to air Releases of mixed radionuclides (fission products and activation products) to the Columbia River	Hanford Environmental Dose Reconstruction Project: • Develop methods to calculate doses (1988-1990) • Estimate doses to reference individuals from the air and Columbia River pathways (1990-1996) Hanford Individual Dose Assessment (IDA) Project: • Provide I-131 dose estimates of exposed individuals using HEDR models (1994-2000) Follow-up Activities: • Columbia River pathway doses, doses from short-lived radionuclides and radioactive particles during early Hanford operations (2001-2002)
Fernald *1951-1988* Uranium feed materials production	Releases of uranium and radon to air	Fernald Dosimetry Reconstruction Project:[a] • Complete dose reconstruction yielding dose estimates for representative individuals (1990-1998) Fernald Risk Assessment:[b]: • Lung cancer risk analysis (1996-1998) • Screening-level estimates of lifetime risk of developing other cancers (kidney, breast, bone, leukemia) (1999)
Savannah River Site (SRS) *1953-2002*[c] Plutonium and tritium production	Releases of I-131, tritium, and Ar-41 to air	Savannah River Site Dose Reconstruction Project: • Document search and database development (1992-1995) • Source term calculation and ingestion pathway data retrieval (1995- 2001) • Risk-based screening of radionuclide releases (2002-2005)[d] • Directed dose assessment (2004-present day)[e]

Idaho National Laboratory (INL) *1949-present day* Development and testing of nuclear reactors and related facilities	Releases of Cs-137, P-32, Sr-90, and I-131 to surface water	Releases of I-131, Cs-137, and Sr-90 to air INL Dose Reconstruction Study[f]: • Document search and database development (1992-1994) • Document retrieval (1998-2000) • Feasibility study for a chemical dose reconstruction (1996-1999) • Identification and prioritization of radionuclide releases (1997-2002) • Doses to the public from atmospheric releases from Idaho Chemical Processing Plant and screening calculations for atmospheric releases from select initial engine tests associated with the Aircraft Nuclear Propulsion Program (2000-2005)
Los Alamos *1953-present day* Nuclear weapons design and development	Preliminary results indicate: releases of plutonium and uranium, explosives, and volatile organic chemicals to air and releases of plutonium in liquid effluents	Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project • Document search and database development (1998-present day)[g]

[a]Initially, the Fernald Project was a congressional mandate. It was later made part of the DOE MOU.

[b]Risk assessments available at http://www.cdc.gov/nceh/radiation/phase2/results.pdf. Last accessed November 2006.

[c]Although the site remains operational, the main production activities at SRS ceased at the end of 1992.

[d]Original purpose of Phase III was to do screening calculations; after the study was under way, NCEH and the Health Effects. Subcommittee jointly decided to go ahead and estimate doses for hypothetical individuals.

[e] Anticipated end date for SRS dose reconstruction is September 2006.

[f]As a result of source term and screening analyses, the dose reconstruction focused on releases of radionuclides from RaLa process operations at the Idaho Chemical Processing Plant (ICPP) and on episodic atmospheric releases from initial engine tests (IET) in the Aircraft Nuclear Propulsion (ANP) Program. A detailed dose reconstruction of I-131 releases from the ICPP was performed (Apostoaei et al. 2005). Bounding estimates of doses to offsite members of the public from other radionuclides released from ICPP yielded low values (Apostoaei et al. 2005). (Fr this reason, a detailed reconstruction of these doses was not performed. Three IETs were identified as responsible for most of the releases during the ANP program, and could have resulted in significant offsite exposures to I-131 (Behling and Mauro 2005). However, there were large uncertainties in the magnitude and temporal distribution of the releases. For these reasons it appears that a more detailed reconstruction of doses was not considered warranted by NCEH and the study was considered complete.

[g]Anticipated end date for LAHDRA document retrieval and assessment is 2009.

NCEH effort did not address all of the major DOE facilities within the United States. This is because some states entered into separate agreements with DOE. For example, the State of Tennessee and DOE entered into the "Tennessee Oversight Agreement," which established a DOE funding source that allowed the Tennessee Department of Health to undertake a two-phase research project aimed at determining whether environmental pollutant releases from the Oak Ridge Reservation created public health problems (ORHASP 1999). Similarly, in June 1989, Colorado Governor Roy Romer and Secretary of Energy James Watkins signed an agreement in principle that included DOE funding for the Rocky Flats Toxicological Review and Dose Reconstruction Project. NCEH provided technical support for both of these major dose reconstruction efforts.[2]

Dose reconstruction studies focus on estimating the doses or risks to individuals exposed to releases from a site. These doses may be calculated for representative individuals or for specific individuals depending on the objectives of the study. In either case, the goal is to develop a good estimate of the magnitude of the releases that occurred and the doses received. In general, the studies focus on individuals who lived in the vicinity of the site and downwind or downstream of it. However, care is required during the early stages of the study not to rule out exposure pathways that may have resulted in doses to individuals more distant from the site.

Because direct measurements of individual exposures are rarely available, computer models must be relied upon to calculate the environmental exposure concentrations. This can range from taking historical measurements and applying them to times and locations for which no data are available, to reconstructing the quantities released (the source term) and the subsequent fate and transport of the material in the environment. The environmental datasets compiled from historical measurement data are typically used either to calibrate or to test the computer models employed in the dose reconstruction, recognizing that a dataset cannot be used for both purposes.

Frequently, the largest releases and exposures have occurred decades earlier than the time when the dose reconstruction is performed, with the end result that the studies invariably require the source term to be reconstructed. The historical records that must be relied upon inevitably contain gaps because the records are incomplete, missing, or not sufficiently detailed. Furthermore, measurement detection limits and biases have changed over time as sampling methods and procedures, analytic instruments, and techniques have developed. This is most apparent during the early years of operation of many of the sites when much of the science was in its infancy. Consequently, there are always uncertainties associ-

[2]Information provided by C.W. Miller at November 4, 2005, presentation to the Worker Health committee.

ated not only with the dose estimates but also with any environmental datasets to which model predictions are compared, and these need to be quantified and used in the epidemiological assessment of risk.

For any dose reconstruction, access to documents and data is central to the success of the study. All documents containing relevant information must be examined and the useful information extracted. If difficulties arise in the document search and review for a dose reconstruction, it is in relation to classified documents. This was a central issue that had to be addressed for the dose reconstruction at Hanford, which was the first study of a DOE facility that was open to the public. At that time, "most of the documents which described Hanford activities—tens of thousands of documents in all—were kept secret by virtue of a classification process. Many documents were automatically classified as soon as they were created" (Niles 1996).

It took time and persistence to establish the need to declassify relevant documents and to achieve a working process. The Technical Steering Panel (TSP) chaired by Dr. John Till pioneered this effort, which was well under way by the time the MOU was established in 1990 and NCEH assumed responsibility for the dose reconstruction at Hanford. The experience at Hanford highlighted the importance of historical documents to the dose reconstruction process, and in March 1990 Secretary of Energy James Watkins placed a moratorium on the destruction of DOE and DOE contractor records useful for epidemiological or health studies (DOE 2000).

To facilitate access to DOE facilities by researchers and investigators involved in the dose reconstruction studies and other activities covered under the MOU, DOE and HHS jointly prepared a handbook to be used as a reference guide (DOE 2003). However, the decentralized, semiautonomous nature of administration of each DOE site has resulted in different levels of cooperation between the sites with regard to document access—none more so than at Los Alamos National Laboratory (LANL), which NCEH has found to be the most difficult to work with of all DOE sites. The Los Alamos Historic Document Retrieval and Assessment (LAHDRA 2006) report on the dose reconstruction efforts states: "Access to classified documents at Los Alamos has been more difficult than LAHDRA team members have experienced at any of the other DOE sites that have been subjects of dose reconstruction investigations."

NCEH and its contractors were denied or restricted access to classified records or document repositories at Los Alamos. These issues continued for more than 5 years before any solution was reached. Some of the difficulties resulted from events unrelated to the dose reconstruction activities and certainly resulted in unavoidable delays. For example, early in the project in May 2000 the towns of Los Alamos and White Rock were evacuated because of the Cerro Grande Fire, and the site was shut down for a number of weeks. Much later, in July 2004 there was an extended shutdown of the site in response to a security incident that involved hard drives missing from an X-Division vault. However, there remains

the underlying impression that LANL has been unwilling to implement the degree of openness necessary for a meaningful dose reconstruction even though the procedures had been established at other DOE sites long before LAHDRA was initiated. Furthermore, the Radiation Studies Branch appears to have allowed this situation to persist for an extended period of time.

It is the committee's understanding that when NCEH completes the LAHDRA project it will no longer be involved in dose reconstructions at the DOE sites. At this time the committee has not identified the need for further dose reconstructions at the DOE sites, but in the event that any further dose reconstructions at DOE sites are required, NCEH, or some other agency independent of DOE, should manage and direct the studies to maintain the independence of the dose reconstruction effort.

The committee concludes that it is important for the findings of the dose reconstruction studies to be readily accessible to all interested parties, not just at the time of the studies but long after their completion. NCEH has made dose reconstruction project findings available on-line via the Radiation Studies Branch web site.[3] For some of the studies, all of the project reports are made available (e.g., the Savannah River Site [SRS], Idaho National Laboratory [INL]); for others, only the final summary reports are provided (e.g., Hanford). In some cases, there are links to the studies from the individual DOE facility's web site. This is sensible since a person seeking information about historical releases from a DOE facility and their potential health effects on the surrounding communities would not necessarily know which organizations would be responsible for studying those releases and effects. The publication of dose reconstruction study findings in the open literature appears to depend on the initiative of the contractors who performed the research. NCEH does not appear to have a consistent policy in this regard, which is probably appropriate given the different ways in which contractors are utilized by NCEH to address a dose reconstruction study and the fact that the findings may not always warrant publication.

Time did not permit the committee to evaluate all of the dose reconstruction studies conducted by the Radiation Studies Branch of NCEH in detail. Instead, the committee focused on three committee-selected DOE sites. NCEH conducted dose reconstruction activities at two of these: Hanford, Washington, and Los Alamos, New Mexico. As explained previously, NCEH did not undertake a dose reconstruction at Oak Ridge. Hanford and LANL represent the two ends of the spectrum of dose reconstruction efforts by NCEH under the MOU. More specifically, at Hanford there was a comprehensive evaluation of historical releases of radionuclides to the environment from operations at the Hanford facility, and doses to representative individuals in the surrounding populations were calculated. The results for iodine-131 (I-131), the principal radioactive material of

[3]See *http://www.cdc.gov/nceh/radiation/*. Last accessed August 2006.

interest, were subsequently used in the Hanford Thyroid Disease Study (HTDS), a major epidemiological study that did not fall under the MOU. In contrast, at Los Alamos the dose reconstruction efforts are still at the initial, information gathering phase. The committee bases its review of the NCEH work upon both its expert judgment of the quality of the work and, for Hanford, a number of reports (NRC 1994, 1995, 1999, 2001, 2002) from previous NRC expert panels that provided ongoing reviews of portions of the HEDR Project, including the dosimetry system ultimately used in the HTDS.

HANFORD ENVIRONMENTAL DOSE RECONSTRUCTION PROJECT

The facility at Hanford, Washington, was designed to create plutonium for nuclear weapons. Operation of the first two plutonium production reactors began in December 1944. A total of nine nuclear production reactors operated at Hanford and were located near the Columbia River. Fuel fabrication facilities were built to prepare uranium fuel for the reactors, and chemical separation plants separated the plutonium from uranium and from fission products created during irradiation in the reactor (TSP 1994). The Hanford facility produced plutonium from 1944 to 1990.

The dose reconstruction study of the Hanford facility was a multiyear project to determine how much radioactive material was released from the Hanford site, how that material may have reached and exposed people, and most importantly, what radiation doses people may have received (TSP 1994). The study began in 1988 prior to the signing of the MOU and was conducted by scientists at Battelle, Pacific Northwest Laboratory (PNNL), a contractor at the Hanford site. A TSP composed of independent scientists and members of the public was created to oversee and direct the HEDR Project. Following the signing of the 1990 MOU, the Centers for Disease Control and Prevention (CDC) assumed responsibility for the HEDR Project.

The HEDR Project provided the dose calculation methodology that was used in a parallel project, the HTDS, that did not fall under the MOU. The HTDS was a congressionally mandated study funded by NCEH and carried out by the Seattle-based Fred Hutchinson Cancer Research Center. The HTDS also began in 1988 and took 9 years to complete.

In Phase I of the dose reconstruction study, the methods for reconstructing the radiation doses to people who lived in the 10 Oregon and Washington counties closest to Hanford were developed and tested. This phase was completed in 1990 (TSP 1990). The major research phase of the dose reconstruction project was completed in 1994, with the conclusion of the Battelle contract and the publication of reports containing estimated radiation doses to reference individuals (typical individuals) from the air and Columbia River pathways (Niles 1996), although follow-up activities that had been identified by the TSP continued for a number of years. These follow-up activities are described later.

The principal radioactive material of interest released to the air was I-131

(TSP 1994). Detailed I-131 dose calculations were prepared for the years of maximum release (1944-1951). The largest doses were calculated for a hypothetical child who drank milk produced by a backyard cow that was fed fresh pasture supplemented by alfalfa and grain. The median cumulative thyroid dose for such a child at Ringold, the maximally exposed location, was about 2.35 Gy (235 rad) (with a dose range from 0.54 to 8.70 Gy [54 to 870 rad]) (TSP 1994).

River water was used to cool the reactors and resulted in releases of radionuclides to the Columbia River. Detailed dose calculations were prepared for the period of largest releases (1950-1971), and ingestion of resident fish was identified as the most significant exposure pathway. The median cumulative effective dose equivalent for the maximally exposed person at Richland, Washington, for all years (1944-1992) was estimated to be about 15 mSv (1.5 rem) with the 10-year period 1956-1965 accounting for most of this cumulative dose (TSP 1994).

Previous NRC Reviews of the HEDR Project

The Radiation Studies Branch of NCEH used the NRC to provide an independent technical review of portions of the HEDR study. The review was considered important by NCEH in light of considerable public concern regarding the historical releases. Furthermore, NCEH hoped that the evaluation of the Hanford site might serve as a model for studies planned by NCEH at other sites. However, the NRC review was not the sole source of independent technical review for the HEDR Project. The TSP provided independent guidance to the project, and TSP activities were conducted in an open public forum. All reports were available in draft form for public review and comment, and many of the technical reports received scientific peer review. Typically, PNNL also organized its own scientific peer review of technical reports prior to any subsequent reviews arranged by the TSP. A brief overview of the different reviews performed by the NRC is provided below.

NCEH first asked the NRC to review four of the early HEDR reports that provided data and procedures for determining the annual and cumulative releases of I-131 (Heeb 1992), techniques for modeling environmental movement of radionuclides (Shipler and Napier 1992), and parameters for calculating doses (Snyder et al. 1992). The NRC issued a favorable review of these four documents and found the modeling approach to be conventional and sound (NRC 1994).

The NRC was later asked by NCEH to critically review draft versions of two HEDR summary reports (Farris et al. 1994a, 1994b). One documented the methods used to estimate doses received by representative individuals who were exposed, directly or indirectly, to I-131 released to the air; the other documented the methods used to estimate doses received by representative individuals who were exposed, directly or indirectly, to radionuclides released to the Columbia River. The committee published its review of the two draft reports the following year (NRC 1995). It commended the authors for producing reports that were signifi-

cantly improved over those the committee had reviewed earlier for the feasibility study, but it also indicated some concerns. The review offered a number of recommendations for improving the reports, and specific comments were presented in an appendix. After the dose estimates had been made for the HEDR Project, NCEH initiated a number of studies to address some remaining issues that had been identified by the TSP or that emerged following publication of the project findings. Those studies are described below.

In 1997, NCEH asked the NRC to address a number of specific issues related to the validation of the HEDR atmospheric I-131 pathway models. A central issue was the discrepancy between sagebrush vegetation measurements and concentrations predicted by the HEDR model. The task required the NRC to review components of the HEDR Project that had not previously been examined in any detail. The NRC issued a letter report concluding that the HEDR model was structurally sound, but there had been errors in the HEDR estimation of I-131 concentrations in pasture grass that needed to be formally documented (NRC 1999).

The HEDR Project focused on I-131 doses to members of the public located off-site. The doses to persons who worked or lived on-site, such as military personnel stationed on the reservation and construction workers present after the first reactors and processing plants became operational, were not addressed. Of potential concern was the exposure of on-site workers to short-lived radionuclides, and the exposure to episodic releases of large radioactive particles in the late 1940s and early 1950s. Radiological Assessments Corporation (RAC)[4] was contracted by NCEH to develop a computer program to estimate "worst-case" doses to people living or working near the production facilities from radioactive particles and short-lived radionuclides. NCEH subsequently asked the NRC to review the draft report prepared by RAC. The NRC issued a letter report of its findings (NRC 2001). RAC's final report to NCEH (Voillequé et al. 2002) took into account the comments of the NRC.

Hoffman et al. (1997), under contract to ATSDR, reviewed the HEDR Project dose estimates for radionuclides released to the Columbia River and suggested that I-131, cobalt-60 (Co-60), and strontium-90 (Sr-90) should have been included in the HEDR dose calculations and in the Hanford Individual Dose Assessment (IDA) process.[5] This question was evaluated by RAC under contract to NCEH. NCEH asked the 2002 NRC committee to review the draft report prepared by RAC on this topic. The 2002 NRC committee issued a letter report with its review (NRC 2002). The review found the methodology that RAC developed

[4]RAC later changed its name to Risk Assessment Corporation. RAC is a consulting group led by John Till. Dr. Till was also the chair of the HEDR technical panel.

[5]NCEH sponsored a Cooperative Agreement with the Washington Department of Health to develop and administer the Hanford IDA Project to allow individuals exposed to Hanford radiation releases to estimate their individual radiation doses. This project was a service, not a study.

to be adequate but identified a number of inconsistencies between input data used by RAC as compared to that documented in HEDR, and the review recommended that the inconsistencies be corrected. The inconsistencies were corrected and the results presented in the final report (Grogan et al. 2002),[6] taking into account the 2002 NRC committee's review. Grogan et al. (2002) did not conclude that HEDR Project dose calculations were warranted for I-131 or Sr-90. The risks calculated for Co-60 accounted for a small fraction (1 to 2 percent) of the total risk from the river pathway scenarios that were evaluated. RAC recommended development of improved release estimates for Co-60 before attempting any further dose calculations. NCEH did not believe the study results indicated the need for any further analysis of this topic.

As stated previously, NCEH did not engage the NRC to review the entire HEDR Project. Instead, NCEH identified specific components for the committee to review as the project progressed. NCEH's approach of assigning isolated portions of a project that lasted more than a decade for NRC review concerned the TSP. Following the earliest reviews, the TSP noted that some of the review conclusions implied that important work was not being done, when in many cases, these concerns were addressed in other reports that were not included in the review (Niles 1996). Furthermore, the NRC reviews were critical of the direction of some of the work and the level of effort invested in the river pathway, for example. TSP Chair Mary Lou Blazek disagreed with the conclusion, stating: "Given Hanford's past operating history, and the huge amounts of radioactive material that we know went into the Columbia River, we had an obligation to those people who lived along the river to thoroughly evaluate the dose they may have received from Hanford releases to the river. I believe the work we have done fulfills that obligation" (Niles 1996).

It is not unusual to find instances in which resources are allocated to an issue that is relatively insignificant from a scientific perspective in terms of dose or risk. The dose reconstruction studies were initiated in response to public concern; although some issues may have a low priority based on scientific analysis, they can be important for establishing the credibility of the project.

LOS ALAMOS DOSE RECONSTRUCTION PROJECT

Los Alamos Laboratory began in 1943 as Project Y of the Manhattan Project with the mission of developing the world's first nuclear weapon. This was achieved in August 1945. The laboratory continues to operate, and its mission has expanded from nuclear weapons development and testing, to stockpile steward-

[6]Helen A. Grogan is a member of the current review committee and was a subcontractor to RAC on some NCEH studies (see committee biographies). The present committee did not evaluate Dr. Grogan's work but reports an evaluation done by a previous NRC committee (NRC 2002).

ship, nuclear reactor and accelerator research, high-explosives and ordinance development and testing, waste disposal and incineration, and other chemical, biological, and energy-related studies. Currently, LANL's mission is described as national security.

LANL is the DOE facility at which NCEH has begun many dose reconstruction activities. A 3-year study to review historical documents about off-site releases from LANL operations and to establish a publicly available database of relevant documents began in early 1999. The LAHDRA was performed under contract to NCEH by ENSR International, ChemRisk, Inc., and Shonka Research Associates, Inc. NCEH extended the contract to 5 years because the task took longer than anticipated. The interim project report issued in July 2004 (LAHDRA 2004) stated the following:

> While millions of documents have been reviewed at Los Alamos, the information gathering is not complete. For various reasons that are discussed in this report, document review at Los Alamos has taken significantly longer than expected. There are now known to be significantly more documents at LANL than was originally estimated, and the processes for access to classified documents and for public release of relevant documents have been more complicated and time consuming than was expected . . . CDC will evaluate whether to competitively procure another contract to continue towards completion of information gathering and assessment at Los Alamos.

NCEH chose to continue the study, awarding a second 5-year contract in September 2004. Document review did not start until February 2005 because LANL was shut down following a number of security incidents. The work was performed by a team led by ChemRisk, Inc., and including Shonka Research Associates, Inc.; ENSR International; and Advanced Technologies and Laboratories International, Inc. The most recent interim report (LAHDRA 2006) issued nearly 7 years after the project started states: "The CDC project at Los Alamos is in the initial information-gathering phase. The process of information gathering and assessment is partially complete."

The interim report (LAHDRA 2006) provides a summary of the information that has been obtained by the LAHDRA project team regarding

- Historical operations at Los Alamos,
- The materials that were used,
- The materials that were likely released off-site,
- Development of residential areas in Los Alamos, and
- The relative importance of identified releases in terms of potential health risks.

The report also states: "Based on the project's findings, CDC will work with stakeholders to determine if more detailed assessments of past releases are war-

ranted, they might be in the form of screening level evaluations, or could progress to detailed dose reconstructions for those releases of highest priority."

The dose reconstruction effort at Los Alamos has progressed extremely slowly compared to any of the other DOE facilities where dose reconstruction studies have been conducted. Although some of the delays have resulted from circumstances beyond the control of NCEH, the length of time required to date suggests a lack of commitment on the part of LANL/DOE toward the dose reconstruction effort and an inability on the part of NCEH to find timely solutions. This extended delay undermines the credibility of the dose reconstruction process.

CONTRIBUTIONS TO DOE

For many of the DOE facilities, NCEH conducted dose reconstruction studies of historical exposures of the public independent of DOE. NCEH has established a scientifically sound public record of the operations of these facilities and the magnitude of the doses received by members of the surrounding communities. This independent and scientifically sound analysis benefits DOE by providing credible dose estimates to the public.

SUMMARY

1. At the request of NCEH, the NRC identified and documented (NRC 1995) the different components and steps that comprise a high-quality, credible dose reconstruction. NCEH used this information to help design and conduct subsequent dose reconstruction activities.

2. Every DOE facility is different, in terms of the materials and quantities released to the environment, the time periods of releases, exposure pathways, demographics, and degree of public concern. This necessarily impacts the appropriate design of a dose reconstruction.

3. The NCEH program has provided valuable data to the communities surrounding DOE facilities in particular, and to the public in general, about the historic operations of those facilities, the environmental impacts, and the doses or health risks of individuals exposed to releases from the site.

FINDINGS AND RECOMMENDATIONS

1. The LAHDRA project at Los Alamos is the sole remaining dose reconstruction activity of NCEH and the public would benefit from the information derived from this activity. The initial data-gathering phase of the LAHDRA project is taking an inordinate length of time compared to similar stages at other DOE facilities. Therefore the committee recommends that:

NCEH complete this project as expeditiously as possible and provide as

much evaluation of the compiled data as feasible to inform the public regarding historical doses and risks.

2. The NCEH program has conducted dose reconstruction studies that are independent of DOE. These studies have provided valuable data to the communities surrounding DOE facilities in particular, and to the public in general, about the historic operations of those facilities, the environmental impacts, and the doses or health risks of individuals exposed to releases from the site. Therefore, the committee recommends that:

NCEH continue to make the findings of its dose reconstruction studies available to the public on-line, ideally including a direct link to the study results from the facility's web site.

In the event that any further dose reconstructions at DOE sites are required, the committee recommends that NCEH or some other agency independent of DOE should manage and direct the studies and the funding for the studies should be provided by DOE.

REFERENCES

Anspaugh, L.R., and B.W. Church. 1986. Historical estimates of external gamma exposure and collective external gamma exposure from testing at the Nevada Test Site. I. Test series through HARDTACK II, 1958. Health Phys 51:35-51.

Anspaugh, L.R., Y.E. Ricker, S.C. Black, R.F. Grossman, D.L. Wheeler, B.W. Church, and V.E. Quinn. 1990. Historical estimates of external gamma exposure and collective external gamma exposure from testing at the Nevada Test Site. II. Test Series after HARDTACK II, 1958, and summary. Health Phys 59:525-532.

Apostoaei, A.I. 2005. Testing prediction capabilities of an 131I terrestrial transport model by using measurements collected at the Hanford nuclear facility. Health Phys 88(5):439-58.

Behling, U.H., and J. Mauro. 2005. A Critical Review of Source Terms for Select Initial Engine Tests Associated with the Aircraft Nuclear Propulsion Program at INEL. Final Report to the Centers for Disease Ccontrol and Prevention, Atlanta, GA. July. Draft.

Church, B.W., D.L. Wheeler, C.M. Campbell, R.V. Nutley, and L.R. Anspaugh. 1990. Overview of the Department of Energy's Off-site Radiation Exposure Review Project (ORERP). Health Phys 59:503-510.

DOE (U.S. Department of Energy). 2000. Review Process: DOE Field Site Records Retained Under the Moratorium on the Destruction of Health Related Records [on-line]. Available: http://www.eh.doe.gov/health/records/retention.html [accessed August 7, 2006].

DOE (U.S. Department of Energy). 2003. Access Handbook: Conducting Studies at Department of Energy Sites. DOE/EH-0556. Washington, DC: U.S. Department of Energy, Office of Health Studies.

Farris, W.T., B.A. Napier, T.A. Ikenberry, J.C. Simpson, and D.B. Shipler. 1994a. Atmospheric Pathway Dosimetry Report, 1944-1992. Hanford Environmental Dose Reconstruction Project. PNWD-2228 HEDR. Richland, WA: Battelle Pacific Northwest Laboratories.

Farris, W.T., B.A. Napier, J.C. Simpson, S.F. Snyder, and D.B. Shipler. 1994b. Columbia River Pathway Dosimetry Report, 1944-1992. Hanford Environmental Dose Reconstruction Project. PNWD-2227 HEDR. Richland, WA: Battelle Pacific Northwest Laboratories.

Grogan, H.A., A.S. Rood, J.W. Aanenson, and E.B. Liebow. 2002. A Risk-Based Screening Analysis for Radionuclides Released to the Columbia River from Past Activities at the U.S. Department of Energy Nuclear Weapons Site in Hanford, Washington. RAC Report No. 3-CDC-Task Order 7-2002-FINAL. Prepared by Risk Assessment Corporation, Neeses, SC. Atlanta, GA: Centers for Disease Control and Prevention.

Heeb, C.M. 1992. Iodine-131 Releases from the Hanford Site, 1944 through 1947, Vol. 1, Text and Vol. 2, Data. PNWD-2033 HEDR. Richland, WA: Battelle Pacific Northwest Laboratories.

Hoffman, F.O., A. Apostoaei, J.S. Hammonds, K.M. Thiessen, B.G. Blaylock, and E.A. Thomas. 1998. Estimation of Health Risks Based on Revised Estimates of HEDR Doses for Maximum Representative Individuals Consuming Fish and Waterfowl from the Columbia River: An Evaluation of HEDR Reports on the Columbia River. Oak Ridge, TN: SENES, Oak Ridge, Inc.

LAHDRA (Los Alamos Historical Document Retrieval and Assessment Project). 2004. Interim Report of the Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project. Version 3b. Atlanta, GA: Centers for Disease Control and Prevention.

LAHDRA (Los Alamos Historical Document Retrieval and Assessment Project). 2006. Interim Report of the Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project. Version 4. Atlanta, GA: Centers for Disease Control and Prevention.

Lloyd, R.D., S.L. Simon, J.E. Till, H.A. Hawthorne, D.C. Gren, M.L. Rallison, and W. Stevens. 1990a. Development of a method to estimate dose from fallout radioiodine in a thyroid cohort study. Health Phys 59:669-691.

Lloyd, R.D., D.C. Gren, S.L. Simon, M.E. Wrenn, H.A. Hawthorne, W. Stevens, J.E. Till, and T.M. Lotz. 1990b. Individual external exposures from Nevada Test Site fallout for leukemia cases and controls. Health Phys 59:723-738.

Niles, K. 1996. Reconstructing Hanford's Past Releases of Radioactive Materials: The History of the Technical Steering Panel 1988-1995. Hanford Environmental Dose Reconstruction (HEDR) Project Technical Steering Panel. Olympia, WA: Washington State Department of Health.

NRC (National Research Council). 1994. The Hanford Environmental Dose Reconstruction Project: A Review of Four Documents. Washington, DC: National Academy Press.

NRC (National Research Council). 1995. A Review of Two Hanford Environmental Dose Reconstruction Project (HEDR) Dosimetry Reports: Columbia River Pathway and Atmospheric Pathway. Washington, DC: National Academy Press.

NRC (National Research Council). 1999. Letter Report—Issues Regarding the Hanford Environmental Dose Reconstruction (HEDR) Atmospheric I-131 Pathway Models. Washington, DC: National Academy Press.

NRC (National Research Council). 2001. Letter Report to Review Identification and Prioritization of Radionuclide Releases from the Idaho National Engineering and Environmental Laboratory. Washington, DC: National Academy Press.

NRC (National Research Council). 2002. Review of Methods for Estimating Radiation Doses to Workers at Hanford: Letter Report. Washington, DC: National Academy Press.

ORHASP (Oak Ridge Health Agreement Steering Panel). 1999. Releases of Contaminants from Oak Ridge Facilities and Risks to Public Health, Final Report of the Oak Ridge Health Agreement Steering Panel. Nashville, TN: Tennessee Department of Health.

Shipler, D.B., and B.A. Napier. 1992. HEDR Modeling Approach. PNWD-1983 HEDR. Richland, WA: Battelle Pacific Northwest Laboratories.

Simon, S.L., L.R. Anspaugh, F.O. Hoffman, A.E. Scholl, M.B. Stone, B.A. Thomas, and J.L. Lyon. 2006. Update of dosimetry for the Utah Thyroid Cohort Study. Radiat Res 165:208-222.

Snyder, S.F., W.T. Farris, B.A. Napier, T.A. Ikenberry, and R.O. Gilbert. 1992. Parameters Used in the Environmental Pathways (DESCARTES) and Radiological Dose (CIDER) Modules of the Hanford Environmental Dose Reconstruction Integrated Codes (HEDRIC) for the Air Pathway. PNWD-2023 HEDR. Richland, WA: Battelle Pacific Northwest Laboratories.

TSP (Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project). 1990. Initial Hanford Radiation Dose Estimates. Richland, WA: Washington State Department of Ecology.

TSP (Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project). 1994. Summary: Radiation Dose Estimates from Hanford Radioactive Material Releases to the Air and the Columbia River. Richland, WA: Washington State Department of Ecology.

Voillequé, P.G., G.G. Killough, and S.K. Rope. 2002. Methods for Estimating Radiation Doses from Short-Lived Gaseous Radionuclides and Radioactive Particles Released to the Atmosphere During Early Hanford Operations. RAC Report No.2-CDC-Task Order 3-2000-FINAL. Atlanta, GA: Centers for Disease Control and Prevention.

5

Evaluating the Department of Health and Human Services Dissemination and Communication Efforts

INTRODUCTION

The committee's charge included evaluating the Department of Health and Human Services' (HHS's) efforts to disseminate the research findings emerging from projects it undertook under its Memorandum of Understanding (MOU) with the Department of Energy (DOE) to affected workers and communities. For the purposes of this report and consistent with its statement of task, the committee drew a distinction between dissemination and communication in the programs of HHS and DOE in pursuit of each objective. This distinction is grounded both in formal definition and in practice. Dissemination is a one-way process—to send information out widely, to publicize or broadcast information. This term was used specifically in the charge to the committee. However, the committee judged that to truly evaluate public understanding of health effects, as described in the MOU, it also had to look closely at the communication efforts of HHS agencies. Communication implies a two-way process—an interchange of knowledge, thoughts, and opinions or—as one dictionary puts it—communication is a back-and-forth process (Webster's Third New International Dictionary 2003).

In keeping with its charge, the committee's findings and recommendations are directed primarily at HHS activities. As noted earlier, the committee functioned under the public policy decision, reflected in the MOU, that to facilitate public understanding and acceptance of scientific findings related to health effects of hazardous exposures, responsibilities for operations and monitoring should be separated between two federal agencies, with DOE administering the nation's nuclear activities and HHS monitoring, measuring, disseminating, and communicating information about worker and community health and safety is-

sues. In describing the events shaping the MOU, this report necessarily addresses previous concerns expressed about DOE's management of these facilities and its actions in communicating the safety and health effects of radiation releases. This report however is not an assessment of DOE's activities. The committee's approach to this evaluation was shaped by a number of considerations, particularly the multiple and diverse ways in which individuals and communities process scientific information related to complex, often adversarial, scientific and technological issues.

COMMUNICATING ABOUT RADIATION RISKS

Communicating effectively about risks such as radiation health effects at DOE facilities to workers and concerned citizens is difficult for a number of reasons. First is the level of public fear about radiation from these sites. Although there is no uniform and consistent perception of radiation risk, research on the general public's attitudes in the United States, Sweden, and Canada has shown that "public perception and acceptance is determined by the context in which radiation is used" (Slovic 2000). This means that although most people do not fear medical or dental X-rays because of the positive health value of these technologies, they do fear the radiation associated with nuclear weapons, nuclear power, and nuclear waste. Research using risk perception analysis in which different factors reflect how lay persons evaluate health and environmental risks on a number of characteristics has found that nuclear power and nuclear waste were rated as extreme in two dimensions: "dreaded" and "unknown" risks (Slovic 1987). Dreaded risks are catastrophic, deadly, and uncontrollable. Unknown risks are poorly understood, are unknown to those exposed, and have delayed effects. "Validation of these psychometric studies occurred when survey respondents were asked for word associations to a high-level radioactive waste repository. The resulting images were overwhelmingly negative, dominated by thoughts of death, destruction, pain, suffering and environmental damage" (Slovic et al. 1991).

Another finding from this research is that in every context of use, with the exception of nuclear weapons, public perceptions of radiation risk differ from the assessments of the majority of technical experts. In most instances, members of the public see far greater risks associated with a radiation technology than do experts (Slovic 2000). This disconnect between what the public and experts see as risks may lead experts to make little effort to understand what drives public fears and to dismiss these fears as trivial or "irrational." A consequence of this disconnect is that communication efforts are frequently one-sided or unidirectional, reflecting the perspective of experts who want to communicate specific messages to the public rather than the view of what the public wants to know.

The second reason why communicating about radiation risks at DOE facilities is difficult is the complex documented history of secrecy at these sites (PSR

1992; Ackland 2002; Schneider 1988; NRC 1990). There is a history of hidden intentional and unintentional radiation releases potentially exposing both workers and citizens, producing serious public concerns about the motives and performance of DOE and its contractors and resulting in a loss of public trust and confidence in federal agency operations of these facilities. This loss of trust and confidence undermines acceptance since public confidence in information and in how well managers understand and control hazards and how trustworthy they are in fulfilling their protective duties is needed (Flynn et al. 2001). Again, the events leading to having three HHS agencies replace DOE as the performer of research on health effects and becoming the lead agencies in conducting research and communicating research findings and operations at DOE facilities were attempts to restore public confidence and trust in the operations of the federal government.

However, restoring or even establishing public trust is not easy. Trust in risk management assessments is difficult to achieve and maintain. It is usually created slowly but can be destroyed very quickly even by a single mistake. Once trust is lost, it may take a long time—if ever—to rebuild to its former state. "The fact that trust is easier to destroy than to create reflects certain fundamental mechanisms of human psychology that Slovic called the 'asymmetry principle'" (Slovic 1993). According to this principle, when it comes to winning trust, the playing field is tilted toward distrust for several reasons. "First, negative (trust-destroying) events are more visible or noticeable than positive (trust-building) events. Negative events often take the form of specific, well-defined incidents such as accidents, lies, discoveries or errors or other mismanagement. Positive events, while sometimes visible, more often are fuzzy or indistinct. Second, negative events have much greater weight on people's opinions than do positive events. Finally, sources of bad news tend to be seen as more credible than sources of good news by both people and the mass media" (Slovic 1993, cited in Kunreuther and Slovic 2001, p. 342).

A third reason why communicating about radiation risks at DOE sites is difficult is the complexity of the technical language and concepts. Radiation terms are foreign to most lay people and even seem contradictory at times (Friedman 1981; Friedman et al. 1987). In addition, when discussing possible radiation health effects, adding to the mix of rems, rads, and alpha or beta particles in radiation terminology is the language of epidemiology with its discussions of cohorts, case-control studies, and statistical power. Even well-intended glossaries often cannot help effectively translate this complex information or help lay people comprehend the concepts involved. More often than not, more can be accomplished in conveying such highly complex information in face-to-face situations where members of the public have the opportunity to ask questions about things they do not understand. This, however, can be a time-consuming and costly task and requires a special set of communication skills as well as specialized technical knowledge (NRC 1989).

Special Risk Communication Challenges for Federal Agencies

There are challenges beyond radiation risk and language that also have to be considered when trying to evaluate HHS dissemination and communication programs for DOE facilities. A fundamental conundrum for federal science agencies dealing with environmental risk controversies is that scientific and technical information alone seldom serves to resolve issues. The best-intentioned and most effectively considered and implemented communications programs encounter at least two major hurdles. First, environmental controversies are typically amalgams of scientific, political, economic, sociological, and ethical considerations. Second, provision of the "best" possible scientific and medical information may serve to lessen disagreement or forge consensus about "technical" aspects of the issue, but even if these goals are achieved, other dimensions of the issue may remain (Johnson 1999, as cited in Tuler et al. 2005).

More immediately germane to the challenges confronted by HHS agencies and DOE in organizing communication programs is that members of a community can have varying preferences about how they want such programs to be conducted and different criteria for determining the effectiveness or success of such programs. For example, a study of the attitudes and preferences of stakeholders living in the environs of Lawrence Livermore National Laboratory in Livermore, California, discerned five different and, in some cases, competing perspectives (Tuler et al. 2005):

1. *Evidence-driven process with good communication to the lay public*. "This perspective describes a process that is about making recommendations based on a good understanding of the evidence about the nature of the problem and to effectively communicate with the community. In this perspective, the definition of the right problem should be locally determined."

2. *Efficiency and focus in a science-driven process*. This perspective emphasizes "addressing the key problem in an efficient and well-run process. . . . The quality of information is important to those holding this perspective. The best available science should be used for analysis. Data must be evaluated to assess their quality for making public health determinations. Thus, it is important to identify weaknesses and gaps. At the same time, there was no support for exploring uncertainties in the data; doing so can lead the process astray."

3. *Meeting the needs of the community through accessibility and information sharing*. This perspective places the concerns and needs of local people at the center while the needs and wishes of the responsible agencies are peripheral. It emphasizes generating and sharing information with the community. It places the highest value on tapping the knowledge of the community, ensuring that participants have equal access to information and that uncertainties are acknowledged and explored.

