MEMORANDUM OF UNDERSTANDING
BETWEEN THE
U.S. DEPARTMENT OF ENERGY
AND THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. Introduction

This Memorandum of Understanding (MOU) serves to set forth the authorities, responsibilities, and procedures between the Department of Energy (DOE) and the Department of Health and Human Services (HHS) for HHS to conduct an independent program of energy-related epidemiologic research and those public health activities mandated under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and the Solid Waste Disposal Act (SWDA) on or around DOE sites. The research and public health activities performed under this MOU focus on the evaluation of, and response to, health effects that could result from past, current, or future DOE operations and activities, including the development and production of nuclear weapons and materials, releases of hazardous substances into the environment, and other DOE nuclear energy-related research and development activities as defined under CERCLA and SWDA.

DOE and HHS will make every effort to ensure that activities conducted under this MOU, and those conducted through other mechanisms are coordinated, nonduplicative, and supportive of a comprehensive public health program.

II. Background

In 1990, DOE and HHS entered into a 5-year MOU for management and conduct by the Centers for Disease Control and Prevention (CDC) of energy-related analytic epidemiologic studies relevant to DOE operations. DOE retained the responsibility to conduct descriptive epidemiologic studies. Since that time, DOE and CDC have coordinated their efforts in studying the potential health effects resulting from nuclear weapons production and research and development activities. In 1996, a new phase of this agreement began with the signing of a revised MOU. This MOU with HHS allowed CDC to continue conducting a program of independent occupational and environmental research studies with funding from DOE. DOE has retained responsibilities for other health-related activities, such as health surveillance of current and former workers and other DOE programs designed to protect the health and safety of DOE workers and community residents.

In 1980, Congress established the Agency for Toxic Substances and Disease Registry (ATSDR) to carry out the health-related authorities of CERCLA at Superfund sites. ATSDR's public health authority was extended in 1984 to SWDA sites, and its full authorities were extended to Federal facilities in 1986. In 1990, ATSDR and DOE's Office

of Environmental Management entered into an MOU to conduct these activities at DOE sites subject to CERCLA and SWDA; it was extended in 1992 and renewed for 1 year in 1997.

Fiscal year 1999 Congressional Appropriations language directed DOE to develop a single MOU with HHS that would set forth the authority, resources, and responsibility for conduct of HHS public health activities conducted by CDC and ATSDR at the DOE sites. This MOU addresses that requirement. The following sections specify the authorities, responsibilities, and procedures for the energy-related epidemiologic research and public health activities being carried out by CDC and ATSDR at the DOE sites. Because CDC and ATSDR carry out their activities under separate legislative authorities that mandate different responsibilities, some aspects of this MOU reflect these differences.

III. Purpose

This MOU replaces the 1996 MOU between HHS and DOE, and sets forth the guidelines for continuing the collaboration between DOE, CDC, and ATSDR for the energy-related research and public health activities program being independently conducted by CDC and ATSDR for DOE. The research and public health activities under this MOU focus on the examination of health effects that may have resulted from DOE operations, including development and production of nuclear weapons and materials and other nuclear energy-related research and development activities. This MOU establishes the responsibilities and procedures under which HHS and DOE will cooperate in the conduct of the HHS proposed research and public health activities.

IV. Authorities

A. General

This MOU is made under the authority of the Economy Act of 1932, as amended (31 U.S.C., Sections 1535 and 1536).

B. HHS/CDC

The Secretary of HHS 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 651 et seq) 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. The National Institute for Occupational Safety and Health (NIOSH) has authority under the Occupational Safety and Health Act, the Federal Mine Safety and Health Act, as amended, (30 U.S.C. 801, 951) and implementing regulations under (42 CFR Parts 85 and 85a) to conduct health hazard evaluations (Part 85) and other workplace investigations (Part 85a).

C. HHS/ATSDR

ATSDR has legislative authority under Section 120 of CERCLA (42 U.S.C. 9620), which concerns the application of CERCLA to Federal facilities, Section 104(i) of CERCLA (42 U.S.C. 9604), which concerns ATSDR's authorities and responsibilities, Section 107 of CERCLA (42 U.S.C. 9067), which concerns liability, and Section 3019 of SWDA (42 U.S.C. Section 6939a) which concerns exposure information and health assessments.

D. DOE

Pursuant to the Atomic Energy Act of 1954, Section 31a (42 U.S.C. Section 2051a), and the Energy Reorganization Act of 1974, Section 103(3) (42 U.S.C. Section 5813(3)), DOE is authorized to conduct and to make arrangements for the conduct of research activities relating to the protection of health, and the promotion of safety related to its research and production activities and the development of energy sources and utilization technologies. To achieve these objectives, DOE may, in addition to its own resources and programs, use the technical and management capabilities of other executive agencies having facilities, personnel, or other resources that can assist in carrying out such responsibilities, Atomic Energy Act, Section 161 (42 U.S.C. Section 2201), Energy Reorganization Act, Section 104(i) (42 U.S.C. Section 5814(i)), and the Economy Act of 1932, as amended (31 U.S.C. Section 1535).

