DOE/EH–0556

ACCESS HANDBOOK

Conducting Health Studies at Department of Energy Sites

U.S. Department of Energy
Office of Health Studies
Washington, D.C.

2003

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FREQUENTLY USED ABBREVIATIONS

AEC	Atomic Energy Commission
ATSDR	Agency for Toxic Substances and Disease Registry
CDC	Centers for Disease Control and Prevention
CEDR	Comprehensive Epidemiologic Data Resource (database managed by EH-6)
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
DSHEFS	NIOSH Division of Surveillance, Hazard Evaluations, and Field Studies
DOE	Department of Energy
ECI	Export Controlled Information
EH	DOE Office of Environment, Safety and Health
EPA	Environmental Protection Agency
ERDA	Energy Research and Development Administration
ES&H	Environment, Safety and Health
FOIA	Freedom of Information Act
HERB	NIOSH Health-Related Energy Research Branch
HHS	Department of Health and Human Services
IRB	Institutional Review Board
MED	Manhattan Engineer District
MOU	Memorandum of Understanding
NCEH	National Center for Environmental Health
NIOSH	National Institute for Occupational Safety and Health
NNSA	National Nuclear Security Administration
NPL	National Priorities List
OHRP	Office for Human Research Protection
PHA	Public Health Assessment
RSB	NCEH Radiation Studies Branch
UCNI	Unclassified Controlled Nuclear Information

1. PURPOSE

The purpose of this handbook is to outline procedures that facilitate access to information needed for conducting public health activities at Department of Energy (DOE) sites. The handbook is intended for use by public health officials conducting studies and by personnel at DOE sites who are responsible for making the requested information available.

2. INTRODUCTION

DOE funds a diverse program of public health activities designed to increase understanding of the health effects of radiation, chemicals, and other hazards to workers and to the public that are related to current and past operations of its facilities. The major components of this research program are:

- A Memorandum of Understanding (MOU) with the Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) for epidemiologic studies of occupational and public health risks and other public health activities.
- Grants to State health departments to address citizen health concerns associated with DOE facilities.
- Medical surveillance studies of current and former workers at DOE sites.
- A program to determine the feasibility of evaluating the health of former workers at DOE sites.

Note to the Reader: The use of the term "public health official" throughout this document refers to public health professionals and researchers who study the past, present, and future impacts that a DOE site and its associated activities may have upon workers, the community, and its inhabitants. Public health officials may be employed by a variety of organizations, including local, State, or Federal government agencies, academic institutions, non-profit organizations, and contractors.

3. CONDUCTING A PROJECT/STUDY OR PUBLIC HEALTH ACTIVITY AT A DOE SITE

The information in this section describes the steps to be followed when conducting a health study/public health activity at a DOE site. The project checklist on page 23 summarizes these steps. For further guidance on health studies conducted under the MOU between the DOE and HHS see Appendix 2. Specific CDC and ATSDR guidance on institutional review board (IRB) procedures and requirements are outlined in Appendices 3 and 4. DOE-wide central IRB to address human subjects in beryllium research is outline in Appendix 5.

The following section provides additional background information only and does not necessarily apply to CDC and ATSDR.

A. Protecting Human Research Subjects

All research conducted at DOE facilities, supported by DOE funds, performed by DOE employees, or involving former or current DOE or contractor employees as subjects, must comply with Federal regulations and DOE orders to protect human subjects. Human subject's research includes a broader range of research than many investigators and program managers may realize. In addition to traditional biomedical and clinical studies, human subjects research may include studies that:

- Use humans to test devices, products, or materials that have been developed through research, including human-machine interfaces.
- Use data collected through intervention or interaction with individuals. Intervention includes physical procedures (such as drawing blood) and also includes the manipulation of a subject's environment. Interaction involves interpersonal contact and other means to collect information.
- Use existing information that can be readily identified with individuals, even if the information was not collected specifically for the study in question.
- Use bodily materials such as cells, blood, urine, tissues, organs, hair, and nail clippings even if the public health official did not collect these materials.
- Use humans to evaluate environmental alterations—for example, weath Gerization options or habitat modifications.

The Federal Policy for the Protection of Human Subjects is called the Common Rule. For DOE, it is codified in Title 10, Code of Federal Regulations (CFR), Part 745 (10 CFR 745). (For HHS, the Common Rule is found at 45 CFR 46.) The primary DOE authority for protection of human subjects is DOE Order 443.1, Policy on the Protection of Human Subjects. DOE Order 4300.2C, Work for Others, also governs protection of human subjects in research that is conducted by DOE or in DOE facilities but is funded by sources other than DOE. The DOE Human Subjects Research Handbook contains the full text of these regulations and orders.

Some activities funded by DOE, such as public health assessments, community health education, and health professions education, are not considered research and not subject to IRB approval. The following discussion of the IRB approval process is not applicable to such activities.

Before health studies can be undertaken, 10 CFR 745 requires that the project or protocol be reviewed and approved by an IRB to determine whether subjects are at risk and, if so, whether the risk is acceptable. For

studies conducted by HHS entities, the HHS IRB is the responsible IRB. However, for health studies conducted at DOE sites, review by a site IRB is also desirable. This local IRB can best evaluate the particular circumstances of the research setting and weigh critical considerations, such as local professional and community standards, the availability of alternative sources of treatment, institutional policy and resources, and the needs of differing subject populations.

For studies that, either wholly or in part, address issues involving the health effects of exposure to beryllium, DOE's central beryllium IRB is responsible for final IRB review and approval of human studies protocols. (See Appendix 5).

Once a researcher has received funding to conduct a health study at a DOE facility, the researcher must submit the study protocol, including applicable informed consent statements and documentation of other IRB reviews, to the chair of the DOE site IRB. If the study is to be conducted at multiple DOE facilities, each site IRB must be provided with the materials necessary for its review and approval. Specific guidance for HHS IRB requirements is located in Appendices 3 and 4.

Following protocol approval by the DOE site IRB, the IRB chair will place a copy of the study protocol, IRB documentation, and any associated material in the site's DOE public reading room to make this information available to the public.

Additional information on protecting human research subjects can be found in the following:

- Protecting Human Subjects and Research Homepage, at http://www.science.doe.gov/ober/humsubj/hsindex.html
- The DOE Human Subjects Research Handbook at http://www.science.doe.gov/ober/humsubj/handbook.htm
- Protecting Human Subjects Newsletters http://www.science.doe.gov/ober/humsubj/newslett.html
- NIH's OPRR 1993, Protection of Human Research Subjects Institutional Review Board Guidebook http://orhp.osophs.dhhs.gov/irb/irb_guidebook.htm)

To obtain hard copies of the DOE human subject's research materials, contact the Office of Science, Office of Biological and Environmental Research, SC-72, Germantown Building, 1000 Independence Ave., Washington, DC 20585-1290, telephone 301-903-4731, email: humansubjects@science.doe.gov.

B. Roles and Responsibilities in Conducting Research and Public Health Activities Pertaining to DOE Facilities

DOE Headquarters offices, along with a nationwide network of field offices, including regional Operations Offices and Area Offices, have differing roles and responsibilities with respect to the conduct of health studies and public health activities.

The Office of Health Studies (EH-6) serves as the point-of-contact for epidemiologic studies and public health activities, including those covered by the MOU with HHS and the Former Workers Medical Surveillance Program studies.

The DOE Operations or Area Office with contractual responsibility for the site chosen for research is responsible for obtaining contractor support for health-related studies as part of its environment, safety, and health (ES&H) activities and for arranging access to the site and site contractors. Only the designated DOE Contracting Officer can direct the contractor to interact with public health officials. Public health officials must understand this organizational structure when seeking access to DOE site information.

1. DOE Headquarters Offices

- Serve as the primary point-of-contact within DOE for health studies or other public health activities.
- Provide information to DOE elements concerning health studies or other public health activities.

a. EH Office of Health Studies

- Prepares notice of worker health studies to be distributed to all employees by the Operations Office when an epidemiologic study is to be undertaken.
- Coordinates introductory site visits.
- Coordinates meetings and facilitates dispute resolution.

b. Headquarters Security Offices

- Develop and implement procedures to facilitate access to classified information and documents.
- Manage declassification requests under the requirements of DOE orders.
- Manage large-scale declassification projects.
- Facilitate review of classified information for use in health-related activities.
- Work with supporting agency's security office to obtain clearance for investigators.
- Arrange access to National Nuclear Security Administration sites and classified document repositories.

c. Other Headquarters Offices (as appropriate)

- Coordinate field support through the lead program secretarial office.
- Resolve issues relating to availability and level of support for research activities.
- Review and comment on site-specific access requests from public health officials.