4. *Ensuring accountability with broad involvement.* "Those holding this per-

spective are interested in addressing and solving problems in a manner that ensures agency accountability and allows full involvement of the community. *There is an underlying distrust of the motivations of the responsible agencies (e.g., DOE, ATSDR [Agency for Toxic Substances and Disease Registry]) to redress public health risks that have arisen as a result of contamination released from the Laboratory"* (italics added for emphasis).

5. *Searching for the truth by thoroughly examining the evidence*. This perspective emphasizes broad and informed discussion of the issue. "Information must be validated and it must be fully available for public discussion and consideration. . . . Those holding this perspective are interested in the truth of the matter."

In effect, these perspectives point to stakeholder proclivities to employ different subjective frames of reference in responding to closed-ended scales of client satisfaction, thus reducing the value of conventional measures of program effectiveness. As noted by Tuler et al. (2005): "The core of our argument is that while generalized guidance about best practices can be useful, it can also be inadequate (and perhaps misleading) for a particular situation. Decisions about, for example, what risks to consider, how to compare and frame risks, and what are credible channels and sources of communication must be made in a process that meets social expectations about what is an appropriate process for the situation. The effectiveness of the risk communication effort may rest, in part, on meeting social preferences for how the process of planning and decision-making is designed."

General Risk Communication Guidelines

As described above, each site and different stakeholders involved at that site have their own ideas, preferences, needs, and problems regarding the risks present or anticipated. Developing an environmental or health risk communication program to meet all of these needs is a complex process that requires considerable levels of commitment, time, money, and personnel on the part of government agencies. However, federal agencies do not enter this difficult territory without some general guidelines derived from a more than 30-year history of research and practice in the field of risk communication.

According to leading risk communication researchers, good risk communication is "communication intended to supply laypeople with the information they need to make informed independent judgments about risks to health, safety and the environment" (Morgan et al. 2002). As described in a National Research Council (NRC 1989) report that addressed the challenges of risk communication: "Risk messages should closely reflect the perspectives, technical capacity, and concerns of the target audience. A message should: (1) emphasize information relevant to any practical actions that individuals can take; (2) be couched in clear

and plain language; (3) respect the audience and its concerns; and (4) seek to inform the recipient, unless conditions clearly warrant the use of influencing techniques."

Effective communication should focus on the issues that recipients most need to understand. Which issues need to be understood should be determined by both the communicator and the recipient. Risk researchers caution that if a communication omits critical information, it leaves the recipients worse off because it could make them believe that the information they have is complete. If it presents irrelevant information, it wastes recipients' time and diverts their attention from more important tasks (Morgan et al. 2002).

Effective risk communication also requires authoritative and trustworthy sources. If communicators are perceived as having a vested interest, then recipients could doubt the truth of the information communicated. This lack of trust makes the communication process far more complex, spreading confusion and suspicion and thereby eroding relationships.

Finally, for a risk communication effort to succeed, the developers of the communication program must ensure that their messages are being understood as intended. Failing to evaluate whether risk messages have been understood or whether a risk program has been effective is a major problem because everyone involved in the process could be miscommunicating or talking past each other and yet no one knows it. When a message is not understood, the recipients, rather than the message, may be blamed for the communication failure. However, if "technical experts view the public as obtuse, ignorant, or hysterical, the public will pick up on the disrespect, further complicating the communication process" (Morgan et al. 2002). Lack of evaluation wastes both communicators' and recipients' valuable time as well as the resources spent in developing and providing the risk communication efforts.

No matter how good a risk communication program looks to its designers, it will be discounted if it is only a one-way dissemination system in which information is given to workers and citizens with no room for their opinions. Using, at the minimum, a two-way risk decision-making process that includes both citizens' and workers' concerns has been increasingly recommended and implemented. For example, in its final report, the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) concluded that a good risk management decision emerges from a process that elicits the views of those affected by the decision, so that differing technical assessments, public values, knowledge, and perceptions are considered. The Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) referred to those affected by a risk or a risk management decision as stakeholders, stating:

"Stakeholders bring to the table important information, knowledge, expertise, and insights for crafting workable solutions. Stakeholders are more likely to accept and implement a risk management decision they have participated in shaping. Stakeholder collaboration is particularly important for risk management

because there are many conflicting interpretations about the nature and significance of risks. Collaboration provides opportunities to bridge gaps in understanding, language, values, and perceptions. It facilitates an exchange of information and ideas that is essential for enabling all parties to make informed decisions about reducing risks" (Presidential/Congressional Commission on Risk Assessment and Risk Management 1997).

An important guideline from an NRC (1989) report also bears directly on the committee's review of HHS's communications activities: "Risk communication is successful only to the extent that it raises the level of understanding of relevant issues or actions and satisfies those involved that they are adequately informed within the limits of available knowledge." All of the guidelines mentioned for effective risk communication in this introduction, taking into consideration the considerable challenges involved, were used to evaluate HHS dissemination and communication efforts to workers and citizens.

COMMITTEE'S APPROACH TO EVALUATING THE HHS EFFORTS

To evaluate HHS's dissemination and communication efforts under the MOU, the committee reviewed information provided by HHS agencies to the affected communities in terms of relevance, accuracy, accessibility, timeliness, comprehensibility, and credibility. For its evaluation, the committee reviewed a sample of written, electronic, and oral communications of the HHS health study findings and other outreach efforts at three sites: Hanford, Oak Ridge, and Los Alamos. These site-specific reviews are described in detail in Annexes 5A, 5B, and 5C, respectively.

Beyond looking at specific efforts, the committee also contacted selected members of the Hanford Advisory Board and others in that region to get their input about the impact of the dissemination and communications efforts on this community. It also solicited information from social scientists who had studied some of the government-public interactions at DOE sites and sought the views of former members of several site-specific committees as well as other knowledgeable individuals. In addition, the committee ran searches in the Lexis-Nexis academic database to identify key public and worker issues that appeared in newspapers at each of the three sites and whether these had been addressed by HHS risk communication efforts. It also searched the Lexis database specifically to see whether information disseminated by the National Institute for Occupational Safety and Health (NIOSH) to workers and the public about various studies had reached a wider audience through newspaper coverage. Finally, to ensure that it had as complete a picture as possible, the committee reviewed NIOSH media coverage in a large collection of articles in the evidence package presented by the agency.

AGENCY COMMUNICATION EFFORTS

The three HHS agencies involved in this study had a number of dissemination and communication responsibilities. NIOSH, through its Office of Occupational Energy Research Program (OERP) and its Health-Related Energy Research Branch (HERB), was responsible for communicating its study findings to workers, the public, Native American tribes, the scientific community, and other stakeholders. The National Center for Environmental Health (NCEH) provided information about its studies to workers and the public primarily through its contractors. Several NCEH contractors, including the Technical Steering Committee for the Hanford Environmental Dose Reconstruction (HEDR) and the Fred Hutchinson Cancer Center for the Hanford Thyroid Disease Study (HTDS), undertook considerable public communication efforts. Of the three HHS agencies, the ATSDR is the most heavily involved in conducting communication, outreach, and education efforts for the general public in the communities surrounding DOE facilities. As part of its broad congressional mandate to evaluate public health concerns related to exposures at hazardous waste sites, ATSDR developed and provided information, education, and training concerning hazardous substances to affected communities across the country, including but not limited to DOE facilities.

National Institute for Occupational Safety and Health

NIOSH is responsible for conducting epidemiological studies of workers at DOE facilities and for communicating the findings to workers and their representatives and to the community at large. The OERP has a number of communication goals related to effectively informing workers, scientists, and the public about its work. These goals include the following (NIOSH 2005):

- "Develop better mechanisms for generating research hypotheses by expanding the involvement of partners and actively seeking their input."
- "Conduct research in an open environment with attention to clear and accurate education of workers and the public."
- "Provide information that enhances the understanding of risks associated with radiation-induced health effects."
- "Solicit and consider worker interests and the public's concerns."
- "Provide relevant occupational exposure and health outcome information for public health research and policy."

NIOSH communication activities include establishing communication plans and channels for the various sites, providing simultaneous communication to management and labor representatives, distributing one-page Brief Reports of Findings, making final technical reports available, and interacting directly with

workers. NIOSH conducted a needs assessment of what workers wanted to see in summaries of research findings, including simplified definitions of technical terms, other language-level issues, and increased availability of information (Ahrenholz 2001).

According to NIOSH, the main mechanisms for OERP and HERB communication efforts include the following (NIOSH 2005):

- *Regular research meetings*. These meetings allow researchers (primarily those funded extramurally) to have an opportunity to communicate about their research.
- *Periodic conference calls and on-site meetings with affected workers to discuss study status and results*. Slide shows and other presentations are given at these meetings for workers, providing an update on findings of studies that had been completed, the studies that are currently under way, and occasionally reminding viewers about the MOU, its various governmental links, and the responsibilities of NIOSH under the MOU (NIOSH 2006b). NIOSH made presentations to both the Hanford and the Oak Ridge Health Effects Subcommittees, including slide shows and other briefing materials (NIOSH 2006b).
- *Brief Reports of Findings issued to workers through the mail, electronically, and on-site*. These one- or two-page summaries are discussed in more detail below.
- *Public meetings*. Occasionally, NIOSH has convened a public meeting such as the one about its epidemiological research program conducted under the MOU in Washington, DC, on October 27, 2005 (NIOSH 2006a). It also has a plan to provide study results to individual workers but has not used it. The 1988 NIOSH Worker Notification Procedures Manual details how these results are to be reported; however, NIOSH has stated that "to date, researchers have not had a study finding that necessitated formal individual worker notification" (NIOSH 2005).

NIOSH Brief Reports of Findings

NIOSH places significant emphasis on the use of short reports of study findings to communicate about research and activities to workers and the general public. These reports have various titles, including "Brief Reports of Findings," "Announcement of Findings," or "Summary of Findings." The Brief Reports typically have included information on the type of study conducted, its purpose, a description of the study population, the study methodology, the main study findings and conclusions, limitations of the study, a glossary of terms, and information about how to obtain a copy of the full study and to reach a contact person for addressing questions (NIOSH 2005). According to NIOSH (NIOSH 2005), these reports were prepared after extensive consultation with workers and management at DOE facilities. The report summaries were converted to a conven-

tional file format (portable document file or pdf) so that they could easily be placed in site newsletters, on bulletin boards, and on web sites. They were also distributed directly to individual workers or to worker representatives as an e-mail attachment. While NIOSH did not require extramural researchers to engage in communications activities, information about a number of their studies was disseminated through these reports.

NIOSH frequently provided the same information to various DOE facilities with these reports, using different "editions," such as the Hanford or Oak Ridge edition. This was particularly true if the study was one that involved multiple sites. It also occasionally issued NIOSH-HERB updates, which related information about two or three main studies that were being conducted at a particular site and also included very brief descriptions of other studies going on at the site. Several updates were evaluated for Hanford, Oak Ridge, and Los Alamos: these usually contained the same basic information for all sites but were tailored to highlight information from the viewpoint of a particular site.

When a study was completed under the OERP, study findings were reported to workers, DOE Headquarters, site managers, and site contractor management. Initially, study results were communicated to workers and worker representatives simultaneously. However, because of concerns expressed by DOE, the procedure was changed and findings were communicated to DOE Headquarters three days before the communication to workers and site management. All of this resulted in a complex communication and clearance procedure, which is diagrammed in Figures 5-1 and 5-2 (see NIOSH 2005).

Agency Communication Evaluation

NIOSH states that these reports have been used to "successfully communicate the findings of approximately thirty internal and external studies to some 300,000 current and former DOE workers" (NIOSH 2005). The basis for this assessment that findings have been "successfully" communicated, however, is not documented in NIOSH reports. It appears to relate to estimates of the number of individuals "reached" by NIOSH activities, rather than to any systematic study or assessment from target audiences about the relevance, quality, and timeliness of the information. NIOSH reports also a lack of evidence about whether or how the information was used or the degree to which this information produced increased agreement within the affected community about any specific scientific or technical aspect of the subject matter under study.

According to NIOSH, there were no external evaluations of its outreach program. Instead, there were internal evaluations by its communications team, which consisted of the assistant branch chief, a health communication specialist, and one or more service fellows. Scientific and technical staff and others at NIOSH with health communications expertise assisted as needed. NIOSH states that "the success of the OERP communication strategies was evaluated periodi-

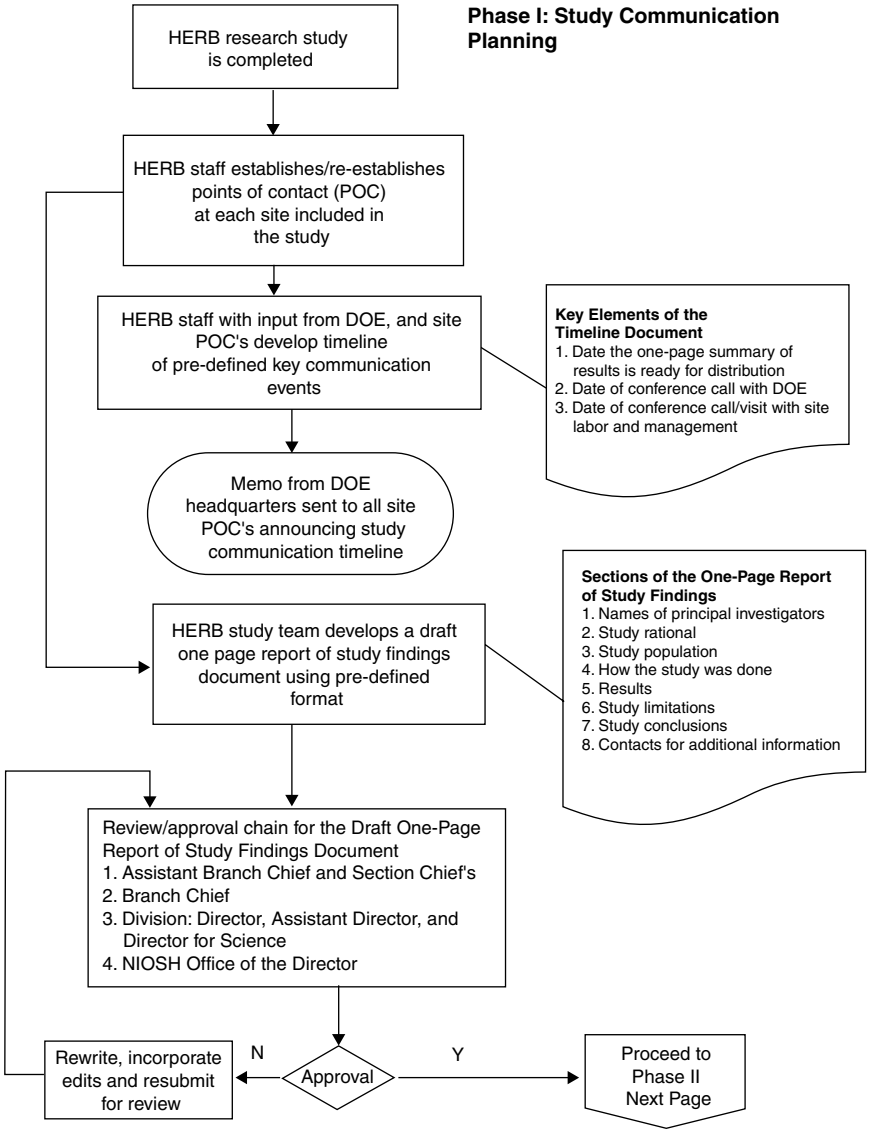

FIGURE 5-1 Phase I: NIOSH's Study Communication Planning. SOURCE: NIOSH (2005).

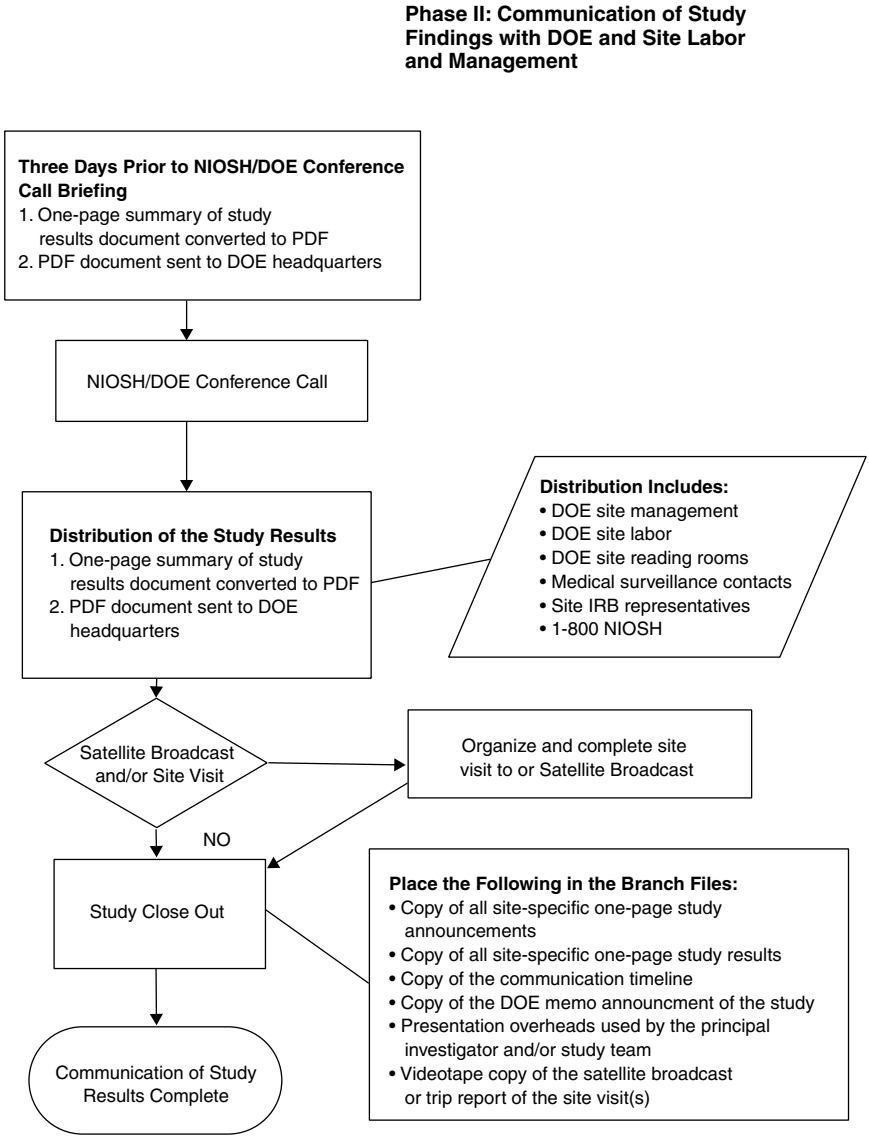

FIGURE 5-2 Phase II: NIOSH's Communication of Study Findings with DOE and Site Labor and Management. SOURCE: NIOSH (2005).

cally by obtaining feedback (primarily verbal) from workers and management on the effectiveness of the communications channels and instruments (e.g., the 'Brief Reports of Findings') and adjustments were continuously made to accommodate this feedback, to make the process and information more useful to the target audience." All formal communications to worker representatives, including the Brief Reports, were reviewed and edited by the NIOSH public information office, whose personnel also provided feedback to OERP on ways to better involve workers and the public in its activities (NIOSH 2006c).

Committee Evaluation of NIOSH Efforts

Despite these evaluation procedures and NIOSH's early concern with target audience needs for simple language in these Brief Reports of Findings, the committee judged that much of the language in these reports was quite technical and would not be easily understandable to readers with a high school education, even though the readers might have had some technical training. The glossaries, which were provided to help comprehension, also were technical and difficult to understand. A Ph.D. social scientist with no radiation background, who also is a technical editor, read one Announcement of Findings on "Epidemiological Evaluation of Cancer and Occupational Exposures at the Rocky Flats Environmental Technology Site" (April 2003)[1] and verbally told an NRC committee member that he thought the main parts of the report and the glossaries were not well written and would not be understood easily by lay readers. He did not consider the glossaries any help to people who were not familiar with the study or radiation terms.

Based on its own review, the committee concurs with these comments, which apply to almost all of the Brief Reports of Findings. It questions whether many workers, their families, or their representatives such as union officials would be able to understand the information conveyed. Unfortunately, this assessment also extends to many of the slide show presentations viewed in the NIOSH evidence package (although one would expect that the presenters would have made special efforts to describe and explain the material being presented orally) (see NIOSH 2005). These materials appear to be written at a level that was too difficult for easy comprehension by a lay audience. One example of the use of such complex language can be found in a 2002 NIOSH Announcement of Findings— "Lung Fibrosis in Plutonium Workers." The brief report states the following: "There was a significantly higher proportion of abnormal chest radiographs among plutonium workers (17.5%) as compared to non-plutonium workers (7.2%), $p = <0.01$. The plutonium workers were significantly older at time of x-ray than were unexposed workers, possibly accounting for the differences. Of those plutonium

[1]See *http://www.cdc.gov/niosh/oerp/pdfs/2001-133g26-1.pdf*. Last accessed November 2006.

workers with absorbed lung doses of 10 Sv or greater, 37.5% had an abnormal chest x-ray, compared to other plutonium workers (16.5%). When we controlled for effects of age, smoking, and asbestos exposure we found that plutonium lung dose of 10 Sv or greater conferred a 5.3-fold risk of having an abnormal chest x-ray when compared to employees with no plutonium exposure (95%C.I. = 1.2 to 23.4)." It is not clear to the committee why these language problems did not surface during OERP personnel contacts and meetings with workers and through other internal evaluation procedures.

As documented in more detail later in the Hanford case study, individuals attentive to worker health issues reported that NIOSH did in fact go beyond the dissemination of documents. While those who commented on this issue uniformly reported that NIOSH did not appear to have consulted with workers or their representatives in the selection of research topics on study design, once NIOSH launched a study, in addition to disseminating information in print, it routinely met with labor groups and kept them well informed as to the progress of the study, as well as the final results. Of the 13 individuals who were contacted as a part of the Hanford case study, only a few indicated that they were generally familiar enough with the activities of all three HHS agencies to offer any observations on their comparative effectiveness. However, these few judged NIOSH to be the most effective in its dissemination activities.

The lack of any external evaluation of NIOSH dissemination and communication efforts handicaps an evaluation process by the committee. Written materials and records provided by NIOSH relating the success of meetings and other communication methods such as slide shows employed by NIOSH to communicate with workers and members of the public about its studies are all based on agency activities and perspectives; they do not provide information or data on how stakeholders responded to these activities, and thus do not provide an adequate basis for a third-party assessment.

Other Communication Efforts to Workers

Newspapers The NIOSH Brief Reports were the likely basis for some newspaper articles that appeared about NIOSH studies. In a two-stage communication process, these articles served to disseminate NIOSH reports to workers and members of the public in a more understandable form. Newspaper articles using lay language were written about at least six of these studies. The largest number of newspaper articles found during the committee's search of Lexis-Nexis covered the Rocky Flats study discussed previously, with slightly different interpretations of the study findings.[2] The Associated Press wire service ran a story emphasizing

[2]Ruttenber, A.J. April 2003. Epidemiologic Evaluation of Cancer and Occupational Exposures at the Rocky Flats Environmental Technology Site. NIOSH Announcement of Findings.

that the 10-year study "found workers who dealt with plutonium were about two times more likely to develop lung cancer than those who were not employed at the plant" (Long 2003). The *Denver Post* emphasized that most Rocky Flats workers are typically healthier than the general public, but some types of cancer are higher for workers (Nicholson 2003). It pointed out that the study did find "a significant risk of lung cancer for weapons workers who inhaled radioactive particles." The *Rocky Mountain News* emphasized that "people who inhale plutonium have a higher risk of lung cancer than previously believed, according to a study of Rocky Flats workers" (Morson 2003).

The details in these news articles encompassed more than those presented in the Rocky Flats Brief Report of Findings, suggesting that reporters obtained additional information. One such source was the study director, who is quoted in the articles, along with state and NIOSH officials and one worker. One article indicated that the report was released at a public meeting (Nicholson 2003). Neither the technical language nor anything from the glossary in the Brief Report of Findings appeared in the newspaper articles, as one would expect.

Other newspaper or wire articles that appeared about NIOSH studies included the following:

- *Epidemiological Evaluation of Childhood Leukemia and Paternal Exposure to Ionizing Radiation, September 1998.*[3] This was a very brief article by Associated Press that represented information in the NIOSH report (Associated Press 1998).
- *Multiple Myeloma Case-Control Study at the Oak Ridge Gaseous Diffusion Plant (K-25), March 2000.*[4] Noted in a NIOSH-HERB Oak Ridge Update, this study was described by Associated Press as relating specifically to Los Alamos although it did mention that other sites also were involved (Associated Press 2000). An article in the *Seattle Post-Intelligencer* discussed the implications of the research for Hanford (Paulson 2000). Both articles emphasized the increased deaths from multiple myeloma, but the Associated Press article discussed the increased sensitivity to radiation of older workers in more detail and earlier in the story than did the Seattle article.
- *Mortality Among Female Nuclear Weapons Workers, June 2000;*[5] *Associated Press wire service*. This article noted that the study director would discuss his findings from Washington, DC, in a live satellite presentation and that this presentation would be videotaped and made available at sites involved in the

[3]Sever, L.E. 1998. Epidemiologic Evaluation of Childhood Leukemia and Paternal Exposure to Ionizing Radiation. NIOSH One-Page Summary.

[4]NIOSH/HERB. 2000. NIOSH/HERB Update: Two NIOSH-Funded Studies of Workers at Oak Ridge Nearing Completion.

[5]Wilkinson, G. 2000. Mortality Among Female Nuclear Weapons Workers. NIOSH/HERB Update.

study. This article accurately summarized the main points of the NIOSH Brief Report of Findings (Hebert 2000).

• *Epidemiological Study of Mortality and Radiation-Related Risk of Cancer Among Workers at the Idaho National Engineering and Environmental Laboratory, a DOE Facility, October 2004.*[6] An article in the *Idaho Falls Post Register* reflected the main findings of the study but also included other information, including comments from one worker (O'Neil 2004).

• *Cancer Risk Following Low Doses of Ionizing Radiation—A 15-Country study*[7] *(no date).* No U.S. articles were found, but one article about the study appeared in the *Irish Times* and one in the *Guardian*, both UK publications, on June 29, 2005. The *Guardian* article represented well the information about the study (Boseley 2005), while the *Irish Times* article went into areas not covered in the NIOSH Brief Report and summarized only its main points (Ahlstrom 2005).

While these newspaper articles did not cover all of the NIOSH studies done at the sites, the newspapers selected a few important ones to present to their target audiences in an understandable and generally accurate manner. These efforts extended the reach of NIOSH information from some of the Brief Reports of Findings.

DOE Communications In the 1990s, DOE provided information to workers about studies, including some by NIOSH, in several different ways. DOE reported on the following studies in Health Bulletins:

• *Mortality Among Workers Exposed to External Ionizing Radiation at a Nuclear Facility in Ohio*. This study was done by Los Alamos scientists and published in a journal in May 1991. This study focused on the Mound Facility near Dayton. There also was a brief discussion of another Mound study for polonium-210 exposure.

• *Epidemiological Study at Oak Ridge*. This study followed up a previous mortality study in 1985. This referenced a study by Dr. Steven Wing and presented results in 1991 of an apparent association between very-long-term, low-

[6]Schubauer-Berigan, M.K., G.V. Macievic, D.F. Utterback, C-Y Tseng, and J. Flora. 2004. An Epidemiologic Study of Mortality and Radiation-Related Risk of Cancer Among Workers at the Idaho National Engineering and Environmental Laboratory (INL), a U.S. Department of Energy Facility. NIOSH Announcement of Findings.

[7]Cardis, E., M. Vrijheid, M. Blettner, E. Gilbert, M. Hakama, C. Hill, G. Howe, J. Kaldor, C.R. Muirhead, M. Schubauer-Berigan, B.F. Yoshimura, G. Cowper, J. Fix, C. Hacker, B. Heinmiller, M. Marshall, I. Thierry-Chef, D. Utterback, Y.-O. Ahn, E. Amoros, P. Ashmore, A. Auvinen, J.-M. Bae, J. Bernar Solano, A. Biau, E. Combalot, P. Deboodt, A. Diez Sacristan, M. Eklof, H. Engels, G. Engholm, G. Gulis, R. Habib, K. Holan, H. Hyvonen, A. Kerekes, J. Kurtinaitis, H. Malker, M. Martuzzi, A. Mastauskas, A. Monnet, M. Moser, M.S. Pearce, D.B. Richardson, F. Rodriguez-Artalejo, A. Rogel, H. Tardy, M. Telle-Lamberton, I. Turai, M. Usel, and K. Veress. Cancer risk following low doses of ionising radiation—a 15-country study. NIOSH One-Page Summary.

level radiation exposure and an increased risk of death from all types of cancer combined.

- *Worker Mortality Study at Los Alamos National Laboratory*. This study was published in a journal in 1994.
- *Uranium Dust Exposure and Lung Cancer Risk in Four Uranium Processing Operations*. This study explored the risk of lung cancer in workers who had inhaled uranium dust at three sites. The study was published in a journal in 1995.
- *Y-12 Worker Mortality Study*. This was conducted by the University of North Carolina in 1996.
- *Mallinkrodt Chemical Works Mortality Study*. This was also the subject of a newspaper article in the *Cincinnati Enquirer*. Results were presented to workers at Mallinckrodt in 1998.
- *Multiple Myeloma Study at Four Sites*. Results of this study by Steven Wing were presented in 1998 to workers at the four study facilities and published in April 2000 in a journal.
- *NIOSH Study of Parents' Exposure to Ionizing Radiation and Cancer Among Their Children*. This study was presented to workers in 1998 at each of the three DOE facilities involved.
- *Mortality Study of Rocketdyne-Atomics International Workers for Exposure to Both Radiation and Asbestos*. These studies were presented to workers and community members soon after completion of each study and portions were published in journals in 1999.

DOE also published two issues of *Health Watch* in 1993, which discussed various rules and standards for workers, and two issues of *Epidemiology News*, which summarized various worker studies. It also published a paper called "Description of CDC [Centers for Disease Control and Prevention] Studies," which summarized various NIOSH studies of the health of workers at individual DOE facilities and mentioned other NIOSH studies, including community studies near DOE facilities by NCEH and a study at multiple sites of maternal and paternal pre-conception exposure to ionizing radiation and childhood leukemia. Except for similar headings, no standardized format was used in these DOE documents as was later done with the NIOSH Brief Reports of Findings. There were no glossaries either. A number of the documents noted that results were reported directly to workers with a date, included information about publication of the research findings in journals, and had a standard line that information from the study was "provided to committees that review and make recommendations regarding radiation health protection standards in the United States." There was always a contact person's name and phone number on these bulletins. The committee judged that some of the writing in these DOE Health Bulletins was clearer and less technical than that in the NIOSH Brief Reports, although these still might have been difficult for lay persons to understand.

National Center for Environmental Health

NCEH studies the "health effects of environmental radiation exposures from nuclear weapons production facilities in the United States" (NCEH 2006a). It is responsible for conducting research on ionizing radiation in the environment.[8] NCEH conducts dose reconstruction and other health studies at DOE facilities. Regarding communication and outreach efforts, NCEH chose to communicate much of its work through the Health Effects Subcommittee (discussed below). "NCEH's goal was to keep the public informed through meeting notifications (by contractor mail-outs) to interested individuals and organization and by posting meeting announcements in the Federal Register" (NCEH 2006c).

NCEH noted that there were dedicated subgroups of the Health Effects Subcommittees (HESs) at Fernald, Hanford, Idaho National Laboratory, and the Savannah River site that worked to evaluate the agency's communication and outreach activities. Also, NCEH used the HES and local community meetings to "help develop effective communication of project research and findings" (NCEH 2006c).

NCEH provided a list of documents that were in storage in boxes but in principle available to the committee upon request (NCEH/ATSDR 2006). Due to time constraints, the committee was not able to review many documents that were included in this list. Instead, the committee chose to review the communications efforts related to larger-scale NCEH projects, including HEDR at the Hanford site and the Los Alamos Historical Document Retrieval and Assessment (LAHDRA) at Los Alamos.

Hanford Environmental Dose Reconstruction Project

Two major projects were conducted by NCEH at the Hanford site. The first was the HEDR Project. The HEDR was initiated to estimate the amount and type of radiation releases to which individuals living at or near the Hanford site may have been exposed during the production of nuclear materials. The purpose of the study was to "address community health concerns by estimating the amount and types of radioactive materials that were released to the environment (via air and river pathways) from the Hanford Site and by estimating radiation doses to representative individuals within the communities downwind from Hanford" (NCEH 2005) (see Chapter 4).

Although this project was inherited by NCEH from DOE, it was still funded in part by NCEH under the MOU for several years and is considered within the purview of the committee's study. Originally, DOE directed Battelle Pacific Northwest Laboratories, one of its contractors, to conduct the HEDR. However, this action did not satisfy a distrustful public, and DOE agreed with Washington

[8]2000 Memorandum of Understanding between the U.S. Department of Energy and the U.S. Department of Health and Human Services.

and Oregon that an independent group needed to direct the study and provide a forum for participation and direction by the states, Native American tribes, and the public. In 1988, a Technical Steering Panel (TSP) was selected to direct the work. Its members were chosen by the deans of research at major universities in the two states. The states and involved Indian tribes also had representatives on the TSP (Niles 1996).

Besides handling the scientific aspects of the HEDR Project, the TSP developed important public communication plans. Interestingly, the desire to provide resources for public information caused an early "internal battle": some members of the TSP were not convinced of the importance of public communication, and some wanted to reserve funds only for scientific research. However, the need for public information eventually was recognized and a subcommittee of the TSP was established to address it. Initial communication efforts focused on dissemination, specifically "establishing and building mailing lists, providing meeting summaries to the public, preparing and sending out meeting notices, drafting a public information plan, and preparing fact sheets that explained the Project work" (Niles 1996). Staff support for the TSP's communication program came from the Washington State Department of Ecology and the Oregon State Department of Energy (Niles 1996). Meeting monthly, the TSP Communications Subcommittee used information gathered in surveys, focus groups, and comment forms to develop annual communication plans and budgets. The TSP used the following tools to support its public information program (Niles 1996):

- A quarterly newsletter;
- Fact sheets written by TSP members on a variety of topics—the TSP produced 18 fact sheets and distributed about 100,000 copies of them;
- Two informational videos explaining how and when radiation releases occurred at Hanford, among other things—more than 300 copies of each were distributed to libraries, hospitals, schools, and community groups throughout the Northwest;
- A poster for use in libraries and meeting places to introduce people to HEDR;
- Public meetings in conjunction with each TSP meeting;
- A question-and-answer brochure;
- A speakers' bureau whose members spoke to civic groups, the medical community, scientific groups, schools, and others;
- Quarterly and annual reports to keep interested parties updated on TSP work: the Communications Subcommittee provided quarterly reports to ensure that the TSP and the public were aware of ongoing public information activities; according to the TSP, public reaction to this approach was good;
- Newspaper advertising for TSP and community meetings to encourage public attendance;

- Reports of major HEDR accomplishments, including short summaries written for the media and the public;
- Direct mail to keep people informed of ongoing meetings and other activities, sent to more than 6,000 citizens and the region's media;
- News releases sent to more than 100 media organizations;
- A toll-free phone line for free and easy access to project information—about 9,000 calls were received from people requesting information or asking questions; and
- Document repositories at 13 public libraries throughout the region.

Agency Communication Evaluation

According to the "History of the TSP," evaluation of its communication materials and program as a whole was a major part of this project (Niles 1996). First, its initial communication plan was developed with input from focus groups on target audience needs for information. Many of its "communication products were reviewed by Downwinder groups and other interested members of the public while still in draft form. This allowed those with a personal interest in the Project to help ensure the written materials were clear and unbiased" (Niles 1996). TSP members believed that these review efforts resulted in better communication products. In 1991, the TSP sponsored a telephone survey by Washington State University to determine citizen attitudes, opinions, and level of knowledge about the project. Overall findings showed that people were interested in the project, that the public information efforts were well targeted, and that the TSP needed to continue to communicate with the public in a variety of ways, including producing fact sheets and newsletters, although the news media proved to be the most effective sources of public information about the project (Niles 1996).

Major efforts also were made to provide clear information for the public when major project announcements were being made. Months of careful planning went into preparing for each announcement at well-attended public meetings in a number of cities in Oregon and Washington, according to the TSP.

The Hanford Thyroid Disease Study Project

The second major NCEH project at Hanford was the HTDS. A similar public information effort was carried out for the HTDS by the Fred Hutchison Cancer Research Center, a CDC contractor in Seattle (see Chapter 4). However, that study is not a topic of this report since it was specifically ordered by Congress. It should be noted that this contractor developed an excellent public information program that ran for 9 years with input from a number of stakeholder groups; many of its elements can be considered best practices. Unfortunately, at the end of the study, some communication problems occurred to mar the record of this otherwise fine program (NRC 2000; Friedman 2001).

Committee Evaluation of NCEH and Contractor Dissemination and Communication Efforts

Details about this public information effort are included in this report not only because the HEDR Project came under NCEH purview in its later stages, but also because it serves as a good example of a concerted effort to communicate with the public. In all, in the committee's view this serves as one of the best examples of best-practice communication techniques encountered in its review of HHS activities. As reviewed by the committee, communication products distributed to the public through this program were understandable, timely, and informative. Large mailing lists and the use of commercial media helped to ensure that the communication messages reached a large regional audience. Some two-way communication also occurred, according to the TSP History, with early input from focus groups on the initial HEDR communication plan and through consultation about and review of communication products still in draft form by Downwinder groups and other interested parties. Finally, this program used various evaluation techniques to make sure that its messages met the needs of the target audience, were understood, and reached the intended audiences. Such evaluation efforts are laudable and speak well for the HEDR communication program.

Comparing the HEDR and HTDS public communication efforts to those used by NIOSH, NCEH for other sites, and ATSDR indicates that these HHS agencies have followed different models and mechanisms for public and worker communication. Based on the information the committee has reviewed, the models used by both the HEDR and the HTDS contractors worked quite well. This observation brings up the question of what organizational arrangements and levels of commitment are needed for effective communication, which are commented on in the discussion, conclusions, and recommendations at the end of this chapter.

Agency for Toxic Substances and Disease Registry

ATSDR is congressionally mandated to evaluate public health concerns related to exposures at hazardous waste sites. A significant part of these efforts includes "information development and dissemination, and education and training concerning hazardous substances" (ATSDR 2006a).

Of the three HHS agencies, ATSDR is the most heavily involved in conducting communication, outreach, and education efforts for the communities surrounding DOE facilities. In 2000, the MOU between the HHS and DOE cited ATSDR's responsibilities:

- *Preparing Public Health Assessments (PHAs) and health consultations for the communities*. PHAs are "in-depth evaluations of data and information on the release of hazardous substances into the environment." The public is encour-

aged to comment on the PHAs during a 45-day public comment period (ATSDR 2006b). ATSDR also prepared press releases and newspaper advertisements announcing that the PHAs were available for public comment (ATSDR 2006b) (see Chapter 3). The PHAs include information on estimated exposure levels (doses) that may be experienced by individuals in the vicinity of the DOE sites.

• *Engaging in health education and promotion activities by developing and implementing strategies to promote health and reduce potential exposures and disease*. Because of its responsibilities under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), ATSDR has often taken the lead in communication and outreach efforts to the affected populations surrounding DOE facilities. Some methods of written communication include news releases, press advisories, letters to the editor, site-specific web pages, public service announcements, and media interviews (ATSDR 2006b).