E. Naval Nuclear Propulsion Program

Where applicable, the Director, Naval Nuclear Propulsion Program (NNPP), will establish the necessary provisions with HHS for epidemiologic studies at Naval nuclear propulsion facilities and activities (42 U.S.C. 7158).

V. Responsibilities

A. CDC and ATSDR

Within HHS, CDC conducts energy-related epidemiologic research: the National Center for Environmental Health conducts research related to ionizing radiation in the environment, and NIOSH conducts research in the workplace. ATSDR conducts public health activities mandated under CERCLA and SWDA at the DOE sites where hazardous substances have been released into the environment.

CDC and ATSDR will have sole responsibility for the selection, design, conduct, analysis, and scientific interpretation of research and public health activities conducted by these agencies, their contractors, grantees, or cooperative agreement holders under this MOU.

CDC and ATSDR will be responsible for grants, contracts, and cooperative agreements with Tribes, States, local health departments, and academic institutions, as required to fulfill their mandates. CDC and ATSDR will collaborate with communities, workers, labor representatives, and Tribes to involve them in planning and goal setting, exchanging information, and in designing, implementing, and evaluating agency programs and activities.

CDC and ATSDR will employ established procedures for awarding research grants, contracts, and cooperative agreements pursuant to HHS regulations under 45 CFR Part 74 and 92. These mechanisms include open competition, peer review, a competitive system for project renewal, and quality assurance for research in progress. The DOE National Laboratories will be eligible to compete in this process along with other applicants to the extent permitted by law and DOE policies.

CDC and ATSDR will include representatives of populations being studied in the review of studies or public health activities being conducted under this MOU. This will allow for public, worker, and American Indian comment on the design and conduct of all studies and public health activities.

CDC and ATSDR will conduct peer review according to their respective policies. Peer review and human subjects review will be performed on all research projects involving human subjects under this MOU.

DOE and CDC/ATSDR will communicate information about studies and public health activities performed under this MOU based on a joint communication plan being developed by these agencies.

B. ATSDR

1. Public Health Assessments and Health Consultations

ATSDR will prepare public health assessments (PHA's), health consultations, public health advisories and related documents for DOE sites as mandated by CERCLA or other authorizing statutes.

2. Health Surveillance, Health Studies, and Exposure and Disease Registries

Where appropriate, ATSDR will develop health surveillance programs which provide periodic screening of a defined population for a specific disease or biological marker of disease for which the population is at significantly increased risk. Health studies commonly use biological markers (biomarkers) that are indicators for exposure, susceptibility, or adverse health effects for the study of health effects resulting from exposures to low concentrations of contaminants. The National Exposure Registry comprises chemical-specific subregistries 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. ATSDR and DOE may agree to conduct other nonmandated activities related to public health and hazardous substances at the discretion of the two agencies.

3. **Toxicological Profiles and Toxicologic Research**
   ATSDR will prepare and revise a priority listing of toxicants released in the past and present from the DOE sites, and prepare toxicological profiles for those elements and radioactive isotopes which are of most public health interest. Toxicological profiles identify the full range of health effects from exposure to particular substances and identify data gaps for which additional research is needed. ATSDR shall assure the initiation of research on the combined toxicity of radionuclides and nonradioactive chemicals that appear at the DOE sites.

4. **Health Education and Promotion**
   ATSDR's environmental health education and promotion program provides a comprehensive approach to health education, environmental disease prevention, health promotion, and public health practice. ATSDR will develop and implement strategies and programs to promote health and provide information and training for reducing exposure, illness, or disease-related hazardous substances in the environment. As a part of its broader prevention program, ATSDR will provide community-based environmental health interventions to interdict exposures, prevent adverse health effects, and develop public health partnerships for ensuring the public health response.

5. **Emergency Response**
   ATSDR will provide proactive and supportive emergency public health response resources. ATSDR works with the National Response Team in developing and implementing emergency planning and preparedness activities. These activities ensure that ATSDR participate in the establishment and maintenance of an effective response infrastructure that emphasizes prevention and rapid response. ATSDR will also participate in the DOE scheduled emergency response training exercises.

C. DOE

The Department's Office of Environment, Safety and Health (ES&H) is responsible for the management of this MOU. DOE responsibilities are specifically set out in other sections of the MOU.