2. DOE Operations Offices, Area Offices, and Site Offices

(See Tara O'Toole memorandum dated October 10, 1995, to DOE Operations and Area Office Managers, Appendix 2.)

- Distribute study notices prepared by EH to workers and communities.
- Place study notices in and supplemental materials in the DOE public reading room.
- Designate a DOE ES&H point-of-contact for each study or public health activity.
- Ensure physical access to the site:
  - facilitate badging
  - arrange for the use of equipment owned by public health officials
  - establish site entry and egress procedures for equipment owned by public health officials, as well as for samples collected onsite.
  - locate workspace for public health officials.
- Participate in and support the introductory site visit.
- Provide samples of records to public health officials.
- Provide information on current and historical site operations and background information, such as plant directories and organization charts.
- Provide descriptive information about records at the site, as well as records stored at Federal Records Centers and other offsite repositories.
- Provide support for locating, accessing, and interpreting records, observing work and processes, collecting exposure data, and talking privately with workers.
- Develop and implement procedures for access to classified and sensitive information and for declassification of records.
- Notify public health officials of difficulties in providing requested assistance.
- Identify and help resolve access issues.
- For worker studies, provide a communications point-of-contact and logistical support for distribution of updates and final results to current and former workers.
- For community studies and other public health activities, provide a communications point-of-contact and logistical support for distribution of updates and final results to current and former workers and the community.

3. Site Points-of-Contact

Site points-of-contact will include individuals from the DOE Operations or Area Offices and from relevant DOE contractors at each study site. Points-of-contact should be identified very early in the process, ideally before the introductory site visit. In most cases, the following DOE or contractor organizations should participate:

- Environment, Safety and Health
- Operations, Area, and Site Office Manager
- Records Management and Privacy Act
- Human Resources and Personnel
- Classification and Security
- General Counsel
- Radiological Protection and Industrial Hygiene.

4. Public Health Officials

a. Public Health Officials will be responsible to the Operations or Area Office as follows:

- Minimize the impact of the visit and avoid duplication of effort.
- Safeguard classified, sensitive, and Privacy Act-protected information.
- Comply with all site safety procedures during onsite activities.

- Prepare and deliver information about planned activities for sites.
- Coordinate introductory and subsequent site visits. Provide advance requests that outline requirements for site support not covered in this handbook.
- Provide advance requests for permission to bring specific equipment onsite.
- Work with sponsor and site communications point-of-contact to inform current and former workers and the community of study results.

b. Public Health Officials will provide EH with the following, as applicable:

- A copy of the study proposal.
- A copy of the human subjects review documents with approvals.
- The request for the introductory visit.
- A description of planned introductory site visit activities.
- Points-of-contact for the study.
- Notice of site support activities that could not be resolved in the field.
- Electronic data files and supporting documentation consistent with Comprehensive Epidemiologic Data Resource (CEDR) format after the research study is completed.

c. For studies that involve human subjects, the public health official will provide the site IRB with the following (not applicable for Public Health Assessments and Health Education activities):

- A copy of the study proposal.
- A copy of human subjects review documents with approvals.

d. The public health official will be responsible for costs associated with site data collection, including:

- Travel to site for introductory and subsequent site visits.
- Preparing site-specific material.
- Copying, filming, or scanning of records to create hard copy/microfilm/microfiche/ optical/electronic images (sample records may be collected without costs to the researcher/public health organization).
- Abstracting data from records.
- Site computer costs to copy files or create new files.
- Costs of technical support that may be required, such as dosimetry calculations.
- Copying of materials for distribution at the site.
- Long distance telephone charges generated at the site.
- Preparing files for inclusion in CEDR.
- Any additional site support requested of the site beyond that listed under site responsibilities.

The public health official will be not be responsible for costs associated with documents required for a Public Health Assessment or Health Consultation conducted by ATSDR. Documents will be provided by the site at no cost to ATSDR.

(For additional information See Charles B. Curtis, Deputy Secretary, DOE, memorandum dated April 15, 1997, to the DOE Secretarial Officers and Operations Office Managers, Appendix 2.)

C. Recordkeeping at the Department of Energy and its Predecessors

To carry out studies and other public health activities, public health officials require access to records and data in the custody of DOE and its contractors. DOE is committed to making records fully available for research and public health activities, taking into account legal requirements relating to privacy and classification.

A number of factors relating to DOE recordkeeping practices and culture affect access to records at DOE sites and should be understood by public health officials working at those sites.

- DOE and its predecessor agencies—the Manhattan Engineering District, the Atomic Energy Commission, and the Energy Research and Development Administration—have primarily used contractors to carry out the work at field sites. The site contractors have traditionally operated with a great deal of independence and continue to do so today.
- As a consequence of this independence, recordkeeping practices and procedures for accessing records often differ significantly from site-to-site. However, all sites and site contractors must conform to basic Department-wide requirements for records access.
- Not all records at DOE sites are Federal records. Some records may belong to contractors and therefore are not subject to laws governing the management of and access to Federal records. Rather, a contractor's records are governed by the specific terms of its DOE contract. DOE contracts contain clauses that provide the right of access to DOE-related contractor records that are required for health studies and/or public health activities.
- As a result of differing management practices among contractors, as well as the pressures of nuclear weapons production during the Cold War, the recordkeeping process was neglected and some records left Government custody. These factors, combined with general problems in recordkeeping that exist across the Federal Government, mean that records sought by public health officials may be difficult and time-consuming to retrieve. In some cases, the records may no longer exist. Experience suggests that data collection generally takes more time than the public health official's estimate.
- Born out of the Manhattan Project, the Department and its predecessor agencies operated in a culture of secrecy for many years. Access to sites and records was, and in some cases is, limited for reasons of national security. Public health officials should be aware that some of the records needed for their studies might be classified. In the past, many DOE records were classified at the time they were created ("born classified"), and some have not yet been reviewed for declassification. DOE is committed to ensuring that declassification requests for health studies are met in a timely fashion. However, declassification is a time-consuming and labor-intensive process and project schedules must include lead-time for document declassification. Public health officials should understand that while the Department's commitment to openness is immediate, the measures necessary to provide access may be slow relative to the timeframe of a study.
- The Department is confident that difficulties associated with access can be resolved through the use of the guidelines set forth in this handbook. DOE officials should be sensitive to the fact that health studies are generally carried out under a grant or contract with very specific time constraints. For access to be meaningful, it must be provided in a timely fashion.

D. Privacy Act and Classified Information

The Privacy Act of 1974 governs access to DOE-owned records that contain personal identifiers. DOE has established Privacy Act systems of records that entitle access to, and review of, all necessary Privacy Act records by authorized public health officials. Records owned by DOE contractors that contain personal identifiers will be made available to health researchers under the access authority of the ownership-of-records clause of the governing contract. The provisions of the Privacy Act govern only public health officials who are Federal employees and contractors. Public health officials funded by grants are not bound by the Privacy Act but must sign an agreement with the agency sponsoring the grant. When researchers obtain a security clearance, they sign an agreement to comply with the procedures specified for classified or controlled information.

DOE Privacy Act Systems of Records for Which Public Health Officials Are Approved as Routine Users

DOE-01, DOE Personnel and General Employment Records
DOE-05, Personnel Records of Contractor Employees
DOE-10, Worker Advocacy Records
DOE-13, Payroll and Leave Records
DOE-15, Payroll and Pay-Related Data for Employees of Terminated Contractors (excluding disciplinary actions)
DOE-33, Personnel Medical Records (including industrial hygiene information)
DOE-35, Personnel Radiation Exposure Records
DOE-36, Statistical Analysis Using Personnel Security Questionnaire (Health and Mortality Study, including only work history and education portions)
DOE-38, Occupational and Industrial Accident Records
DOE-40, Contractor Employees Insurance Claims
DOE-67, Participants in Experiments, Studies, and Surveys (Hanford site only)
DOE-71, The Radiation Accident Registry
DOE-72, The Department of Energy Radiation Study Registry
DOE-73, The US-DTPA Registry

Detailed descriptions of each of these systems of records can be found in the Federal Register, 60 FR 33510 and 64424. These systems are not found at every DOE site. Each system is subject to different record retention requirements.