• *Conducting site-specific health surveillance, health studies, and exposure and disease registries*. Health surveillance efforts are used to screen the affected population for biological markers of disease, while health studies use biomarkers to study health effects related to exposure to low levels of toxicants. The National Exposure Registry, which includes data from specific subregistries, is "designed to communicate to individuals the best available information to the long-term health consequences of low-level, long-term exposures to hazardous chemicals identified at hazardous waste sites."[9]

• *Developing toxicological profiles at the site*. ATSDR is congressionally mandated to develop toxicological profiles for environmental contaminants present at Superfund sites. The profiles are designed to "succinctly characterize the toxicologic and adverse health effects information for the hazardous substance."[10] ATSDR produced seven toxicological profiles on radioisotopes under the MOU for americium, cesium, cobalt, iodine, ionizing radiation, strontium, and uranium. An evaluation of these profiles can be found in the scientific program assessment (Chapter 3).

Public Health Assessments

ATSDR prepared separate PHAs for four areas at Hanford: the 100-, 200-, 300-, and 1100-Areas. The agency also prepared five PHAs for Oak Ridge and one for Los Alamos. Each of these followed a similar format, with brief summaries, followed by sections on background of the site and the area being studied; community and Native American health concerns; environmental contamination and other hazards; pathway analysis; public health implications; conclusions; and

[9]2000 Memorandum of Understanding between the U.S. Department of Energy and the U.S. Department of Health and Human Services.

[10]See *http://www.atsdr.cdc.gov/toxpro2.html.* Last accessed August 2006.

recommendations. For the Hanford PHA on the 200-Area, a public health plan was also included at the end of the report. In final versions of the PHAs, public comments were included in tabular form with agency responses. The three Hanford documents viewed by the committee were relatively brief and understandable in the summary, conclusions, recommendations, and sections related to community health concerns and public health implications. The scientific discussion sections, as expected, were more difficult for the public to comprehend.

One of the PHAs on the 300-Area at Hanford described how ATSDR attempted to find out about community health concerns by distributing flyers to more than 1,000 Hanford residents. It received 93 replies and made 12 additional telephone calls in response to requests for oral responses. In addition to the flyers, ATSDR staff and scientists exchanged communications with representatives of the nine tribal nations in the area (ATSDR 1997b). Perhaps due to the low response rate to its flyers or other unknown factors, the discussions of community health concerns in the Hanford PHAs appear to be formulaic. For example, similar paragraphs are repeated in different reports. Some of this could be attributed to a conventional "front-end boilerplate" approach, but other aspects involving substantive sections of the reports also appeared forced into a standard pattern that curtailed more explanatory and less technical information about site-specific findings.

A later PHA for the Y-12 uranium releases at Oak Ridge Reservation, issued on July 30, 2004, showed improvement in quantity and quality over the Hanford reports (ATSDR 2004c). All sections of the PHA were more developed, particularly the public health implications and community health concerns. A new section had been added about children's health considerations; a public health action plan was also part of the PHA. The summary section had several blocks of print that either highlighted the major finding of the PHA or explained technical information to readers. This report had 16 pages of tabular public comments and responses, although many of the responses were not very informative.

Toxicological Profiles and Tox FAQs

When a draft toxicological profile is released, the public has 90 days to comment. After the comment period has ended, ATSDR states that it "considers incorporating all comments into the documents" and finalizes the profiles, which are then available on the Internet and through the National Technical Information Service. Copies also are sent to state health and environmental agencies and other interested parties.[11]

The first chapter of a toxicological profile is directed at the public. Called the Public Health Statement (PHS), it provides a summary of the toxicological profile in understandable language and is prepared as a series of questions. For example, in the profile on americium, topics include (ATSDR 2004b) the following: What is americium? What happens to americium when it enters the environ-

ment? How might I be exposed to americium? How can americium enter and leave my body? How can americium affect my health? How can americium affect children? How can families reduce the risk of exposure to americium? Is there a medical test to determine whether I have been exposed to americium? What recommendations has the federal government made to protect human health? Where can I get more information? The PHS is available as a stand-alone document in both English and Spanish. The toxicological profiles also include a "Quick Reference for Health Care Providers," which describes the chapters of the profiles and refers to information that might be relevant to a health care provider, including the sections related to pediatrics and child health issues.

In addition to the toxicological profiles, ATSDR produces ToxFAQs, brief two-page fact sheets with information about a substance, available in both English and Spanish. The sections of the ToxFAQs closely mirror those of the PHS, but the text is reduced and simplified substantially. The documents also include a box of highlights summarizing the main findings in the toxicological profile. For example, the highlights section of the americium document states: "Very low levels of americium occur in air, water, soil, and food, as well as in smoke detectors. Exposure to radioactive americium may result in increased cancer risk. Americium has been found in at least 8 of the 1,636 National Priorities List (NPL) sites identified by the Environmental Protection Agency (EPA)" (ASTDR 2004b).

Agency Communication Evaluation

To evaluate the communication quality of its documents, in addition to requesting public comment, ATSDR included surveys approved by the Office of Management and Budget with each PHA and health consultation to request public input. Of the 2,214 surveys distributed, 82 completed surveys were returned to ATSDR, resulting in a rate of return of 3.7 percent. ATSDR reported that the "affirmative response rate of community members regarding whether their health concerns were addressed in ATSDR documents increased from 65 percent in FY2003 to 78 percent in FY2004." Of the responses received on surveys of PHAs and health consultations, the public was generally pleased: the questions were answered 81 percent positively, 13 percent negatively, and 6 percent with no opinion. One question on the survey (Were the customers' health concerns addressed?) received 78 percent positive replies, 16 percent negative replies, and 6 percent no opinion. ATSDR used three other survey tools in FY 2004 to obtain public feedback including the following: "3,612 community health concerns surveys mailed out to communities resulted in an 11% return; distribution of 298 community meeting surveys at the meetings resulted in a return rate of 46%; and

[11]See *http://www.atsdr.cdc.gov/toxpro2.html*. Last accessed August 2006.

distribution of 9,363 fact sheets surveys resulted in a 7.0% return." (ATSDR/NCEH 2006). The community meeting survey had the highest response rate and the response rate for the community health concerns and fact sheet surveys were two to three times higher than those for PHAs and the health consultations (ATSDR/NCEH 2006).

Committee Evaluation of ATSDR Efforts

In general, based on its examination of the communications sections of the four PHAs discussed above, the committee believes that ATSDR made an effort to make sections of these reports understandable to interested members of the public and to address their concerns in these reports. Most of the sections of the PHAs that members of the public would be interested in and would have read were written in language that would be understandable for a general audience.

In general, the ToxFAQs were condensed to a reasonable length, were relatively easy to read, and translated the health information into understandable language. Since the documents were not site-specific, they did not include information about potential exposure scenarios at the sites. The format followed that of the PHS and included a number of questions about which those living near the sites might be interested in learning more, including questions about childhood exposures and how families could reduce exposure.

Generally, ATSDR appears to have fulfilled its requirements to disseminate information to citizens living near DOE facilities. Its web site has many items and links, conveying and explaining information to interested readers about health issues at these sites. Although the percentage returns from the public on some of its evaluative efforts were low, it appears that the agency did make a concerted effort to obtain public input and feedback to improve its efforts. Some specific programs and issues related to ATSDR efforts are discussed later in the site-specific sections of the annexes to this chapter.

AGENCY COMMUNICATION EFFORTS WITH ADVISORY COMMITTEES

Advisory committees also played an important role in communicating and disseminating information about health risks to the public at or near the DOE sites. Some such committees are discussed below.

Health Effects Subcommittees

Health Effects Subcommittees were established at some DOE facilities as a major way to establish two-way communication and allow for public input and advice on decision making. These were established under the Federal Advisory Committee Act (FACA) "to provide advice to CDC and ATSDR about public

health and research activities conducted by CDC and ATSDR at DOE sites."[12] Originally, subcommittees were formed at four DOE facilities including Hanford, Fernald, Idaho National Laboratory (INL), and the Savannah River site. The Oak Ridge HES was established in 2000. The HESs were used as the primary mechanism for public involvement in NCEH activities at DOE facilities (COSMOS 2001a, 2001b).

These subcommittees were used by NCEH, NIOSH, and ATSDR to facilitate public involvement. Several HESs had subgroups that dealt with and provided advice on public communication issues (NCEH/ATSDR 2006). The general public was informed about meetings through announcements in local papers, flyers sent to area libraries, the DOE facility, direct mailings, and announcements in the *Federal Register*. At the meetings, the subcommittees often made consensus recommendations to the agencies. More details about recommendations and an evaluation of the Hanford and Oak Ridge HESs are discussed in the case studies of these sites in the annexes to this chapter.

To make sure that the HESs were operating effectively, HHS sponsored an independent evaluation of their activities. The evaluation was conducted by the COSMOS Corporation in 2001 and covered the years 1999-2001. The COSMOS study examined four HES programs: Fernald, Hanford, INL, and the Savannah River site. The committee cites this study extensively because it is the one example that the committee has been able to identify within the scope of its review in which a large-scale independent external evaluation has been conducted of any of HHS's communication activities.

The evaluation criteria and questions contained in the COSMOS report addressed both process and outcome dimensions of the HES's communication program. COSMOS gathered its information by (1) conducting interviews with representatives from the agencies (NIOSH, NCEH, ATSDR, DOE), HES chairs, and affected community members; (2) distributing surveys to HES members; and (3) reviewing minutes from HES meetings (COSMOS 2001a, 2001b). The COSMOS evaluation included "findings about the operations, effectiveness, and outcomes of the advisory process" in addition to addressing five evaluation questions (COSMOS 2001a):

1. How effective are the subcommittees in providing relevant and timely advice to the agencies on site-specific public health activities and research?

2. How effective are the agencies in providing feedback on the advice received from the subcommittees; considering this advice in decision making; and creating or changing programs, policies, and practices to reflect advice?

[12]2000 Memorandum of Understanding between the U.S. Department of Energy and the U.S. Department of Health and Human Services.

3. To what extent are the advisory systems' efforts to promote public involvement helping to improve perceptions that the public health activities and research are credible and to improve trust between groups?

4. To what extent is the advisory system helping to deliver the appropriate prevention services?

5. Is the FACA-chartered subcommittee process the most appropriate and effective mechanism for obtaining public involvement in health research and public health activities?

Among the findings from the evaluation were the following:

- Regarding the public benefits of the subcommittees, these included "providing a formal way of advising the government on public concerns; improving communication with the government; and providing access to information." In addition, the agencies noted that the process encouraged them to learn more about community concerns (COSMOS 2001a).
- While outreach by the HESs was not identified as a specific subcommittee function by the FACA charter, implementing outreach activities by the subcommittees could achieve several key objectives of the advisory process. These included broad public participation in public health activities and research, representation of diverse viewpoints on the subcommittee, communication of the findings of public health activities and research, and identification and communication to the federal government of the community's concerns. The report noted that at the time, confusion existed among some agencies about the appropriateness of subcommittee outreach activities. Also, agencies had allocated "relatively few resources to outreach activities" (COSMOS 2001a).
- NCEH and ATSDR should evaluate the value of subcommittee's outreach activities and, if indicated: "1) identify outreach as an expected subcommittee function in the next FACA charter, and 2) allocate resources to support subcommittees' outreach activities" (COSMOS 2001a).
- In collaboration with the HES, ATSDR and NCEH should continue to evaluate and assess the effectiveness of the HES.

Further information on this evaluation is continued in the discussion of the Hanford site in the annex; however, it is important to note that in 2000, the director of the Hanford Education and Action League evaluated the HES and concluded that "the Hanford Health Effects Subcommittee stands as a sterling example of what can be accomplished when citizens are included early and often to deal with complex issues" (NCEH/ATSDR 2006). When HES subcommittee members were asked about the impact of NCEH and ATSDR at the sites, they noted that "health care providers are more aware than they used to be about potential health effects of chemical and radiation exposure at the DOE sites because of the work of CDC and ATSDR." Also, many HES subcommittee

members reported that ATSDR played an important role in improving health education at the sites (COSMOS 2001a, 2001b).

Community and Tribal Subcommittee

In 1997, ATSDR established the Community and Tribal Subcommittee. The subcommittee, whose membership includes people living near Superfund sites as well as individuals representing organizations, was charged with the following: "(1) serv[ing] as an advocate for communities; (2) serv[ing] as a sounding board for ATSDR to develop policies and programs related to communities; (3) serv[ing] as a conduit to provide input, opinions, and feedback from communities to the BSC; and (4) facilitat[ing] outreach for the BSC to communities" (ATSDR/NCEH 2006). The subcommittee also developed *The Community/Tribal Advisory Process: A Citizens' Guide* (ATDSR/NCEH 2006).

ATSDR has reported that as a result of recommendations from the Community and Tribal Subcommittee:

- "ATSDR worked with EPA to include health-based technical assistant grants in the Superfund Technical Assistance Grant program.
- ATSDR established a formal Office of Tribal Affairs that coordinates ATSDR activities with tribes impacted by Los Alamos and Hanford.
- ATSDR produced a video to train agency staff on how to work more sensitively with diverse communities and culture" (ATSDR/NCEH 2006).

Committee Evaluations of Site-Specific Communication Efforts

In addition to reviewing the overall agency dissemination and communication activities, the committee reviewed these activities in detail at three DOE sites: Hanford, Oak Ridge, and Los Alamos. These reviews are described in Annexes 5A, 5B, and 5C, respectively, to this chapter. The committee's conclusions from these reviews are summarized in the following sections.

Hanford Community

NIOSH and NCEH Many of the dissemination and some communication efforts at Hanford for these two agencies have been evaluated earlier in this chapter under the non-site-specific activities of these agencies. Related to additional communication activities, discussions held by the committee with 13 knowledgeable non-DOE and non-HHS individuals involved with Hanford from 1990 to 2005 revealed some consistent themes regarding both NIOSH and NCEH. First, there was awareness—in some cases, quite detailed—of the information dissemination activities of these two agencies. While value was placed on the techniques

of presentations at many types of public events, press releases, and the printed materials previously described, particular emphasis was placed on NIOSH's efforts to inform workers and their representatives—and site managers—of both the progress and the results of various NIOSH projects. The Hanford Tanks Vapor Study was specifically mentioned several times as a good, recent example of NIOSH endeavors and also of a study that had a direct effect on policies and practices at Hanford.

There was also general agreement on a less positive feature. With only a few exceptions for both agencies, decisions about what to study, and how to study it, were made seemingly without any advance consultation with any affected workers or the general public or with technical experts affiliated with them. Similarly, while the one-way dissemination of progress and results was often quite satisfactory, there generally was no effective two-way communication back to either agency regarding, for example, midcourse additions or suggestions for the study. This was forcefully expressed by technical experts affiliated with various tribes, who perceived that their suggestions regarding potential exposure pathways were ignored (also, in this case, in their interactions with ATSDR).

ATSDR Based on reported materials from ATSDR, the Hanford Community Health Project (HCHP) appears to be a successful program. Its communication materials are understandable and useful to both the lay and the physician community, and its practice of partnering with various professional societies is commendable. Its web site has useful and understandable information and is easy to use. It is laudable that the agency brought in an outside public relations firm to evaluate its communication efforts and then made adjustments to help bring its important health education information to greater numbers of people in the region.

To its credit, ATSDR appears to have attempted to work with community groups and site-specific subcommittees to alter some of its studies or include within its action plans aspects of research or other actions favored by the community. That the agency was so invested in the medical monitoring issue and then that program was not funded indicated to citizens that a program that had been promised and planned over time was never a sure thing. The loss of the Hanford Health Information Network (HHIN) was a blow to many in the Hanford community who felt that this central information network was a considerable asset for informing individuals of happenings related to cleanup and remediation at the site as well as public health issues and may have detracted from the community's trust in the agency. Whether the HCHP completely fulfilled the role originally established by the HHIN cannot easily be determined, although it did take on some of the group's activities.

Advisory Groups According to the COSMOS evaluation, the Hanford HES was an active group that sought interaction and provided advice to NCEH and ATSDR. It appeared to be fully involved in many activities, providing advice that some-

times was used. The DOE site advisory board seemed much more removed from most HHS communication activities, and this was a missed opportunity for the HHS agencies to communicate with site opinion leaders and, through them, the various groups they represent.

Mass Media The newspapers examined provided frequent coverage of activities at Hanford, including relating scientific studies in lay language for workers and citizens. They also covered a number of important issues such as medical monitoring and cleanup concerns. They were actively engaged in relating Hanford information to readers in both Washington and Oregon.

To conclude, Hanford was rich in dissemination and communication opportunities for the HHS agencies, particularly going beyond conventional programs and developing ones that serviced an anxious worker and citizen population.

NIOSH and NCEH appear to have performed only their required communication tasks and not taken advantage of the potential for working with stakeholders in a more meaningful way. The exception to this is the TSP's activities for HEDR, which were truly comprehensive and impressive as early communication efforts. ATSDR, given its mandate, had more flexibility to work directly with citizens, adjusting some programming and research to meet concerns and needs, in particular by developing the HCHP. Its programs appeared to be effective and, according to the agency, reached large numbers of individuals. However, without independent outside evaluation, the committee cannot estimate the impact of any of these programs on Hanford workers, their families, and other citizens in the region.

Oak Ridge Community

In the absence of any independent professional evaluation, assessment of the effectiveness and impact of all communications efforts with communities at the Oak Ridge Reservation and surrounding area is subjective and anecdotal. Comparing the communication and outreach situation in Oak Ridge in 2004 versus 1990 at the beginning of this program, it is safe to say that progress was made.

ATSDR should be given high grades for its very active and engaged connection with the Oak Ridge communities. It offered opportunities for the workers and the community in general to air their health concerns as well as to provide informative presentations to professionals in the medical community and the general public. The briefs that it published attempted to inform the populace on various issues that had been brought to their attention through community meetings. It is difficult to judge the value of this information to members of the community since there was no independent assessment of the communication effort. The committee feels that the communication efforts stopped short of achieving an open and trusting dialogue at this site, as evidenced by published

letters to the editor in the *Oak Ridger*, a local newspaper, which indicated a divided option regarding the closing of the ATSDR office in Oak Ridge last year.

There is clearly a higher level of community involvement in health and environmental issues through a number of organizations (Oak Ridge Health Agreement Steering Panel, Oak Ridge Reservation Site Specific Advisory Board, Oak Ridge Reservation Local Oversight Committee, Oak Ridge Reservation Health Effects Subcommittee) as well as activist groups (Oak Ridge Environmental Peace Alliance, Coalition for a Healthy Environment), which get the attention of and are responded to by DOE management. While these channels of communication to DOE exist, to characterize them as effective in creating a common agenda for health and environment would be an overstatement. Nonetheless this community involvement through organizations and advocacy groups has resulted in an improvement of the situation in Oak Ridge regarding availability of information on health and environmental issues. The recent elimination of ATSDR activities in Oak Ridge does not bode well for further improvements in the dialogue with the community and workers, given that hazardous cleanup and incinerator operation will continue at Oak Ridge.

DOE's establishment of a "one-stop" information center on such issues is further evidence of a greater degree of openness toward the community on the part of DOE. The large number of publications from both ATSDR and DOE regarding health and environmental issues in the Oak Ridge community are available publicly through the DOE Oak Ridge Office Information Center. However, as stated throughout this chapter, it is clear that most of these publications were not designed particularly well for understandability by the average person in the community and therefore were interpreted by many as government "propaganda."

The Oak Ridge Reservation HES itself appeared to be controversial, according to a review of its meeting minutes as well as press reports about it. Some citizens claimed that the committee was serving the government agenda. Still others lamented the demise of this committee due to budgetary cutbacks because its disappearance marks the end of a useful channel of communication with the government about community health problems. Undoubtedly, both positions have some merit to their claims (Rogers 2005d).

Los Alamos Community

Los Alamos appears to have the least developed dissemination and communication program of the three sites studied in depth by the committee. The LAHDRA web site provides understandable information about the project. The full text of the interim report is available on the site as are the locations of libraries where members of the public can view retrieved documents and directions for getting to these libraries. Although much of the information on various "pages" of the web site was brief, there were links to other sites with more

information. The web site itself was easily used, providing basic information about the project. It was not clear when the web site had last been updated.[13]

NIOSH has included Los Alamos in some of its multisite studies and disseminated information about the results of these studies to workers in its usual manner. ATSDR appears to have less of a presence at this site than at Hanford and Oak Ridge, in both PHA and educational activities. The site-specific advisory board seems active and offered some communication evaluation advice to ATSDR through 2005 from its Community Involvement Committee. The fact that this committee has now disbanded is not seen as a good sign. Media coverage does not appear to have been as heavy at this site as at Oak Ridge or Hanford, although there seems to be a range of topics being presented to readers about worker and citizen issues at Los Alamos.

To summarize, less effort appears to have been put into dissemination and communication efforts for workers and citizens at this site than at the other two studied. However, no information is available from any internal or outside evaluation of the dissemination and communication programs occurring at Los Alamos, which handicaps the committee's evaluation of these efforts.

DISCUSSION

As noted early in this chapter, communicating about radiation risks is difficult, and federal agencies trying to do this face a number of serious challenges. These include the level of public fear about radiation from these sites; the history of secrecy at these sites, which resulted in a loss of public trust and confidence in federal agency operations that undermined information acceptance; and the complexity of the technical language and concepts of both the radiation and the epidemiology.

In addition, as noted in the beginning of this chapter, scientific and technical information alone seldom serves to resolve issues. Environmental controversies are typically amalgams of scientific, political, economic, sociological, and ethical considerations, and while providing the best possible scientific and medical information may serve to lessen disagreement or forge consensus about "technical" aspects of the issue, even if these goals are achieved, other dimensions of the issue may remain (Johnson 1999, as cited in Tuler et al. 2005). Research has shown that different members of a community can have different preferences about how they want such programs to be conducted and about their criteria for determining the effectiveness of such programs. For all of these reasons, developing an environmental or health risk communication program to meet all of these

[13]Los Alamos Historic Document Retrieval and Assessment Project. 2006. Available at *http://www.lahdra.org/*.

needs is a complex process that requires considerable levels of commitment, time, money, and personnel on the part of government agencies.

The committee used a number of criteria developed over the years in the field of risk communication to evaluate the HHS agencies' communication efforts. These included that a message should "(1) emphasize information relevant to any practical actions individuals can take; (2) be couched in clear and plain language; (3) respect the audience and its concerns; and (4) seek to inform the recipient, unless conditions clearly warrant the use of influencing techniques" (NRC 1989). To evaluate these factors, committee members reviewed a sample of printed and electronic materials from HHS agencies for relevance, accuracy, accessibility, timeliness, comprehensibility, and credibility. Credibility was particularly important because effective communication requires authoritative and trustworthy sources who focus on the issues that recipients most need to understand. In addition, the committee tried to establish whether the developers of the communication programs had evaluated both internally and externally whether their risk messages had been understood and their risk communication programs were effective. Finally, believing as many others do that an effective risk communication program must have a minimum of two-way communication interactions, the committee looked at methods used by HHS agencies for the public and workers to provide opinions, recommendations, and other inputs as well as have an influence on decision making.

Although bringing the public into a participatory process is important and has been included by both DOE and HHS in their site-specific Citizen Advisory Boards and HESs, respectively, two important priorities for the sponsoring government agency should be present for successful public and stakeholder participation outcomes and increasing public trust. The first is that the agency initiating the public participation process should be willing (or able) to make the kinds of commitments needed to make the process successful. This goes beyond time and money, although those are important. In such a situation, agency decision makers have to be flexible and open-minded about the nature of the participation and its outcomes. For example, they should welcome the desire of public participants to "redefine problems, focus on different issues, or otherwise change the nature of questions that agencies ask" (Beierle and Cayford 2002).

The second important priority is for agency decision makers to recognize the legitimacy of public values and understand that those values may lead to priorities and conclusions that agency personnel, who have their own understanding of what the public interest is, originally may consider "wrong." According to a recent meta-analysis (a statistical analysis of several or more studies that address a set of related research hypotheses) of 239 cases of public involvement in environmental decision making over the past 30 years, failure of an agency to commit to these two important priorities threatens the legitimacy of the public participation process and whatever public trust the lead agency may have (Beierle and

Cayford 2002). To paraphrase, "truth is in the eye of the beholder" and the goal for a successful communications effort should be to keep that in mind at all times.

Another issue that complicates public and stakeholder involvement is how much influence should be given to the public and stakeholders. Many people agree that the public participation process requires some level of public influence. Yet, in most public meetings, citizens only provide information and comments and agencies have little legal obligation to act on these contributions. According to the meta-analysis, "one of the principal reasons offered for low levels of participant motivation was a perception that the public had little influence over agency decisions." Such perceptions work against building public trust. The same study showed that "the goal of incorporating public values, which essentially measures the public's influence, is highly and significantly correlated with the goal of public trust. In low-trust situations, then, the public may need to be granted more influence to convince them of the legitimacy of the public participation process" (Beierle and Cayford 2002).

Expanding on this concept, a report on risk by the NRC (1989) noted: "Citizens of a democracy expect to participate in debate about controversial political issues and about the institutional mechanisms to which they sometimes delegate decision-making power. A problem formulation that appears to substitute technical analysis for political debate, or to disenfranchise people who lack technical training, or to treat technical analysis as more important to decision making than the clash of values and interests is bound to elicit resentment from a democratic citizenry" (NRC 1989). This issue becomes quite important when considering actions and opinions of members of site-specific Citizens Advisory Boards and HESs at DOE facilities.

Information dissemination activities to citizens and workers at DOE sites by the HHS agencies were extensive, often tailored to the needs of specific audiences, and sometimes accompanied by useful public meetings, small group discussions, and other face-to-face exchanges. These activities benefited citizens and workers by providing them with needed information about health risk concerns. Transfer of these communication activities from DOE to the HHS agencies fulfilled an important component of the commitment in the MOU to provide objective information from a health-oriented agency. This transfer also allowed DOE to focus on a new primary mission of site cleanup and eased some of the public criticism directed at it concerning radiation exposures.

Each of the HHS agencies had its own charge and special responsibilities for communicating with DOE site workers and surrounding community members. These agencies carried out their dissemination and communication efforts with varying degrees of success related to their charges. Because NIOSH efforts centered on communicating research findings to workers, among others, its efforts were more limited in scope than those of ATSDR, which has a major communication role with the community defined as part of its mission. NCEH itself appeared to undertake few direct communication efforts, but functioned prima-

rily—at least in the elements the committee reviewed—through its subcontractor, which performed admirably in communicating about HEDR issues at Hanford.

Both NIOSH and ATSDR had identifiable, discrete communication plans, although the degree to which each carried out those plans varied. NCEH did not appear to have a communication plan. It told the committee that "NCEH's goal was to keep the public informed through meeting notifications (by contractor mail-outs) to interested individuals and organizations and by posting meeting announcements in the *Federal Register*" (NCEH 2006c).

NIOSH's main instrument of communication to workers, the Brief Report of Findings, was not user-friendly. While these reports sought to inform their readers about the results of scientific studies that were important to workers and their families, extensive technical language was used in the reports and the committee questions the effectiveness of this tool. NIOSH said that it "held extensive consultations with workers and management" and assessed what workers wanted to see in the summaries, which included clear language, but the committee does not think this objective was achieved.

While NIOSH appeared to internally evaluate its written products, the lack of any external evaluation of the NIOSH dissemination efforts handicapped an evaluation by this committee. Written materials and records provided by NIOSH relating the success of meetings and other communication methods employed by the agency to interact with workers and members of the public about its studies were all presented from the view of the agency itself and were activity-based. NIOSH did not provide information or data on how the audience responded to these activities; therefore there was no adequate basis for a third-party assessment.

The HEDR Project, which came under NCEH purview in its later stages, serves as a good example of a concerted effort to communicate with the public. Selected written products distributed to the public through this program were reviewed by the committee and found to be understandable, timely, and informative. Large mailing lists and use of commercial media helped to ensure that the messages reached a large regional audience. This program used various internal and external evaluation techniques to make sure that its messages met the needs of the target audience, reached the intended audiences, and were understood.

Generally, ATSDR appears to have fulfilled its requirements to provide information to citizens living near nuclear weapons sites. Based on its examination of the communications sections of four PHAs, the committee believes that ATSDR made an effort to make sections of these reports understandable to interested members of the public and to address their concerns in these reports. However, a number of responses to questions from the public in the completed PHAs seemed perfunctory and not very informative. In addition, the agency's discussion about using the most conservative measures in PHAs for evaluating public health concerns could be construed as misleading by concerned citizens since the ATSDR definition of what is considered scientifically "conservative" does not agree with the linear extrapolation of health effects to very low doses used by

other federal agencies such as the EPA or the United States Nuclear Regulatory Commission. If it has not done so already, this policy could create public distrust related to PHAs. The introductory chapter of the ATSDR's toxicological profiles (PHSs) and the ToxFAQs based on the profiles were relatively easy to read and translated the health information into understandable language. The use of a question-and-answer format provided easily accessible information for those living at the sites.

ATSDR's web site has many items and links on it conveying and explaining information to interested readers about health issues at these sites. In its overall evaluative efforts, it appeared that the agency made a concerted attempt to obtain public input and feedback to improve its dissemination efforts. As discussed in the annex on Hanford site activities, ATSDR's targeted efforts such as those in the HCHP for communicating with different constituencies appeared to the committee to be successful, although there was no actual discussion with recipients of information about these programs. Developing materials for Hanford area physicians to help them recognize symptoms and specific illnesses related to radiation exposure and then developing partnerships with various professional organizations to distribute these materials within professional communities constituted an excellent endeavor. Also, hiring a public relations firm to reinvigorate efforts to contact citizens who had lived at Hanford during the plant's operational years to provide them with information about potential risks and what to do about them was an effective move on the agency's part. Better external evaluation of these efforts beyond just numbers of individuals reached or stories placed in newspapers would have given this committee, and more importantly ATSDR, a more accurate measure of this plan's success.

The two other HHS agencies also have web sites. All three agencies appear to depend on these web sites for communicating to workers and the public. Although web sites are useful and efficient, and can reach large numbers of people, they do not constitute in themselves an effective total communication strategy, nor is counting hits on a site an evaluation of its effectiveness.

Another method for reaching large numbers of people—providing information to the mass media—appeared to be used by the three HHS agencies to varying degrees. However, the committee did not review many press releases or other agency activities directed at the media and therefore cannot comment on their effectiveness.

Seeking input from citizens in affected communities through Citizen Advisory Boards and HESs can be an effective public participation mechanism, although it is not the only one that can be employed. Working with citizen groups can be both a rewarding and a frustrating experience for government officials. Regarding the public benefits of the HES, an external evaluation effort, the COSMOS report, found that the HES provided "a formal way of advising the government on public concerns; improving communication with the government; and providing access to information." In addition, the federal agencies noted that

the process encouraged them to learn more about community concerns (COSMOS 2001a, 2001b).

Part of the problem government officials have when dealing with advisory boards and committees relates to issues discussed in the introduction to this section: perceptions, perspectives, and needs of stakeholders differ from those of government officials. Reconciling these differences is not an easy task, yet it is a critically important one to ensure citizen input and public participation into both communication and decision-making processes.

To its credit, ATSDR appears to have attempted to work with community groups and site-specific subcommittees to alter some of its studies or include within its action plans developing aspects of research or other actions that the community favored, particularly related to the Infant Mortality Study and medical monitoring at Hanford (see Annex 5A). The COSMOS evaluation found that the Hanford HES provided consensus advice and recommendations to HHS agencies about a variety of issues, including communication, and that agencies often responded to the recommendations in writing and orally at the meetings (COSMOS 2001a, 2001b). The COSMOS evaluation indicated that the subcommittee members surveyed strongly or generally agreed that ATSDR provided feedback on their recommendations, while NCEH and NIOSH were found to be slightly less likely to consider the advice of the subcommittee (COSMOS 2001a, 2001b). Several subcommittee members, in particular, noted that NCEH staff did not always stay for full meetings. They perceived this as a lack of interest and commitment to the advisory process (COSMOS 2001a, 2001b). Related to Hanford, the committee was surprised to find that some members of DOE's Hanford Advisory Board knew very little about most of the HHS activities at the site. That such an influential group was not effectively informed about these efforts was definitely problematic for keeping people at the site informed.

Not every person or citizen group related to DOE sites has had good interactions with site-specific committee activities. In 2004, three organizations—Tri-Valley CAREs (Communities Against a Radioactive Environment), Western States Legal Foundation, and San Francisco Bay Area Physicians for Social Responsibility—and several citizens resigned from the ATSDR Livermore Lab "site team." According to a letter sent to ATSDR, these groups and individuals had "participated in good faith in the process for eight years, attempting always to mend the flaws in the ATSDR's PHA process. We have used our individual and organizational in-house scientific expertise and have also hired independent scientists to offer needed comment and criticism on the individual 'health consults' and studies undertaken by ATSDR that comprise this final document. For eight years, ATSDR has disregarded our individual and collective technical, scientific and community expertise. Similarly, our input on improving the site team process and the need to enhance its community involvement has fallen on deaf ears." They resigned, they added, because the site team process was being used by

ATSDR to imply community participation and acceptance of ATSDR's "flawed science and the resulting conclusions" (Kelley et al. 2004).

A group of citizens at Rocky Flats also took exception to the methods and conclusions of an ATSDR PHA done for that site, although most of their points related more to the science of the PHA than to communication issues (Moore 2004).

While the public participation process is not an easy one for any of the agencies or citizen groups involved, the committee believes that such participation, particularly related to Site-Specific Advisory Boards and HESs, is vital. Committee members were very concerned to learn that the activities of the HHS HESs at almost all of the sites studied had been ended. While there are still DOE Site-Specific Advisory Boards active, they may not be sufficient to provide the citizen and worker input needed for either DOE or HHS agency research programs that still exist and need to continue.

Also of great concern to this committee was that the efforts made by the three HHS agencies over the years to communicate with workers and citizens about radiation risk issues are being curtailed. The need for HHS, working under the terms of the MOU, to develop more effective two-way communication programs containing relevant, accessible, and comprehensible information about the safety and health effects of the operations of DOE facilities is a central theme of this report. This need can be expected to increase as the operations of several of these facilities change and perhaps expand. Cleanup activities entail a somewhat different set of worker safety and community health issues than production. As facilities change their activities, new or differently prioritized safety and health issues will emerge; new research questions may arise; new organizations or advisory bodies may form; and new modes of interaction may be necessary. All of this points to a need for DOE and HHS to ensure that the scope of research and communications activities remains aligned with the activities of the facilities. Despite budgetary constraints, there is still a serious need for getting information to and from workers and citizens about these cleanup activities and the risks involved with them, whether the information is with HHS, DOE, or site contractors. It seems that the lessons learned from 15 years of more open communication under the MOU are now not being heeded, and as a result, continuing and new suspicions and mistrust could again polarize these communities.

FINDINGS AND RECOMMENDATIONS

1. Information dissemination activities to citizens and workers at DOE sites by HHS agencies were extensive and benefited the target audiences by giving them needed information about health risk issues. Cleanup activities at DOE sites have led to continuing perceptions of significant health risks for citizens and workers, particularly as they age. This situation necessitates continuing and im-

proving health risk communication and education programs at DOE sites. As a result, the committee recommends the following:

- HHS agencies should be the continuing main source of active risk communication and education programs at DOE facilities due to significant evidence of continuing distrust of DOE and its contractors. DOE should work with the HHS agencies, its own contractors, and citizens' advisory boards to try to gain back trust in communities near its facilities with its own open, two-way communication efforts.

- Dissemination and communication efforts should be coordinated among the federal agencies involved as long as such coordination does not affect trust issues for HHS agencies among workers and citizens in and near DOE facilities.

2. While HHS information dissemination was generally laudable, communication activities related to worker and public health were variable in quality and uneven, agency to agency. Again, for the purposes of this report, the committee drew a distinction between dissemination and communication. Dissemination is typically referred to as a one-way process, where information is distributed, publicized, or broadcast widely, while communication implies a two-way process, including an interchange of knowledge, thoughts, and opinions. In its evaluation, the committee also had to look closely at the communication efforts of the HHS agencies. Guiding principles for effective risk communication, as discussed previously, were not always employed by the HHS agencies. Many studies of the nuclear industry as well as other hazardous operations (many of them cited earlier) have recommended best practices that could be effective in communicating the risks involved in such operations to both worker and community groups. As a result, the committee recommends the following:

- Both DOE and HHS agencies should develop improved long-term communication plans that incorporate risk communication lessons learned during the past 15 years from scholars and practitioners (including those at these agencies). These improved communication plans should continually be updated and reviewed by outside risk communication experts every few years.

- DOE and the HHS agencies should significantly increase organizational, financial, and personnel assistance for communication activities at DOE facilities.

3. While the committee recognizes difficulties inherent in communicating about risk to lay persons and in the public participatory process, it believes that open communication involving dialogue among the agencies, workers, advisory

bodies, and the public is critically important and needs improvement in a number of areas. As a result, the committee recommends the following:

- DOE and the HHS agencies should specify mechanisms in their improved risk communication plans for achieving more effective, open, two-way communication with workers and the public about health risks associated with cleanup activities as well as continuing or new missions at DOE facilities. Risk communication research on how best to incorporate public participation and work with citizen groups should be applied to these plans, remembering that the specific best practices at one site might not necessarily be the best practices at another site. Agendas for public and worker meetings should be developed in concert with citizen and worker representatives to ensure that stakeholders' concerns and opinions are treated with respect and responded to seriously.

- The HCHP directed by ATSDR should be continued to ensure good public health information about risks at that site, particularly during cleanup activities. Similar projects should be established at other DOE sites where serious health effects issues exist.

- DOE Site-Specific Advisory Boards have been an important communication element at DOE sites. These should be continued as long as cleanup work continues at the sites and can be improved by including ex officio representatives from both DOE and HHS agencies.

- Similarly, the HESs at DOE sites, which were considered highly successful in the COSMOS report evaluation, were a very important communication tool and should be reconstituted at DOE sites where serious concerns about health effects issues exist.

- All site-specific advisory boards and any reconstituted HESs should have a subcommittee that reviews and recommends actions on risk communication to workers and the public. This subcommittee should work with DOE and relevant HHS agencies to provide overview, feedback, and advice on communication activities. To further these goals, site-specific advisory boards, reconstituted HESs, or these risk communication subgroups should add a communication professional as a member, if there is no such person already on the group.

4. There has not been enough outside evaluation of the communication aspects of the HHS programs. Best practices in risk communication need professional evaluation, particularly to meet the needs of different stakeholders. As a result the committee recommends the following:

- HHS agencies and DOE should engage in periodic and systematic evaluations of their communication efforts using the most current risk communication research and practices available. These evaluations should include development of a framework by which to assess the effectiveness of their communications to stakeholders, as well as the use of both internal and external evaluators.

- Such assessments would include not only evaluating the quality of the communication products and the ability to disseminate information effectively but, more importantly, an assessment of how the information is interpreted, perceived, and accepted by the affected communities and workers. To ensure that these evaluated efforts are adjusted to make them more effective, internal evaluations should be done yearly and external evaluations should be done at least every 3 years to ensure that the most current feasible risk communication research and practices are being applied.

ANNEX 5A THE HANFORD COMMUNITY

The Hanford Nuclear Reservation, now known as the Hanford site, was selected in 1943 as one of the sites for the Manhattan Project to produce plutonium for nuclear weapons production. That spring, residents from three towns were evacuated from a 640-square-mile area. A 560-square-mile portion of that area was later renamed the Hanford Nuclear Reservation. For a number of years, the reservation was used to process spent nuclear fuel and to extract plutonium for national defense. In 1990, its final reactor was stopped and the Hanford mission became waste management and remediation. Also in 1988-1989, the Hanford site was placed on the NPL by the EPA with four areas identified as priorities—the 100-, 200-, 300-, and 1100-Areas. On May 15, 1989, representatives of DOE, the Washington State Department of Ecology, and the EPA signed an agreement to clean up radioactive and chemical wastes over the next 30 years. This agreement is known as the Tri-Party Agreement, or the Hanford Federal Facilities Agreement and Consent Order (ATSDR 1997b). As noted earlier, public distrust in DOE's handling of worker and community health studies at the site led to the MOU between DOE and HHS to transfer not only the worker and public health studies, but also the communication of their results to workers and citizens, from DOE to HHS. Effective communication, particularly regarding studies of health effects related to exposure to ionizing radiation, is an especially important component of the current epidemiological research program managed by HHS.