VI. Agenda for Public Health Activities at DOE Sites

DOE and HHS have developed a coordinated and coherent draft public health agenda that includes stakeholder involvement. The public health agenda, with continued stakeholder input, will be expanded into a 5-year plan that will be updated annually to guide activities conducted under this MOU beginning in fiscal year 2001.

VII. Protection of Human Subjects

All projects conducted under this MOU that involve human subjects shall comply with Federal Regulations and DOE Orders (45 CFR Part 46; 10 CFR Part 745; DOE Orders 1300.3, 481.1C) to protect human subjects. Additional guidance for health studies conducted under this MOU are detailed in the agreement between HHS and DOE. This agreement can be found as Appendix 2 in the "Access Handbook, Conducting Health Studies at the Department of Energy Sites."

VIII. HHS Advisory Committees

A. Advisory Committee on Energy-Related Epidemiologic Research (ACERER)

HHS will continue to support ACERER to provide advice to the Secretary of HHS in recommending research approaches and a research agenda, and in conducting the research program. Members of the advisory committee will consist of individuals 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., American Indian Tribes, workers, community residents). Both HHS and DOE will have nonvoting members on this committee.

ACERER's mandate as an advisory committee is to attempt to ensure that Federal research in this field is commissioned and conducted in a manner that is scientifically sound and publicly credible. The ACERER advisory process shall include stakeholder and public input via the ACERER subcommittee on community affairs or other mechanism established by ACERER.

HHS will propose a draft research agenda to the ACERER for its advice and recommendations on energy-related epidemiologic studies to be conducted under this MOU. ACERER also will consider information and proposals from DOE, other agencies, and organizations to be conducted under this MOU. DOE's comments will include an assessment of the priority to be given to each research project based on DOE's health research needs.

B. ATSDR Board of Scientific Counselors

ATSDR's Board of Scientific Counselors is authorized by the Public Health Service Act (42 U.S.C. 217a, Section 222) and is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

In accordance with its charter, ATSDR's Board of Scientific Counselors will continue to provide advice and guidance to the Secretary of HHS, the Assistant Secretary for Health, and the Administrator, ATSDR, on ATSDR's public health activities mandated

under Section 104(i) of CERCLA and other Federal environmental statutes to ensure scientific quality. In addition, the Board shall recommend research programs and conference support for sites for which ATSDR seeks funding to universities, colleges, research institutions, hospitals, and other public and private organizations. DOE may participate in the development of ATSDR' s program activities by suggesting issues for discussion with the Board of Scientific Counselors through ATSDR's Office of Federal Programs.

Any energy-related epidemiologic research projects identified by ATSDR will be referred to CDC for development of coordinated site plans and to the HHS ACERER for consideration as part of the energy-related health research agenda.

C. Health Effects Subcommittees

CDC and ATSDR have established the Citizens Advisory Committee on Public Health Activities at DOE Sites. The committee may consist of up to six health effects subcommittees chartered under the Federal Advisory Committee Act to provide advice to CDC and ATSDR about public health and research activities conducted by CDC and ATSDR at DOE sites. Subcommittees have already been established at the DOE Hanford site, Idaho National Engineering and Environmental Laboratory, Savannah River Site, and Fernald Environmental Management Project.

IX. Data Management

HHS will be responsible for the management of all data collected by HHS employees, its contractors, grantees, and cooperative agreement holders, including data obtained from DOE and its contractors. HHS shall ensure that any reviews of record systems containing personally identified data, undertaken as a basis for study project/protocol development, are reasonably limited in scope and duration and that information collected is directed to preparation of forms and procedures for use in such project/protocol plan(s).

HHS will maintain the necessary Privacy Act systems of records for information provided to HHS by DOE. HHS will explore revisions to their systems of records to include routine use by DOE of information necessary for DOE's ES&H responsibilities for Federal and contractor employees.

Information provided to HHS under this agreement may be made available by HHS in response to requests under the Freedom of Information Act (5 U.S.C. Section 552) and implementing regulations (45 CFR Part 5).

HHS will only use or disclose any personally identifiable information obtained from DOE or its contractors as permitted by Federal law. HHS will not use information in an identifiable form to make any determination about the rights, benefits, or privileges of any individual. To the extent consistent with the Federal Privacy Act, DOE regulations and contracts, and

agreements between DOE and its contractors, DOE will allow HHS and its agents with appropriate security clearances access to all DOE and DOE-owned facilities for the purpose of independently reviewing or collecting information or samples that HHS determines are necessary for conducting work under this MOU. DOE and HHS will work together to develop contract clauses to be added to DOE contracts to ensure the DOE contractors collect and maintain information needed to perform the research under this MOU, and HHS and its agents have the necessary access to that information.