CATEGORIES OF CLASSIFIED OR CONTROLLED INFORMATION

Classified Information

CATEGORY	LEGAL BASIS	"LEGAL" DEFINITION	TYPES OF INFORMATION
Restricted Data (RD) includes: weapons data nuclear materials production data of special nuclear material; production	Atomic Energy Act of 1954, as amended	All information concerning (1) design, manufacture, or utilization of atomic weapons; (2) the production of special nuclear material; (3) the use of special nuclear material in the production of energy.	Nuclear weapon designs • Nuclear material production • Naval nuclear propulsion
Formerly Restricted Data (FRD) includes: weapons data nuclear materials production data of special nuclear material; production	Atomic Energy Act of 1954, as amended	Information jointly determined by the Departments of Energy and Defense to relate primarily to the military utilization of atomic weapons.	• Stockpile size • Yields • Storage sites of special nuclear material; production
National Security Information (NSI) includes special compartmentalized and intelligence data	Executive Order 12958	Information that has been determined by an Executive Order to require protection against unauthorized disclosure and that is so designated.	• Conventional weapons • Security systems • Foreign relations • Intelligence production

Controlled Information, Which May Be Classified, or Unclassified

Naval Nuclear Propulsion Information (NNPI)	42 U.S.C. 7158	Information concerning the propulsion plants of naval nuclear powered ships and associated nuclear support facilities.	May be classified or unclassified
Work for Others (WFO)	DOE Order 0481.1	Work for others is the performance of work for non-DOE entities by DOE/contractor personnel and/or the utilization of DOE facilities that is not directly funded by DOE.	May be classified or unclassified

Unclassified Controlled Information

CATEGORY	LEGAL BASIS	"LEGAL" DEFINITION	TYPES OF INFORMATION
Unclassified Controlled Nuclear Information (UCNI)	Atomic Energy Act of 1954, as amended	Certain unclassified sensitive information related to production or utilization facility design, safeguards and security measures, or previously classified nuclear weapons information.	Security plans • Facility designs • Certain isotope separation technologies
Official Use Only (OUO)	Other Freedom of Information Act exemptions	Certain unclassified but sensitive information that may be exempt from public release under the Freedom of Information Act.	• Privacy • Predecisional • Proprietary • OpSec
Export Controlled Information (ECI)	• Nuclear Non-proliferation Act • Arms Export Control Act • Atomic Energy Act of 1954, as amended • Export Administration Act of 1979, as amended	Information that may be of use to a nuclear proliferant.	Technologies useful to nuclear proliferants

What is Meant by "Access"?

"Access" to records and information gives public health officials the ability to do any or all of the following at a DOE site:

- Review record systems.
- Review classified material (for public health officials with appropriate security clearance).
- Take sample copies of records.
- Make copies necessary for research and other public health activities.
- Obtain copies of electronic records and the documentation necessary to understand them.
- Observe work and processes in progress.
- Talk privately with workers.
- Collect exposure data.
- Hold meetings with all interested parties.

E. Steps in Conducting a Study or Public Health Activity

This section explains the major steps in the process of planning and performing a study or public health activity.

When Does a Study or Public Health Activity Begin? A research study begins when an investigator (1) requests records from site officials; (2) requests permission to perform walk-through surveys; or (3) seeks permission to interview employees about their heath or working conditions. The public health activity under CERCLA 104.1 begins when a site is proposed for inclusion on the Environmental Protection Agency's (EPA) National Priorities List (NPL) or when the agency receives a petition to perform a Public Health Assessment (PHA) or other public health activity.

1. Notification of DOE by the Agency or Organization Sponsoring the Public Health Official

When DOE sites have been selected for a study, the agency supporting the study will provide written notification to the DOE Office of Health Studies.

The notification will include a list of researchers and other public health officials needing access to DOE facilities.

Notice of the initiation of new projects or research efforts will be shared in a timely fashion with partner agencies and with those impacted. Each agency will act in accordance with a project/study-specific communication plan as appropriate for the agency and activity.

2. Notification of the Site and the Workers

For each worker study at each site, the Office of Health Studies will prepare a notice that outlines the basic intent of the study and lists contacts for additional information.

This notice will be sent to the DOE Operations Office for distribution to all current workers at the site. Data collection cannot begin before notices have been distributed at the site.

For studies that do not involve workers or their records, the Office of Health Studies will prepare a short notice that outlines the basic intent of the study and lists agency contacts for additional information. The notice will include a communications section. The communications section includes (1) the name and telephone number of the person responsible for communicating about the activity; (2) the expected frequency of communications; and (3) the place where notices of upcoming meetings will be posted or advertised. The notice will request that the site communications point-of-contact work directly with the agency point-of-contact.

If applicable for the specific activity, a copy of the study plan or protocol, IRB documentation, and any special local agreements will be provided by the researcher to the Office of Health Studies, the IRB chair at the site, and the DOE Operations Office that manages the selected site. The Operations Office will place copies of the documents in the DOE reading rooms.

3. Preliminary Site Visit

A preliminary site visit is required for all studies and public health activities. The Office of Health Studies will schedule and coordinate a preliminary site visit, working closely with the DOE Operations or Area Office ES&H point-of-contact. Participants in the meeting should include representatives from DOE, site contractors, organized labor, and public health officials involved in the project. Once a date has been established for the visit, the site office will initiate advance badging procedures for visitors and public health officials.

The preliminary visit ensures that all parties are provided information about the purpose of the public health activity and understand the process that will take place. It also establishes the lines of communication and cooperation essential to a successful investigation. During the preliminary visit, the parties will:

- Discuss work the plan for data collection and identify information needs of public health officials.
- Determine appropriate technical contacts at the DOE Operations or Area Office and among DOE contractors.
- Gather preliminary information relevant to the research or public health activity.
- Discuss procedures.
- Identify potential issues requiring resolution.

As a result of the initial site meeting, the DOE Operations or Area Office will designate a DOE site point-of-contact and the public health official will designate a lead point-of-contact. When contractors, cooperative agreement holders, or grantees are conducting research or other studies, a point of contact will be designated at the sponsoring agency.

4. Site Work Plan

After the initial meeting, the lead researcher or public health official will work with the DOE and site points-of-contact to acquire the information needed to perform the public health assessment, research study, or other public health activity. Continuing discussion between participants may include the following topics:

- Estimated timetable for completion of major tasks.
- Identification of resources needed from the site.
- Agreements from the site regarding the availability, time commitment, and roles of DOE and contractor personnel.
- Progress in receiving previously requested data and information.
- Identification of additional information needs.
- Requirements for document declassification, security clearances, and special training.

5. Site Access Requirements

Each DOE site is unique. Access procedures may vary from site to site, depending on the contract with DOE and the work conducted at that site. Authorization is generally required for entry to certain areas of many DOE sites. At some sites, it may be necessary for public health officials to attend special training sessions before site access is granted.

Special arrangements must be made with the site point-of-contact to bring equipment onsite. Approval of such requests may be governed by Federal regulations or by the requirements of the specific site.

6. Requests for Security Clearances

A public health official may require a security clearance to enter a DOE facility, parts of a facility, or to access certain records at the site. The level of access authorization, either "L" or "Q", is based upon work performed at the site or level of classified matter to be reviewed and will be determined through an evaluation of the public health official's needs with the sponsoring agency and with records managers at the DOE site. Applicants for "L" or "Q" access authorizations are subject to a Federal background investigation by the Office of Personnel Management or the Federal Bureau of Investigation. The time required for a clearance may take up to 12 months or longer.

If the applicant has an HHS security clearance at the appropriate level, DOE's Personnel Security Office has a process for quickly granting a DOE "Q" security clearance. Public health officials whose work is funded by CDC or ATSDR can apply for clearance through the HHS Security Office, which works with the DOE Personnel Security Office to obtain the necessary clearance.

If there is an immediate need for a Q-level clearance, the investigator may request an expedited "Q" access authorization, an Interim Access Authorization that requires a 2-day visit to a Federal site and involves drug testing, psychological evaluation, and a polygraph test.

Applicants who are not U.S. citizens cannot have access to certain categories and levels of classified matter.

7. Requests to Review Records

a) Unclassified Documents

To help public health officials identify records most pertinent to their work, as well as to minimize the impact of the data collection phase on DOE records personnel, requirements should be discussed with DOE and contractor records management staff prior to submitting formal, written requests. The DOE point-of-contact is responsible for coordinating such discussions. In general, public health officials are permitted to review any unclassified DOE-owned records that contribute to the successful completion of a study.

Once these introductory discussions have taken place, public health officials will submit written requests for records to the DOE site records management staff. All requests for records review will be made in writing, at the beginning of the study or at any time during the data collection phase. The response is coordinated through the DOE site point-of-contact and a copy of the request is sent to the Office of Health Studies. When possible, the written request should be in the form of itemized lists of specific records boxes or documents. Requests must be made at least 10 to 15 working days prior to a site visit. The site may require additional time to make needed materials available. Unclassified environmental data for public health assessments does not require a written request, but will be provided after discussion with the DOE site point-of-contact.

The DOE site records staff will coordinate each request with all affected site organizations, including notification of DOE and contractor staff if classified records are known to be included in the request. Site records staff will provide the public health official with a timely response to each request, confirming that the records are available for review or explaining why some or all of the requested information is unavailable.

Unclassified documents will be made available at the site for review. Documents stored offsite at Federal Record Centers and other repositories will be recalled to the site unless other arrangements are made through DOE records management staff.

It is the responsibility of DOE site records officials to determine the status of any records that have been checked out of a repository and to provide the requested records as soon as possible. If requested records cannot be located, the DOE site point-of-contact will promptly notify the Office of Health Studies and the public health official.

Requesters will be informed in writing if requested records have been destroyed according to approved procedures and authorized records disposition schedules, including the date of destruction.

b) Classified or Controlled Documents

DOE and contractor organizations having custody of classified material are required to work within the appropriate laws, regulations, and DOE orders when providing access to site records and when declassifying records to meet the needs of researchers and/or public health officials.

Public health officials with security clearances are considered to have the necessary "need-to-know" status for access to most site records. "Need-to-know" status means that a cleared individual requires access to classified information in the performance of official duties or to satisfy contractual obligations. The Office of Health Studies will provide verification of this status to the DOE office with custodial responsibility for the records, if necessary. Categories of records to which access may be restricted include Work for Others, Special Compartmentalized and Intelligence Information, Weapons Data and Nuclear Materials Production Data Information, Export Controlled Information, Unclassified Controlled Nuclear Information and Naval Nuclear Propulsion Information (see Section c below for more information on these types of records).

Within ten (10) working days, the site point-of-contact will notify the researcher, the Office of Security, and the Office of Health Studies of any potential delays pertaining to a request for access to classified documents.

Once a request to review classified documents has been processed by the site designee, the documents will be made available for review. Public health officials must plan their work so that the number of individuals requiring access to classified information is limited.

i) **Document Declassification**

Declassification activities for the study should be carried out according to the MOU between DOE and HHS. Periodic meetings should be held to evaluate progress and resolve problems.

Written requests to declassify, downgrade, or sanitize site documents will be submitted by the public health official to the DOE site point-of-contact. Sanitizing a document means removing (redacting) sensitive portions of a document to make it unclassified and available to the public. The Office of Health Studies also should be notified of any declassification requests.

If a document is outside the purview of the site declassification staff (i.e., the classified information relates to another agency), the DOE site point-of-contact will notify the Office of Health Studies for coordination assistance. The DOE site point-of-contact will also notify the public health officials in writing about the action and provide a time estimate for a decision.

The DOE site point-of-contact will provide a written explanation for any document that cannot be declassified.

ii) **Review of Notes, Papers, and Other Information Prepared or Duplicated at a Site**
All notes, papers, computer disks, recordings, photographs, copies, and other information prepared at a site by public health officials may be reviewed for classified or sensitive unclassified information before the materials are allowed to leave the site. Such review will be completed within ten (10) working days unless the material requires declassification or redaction. Materials containing nonsensitive, unclassified information will be released to the researcher; materials containing classified or sensitive information will be retained.

Materials containing classified information will be discussed with the public health official to determine whether it can be suitably redacted or declassified. The DOE point-of-contact will be notified if it cannot. If a mutually satisfactory resolution cannot be reached, the DOE point-of-contact will notify and request further assistance from the Office of Health Studies.

c) Documents with Special Access Requirements
The following types of information may require special procedures before access is granted. If access must be denied, the DOE point-of-contact will provide written notification within five (5) working days to the requester and to the Office of Health Studies, explaining the reason for denial and available appeals processes or other possible solutions.

i) **Work for Others**
A DOE site cannot release information about work done for other agencies, countries, or other DOE sites without the data owner's approval. The DOE site point-of-contact will notify the Office of Security and the Office of Classified and Controlled Information Review. The Office of Classified and Controlled Information Review will coordinate and request permission from other agencies or countries to grant access. For work performed for other DOE sites, the point-of-contact is the classification officer or other appropriate management official. If other countries or agencies refuse to permit disclosure, the request cannot be granted.

ii) **Special Compartmentalized and Intelligence Information**
Access to special compartmentalized and intelligence information, a category of classified National Security Information (NSI), must be authorized through DOE Headquarters and possibly through another Federal agency. The public health official will limit the number of security-cleared individuals requesting access to this sensitive information.

iii) **Weapons Data and Nuclear Materials Production Data Information**
Access to weapons data and nuclear materials production data information requires a security clearance through the Headquarters Support Division, NNSA. The DOE point-of-contact will coordinate the completion of the required form and its submission and review by the Security Support Division, which should respond within 15 working days. If processing of the form is significantly delayed, the site point-of-contact will notify the Office of Health Studies and the public health point-of-contact to request further assistance.

iv) **Export Controlled Information**
Most Export Controlled Information (ECI) does not raise proliferation or other national security concerns, such that it could not be publicly disclosed as part of the record of a health study. ECI deemed relevant and necessary for the study or public health activity by the public health official will be reviewed by the DOE program manager at the site to determine whether the value of the ECI to a country of national security concern or to a nuclear proliferant warrants that it be withheld from public disclosure. Every effort will be made to provide the information to public health officials. The Export Control Division will adjudicate any concerns or disputes about the identification and protection of ECI.

v) **Unclassified Controlled Nuclear Information**
Documents containing Unclassified Controlled Nuclear Information (UCNI) may have special access or handling requirements. The DOE records staff will provide details to the requester and the Office of Health Studies point-of-contact with regard to access to and control of UCNI.

vi) **Naval Nuclear Propulsion Information**
The Deputy Administrator for Naval Reactors must approve access to information regarding the Naval Nuclear Propulsion Program and naval nuclear powered vessels. Access is granted to U.S. citizens only.

F. Resolving Conflicts

If public health officials encounter problems that cannot be resolved by negotiation with officials at the DOE site, they should immediately notify, in writing, the Office of Health Studies and the HHS agency sponsoring their research or public health activity. The notification should include a detailed description of the problem; the efforts made to resolve it; and proposed solutions, if any.

Similarly, DOE site officials should immediately notify the Office of Health Studies, the public health official, and the sponsoring HHS agency of any difficulties that arise for the site that cannot be resolved at that level, particularly instances where requested support, records, or information cannot be provided to public health officials. This notification should include the nature of the request, the reason it cannot be met, and any proposed alternatives.

The Office of Health Studies, with the support of the sponsoring agency, other DOE ES&H officials, and representatives from the DOE Office of General Counsel, will mediate these disputes. As necessary, officials from other DOE line and staff organizations will be involved.

To build on past experience and identify potential problems, public health officials will be asked by their sponsoring agencies to provide regular assessments of how the research is proceeding at the site relative to the issues covered in this handbook. This information will be shared with the Office of Health Studies.

Similarly, DOE site officials, both Federal and contractors, will be polled regularly by the Office of Health Studies to determine how the process is working. The Office of Health Studies will share this information with senior officials in the Office of Environment, Safety and Health, with the public health official, and with the sponsoring agency.

STUDY OR OTHER PUBLIC HEALTH ACTIVITIES CHECKLIST

This is a checklist that serves as a quick reminder of tasks. It is not intended to be a list of responsibilities.

- ✓ Draft initial site visit plan.
- ✓ Obtain approval of Institutional Review Board, as appropriate
- ✓ Identify key individuals (management, worker, and union groups).
- ✓ Arrange for key individuals to participate.
- ✓ Arrange special side meetings between key individuals.
- ✓ Identify requirement for worker time away from job.
- ✓ Approve worker time away from job.
- ✓ Notify Records Management officials of special records requirements.
- ✓ Determine availability of requested records.
- ✓ Arrange for sample of requested records to be made available.
- ✓ Apply for security clearances and arrange for ID badges.
- ✓ Provide previsit site questionnaires.
- ✓ Approve site questionnaire effort and complete site survey.
- ✓ Identify equipment to be brought onsite.
- ✓ Obtain property passes for equipment to be brought onsite.
- ✓ Identify classified information issues.
- ✓ Refer classified information issues to Operations Office.
- ✓ Prepare declassification plan.
- ✓ Arrange required facility-specific training.
- ✓ Identify space and equipment needs.
- ✓ Arrange for space and equipment needs.
- ✓ Agree on assignment of costs.
- ✓ Complete initial site visit plan.
- ✓ Conduct initial site visit.
- ✓ Complete and sign facility-required agreements.
- ✓ Prepare communication plan to report results to workers.
- ✓ Agree on site work plan.
- ✓ Complete security training.
- ✓ Complete and distribute site work plan.

- ✓ Report results.

APPENDIX 1:
CDC/ATSDR ORGANIZATIONS AND ACTIVITIES

CDC/ATSDR Health-Related Research Conducted for the Department of Energy

The CDC energy-related research program seeks to create an interdisciplinary approach in which occupational and environmental health studies, exposure assessment and dosimetry, health communication, and community or worker-based involvement efforts work in unison to answer questions about the potential public health effects of DOE-related radiation and chemical exposures. The research and public health activity priorities have been to address the historical operations of the nuclear weapons complex, to quantify community or worker exposures, and to study possible health effects of those exposures. The advancement of science in radiation and/or chemical exposure is aimed at quantifying the risk to population groups who were exposed to radiation and/or chemicals as a result of having lived around or having worked in the DOE nuclear weapons complex. The information gained may assist in the adjustment of radiation and chemical exposure standards by regulatory or advisory groups. This knowledge may also improve our capability for early detection and prevention of future radiation and chemically related cancers and other diseases.

NCEH

In 1980, as an expression of its commitment to solving health problems related to the environment, CDC established the Center for Environmental Health to focus on preventing disability, disease, and death due to environmental factors. In 1991, "National" was added to the center's name to reflect the breadth of its activities. The National Center for Environmental Health (NCEH), located in Atlanta, employs approximately 100 personnel dedicated to carrying out a national environmental health program. In addition to ongoing research into the health effects of environmental hazards, NCEH provides immediate response to requests for assistance from States and countries throughout the world to investigate outbreaks of noncommunicable diseases. It operates a world-class laboratory that measures toxicants and their effects on people. NCEH is a leader in determining the health effects on humans of numerous environmental hazards, both technological and natural.

NCEH, within its Division of Environmental Hazards and Health Effects, established the Radiation Studies Branch (RSB) to conduct the environmental health research component of the program. The RSB is structured to ensure an interdisciplinary approach that links community involvement, environmental dosimetry, radiation epidemiology, health risk analysis, and health communication.

In general, HHS/Public Health Service/CDC has legislative authority under Section 301(a) of the Public Health Service Act (42 U.S.C. sec. 241) to conduct research into the health effects of a broad range of environmental hazards and to cooperate with other appropriate authorities in the conduct of such research. As an agency within CDC, NCEH conducts health research and related studies at DOE facilities. The studies are organized into three (3) general categories: community-based environmental dose reconstruction, risk analysis, and epidemiologic research.

I. Environmental Dose Reconstruction

The purpose of environmental dose reconstruction is to determine whether past releases of radiation and chemicals might pose a health risk to the community. The goal is to develop a complete historical record of radiation and chemical releases, demographic and lifestyle information for persons in surrounding communities, and pathways by which persons living in surrounding communities may have been exposed. This information may be used to estimate individual doses that these persons may have received or to assess the feasibility of an epidemiologic study at a site.

II. Risk Analysis

The goal of risk analysis is to comprehensively determine potential health risks associated with ionizing radiation exposure and hazardous materials and effectively communicate this knowledge to the public. Risk analysis is conducted using well-established statistical models and methods and may include data from environmental dose reconstruction and epidemiologic activities. State-of-the-art dose-estimation methods and geographic analysis of public health data enhance these study methods. Information from the risk analysis is provided to the public in such a way as to both inform and empower potentially affected citizens in evaluating their exposure-related risks.

III. Epidemiologic Research

The purpose of energy-related environmental epidemiologic research is to determine whether there are associations between past radiation and chemical exposures and adverse health effects in communities located around DOE sites. Epidemiologic studies must be both scientifically credible and reflective of concerns that community residents have relative to the possible health effects of radiation and chemical exposures. Historical records, on the occurrence of disease (incidence and/or mortality) in these communities, are compiled and analyzed to determine if the rates of disease in the exposed population are greater than those in an unexposed population. Epidemiologic studies may be used to assess relationships between individual exposures to either radiation or other chemical or physical agents and the occurrence of cancer and other diseases.

NIOSH

In 1970, Congress passed the Occupational Safety and Health Act "to assure, so far as possible, every working man and woman in the Nation safe and healthful working conditions." The Act created the National Institute for Occupational Safety and Health (NIOSH) to identify the causes of work-related diseases and injuries, evaluate the hazards of new technologies and work practices, create ways to control hazards so that workers are protected, and recommend occupational safety and health standards. NIOSH and its staff of about 1,300 are part of the CDC within the HHS. Headquartered in Washington, DC, NIOSH has offices in Atlanta, GA., and research divisions in Cincinnati, OH., Morgantown, W VA., Bruceton, PA., and Spokane, WA.

NIOSH, within its Division of Surveillance, Hazard Evaluations, and Field Studies (DSHEFS), established the Health-Related Energy Research Branch (HERB) to conduct the occupational health research component of the program. NIOSH researchers are committed to the continuing development and implementation of a research agenda that addresses the needs of the workers in the DOE system, as well as those of the radiation research community. The NIOSH agenda has been developed with input from a variety of sources, including experts from different research fields and representatives from labor and community organizations.

In general, NIOSH has authority, pursuant to 29 U.S.C. sec. 669(a), to conduct health hazard evaluations (Part 85). NIOSH regulations at 42 CFR 85 and 85a govern the conduct of such projects, including provisions for initiation and conduct of investigations, interviews of employees, use of space provided by the employer, and access to the employer's records and facilities. Although these regulations do not apply to DOE, DOE seeks to ensure NIOSH access to DOE facilities consistent with these regulations.

NIOSH health research and related activities at DOE facilities are organized into two broad categories: occupational health studies and site surveys. Each category contains a variety of research approaches with specific goals.

I. Occupational Health Studies

The purpose of occupational epidemiologic research is to determine whether workers have experienced excessive mortality or morbidity from any cause associated with exposure to ionizing radiation, chemicals, other physical agents, and stressors in the workplace. These types of studies include retrospective all-cause mortality studies, morbidity studies, and retrospective (past) exposure assessments. Each type is designed with specific goals in mind.

The goals of retrospective all-cause mortality studies are as follows:

- To determine whether workers have experienced greater mortality from any cause in comparison with an external standard or with a reference population that has not worked at the study site.

- To determine whether workers who have had occupational exposures to ionizing radiation or other agents have experienced greater mortality from any cause than workers (at the same study site) who were either exposed to low levels of these agents or not exposed at all.

The goals of morbidity studies are as follows:

- To determine whether workers have experienced greater cancer rates than the regional population at large. Prospective cancer incidence studies may be conducted, especially at DOE facilities within a population-based tumor registry area (e.g., Colorado, Idaho, New Mexico, or California), to determine whether workers experience higher rates of occurrence of various cancers than do other groups.

- To determine whether workers with some types of cancer (e.g., leukemia or brain tumors) are similar to their coworkers with respect to workplace exposures, stressors, and personal factors. These types of studies may involve personal interviews with workers or their next-of-kin to obtain detailed personal, medical, and smoking histories.

- To determine whether workers at DOE facilities have been at greater risk for other, non-cancer health outcomes related to their employment. These may include (but are not limited to) diseases of the nervous, respiratory, and immune systems.

The goals of retrospective exposure assessment are as follows:

- To characterize past worker exposures and to understand past exposure circumstances through examination of current workers who are performing tasks or specific jobs similar to those done in the past. This activity is preparatory to recommendation or conduct of epidemiologic analyses.

- To determine the feasibility of a study by augmenting existing exposure information, filling information gaps about exposure, addressing issues of confounding exposure, and evaluating new exposure concerns for which exposure data do not exist. The determination may require surveys using industrial hygiene or health physics monitoring practices to derive or improve estimates of exposure for an epidemiologic study.

II. NIOSH Site Surveys

NIOSH, its contractors, and grantees may visit a site where they have no current study under way for a variety of survey purposes. The most common surveys and their underlying goals are as follows:

- Study feasibility surveys – designed to gain site history overviews; conduct records system reviews (personnel, medical, health physics, and industrial hygiene); and determine site suitability for a study.

- Walk-through surveys – focusing on specific areas of interest, such as the review of a process or operation to determine exposure potential, or the review of sample medical records for smoking history data or radiographic exposure information. Walk-through surveys may be conducted to obtain site aspect information for inclusion in a multisite study effort.

- Sampling surveys – conducted to collect industrial hygiene or health physics samples as part of the exposure assessment process outlined above. NIOSH personnel or NIOSH contractors plan to use NIOSH-owned equipment and analytical laboratory support for sample collection. NIOSH grantees or contractors may provide their own equipment.

ATSDR

In 1980, Congress created the Agency for Toxic Substances and Disease Registry (ATSDR) to implement the health-related sections of laws that protect the public from hazardous wastes and environmental spills of hazardous substances. The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the "Superfund" Act, provided the congressional mandate to remove or clean up abandoned and inactive hazardous waste sites and to provide Federal assistance in toxic emergencies. As the lead Agency within the Public Health Service for implementing the health-related provisions of CERCLA, ATSDR is charged under the Superfund Act to assess the presence and nature of health hazards at specific Superfund sites, to help prevent or reduce further exposure and illness that result from such exposures, and to expand the knowledge base about health effects from exposure to hazardous substances.

In 1984, amendments to the Resource Conservation and Recovery Act of 1976 (RCRA), which provides for the management of legitimate hazardous waste storage or destruction facilities, authorized ATSDR to conduct public health assessments at these sites, when requested by the Environmental Protection Agency (EPA), States, or individuals. ATSDR was also authorized to assist EPA in determining which substances should be regulated and the levels at which sub- stances may pose a threat to human health.

With the passage of the Superfund Amendments and Reauthorization Act of 1986 (SARA), ATSDR received additional responsibilities in environmental public health. This act broadened ATSDR's responsibilities in the areas of public health assessments, establishment and maintenance of toxicologic databases, information dissemination, and medical education.

I. Public Health Assessment Process

Since 1986, ATSDR has been required by law to conduct a public health assessment at each of the sites on the EPA National Priorities List. The aim of these evaluations is to find out if people are being exposed to hazardous substances and, if so, whether that exposure is harmful and should be stopped or reduced. If appropriate, ATSDR also conducts public health assessments when petitioned by concerned individuals. Public health assessments are carried out by environmental and health scientists from ATSDR and from the States with which ATSDR have cooperative agreements.

- Exposure: As the first step in the evaluation, ATSDR scientists review environmental data to see how much contamination is at a site, where it is, and how people might come into contact with it. Generally, ATSDR does not collect its own environmental sampling data, but reviews information provided by DOE, EPA, other Government agencies, businesses, and the public. When there is not enough environmental information available, the report will indicate what further sampling data is needed.

- Health Effects: If the review of the environmental data shows that people have or could come into contact with hazardous substances, ATSDR scientists then evaluate whether or not there will be any harmful effects from these exposures. The report focuses on public health, or the health impact on the community as a whole, rather than on individual risks. Again, ATSDR generally makes use of existing scientific information, which can include the results of medical, toxicologic, and epidemiologic studies and the data collected in disease registries. The science of environmental health is still developing, and sometimes scientific information on the health effects of certain substances is not available. When this is so, the report will suggest what further research studies are needed.

- Conclusions: The report presents conclusions about the level of health threat, if any, posed by a site and recommends ways to stop or reduce exposure in its public health action plan. ATSDR is primarily an advisory agency, so usually these reports identify what actions are appropriate to be undertaken by EPA, other responsible parties, or the research or education divisions of ATSDR. However, if there is an urgent health threat, ATSDR can issue a public health advisory warning people of the danger. ATSDR can also authorize health education or pilot studies of health effects, full-scale epidemiology studies, disease registries, surveillance studies, or research on specific hazardous substances.

- Interactive Process: The health assessment is an interactive process. ATSDR solicits and evaluates information from numerous city, State and Federal agencies, the companies responsible for cleaning up the site, and the community. It then shares its conclusions with them. Agencies are asked to respond to an early version of the report to make sure that the data they have provided is accurate and current. When informed of ATSDR's conclusions and recommendations, sometimes the agencies will begin to act on them before the final release of the report.

- Community: ATSDR also needs to learn what people in the area know about the site and what concerns they may have about its impact on their health. Consequently, throughout the evaluation process, ATSDR actively gathers information and comments from people who live or work near a site, including residents of the area, civic leaders, health professionals, and community groups. To ensure that the report responds to the community's health concerns, an early version is also distributed to the public for their comments. All the comments received from the public are responded to in the final version of the report.

APPENDIX 2: MEMORANDA FROM FORMER DEPUTY SECRETARY CHARLES B. CURTIS, DATED APRIL 15, 1997, AND FORMER ASSISTANT SECRETARY, ENVIRONMENT, SAFETY AND HEALTH, TARA O'TOOLE, DATED OCTOBER 10, 1995, TO DOE OPERATIONS AND AREA OFFICE MANAGERS

DOE F 1325.8
(08-93)

United States Government **Department of Energy**

memorandum

DATE: October 10, 1995

REPLY TO
ATTN OF: Office of Epidemiologic Studies:G. Petersen:3-2340

SUBJECT: ACCESS TO DEPARTMENT OF ENERGY (DOE) FACILITIES AND RECORDS BY CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) INVESTIGATORS

TO: DOE Operations and Area Office Managers

On December 24, 1990, DOE and the Department of Health and Human Services (HHS) signed a Memorandum of Understanding (MOU) that transferred responsibility for the management and conduct of energy-related analytic epidemiologic research to HHS. HHS has designated CDC as the lead agency. The MOU established the need for CDC personnel, their contractors, and grantees to access DOE facilities, workers, and records to conduct community, and workerbased health research and related studies. The conduct of the health research and related activities are an essential and routine part of the work of the Office of Environment, Safety and Health.

The purpose of this memorandum is to encourage DOE Operations and Area Offices to plan for the costs associated with access to information required for these research activities. These costs result from the need for DOE and DOE-contractor support when CDC researchers request access to DOE facilities and records for a study. During this process, CDC investigators usually request an initial 2-day site visit to discuss information resources, identify the location of records, and obtain expert assistance in characterizing record holdings and historical processes. These visits will require site contractors to make key staff available for brief periods of time. These key staff include records managers, industrial hygienists, health physicists, and medical staff. In some cases, followup visits will be scheduled to allow the collection of information needed by study investigators and may require support from DOE contractors. Although costs associated with these support activities are expected to be minimal, Operations and Area Office budget processes should take them into account.

The ability of CDC to successfully perform health related activities and studies is an essential part of DOE's health mission. It requires that we adequately plan for the associated support that will be needed from DOE and its contractors. Please contact Heather Stockwell, Acting Director, Office of Epidemiologic Studies, telephone- 301-903-3721, with questions or concerns.

Tara O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety and Health

DOE F 132@ 9
(08 93)

United States Government **Department of Energy**

memorandum

DATE: April 15, 1997

REPLY TO ATTN OF: Office of Epiderniologic Studies: Heather Stockwell:301-903-3721

SUBJECT: ACCESS TO DEPARTMENT OF ENERGY (DOE) RECORDS IN THE CONDUCT OF HEALTH STUDIES AT DOE SITES

TO: Secretarial Officers
Operations Office Managers

In 1990, the Secretary of Energy signed a Memorandum of Understanding (MOU) with the Secretary of Health and Human Services (HHS) transferring the conduct of epidemiologic studies of the DOE workforce and surrounding community to HHS. As part of this MOU, the Secretary of Energy committed to provide access to DOE-owned and contractor-owned records needed to conduct these studies. In addition, pursuant to the National Defense Authorization Act for Fiscal Year 1993, some health-related studies of the DOE workforce are being conducted directly by DOE or its grantees.

Health studies, whether conducted by DOE or its designee, are an integral part of DOE's commitment to monitor and protect the health of the workforce. The conduct of the health research and related activities, both by HHS through the MOU and directly by DOE or its contractors and grantees, needs the Department's full support to ensure their credibility to the public and the DOE workforce.

Therefore, it is the responsibility of the DOE Secretarial Officers to budget for the costs associated with these studies, and it is the responsibility of the Operations Offices to plan for these studies and facilitate record access by health researchers. Costs may include activities, such as commitment of staff and resources to familiarize researchers with the facility and historical operations the identification and retrieval of records relating to DOE activities; and declassification of records, as needed, for these studies. These expenditures should be tracked carefully so that the cost of the program can be accurately assessed.

The health researchers are responsible for copying, filing, scanning, or abstracting data needed for the study, charges associated with site computer programming, and any additional support not listed above.

In the Office of Environment, Safety and Health, the Office of Epidemiologic Studies is working with HHS to establish a more formal coordination and notification process.

This process will ensure that the Operations Office receives adequate notification, including planning information regarding study participants, schedule, and scope. If you have any questions, please contact Dr. Heather Stockwell at 301-903-3721.

This memorandum is to ensure that DOE works together to plan, scope, budget, and facilitate the conduct of these important epidemiologic studies, and that we continue our demonstrated commitment to openness.

Charles B. Curtis
Deputy Secretary

APPENDIX 3:
NCEH and ATSDR IRB Procedures and Approval

This section outlines procedures for Institutional Review Board (IRB) review of health research and related studies at DOE facilities when the study is managed by either the ATSDR or NECH within the CDC. Both ATSDR and NCEH, conduct their work under the MOU between DOE and HHS.

In 1996, DOE and HHS renewed the MOU, initiated in 1990, under which HHS conducts a program of independent, energy-related occupational and environmental research studies with funding from DOE. In 1999, public health activities conducted by ATSDR at DOE sites were transferred to DOE's Office of Environment, Safety and Health. In 2000, a revised MOU incorporating activities of ATSDR and NCEH was signed by HHS and DOE Secretaries. DOE, ATSDR and NCEH are committed to ensuring the scientific integrity and independence of research and public health activities conducted under the MOU while protecting study subjects from research risks.

Prior to conducting research involving human subjects at DOE facilities, it is necessary to comply with the requirements of the Federal Policy for Protection of Human Subjects. Implementation of the Federal Policy is achieved by complying with the procedures and requirements at 10 CFR Part 745 or, where applicable, 45 CFR Part 46. Studies involving human subjects are required to be reviewed by an IRB under both DOE and HHS regulations to ensure that the rights and welfare of all study subjects are protected.

The Office for Human Research Protections (OHRP), which has responsibility for enforcing the HHS human subjects regulations, requires IRB review and approval/exemption by all institutions considered "engaged" in the research, including local institutions when appropriate. Generally, a local IRB is in position to evaluate the particular circumstances of the research setting and to weigh critical considerations like local professional and community standards; the availability of alternative sources of treatment, institutional policies, and resources; and the needs of differing subject populations.

DOE-owned facilities intended to be the focus of health research and related studies conducted pursuant to the MOU are operated for DOE under contract by profit or nonprofit entities. These entities are organizationally independent from and, for a number of purposes, have organizational obligations and interests that are different and potentially divergent from those of DOE. To protect their respective independent obligations and to avoid potential conflicts between their independent interests and those of DOE, DOE contractors may wish to review and comment on proposed protocols applicable to DOE sites operated by them as part of, or in addition to, the requirements of the Federal Policy.

Therefore, to ensure the protection of the privacy rights of study subjects, to maintain the independence of CDC and ATSDR to conduct health research and public health activities at DOE facilities, to ensure local input in a timely fashion, and to respect the independent obligations and interests of DOE contractors, whether by contract or law, the parties and their assignees to this Agreement agree to abide by the following procedures concerning the review of research protocols related to DOE facilities:

1. The appropriate HHS IRB will serve as the responsible IRB for purposes of satisfying the requirements of the DOE and HHS human subject's requirements. However, upon completion of the scientific peer review of the protocol, NCEH or ATSDR, their contractors, grantees, or cooperative agreement holders will send a copy

of the research protocol to DOE's Human Subjects Program Manager, Office of Biological and Environmental Research (SC-72) for transmittal to the chair of the IRB committee at the DOE facility (the site or local IRB) for review and comment. The review and comment period shall be at least two (2) weeks, but is not to exceed four (4) weeks from the date of receipt of the protocol by the site IRB.

In so far as most of these studies will involve existing record systems devoid of personal identifiers, it is expected they will qualify for an exemption or an expedited review. The chair of the site IRB will send copies of the comments to the NCEH or ATSDR designated project officer, to the Chair of the HHS IRB, and to DOE Office of Health Studies.

Comments from site IRB must be received within four (4) weeks from the date of receipt by the site IRB for consideration.

If the site IRB review concludes that more than minimal risk to subjects is possible, the site IRB official representative, generally the chairperson, should be present in person or through a video or telephone conference call at the HHS IRB review to resolve the issue.

2. As part of the NCEH or ATSDR review process, the HHS IRB will consider all comments from the site IRB, discuss with the NCEH or ATSDR project officer, and respond to the site IRB.

   If the HHS IRB, the site IRB or DOE determines that discussion is needed to resolve issues, the HHS IRB will invite the site IRB to attend or participate via video or telephone conference call in the HHS IRB review.

   If site IRB disagrees with recommendation of HHS IRB, a convened meeting of the HHS IRB will be held with a representative of the site IRB, in attendance.

   The HHS IRB will make the final determination regarding approval of the protocol if unresolvable conflicts arise.

3. When a project conducted under this MOU is funded as a grant, the project receives a provisional IRB approval from the grantee institution's IRB, in lieu of the HHS IRB. After the grant has been awarded and the scientific peer review has been completed, the grantee will follow the same procedures in (1) and (2), with the grantee institution's IRB serving in the role of the HHS IRB. Notice of this change of procedure will be provided to potential applicants in the Request for Applications.

4. For studies supported by a grant, the grant recipient will provide copies of all IRB approvals, the final protocol, review comments of the protocol by the site IRB, and the grantee's responses to these comments, to DOE Office of Health Studies and to the NCEH or ATSDR designated project officer before a study begins.

5. Sites may rely on the responsible HHS IRB for review and approval of the protocol if they choose not to form a site IRB.

6. Once a protocol has been approved, it should be reviewed at least annually for the life of the project. The project officer will send to DOE Office of Science (SC-72), the continuing review application and will forward the continuing review application to the local site for review. The same procedures as described in (1) will follow.

APPENDIX 4: NIOSH IRB Procedures

Appendix 4: NIOSH IRB Procedures were signed on 12/6/99 by DOE Approving Official and CDC Approving Official

This section outlines procedures for IRB review of health research and related studies at DOE facilities, when the study is managed by the Department of Health and Human Services under the MOU between HHS and DOE.

In 1996, DOE and HHS renewed the MOU, initiated in 1990, under which HHS conducts a program of independent, occupational, and environmental research studies at DOE sites with funding from DOE. Under this MOU, the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) is the principal HHS agency that conducts health research and related activities involving workers at DOE facilities. Both DOE and HHS are committed to ensuring the scientific integrity and independence of research conducted under the MOU while protecting study subjects from research risks.

Prior to conducting research involving human subjects at DOE facilities, compliance with the requirements of the Federal Policy for Protection of Human Subjects at 10 CFR Part 745 or, where applicable, 45 CFR Part 46 is required. Studies involving human subjects are required to be reviewed by an IRB under both DOE and HHS regulations to ensure that the rights and welfare of all study subjects are protected. In some cases, either DOE or HHS or both may choose to conduct an IRB review of a proposed research study.

The Office of Human Research Protections (OHRP), which has responsibility for enforcing the HHS human subject's regulations, requires IRB by all institutions considered "engaged" in the research. Further, OHRP normally requires review by a local IRB. Generally, a local IRB is in the best position to evaluate the particular circumstances of the research setting and to weigh critical considerations such as local professional and community standards; the availability and feasibility of alternative research methods, institutional policies, and resources; and the needs of differing subject populations. Where local review is not possible, OHRP requires that the reviewing IRB have knowledge about the local setting.

NIOSH investigators have previously involved the local sites by soliciting comments on the scientific, administrative, and ethical aspects of the draft protocols from worker and management representatives at public meetings and by mail for those unable to attend. These comments were submitted to the NIOSH IRB, along with the protocol and other required documentation, for consideration and deliberation as part of the human subjects' review process prior to beginning a study.

DOE-owned facilities that are the sites for health research and related studies conducted pursuant to the MOU are operated for DOE under contract by profit or non-profit entities. These entities are organizationally independent from and, for a number of purposes, have organizational obligations and interests that are different and potentially divergent form those of DOE. To protect their respective independent obligations and to avoid potential conflicts between their independent interests and those of DOE, DOE contactors' IRBs may wish to review and comment on proposed protocols applicable to DOE sites operated by them as part of, or in addition to, the requirements of the HHS, regulations.

Reconciling the need to conduct timely research into the health hazards confronting employees at DOE sites with the equally compelling need for review of research protocols by the local site's IRB presents unique challenges.

This is especially true in multiple site studies where uncoordinated site reviews could significantly delay a study's onset. For this reason, time requirements have been established for the review process described below to allow for local site review while avoiding lengthy delays.

To ensure the protection of the privacy rights of study subjects, to maintain the independence of NIOSH and other HHS agencies to conduct health research and related studies at DOE facilities, to ensure local input in a timely fashion, and to respect the independent obligations and interests of DOE contractors, whether by contract or law; the parties and their assignees to this Agreement agree to abide by the following procedures concerning the review of research protocols related to DOE facilities:

1. The NIOSH IRB will serve as the IRB of record for purposes of satisfying the requirements of the DOE and HHS human subjects requirements. When a research protocol is ready for IRB review, NIOSH, its contractors, grantees, or cooperatives agreement holders will send a copy of the research protocol, including the scientific peer review comments and responses and identification of the DOE sites (preceded by an e-mail alert), to Dr. Susan L. Rose/Ms. Kim Laing, DOE Office of Science (SC-72) for transmittal within two (2) weeks to the chair of the IRB committee at the DOE facility ("the site IRB") for review and comment. Ms. Laing will send via Federal Express the protocol to the DOE site(s) and retain a copy of the receipt for documentation. The DOE site(s) will notify Ms. Laing by email when the protocol is received via Federal Express. The review and comment period shall be at least two (2) weeks, but is not to exceed four (4) weeks from the date of receipt of the protocol by the site IRB. In so far as most of these studies will involve existing record systems devoid of personal identifiers, it is expected they will qualify for either an exemption or an expedited review. The chair of the site IRB will send copies of the comments to the NIOSH-designated project officer (who is identified in the protocol), to the Chair of the NIOSH IRB, and to DOE Office of Science (SC-72). Comments from the IRB(s) must be received by the Chair of the NIOSH IRB within four (4) weeks from the date of receipt by the site IRB for consideration at the NIOSH IRB review of the protocol. If the site IRB review concludes that the research involves more than minimal risk to subjects, or other important issues are raised, the site IRB official representative, generally the chairperson, should be present in person or through a video conference call at the NIOSH IRB review to resolve the issue.

2. As part of the NIOSH review process, the NIOSH IRB will consider all comments from the site IRB, discuss these with the NIOSH project officer, and provide responses to the site IRB. In the event of a disagreement between the NIOSH IRB and site IRB, a convened meeting of the NIOSH IRB will be held with a representative of the site IRB in attendance. NIOSH IRB will make the final determination regarding approval of the protocol if unresolved conflicts arise.

3. NIOSH grants generally receive their IRB approval from the grantee institution's IRB, rather than the NIOSH IRB. Such approval is obtained prior to submission of the grant proposal to NIOSH, and is an integral part of the grant application process. This approval from the grantee institution's IRB shall be considered provisional. After the grant has been awarded and the scientific peer review has been completed, the grantee will follow the same procedures in (1) with the grantee institution's IRB serving in the role of the NIOSH IRB. As part of the grantee's review process, the grantee's IRB will consider all comments from the site IRB and provide responses to the site IRB. In the event of a disagreement between the grantee's IRB and site IRB, a convened meeting of the grantee's IRB will be held with a representative of the site IRB in attendance. Unresolved conflicts between the grantee's IRB and the

site IRB will be referred to the CDC Human Subjects Office for resolution. Notice of this change of procedure will be provided to potential applicants in the Request for Applications.

4. For studies conducted by a grant, the grant recipient will provide copies of all IRB approvals, the final protocol, review comments of the protocol by the site IRB, and the grantee's responses to these comments, to DOE Office of Science (SC-72) and to the NIOSH-designated project officer before a study begins.

5. Sites may rely on the responsible NIOSH IRB for review and approval of the protocol if they choose not to form a site IRB, or conversely DOE Office of Science, (SC-72) may make this determination.

6. When HHS agencies conduct outbreak or health hazard investigations they may need to access personally identified records managed or maintained by DOE contractors. In these cases, the activity is not research and does not require IRB review. However, when information is collected that is beyond the scope of the emergency response, the collection of the information is research. Additionally, other types of activities that constitute research may be undertaken by HHS agencies. When research is conducted and other HHS agencies need to access personally identified records managed or maintained by DOE contractors, the contractors are considered engaged in the research. Local IRB review is required in this case, and the researcher will follow the same general procedures in (1) through (5) above and 7 below. The HHS agency's IRB (or, as appropriate, a funded grantee's IRB) shall serve as the IRB of record.

7. Once a protocol has been approved, it must be reviewed at least annually for the life of the project. The project officer will send to Dr. Susan L. Rose/Ms. Laing, DOE Office of Science (SC-72), via e-mail, the continuing review application. Ms. Laing will forward the continuing review application to the local site for review. The same procedures as described in (1) will be followed.

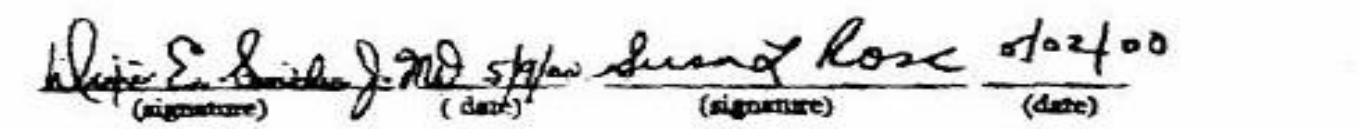
8. This agreement will be in effect on the date of the later signature and may be modified in writing only with the joint approval of both signature parties or their designees. Cancellation of the agreement maybe accomplished only at the expiration of a 90- day advanced notification in writing by either party.

Susan L Rose
Approving DOE Official
Date 12/6/99

Marjorie A Speers
Approving CDC Official
Date 12/6/99

COOPERATIVE AGREEMENT

The officials having signed below commit their respective institutions to the following binding cooperative amendment with regard to reliance upon the NIOSH, CDC, Institutional Review Board (IRB) for continuing annual review of NIOSH-conducted research at DOE local institutions. Each institution reserves the right to review by its own IRB regardless of this amendment, so long as that preference is in writing and provided to the Chairs of both IRBs. IRB reviews shall occur with voting membership and/or consultant supplementation appropriate to any given activity. The cooperating institutions agree that the reviewing IRB shall be adequately supported in its function, cooperate with reporting requirements and requests for additional information, and abide with IRB decisions. Neither cooperating institution may administratively overrule disapprovals. Relevant minutes of IRB meetings shall be made available to both cooperating institutions.



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APPENDIX 5: DOE-WIDE CENTRAL INSTITUTIONAL REVIEW BOARD TO ADDRESS HUMAN SUBJECTS IN BERYLLIUM RESEARCH

The Office of Science (SC), with support from the Office of Environment, Safety and Health (EH), under the authority of 10 CFR 745, *Protection of Human Subjects*, and DOE P 443.1, *Protection of Human Subjects*, is announcing the establishment of a Central Beryllium Institutional Review Board (Be IRB). The Be IRB provides a high-level of expertise and diverse, experienced members to address beryllium-related human subject's protection issues. It provides the Department of Energy (DOE), DOE contractors, and other organizations engaged in research on the exposure, testing, or disease funded by DOE and/or involving the DOE work force with a thorough and consistent review that is essential to protection of the volunteer subjects in these programs. Ongoing programs subject to review by the Be IRB are:

1) Beryllium research activities;
2) the Former Beryllium Workers Medical Surveillance Program (see website for list of DOE sites); and
3) the beryllium screening component of the Former Workers Program (see website for list of DOE sites).Policy and procedures for the Central Be IRB may be found at:
http://www.science.doe.gov/ober/humsubj/Be_procedures.html.

Questions regarding this process may be addressed to Dr. Susan Rose at 301-903-4731, or by email:(Susan.L.Rose@science.doe.gov). The DOE Human Subjects program website can be found at:
http://www.science.doe.gov/ober/humsubj/index.html.