Essential components of the HHS outreach efforts include distributing the findings of health studies and providing the workforce and the community with information about potential exposures to toxic agents associated with the sites.

NIOSH has been involved primarily in conducting health studies of workers, while NCEH and ATSDR have conducted studies to evaluate exposures of the surrounding communities. A variety of techniques have been used by these agencies to varying degrees, ranging from presenting results in public meetings, to sending mailings to affected individuals and providing advice to the medical community. Many of the three agencies' general communication activities have already been discussed in this chapter, so the site information here deals with additional programs at each of the sites selected for review by the committee.

Agency Communication Efforts

NIOSH and NCEH

NIOSH has conducted more than 10 studies at the Hanford site and has produced numerous publications resulting from these studies, including the Brief Reports of Findings discussed earlier. Its primary responsibility is to interact with workers and their representatives, and it appeared to treat those at Hanford in the same manner as it treated those at other DOE facilities.

NCEH's research at the Hanford site, as noted earlier, included the HEDR Project and the HTDS. As noted earlier, the latter effort was congressionally mandated in 1998 and is not considered part of the work under the 1990 MOU, thus, it is not discussed in detail in this report.

NCEH was responsible for presenting results of the HEDR to the affected communities but was not responsible for directly informing workers. Although NCEH inherited the HEDR Project, it did not interfere with the communication plan developed and run by HEDR's Technical Steering Panel. Again, NCEH stated that its "goal was to keep the public informed through meeting notifications (by contractor mail-outs) to interested individuals and organizations and by posting meeting announcements in the *Federal Register*" (NCEH 2006c). In terms of written materials that supported communication efforts, NCEH and HEDR's Technical Steering Panel produced several booklets: *Initial Hanford Dose Estimates*; *Summary: Radiation Dose Estimates from Hanford Radioactive Material Releases to the Air and the Columbia River*; and *Evaluation of the HEDR Source Term and HTDS Power Calculations* (NCEH 2006b). The committee reviewed the first publication and found it targeted to its lay audience and relatively easy to read given the difficulty of the technical material. It included some useful charts and illustrations plus a question-and-answer section.

Other NCEH methods of outreach included agency personnel attending meetings with formally established advisory committees, including the Hanford Health Effects Subcommittee (HHES) (NCEH 2006b).

ATSDR

ATSDR, with major communication responsibilities at DOE sites, has been very active at Hanford in a number of areas. Its activities at the Hanford site began in 1989, and it produced PHAs for the 100-, 200-, 300-, and 1100-Areas. The communication aspects of these PHAs have been discussed in the general section on ATSDR in this chapter. However, other important communication elements of the ATSDR program were specific to Hanford and are reviewed here (see Chapter 3).

Public Health Action Plans Environmental health education was one of the major components of public health action plans that resulted from the PHAs done by ATSDR at Hanford. These plans recommended that such education "be undertaken to help the community and tribes understand their potential for exposure and to assess adverse health effects potentially related to activities in the Hanford 100, 200, and 300 Areas. The agency, in concert with the communities and tribes, will determine the necessary education programs that interface with existing local programs and focus on the information needs of the tribes and the concerned members of the community. This activity and implementation of the necessary programs will be coordinated with the Hanford Health Information Network, the Hanford Health Effects Subcommittee, and other relevant groups" (ATSDR 1997b).

The plans also called for environmental health education to advise public health professionals and the medical community of the health concerns of communities near Hanford and the nature and possible consequences of exposure to Hanford contaminants. As a result of these plans, ATSDR established a number of health education and promotion activities.

Hanford Community Health Project One of the results of this need for an environmental health education program at Hanford is the Hanford Community Health Project (HCHP). The goal of the project is to "assist individuals and their health care providers in making informed choices regarding their thyroid health as a result of potential exposure to radioactive iodine from Hanford" (ATSDR 2006b).

Much of the information on ATSDR's web site about Hanford *(http://www.atsdr.cdc.gov/hanford/educational/)* has been developed by and or coordinated through the HCHP. The web site includes the following information:

- A community resource area with brief information about health effects related to exposure to iodine-131, a map of the Hanford site, a list of methods for sharing information with family and friends about I-131 exposure, and an exposure self-assessment quiz (ATSDR 2005a);
- An informational pamphlet describing types of cancers in easily understood terms; and

- Numerous links to information developed for the now defunct HHIN, which is discussed below.

In developing the HCHP, ATSDR had to overcome not only a distrust of government agencies, but also message fatigue and a 40- to 50-year time span since the radiation releases occurred. To do so, it used public relations strategies to re-engage and revive interest among "community members who had become apathetic after years of perceived government inaction" (ATSDR 2005b).

To help establish the HCHP, ATSDR awarded a contract to the National Opinion Research Center in 1999.

The HCHP faced a number of challenges in developing its Hanford program:

- Radiation exposure had occurred as much as 50 years ago, so those exposed might be disengaged from the issue or unaware of information made available since exposure.
- The exposed population was geographically disperse because many had moved from the area.
- Public anger and mistrust resulted from the federal government's role in exposing citizens to radiation, creating barriers to effective communication by a government agency.
- The HTDS had failed to show a link between exposure and increased incidence of thyroid disease, but this finding was in direct opposition to what the public believed.
- There was a desire among downwinders for additional health-related information but a lack of awareness of where to access that information (ATSDR 2005b).

To assess community needs, the HCHP initially surveyed approximately 500 individuals who were potentially exposed to I-131 at the Hanford site to determine their information and health care service needs. More than 80 percent of those surveyed indicated that they were interested in receiving educational materials about thyroid disease and I-131 exposure (ATSDR 2006b). Based on this initial survey, the HCHP set out to establish a clearinghouse of related health information, design a web page to disseminate information and materials, and improve and expand outreach efforts (ATSDR 2006d). As part of these efforts, the HCHP developed the following:

- A two-page pamphlet, "Request for Medical Evaluations for Past Exposure to Iodine-131," was developed for individuals concerned about thyroid disease to give to their physicians during an examination. The pamphlet includes a map, information to discuss with the physician about potential exposure to iodine, background discussion of the Hanford site, health effects of I-131 exposure, International Classification of Disease codes for procedures and symptoms re-

lated to thyroid disease, a brief radiation primer, and additional contact information (ATSDR 2006c).

- Health care provider information contained a physician's guide to I-131 exposure; case studies developed for physicians; and two instructional videos for physicians, "Hanford: The Psychological Dimensions of Radiation Exposure" and "Thyroid Disease Management and Radiation Exposure" (ATSDR 2005a). The guide for physicians includes background about the Hanford site, a list of relevant clinical tests, and a list of additional resources (ATSDR 2004a). The thyroid disease management video includes a review of thyroid disease and related exposure to I-131, expert discussion of the disease with information about symptoms and treatment options, and background about the HTDS, in addition to other information available on the topic (ATSDR 2005a).
- The HCHP offered seminars at physician meetings, set up booths at medical society meetings, and mailed information directly to physicians (ATSDR 2006b). It also provided continuing education credits. These efforts were aimed at increasing physicians' awareness and addressing the perception among downwinders that their health care providers knew little about Hanford's history.

In 2004, a public relations firm was hired to assist with HCHP efforts. The objectives were to increases awareness about the potential risk of exposure and to increase enrollment on the mailing list and visits to the HCHP web site. The firm targeted the audience using a variety of communication routes and trusted sources including the health care community, local media, and community organizations (ATSDR 2006b). Outreach to medical organizations resulted in 40 partnerships with clinical endocrinologists, physicians assistants, and nurses. These organizations agreed to disseminate information in newsletters and magazines, post information on their organizational listserves and web sites, and distribute information during meetings, with a total potential reach of more than 215,000 health care providers.

In distributing information to community organizations, the HCHP contacted unions, labor councils, city chambers, major employers, lodges, and other local community organizations and encouraged them to link to the HCHP web site. Partnerships were formed with 24 community organizations that agreed to disseminate information.

The public relations strategy used the interpersonal communication influence of family and friends by encouraging downwinders on the HCHP mailing list to send pre-stamped postcards to their friends and family who might be unaware of potential exposure and prompt them to learn more about potential health risks. Convincing journalists in the region of the importance of this health information and the need for disseminating it proved difficult, but some articles and television news stories were generated.

ATSDR reported that "in less than eight months, over 70 partnerships were generated with health care, the community and peer-to-peer organizations, 27

media outlets covered HCHP and mailings were sent to 34,500 people throughout five states, resulting in over 1.6 million total program impressions. This outreach generated over 8,000 unique web site visitors as of August 21, 2005, increasing the average weekly unique visitor from 21 to 280" (ATSDR 2006b).

Follow-up Activities to a Public Health Plan That Involved Community Interaction at Hanford

1. *Infant mortality study*. The public health action plan for the Hanford 200 site recommended a follow-up study related to infant and fetal death (ATSDR 1997a). The request for this study came from the HHES, described in more detail below, which recommended that ATSDR evaluate reports of an increased infant mortality rate during 1940 to 1952 in communities that were likely exposed to I-131 near the Hanford site. Subsequently, ATSDR initiated the Hanford Infant Mortality and Fetal Death Analysis, which reviewed the infant and fetal mortality rate in eight Washington counties during these years. The results indicated that the mother's residence in a potentially high I-131 exposure area during a specific period of time may have resulted in preterm births (ATSDR 2000).

2. *Medical monitoring*. Another follow-up activity from the same public health plan was a recommendation for medical monitoring at Hanford. CERCLA allows ATSDR to develop medical surveillance programs for communities potentially exposed to contaminants at Superfund sites, including Hanford. ATSDR estimated that 14,000 people who lived in areas surrounding the Hanford facility were potentially exposed to iodine-131 at levels high enough to pose a significant health risk, including thyroid disease and a number of other health issues. ATSDR announced its decision on February 7, 1997, that a medical monitoring program was necessary for people exposed to radiation from the Hanford site (ATSDR 1997c). The agency signed a decision memo to implement the program, pending funding from DOE (ATSDR 1997c). At that time, the purpose of the program was to "provide medical evaluation of specific health outcomes in the population at significantly increased risk after past exposures to iodine-131 releases from the Hanford Nuclear Reservation" (ATSDR 1997c).

ATSDR noted that it worked closely with the HHES in designing the proposed medical monitoring program by "developing information, including radiation risks, eligibility criteria, medical and laboratory procedures, referral mechanisms, program operations, ethical concerns, and confidentiality issues" (ATSDR 1997c). The HHES made more than 20 consensus recommendations to ATSDR regarding the proposed medical monitoring program (COSMOS 2001a, 2001b). Beginning in 1995, five workshops were held to discuss the need for the medical monitoring program.

In 1997, ATSDR produced a document describing its position, *Hanford Medical Monitoring Program: Background Consideration Document and ATSDR Decision* (ATSDR 1997c). It included a proposed plan for education and out-

reach activities to be utilized during the program. The outreach goal for the medical monitoring program was "to build upon and enhance services and networks whenever possible to identify eligible people, disseminate program information, and coordinate program education activities" (ATSDR 1997c).

However, several factors worked against development of the Hanford Medical Monitoring Program. In 1999, the Institute of Medicine (IOM) and the NRC released a report reviewing the National Cancer Institute's study of estimated exposures and thyroid doses received by the American people from iodine-131 in fallout following Nevada atmospheric nuclear bomb tests (IOM 1999), which found that there was "no direct evidence that early detection of thyroid cancer through systematic screening (rather than through routine clinical care) improved survival or other health outcomes" (IOM 1999). This may be due to the fact that thyroid cancer screening has two problems. First it is biased towards finding tumors that are slow-growing or benign and that might never have led to significant morbidity if left untreated. Second there are risks and costs involved in any procedures, ranging from simple biopsies to surgical removal of thyroid gland itself, that may result from screening. The report recommended against a systematic screening program for thyroid cancer for either the American population generally or regional populations believed to have been exposed to iodine-131 from the Nevada tests. It suggested instead that HHS should focus on a program of public information and education about the consequences of the Nevada weapons test (IOM 1999).

Ultimately, the Hanford proposed medical monitoring program was not funded. Because there was extensive community support for the program, its elimination posed a number of communication challenges for ATSDR. One report noted that most HHES members felt that they have not "received an honest or complete explanation for why the medical monitoring program was not funded" (COSMOS 2001a, 2001b).

Additional Communication Resources: Hanford Health Information Network In addition to information being supplied by HHS agencies and subcontractors, the Hanford community had a major information source available for 9 years. Established by Congress in 1991, the HHIN served as a primary educational and outreach resource for individuals concerned about health effects related to past radioactive releases at the Hanford site. The HHIN included the collaboration of the Washington, Oregon, and Idaho health agencies and nine Indian Nations. During its existence, the HHIN maintained an extensive mailing list, a toll-free number for people with questions, a directory of organizations, a web site, and an extensive list of outreach materials. Some of the outreach materials included: Overview of Radiation and Known and Potential Health Effects; Health Care: Finding a Provider and Getting Health-Related Records; How to Find and Work with a Health Care Provider; Coping with Uncertainty and Ill-

ness: Strategies; Maps of the Exposure Area, Indian Nations Affected, and the HEDR Study Area; Glossary; and Monograph for Health Care Providers.[14]

The HHIN was closed in 2000 due to lack of funding. Archives of its work are maintained by Gonzaga University, and its web site is currently linked to the Washington Department of Health. Many of the materials developed by the HHIN also are currently linked to the HCHP web site.

Stakeholder Input: Citizen Health Effects Subcommittees and Advisory Boards

Hanford Health Effects Subcommittee

The HHES was created in 1994 by ATSDR under the Citizen's Advisory Committee on Public Health Service Activities and Research, and ATSDR was responsible for its administration. Representing a variety of interests, members included tribal nations, affected downwinders, labor organizations, and scientific and medical experts, among others. The HHES provided HHS agencies with guidance on handling public health activities at the Hanford site. In addition, its meetings provided a public forum for educating the community. For example, although ATSDR is not responsible for communicating health-related information to affected workers, HHES meetings still served as a forum for communicating information to workers about off-site and non-occupational exposures (ATSDR 2006b).

Four work groups were established to address a variety of issues: (1) public health assessment; (2) outreach; (3) studies; and (4) public health activities. During its duration, 25 meetings of the HHES were held. All meetings were open to the public and were publicized through the *Federal Register*, and mailings to advertise the meetings were sent out to approximately 30,000 individuals (COSMOS 2001a, 2001b). The subcommittee was disbanded in 2004.

COSMOS Evaluation of HHS Health Effects Subcommittees In 2001, the COSMOS Corporation published an evaluation of the HESs that included an in-depth evaluation of some site-specific activities, including those at Hanford. As discussed previously, COSMOS surveyed subcommittee and community members as part of its evaluation, although there has been some criticism of this study because of the small numbers of individuals who participated (Tuler et al. 2005). Despite this criticism, it is one of the only outside evaluations of HHS and stakeholder communication activities, and therefore some of its results are presented here.

The evaluation found that HHES provided consensus advice and recommen-

[14]Hanford Health Information Network. Washington State Department of Health. 2004. Available at *http://www.doh.wa.gov/hanford/*.

dations to HHS agencies about a variety of issues, including communication issues (see Table 6A-2). Agencies often responded to the recommendations in writing and orally at the meetings (COSMOS 2001a, 2001b). The COSMOS evaluation indicated that subcommittee members surveyed strongly or generally agreed that ATSDR provided feedback on their recommendations, while NCEH and NIOSH were found to be slightly less likely to consider the advice of the subcommittee (COSMOS 2001a,b).

The COSMOS report indicated that some members of the HHES felt a lack of agency involvement in the HES process including the suggestion that "NIOSH and NCEH staff, in particular, could have been better represented at meetings." Several subcommittee members and ATSDR staff noted, in particular, that NCEH staff did not always stay for the full meeting. They perceived this as a lack of interest and commitment to the advisory process" (COSMOS 2001a, 2001b).

Although public outreach was considered a primary function of the Hanford HES, the COSMOS survey findings noted that more than half of the HHES members perceived that resources for outreach and education were generally or very inadequate, and although ATSDR had recently worked with the subcommittee and its Outreach Work Group to develop a web page for the subcommittee, members still wanted to expand their outreach activities (COSMOS 2001a, 2001b). Funding was a significant factor limiting public health activities at the sites, and subcommittee members cited this as a major deterrent in implementing projects.

The COSMOS report cited a number of examples where the HHES made notable recommendations including recommending changes in the Hanford PHAs and the infant mortality study and trying to implement the Hanford Medical Monitoring Program. These served as examples of the subcommittees recommending "new research or public health activities that their members would like CDC or ATSDR to conduct" (COSMOS 2001a, 2001b).

In another example, ATSDR, using recommendations made by the subcommittee, conducted a single PHA for a number of areas of concern and revised the process for conducting a particular Hanford PHA. The agency noted that collaborative efforts with subcommittee members on the PHAs ultimately made the documents more readable and useful to the community in addition to addressing more community concerns (COSMOS 2001a, 2001b).

Hanford Advisory Board

While some individuals contacted by the committee about Hanford dissemination and communication activities seemed somewhat informed about various NIOSH activities, others who were or had been members of this DOE board did not recall much direct interaction with or information dissemination directly from HHS agencies.

Although not much information about HHS activities came from these indi-

viduals, this finding itself provides a perplexing picture of communication at Hanford. The fact that studies done by the three HHS agencies were not well known to individuals who sat on a major advisory board for Hanford is surprising to say the least. Indeed, why weren't they on the NIOSH, NCEH, or ATSDR mailing lists? Providing information to these influential public opinion leaders should have been something that the HHS agencies went out of their way to do.

Media Coverage of HHS Activities at the Hanford Site

Another way to evaluate the effectiveness of HHS communication activities beyond very limited interviews with individuals and reliance on agency materials and their own interpretations of success is to review general media coverage of HHS activities. The committee conducted a limited search of news articles in the Lexis-Nexis database related to HHS activities at the Hanford site between 1990 and 2006. Many articles discussed the Energy Employees Occupational Illness Compensation Program and the HTDS. These are not included here because neither activity was conducted under the MOU.

Other activities covered by the news media included NIOSH's worker studies; HEDR; ATSDR's studies of infant mortality, heart, and autoimmune disease among people living near the Hanford site; ATSDR's community outreach efforts including the HCHP; the HHIN; and the proposed Medical Monitoring Program. Some examples of the news coverage for each agency are discussed below.

NIOSH A majority of the news coverage of NIOSH's work at the Hanford Site included discussion of the agency's difficulty in obtaining data to support individual dose reconstruction for compensation purposes; NIOSH's investigation of worker complaints related to exposure to vapors at the site; an investigation of potential hazards to workers during cleanup; and the NIOSH-sponsored Wing et al. study on multiple myeloma (Paulson 2000) (see also Chapter 2).

NCEH Many of the articles discussing NCEH's work were related to the HTDS and HEDR. Comments in the articles noted the delay in release of the HEDR report; for example, "nearly three years and $10 million later, Hanford 'downwinders' and watchdog groups wonder if they'll ever know how much radiation reached people living near the nuclear reservation" (Schumacher 1999). Many articles were written on the HTDS over the years, but that study does not fall under the MOU and is not covered in this report.

ATSDR A number of articles discussed ATSDR's community outreach and education efforts, with particular emphasis on the HCHP. Providing much detail about the effort and what it would do, the following articles appeared in 2005:

• An Associated Press article on August 18, 2005, related that doctors needed to focus on the mental health of downwinders and that there was a new video to instruct doctors across the nation about how to deal with the mental, as well as physical, ailments of downwinders. The story noted that ATSDR had produced the 30-minute video as a way to help the tens of thousands of people who grew up downwind of Hanford get proper medical care. The article also discussed potential exposure routes and the web site where more information could be found (Geranios 2005).

• A March 23, 2005, article in the *Oregonian* related that ATSDR officials wanted to educate those who lived near the DOE site decades ago about possible health risks. It explained the HCHP and the information it provides on its web site, noting that DOE funding for the project would run out in the fall (Dworkin 2005).

• A February 1, 2005, article in the *Tri-City Herald* said that the HCHP had launched what might be its final campaign to answer questions about health problems that may be related to living near Hanford and went into much detail about various aspects of the campaign and what it would do for downwinders (Cary 2005a).

ATSDR's health studies were also mentioned in media reports. Examples included the agency's study of heart and autoimmune disease in children exposed at the site and the infant mortality study. An article on January 17, 2005, in the *Tri-City Herald* discussed an ATSDR study of the rates of heart and autoimmune disease in children who were exposed to radiation from the Hanford site. The article noted the role of the HHES in the process: the HHES "which is no longer funded by the federal government, said those who lived downwind of the nuclear reservation feared they were experiencing other health problems because of exposure to radiation" (Cary 2005b).

The issue of medical monitoring at the Hanford site was also covered extensively by the news media. Many of the articles discussed ATSDR's decision to initiate a monitoring program and the agency's attempts to secure funding. There was a general sense that the community strongly supported the proposal for a monitoring program, and many articles reflected confusion and disappointment that the program was not ultimately funded by Congress.

Finally, a number of articles discussed agency requests for public input on the proposed public health agenda for DOE facilities. The agencies requested that comments be sent to ATSDR (Business and News Desks 1999).

Hanford Health Information Network Numerous articles criticized the budget cuts that eliminated the HHIN, a congressionally established regional outreach and information service for the Hanford community. The news articles cited the value of the network, because it was said to be the sole service provider of information about health effects related to exposures at or near the site. One

article noted the following: "HHIN Director, Chris Townley, said 'After all these years of HHIN being good about the way they interact with downwinders, suddenly DOE decides to shut us down'" (Steele 2000).

ANNEX 5B THE OAK RIDGE COMMUNITY

Background

In 1942, the Oak Ridge Reservation (ORR) was built in less than a year on isolated farmlands in the mountains of East Tennessee. Built by the U.S. Army Corps of Engineers, ORR was part of the Manhattan Project that within 3 years housed more than 75,000 residents (ATSDR 2004c). One of the country's DOE sites, the ORR at its peak in the mid-1940s "demanded a workforce of 80,000."[15]

The original goal of the work at Oak Ridge was to separate and produce uranium and plutonium for use in developing nuclear weapons. This work was carried out in three facilities, code-named Y-12, X-10 (later to become Oak Ridge National Laboratory), and K-25. K-25 was a gaseous diffusion plant designed to separate uranium-235 (U-235) from U-238. Y-12 was dedicated to the electromagnetic separation of U-235. X-10 was a demonstration plant producing plutonium from uranium by nuclear bombardment. Operational personnel in these three facilities during the 1940s totaled more than 35,000 people (ORNL 2002) (see Chapter 3).

During the 1950s and 1960s, Oak Ridge was an international center for the study of nuclear energy and related research in the physical and life sciences. The creation of DOE in the 1970s led to an expansion of the research program at Oak Ridge into areas of energy production, transmission, and conservation. Presently the facility has a broad science and technology mission that is very different from the days of the Manhattan Project.

Production at the Oak Ridge facility ceased in 1987. In 1996, reindustrialization of the area under the name East Tennessee Technology Park (ETTP) went into effect with efforts focusing on the restoration of the environment, decontamination and decommissioning of the facilities, and management of legacy wastes. Presently, Bechtel Jacobs Company, LLC, is the environmental management contractor for the DOE's Oak Ridge Operations Office that is performing this cleanup work, with completion slated at ETTP for 2008. The goal is to create an industrial park known as Heritage Center under the coordination of the Community Reuse Organization of East Tennessee.

As part of the reindustrialization of this area, an incinerator was installed in what is now ETTP. The incinerator is an industrial operation that is used to destroy

[15]See *http://tennesseeencyclopedia.net/ imagegallery.php?EntryID=100*. Last accessed August 2006.

organic chemicals and reduce the volume of waste materials that contain low-level radioactive contamination. The incinerator operates under the Toxic Substances Control Act (TSCA), which governs how the incinerator operates and controls its releases. The TSCA incinerator began routine operations in 1991 and continues to operate today. Overall, it has treated more than 16,000 tons of hazardous and radioactive waste from ORR and other DOE facilities. Most of this waste is destroyed in the incinerator or collected as ash, and some by-products are vented into the air through the incinerator's main smoke stack.

During the period covered by this health program review, total employment at the Oak Ridge facilities was about 21,000 in 1990 decreasing to 12,000 in 2004. The foregoing brief history of this facility points out the great changes in the type of operations that have occurred at Oak Ridge in its 60-year history. The significant hazards and risks to workers and the community associated with these various operations differ and were managed and communicated by DOE as the responsible party. In March 2002, DOE opened the Oak Ridge Information Center which consolidated the former DOE Public Reading Room and the Information Resource Center, and now provides a centralized resource center for public information about DOE archival and present operations at Oak Ridge.

An assessment of HHS communication activities at ORR is provided below.

Agency Communication Efforts

NIOSH

NIOSH, as part of OERP, carried out numerous studies of health effects among workers at the Oak Ridge Reservation. Some of these were multisite studies involving other DOE sites, while others were specific to ORR workers. A list of NIOSH studies that involved the Oak Ridge Reservation includes the 20 listed in Annex 2A.

Like other sites, NIOSH used one-page Brief Reports of Findings to communicate the purpose, activities, and findings of its studies to DOE workers. According to NIOSH, the information developed in these studies was widely and conveniently distributed through these mechanisms to individual workers and their management. General comments on the Brief Reports can be found earlier in this chapter.

NCEH

The NCEH conducted the following health studies to evaluate reported illnesses afflicting residents in communities surrounding the ORR:

- In 1983, NCEH (before the existence of the MOU between DOE and HHS) was involved with the Tennessee Department of Health and Environment

in a pilot survey in Oak Ridge in response to community concerns about mercury contamination in the East Fork Poplar Creek floodplain and the sewer line beltway.

- In 1993, together with ATSDR and CDC, NCEH participated in the clinical evaluations of selected patients who had been referred to Dr. Howard Frumkin of the Emory University School of Public Health by their Oak Ridge physicians. Dr. Frumkin subsequently became the director of NCEH. These follow-up evaluations reported no evidence of any hazardous substance exposure.[16]
- In 1998, NCEH was involved in a health investigation of the Scarboro Community based on a self-reporting health survey that indicated elevated rates of asthma and wheezing. No statistically significant association was found and no urgent health problems were identified.

Overall, it appears that NCEH's role in health studies at ORR was relatively limited. It did not appear to have an independent communication program at Oak Ridge. The limited studies carried out at Oak Ridge, such as the agency's study of asthma and respiratory illnesses in the Scarboro Community, were joint studies reported to the community through ATSDR at a meeting with the community and as part of the Public Health Assessment on Y-12 uranium releases.[17] The contribution of NCEH is noted in the brief.

ATSDR

ATSDR iniated a number of PHAs with DOE funding.

Public Health Assessments ATSDR began its public health activities at ORR in 1992. Initially, the agency's effort focused on Superfund cleanup activities at the East Fork Poplar Creek and the Watts Bar reservoir. ATSDR began work on the PHA process in 2000 when results of the Oak Ridge Health Studies were available and the Oak Ridge Reservation HES (ORRHES) had been established to provide a forum for community interaction. The ORRHES is discussed in more detail below.

ATSDR uses the PHA process to evaluate previous studies and environmental data to determine whether releases of hazardous substances from the ORR could have affected the health of people in communities near the reservation.

Health concerns and issues were collected and documented in the 1990s by ATSDR health scientists during ATSDR's site visits, stakeholder meetings, calls to ATSDR, and public meetings conducted by other agencies in Oak Ridge and surrounding communities.

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[16]See *http://www.atsdr.cdc.gov/hac/oakridge/phact/cdc.html*. Last accessed August 2006.

[17]See *http://www.atsdr.cdc.gov/HAC/PHA/oakridgey12/oak_p1.html#backf*. Last accessed August 2006.

The major public health issues and concerns during the 1990s included the following:

- A local physician's report that he believed approximately 60 of his patients had experienced occupational and environmental exposures to several heavy metals that resulted in increased cancer, immunosuppression, and autoimmune disease;
- Exposure to mercury and other hazardous substances released from the Y-12 Plant into the Lower East Fork Poplar Creek;
- DOE's proposed cleanup level for inorganic mercury in the Lower East Fork Poplar Creek floodplain soil;
- Exposure to chemical and radiological substances released from the three ORR complexes (Y-12 Plant [currently known as Y-12 National Security Complex], X-10 [currently known as the Oak Ridge National Laboratory], and K-25 [currently known as the East Tennessee Technology Park] into the Watts Bar Reservoir;
- Exposure to polychlorinated biphenyls (PCBs) via ingestion of Watts Bar Reservoir fish and turtles;
- Exposure to hazardous substances in the Scarboro Community and the validity of measurements taken at the off-site air monitoring station 46 (located in the Scarboro Community) and external radiation results collected during past aerial surveys;
- An unusual number of children affected by chronic respiratory illness in the Scarboro Community;
- Residents' reports of numerous cases of amyotrophic lateral sclerosis and multiple sclerosis in the community;
- ETTP employees' concerns about possible exposure to cyanide;
- Exposure to hazardous substances released from the TSCA incinerator at ETTP;
- Sick workers at ETTP and sick residents in the vicinity of the facility who believed that their illness was caused by releases from the facility;
- Dissatisfaction of many of the workers and members of the public with the availability, quality, and extent of medical care in Oak Ridge—they wanted an independent clinic to provide care and conduct research; and
- Need for an ongoing public health forum to address outstanding public health issues.

According to ATSDR reports, from 2000 to 2005 ATSDR health scientists collected and documented health concerns and issues in the ATSDR Community Health Concerns Database for the ORR. This database allowed ATSDR to record, track, and address community concerns obtained from written correspondence, phone calls, newspapers, concern comment sheets, and comments made at public meetings.

ATSDR scientists are conducting PHAs on the following releases: Y-12

releases of uranium, Y-12 releases of mercury, X-10 release of iodine-131, X-10 release of radionuclides from White Oak Creek, K-25 releases of uranium and fluoride, and PCBs released from all three facilities. PHAs will also be conducted on other issues of concern, such as the TSCA incinerator and off-site groundwater. ATSDR is also screening current (1990 to 2003) environmental data to determine whether additional chemicals will require further evaluation.

In general, ATSDR communication activities at Oak Ridge were similar to those described for the Hanford site. However, unlike the Hanford site, there was no equivalent of the apparently successful HCHP. At Oak Ridge the primary community contact from ATSDR was through the ORRHES.

Educational Efforts for Public Health Care Providers and the Community ATSDR published a wide range of instructional health materials for the Oak Ridge community and held periodic public presentations on some of the same topics. Some of the tutorial materials were of a general nature, for example, regarding ionizing radiation and its hazards, while others were specific such as uranium release from the Y-12 facility and its implications. In reviewing samples of these materials, they seemed short on content but emphasized the communication process and how to communicate with ATSDR. For example, in one four-page fact sheet on the Y-12 uranium release, more than half of the document is devoted to describing ATSDR and what it does, rather than details of the uranium release. A second brochure on this same subject, which was six pages in length, had a better proportion of content to agency information. Such materials appear to emphasize the presence of the government agency rather than provide useful health information.

ATSDR also published a series of publications entitled "ORRHES Brief" on a variety of topics such as mercury exposure investigation, Scarboro environmental study, uranium releases from ORR, dose reconstruction feasibility study, and others. These are 6- to 10-page reports that have useful, understandable information based on PHAs prepared and published by ATSDR. These are well done and understandable. However, it is not clear what impact the reports had on or the breadth of readership they received in the community.

Stakeholder Input—Citizens Committees at Oak Ridge The ORRHES, chartered in 2000 by ATSDR, was not the first committee at Oak Ridge to involve stakeholders. Various "public" activities developed during the period of time that HHS was working with DOE on health activities at the site. It appears that many of the committees began their activities shortly after the signing of the first MOU between DOE and HHS in 1990. These initiatives may have resulted from the criticism of the DOE program prior to 1990 or been stimulated by the signing of the MOU. Several of these committees were focused on the public health of the community, while others were focused primarily on the environment. Each appeared to have a community outreach responsibility.

• *Oak Ridge Reservation Health Agreement Steering Panel (ORRHASP)*. In 1991, DOE and the State of Tennessee, through the Tennessee Department of Environment and Conservation, entered into the Tennessee Oversight Agreement (TOA), which included a number of environmental regulatory oversight functions. The oversight agreement also established a DOE funding source that allowed the Tennessee Department of Health (TDH) to undertake a two-phase research project aimed at determining whether environmental pollutant releases from ORR created public health problems. ORRHASP existed from early 1992 until December 1999 when it issued its final report. It had two primary responsibilities to TDH: (1) to perform technical oversight of work conducted by contractors, and (2) to provide some reflection of community opinion to guide project activities. Ten contractor reports about the health effects of effluents from ORR resulted from this health agreement. All were peer-reviewed. The Steering Panel published its final report in December 1999 (Oak Ridge Health Agreement Steering Panel 1999). In its 8-year existence, this committee held 48 meetings, all of which were open to the public and some were specifically designated to focus on public input. The health reports covered many of the same topics that were covered by ATSDR in its PHAs.

• *Oak Ridge Reservation Site-Specific Advisory Board (ORRSSAB)*. The first steps toward development of an SSAB began in May 1993 under the auspices of DOE. A local stakeholder group was formed to discuss environmental restoration and waste management issues. Six months later, the 45 members formed a steering committee to outline a proposal regarding establishment of an SSAB in Oak Ridge. While this board did not have specific health activities as part of its charter, it had a very active community interface. The board continues to meet monthly, and its proceedings are posted on a web site.[18]

• *Oak Ridge Reservation Local Oversight Committee (ORRLOC)*. This group was created in 1991 to represent those counties and communities affected most directly by DOE's activities at Oak Ridge. The ORRLOC is funded by a grant from the Tennessee Department of Environment and Conservation's DOE Oversight Division, which is in turn funded by DOE under the terms of the TOA. Members of this committee are government officials of the affected towns and counties surrounding the ORR.

• *ORRHES*. ORRHES was created to provide a forum for communication and collaboration between citizens and the agencies that are evaluating public health issues and conducting public health activities at ORR. The subcommittee was formed in 1999 by ATSDR under the guidelines and rules of FACA. Members of ORRHES:

o Serve as a citizen advisory group to CDC and ATSDR and provide rec-

[18]See *http://www.oakridge.doe.gov/em/ssab/minutes.htm*. Last accessed August 2006.

ommendations on matters related to public health activities and research at ORR;
- o Provide an opportunity for citizens to collaborate with agency staff members and learn more about the PHA process and other public health activities; and
- o Help prioritize public health issues and community concerns to be evaluated by ATSDR.

This is the only citizens committee at Oak Ridge that was formed under the auspices of the MOUs signed between DOE and HHS. Members from the community were nominated through a community-based process and finally selected jointly by NCEH and ATSDR administrators. The committee's charge was to provide public health advice and recommendations to help steer the research that will be carried out by ATSDR in support of concerns from the Oak Ridge area, both for workers and the community. From 1999 to the end of 2005, this committee met 28 times.

The ORRHES also established a Communications and Outreach Work Group (COWG) whose purpose was: "(1) to encourage and facilitate communications among the Oak Ridge Reservation Health Effects Subcommittee (ORRHES) members; community members living in areas potentially impacted by releases from the Dept. of Energy (DOE) sites in Oak Ridge; the Centers for Disease Control (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR); and federal, state, and local agencies; and (2) to maximize public participation and involvement in CDC and ATSDR public health activities in the communities surrounding the Oak Ridge Reservation" (ATSDR/NCEH 2006). At a meeting on March 20, 2001, ORRHES approved an initial communications strategy developed by COWG. The strategy included the following components: publishing a *Federal Register* notice prior to meetings; placing advertisements in area newspapers; announcing the meeting via press releases to the media; issuing a press released to describe the agenda of a work group meeting; announcing the ORRHES meetings in the DOE Public Involvement Newsletter and developing other channels to inform the public; issuing a press release after the meetings; preparing a newsletter following the meetings; and placing announcements on the ORRHES web site (ATSDR/NCEH 2006).

The ORRHES apparently ceased operations in January 2006 when funding reductions resulted in a cutback of continuing programs at Oak Ridge and closure of the ATSDR office there. The ATSDR web site for Oak Ridge[19] gives the impression that ATSDR continues to support the Oak Ridge community, although the calendar of events does not go beyond 2005 and all but one contact is listed at CDC in Atlanta.

The actions of ORRHES included reviews of ATSDR-funded extramural

[19]See *http://www.atsdr.cdc.gov/HAC/oakridge/*. Last accessed August 2006.

studies prepared for ORR. In undated minutes supplied to the committee by ATSDR, a 1994 externally published paper by Mangano (1994) was rejected and a resolution was passed "to ignore this paper as scientifically inaccurate in its conclusions which they claim could not be arrived at from the data presented in the paper."

A more recent, extensive study entitled *Assessing the Health Education Needs of Residents in the Area of Oak Ridge Reservation, Tennessee* (Parkin et al. 2003) was rejected in ORRHES minutes dated August 8, 2003. Yet this study appears in a PHA for ORR, dated January 20, 2004, which notes that this "needs assessment will help planning, implementing and evaluating the health education for this site." This report received negative reviews by several reviewers and by the Needs Assessment Working Group of ORRHES, which stated that "the collected comments reveal serious deficiencies in the report and generally reject the report as a further basis for any Public Health Education Program (PHEP), be it therefore recommended that the subject report not be used as the basis for any future health education program conducted in the ORR region."[20] A discussion with the executive director of the agency that funded this study with ATSDR monies indicated that the timing and management of the study were not ideal. Field work was encumbered by bureaucratic processes, and the population that was being studied had been "over-sampled" so responses to inquiries for input and participation were low, resulting in a report based on a small sampling of people.

These two incidents raise questions about the effectiveness of communication and coordination of ATSDR's extramural studies including one that was based on community input.

Newspaper Coverage and Other Communication Programs at Oak Ridge The committee reviewed local newspaper coverage of health-related concerns and activities from 1998 until recently through local and statewide newspapers such as the *Oak Ridger* (local), the *Knoxville News Sentinel,* and the *Tennessean* (statewide, published in Nashville). NIOSH Brief Reports did not appear to receive coverage in the local newspaper. Broader studies of the type carried out by NIOSH received some coverage in detailed articles on the broad health issues such as those covered in the *Tennessean*. ATSDR announcements of activities, meetings, and closures appeared in the newspaper reports, along with editorial articles about controversial ATSDR issues such as the Oak Ridge Environmental Peace Alliance (OREPA) challenge (Rogers 2005a) of the draft PHA on White Oak Creek radionuclide releases. This draft PHA was also criticized by Owen Hoffman, president of Specialists in Energy, Nuclear and Environmental Studies

[20]Recommendations to the ORR Health Effects Subcommittee by the Needs Assessment Working Group on *Assessing the Health Education Needs of Residents in the Area of the Oak Ridge, Tennessee—Final Report,* May 23, 2003.

as being "misleading, technically deficient and inappropriate" (Rogers 2005b). Another issue discussed in the local press was ATSDR's report on health risks associated with exposure to low-level radiation, which was disputed by the ORRLOC group as being "deeply distressed" over conclusions drawn in a study for ATSDR by investigators from Massachusetts-based Clark University (Rogers 2005c).

The decision by the U.S. Senate Appropriations Subcommittee on Energy and Water Appropriations to eliminate ATSDR's budget for activities at DOE facilities for FY 2006 brought forth further debate about the value of these activities in the local press (Rogers 2005d). ORRLOC advisory committee member Al Brooks, in a letter to local government representatives, called the decision "a serious reduction" that would leave Oak Ridge without assurance that its city is a safe place to live and work, a position supported by the advisory committee as a whole. On the other side, Janet Michel, Coalition for a Healthy Environment secretary, stated that "ATSDR has squandered far too much money on endless meetings of the ORRHES—a group the agency manipulates to its own benefit and whose recommendations they are free to ignore. I have found that ATSDR's PHAs are leaving much to be desired. ATSDR scientists are not following their own guidance documents on cancer risk for radiation exposure" (Michel 2005).

Independent of HHS health communication activities, DOE itself established mechanisms to provide the community with information regarding operations in Oak Ridge. Initially, there was a DOE Public Reading Room and a DOE Information Resource Center. In 2003, these were combined into the DOE Oak Ridge Office Information Center "One Stop Shop," which is staffed by a contractor to DOE and serves as an information resource to the community. This center does not contain health information on employees and advises that such concerns be investigated through the Department of Labor's Energy Employees Compensation Resource Center.

ANNEX 5C THE LOS ALAMOS COMMUNITY

The Los Alamos Laboratory (LANL), or Project Y, came into existence in early 1943 for a single purpose: to design and build an atomic bomb (see also Chapter 3). Sited in northern New Mexico and owned by DOE, LANL has been managed by the University of California since 1943, when the laboratory was born as part of the Manhattan Project. During subsequent years, the mission of the 28,000-acre site changed and expanded to include thermonuclear weapons design, high-explosives and ordnance development and testing, weapons safety, nuclear reactor research, waste disposal or incineration, chemistry, criticality experimentation, tritium handling, biophysics, and radiobiology.[21] Its current

[21]Los Alamos Historical Document Retrieval and Assessment Project. 2006. Available at *http://www.lahdra.org/*.

research efforts focus on national security, environmental quality, and energy resources (ATSDR 2005c). The LANL workforce in 2003 was estimated to include 7,500 University of California employees and over 3,000 contractors (ATSDR 2005c). LANL is now managed by a consortium of University of California system and three private companies.

Nuclear weapons production at the LANL site left an environmental legacy, including contamination of the air, water, and soil through releases of radioactive materials and chemicals during production (ATSDR 2005c). The releases occurred through a variety of activities including "direct discharge of liquid wastes to canyons, burial of solid wastes, direct release of air emissions to the atmosphere, and accidental spills" (ATSDR 2005c). Significant quantities of plutonium, uranium, and a wide variety of other toxic substances were processed and released to the environment in quantities that are not well known. The contamination of the site was of particular concern to workers and the surrounding community. ATSDR noted that citizens living near the site expressed concern about elevated cancer rates possibly linked to exposures at the site; other non-cancer health issues related to potential exposures including thyroid disease, allergies, asthma, and congenital anomalies; tribal exposures; and potential contamination of food and drinking water (ATSDR 2005c). NIOSH, NCEH, and ATSDR have worked in different capacities to examine the effects of these releases at the site on human health, particularly among former and current workers and in surrounding communities.

Agency Communication Efforts

An assessment of HHS communication activities at LANL is provided below.

NIOSH

As discussed previously, NIOSH produced one-page Brief Reports of Findings to communicate study results to workers and the community. Two multisite studies involved LANL. These were the study on "Mortality Among Female Nuclear Weapons Workers" by Gregg S. Wilkinson (Wilkinson 2000), and "The Impact of Downsizing and Reorganization on Employee Health and Well-Being at the DOE LANL Facility" by Lewis D. Pepper (Pepper 2000).

NCEH

In 1999, NCEH initiated the Los Alamos Historical Document Retrieval and Assessment Project to systematically review and evaluate documents related to site operations for information about releases of contaminants from 1943 to the present (Shonka et al. 2006). The LAHDRA project team was established to investigate materials used throughout LANL's history of operations to identify

and prioritize releases in terms of their apparent relative importance from the standpoint of potential off-site health effects. Based on the project's findings, NCEH will work with stakeholders to determine if more detailed assessments of past releases are warranted. Should additional investigations be warranted, they might be in the form of screening-level evaluations, or they could progress to detailed dose reconstruction for the releases of highest priority.[22] In January 2006, an interim report of the LAHDRA Project V4 was updated and is available on the project's web site.[23] (See Chapter 4 for more information about the document retrieval project at LANL.)

According to the LAHDRA project, its "comprehensive study of LANL records is providing useful information to CDC [NCEH] and others who are interested in LANL releases and potential public health effects. Possessing the security clearances and 'need to know' associated with this study, the project will bring about public release of relevant documents that, until now, have been kept from public view simply because no one had authorization to locate them and request that they be reviewed for public release." Documents declassified and released from LANL that the project team considers to contain useful information regarding off-site releases are available to the public at the University of New Mexico and at various libraries. These documents are summarized in a searchable database, which also will be available in the reading rooms.[24]

The LAHDRA web site notes that public outreach has been an important part of the project, including ongoing solicitation of public input and active outreach efforts in public education. The goal of the public outreach program is to present a complete and accurate picture of past operations and releases. The project's Web page and public meetings solicit the public's participation and input. The public is informed about the project's purpose, methods, and progress through publication and distribution of newsletters and fact sheets. The project's responsiveness to the public's input about and awareness of project activities is continuously evaluated and will be summarized at conclusion of the project. The LAHDRA project team hosted 13 public meetings from 1999 to 2005 and members have given additional presentations to organizations, communities, tribes, and pueblos throughout northern New Mexico.[25]

ATSDR

ATSDR has conducted a number of communication and outreach activities at Los Alamos. These include PHAs and educational efforts geared toward edu-

[22]See *http://www.lahdra.org/*. Last accessed August 2006.
[23]See *http://www.lahdra.org/*. Last accessed August 2006.
[24]See *http://www.lahdra.org/*. Last accessed August 2006.
[25]See *http://www.lahdra.org/outreach/outreach.htm*. Last accessed August 2006.

cating the surrounding community as well as health professionals about potentially relevant exposures at the site.

Public Health Assessments In 2005, ATSDR released a PHA for LANL for public comment. The PHA evaluated monitoring data from the site from 1980 to 2001 to assess possible exposures to chemical contaminants and radionuclides in a variety of environmental media. In preparing the document, ATSDR "collected relevant health data, environmental data, and community health concerns from the Environmental Protection Agency, state and local health and environmental agencies, the community, and potentially responsible parties, where appropriate." According to ATSDR, the document represents the agency's best efforts, based on currently available information, to fulfill the statutory criteria set out in CERCLA section 104 (i)(6) within a limited time frame.

To assess community health concerns for the PHA, in 1994, Boston University conducted a survey to identify the public health concerns of the community surrounding LANL under an ATSDR grant. Initially, surveys were mailed to 71 citizens and organizations on an NCEH contact list. Follow-up telephone interviews were conducted and additional community concerns were collected more informally. Distinct communities within the areas surrounding LANL were identified, each with unique concerns about LANL's operations.

Among the community concerns expressed were the following:

- Elevated cancer rates;
- Non-cancer health impacts, including thyroid disease, allergies, genetic effects or reproductive outcomes, asthma at pueblos, and rheumatism;
- Health impacts of LANL releases on tribal nations including questions based on exposures through unique tribal practices, such as the use of surface water from streams for ceremonies and irrigation, as well as impacts on sacred areas; and
- Long-term health impacts of earlier accidental releases.

The PHA evaluation concluded that "no harmful exposures are occurring or are expected to occur in the future because of chemical or radioactive contamination detected in groundwater, surface soil, surface water and sediment, air or biota" (ATSDR 2005b). More information about the scientific aspects of this PHA can be found in Chapter 3.

As mentioned previously, the PHAs are released to the public for a 45-day public comment period, after which the agency typically addresses these comments in a revised PHA (see discussion of Oak Ridge PHA and Hanford PHA). The committee reviewed the PHA for LANL that was released for public comment on April 26, 2005.

Educational Efforts to Health Care Providers and the Community ATSDR conducted a number of health education programs in the communities surrounding LANL. The agency partnered with the Association of Occupational and Environmental Clinics and the University of New Mexico through a cooperative agreement to develop and implement health education materials and promotional activities related to community and health professional environmental education for communities living near Los Alamos (ATSDR 2006b).

It was also involved in funding educational projects through the National Alliance for Hispanic Health (NAHH) "to increase knowledge about Hispanic children's exposure to hazardous substances" (ATSDR 2006b). Through this funding, the National Hispanic Environmental Health Education Network was developed to "increase knowledge about Hispanic children's exposure to toxic substances among health and human service professionals within the Alliance's network and to build the capacity of community-based organizations to develop and implement culturally proficient environmental education programs for Hispanic families" (ATSDR 2006b). Fact sheets, developed in English and Spanish and posted on the NAHH web site, have been developed on a variety of environmental health issues including smoking and radon exposure. ATSDR notes that the NAHH also worked closely with Youth Development, Inc. in developing community education programs related to potential exposures to contaminants of concern at LANL. This included developing three environmental health modules and training nearly 90 people in 2003.

Stakeholder Input: Citizens Advisory Board

The Northern New Mexico Citizens' Advisory Board (NNMCAB) is the site-specific community advisory group chartered under FACA in 1997 to provide citizen input to the DOE on issues of environmental remediation and cleanup, waste management, monitoring and surveillance, and long-term stewardship at LANL. For Los Alamos, ATSDR also has been working through this DOE site-specific advisory board.

According to its web site, the NNMCAB is "dedicated to increasing public involvement, awareness and education relating to environmental remediation and management activities at LANL." It strives to ensure that decisions about LANL include informed advice from the community, and it openly solicits public participation in all deliberations. The NNMCAB committee's goal is to make it easier for members of the public to make their voices heard by DOE decision makers, emphasizing the continuing need for intensive public information and involvement efforts by LANL and DOE.[26]

The NNMCAB stresses that such public information and involvement events

[26]See *http://www.nnmcab.org/*. Last accessed August 2006.

should be well organized and well managed so that the information presented is comprehensible to the intended audience and the public has ample opportunity to interact with the presenters. According to its Community Involvement Committee (CIC), which existed through 2005, the public requires understandable and usable information about environmental remediation and waste management at LANL.[27]

In 2005 the CIC made two major recommendations to DOE approved by the parent board to improve public interaction and comprehension of the information. The first was a series of recommendations for meetings aimed primarily at conveying information to the public (Recommendation 2005-4), and the second noted that the executive summaries of some specific DOE reports on environmental surveillance at Los Alamos "did not adequately summarize the key points and conclusions in a way that would be understandable to the general public" (July 27, Recommendation 2002-05). Although both of these recommendations are for DOE because this body advises that agency, many of its comments also could be applied to efforts reviewed by this committee for HHS agencies at other DOE sites.

In 2006, the duties of the CIC were transferred to the NNMCAB staff to be more effective and to help incorporate communication concerns into the efforts of two technical subcommittees of this group (L. Novak, NNMCAB, Santa Fe, NM, personal communication, July 27, 2006).

Media Coverage of HHS Activities at the Los Alamos Site

The committee conducted a limited search of news articles related to HHS activities at Los Alamos between 1990 and 2006. Many articles discussed the Energy Employees Occupational Illness Compensation Program, but as mentioned previously, this program is not included under the MOU and is not discussed here. Other activities covered by the news media included the difficulty that researchers had in obtaining data from the LANL for use in health studies; ATSDR's PHA; and LAHDRA.

NIOSH

An early article in the *Santa Fe New Mexican* in 1996 described difficulties encountered by NIOSH in obtaining data from LANL for use in health studies. It noted that "Los Alamos National Laboratory has dragged its feet in making information available to outside researchers studying cancer rates in federal DOE workers, federal and academic health researchers say." According to the article,

[27]NNMCAB Recommendation to DOE No. 2005-04, "Improvements to DOE/LANL Public Meetings," 2005. Available at *http://www.nnmcab.org/recommendations/recommendation-2005-04.pdr*.

"the researchers said that in the cases where they have been able to get their hands on records, the information has been spotty and difficult to interpret" (Easthouse 1996).

Another article in 2004 showed that the situation had not changed very much. It discussed NIOSH's difficulty in obtaining data to estimate exposure for compensation claims: "The National Institute for Occupational Safety and Health says it is having a hard time getting data on the amount of radiation to which Cold War-era nuclear weapons plant workers may have been exposed" (Zuckerbrod 2004).

NCEH

The LAHDRA project was also the subject of many articles. Some issues discussed included the release of an interim report that provided information about the status of the LAHDRA project, difficulties in obtaining needed records from the laboratory, and the delay in completing the project. One article noted, "Begun in 1999, the project is taking much longer than anticipated" (Rankin 2004). Another noted that "work on the project has at times been slowed down because the CDC and the lab have disagreed over access to various documents. The CDC at one point threatened to terminate work altogether after the current $4.2 million contract ran its course this year" (Associated Press 2004).

ATSDR

A few articles in 2005 discussed the release of the PHA for the site. One article discussed the findings of the PHA and provided details about how the public could submit comments. One article noted criticisms of the PHA: "At least one LANL environmental watchdog group, however, isn't buying the conclusions and is concerned the study's authors didn't seek input from any sources beyond LANL and the federal Department of Energy" (Rankin 2005).

REFERENCES

Ackland, L. 2002. Making a Real Killing: Rocky Flats and the Nuclear West. Albuquerque, NM: University of New Mexico Press.

Ahlstrom, D. 2005. Low level radiation dose poses higher cancer risk. Irish Times, June 29, pp. 3.

Ahrenholz, S. 2001. Overview of Current NIOSH/HERB Occupational Research & Worker Outreach Efforts at Hanford. NIOSH's Response to the National Academies' Request 12/9/05, Supporting Documents, CD ROM-2. Presentation to the Committee to Review the Worker and Public Health Activities Program Washington, DC, January 25.

Associated Press. 1998. Study finds no link between DOE workers, children's disease. Associated Press, October 16.

Associated Press. 2000. Study finds increased radiation exposure boosts risk of blood cancer. Associated Press, April 10.

Associated Press. 2004. CDC looking at pollution caused by nuclear work at Los Alamos. Associated Press, April 3.

ATSDR (Agency for Toxic Substances and Disease Registry). 1997a. Hanford Public Health Assessment—Initial Release 200 Area. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances Disease Registry). 1997b. Public Health Assessment for Hanford—300 Area. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 1997c. Hanford Medical Monitoring Program: Background Consideration Document and ATSDR Decision. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2000. Hanford Infant Mortality & Fetal Death Analysis 1940-1952. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2004a. A Guide for Physicians. Thyroid Evaluation of Patients Who Are Concerned About Hanford Iodine-131 Releases [on-line]. Available: http://www.atsdr.cdc.gov/hanford/docs/guide_for_physicians_brochure.pdf [accessed August 16, 2006].

ATSDR (Agency for Toxic Substances and Disease Registry). 2004b. Toxicological Profile for Americium. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2004c. Public Health Assessment for Oak Ridge Reservation, Oak Ridge, Anderson Country, Tennessee, EPA Facility ID: TN1890090003. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2005a. Educational Materials Clearinghouse. Educational Materials about Hanford, Radioactive Iodine and Related Topics [online]. Available: http://www.atsdr.cdc.gov/hanford/educational/ [accessed August 16, 2006].

ATSDR (Agency for Toxic Substances and Disease Registry). 2005b. Using Public Relations Strategies to Prompt Populations at Risk to Seek Health Information: The Hanford Community Health Project (draft journal article). Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2005c. Public Health Assessment for Los Alamos. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

ATSDR (Agency for Toxic Substances and Disease Registry). 2006a. Statement of Mission [online]. Available: http://www.atsdr.cdc.gov/mission.html [accessed August 16, 2006].

ATSDR (Agency for Toxic Substances and Disease Registry). 2006b. NCEH/ATSDR Response to Committee Questions. The Committee to Review the Worker and Public Health Activities Program, Worker and Public Health Committee's Public Access File. No. 40, Atlanta, GA, February 19.

ATSDR (Agency for Toxic Substances and Disease Registry). 2006c. Hanford Community Health Project. Request for Medical Evaluation for Past Exposure's to Iodine-131 (Physician's pamphlet) [on-line]. Available: http://www.atsdr.cdc.gov/hanford/docs/physic1.pdf [accessed August 16, 2006].

ATSDR (Agency for Toxic Substances and Disease Registry). 2006d. Results of the Hanford Community Health Project Survey [on-line]. Available: http://www.atsdr.cdc.gov/hanford/docs/survrlt.pdf [accessed August 16, 2006].

ATSDR/NCEH (Agency for Toxic Substances and Disease Registry/National Center for Environmental Health). 2006. ATSDR and NCEH responses to the NRC committee questions. The Committee to Review the Worker and Public Health Activities Program, July 24, 2006, Atlanta, GA.

Beierle, T.C., and J. Cayford. 2002. Democracy in Practice: Public Participation in Environmental Decisions. Washington, DC: Resources for the Future.

Boseley, S. 2005. Workers in N-plants risk cancer. The Guardian (London), June 29, pp. 7.

Business & News Desks. 1999. Public comment sought on proposed public health activities at energy department sites. Business & News Desks/Energy & Health Writers, June 4.

Cary, A. 2005a. Hanford project continues. Tri-City Herald (Richland, WA), February 1.

Cary, A. 2005b. Federal agency completes study of radiation at Hanford Nuclear Reservation. Tri-City Herald (Richland, WA), January 17.

COSMOS. 2001a. Final Report for the Evaluation of the Health Effects Subcommittee Advisory Process, Vol. 1. Report submitted by COSMOS to Centers for Disease Control and Prevention. Contract No. 282-98-0027. Atlanta, GA: Centers for Disease Control and Prevention.

COSMOS. 2001b. Final Report for the Evaluation of the Health Effects Subcommittee Advisory Process, Vol. 2. Report submitted by COSMOS to Centers for Disease Control and Prevention. Contract No. 282-98-0027. Atlanta, GA: Centers for Disease Control and Prevention.

Dworkin, A. 2005. Hanford health project seeks former "downwinders," officials want to educate those who lived near the nuclear site decades ago about possible health risks. Science, March 23, p. A17.

Easthouse, K. 1996. LANL slow responding to health studies, cancer researchers say problems with lab worse than most. Santa Fe New Mexican, April 28, p. A-1.

Flynn, J., E. Peters, C.K. Mertz, and P. Slovic. 2001. Risk, media and stigma at Rocky Flats. Pp. 309-327 in Risk, Media and Stigma, Flynn, J., P. Slovic, and H. Kunrether, eds. London: Earthscan Publications.

Friedman, S.M. 1981. Blueprint for breakdown: Three Mile Island and the media before the accident. J Commun 31:116-128.

Friedman, S.M. 2001. Risk communication, the Hanford Thyroid Disease Study and draft reports. Risk: Health Safety & Environment Spring:91-105.

Friedman, S.M., C.M. Gorney, and B.P. Egolf. 1987. Reporting on radiation: a content analysis of Chernobyl coverage. J Commun 37(3):58-78.

Geranios, N.K. 2005. Doctors also need to focus on mental health of downwinders. Associated Press, August 18.

Hebert, H.J. 2000. Study examines mortality rates of women in nuclear weapons plants. Associated Press, June 29.

IOM (Institute of Medicine). 1999. Exposure of the American People to IODINE-131 from Nevada Nuclear-Bomb Tests. Review of the National Cancer Institute Report and Public Health Implications. Washington, DC: National Academy Press.

Johnson, B. 1999. Ethical issues in risk communication: continuing the discussion. Risk Anal 19:335-348.

Kelley, M., P. Sutton, R. Gould, T. Pritikin, and M. Ferrucci. 2004. Letter to Mark Evans, Environmental Geologist, ATSDR, August 11, 2004 [letter]. Submitted to the Committee to Review the Worker and Public Health Activities Program, June 24, 2006.

Kunreuther, H., and P. Slovic. 2001. Coping with stigma: challenges and opportunities. Pp. 331-352 in Risk, Media and Stigma, Flynn, J., P. Slovic, and H. Kunrether, eds. London: Earthscan Publications.

Long, C. 2003. Study finds Rocky Flats workers have increased risk. Associated Press, April 18.

Mangano, J.J. 1994. Cancer mortality near Oak Ridge, Tennessee. Int J Health Serv 24:521.

Michel, J. 2005. Oak Ridger, July 18. "ATSDR Rife with Problems."

Moore, L. 2004. Letter from Leroy Moore, Ph.D., Rocky Mountain Peace and Justice Center, and others to ATSDR, October 20, 2004. Submitted to the Committee to Review the Worker and Public Health Activities Program, June 24, 2006.

Morgan, M.G., B. Fischhoff, A. Bostrom, and C.J. Atman. 2002. Introduction. Pp. 1-16 in Risk Communication, A Mental Models Approach. Cambridge, UK: Cambridge University Press.

Morson, B. 2003. Plutonium might be deadlier than thought: lung cancer danger occurs even at "safe" levels, study says. Rocky Mountain News, April 18, p. 12A.

NCEH (National Center for Environmental Health). 2005. Project Profiles: Hanford [on-line]. Available: http://www.cdc.gov/nceh/radiation/brochure/profile_hanford.htm [accessed August 16, 2006].

NCEH (National Center for Environmental Health). 2006a. Radiation Studies [on-line]. Available: http://www.cdc.gov/nceh/radiation/default.htm [accessed August 16, 2006].

NCEH (National Center for Environmental Health). 2006b. NCEH/ATSDR Response to Committee Questions. The Committee to Review the Worker and Public Health Activities Program, Atlanta, GA, February 19.

NCEH (National Center for Environmental Health). 2006c. Response to NRC committee's questions. The Committee to Review the Worker and Public Health Activities Program, May 23, 2006, Atlanta, GA.

NCEH/ATSDR (National Center for Environmental Health/Agency for Toxic Substances and Disease Registry). 2006. Response to Committee Questions. The Committee to Review the Worker and Public Health Activities Program, Atlanta, GA, February 19.

Nicholson, K. 2003. Some cancer rates at flats above average; fatal doses tied to single incidents. Denver Post, April 18, p. B-01.

Niles, K. 1996. Reconstructing Hanford's Past Releases of Radioactive Materials: The History of the Technical Steering Panel 1988-1995. Hanford Environmental Dose Reconstruction (HEDR) Project Technical Steering Panel. Olympia, WA: Washington State Department of Health.

NIOSH (National Institute for Occupational Safety and Health). 2005. Evidence for the National Academies' Review of the Worker and Public Health Activities Program Administered by the Department of Energy and the Department of Health and Human Services, Cincinatti, OH [on-line]. Available: http://www.cdc.gov/niosh/nas/oerp/pdfs/OERP-NAS.pdf [accessed August 16, 2006].

NIOSH (National Institute for Occupational Safety and Health). 2006a. Verbatim Transcript, Public Communication, NIOSH's Response to the National Academies' Request 12/9/05, Supporting Documents, CD ROM-2. Atlanta, GA: Centers for Disease Control and Prevention.

NIOSH (National Institute for Occupational Safety and Health). 2006b. NIOSH's Response to the National Academies' Request 12/9/05, Supporting Documents, CD ROM-2. Atlanta, GA: Centers for Disease Control and Prevention.

NIOSH (National Institute for Occupational Safety and Health). 2006c. Response by Schubauer-Berigan to NAS committee's questions. Atlanta, GA: Centers for Disease Control and Prevention.

NRC (National Research Council). 1989. Improving Risk Communication. Washington, DC: National Academy Press.

NRC (National Research Council). 1990. Providing Access to Epidemiological Data. Washington, DC: National Academy Press.

NRC (National Research Council). 2000. Review of the Hanford Thyroid Disease Study Draft Final Report. Washington, DC: National Academy Press.

O'Neil, K. 2004. INEEL health, safety report released; study of workers at the INEEL finds higher risk of some cancers. Idaho Falls Post Register, October 28, p. B1.

ORHASP (Oak Ridge Health Agreement Steering Panel). 1999. Releases of Contaminants from Oak Ridge Facilities and Risks to Public Health, Final Report of the Oak Ridge Health Agreement Steering Panel. Nashville, TN: Tennessee Department of Health.

ORNL (Oak Ridge National Laboratory). ORNL Review. 2002. Chapter 1. 25(3 and 4). Oak Ridge, TN: Oak Ridge National Laboratory.

Parkin, R.T., L. Ragain, T. Guidotti, and G. Paranzino. 2003. Assessing the Health Education Needs of Residents in the Area of Oak Ridge Reservation, Tennessee. Final report. Washington, DC: Association of Occupational and Environmental Clinics.

Paulson, T. 2000. Hanford study finds high risk in low radiation; exposed workers died of cancer. Seattle Post-Intelligencer, April 11, p. A1.

Pepper, L. 2000. The health effects of downsizing in the nuclear industry: findings at the Los Alamos National Laboratory. Boston, MA: Boston University School of Public Health. Available from NIOSH/HERB, Cincinnati, OH; 135 pp.

Presidential/Congressional Commission on Risk Assessment and Risk Management. 1997. Final Report, Volume 1. Framework for Environmental Health Risk Management. Washington, DC.

PSR (Physicians for Social Responsibility). 1992. Dead Reckoning. Washington, DC.

Rankin, A. 2004. Lab problems not affecting CDC project. Albuquerque Journal, July 28.

Rankin, A. 2005. No contamination woes at LANL, report says. Albuquerque Journal, June 25, p. E2.

Rogers, E. 2005a. Oak Ridger, May 16. "ATSDR Defends Health Check."

Rogers E. 2005b. Oak Ridger, June 15. "SENES President Claims PHA is 'Misleading'."

Rogers, E. 2005c. Oak Ridger, July 21. "ATSDR Discusses Clark University Study."

Rogers, E. 2005d. Oak Ridger, July 18. "ATSDR Budget Reduction Debate."

Schneider, K. 1988. How secrecy on atomic weapons helped breed a policy of disregard. New York Times, November 13, p. E7.

Schumacher, E. 1999. Many Hanford "downwinders" losing faith—those on Hanford dosage-study panel seek elusive radiation figures. Seattle Times, February 10, p. B2.

Seattle Post-Intelligencer. 2000. Hanford study finds high risk in low radiation; exposed workers died of cancer. April 11, p. A1.

Shonka, J., S. Flack, R. Burns, J. Budenbaum, J. O'Brien, K. Robinson, J. Knutsen, and D. Shonka. 2006. Interim report of the Los Alamos Historic Document Retrieval and Assessment (LAHDRA) Project. Version 4. Atlanta, GA: Centers for Disease Control and Prevention.

Slovic, P. 1987. Perception of risk. Science 236:280-285.

Slovic, P. 1993. Perceived risk, trust, and democracy. Risk Anal 13:675-682.

Slovic, P. 2000. Perception of risk from radiation. Pp. 264-274 in The Perception of Risk. London: Earthscan Publications.

Slovic, P., J. Flynn, and M. Layman. 1991. Perceived risk, trust and the politics of nuclear waste. Science 254:1603-1607.

Steele, K.D. 2000. Hanford health network to close; information service a victim of budget cuts at DOE. Spokane Spokesman Review, March 23.

Tuler, S., T. Webler, and R. Finson. 2005. Competing perspectives on public involvement: planning for risk characterization and risk communication about radiological contamination from a national laboratory. Health Risk & Society 7:247-266.

Webster's Third New International Dictionary. 2003. Springfield, MA: Merriam-Webster Incorporated.

Wilkinson, G.S., N. Trieff, and R. Graham. 2000. Final Report: Study of Mortality Among Female Nuclear Weapons Workers. Buffalo, NY: State University of New York at Buffalo.

Zuckerbrod, N. 2004. Government having problems getting data on weapons plant workers' exposure to radiation. Associated Press, May 13.

6

Program Management Assessment

For the program management assessment, the committee attempted to describe how the research program that had been transferred from the Department of Energy (DOE) to the Department of Health and Human Services (HHS) was managed, explore the extent to which program management facilitated or failed to facilitate the scientific aims, and identify opportunities for improvement. Although the initial charge to HHS was to assume responsibility for analytic epidemiological studies, as described in previous chapters, this also required development of exposure assessment methods as well as non-research activities such as outreach education and public health assessments. The research program begins by incorporating appropriate advice from scientists and from affected community members and continues through the conduct of specific research projects as part of an overall program to use the scientific knowledge generated to enhance public health.

The committee has reviewed the roles that various external advisory bodies played in the development and execution of scientific studies and the dissemination of research products over the nearly 15-year time span of the program; reviewed aspects of budget development and expenditures to the extent that data were available; and sampled internal meeting notes and reports to assess the extent and adequacy of interagency and intra-agency communication.

BACKGROUND

In 1989, soon after being sworn in as the Secretary of Energy, Admiral James D. Watkins authorized the establishment of two external expert panels to

provide advice to the department regarding its long-standing programs in epidemiological research. One was the DOE's Secretarial Panel for the Evaluation of Epidemiological Research Activities (SPEERA) (see Appendix B) described below, and the other was the National Research Council (NRC) Committee on the Department of Energy Radiation Epidemiological Research Programs (RERP) described later in the section "DOE's Advisory Committees." These two panels (SPEERA and RERP), which were working over roughly the same time span, were independent of one another, although their work was complementary.

On August 1, 1989, the charter creating SPEERA was signed. The panel was charged with providing to the Secretary "an independent evaluation of the Department of Energy's (DOE) epidemiology program and the appropriateness, effectiveness and overall quality of DOE's epidemiological research activities." The committee's objectives and scope of activities and duties included examination of, and recommendations regarding, the following:

- The goals of the research program;
- Its management and reporting structure;
- Its internal and external human and budget resources;
- The use of contract scientists for ongoing and special projects;
- Data quality control mechanisms;
- The utility and feasibility of transferring the epidemiological research function, including the necessary data, to another entity;
- Maintenance of and access to related records;
- Current and proposed mechanisms for determining data release policies and for storage of data;
- DOE's response to the data-related request of the Three Mile Island Public Health Fund; and
- The long-term role of the NRC Committee on Radiation and Epidemiological Research Programs.

In its March 1990 report, SPEERA noted two distinct problem areas relevant to the present review that needed particular attention: (1) DOE did not have an internally coordinated, comprehensive occupational and environmental health program, and (2) the results of DOE's epidemiological research conducted up until that time were not viewed as credible by many affected parties. SPEERA's recommendations included (1) creating a single centralized, strong program within DOE that combined the existing health and safety elements then managed by several different offices, with sufficient visibility and authority to build credibility and trust and (2) allocating the funds for analytical epidemiological research to a federal agency whose primary responsibility was human health that was also involved in epidemiological research. Within a few months after receiving the SPEERA report, DOE moved quickly to combine all of its epidemiology

programs under the oversight of an Assistant Secretary for Environment, Safety and Health and to establish a Memorandum of Understanding (MOU) with HHS.

MEMORANDA OF UNDERSTANDING

As noted above, one of SPEERA's key recommendations was to "enter quickly into a Memorandum of Understanding with the Department of Health and Human Services to manage the Department's analytic epidemiological research." Within months of the release of the SPEERA report, DOE and HHS did, in fact, establish the first MOU, which was to be in effect for 5 years. The MOU was renewed in 1996 and 2000. A fourth MOU, scheduled to begin in 2005, remains unsigned.

SPEERA (1990) stated that the MOU should cover several specific areas:

> The Department of Energy would continue to budget for analytic epidemiology, with the funds to be allocated to the Department of Health and Human Services.
>
> Current grants and contracts would be continued. Research-in-progress would become subject to the Department of Health and Human Services' regular monitoring process and would move toward open competition for grants and contracts. There would be a transition to a competitive system for project renewals and for add-on studies.
>
> The Department of Health and Human Services would use its usual methods to set the research agenda, provide for peer review of research proposals, provide quality assurance for research-in-progress, and provide access to data.
>
> Several communication channels between the Department of Energy and the Department of Health and Human Services would be established to share information about surveillance data, research findings, and policy implications. Information sharing would be routine and frequent.
>
> The Department of Health and Human Services would establish an advisory committee for the Department of Energy's analytic epidemiological research. Such an advisory committee could serve as a vehicle for public comment. Its members would represent all affected parties: including workers, communities, academicians, public health officials, and public interest groups.

All three MOUs (1990, 1996, 2000) and the 2005 draft MOU contain provisions for DOE to submit budget requests to Congress and then transfer those resources to HHS for the purpose of conducting the public health activities under the MOUs.

As noted in the MOUs, the scope of HHS responsibilities "includes the authority, resources, and responsibility for the design, implementation, analysis, and scientific interpretation of analytic epidemiological studies of the following populations: workers at DOE facilities; residents of communities in the vicinity of DOE facilities; other persons potentially exposed to radiation; and persons

exposed to potential hazards resulting from non-nuclear energy production and use." In the first MOU (see Appendix A), the responsibilities for conducting research activities were delegated to the Centers for Disease Control and Prevention (CDC), specifically the National Institute for Occupational Safety and Health (NIOSH) for occupational studies and the National Center for Environmental Health (NCEH) for dose reconstructions and community studies. Accompanying the implementation of this MOU were resource specifications for FY 1991 and FY 1992. In response to congressional appropriations language for FY 1999, DOE was directed to develop a single MOU with HHS for this program; thus, the 2000 MOU also applies to relevant activities undertaken by the Agency for Toxic Substances and Disease Registry (ATSDR), in addition to NIOSH and NCEH.

There currently is no MOU in place. A version signed by the Secretary of Energy was sent to the Secretary of Health and Human Services in April 2005 for his signature. A July 2005 letter to the DOE Assistant Secretary for Environment, Safety and Health from the Principal Deputy Assistant Secretary of HHS requested several text changes as condition for HHS signature. No further action appears to have been taken since that date.

INPUT FROM EXTERNAL SOURCES

The recommendations and impact of DOE's SPEERA advisory committee, which initiated this program, is discussed above. However, this was only the first of several advisory committees established under or relevant to the program. Some were established by DOE and others by HHS. As far as this committee has been able to determine, there was little or no communication between these different advisory committees, even when they were established by the same agency. Although agencies may have no legal obligation to accept such advice, they may take such advice into consideration and often will communicate back to the sources the reason it was accepted and incorporated into their decision making (or not accepted).

At the time the 1994 NRC report was under development (see below), at least two additional advisory committees charged with providing input to DOE and HHS were being chartered under the Federal Advisory Committee Act (FACA). In addition to the NRC committee, DOE was establishing its Environment, Safety and Health Committee. This committee was short-lived, beginning sometime in late 1993-early 1994 and being terminated in January 1995. Separately, HHS established the Advisory Committee on Energy-Related Epidemiology Research (ACERER) in early 1992, with its first meeting occurring in January 1993. Additionally, DOE advisory boards were established at specific sites.

DOE Advisory Committees

The National Research Council Committee on the Department of Energy Radiation Epidemiological Research Programs

This committee was established in June 1989 at the request of DOE's Office of Energy Research primarily to review the scientific and technical aspects of DOE's existing epidemiological research program. This request preceded the reorganization of DOE's programs. RERP appears to have been envisioned as a standing committee intended to provide advice over time. The findings of that committee's first effort are available in a report entitled *Providing Access to Epidemiological Data* (NRC 1990).

The NRC committee expressed concern about the long-term effectiveness of an MOU between DOE and HHS unless plans were made and implemented to ensure continuing coordination between the two agencies. It noted that the recommendation to transfer authority for analytical epidemiological research to HHS while retaining the responsibilities for data collection and generation, quality control, descriptive epidemiology, *and* full authority for funding with DOE would lead to friction between the agencies. The committee expressed its belief that "trouble lies ahead, unless preventive measures are taken immediately" (NRC 1990). To assist in guaranteeing coordination, the committee recommended the following:

1. "A high-level joint advisory committee to *supervise* the operation of the joint epidemiological activities of DOE and HHS should be established at the earliest possible date. The term high-level means that the advisory committee should be jointly appointed by the secretaries of DOE and HHS. The advisory committee should have the capacity and responsibility to provide both *scientific* advice and *policy* advice to the secretaries or their designees."

2. "Although authority for the supervision of analytical epidemiological studies involving DOE data is being transferred to HHS, DOE employees and the employees of DOE contractors should not be precluded from carrying out specific analytical studies. Because analytical studies can ultimately improve the overall quality of the DOE epidemiological data base, it is in the best interests of DOE to encourage employees to carry out suitable studies."

3. "If DOE is to maintain the trust and confidence of the general public with regard to its responsibility for the health and safety of those in and around its facilities, it must take the responsibility for initiation of data collection and safety issues. Such data collection should be guided by the results of continuing scientific research, in part carried out directly under DOE auspices, so as to maintain the direct involvement of DOE in health and scientific issues."

In 1994, RERP issued a report in response to a request from DOE's Office of

Epidemiology and Health Surveillance (OEHS) to provide advice regarding the future directions (>5 years) of the office's research (NRC 1994). This report does provide such advice, but more importantly, the committee continued to express its concern about the MOU between DOE and HHS, noting that its earlier concerns (NRC, 1990) had not been resolved satisfactorily. Specifically, issues included the following:

1. The inefficiency of multiple oversight committees,
2. The absence of an advisory committee specifically to advise OEHS,
3. The lack of integration of and communication between existing oversight committees,
4. The absence of clear lines of accountability, and
5. The lack of a cooperatively defined overall research agenda

The committee's bottom line recommendation, presented in bold type, was that "a cooperatively defined overall epidemiology research agenda be developed and that the MOU be revisited and altered to enable this to happen and to address the administrative difficulties that will continue to impede the functioning of OESH" (NRC 1994).

Site-Specific Advisory Boards

As discussed in Chapter 5, in carrying out its cleanup responsibilities under the Superfund program, DOE established site-specific advisory boards (SSABs) at many of its facilities. These boards were established to "provide consensus advice and recommendations to the U.S. Department of Energy's (DOE) environmental restoration and waste management activities."[1] Although these boards were not established for the specific purpose of providing advice regarding the work being carried out under the MOU with HHS, some of this work was directly relevant to cleanup activities at the site, and much of the work was potentially of interest to these SSABs. Nevertheless, as far as the committee has been able to determine, the SSABs were never informed about this work, even when it pertained to potential risks at the specific facilities in which they were interested, and were never asked for advice regarding this work.

HHS Advisory Committees

HHS (CDC and NCEH and ATSDR) received input on the development and execution of its research agenda from many external sources, a number of which were formally constituted advisory committees. The initial MOU between DOE and HHS called for HHS to establish an (external) advisory committee to provide

[1]DOE web site *http://www.em.doe.gov/public/ssab/index.html*. Accessed July 4, 2006.

advice to the Secretary of HHS in establishing the research agenda and conducting the research program. To that end, ACERER was chartered in 1992 and met for the first time in January 1993. It of interest to note that the 1990 MOU states that DOE will participate in the development of the research agenda for analytical epidemiology studies by having its representative(s) serve along with HHS representatives as non-voting members of ACERER. The MOU also notes that HHS staff would serve as non-voting members of the DOE advisory committee, which would be responsible for providing direction, oversight, and evaluation to DOE's Office of Environment, Safety and Health.

Prior to the establishment of ACERER, CDC's Center for Environmental Health and Injury Control convened a 2-day workshop in Atlanta, Georgia, on December 3-4, 1991, for the purpose of soliciting input into the development of its energy-related epidemiology research program (NIOSH 2005). The goal was not to achieve consensus, but rather to elicit ideas from workshop panel members and participants for CDC to consider when developing its research strategy. Approximately 150-200 scientists and stakeholders attended. Five working groups were designated to identify strategies and methods for further evaluation of health risk potentially associated with workplace and ambient exposure at DOE sites. Recommendations were made in five areas: communication and public involvement, epidemiology, exposure assessment, dose reconstruction, and other.

The following were some of the key recommendations related to the NIOSH Occupational Energy Research Program (OERP) agenda:

- Evaluate populations not included in previous cohorts.
- Combine cohort data for increased statistical power.
- Complete health studies for mercury and beryllium exposures.
- Examine outcomes other than cancer such as reproductive health.
- Continue follow-up of plutonium-exposed workers.
- Evaluate emerging issues such as cleanup workers and Chernobyl liquidators.
- Capture radiological and chemical exposure data and procedures.
- Obtain institutional memory of site senior staff.
- Assess additional chemical and non-ionizing exposures and risk.

Advisory Committee on Energy-Related Epidemiological Research Consistent with the SPEERA recommendations and the 1990 MOU, HHS established ACERER in 1992. ACERER met periodically from early 1993 until 2000. Its charter lapsed in 2002 and was not renewed. At the beginning, 13 members constituted the committee. Members included scientists with expertise in energy-related epidemiological research and public health (including occupational and environmental health), as well as representatives of public interest groups and affected parties such as workers, energy development advocates, and community residents. In addition to the 13 voting members, provisions were made for repre-

sentatives from DOE and HHS to serve as nonvoting ex officio members. Over time, the number of committee members was increased to 15, and the nonvoting ex officio members were specified as designees of the DOE Assistant Secretary for Environment, Safety and Health, the DOE Assistant Secretary for Environmental Management, the Director of the National Cancer Institute of the National Institutes of Health (NIH), and any additional officers of the U.S. government deemed by the HHS Secretary as necessary to carry out the function of the committee. The committee's mission initially was to provide advice and recommendations to the Secretary and Assistant Secretary of Health of HHS, the Director of CDC, and the Administrator of ATSDR on the establishment of a research program pertaining to energy-related analytic epidemiological studies. In later committee charters, it was noted that advice and recommendations also covered the "appropriate interaction between the Committee and DOE regarding the direction HHS should take in establishing a research agenda and developing a research plan, and the respective roles of HHS and DOE in energy-related research."

Thus, it would appear that the committee was being asked to expand its scope from addressing purely scientific issues to addressing those involving program management and execution. Over time, ACERER lost its original focus, meetings often were not planned and executed as responses to a set of charge questions related to the agendas, and the spirit of positive communication and collaboration that marked the early days deteriorated. It became an ineffective tool for soliciting advice, and its charter has not been renewed. Nonetheless, ACERER did provide many recommendations over the course of its existence. These are summarized in Table 6A-2 in the annex to this chapter (adapted from the NIOSH Evidence Package).

NIOSH staff presented a proposed research agenda at the first ACERER meeting in January 1993. At the time, the agenda consisted of the studies to be continued after the transfer from DOE along with a set of proposed new studies (Table 6-1). When NIOSH assumed responsibility for the conduct and management of all ongoing studies performed by Oak Ridge Associated Universities (ORAU), Los Alamos National Laboratory (LANL), and Battelle-Pacific Northwest National Laboratory (PNNL) under DOE's supervision, beginning in FY 1991, the decision was made to continue only 20 of those studies. These decisions reflect the recommendations prepared at the 2-day CDC meeting in Atlanta, in which DOE scientists participated, and were subsequently approved by ACERER. It is not clear whether the discontinuation of ongoing studies exacerbated tensions or affected the level of cooperation offered by the DOE sites to subsequent investigators.

At its second meeting (April 1993), ACERER endorsed the concepts presented in the NIOSH work plan and in NCEH's work plan in the areas of environmental dosimetry and dose reconstruction, environmental epidemiology, and risk estimation. No documentation was made available to this committee that de-

TABLE 6-1 DOE Studies Assumed by NIOSH Under the MOU

No.	Study	Principal Investigator
1	Oak Ridge National Laboratory (ORNL)	ORAU
2	Mortality of Workers at a Nuclear Materials Production Plant (Y-12) in Oak Ridge, Tennessee	ORAU
3	Oak Ridge Gaseous Diffusion Plant (K-25) Cohort Mortality Study	ORAU
4	Combined Oak Ridge Facilities (Tennessee Eastman Corporation [TEC], Y-12, X-10, K-25)	ORAU
5	Cohort Mortality Study of Welders at ORNL	ORAU
6	Savannah River Site Cohort Mortality Study	ORAU
7	Fernald Feed Materials Cohort Mortality Study	ORAU
8	Uranium Dust Lung Cancer Case-Control Study	ORAU
9	Mallinckrodt Chemical Works Cohort Mortality Study	ORAU
10	5-rem Study	ORAU
11	Mound Facility Cohort Mortality Study	LANL
12	Los Alamos National Laboratory Cohort Study	LANL
13	Rocky Flats Nuclear Weapons Plant Cohort Mortality Study	LANL
14	Zia Company Cohort Mortality Study	LANL
15	Los Alamos "241 Cohort" Study	LANL
16	Hanford Health and Mortality Study	PNNL
17	Evaluation of Follow-up for Hanford Workers	PNNL
18	Combined Data on Hanford and ORNL	PNNL
19	External Radiation Dosimetry Data in Epidemiological Analysis	PNNL
20	Combined International Studies	PNNL

SOURCE: NIOSH (2005).

scribed those original elements of the NCEH work plan in detail. Thus, the committee could not compare them with subsequent NCEH activities and accomplishments. At subsequent meetings, NIOSH, NCEH, and ATSDR provided an update of their activities relevant to the DOE sites. Also, on a periodic basis, ACERER was asked to comment on the updated work plans of the two agencies. (See Table 6A-1 for ACERER recommendations.) Only once, according to meeting minutes, did ACERER provide a formal recommendation on an ATSDR initiative. The committee endorsed the recommendations (relating to community involvement plans) in a memo to Dr. Satcher: "That the Director, CDC, and Administrator, ATSDR, approve ATSDR's and CDC's approach to implement the program which includes both Community Approach #1, community forums for individual advice and Community Approach #2, Federal advisory committees chartered under the FACA" (ACERER 1993).

Site-Specific Health Effects Committees In addition to ACERER, HHS-CDC received input from advisory committees created at six DOE sites. CDC acknowledged that implementing the DOE-HHS MOU required that it engage in a

high level of interaction with communities proximate to DOE sites. Citizens Advisory Committees on Public Health Service Activities and Research at Department of Energy Sites were established at Hanford Nuclear Weapons Facility, Oak Ridge Reservation, Savannah River, Los Alamos National Laboratory, Fernald Feed Processing Center, and Idaho National Laboratory at the request of representatives of the communities surrounding DOE sites. These committees were established to provide consensus advice and recommendations on the community's concerns regarding NIOSH-NCEH-ATSDR activities related to the sites. Some of these advisory committees also established Health Effects Subcommittees. These subcommittees provided input primarily to NCEH-ATSDR on matters of community and worker health concerns. It was expected that they would work in partnership with CDC as it designed and conducted dosimetry, epidemiological, and risk assessment research at these facilities. As with ACERER, this partnership began on amicable terms, but again, as time went by, possible frustration at the lack of pace in conducting the work and a deterioration of the lines of communication, among other factors, led to the airing of complaints by various subcommittee members at both sites. In the case of the Hanford Health Effects Subcommittee (HES), these concerns resulted in a letter to Dr. Linda Rosenstock, then head of NIOSH, in 1999, stating that NIOSH should no longer attend HES meetings and should withdraw from the DOE FACA process (see Table 6A-1).

Two of the three committee-selected study sites had Health Effects Subcommittees (Hanford and Oak Ridge). No HES was established at Los Alamos, the third committee-selected study site. The New Mexico Department of Health, the Oversight Committee of the New Mexico Department of the Environment, and two local environmental groups were opposed to establishing an HES under FACA. Early in the Los Alamos project, several attendees at a public meeting held by NCEH stated their opposition to the formation of an HES because of their negative perceptions of the DOE's Citizens' Advisory Board (CAB). NCEH talked with many citizens both inside and outside environmental groups and virtually none wanted a subcommittee. The reason given was that their experience with the DOE CAB was so negative that they wanted nothing to do with any more committees.

Hanford Health Effects Subcommittee The Hanford Health Effects Subcommittee was active for nearly a decade (September 1994 to January 2004). It met for the first time in January 1995. Table 6A-2 summarizes the consensus advice and recommendations that the subcommittee provided to HHS (NIOSH, NCEH, and ATSDR) from 1995 to 2000 (COSMOS 2001a, 2001b).

Oak Ridge Reservation Health Effects Subcommittee The Oak Ridge Reservation Health Effects Subcommittee was active from November 2000 through September 2005. No date for another meeting was set at the September 2005 meet-

ing, given uncertainty about the level of funding that ATSDR would be receiving in FY 2006 for Oak Ridge activities. None have been scheduled since, even though ATSDR has not completed all of the Public Health Assessments (PHAs) planned for sites affected by activities on or near the reservation. The original timeline for completion was June 2006.

The Oak Ridge Reservation's HES charter stated that its purpose is to provide advice and recommendations concerning public health activities and research conducted by ATSDR and CDC at the Oak Ridge Reservation. Its charter is to provide advice on the selection, design, scope, prioritization, and adequacy of ATSDR's public health activities for the Oak Ridge Reservation. It is also to provide critical input to the public health assessment process, community needs assessment process, and any recommendation for follow-up public health activities. However, recommending activities of any other federal, state, or local agency is not within its charter. Table 6A-3 summarizes the consensus advice and recommendations that the subcommittee provided to HHS (primarily ATSDR) over that time frame.[2]

DISCUSSION: MANAGING INTERAGENCY RESEARCH PROGRAMS

Interagency programs are difficult to manage even under the best of circumstances. Some of the factors that can help make them effective include the following:

1. Substantial support from the top,
2. Effective communication and cooperation within each of the agencies and between the agencies at all levels,
3. A detailed agreement on what is to be accomplished and how,
4. Continuous feedback mechanisms to ensure that priorities are agreed upon and funding is adequate, and
5. The ability of both agencies to take credit for the success of the program.

The committee discussed the administration and management of the research program with a number of past and present representatives from DOE and HHS (see list of presenters in front matter). On the basis of these discussions, in the committee's judgment, during the decade and a half that the DOE-HHS program has been under way, serious deficiencies in all of these factors have been present—some for the entire period, others for a portion of the period.

Difficulties emerged from the start in the way the program was initially designed by DOE. Although the reasons for these deficiencies are understandable given the widespread controversy and suspicion that stimulated DOE to propose the program, they have, as repeatedly pointed out by the National Research Council Committee on the Department of Energy Radiation Epidemiological

[2]See *http://www.atsdr.cdc.gov/HAC/oakridge/meet/orrhes.html*. Last accessed August 2006.

Research Programs, caused problems that have probably led the program to be less effective than it could have been (NRC 1990, 1994).

Substantial Support from the Top

When it was started, the program certainly had substantial support from the top level of DOE. Without Admiral Watkins' personal interest and commitment to the program, it is unlikely that it would have been as comprehensive, or established as quickly, as it was. There was also high-level interest at HHS, and the importance of senior-level policy communication between DOE and HHS was recognized in the agreement to hold periodic "principals' meetings" that were to include the DOE Assistant Secretary for Environment, Safety and Health and the directors of the three HHS agencies directly involved—ATSDR, NCEH, and NIOSH. When the program began, the fact that all four individuals in these leadership positions were biomedical scientists with extensive epidemiological expertise and collegial professional ties undoubtedly strengthened this high-level commitment.

Maintaining this high level of support within HHS as personnel changed, however, was a challenge because of the way that department has been organized over time. Organizational charts available from the HHS web site[3] as of November 2006 identify ATSDR as reporting directly to the Secretary of HHS. NCEH and NIOSH are components of the CDC, the Director of which also reports directly to the Secretary of HHS.[4] However, in fact, the Director of ATSDR reports to the CDC Director, since the current Director of CDC also is the Administrator of ATSDR.[5] Such was not always the case; thus, there has been organizational confusion over the lifetime of the OERP which matters because it has interfered with the ability of HHS to offer a single point of contact at a comparable organizational level to DOE.

The situation at DOE is no less complex. Originally, the responsible official (the Assistant Secretary for Environment, Safety and Health) reported directly to the DOE Secretary, with the Deputy Assistant Secretary for health as a direct report to the Secretary. However, it appears as if interest at this higher level may have diminished after the program was transferred and the agency heads were replaced during changes in the administration. In August 2006 the DOE Secretary announced a reorganization plan, creating the Office of Health, Safety and Security.[6] The departmental responsibilities related to the research program are transferred to this new office and combined with many others, existing and new.

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[3]See *http://www.hhs.gov/about/orgchart.html*. Last accessed November 9, 2006.
[4]See *http://www.cdc.gov/maso/cdcstmenu.htm*. Last accessed November 9, 2006.
[5]See *http://www.cdc.gov/about/director.htm*. Last accessed November 9, 2006.
[6]See *http://www.hss.energy.gov/*. Last accessed November 9, 2006.

The new office will be led by a Chief Health, Safety and Security Officer, a career professional, who will report directly to the Office of the Secretary.

In the committee's judgment, as personnel changed, the absence of engaged points of contact in both DOE and HHS has reduced interagency communication below a minimally effective level. The absence of a senior point of contact also may have blunted the ability of HHS to effectively convey information needs to DOE in a manner that would elicit meaningful response.

Effective Communication and Cooperation Within Each of the Agencies and Between the Agencies at All Levels

When federal agencies have shared responsibilities, the extent to which they communicate effectively is extremely important to their success in implementing programs successfully. The free flow of information among scientists is equally important for scientific research to flourish.

The first aspect of communication is horizontal: How freely did information flow between DOE and HHS at the policy level? How freely were scientists able to communicate across agencies? Secondly, within each organization, how effective was the communication between scientists and policy makers?

In the committee's judgment, the DOE-HHS program has been seriously deficient with respect to establishing and maintaining good communications. To a large extent, this deficiency was designed initially into the program. Because of the deep suspicion the communities had of DOE's efforts to assess human health risks, the top levels at DOE decided that the HHS work should be conducted completely independently of any DOE oversight or involvement (presentation to committee by Paul Ziemer). HHS concurred, and thus was established a policy of minimal communication about the studies between the two agencies at any level. A former DOE Assistant Secretary, for instance, described how he learned about the results of one of the studies when newspaper reporters asked him to comment on the study (presentation to committee by Paul Ziemer). However, as he pointed out, this was the way it was designed, although the procedure for release of study information was subsequently modified to provide a courtesy advance copy for future reports. Occurrences such as this, however, may have led to further deterioration in the already low level of support for the program at all levels of DOE program staff.

Scientific communication between HHS and DOE was documented through quarterly reports of HHS scientific meetings attended by DOE representatives and reported to DOE leadership. DOE, however, estimates that it devoted only one full-time equivalent to the effort. This low level of involvement combined with the substantial loss of expertise when the DOE epidemiological positions were transferred to HHS, reduced the department's ability to effectively use information that the program provided. For much of the 1990s, the DOE Deputy Assistant for Health was able to provide an additional line of communication

between the two departments and to troubleshoot some of these difficulties, primarily at the administrative but also at the scientific level. As a senior scientist on detail to DOE from HHS, he was in a position to bridge some of the communication gaps between the two departments at the scientific level and to maintain effective communications within DOE. However, subsequent leadership turnover eliminated these bridges between the agencies and between the policy aspects and the scientists.

Vertical communication within DOE followed clear reporting lines, with meeting reports directed from staff scientists to administration. However, for the reasons given above, there was not a great deal of information to communicate. The department's internal communications were also severely hindered by the fact that the facilities themselves are managed by contractors that operate with substantial independence. The relationship between these contractors and DOE's Office of Environment, Safety and Health is unclear to the committee. An additional complication is that defense-related national labs such as LANL report to different DOE Assistant Secretaries than do science-related activities.

Vertical communication within HHS is well documented through ACERER and staff meetings, although senior-level policy input is not evident and there are indications that staff scientists were inappropriately left to sort out policy conflicts with insufficient backing. However, as far as the committee has been able to determine, the flow of scientific information among the three components of HHS, and with the extramural scientific community at large, appears to have been effective, facilitated by the deputy directors of the three organizations and by a reasonable fit between intramural and extramural research portfolios.

One manifestation of the problem of inadequate communication and cooperation was a disagreement over accounting procedures. DOE and NIOSH apparently operate under different accounting rules.[7] According to NIOSH, when that agency enters into a grant agreement with a non-government researcher, it is required to "encumber" the entire amount needed to carry out this research "at the beginning of each budget period" even though the research may take several years to complete. DOE, however, apparently does not consider the funds obligated (or "encumbered") until they are spent. As a result, DOE would show large amounts of unobligated funds, which NIOSH reported as encumbered.

Why this should have been a major issue is unknown to the committee, but apparently the two agencies were unable to work out a solution. The result seems to be that the agencies spent substantial time discussing accounting practices rather than the substance of the research being conducted.

[7]See the NIOSH Occupational Energy Research Program, Evidence for the National Academies' "Review of the Worker and Public Health Activities Program Administered by the Department of Energy and the Department of Health and Human Services" November 2005, pp. 33-34.

A Detailed Agreement on What Is to Be Accomplished and How

When the program began, most of the studies had already been initiated by DOE, and HHS agreed to complete them. Thus, the original agreement incorporated a research agenda that was mutually agreed upon and was closely aligned with the recommendations of SPEERA.

However, again by design, no effort was made to establish a process for mutually developing a research agenda in the future. HHS was given the responsibility for deciding what research would be done, and it would report its decisions to DOE at the quarterly interagency meetings. Again, the reasons for initially designing the agreement to allow HHS to operate independently are understandable. Nevertheless, the committee judges that the lack of substantive input was likely to reduce DOE's interest in and support for the program.

The size of the two departments also presented challenges. Within HHS, for example, additional institutes in the NIH, including the National Institute of Environmental Health Sciences and the National Cancer Institute (NCI), also conducted or sponsored research related to DOE needs, including the health effects of electromagnetic fields (NRC 1999) and epidemiological studies on cancer outcomes from exposure to ionizing radiation.

The committee was unable to identify any specific agreement or process within HHS regarding what studies were to be undertaken by different agencies and how the monies were to be divided among agencies. It appears as if the funds transferred annually were divided among the HHS agencies in some unspecified manner, and each agency then proceeded with its own research agenda. The research agenda was guided by recommendations of ACERER. After its termination in 2002, the research agenda appears to have been updated more informally by HHS scientific staff and program managers through public and stakeholder meetings, as well as consultation with individual scientific experts about research needed in specific areas. Representatives from DOE and HHS who made presentations to the committee disagreed on whether or not DOE had sufficient opportunity to contribute to the development of the research agenda, particularly over these last several years. This issue appears to have been a source of tension between the two agencies.

Both between DOE and HHS and among the three HHS agencies, there existed significant differences in what implementing a research agenda meant. DOE had come under criticism for having too close an oversight role in contracting and overseeing research at a time when the perception of conflict of interest was prominent. Within HHS, NCEH followed the approach used by CDC as a whole, which emphasized the use of research contracts that permitted the agency to specify products and expectations, allowing for a greater degree of control.

NIOSH, by contrast, depended primarily on a grants program that followed the NIH approach and was managed by NIH. This approach emphasizes the separation of intramural and extramural grants management. NIOSH scientists developed requests for proposals that incorporated the broad scope of research

needs as described in the overall agenda, but the proposals that were submitted by extramural scientists were peer-reviewed for scientific merit by independent panels of non-government scientists. This primary review scored all proposals that were deemed to have any scientific merit.

NIOSH managers then conducted a secondary review for policy considerations, but there is no information to suggest that the specific needs of an overall research agenda were incorporated by agency policy makers, and staff scientists would not have been part of the selection process. Although this approach has succeeded in funding scientifically meritorious projects (it resulted, for instance, in extramural scientists' producing a higher rate of peer-reviewed publications than agency scientists), it deliberately lacks the linearity and directedness of research contracts.

ATSDR, by contrast, essentially focused on community risk assessments and educational outreach. While the overall result appears to have been generally successful from a scientific standpoint, leading to the development of methods of measuring exposure, exposure assessment, and health outcomes assessment research, the absence of a clear research agenda was a policy limitation.

NIOSH informed the committee that, beginning in FY 2000, it corrected this problem by developing a detailed 5-year research agenda that is revised annually. This should be a substantial benefit to the program if it continues.

Continuous Feedback Mechanisms to Ensure That Priorities Are Agreed Upon and Funding is Adequate

While the nature of long-term epidemiological studies places limits on the ability to provide early feedback for extramural studies, communication at the scientific level allowed the agencies to emphasize different activities related to measurement and exposure assessment that fed into other questions. The major concern expressed by DOE and others has been the length of time it has taken to produce results from analytic epidemiological research. In part, this has resulted from difficulties in obtaining exposure data at the various work sites. HHS scientists raised this issue at meetings of ACERER, but the committee was unable to identify any improvements that might have resulted from this attempt at feedback to the committee.

The new research agenda, with its annual updates, should provide an effective mechanism for formalizing the necessary feedback process within NIOSH. Expanding this effort to include the other HHS agencies and DOE in a meaningful way could go a long way toward solving the problem for the entire program.

Ability of Both Agencies to Take Credit for Program

If an agency involved in an interagency research program does not take pride in and ownership of the results of the program, that agency is likely to quickly

lose interest in supporting the program. Presentations to the committee strongly indicated that this was a major weakness of the DOE-HHS program. As described by both current and former DOE officials in open sessions of this committee, public and congressional concerns about the DOE program were significant factors in initiating the program under the MOU, and part of the response to this criticism was to structure a relationship with distance between DOE as the funding agency and the scientists who conducted the work. This strategy unfortunately would be expected to diminish the sense of ownership or pride in accomplishment on the part of DOE personnel that is a central feature of large scientific endeavors. The minutes from the most recent ACERER meetings indicate that HHS scientists also experienced similar criticisms about the conduct of the scientific investigations from community advocacy groups that had initially been critical of DOE, suggesting that more effective approaches to conflict management would have been a better strategy than one relying on distancing the two agencies.

THE DATA PROBLEM

One of the biggest challenges affecting the program, particularly in terms of the NIOSH epidemiological studies, has been the difficulty researchers have had in obtaining exposure data. For instance, NCEH and NIOSH report that they have spent millions of dollars attempting to retrieve and compile data from DOE facilities. There are several reasons for this, some of which would have existed regardless of who was doing the research. However, some undoubtedly were exacerbated by weaknesses in the interagency effort discussed above.

The fundamental problem was that the worker exposure data had never been collected, processed, or stored with any regard to the possibility that they might be needed in the future for such studies. Retrieving these data would have been a major undertaking under the best of circumstances, but this program was not operating under the best of circumstances. Among the difficulties encountered were the following:

- Because the data belonged to DOE, HHS would have to make formal interagency requests to have access to them.
- Since much of DOE's work is covered by national security restrictions, the next problem was whether the researchers had adequate security clearances or, alternatively, whether the security restrictions could be removed. Determining this is a time-consuming process.
- Although the data belonged to DOE they were actually under the "control" of the contractors managing DOE facilities. The DOE office responsible for the interagency program had no direct authority over these contractors.
- Contractors had little incentive to facilitate access to the data because this required the diversion of resources away from their primary mission, and federal

contracts were placing increased emphasis on the contractor's performance in pursuing its mission.

At the same time, DOE was implementing both a new emphasis on environmental safety and health and a significant decentralization of management authority through government-owned, contractor-operated facilities. This decentralization, and the difficulty on-site managers and HHS scientists encountered with conflicting needs and resource constraints, seriously delayed the collection of necessary information on worker exposures, primarily impacting NIOSH scientists. Most of the searches for source data for NCEH from DOE contractors was carried out by NCEH contractors rather than government employees. That fact may also have increased the difficulties in obtaining the data. The list of failed communications, delayed or prohibited access to information, and absent or contradictory responses to information access requests is well documented by NIOSH scientists over a prolonged period between 1992 and 1997. The committee was not provided direct documentation from the perspective of DOE or the contractors, although both former Assistant Secretaries (Dr. Ziemer and Dr. Michaels) who discussed the program with the committee emphasized the difficulties they had experienced pulling together information and gaining the cooperation of many DOE employees, along with the extremely difficult nature of gaining cooperation from contractors who were essentially being asked to respond to an unfunded mandate. It is entirely possible that staff-level scientists may have been less sensitive to the production and other needs of the subcontractors than senior-level management, and it is not clear whether attempts were made to facilitate these communication requests at the site level.

ACERER, in its role as a federal advisory committee to the Secretary of Health and Human Services, was well aware of the extent and nature of the problem, but was empowered to communicate directly only with the HHS Secretary, which it did on two occasions to call attention to the seriousness of the data access problem. In an April 13, 1995, letter from the chair of ACERER to the Secretary of HHS, the chair notes: "Unfortunately, in the fifth year of the Memorandum of Understanding (MOU) between HHS and DOE, access is still a problem." The letter and the HHS response also illustrate the extent to which agency staff scientists may have been left without senior policy-level support (i.e., the concerns expressed in the letter about lack of NIOSH access to data were prompted by NIOSH scientific presentations and were directed to the HHS Secretary); however, the letter was delegated back down to staff scientists for response and was signed by the program manager, with a very brief cover letter from the Assistant Secretary for Health (June 6, 1995). In a July 18, 2006, letter from a NIOSH section chief to his DOE counterpart, an eight-page attachment lists problems with access and other issues on an item-by-item basis. A follow up letter to ACERER from NIOSH staff (October 26, 1995) indicated that some progress was being made. The committee was unable to find any indication of

senior-level communication between HHS and DOE on this topic, which would have been anticipated given the inability of senior-level HHS leadership to correct the problem directly. While specific responses from NIOSH eventually included the development of formal access procedures, this appears to have been accomplished only in 1997. The inability of ACERER to address both DOE and HHS jointly appears to have contributed to this delay.

Against this backdrop, extraordinary efforts were required to develop, implement, revise, and follow through on a coherent research program in order to achieve meaningful outcomes. To the extent that these occurred or failed to occur, both departments share responsibility and both may benefit from a review of lessons learned.

IMPACT OR VALUE OF RESEARCH PROGRAM

Ultimately, the important question is whether the program produced useful information that had an impact on policy and decision making. Even here, there is no agreement. The following example is excerpted from 2006 written communications and, although derived from long response letters, captures the tenor of the relationship. Between the first committee meeting (November 3-4, 2005) and the second meeting (February 21-22, 2006), in response to committee requests to DOE and HHS for information about the impact of HHS research on DOE policy, the following statements were included:

> *DOE*: "There have been no policy modifications as a result of the worker and public health research. . ." (S. Cary response to committee, January 20, 2006, p. 4).
>
> *HHS (ATSDR)*: "We are not in a position to speak for DOE and say how DOE changed their policy as a result of our work. . ." (T. Sinks response to committee, February 10, 2006, p. 7).
>
> *HHS (NIOSH)*: "Notice of specific modifications to DOE policies or procedures as a result of NIOSH recommendations under the OERP have not been communicated to NIOSH" (M.K. Schubauer-Berigan response to committee, January 19, 2006, p. 2).

However, in his February 10, 2006, response, Dr. Sinks also describes a number of specific impacts resulting from ATSDR activities, many of which relied on NCEH exposure assessments. Among others, a risk assessment conducted by ATSDR of organically bound tritium resulting from environmental releases at the Savannah River site eliminated the need for continued DOE monitoring; another risk assessment at Oak Ridge reduced the area requiring environmental cleanup of mercury contamination, both resulting in significant DOE cost savings (ATSDR Response, February 10, 2006, p. 8). Similarly, former Assistant Secretary for Environment, Safety and Health Dr. Paul Ziemer clarified at the May 3, 2006, committee meeting that DOE sets scientific policy regarding expo-

sure standards for workers in accordance with international consensus established by the National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection. To the extent that HHS research contributes to the body of knowledge and to the scientific deliberations involving these bodies, it contributes to those policies. Risk data that comes out of some of the epidemiological studies also contributes to assessments of risk such as the recent BEIR VII report (NRC 2006). NIOSH has contributed to the multinational studies on an ongoing basis and currently has scientists serving as representatives to these bodies.

Despite the apparent absence of recognition by the current agency participants in both departments, there is evidence that HHS work in exposure assessment, risk assessment, and analytic epidemiological studies has addressed a number of the important health outcome questions, although there continue to be areas of information gaps. Furthermore, these assessments have directly affected DOE cleanup and other activities and have helped to shape regulations.

Measuring Impact

To have measurable impact on occupational and environmental health outcomes, research findings need to be translated into policy changes that are implemented and evaluated. International standards organizations, federal agencies, and organizations such as the National Safety Council have developed approaches based on continuous quality improvement to drive impact. In general, these principles begin with management commitment. Because measuring impact is an ongoing task, the committee feels compelled to comment on aspects of future application of research findings in the context of ongoing operation of DOE facilities, including cleanup operations.

DOE is a major enterprise engaged in research, development, and manufacturing. As such, it will continue to face issues involving worker safety and health, community safety and health, and environmental protection and enhancement and will face a continuing challenge in complying with state and federal regulations pertaining to all these areas. The challenge the DOE faces in dealing with these issues is complicated by two facts. The first is that its major facilities are managed predominantly by contractors. The second is that these facilities are, by their very nature, often working on projects and with chemical substances that have not been evaluated thoroughly, in terms of the health and safety risks they may pose. On the other hand, significant improvements have been made with regard to monitoring for exposure and health impacts of radioactive agents.

In addition to management commitment to a continuous quality improvement program on these sites, other basic components include employee participation, hazard identification, hazard remediation, training, and program evaluation. Whereas site-specific hazards in a given location should be identified and managed at that location, the committee believes that the larger goal of creating

sufficient information from large-scale studies to create and implement new policy requires a strong central office. One of the responsibilities of DOE is the compilation, management, and storage of information collected at its facilities regarding worker and community exposures.

As described in previous chapters, both the quality of the scientific research and the scope of the communication activities conducted by HHS under the previous MOUs addressed important, ongoing DOE needs. While significant opportunities for improvement are identified, the scope remains large and federal. Among federal agencies, the expertise for etiologic research into human health effects is located within HHS generally. More specifically, federal scientific expertise addressing occupational and environmental health effects from chronic exposure to low-level radiation, beryllium, and other important exposures on DOE sites has been developed within HHS. Finally, while the committee believes that improved communication between agencies requires greater involvement of DOE in the scientific process, it does not believe that this should entail a return to DOE sole oversight. Public confidence that the health consequences of prior DOE activity will be adequately investigated requires greater independence than would be perceived to be the case with sole DOE oversight. Furthermore, there appears to be no justification for the disruption and added cost that dismantling an established research operation and rebuilding it elsewhere would entail.

After reviewing how to improve the program of the past 15 years, the committee concludes that the preferred arrangement for the continuing worker and public health program at DOE sites is for DOE to maintain a relationship with HHS for this purpose. HHS provides both the expertise and the independence that DOE requires. However, if it is to continue, this relationship needs to be restructured to solve the problems that have appeared over the past decade and a half. The committee concludes that this program should report to the Assistant Secretary level in HHS and the equivalent level in DOE, and it should be a truly collaborative relationship. Both agencies should agree to the study agenda and both should be involved in overseeing the research—HHS overseeing the technical aspects, and DOE ensuring that the work is being conducted according to budget and schedule, that there is rapid and effective feedback of the information being obtained to facility managers as well as the research program, and that there is effective communication with the populations potentially at risk.

Findings

Much of the tension reflected in the DOE Worker and Public Health Activities Program has been present since its outset, which grew out of deep public concern about the legacy of nuclear waste and other environmental contaminants resulting from secret activities that occurred in the tense climate of the Cold War. Beginning in the mid-1980s, congressional hearings, lawsuits, and the DOE In-

spector General raised concerns about aspects of DOE and predecessor agencies' ability to transparently assess the adverse health impacts of those activities on both workers and community members. As described earlier, the transfer of epidemiological research for domestic (but not foreign) outcomes reflected a vote of "no confidence" in DOE scientific capability and integrity.

1. *Science got done; questions got answered.* The scientific program produced studies that addressed many of the questions and concerns regarding worker, community, and environmental health and safety at the DOE facilities. The studies not only contributed to better understanding of conditions at DOE sites, but also contributed to improved scientific understanding of these risks internationally.

2. *Credibility was improved.* The credibility of the Worker Health program among the affected workers and the public appears to have been improved in the early years after implementation of the MOU, although some dissatisfaction with the HHS agencies appears to have developed over time and within some segments of the affected population.

3. *There was some impact on policy.* Although difficult to quantify, there are a number of examples of how the research and analyses conducted under the MOU have influenced DOE decisions and policy. Although many of these influences may have affected decisions at only a single facility the epidemiological studies and dose reconstruction work have much broader ramifications, and add to a knowledge base that has the potential to contribute to international standards and risk analysis procedures.

4. *Further work is needed.* The MOU approach for carrying out the worker and public health programs for DOE through HHS partly solved the problems that were building during the time period prior to 1990 in which DOE managed the program internally. Both the quality of the research and the scope of the communication activities conducted by HHS addressed important ongoing DOE needs. Specifically, scientific knowledge that addressed occupational and environmental health effects from chronic exposure to low level radiation, beryllium and other hazardous exposures on DOE sites was developed by the HHS program. Dissemination of these results was extensive. However, the committee found that there were significant opportunities for improvement, as identified in the individual areas of science, communication and management. Scientifically, there are several study areas that have been specifically identified which need to be addressed as well as identifying new areas of health studies based on the continuing remediation and cleanup work that DOE is carrying out. Overall, the committee concludes that improved communication between agencies requires a greater involvement of DOE in establishing and managing the priorities in these studies. However, the committee does not believe that the program should revert to sole management by DOE. Public confidence that the health consequences of DOE activity will be adequately investigated requires this to be done by an

independent department such as HHS. Since the MOU approach has worked partially, it seems reasonable to improve it along the lines recommended by this committee, as opposed to starting with a totally difference arrangement which might be disruptive, costly, and not necessarily an improvement.

Although a substantial body of work has accumulated, important work remains. Scientific questions that should be explored through analytic epidemiological studies that include the worker and community populations are outlined in the Chapter 2 recommendations. The committee concludes that a health program is needed at DOE sites as long as exposures to ionizing radiation and radioactive materials from hazardous operations (including cleanup and remediation) continue at these sites. Studies in progress should be completed and follow-up of exposed workers should continue.

5. *DOE retains the responsibility for protecting worker, community, and environmental health*, given that many of these sites remain active and there remain substantial legacy issues at all of the sites.

6. *The process for managing the program can be improved.* Although the process established by DOE and HHS may have been appropriate initially, many of the management problems identified by earlier NRC reviews remain, and the management and collaboration process could clearly be improved.

FINDINGS AND RECOMMENDATIONS

1. Review of key scientific studies conducted to date is presented in Chapters 2-4. The Committee finds that there remains critical information to be gathered and assessed. A health program is needed at DOE sites as long as hazardous operations (including cleanup and remediation) continue at these sites. To that end, a mechanism needs to exist for the purpose of developing the research agenda, providing funding for the research, soliciting input into the design, conduct and review of such studies and communication of the results to relevant stakeholders, with clear articulation of the roles and responsibilities of the various parties. In the past, the MOUs between DOE and HHS have served as this vehicle, and could do so in the future. Therefore, the Committee recommends that:

> DOE and HHS should sign and implement a new MOU enabling continued work on the Worker and Public Health Activities Program. This MOU should document the responsibilities of DOE and HHS as well as provide the framework for managing the process for interaction and collaboration between DOE and HHS. In addition to incorporating the recommendations made here with respect to managing the program, the new MOU should incorporate the recommendations presented elsewhere in this report.

2. As noted earlier, one of the biggest problems affecting the program has been the difficulty researchers have had in obtaining exposure and other relevant

data to use in their epidemiological studies. The fundamental problem was that the worker exposure data had never been collected, processed, or stored with any regard to the possibility that they might be needed in the future for such studies. This situation leads to difficulty in comparing health outcomes with exposure characteristics and in the investigators' ability to combine information from more than one source in order to increase the power of the studies. As a remedy to this, the committee recommends that:

> DOE support the development and integration of a repository for exposure records. The committee recommends that all contractor-assembled data be submitted to DOE's Office of Environment, Safety and Health for compilation, management, and storage in centralized databases, using standardized formats. DOE should consider developing a process that captures current exposure data as well as health outcome data, including external radiation exposure, internal radiation exposure, chemical exposure, medical surveillance (e.g., spirometry, liver function tests, smoker-never smoker), biologic monitoring, and social security number and demographic information (e.g., gender, birth date) on a continual basis for DOE employees, contractors, and subcontractors, for placement in a secure centralized repository. The database would have to be integrated with existing data repositories (e.g., Radiation Exposure Monitoring Systems, Comprehensive Epidemiologic Data Resource [CEDR]). However, unlike CEDR, which facilitates public access to data collected for studies regarding the health impacts associated with working at or living near DOE operations, information compiled in the recommended repository would be available to NIOSH's scientific investigators or researchers funded extramurally through NIOSH to perform DOE-related health studies. Such a database would be of paramount importance for expanding existing cohort studies or performing nested case-control studies.

3. The quality and integrity of any research program is improved if it is subjected to expert scientific review during its development stage, as the studies in the research agenda are being conducted, and after the results have been gathered by the investigators. In the past, HHS did convene an advisory committee whose mission included the provision of advice and comment (only) to HHS on the OERP. This committee (ACERER) did not have authority to formally communicate its findings to DOE. This circumstance, along with others, resulted in a sense of disenfranchisement on the part of DOE, and only sporadic interest on the part of DOE senior management in the outcomes of the HHS investigations. As a measure of improvement in the future, the Committee recommends that:

> A single advisory committee, with a charter issued jointly by DOE and HHS, should be established to review and comment on the research program. Management of the program would be made more efficient if the advisory committee charged with reviewing and providing recommendations on the ele-

ments of the research program could report directly to all of the agencies charged with its development, funding, implementation, and translation of results into policies and practices.

4. In the federal government, the success of a program, particularly a scientific research program, is dependent upon the level of attention and oversight given by senior management. At the beginning, as the research program was being transferred from DOE to HHS, the Secretaries of each agency were involved. However, over time, management and oversight responsibilities drifted downward through the chain of command until they became virtually invisible to the most senior levels. The committee therefore recommends that:

DOE and HHS should reestablish and maintain oversight and coordination of the program at the Assistant Secretary level.[8] Communication and coordination at a senior level within an organization enhances the probability of success of any program initiative. In this instance, attention given to the program at this level provides greater support to the participating agencies in achieving their mission to protect worker and public health and the environment.

5. It is important that both HHS and DOE understand the human and environmental health impacts of activities conducted on DOE sites which may affect both workers and communities. While the Committee supports the concept that HHS currently has, and should continue to have, the lead on developing and carrying out the research agenda, it also believes that DOE has a stake in its success and therefore, should participate more substantively in the updating of the research agenda as work goes forward. Therefore, the committee recommends that:

DOE and the relevant HHS agencies should collaborate to update the research agenda annually. It is critical that the resources committed to funding the worker and public health research program be spent in the most efficient manner, yielding the most useful information to understand the potential health and environmental impacts of activities at DOE facilities. Both HHS and DOE can provide important perspectives, based on their extensive experiences in this realm. These collective experiences, along with those contrib-

[8]The committee developed and unanimously approved this recommendation prior to a recent reorganization within DOE that merged existing safety and health functions into another unit. Because we believe that occupational and environmental health issues remain critically important to DOE workers and surrounding communities, and because we believe that senior level management engagement is a pre-requisite for effective safety and health program management, the committee recommends that DOE and HHS should establish and maintain oversight and coordination of the program at the Assistant Secretary level in HHS and the equivalent level in DOE.

uted by technical experts on the external advisory committee, should result in a more relevant, scientifically sound research program.

6. During the 15 years that HHS has had the lead for the research program, communication between HHS and DOE has been spotty at its best, and nonproductive at its worst. This does not serve either the government agencies or the worker and community populations at or around the DOE sites very well, and can lead to mistrust. As the research program goes forward, it is imperative that this situation be remedied. To that end, the committee recommends that:

DOE and HHS should establish functional feedback mechanisms to each other for all aspects of the research program. To ensure the greatest level of success for any program of research, a robust program of communication and dissemination about the design and execution of, and results from, a research program should establish linkages not only between the program's executors and the affected populations, but also between those charged with developing and executing the program. This ensures the probability that the program will be robust, yield useful results, and will be of value in enhancing the scientific basis of our understanding of the potential health and environmental risks associated with DOE facility activities. It also enhances the respective agencies' credibility and accountability in meeting their governmental responsibilities.

ANNEX 6A ANNEX TABLES

TABLE 6A-1 ACERER Recommendations or Action Items Directed to NIOSH, NCEH, and ATSDR

Meeting Dates	Recommendations or Action Items	Comments
January 1993	Endorsed NIOSH initial listing of research priorities, in principle Voted to require NCEH, NIOSH, and ATSDR to report annually regarding access to DOE data and personnel, regarding obtaining information pertinent to health and epidemiological research activities. In particular, the report should address problems and limits to access existing information, as well as to collection of descriptive information for future epidemiological and health studies	Committee felt it did not have sufficient information to comment on specifics of priority rankings
April 1993	Endorsed concepts presented in NCEH's workplan in areas of environmental dosimetry and dose reconstruction, environmental epidemiology, and risk estimation	Committee expressed some concern about proposed laboratory studies and asked for further information on them (no detailed background information on elements of the workplan attached as appendix to minutes or transcripts of this meeting)
December 1993	Electronic data should be placed into CEDR; storage for hard copies of these data should be sought at Washington State University, pending assurances that it has the facilities to keep them properly Committee endorsed NIOSH's list of potential radiation issues and future workshop topics, leaving their prioritization to NIOSH: 1. The energy and geometry of radiation exposures, particularly to organs, as factors in bias and uncertainty of dose estimates 2. Problems with data collection, abstraction, computerization, and prioritization issues: how these should best be addressed to gather appropriate information for epidemiological studies	Committee added further topics for consideration: 1. Workshop to identify fruitful interactions, if any, between exposures to ionizing radiation and other hazards such as non-ionizing radiation or chemical exposures, addressing issues such as synergism and antagonism 2. Workshop (with NCEH) on estimates of uncertain doses (particularly internal) and how these are factored into epidemiological study feasibility. Assess the actual utility of "reference man"

	3. Calculation of uncertainties associated with internal radiation estimation and its use in epidemiology studies Recommended that CDC and other agencies establish training monies for this field Committee endorsed research recommended by NIOSH, with the exception of adding a caution to move slowly regarding biomarkers Committee endorsed the recommendations (relating to community involvement plans) in the memo to Dr. Satcher ("That the Director, CDC, and Administrator, ATSDR, approve ATSDR's and CDC's approach to implement the program which includes both Community Approach #1, community forums for individual advice and Community Approach #2, Federal advisory committees chartered under the FACA")	3. Address core data and their storage, as well as compatibility and use across sites of new data 4. For uniform data, apply those solutions found for dose reconstruction problems to epidemiological studies of personnel exposure; add a focus on estimating uncertainties
April 1994	Committee moved to write a letter to Dr. Satcher (HHS) to be forwarded to Dr. O'Toole (DOE) that recognizes the attention and work devoted to the issue of DOE site access and the fact that progress has been made; however, problems are continuing. Structural change is needed to definitively resolve these issues, independent of agency personnel at any given time. This work should be carried out under OSHA (Occupational Safety and Health Administration) regulations	
July 1994	Scope of advisory committee: "The advisory committee will solicit information necessary to its development of an appropriate research agenda, and make its recommendations to the Secretary of HHS and that these recommendations are	The three motions for these changes passed unanimously:

continued

TABLE 6A-1 Coninued

Meeting Dates	Recommendations or Action Items	Comments
	shared with the Secretary of DOE on all health research issues associated with DOE operations: 1) "Epidemiological research and exposure assessment of workers at federal nuclear facilities and the collection of surveillance monitoring data for epidemiological purposes. 2) . . .(relating to community health studies). . . 3) The committee shall encourage the continued involvement of workers and communities in the planning, conduct, and discussion of such research. In addition, where related to the scope of the committee's work as defined above, the committee may request and consider information provided by the HHS agencies on matters such as studies of health service needs and resources for communities affected by DOE operations, public health consultations and assessments, and studies on chemical, biological or physical agents that may have public health significance."	• Removed language in scope definition that had ACERER reporting to Secretaries of both HHS and DOE • Included language that recommendations to the Secretary of HHS are shared with the Secretary of DOE • Inclusion of an exposure assessment element for worker studies, providing parallel activities with community health studies (which included an assessment of exposure)
	Research addressed by the committee: Drop the "analytic" delineation from the type of epidemiology addressed by the committee	Committee unanimously agreed to this change due to the difficulty in distinguishing between analytic and descriptive epidemiology
October 1994	Creation of a cleanup worker registry including a tracking mechanism, by whatever mechanism deemed appropriate (identification card, etc.). The ACERER chair requested implementation of this recommendation by no later than the second meeting from this one (April 1996 would be the second meeting)	Committee unanimously approved this motion. The ACERER chair, when questioned as to whom the motion to establish a registry was directed—NIOSH or HHS—clarified that the committee advises HHS .The committee would let the agencies determine the best way to implement the recommendation. Dr. Seligman

	Recommend that HHS recommend to DOE that Regulations 85/85A be incorporated into any new DOE contracts	of DOE summarized committee's intent as a call to address how to track and support workers, possibly through a surveillance program
	Committee vote on NIOSH Research agenda: 1. Beryllium worker exposure follow-up—High priority 2. Job stresses: Medium 3. Exposure assessment of nuclear waste and cleanup workers: High 4. Epidemiology of non-fatal injuries and ergonomic disorders in DOE facilities: Low 5. Predictors of elevated exposure to EMF (electromagnetic fields): High as a confounder 6. Adverse reproductive outcomes of male workers: High 7. Previously studied cohorts: High 8. Case-control study of multiple myeloma at K-25: High 9. Pantex and Nevada Test Site: Deferred until NIOSH site visit is done 10. Feasibility of cohort mortality study of DOE chemical laboratory workers: High, if determined to be feasible 11. Workshop on radiation issues: High	Committee unanimously approved motion and sought to provide a mechanism to address access issues that NIOSH encountered in obtaining records, data, and cooperation from DOE sites and contractors to initiate and conduct studies
	Committee vote on NCEH research plan: 1. Environmental dose reconstruction projects: All ranked high priority 2. Epidemiological research projects: All ranked high 3. Risk estimation: All ranked high 4. Interdisciplinary activities: All ranked high 5. Technical support activities: High 6. Public involvement in environmental health research: Ranking deferred	
August 1995	Committee voted that a subcommittee be established to facilitate community input to the ACERER agenda and recommended the addition of at least two community members to ACERER	

continued

TABLE 6A-1 Coninued

Meeting Dates	Recommendations or Action Items	Comments
	Recommended that the Secretary of HHS request that funding provisions be presented as a line item in the President's budget request for federal health activities, and no longer appear in the MOU between the two agencies, in order to enhance the viability and stability of the HHES energy-related epidemiological program	
	The committee recommended the DOE consider pilot studies to increase utilization of the CEDR database	
	The committee strongly supported a national registry for cleanup workers involved in DOE nuclear weapons production and testing and at other relevant sites, established by HHS at the earliest possible date and assigned the highest priority, with the necessary administrative and budgetary steps initiated	
April 1996	CDC should work with DOE-EH and NCI to seek collaboration on all national and international activities in which results of research may complement informative needs of CDC for sites at which dose reconstruction is ongoing or planned. Activities of particular interest would be: (issues 1 and 2 dealt with non-occupational exposures) and 3. Dose reconstructions of inhalation or ingestion of plutonium, strontium, and ^{131}I at the Techa River, Chelyabinsk, and Mayak facility in Russia	Committee discussed research activities supported by DOE outside of the MOU within the U.S. (Center for Risk Evaluation and Stakeholder Participation [CRESP]) and international studies
	Committee voted to adopt an additional paragraph to the ACERER working group guidelines to invite more community participation in order to extensively address community education	
July 1997	"The HHS Advisory Committee on Energy-Related Epidemiological Research shall request that the Secretary of HHS ask the Secretary of DOE to provide a	

	mechanism to ensure that DOE contractors adopt and follow NIOSH procedures for research as contained in CFR 42, 85 and 85A" Committee approved the NCEH research proposals for FY 1998-1999: 1. Dose reconstruction studies • Hanford, Savannah River, and INL (continuations) • Marshall Islands (new) • Los Alamos (under consideration) 2. Follow-up on HTDS cohort 3. Methodological issues development (continuation) 4. Post-Chernobyl study of thyroid cancer epidemic 5. Other micronutrient deficiency issues in Russia 6. Review of coast-to-coast data set of NCI Utah fallout study Committee requested the Secretary of HHS to work with the Secretary of DOE to establish a formal link between ACERER and the DOE at the secretarial level, and that this linkage be reflected in the ACERER charter and the MOU between the two departments	
December 1997	A proposal to include in ACERER's purview DOE activities in the areas of health research, worker monitoring, etc. Move sought to amend a sentence in the draft charter to read: "ACERER will provide advice to the Secretary of HHS to assure appropriate interaction between ACERER and DOE regarding the direction HHS should take in establishing the research agenda, developing the research plan, and for effectively resolving issues concerning the respective roles of DOE and HHS in commissioning and managing health-related activities"	Committee unanimously approved this motion
September 1998	Developed set of recommendations for HHS concerning its research into the occupational and public health consequences of nuclear weapons production and testing activities (the Nevada Test Site [NTS] fallout study):	

continued

TABLE 6A-1 Coninued

Meeting Dates	Recommendations or Action Items	Comments
	1. Fulfill the legislative intent of Public Law 97-414 2. Complete a comprehensive dose reconstruction project for NTS fallout 3. Notify Americans of the factors that might help them to determine whether they received significant radiation doses from NTS fallout 4. Create a public health care provider information service on NTS exposures and resulting public health concerns 5. Support archival projects to document experiences of exposed peoples 6. Further evaluate screening opportunities for thyroid cancer	
December 1999	*Action item:* NIOSH Research/Worker Right to Know Policy: That NIOSH work with ACERER in developing a 'worker right to know' policy regarding the potential health risks associated with occupational exposure to workplace contaminants. Policy should be extended to conditions in which epidemiological studies either are not feasible or are likely to be inconclusive. Efforts to communicate with the worker community should commence at the earliest opportunity. The exposed employee should be made aware of the range of uncertainty associatedwith the individual and cohort risk estimates	Response to ACERER request for information on processes that NIOSH uses to inform workers of study results. Previous ACERER discussionsalso sought information on how NIOSH obtains worker input on its studies and for its research agenda

SOURCE: Adapted/assembled from Table A-1 of the NIOSH evidence package and ACERER meeting minutes/transcripts that were included on the CD-ROM accompanying the evidence package (NIOSH 2005).

TABLE 6A-2 Consensus Advice and Recommendations from Hanford Health Effects Subcommittee (HHES)

Advice to NIOSH	Advice to NCEH	Advice to ATSDR	Nonspecific Advice
Strengthen ties to NIOSH; requested that NIOSH provide study schedules and protocols to Studies Work Group (9/96)	Assess potential health impacts of agricultural and industrial pollution on Columbia River basin (5/96)	Pursue additional work on 1-131 Subregistry (3/95)	Add African-American representative to HHES (9/94)
Request that NIOSH do fullest possible health hazard investigation of 5/97 Plutonium Finishing Plant explosion and send letter to DOE requesting full support for this investigation (10/97)	CDC should catalogue data from the HEDR (9/96)	Consider linking MMP and I-131 Subregistry (3/95)	Use Gonzaga University as HHES repository (3/95)
Recommend specific HHES members to serve as reviewers for NIOSH Construction Worker Mortality Study (4/98)	CDC should compile Columbia River use profile (9/96)	Assign lesser priority to analysis of cancer mortality (3/95)	Completed outreach package (7/95)
	CDC should plan for resources to carry out tasks to complete Columbia River review (2/97)	Assign lesser priority to review of Hanford area school children survey (3/95)	Offered advice on membership recommendation procedures (9/95)
	CDC should direct contractor resources to carry out tasks necessary to complete Columbia River review (2/97)	Proceed with Phase II of MMP evaluation (3/95)	Fill Oregon downwinder seat from existing pool of nominees (12/95)
	Individual Dose Assessment Project (IDA) and MMP should coordinate use of dose units (2/97)	Develop draft protocol for Birth Outcomes study using HHES input (5/95)	Preserve public comments verbatim (2/96)
	Recommend several changes in Columbia River dose pathway work (e.g., additions re individual exposure estimate input parameters) (7/97)	Suggest changes to protocol for Birth Outcomes study (7/95)	Provide legal opinion re conflict of interest (5/96)
		Proceed with next phase of MMP evaluation and developing I-131 Subregistry (12/95)	Fill vacant labor seat on HHES (7/96)
			Consider continuity of knowledge and experience when reappointing members to HHES (7/96)

continued

TABLE 6A-2 Continued

Advice to NIOSH	Advice to NCEH	Advice to ATSDR	Nonspecific Advice
	All IDA dose estimates and individual information should be retained with maximum confidentiality (7/97)	Approved study protocol for Birth Outcomes Study (12/95)	Add two to three seats for expertise in toxicology, health care practitioner, and medical sociology (7/96)
	Proceed with Plutonium Finishing Plant for Columbia River pathway work (4/98)	Cohort for I-131 Subregistry proposed and another, older cohort identified (2/96)	Recommend more agency representation at workgroup meetings (9/96)
	Request that HHES and Inter-Tribal Council on Hanford Health Projects (ICHHP) be briefed prior to HTDS press release (12/98)	Proceed with Birth Outcomes Study (2/96)	CDC should inform HHES in advance if CDC representative cannot attend meeting (2/97)
	Request that CDC pursue funding to support HHES inclusion as participants or observers in NRC review of HTDS (12/98)	Consensus that HHES cannot currently recommend biomarker use in future studies (2/96)	Add vision statement to HHES fact sheet
	HHES to send letter to NCEH and DOE urging funding of IDA project at least through end of FY 2000 (12/98)	Add autoimmune diseases to MMP questionnaire (2/96)	Make meeting minutes of other HESs available (2/97)
	HHES to send letter to NRC stating that comments re HTDS will be	Review potential conflict of interest of thyroid expert on medical monitoring panel (5/96)	Send material to HHES via regular surface mail (5/97)
		Advised on MMP eligibility criteria (7/96)	Requested budget and expenditure information from ATSDR re HHES, studies, and DOE (7/97)
		Include Native Americans in MMP (9/96)	

forthcoming, urge addition of outside thyroid expertise to panel, and to holding public meeting in Northwest (2/99)

Recommend immediate issuance of press release to emphasize that HTDS results were still draft form (2/99)

HHES to send letter to CDC re support of continued funding of IDA activities past March 2000 deadline (11/99)

Recommend that CDC, NCEH, and ATSDR continue efforts to determine methods and needs for development of combined-dose approach to evaluate doses of I-131 from weapons test fallout and Hanford exposures (11/99)

Work with Washington State to maintain all IDA data, including individual identifiers for future use (5/00)

Define more completely the appeal process for inclusion in MMP (9/96)

ATSDR should determine use of medical monitoring data (9/96)

Use IDA estimates for reevaluation of Columbia River pathway for medical monitoring (9/96)

HHES endorses proposed MMP for thyroid neoplasms and other thyroid and parathyroid conditions (12/96)

Begin MMP as soon as possible (12/96)

Consider other contaminants and exposure pathways for MMP as data become available (12/96)

Do not wait for HTDS results for MMP (12/96)

Ad hoc work group to work with Dr. Spengler re MMP press conference (2/97)

HHES to cosponsor Health of the Hanford Site conference (2/97)

Recommend that chair of HHES compile action list and distribute within 2 weeks (7/97)

Send recommendations to agencies in writing (7/97)

Create historical advice tracking form (7/97)

Send follow-up letters to agencies re open action items (10/97) and letters marked “second request” if no response received (1/98)

Send letter to Division of Financial Operations re funding to support communication with other HESs (10/97)

Ad hoc group to develop packet for new members (10/97)

Notify members of change in meeting dates a minimum of 2 months in advance (10/97)

HHES believes membership is no longer balanced, recommends reviewing candidate pool and

continued

TABLE 6A-2 Continued

Advice to NIOSH	Advice to NCEH	Advice to ATSDR	Nonspecific Advice
			advising on adjusting membership (1/98)
		Break down DOE budget re HHES and MMP and subregistry budget by line item (5/97)	HHES would like to work with ATSDR in the future in refining and improving membership recruiting process (1/98)
		Write and send letter to CDC Director re HHES dismay over no press conference (5/97)	ATSDR should encourage former members to attend 4/98 meeting and pay expenses (1/98)
		Ad hoc group within Public Health Assessment Work Group to work with ATSDR on outreach for I-131 Subregistry (10/97)	Include 2- to 3-hour blocks of time on agenda for workgroups (4/98)
		Form new work group for PHAs (4/98)	Letter to be sent to DOE-RL requesting staff be designated to tri-cities HHES meetings to ensure consistent contact (4/98)
		Send letter of support to project administratorfor continuing HHIN (4/98)	Consider adding seats for expertise in risk communication and human chemical toxicology (4/98)
		Send letter to DOE HQ expressing support for funding HHIN through FY 1999 and urging discussions on how to replicate or continue beyond that date (12/98)	

Rank the following as funding priorities: tribal cooperative agreements, MMP, I-131 Subregistry, HHES/CHHP, and PHAs (12/98)	Recommend ad hoc group interview member candidates (4/98)
Request that $7 million from DOE-EM currently unallocated be reserved for ATSDR (12/98)	Recommended changes to memo regarding membership solicitation and recruitment (12/98)
Endorsement of revised MMP (2/99)	Begin with fresh pool of applicants for next membership selection round (12/98)
Specific plans re including tribes as MMP proceeds should be developed and incorporated in MMP documents (2/99)	Revise HHES fact sheet (2/99)
Establish MMP advisory board as soon as possible (2/99)	Do not schedule outreach and PHA work groups in same time slot (2/99)
HHES to send letter to Dr. Falk urging ATSDR to request that DOE fund I-131 Subregistry for implementation phase (11/99)	HHES shall not participate in national HES evaluation processes currently under way (2/99)
Proceed with pre-proposal for I-131 Subregistry (2/00)	Add Idaho, Japanese American, social science-psychology, environmental group, toxicology, and economics representation to HHES (5/99)
Begin conversation with Dr. Michaels re screening and health effects issues for highest-risk exposures of	

continued

TABLE 6A-2 Continued

Advice to NIOSH	Advice to NCEH	Advice to ATSDR	Nonspecific Advice
		community members around Hanford (5/00)	Outreach work group to continue development of HHES web site (7/99)
		Develop protocol for HHES review to include detailed evaluation of prevalence of immune disorders and cardiovascular disease (5/00)	Participate in internal evaluation of HHES (11/99)
			HHES to continue to participate in development of national HES evaluation (7/99)
			Support continuing participation in development of national evaluation reserving consideration of site-specific evaluation (11/99)
			HHES supports development and maintenance of HHES web page and its reflection of diversity of opinions regarding exposure and health effects of exposure (2/00)
			HHES to write letter to DOE suggesting HHIN be used for outreach and education efforts for Hanford workers (2/00)

SOURCE: Adapted from COSMOS (2001a, 2001b).

TABLE 6A-3 Consensus Advice and Recommendations from the Oak Ridge Health Effects Committee November 2000-September 2005[a]

Advice to CDC and ATSDR	Other Advice Including Advice on Administrative Issues
Geographic scope for health effects studies should include Anderson, Knox, Roane, Loudon, Meigs, Rhea, and Morgan counties and the City of Oak Ridge (1/01)	ATSDR should upgrade the field office's resources available for use by the Oak Ridge Reservation (ORR) HES and the public in a timely manner (3/01)
At least 7-11 PHA Workgroup members should participate in pilot test with George Washington University (GWU) to determine appropriateness of survey questions for the needs assessment (3/01)	A collective biography of the subcommittee should be developed to challenge comments about the need for the representation of an ill worker on the subcommittee without requiring anyone to self-identify (6/01)
Developed four categories (health care providers and health researchers, community organization, health officials, and others) as key resources of information for GWU as it conducts the needs assessment (3/01)	Nomination process for subcommittee membership should be opened, with preference given to a sick resident (6/01)
Recommended focus group categories for the needs assessment (4/01)	Proposed to add a (non-voting) EPA representative to the subcommittee (9/01)
Approved written description of the demographic map of phone survey area for the needs assessment (4/01)	Subcommittee meetings should be scheduled as one, full-day meeting every 6 weeks. ATSDR should consider rotating the meeting sites, at its discretion (12/01)
ATSDR and GWU-Hahneman should provide information necessary to form a program of work and a milestone chart for the public health needs project, similar in content to those for the PHA (6/01)	Adopted guidance document entitled "Suggestions for Facilitating ORRHES shall have four workgroups: Guidelines and Procedures; Communications and Outreach; Health Needs Assessment; and Public Health Assessment (12/01)
ATSDR should create an article for local media on the screening process. This article should include information about declassified chemicals used for dose reconstruction and information about the ORRHES accomplishments and changes in subcommittee processes (12/01)	Letter to Dr. Falk (ATSDR assistant administrator) requesting provision of administrative support in the Oak Ridge field office to improve efficiency (12/01)

continued

TABLE 6A-3 Continued

Advice to CDC and ATSDR	Other Advice Including Advice on Administrative Issues
The Mangano paper should not be used as a basis for the ORR Public Health Assessment (12/01)	
Letter to Dr. Koplan (ATSDR administrator) requesting that ORRHES have input into the process of sampling environmental media in the Oak Ridge area and that the process be better developed and explained to the public (12/01)	Motion offered, then withdrawn to add (non-voting) DOE representative to the subcommittee (12/01)
ATSDR should move ahead with a database that captures community concerns and issues and has links to the resolutions associated with them (12/01)	ATSDR should open up new position on subcommittee to replace the physician member (3/02)
ATSDR should look at the feasibility of reviewing Oak Ridge Health Agreement Steering Panel minutes to capture historical concerns of the Oak Ridge community (12/01)	Adopted guidance document entitleled "Suggestions for Facilitating Effective Work Group Meetings" (8/02)
ORRHES endorsed the ATSDR screening process for determining contaminants of concern for the exposure periods 1944-1990 and 1991-2001 (2/02)	Sent two documents ("Target Characteristics for Facilitator Candidates" and "What is a Group Facilitator?") to ATSDR for its consideration of facilitation skills as one factor in hiring a person for the Oak Ridge Field Office (8/02)
ATSDR should develop a detailed project management plan by the next ORRHES meeting that: • Shows all the tasks within the various divisions and branches of ATSDR • Outlines how those efforts will come together to support the PHA • Designates who will be delegated to manage the effort and how the authority to manage will be provided across divisions • Shows the anticipated schedule and budget • Explains how ATSDR will manage around the "yo-yo" funding (3/02)	ORRHES letter to DOE-Oak Ridge Operation Office manager requesting DOE's continued commitment to support involvement of the DOE liaison to the subcommittee (3/03)

The ATSDR should work with ORRHES to

1. Develop a complete list of work groups, work group activities, and other public health activities, (including meetings) that are considered essential to achieve the goals and mission of the ORRHES as outlined in the project plan
2. Prioritize all significant activities in a top-down ranking according to the contribution and value to ATSDR in meeting the mission of the ORRHES
3. Relate available and anticipated funding according to the top-down ranking
4. Identify shortfalls in funding and relate this to the top-down ranking
5. Identify mission components that cannot be funded
6. Identify the impact on mission success (3/02)

If ATSDR determines that there is unavoidable delay in completion of the I-131 evaluation, the evaluation of one or more other contaminants of concern should be expedited and presented before the I-131 Public Health Assessment (10/02)

ATSDR, in collaboration with ORRHES, should develop a briefing book to be provided to the 44 media and key community groups, and should provide periodic updates to the briefing book (3/03)

ATSDR, in collaboration with ORRHES, should develop a semiannual newsletter for program 15 overview and updates (3/03)

ATSDR, in collaboration with ORRHES, should develop an issue-based, cross-referenced index of key issues, based on the various agenda from meetings, to be placed on the web site (3/03)

ATSDR should prepare verbatim transcripts of meetings, given that minutes of ORRHES meetings frequently leave out important comments of subcommittee members (2/04)

continued

TABLE 6A-3 Continued

Advice to CDC and ATSDR	Other Advice Including Advice on Administrative Issues
ATSDR should place a summary of the project plan on the web site and place the PHA process flow sheet for assessment if contaminants of concern, depicting ATSDR and ORRHES work group interactions, on the web site (3/03) ATSDR, in collaboration with ORRHES, should make presentations on each contaminant of concern as necessary (3/03) ORRHES provided comments to ATSDR on its draft ATSDR Public Health Assessment for Y-12 uranium releases (3/03) ORRHES provided comments on the Division of Health Education and Promotion-ATSDR report entitled "Assessing the Health Education Needs of Residents in the Area of Oak Ridge Reservation, Tennessee—Final Report, May 23, 2003" (8/03) Recommendations from that review included the following: The report should not be used as the basis for any future public health education program to be conducted in the ORR Future ATSDR-Public Health Education Program activities related to the PHA should be based on the findings of the public health assessment program which should, with the advice of ORRHES, ascertain the following: 1. The degree to which releases of contaminants from DOE sites contributed to regional public health problems 2. The degree to which there is a need for additional public health educational services	

3. The degree to which the existing public health and medical services establishment can supply any substantive unmet public health education needs in both rural and urban areas
4. The degree to which ATSDR might meet any additional needs by augmenting the current system with printed material or presentations by experts. Not to do this will very probably result in the duplication of much effort as well as be an affront to the existing health care system
5. The degree to which any necessary educational effort can avoid the onus of distrust that has cursed all previous efforts

ATSDR should examine the project's structural and management components, which enabled the report and project to reach this state without ATSDR overview and without subcommittee or working group review that could have remedied its shortcomings

ATSDR should adopt the proposed plan for collecting information about the ORR community suggested timeline that is outlined as a process to fill the gaps that were left after the GWU study (2/04)

ATSDR should develop a comprehensive communication-education plan for disseminating key information (e.g., videos, fact sheets, briefing papers, presentations), in accordance with the process flow sheet for producing the PHAs. This effort should start at the beginning of the PHA process. The PHA should address the concerns, health data, and environmental exposures. The tools should be crafted to the needs of individual communities. ATSDR should revitalize the needs assessment effort by pulling together neighborhood groups to identify specific issues and concerns, and ATSDR should return with feedback to those same neighborhood contacts in an accelerated manner (2/04)

continued

TABLE 6A-3 Continued

Advice to CDC and ATSDR	Other Advice Including Advice on Administrative Issues
The final Y-12 uranium releases PHA should be released in the ORR area, in the presence of both the public and the media. The presentation should include an official explanation regarding the differences between ATSDR and EPA methodologies in determining risk versus dose, even though both reached the same conclusion (2/04)	
ATSDR should have a community strategy in place prior to the release of the health statistics review results (4/04)	
ATSDR's cancer incidence review's strategy and data should be reviewed by ORRHES prior to its release to the public (4/04)	
ORRHES to hold a public forum on the Monday prior to the June ORRHES meeting to discuss EPA issues. EPA Region IV, members of Office of Radiation and Indoor Air, ATSDR, and members of the public will be in attendance. This meeting will not be a full ORRHES meeting, and ORRHES members may attend by choice. It was recommended that a court reporter be present to take verbatim minutes of the public meeting (4/04)	
ORRHES to provide comments on TASDR draft TSCA incinerator PHA (3/05)	
The cancer incidence review report should include an analysis of each of the eight counties individually; a modified census tract analysis that will include all of Meigs County, all of Rhea County, and all of Morgan County, but will exclude Blount County. Otherwise, remaining counties stay as they are in the census tract (6/05)	

ATSDR should conduct a cancer incidence analysis by plume if data indicate that it can be done (6/05)

ORRHES to comment on ATSDR draft groundwater PHA (6/05)

ORRHES to comment on draft summary documents for two PHAs: White Oak Creek and the modified TSCA incinerator (6/05)

ATSDR ahould address and respond to the ORRHES comments on the PHA for ORR White Oak Creek radionuclide releases (6/05)

ORRHES will provide comments on the draft PHA titled *Evaluation of Current (1990 to 2003) and Future Chemical Exposures in the Vicinity of the Oak Ridge Reservation* (9/05)

ATSDR should address and respond to ORRHES comments on the PHA for *Evaluation of Potential Exposures to Contaminated Off-site Groundwater from the Oak Ridge Reservation* (9/05)

ATSDR should prioritize the remaining chemicals (for which PHAs would be developed) in the following order: iodine, mercury, uranium from K-25, and polychlorinated biphenyls (9/05)

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[a]Adapted from Table A-1 and ACERER meeting minutes or transcripts (*http://www.atsdr.cdc.gov/HAC/oakridge/meet/orrhes.html;* last accessed 11/05/06).

REFERENCES

ACERER (Advisory Committee for Energy-Related Epidemiological Research). 1993. Minutes of the meeting held January 12 and 13, 1993, at the Centers for Disease Control and Prevention, Chamblee Facility, Building 101. Atlanta, GA: Centers for Disease Control and Prevention.

COSMOS. 2001a. Final Report for the Evaluation of the Health Effects Subcommittee Advisory Process, Vol. 1. Report submitted by COSMOS to Centers for Disease Control and Prevention. Contract No. 282-98-0027. Atlanta, GA: Centers for Disease Control and Prevention.

COSMOS. 2001b. Final Report for the Evaluation of the Health Effects Subcommittee Advisory Process, Vol. 2. Report submitted by COSMOS to Centers for Disease Control and Prevention. Contract No. 282-98-0027. Atlanta, GA: Centers for Disease Control and Prevention.

DOE/HHS (U.S. Department of Energy/U.S. Department of Health and Human Services). 1990. Memorandum of Understanding between U.S. Department of Energy and U.S. Department of Health and Human Services. Washington, DC: U.S. Department of Energy and U.S. Department of Health and Human Services.

DOE/HHS (U.S. Department of Energy/U.S. Department of Health and Human Services). 1996. Memorandum of Understanding between U.S. Department of Energy and U.S. Department of Health and Human Services. Washington, DC: U.S. Department of Energy and U.S. Department of Health and Human Services.

DOE/HHS (U.S. Department of Energy/U.S. Department of Health and Human Services). 2000. Memorandum of Understanding between U.S. Department of Energy and U.S. Department of Health and Human Services. Washington, DC: U.S. Department of Energy and U.S. Department of Health and Human Services.

NIOSH (National Institute for Occupational Safety and Health). 2005. The NIOSH Occupational Energy Research Program: Evidence for the National Academies' Review of the Worker and Public Health Activities Program Administered by the Department of Energy and the Department of Health and Human Services. Atlanta, GA: Centers for Disease Control and Prevention.

NRC (National Research Council). 1990. Providing Access to Epidemiological Data. Washington, DC: National Academy Press.

NRC (National Research Council). 1994. Epidemiological Research Programs at the Department of Energy: Looking to the Future. Washington, DC: National Academies Press.

NRC (National Research Council). 1999. Research on Power-Frequency Fields Completed Under the Energy Policy Act of 1992. Washington, DC: National Academy Press.

NRC (National Research Council). 2006. Health Risks from Exposure to Low Levels of Ionizing Radiation. BEIR VII Phase 2. Washington, DC: National Academy Press.

SPEERA (Secretarial Panel for the Evaluation of Epidemiological Research Activities for the Department of Energy). 1990. Report to the Secretary: Secretarial Panel for the Evaluation of Epidemiological Research Activities for the Department of Energy. Washington, DC: U.S. Department of Energy.

Ziemer, Paul. 2006. Personal communication. Presentation to the Committee to Review the Worker and Public Health Activities Program, Washington, DC. May 3.

Appendixes

A

1990 Memorandum of Understanding

MEMORANDUM OF UNDERSTANDING

BETWEEN
DEPARTMENT OF ENERGY
AND
DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. Background

The Secretary of Energy established an advisory committee to make recommendations on strengthening the Department of Energy's (DOE) epidemiologic research activities. This advisory committee--the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA)--recommended that DOE enter into a Memorandum of Understanding (MOU) with the Department of Health and Human Services (HHS) to manage and conduct analytic epidemiologic research (studies which test hypotheses). The Panel also recommended that DOE conduct descriptive epidemiologic studies, e.g., occupational health surveillance. The Secretary of Energy agreed with the Panel's recommendations and has requested that HHS enter into an MOU to implement them.

II. Purpose

This MOU sets forth the guidelines for coordination between DOE and HHS to carry out the recommendations of the SPEERA for the management and conduct of energy-related analytic epidemiologic health research by HHS.[1] This includes the authority, resources, and responsibility for the design, implementation, analysis, and scientific interpretation of analytic epidemiologic studies of the following populations: workers at DOE facilities; residents of communities in the vicinity of DOE facilities; other persons potentially exposed to radiation; and persons exposed to potential hazards resulting from non-nuclear energy production and use. This agreement is not meant to affect existing MOUs and Interagency Agreements (IA) between DOE and HHS or to preclude DOE and HHS agencies from entering into MOUs or IAs for other purposes.

[1]This agreement does not apply to activities and facilities covered under Executive Order 12344 (42 USC 7158 note).

III. Authorities

A. The Department of Health and Human Services/Public Health Service/Centers for Disease Control has legislative authority under Section 301(a) of the Public Health Service Act (42 U.S.C. Section 241) and under the Occupational Safety and Health Act [29 U.S.C. Section 669(a)] to conduct research into the health effects of a broad range of environmental and occupational hazards and to cooperate with other appropriate authorities in the conduct of such research.

B. The DOE may enter into agreements with HHS for the management of epidemiologic research pursuant to Section 103 (3) and 103 (ll) of the Energy Reorganization Act of 1974 [42 U.S.C. Sections 5813 (3) and 5813 (ll)]; The Economy Act of 1932 as amended (31 U.S.C. Section 1535); and DOE Order 1280.1, MEMORANDUMS OF UNDERSTANDING, of 9-20-85.

IV. DOE Responsibilities

A. Access to DOE Data Sources

DOE will provide HHS with access to data and other documents that may be pertinent to the management and conduct of analytic epidemiologic studies and programs, including data on occupational and community exposures, and environmental releases.

DOE will solicit input from HHS on the development and maintenance of the Comprehensive Epidemiologic Data Resource (CEDR) and the selection of data to include in CEDR.

DOE will allow HHS personnel, contractors, and grantees with appropriate security clearances access to all DOE and DOE-owned, contractor-operated facilities for the purpose of independently reviewing or collecting any health or environmental information or samples that HHS determines are necessary for conducting analytic epidemiologic research.

To the extent that existing regulations, Privacy Act routine uses, or agreements with its own contractors preclude disclosure of data held by DOE or its contractors to HHS, or subsequent use by HHS under section V.G., below, DOE will amend the regulations and routine uses, and renegotiate the agreements, so as to permit such disclosure and use.

To the extent that existing agreements with other entities preclude disclosure of data held by DOE or its contractors to HHS, or subsequent use by HHS under Section V.G., below, DOE will take distinct affirmative steps to negotiate those agreements so as to permit such disclosure and use. All future agreements entered into by DOE governing data that may be useful for the studies to be conducted by HHS under this MOU will permit disclosure of that data to HHS and subsequent use under Section V.H., below.

B. Programs to be Transferred

The health research programs to be managed by HHS will include selected ongoing and future epidemiologic health studies that test hypotheses, e.g., cohort, case-control, and cross-sectional mortality and morbidity studies, including dose reconstruction and exposure assessment studies that are essential for conducting these epidemiologic studies. The ongoing studies and FY 1991 resources to be transferred are identified in Appendix A. See also Section V., below.

C. Classification of Documents and Security Clearances

As soon as possible following the effective date of this MOU, DOE will perform a classification review of documents and data necessary for HHS to conduct the studies and programs described herein. HHS personnel with appropriate security clearances will participate in this review which will include an examination of existing procedures for the classification of documents that will be needed to conduct analytic epidemiologic research. DOE will, wherever possible, declassify or downgrade these documents and data. DOE will expedite appropriate security clearances for designated HHS personnel, and when possible honor current HHS security clearances (Top Secret), so that HHS personnel may examine classified documents and enter DOE and DOE-owned, contractor-operated facilities as necessary.

D. Committee Representation

The DOE will participate in the development of the research agenda for analytic epidemiologic studies by having DOE representative(s) serve as non-voting member(s) of the HHS Advisory Committee which will provide advice to HHS in setting the research agenda and in conducting the research program.

E. Office of Management and Budget/Congressional Submissions

For FY 1992, DOE will forward to the Office of Management and Budget (OMB) for inclusion in the President's Budget a request for resources necessary to support the conduct of the aforementioned studies and programs.

F. Official Point of Contact

DOE designates the following individual as the official point of contact for this MOU:

Name: Paul L. Ziemer, Ph.D.
Title: Assistant Secretary for Environment, Safety and Health
Address: U.S. Department of Energy, Washington, DC 20585
Telephone: (202) 586-6151

V. HHS Responsibilities

A. HHS Advisory Committee

HHS will establish an Advisory Committee to provide advice to the Secretary of HHS in setting the research agenda and in conducting the research program. Members of the Advisory Committee will consist of representatives selected by the Secretary of HHS from non-federal employees and will include research scientists, public health officials, representatives of public interest groups, and representatives of affected parties (e.g., workers, community residents). Both HHS and DOE will have nonvoting members on this Committee.

This HHS Advisory Committee will have an open channel of communication with the DOE's Advisory Committee which will be established to advise DOE's Assistant Secretary, Environment, Safety and Health, on the conduct of its environmental, health, and safety programs.

B. Committee Representation

Representative(s) of HHS will serve as non-voting member(s) of the DOE Advisory Committee which will provide direction, oversight, and evaluation to the DOE's Office of Environment, Safety and Health.

Additionally, there exist currently DOE-funded host State health agreements. For these existing and future agreements, HHS representatives will provide technical and public health assistance to the host States, including participating on the Technical Review/Oversight Committees at the request of the host States. DHHS' role in future analytic epidemiologic studies conducted through States will be discussed by DOE with HHS prior to negotiations of their agreement with States.

C. Establishing the Research Agenda

The HHS Advisory Committee will provide advice and recommendations to HHS on establishing the research agenda. All energy-related analytic epidemiologic health studies proposed by DOE and HHS will be submitted to the HHS Advisory Committee. The HHS Advisory Committee will take into consideration information and proposals provided by DOE and its Advisory Committee as well as information and proposals from other agencies and organizations. HHS will then establish the research agenda and develop a research plan.

HHS will provide DOE the research plan for review and comment. The HHS research plan will be revised each fiscal year to incorporate changes in the research agenda and to reflect changes in available resources.

All DOE initiated analytic epidemiologic research projects, including dose reconstruction and exposure assessment studies essential for conducting these epidemiologic studies, would be offered first to HHS for consideration. However, DOE may conduct through alternate means an analytic epidemiologic study that it referred to HHS if the HHS Advisory Committee has recommended the study but HHS has chosen not to include it in its research agenda. Funding for such will come from a DOE source separate from that funding level set aside for HHS-managed studies to be conducted under this MOU.

D. Conducting Research Activities

HHS will have sole responsibility for the design, conduct, analysis and scientific interpretation of the results for all transferred studies beginning at the time of transfer and for all future studies and programs covered under this MOU. HHS agrees to initially continue existing DOE grants and contracts listed in Appendix A. However, HHS will review all existing grants and contracts and continue, expand, or discontinue the projects based on this evaluation. This initial evaluation of current research activities and inclusion of those studies on a defined research agenda shall proceed with the advice of the HHS Advisory Committee and shall adhere to the principles specified in Section V.C. of this MOU.

HHS will decide which studies will be performed intramurally and which will move to open competition for all extramural research. HHS will develop a schedule for determining when continuing programs will be recompeted. HHS has the discretion to begin new intramural or extramural research consistent with the approved research agenda and resource availability.

E. HHS Data Sources

HHS will be responsible for the management of all data collected by HHS scientists, including data obtained from DOE. HHS will have access to all DOE and DOE-owned, contractor-operated facilities for the purpose of independently reviewing or collecting any health or environmental information or samples that HHS determines are necessary for conducting the analytic epidemiologic research consistent with the approved agenda.

F. Procedures for Conducting Research

HHS will employ established HHS peer review procedures for awarding research grants and contracts. These mechanisms include open competition, peer review, a competitive system for project renewals, and quality assurance for research in progress. The National Laboratories would be eligible to compete in this process along with other applicants to the extent permitted by law and DOE policies.

Intramural research will be conducted in accordance with established mechanisms for assuring scientific peer review. After coordination with DOE, HHS will prepare and submit the necessary information collection proposals to OMB under the Paperwork Reduction Act. Representatives of populations being studied shall be included in review panels which will be established as appropriate for studies conducted under this MOU. These panels will allow for public comment on the design and conduct of all studies. Results of the studies will be communicated directly to the Secretary of DOE and HHS and openly communicated to all interested parties. Notification of workers will be performed through existing HHS procedures and coordinated through DOE if the workers are from DOE or DOE owned, contractor-operated facilities.

G. Classification of Documents and Security Clearances

As soon as possible following the effective date of this MOU, HHS personnel with appropriate security clearances will participate in a DOE classification review of documents and data necessary for HHS to conduct the studies and programs described herein. HHS will complete all necessary paperwork for appropriate security clearances for its personnel so that they may examine classified documents and enter DOE and DOE-owned, contractor-operated facilities.

H. Use and Disclosure of Information

Establishment of Privacy Act Systems

HHS will establish the necessary Privacy Act systems of records for information provided to HHS by DOE (or will include such information in existing systems). Before integrating DOE data into a HHS system of records, HHS will consult DOE about provisions of the system notice, including the routine uses, applicable to the DOE data in the system. Before establishing a new system of records for DOE data, HHS will consult DOE about the provisions of the system notice, including the routine uses.

Disclosure of Information to the Public Generally

Information provided to HHS under this agreement that is requested by the public under the Freedom of Information Act shall be made available by HHS in accordance with the Act, 5 U.S.C. Section 552 and implementing regulations, 45 C.F.R. Part 5. In making decisions about disclosure, HHS will consult DOE about any information provided by DOE and identified in advance by DOE as warranting such consultation.

Disclosure of Personally-Identifiable Information for Research Purposes

As provided under applicable laws, HHS will not use or disclose any personally-identifiable information obtained from DOE or its contractors except for research purposes. HHS will not use information in identifiable form to make any determination about the rights, benefits, or privileges of any individual. HHS will use and disclose this information in accord with agreements under which the personally-identifiable information was obtained by DOE or its contractors provided this is consistent with applicable law. Subject to applicable law and such agreements, HHS will provide this information to DOE's Comprehensive Epidemiologic Data Resource (CEDR) data base and otherwise may disclose this information outside HHS for research to persons or entities it deems qualified, after consultation with DOE and in accord with the provisions for disclosure in HHS Privacy Act notices. HHS shall notify DOE of any efforts on the part of anyone to obtain or use personally-identifiable information for purposes other than research and shall use and take appropriate steps to prevent improper disclosure. HHS will assist DOE as necessary in renegotiating (as required by section IV.A., above) any agreements that preclude disclosure to HHS of data held by DOE or its contractors.

I. Release of Data from Completed Studies

HHS will promptly disseminate results obtained through research covered by this MOU to the populations being studied. Public access, including DOE access, to data in HHS epidemiologic studies will be governed by applicable Federal laws and HHS implementing regulations. After HHS epidemiologic studies have been completed and reported, study data will be made available to the public and to CEDR without personal identifiers subject to the provisions of Sections V.G. and V.H. above.

J. Reports to DOE

HHS will report its progress to DOE on a quarterly basis for the first year of this MOU. After the first year, DOE and HHS will evaluate the reporting needs and determine the frequency of future reporting.

K. Responsible Official

HHS designates the following individual as the official point of contact for this MOU:

Name: William L. Roper, M.D., M.P.H.
Title: Director, Centers for Disease Control
Address: 1600 Clifton Road, N.E., Atlanta, GA
Telephone: (404) 639-3291 (FTS 236-3291)

VI. Implementation of MOU

The Secretaries of DOE and HHS will appoint a task force to oversee and assist in implementing this MOU, including transfer of the analytic epidemiologic research programs listed in Appendix A. This task force will be appointed for one year and will report to the Secretaries at the end of its term. The task force will consist of staff from DOE and HHS.

VII. Resources

DOE will provide and transfer resources to HHS for the purpose of managing the DOE energy-related analytic epidemiologic research program. The funding and full-time equivalent (FTE) employment levels will be determined annually by agreement between designated agency official points of contact for this MOU (for DOE, see Section IV.F.; for HHS, see Section V.K.) For FY 1991, funding for this program will be $14,145,000 for grants and contracts and $2,855,000 and 25 FTEs for program operations, and for FY 1992, program levels will be $14,725,000 for grants and contracts and $6,200,000 and 44 FTEs for program operations. Upon mutual agreement, resource levels may be amended at any time during the fiscal year, however in the event that HHS incurs extraordinary expenses as a result of DOE's action to amend or constrain this MOU, HHS will be entitled to reimbursement for these expenses upon demonstration that additional and extraordinary costs were necessarily incurred. A copy of the signed agreement can be used by DOE as the basis for DOE to request the allocation of FTEs to HHS to carry out the terms of this agreement.

The details of the levels of support to be furnished by DOE to HHS will be developed annually through a single interagency agreement. HHS will provide to DOE a description and justification for funding and FTE resource requirements for submission to OMB and Congress for the studies and programs described under this MOU. These submissions will be provided by HHS to DOE in a timeframe agreed upon that is consistent with DOE's budget cycle.

HHS will not accept responsibility for specific studies or undertake new programs unless the mutually agreed level of resources is sufficient to achieve the intended goals and objectives. If equipment is procured in order to provide service under this MOU, HHS will retain title to the equipment.

Any requirement for the payment or obligation of funds by DOE established by the terms of this Agreement shall be subject to the availability of appropriated funds.

For the purposes of studies conducted by HHS or its grantees and contractors, HHS will prepare the necessary information collection proposals for OMB approval under the Paperwork Reduction Act. These proposals will be submitted by HHS to OMB. In the event that OMB fails to approve the information collection or allow adequate burden hours, HHS will be under no obligation to undertake or complete individual studies but will advise DOE and work with DOE to secure OMB approval which may result in necessary modification of reporting requirements.

VIII. Duration of Agreement

This agreement is effective when signed by both parties, shall initially remain in effect through FY 1995 unless amended by mutual written consent of both parties. The agreement is to be renewed annually thereafter by written mutual agreement. There is every intention to continue this agreement over the long-term.

IX. Modification or Cancellation

This agreement, or any of its specific provisions, may be revised by signature approval of both of the parties signatory hereto, or their respective designees.

Cancellation of the agreement may be accomplished only at the expiration of 90-day advanced notification by either party.

DEPARTMENT OF ENERGY	DEPARTMENT OF HEALTH AND HUMAN SERVICES
By: James D. Watkins Admiral, U.S. Navy (ret.) Secretary	By: Louis W. Sullivan, M.D. Secretary
Date 12/19/90	Date DEC 24 1990

Appendix A

DOE Analytic Epidemiologic Studies and FY 1991 Resources to be Transferred to HHS

The ongoing studies, which are the subject of this Memorandum of Understanding, are listed by contractor, year of expected study update*, program title (underlined), program funding level for FY 1991, and specific tasks.

HARVARD 1992 In vivo mutagenicity & clastogenicity of ionizing radiation. $200,000.

HEHF DOE Hanford Health and Mortality Study. $383,000. Companion study to the PNL Statistical Health Effects Studies. HEHF is responsible for employment and medical records.

1991 Hanford health and mortality study. Deaths through 1984/5 for all states, and through 1989 for Washington State.

LANL Human health effects of plutonium. $700,000.

1991 Analysis of mortality among employees of the Mound facility. Deaths through 1983.
1991 Cohort mortality surveillance among workers employed at the Los Alamos National Laboratory. Female subcohort completed; males scheduled for FY92.
1991 Investigation of mortality among employees of the Zia Company a subcontractor to the Los Alamos National Laboratory.
1991 Investigation of mortality among employees at the Rocky Flats nuclear weapons facility. Deaths through 1983.
1992 Analysis of mortality among plutonium exposed workers. Phase I of the pooled study including Rocky Flats and Mound. Deaths through 1983.
1992 Epidemiologic studies of Pantex workers.
Open Medical surveillance of Manhattan Project plutonium workers.
Open Mortality surveillance among 241 plutonium exposed workers.
Open Radiation exposure assessment study to support morbidity and mortality studies of workers.

LLNL Melanoma studies at the Lawrence Livermore NL. Internal laboratory funding.

ORAU

Health and Mortality Study. $2,817,000. (Includes $200K transferred to EH from NE for K-25 study)

1991 Non-malignant respiratory morbidity among workers in a uranium processing plant (Fernald).
1991 Mortality experience of workers in a uranium processing plant (I) (Fernald).
1991 Retrospective cohort mortality study of workers at the Oak Ridge Y-12 Plant (deaths through 1984).
1991 Mortality study of Y-12/UCC workers previously employed at Y-12/TEC.
1991 Mortality among workers at a uranium processing plant (Linde).
1991 Retrospective cohort mortality study of workers at the Oak Ridge National Laboratory (deaths through 1984).
1991 Oak Ridge facility comparison study (ORFCOM II), Phase I: WWII workers.
1991 Mortality study among welders in Oak Ridge facilities (deaths through 1984).
1991 Retrospective cohort mortality study of workers in the Savannah River Plant (deaths through 1985).
1991 Follow-up study of mortality and morbidity among DOE workers reported to have received ≥5 rem in a year.
1992 Case-control study of brain cancer among Oak Ridge workers.
1992 Oak Ridge facility comparison study (ORFCOM II), Phase II: The monitored workers and Phase III: All monitored and non-monitored workers (deaths through 1984).
1992 Study of mortality among chemical operators at all DOE plants in Oak Ridge.
1992 Retrospective cohort mortality study of workers in a uranium processing plant (Y-12).
1992 Case-control study of lung cancer deaths among workers at four uranium processing plants.
1992 Exploratory study of mortality among females employed at a uranium processing plant.
1992 Epidemiologic study of mortality among workers employed at the Oak Ridge Gaseous Diffusion Plant.
1992 Mortality experience of workers in a uranium processing plant (II) (Fernald) (deaths through 1984).
1992 K-25 Centrifuge workers study $200,000.
1993 Mortality among employees at Lawrence Livermore National Laboratory (LLNL).
1993 An epidemiologic study of mortality among workers at the Portsmouth Goodyear Atomic Corporation Gaseous Diffusion Plant.

	1993	A study of mortality among workers at the Paducah Gaseous Diffusion Plant.
	1993	Mortality among workers at a uranium refining and processing plant (Mallinckrodt).
	1993	Mortality among short-term workers at the Oak Ridge Gaseous Diffusion Plant.
	Open	Case-control study of renal disease among workers at a uranium processing plant (Fernald).
ORO	1992	CDC/Fernald dose reconstruction. $6,100,000.
PNL		Statistical health effects studies. $295,000.
	1991	Hanford health and mortality study. Deaths through 1984 for all states and through 1989 for Washington State. Joint HEHF/PNL project.
	1992	Case-control study of childhood leukemia and non-Hodgkin's lymphoma and of late fetal deaths in populations around the Hanford Nuclear facility.
	1992	IARC combined analyses of cancer mortality among nuclear industry workers. IARC and DOE scientists are involved in analysis of health effects and occupational exposure to external sources of irradiation. Dr. Gilbert is the DOE contractor representative for this activity.
RL	1993	Hanford dose reconstruction - Support to PNL. $3,650,000.

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* The year shown in the second column represents the estimated completion date of the initial or updated analysis. In general, this represents completion of a manuscript or submission of a study for scientific peer-review. "Open" implies that the work is on-going, a start date has not been assigned, or additional funding has not been provided.

B

SPEERA Executive Summary[1]

In this report, the Panel makes recommendations to improve the quality of the epidemiology program and its value to the Department of Energy, its workers, and the communities near its facilities. This summary contains the Panel's major observations and recommendations.

Epidemiology provides a scientific evaluation of the health effects of worker and public exposures to potentially harmful materials. It uses health records, exposure records, environmental monitoring records, and personnel records to analyze health effects and to evaluate methods of protection and prevention. The Panel has distinguished between two types of epidemiology: descriptive epidemiology, which includes health surveillance; and analytic epidemiology, which tests hypotheses and often includes long-term research studies.

Over the years, epidemiologic activities have become scattered throughout the Department. Although the main epidemiologic research program is located within the Office of Energy Research, nevertheless, the Offices of Defense Programs and Nuclear Energy also conduct epidemiologic research. The Office of Environment, Safety, and Health is responsible for the data upon which analytic and descriptive epidemiologic research depends. There is no coordination of epidemiologic data collected by the Department's site operations contractors.

[1]SOURCE: SPEERA (Secretarial Panel for the Evaluation of Epidemiological Research Activities for the Department of Energy). 1990. Report to the Secretary. Washington, DC: U.S. Department of Energy.

Epidemiologic activities are inherently part of a comprehensive occupational and environmental health program. All the descriptive epidemiologic activities now scattered throughout the Department should be consolidated with the Department's other health and safety activities.

The Panel recommends that the Department establish a strong, comprehensive program by restructuring and expanding the current Office of Environment, Safety and Health. This office should be restructured as the Office of Occupational and Environmental Health and Safety and continue to be directed by an Assistant Secretary. The office should contain a descriptive epidemiologic research component that includes a health surveillance system. When tightly linked with occupational and environmental health and safety activities, epidemiologic activities will give the Department another powerful tool to monitor day-to-day worker health, to measure the performance of health and safety activities, and to guide policy decisions.

A recurrent theme of witnesses at every meeting was a lack of credibility in the Department and its epidemiologic activities. The Panel believes that to restore public trust, to assure the highest scientific quality, and to assure the independence of investigators, the Department needs an independent system for managing its analytic epidemiologic research which can transcend changes in Departmental administrations. This can be achieved without statutory changes.

The Panel recommends that the Department enter quickly into a Memorandum of Understanding with the Department of Health and Human Services to manage the Department's analytic epidemiologic research. The Department of Energy would continue to allocate funds for analytic epidemiologic research and the Department of Health and Human Services would use its customary procedures for conducting scientific research, including peer review and open competition for research projects. This analytic research should be managed by one of the Department of Health and Human Services' epidemiologic research agencies.

The quality of epidemiologic research rests heavily on the quality of the data used. Many different programs—industrial hygiene, health physics, environmental monitoring, and medical care—have kept their records separately and in various formats. The Panel recommends that the Department identify a standard minimum set of data, including health and exposure data, necessary for epidemiologic research. These data should be standardized throughout the Department and collected routinely at all facilities.

Scientific quality and public credibility are related to the degree of openness with which data are collected, maintained, and analyzed. The Panel values the benefits that flow from allowing independent scientists to examine and reexamine data from different perspectives. Therefore, the Panel recommends that the Department take specific steps toward opening its epidemiologic data to scientific investigators; for example, requiring documentation about data preparation and assumptions; removing personal identifiers from data sets; and establishing new procedures for the timely release of data.

The Panel recommends that the Department make liberal use of committees to foster quality science, to assure independence of research, and to gain participation by outside experts and those who might be affected by the research.

The Department has an obligation to communicate epidemiologic findings to all affected people: workers, former workers, and communities. The Panel recommends that communications be prompt, direct, and understandable. People need to know the nature of studies and their results, whether the findings are good, bad, or inconclusive.

Beryllium disease is an occupational health risk and should be addressed by the Department's occupational health program and by the analytic epidemiologic research program managed by the Department of Health and Human Services. The Panel recommends that the Department use a liberal definition of exposure to identify workers throughout its complex who have been exposed to beryllium and who ought to be included in research studies. The Panel also recommends that the Department establish whether beryllium disease may have occurred at facilities other than Rocky Flats.

The Department of Energy has shown a continuing commitment to funding energy-related epidemiology. The recommendations in this report will require additional funds for epidemiologic activities. These would be new or reallocated funds above those budgeted for epidemiology in the proposed Fiscal Year 1991 budget. The Panel recommends an additional $4 million for health surveillance and descriptive epidemiology and an additional $1.1 million for analytic epidemiology.

The reader should put this summary in perspective by, at a minimum, reading "Introduction: Guiding Principles" to understand the beliefs that guided the Panel.

C

Abbreviations, Acronyms, and Definitions

ACBM: Advisory Committee for Biology and Medicine
ACERER: Advisory Committee for Energy-Related Epidemiological Research
ATSDR: Agency for Toxic Substances and Disease Registry

BEIR: Biological Effects of Ionizing Radiation (NRC)
Bias: Factors that influence the outcome of data collection, such as causing certain measurements to have a greater chance of being included than others
BSC: Board of Scientific Counselors

CAB: Citizens' Advisory Board
CAREs: Communities Against a Radioactive Environment
Case-control study: Epidemiologic study in which people with disease and a similarly composed control group are compared in terms of exposures to a putative causative agent
CDC: Centers for Disease Control and Prevention
CEDR: Comprehensive Epidemiologic Data Resource (DOE)
CEHIC: Center for Environmental Health and Injury Control (CDC)
CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act; CERCLA provides a federal "Superfund" to clean up uncontrolled or abandoned hazardous waste sites as well as accidents, spills, and other emergency releases of pollutants and contaminants into the environment
CHE: Coalition for a Healthy Environment

CI (confidence interval): Interval estimate of an unknown parameter such as a risk; 95% CI, as an example, is constructed from a procedure that is theoretically successful in capturing the parameter of interest in 95% of its applications. Confidence limits are the end points of a confidence interval
CIC: Community Involvement Committee (LANL)
CLL: Chronic lymphocytic leukemia
COWG: Communications and Outreach Workgroup (Oak Ridge)

DOE: U.S. Department of Energy
Dose: Short name for absorbed dose (1 Gy = 1 J/kg) and also for equivalent dose, effective dose, and weighted dose (1 Sv = 1 J/kg)

EEOICPA: Energy Employees Occupational Illness Compensation Program Act
EPA: U.S. Environmental Protection Agency
Epidemiology: Study of the determinants of the frequency of disease in humans.The two main types of epidemiologic studies of chronic disease are cohort (or follow-up) studies and case-control studies
EPR: Electron paramagnetic resonance
ERDA: Energy Research and Development Administration
ERR: Estimated excess relative risk. The rate of disease in an exposed population divided by the rate of disease in an unexposed population minus 1.0.
ES&H: Office of Environment, Safety and Health (DOE)
ETTP: East Tennessee Technology Park
Exposure: Condition of having contact with a physical or chemical agent

FACA: Federal Advisory Committee Act
FWMSP: Former Worker Medical Surveillance Program (DOE)

HCHP: Hanford Community Health Project
HEDR: Hanford Environmental Dose Reconstruction Project
HEHF: Hanford Environmental Health Foundation·
HERB: Health-Related Energy Research Branch (NIOSH)
HES: Health Effects Subcommittee
HETA: Hazard Evaluation and Technical Assistance
HHE: Health Hazard Evaluation
HHES: Hanford Health Effects Subcommittee
HHIN: Hanford Health Information Network
HHS: U.S. Department of Health and Human Services
HTDS: Hanford Thyroid Disease Study

I-131: Iodine-131
ICD: International Classification of Diseases
ICRP International Commission on Radiological Protection*:* Independent inter-

national organization that provides recommendations and guidance on protection against ionizing radiation

IDA: Individual Dose Assessment Project (Hanford)

Incidence (also incidence rate): Rate of occurrence of a disease within a specified period of time, often expressed as a number of cases per 100,000 individuals per year

INL: Idaho National Laboratory

IOM: Institute of Medicine

Ionizing radiation: Radiation sufficiently energetic to dislodge electrons from an atom, thereby producing an ion pair; ionizing radiation includes X- and gamma radiation, electrons (beta radiation), alpha particles (helium nuclei), and heavier-charged atomic nuclei. Neutrons ionize indirectly by first colliding with components of atomic nuclei

LAHDRA: Los Alamos Historical Document Retrieval and Assessment

LANL: Los Alamos National Laboratory

LET: Linear energy transfer

*Linear (L) model or relationship (*also *linear dose-effect relationship):* A special case of the linear-quadratic model, with the quadratic coefficient equal to zero; this model expresses the effect (e.g., cancer, mutation) as proportional to dose (linear function of the dose)

Linear-quadratic (LQ) model (also *linear-quadratic dose-effect relationship*)*:* This model expresses the effect (e.g., cancer) as the sum of two components, one proportional to the dose (linear term) and one proportional to the square of the dose (quadratic term). The linear term predominates at low doses; the quadratic term, at high doses

LLNL: Lawrence Livermore National Laboratory

LNT model: Linear no-threshold dose-response for which any dose greater than zero has a positive probability of producing an effect (e.g., mutation, cancer); the probability is calculated either from the slope of a linear (L) model or from the limiting slope, as the dose approaches zero, of a linear-quadratic (LQ) model

LOAEL: Lowest-observed-adverse-effect level

MED: Manhattan Engineering District

Meta-analysis: Analysis of epidemiologic data from several studies based on data included in publications

Minimal risk level (MRL): Estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure

MMP: Medical Monitoring Program

Model: Schematic description of a system, theory, or phenomenon that accounts

for its known or inferred properties and may be used for further study of its characteristics

Mortality (rate): Frequency at which people die from a disease (e.g., a specific cancer), often expressed as the number of deaths per 100,000 population per year

NAHH: National Alliance for Hispanic Health
NAS: National Academy of Sciences
NBS: National Bureau of Standards (now National Institute of Standards and Technology)
NCEH: National Center for Environmental Health
NCRP (National Council on Radiation Protection and Measurements): U.S. council commissioned to formulate and disseminate information, guidance, and recommendations about radiation protection and measurements
NER: National Exposure Registry (ATSDR)
NIOSH: National Institute for Occupational Safety and Health
NNMCAB: Northern New Mexico Citizens' Advisory Board
NOAEL: No-observed-adverse-effect level
NPCR: National Program of Cancer Registries (CDC)
NPL: National Priorities List; a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States and its territories
NRC: National Research Council
NTS: Nevada Test Site

OEHS: Office of Epidemiology and Health Surveillance (DOE)
OERP: Occupational Energy Research Program (NIOSH)
OMB: Office of Management and Budget
OR (Odds ratio): the odds of being exposed among diseased persons divided by the odds of being exposed among nondiseased persons
ORAU: Oak Ridge Associated Universities
OREPA: Oak Ridge Environmental Peace Alliance
ORERP: Offsite Radiation Exposure Review Project
ORNL: Oak Ridge National Laboratory
ORO: Oak Ridge Operations Office
ORR: Oak Ridge Reservation
ORRHASP: Oak Ridge Reservation Health Agreement Steering Panel
ORRHES: Oak Ridge Reservation Health Effects Subcommittee
ORRLOC: Oak Ridge Reservation Local Oversight Committee
ORRSSAB: Oak Ridge Reservation Site Specific Advisory Board
OTA: Office of Technology Assessment

PCB: Polychlorinated biphenyl
PHA: Public Health Assessment
PHEP: Public Health Education Program
PHS: Public Health Statement; the first chapter of ATSDR's Toxicological Profiles
PNNL: Battelle, Pacific Northwest National Laboratory, a contractor at the Hanford Site
Pooled analysis: An analysis of epidemiologic data from several studies based on original data from the studies
PSR: Physicians for Social Responsibility

RAC: Radiological Assessment Corporation (later, Risk Assessment Corporation)
Rad: A special unit of absorbed dose, now replaced by the SI unit gray; 1 rad = 0.01 Gy = 100 erg/g
Radiation: Energy emitted in the form of waves or particles by radioactive atoms as a result of radioactive decay or produced by artificial means, such as X-ray generators
Radiogenic: Caused by radiation
Radionuclide: Radioactive species of an atom characterized by the constitution of its nucleus
Rem (*rad equivalent man*)*:* A special unit of dose equivalent, now replaced by the SI unit sievert; 1 rem = 0.01 Sv
REMS: Radiation Exposure Monitoring System (DOE)
RERP: Committee on the Department of Energy Radiation Epidemiological Research Programs (NRC)
RfD: Reference dose (DOE)
Risk: Chance of injury, loss, or detriment; a measure of the deleterious effects that may be expected as the result of an action or inaction
Risk assessment: Process by which the risks associated with an action or inaction are identified and quantified
Risk estimate: Increment of the incidence or mortality rate projected to occur in a specified exposed population per unit dose for a specified exposure regime and expression period
RL: Richland Operations Office (DOE)

SENES: Specialists in Energy, Nuclear and Environmental Studies
Sievert (Sv): Special name of the SI unit of dose equivalent; 1 Sv = 1 J/kg = 100 rem
SI units: International System of Units as defined by the General Conference of Weights and Measures in 1960; these are the base units, such as meter (m), kilogram (kg), second (s), and their combinations, which have special names

(e.g., the unit of energy 1 J = 1 kg m^2/s^2, or of absorbed dose 1 Gy = 1 J/kg = 1 m^2/s^2)

SPEERA: Secretarial Panel for the Evaluation of Epidemiological Research Activities (DOE)

SRS: Savannah River site

SSAB: Site-Specific Advisory Board (DOE)

Standardized morbidity ratio or *standardized mortality rate (SMR):* Rate (multiplied by 100) of mortality from a disease in the population being studied divided by the comparable rate in a standard population; ratio is similar to a relative risk times 100

TAG: Technical Assistance Grant

TCA: Trichloroethane

TCE: Trichloroethylene

TDH: Tennessee Department of Health

Threshold hypothesis: Assumption that no injury occurs below a specified dose

TSCA: Toxic Substances Control Act

TSP: Technical Steering Panel composed of independent scientists and members of the public created to oversee and direct HEDR

Uncertainty: Range of values within which the true value is estimated to lie; a best estimate of possible inaccuracy due to both random and systemic errors:

Random Errors: Errors that vary in a nonreproducible way around a limiting mean; these can be treated statistically by use of the laws of probability

Systemic Errors: Errors that are reproducible and tend to bias a result in one direction; their causes can be assigned, at least in principle, and they can have constant and variable components; generally, these errors cannot be treated statistically

UNSCEAR: United Nations Scientific Committee on the Effects of Atomic Radiation

X-rays: Penetrating electromagnetic radiation, usually produced by bombarding a metallic target with fast electrons in a high vacuum

YDI: Youth Development, Inc.

D

Committee Biographies

Edwin P. Przybylowicz, Ph.D. (NAE), retired in 1991 after more than 35 years with the Eastman Kodak Company as senior vice president and director of research. He became assistant director of Kodak Research Laboratories in 1983, and was named director of research and elected senior vice president of the company in August 1985. Dr. Przybylowicz received his B.S. in chemistry from the University of Michigan and a Ph.D. in analytical chemistry from Massachusetts Institute of Technology. He has served as a commissioner of the U.S.-Polish Joint Fund for Cooperation in Science and Engineering, a program that fosters the collaboration of Polish and U.S. scientists, chairing conferences and workshops on technology transfer in Poland, the Czech Republic, and Russia. From 1994 to 1996, he was director of the Center for Imaging Science at the Rochester Institute of Technology. He is currently an elected member of the International Union of Pure and Applied Chemistry (IUPAC) Bureau and Executive Committee, and is past chair of the U.S. National Committee for IUPAC. He was elected to the National Academy of Engineering in 1990 and has served on numerous National Research Council (NRC) committees.

Edwin H. Clark, II, Ph.D., is president of Clean Sites Inc. in Alexandria, VA. He holds a Ph.D. in applied economics from Princeton University. Dr. Clark is the former secretary of natural resources and environmental control for the state of Delaware, vice president of the Conservation Foundation, and associate assistant administrator for pesticides and toxic substances in the U.S. Environmental Protection Agency. He has served as a member of the National Academies Board on Environmental Studies and Toxicology and on several committees, including

the Committee to Evaluate the Science, Engineering, and Health Basis of the DOE's Environmental Management Program, the Committee on Risk-Based Criteria for Non-RCRA Hazardous Waste, and the Committee on Superfund Site Assessment and Remediation in the Coeur D'Alene River Basin.

Irwin Feller, Ph.D., is currently a senior visiting scientist at the American Association for the Advancement of Science (AAAS), having recently completed 24 years as the director of Pennsylvania State's Institute for Policy Research and Evaluation. He also serves as a professor emeritus of Pennsylvania State's Department of Economics, where he was on the faculty for nearly three decades. Dr. Feller received his Ph.D. in economics from the University of Minnesota. He has a long history of publishing scholarly articles on the economics of technological innovation, and the effects of innovations on the creation of knowledge and societal benefits, using both universities and government programs as objects of study. This expertise has been applied to problems of nucleation and growth of new scientific fields, to the anatomy and function of interdisciplinary research programs, to the effectiveness of various technology transfer mechanisms, to the metrics used to evaluate research in government programs, and to a host of other mechanisms and institutions of importance to the scientific enterprise. From 2002-2004, Irwin Feller served as chair of the National Science Foundation's Advisory Committee to the Assistant Director of Social, Behavioral, and Economic Sciences, a committee of which he has been a member from 1999. Dr. Feller has served on six National Research Council committees, including as chair of the Panel on Assessing Behavioral and Social Science Research on Aging.

Penny Fenner-Crisp, Ph.D., is currently a private consultant. She received her Ph.D. in pharmacology from the University of Texas Medical Branch in Galveston. She recently retired from her position as executive director of the ILSI Risk Science Institute . Dr. Fenner-Crisp came to ILSI from the U.S. Environmental Protection Agency (EPA) where she was senior science adviser to the director of the Office of Pesticide Programs (OPP). In that capacity, she provided guidance and oversight for programmatic activities related to science and science policy in OPP, particularly those related to implementation of the 1996 Food Quality Protection Act. Her responsibilities included many newly developed or updated human health risk assessment methodologies, the Endocrine Disrupter Screening Program, OPP's implementation of the agency peer-review policy, research planning, and preparation of agency staff for presentations before the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel and the EPA Science Advisory Board. At EPA, she also served as special assistant to the assistant administrator for the Office of Prevention, Pesticides, and Toxic Substances; deputy director of the Office of Pesticide Programs; and director of the Health and Environmental Review Division of the Office of Pollution

Prevention and Toxics. Dr. Fenner-Crisp has been involved in many international activities including serving as an expert on a number of World Health Organization (WHO) International Programme on Chemical Safety working groups charged with drafting environmental health criteria documents; on the WHO Expert Panel for the Joint Meeting on Pesticide Residues; as the lead U.S. delegate to the Organization for Economic Co-operation and Development's Endocrine Disrupter Testing and Assessment workgroup; and as lead U.S. delegate to the Expert Consultation on Acute Toxicity.

R. William Field, Ph.D., M.S., is an associate professor in the Department of Occupational and Environmental Health with a joint appointment in the Department of Epidemiology in the College of Public Health at the University of Iowa. He is also the director of the Occupational Epidemiology Training Program at the Heartland Center for Occupational Health and Safety, funded by the National Institute for Occupational Safety and Health (NIOSH), and co-director of the pulmonary outcomes core of the Environmental Health Sciences Research Center, funded by the National Institute of Environmental Health Science, both at the University of Iowa. He currently chairs a WHO working group tasked with recommending radon measurement and mitigation strategies for member countries and serves on several other radon-related WHO working groups. Dr. Field has been active in numerous national and international collaborative radiation-related epidemiolgic projects for many years and has served on the editorial boards of several national and international scientific journals. Dr. Field received his Ph.D. in preventive medicine and environmental health from the University of Iowa in 1994. His research interests fall into the broad categories of environmental epidemiology, occupational epidemiology, radioepidemiology, cancer epidemiology, immune-mediated disease epidemiology, health physics, biomonitoring, risk perception, and novel methods of retrospective exposure assessment.

Sharon M. Friedman, M.A., B.A., is professor of journalism and communication and director of the science and environmental writing program at Lehigh University in Bethlehem, Pennsylvania. She received her M.A. in journalism from Pennsylvania State University in 1974, a graduate certificate in public relations from American University in 1970, and her B.A. in biology from Temple University in 1964. Her research and consulting activities focus on how scientific, environmental, and health risk issues are communicated to the public. Professor Friedman chaired the Department of Energy's Advisory Committee for its low-dose-radiation research program for 3 years. She has served as a consultant to the President's Commission on the Accident at Three Mile Island, the United Nations Economic and Social Commission for Asia and the Pacific, and various U.S. government agencies and industries on environmental and risk communication. Elected a fellow of the American Association for the Advancement of Science (AAAS) in 1989 for her contributions toward furthering the public un-

derstanding of science and technology, she served as a member of the AAAS Council for 6 years. She has written one book, co-edited two books, and authored numerous articles and book chapters. Professor Friedman is a member of the editorial advisory board of the journal *Science Communication*. She was a member of the National Academies' Committee on Assessment of the Centers for Disease Control and Prevention's Radiation Studies and was a member of its Committee on Improving Practices for Regulating and Managing Low-Activity Radioactive Waste.

Helen Grogan, Ph.D., is the founder of a consulting company, Cascade Scientific, Inc. Dr. Grogan earned her Ph.D. from Imperial College of Science and Technology, University of London, in 1984. Previously, Dr. Grogan worked with the Paul Scherrer Institute (formerly the Swiss Federal Institute for Reactor Research) as a member of the Repository Performance Assessment Group, where she was responsible for the biosphere modeling aspects of the safety assessment of both high-level waste and low-or intermediate-level waste repositories. At Cascade Scientific, Inc., Dr. Grogan has worked with the Risk Assessment Corporation (RAC) on a variety of projects including Phase I (data retrieval and assessment) and Phase II (source term calculation and ingestion pathway data retrieval) of the Savannah River Site Dose Reconstruction Project. Dr. Grogan worked with other subcontractors to RAC to develop a risk-based screening methodology for radionuclide releases to the Columbia River from past operations of the Hanford site. She also worked on Phase II of the Historical Public Exposures Studies on Rocky Flats, focusing on quantifying the organ-specific cancer incidence risk and its uncertainty following exposure to plutonium from inhalation. The Savannah River dose reconstructions and the Hanford dose reconstructions were a part of the dose reconstruction efforts of the Centers for Disease Control and Prevention (CDC) and the National Center for Environmental Health and, thus, were a component of the program to be reviewed in the present National Academies study. Dr. Grogan serves as a member of the EPA Science Advisory Board's Radiation Advisory Committee.

Jack Mandel, M.P.H., Ph.D., is Rollins Professor and chair of the Department of Epidemiology in the Rollins School of Public Health at Emory University. He is also a Georgia Cancer Coalition distinguished cancer scholar. Dr. Mandel earned his M.P.H. and Ph.D. in epidemiology from the University of Minnesota. Dr. Mandel has an international reputation in epidemiology and is a leader in cancer screening research. He has conducted many case-control, cohort (both prospective and retrospective), cross-sectional, experimental, and methodological studies related to prostate, colorectal, kidney, pancreatic, breast, lung, stomach, hematopoietic, and skin cancers. His research interests in cancer epidemiology include etiologic and both primary and secondary prevention research. Dr. Mandel was previously group vice president at Exponent and prior to that served

as the Mayo Chair and head of the Division of Environmental and Occupational Health at the University of Minnesota School of Public Health. He is currently serving as chair of the CH2M HILL's Health Effects Panel. The panel is tasked with evaluating health effects related to occupational exposures at the Hanford Site.

Glenn Paulson, Ph.D., is professor in the Environmental and Occupational Health Department and associate dean for research at the University of Medicine and Dentistry of New Jersey's School of Public Health. Dr. Paulson earned his Ph.D. in environmental sciences and ecology from the Rockefeller University. In addition to having previously been research professor at the Illinois Institute of Technology and holding regular or adjunct faculty positions at the New School University, the Medical University of South Carolina, the State University of New York, and other colleges and universities, he served as assistant commissioner in the New Jersey Department of Environmental Protection, among other positions. He has served as member or chairman of numerous advisory boards for federal, state, and local agencies as well as nonprofit organizations. Dr. Paulson has also served on numerous National Academies study panels, including the Committee on Remediation of Buried and Tank Wastes, the Board on Radioactive Waste Management, and the Committee on Remedial Action Priorities for Hazardous Waste Sites.

Rosemary K. Sokas, M.D., M.O.H., M.Sc., is professor and director of Environmental and Occupational Health Sciences Division at the University of Illinois at Chicago School of Public Health. She previously served in the office of the director of NIOSH as lead medical officer and associate director for science. While at NIOSH she led a team of senior scientists that coordinated institute policy and science, promoted the National Occupational Research Agenda, and developed NIOSH-wide initiatives, including ones to focus on health care workers and underserved minority workers. Prior to that, Dr. Sokas directed the Office of Occupational Medicine for the Occupational Safety and Health Administration. She has previously served as professor of medicine and of health sciences at the George Washington University School of Medicine and School of Public Health and as assistant professor of medicine at the University of Pennsylvania. Her research areas focus on intervention effectiveness projects for high-risk and low-wage workers. Dr. Sokas currently serves on the NRC Committee on the Review of NIOSH Research Programs. She earned her M.D. from Boston University and her M.O.H. and M.Sc. from the Harvard School of Public Health.

Daniel O. Stram, Ph.D., is a professor in the Department of Preventive Medicine at the University of Southern California. Dr. Stram earned his Ph.D. in statistics from Temple University and subsequently engaged in postdoctoral research in biostatistics at the Harvard School of Public Health. From 1986 to 1989 he was a

member of the Statistics Department of the Radiation Effects Research Foundation in Hiroshima. Since 1990, Dr. Stram has been a major participant in National Institutes of Health-funded clinical research in and epidemiology of childhood and adult cancers at the University of Southern California and the Children's Oncology Group. He has special interest in the measurement error characteristics of radiation dosimetry systems and other exposure assessment methods when they are applied to epidemiological research. He was a member of the National Academies' Committee on Assessment of the Centers for Disease Control and Prevention's Radiation Studies and of the Board on Radiation Effects Research.

Tongzhang Zheng, B.Med., Sc.D., Sc.M., is professor and head of the Division of Environmental Health Sciences, Yale School of Public Health. His research interests have been in the area of cancer epidemiology, environmental epidemiology, and gene-environment interaction. Dr. Zheng is the principal investigator (PI) for two case-control studies: CYP1A1 genetic polymorphism, environmental exposure, and risk of breast cancer; and GSTM1, GSTT1, and GSTP1 genetic polymorphism and breast cancer risk. Dr. Zheng was the PI for case-control studies of non-Hodgkin's lymphoma, multiple myeloma, and Hodgkin's lymphoma in Connecticut and of organochlorine compounds and breast cancer risk in Connecticut women. Dr. Zheng has 100 publications, many of which report on health effects of chemical exposures. Dr. Zheng was a panel member on the National Academies Committee on Gulf War and Health: Review of the Literature on Pesticides and Solvents: Pesticide Panel.