DOE and HHS have jointly prepared a handbook, "Access Handbook: A Guide for Conducting Health Studies at DOE Sites," to be used as a reference guide to facilitate access to DOE sites by researchers and investigators. DOE and its contractors shall continue to maintain documents, records, record systems, and other information sources for the conduct of epidemiologic research. The moratorium on the destruction of DOE and DOE-contractor records relevant to the conduct of epidemiological studies at DOE sites shall remain in effect.

DOE will revise current and future regulations, systems of records, and contracts and agreements, as necessary and appropriate, to accommodate use by HHS under this MOU.

HHS personnel with appropriate security clearances may review documents and data, both classified and unclassified, necessary for studies and public health activities. DOE will, wherever possible, declassify or downgrade these documents and data for use by HHS.

X. Release of Results

HHS, jointly with DOE, will promptly disseminate results obtained through work carried out under this MOU to the populations being studied in accordance with the communication plan being developed jointly by DOE and HHS.

After HHS studies have been completed, study data will be made available to the Comprehensive Epidemiologic Data Resource (CEDR), without personal identifiers, subject to the provisions of the sections above. The data, with appropriate documentation, will be provided to CEDR without personal identifiers no later than 6 months after the completion of the study, or at termination of a contract, grant, or cooperative agreement, whichever occurs first. DOE will also solicit input from HHS on CEDR's continuing development and expansion. For reports routinely available through ATSDR's website, the Internet address will be provided to CEDR to link the two websites.

XI. Administration of the MOU

CDC and ATSDR will continue to provide complete fiscal and progress reports to DOE on a quarterly basis.

HHS designates the following individual as the official point of contact for this MOU:

Name:	Jeffrey Koplan, M.D.
Titles:	Director, Centers for Disease Control and Prevention, and Administrator, Agency for Toxic Substances and Disease Registry
Address:	1600 Clifton Road, NE, Atlanta, GA 30333
Telephone:	(404) 639-7000; Facsimile (404) 639-7111

DOE designates the following individual as the official point of contact for this MOU:

Name:	David Michaels, PhD, MPH
Title:	Assistant Secretary for Environment, Safety and Health
Address:	U.S. Department of Energy, Washington, DC 20585
Telephone:	(202) 586-6151; Facsimile (202) 586-0956

A. Resources

DOE will provide and transfer resources to CDC and ATSDR for the purpose of conducting activities under this MOU. Activities will be based on the agenda for public health activities at DOE sites and subsequent 5-year plan, and will focus on those areas of greatest public health concern identified in the planning process.

Annually, CDC and ATSDR will provide to DOE a description and justification of funding for submission to the Office of Management and Budget (OMB) and Congress for studies and public health activities planned under this MOU. These submissions will be provided by CDC and ATSDR to DOE in an agreed upon timeframe that is consistent with DOE's budget cycle. A request for resources for these activities will then be forwarded by DOE to OMB for inclusion in the President's budget.

DOE will notify CDC and ATSDR of the amount requested and, at the earliest opportunity, notify HHS of the amount appropriated. Funds will be transferred annually through an interagency agreement that outlines the planned activities for that fiscal year. Upon mutual agreement, resource levels may be amended at any time during the fiscal year. Any requirement for payment or obligation of funds by DOE established by the terms of this agreement shall be subject to the availability of appropriated funds.

CDC and ATSDR will not accept responsibility for or undertake any new programs or activities unless the mutually agreed level of resources is sufficient to achieve the intended goals and objectives. Activities will be undertaken after all parties agree upon a level of resources to support the intended goals and objectives. If equipment is procured by CDC or ATSDR to provide service under this MOU, these agencies will retain title to the equipment.

B. Compliance with CERCLA

This MOU is written with the understanding of both parties that this agreement is not intended to restrict, circumvent, or limit compliance with CERCLA Section 120 (42 U.S.C. Section 9620) relating to the application of CERCLA to Federal facilities.

C. Duration of Agreement

This agreement, effective when signed by both parties, shall initially remain in effect through Fiscal year 2004, unless amended by mutual, written consent of both parties, or canceled. There is every intention to renew this agreement after 5 years.

D. Modification or Cancellation

This agreement, or any of its specific provisions, may be revised by signature approval of both parties. Cancellation of the agreement may be accomplished by a 90-day, advance written notification by either HHS or DOE.

DOE, CDC, and ATSDR may mutually agree in the future to extend health research and public health activities to potential hazards resulting from nonnuclear energy production and use.

XII. Responsible Officials

DEPARTMENT OF ENERGY	DEPARTMENT OF HEALTH AND HUMAN SERVICES
By:_____	By: _____
Bill Richardson	Donna Shalala
Secretary	Secretary
Date:	Date: