DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

National Institute for Occupational Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati OH 45226-1998

[redacted]

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October 19, 1995

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WITHOUT ENCL/ATTACHMENTS

Mr. Bryan Walker, DOE K-25 Site Manager
Oak Ridge K-25 Site
Lockheed Martin Energy Systems
Oak Ridge, TN 37831-7134

DEPARTMENT OF ENERGY DECLASSIFICATION REVIEW

1ST REVIEW-DATE: 08/08/97
AUTHORITY: ☐ADC ☐ADC ☐ADD
NAME: B Erwin
2ND REVIEW-DATE: 10/4/97
AUTHORITY: ADD
NAME: [illegible]

DETERMINATION (CIRCLE NUMBER(S))
1. CLASSIFICATION RETAINED
2. CLASSIFICATION CHANGED TO:
3. CONTAINS NO DOE CLASSIFIED INFO
4. COORDINATE WITH:
5. CLASSIFICATION CANCELLED
6. CLASSIFIED INFO BRACKETED
7. OTHER (SPECIFY): The Letter only!

Dear Mr. Walker:

(U) "DECLASSIFICATION OF EXPOSURE INFORMATION REQUEST" WITH ATTACHMENTS/ENCL 1, 2, & 3.

This letter serves to provide justification for the request from the National Institute for Occupational Safety and Health (NIOSH) for declassification of records and other information needed for the conduct of an epidemiologic study of multiple myeloma among workers at the K-25 Plant.

Sanitized by NN-523 on 2/5/98

The United States Government has an interest in matters of occupational safety and health, and has a duty to establish appropriate measures to protect U.S. workers. This is not only to preserve the health of the workforce, but also to minimize the economic impact of debilitative disease. Certain U.S. Government organizations have been charged with establishing appropriate health protective measures including the conduct of research into the causes of disease. Among these are the Department of Energy (DOE) and the Department of Health and Human Services (DHHS).

The DOE historically has conducted studies of community and occupational populations (Attachment 1 [MOU transferred studies]). In 1988, Sec. Watkins convened The Secretarial Panel to Evaluate Epidemiologic Research Activities (SPEERA) to examine this research and determine how it should be conducted. One of the recommendations was to transfer this research from DOE to an independent health agency, specifically DHHS. In December 1990, a Memorandum of Understanding (MOU) was signed by DOE and DHHS (Attachment 2 [MOU]), which transferred responsibility for conducting epidemiologic research related to DOE facilities to DHHS. DHHS has delegated authority for conducting the research program to the Centers for Disease Control and Prevention (CDC). Within CDC, NIOSH is responsible for research involving worker populations. The National Center for Environmental Health (NCEH) is responsible for conducting epidemiologic research involving the communities surrounding DOE sites. The investigations being conducted include epidemiologic studies, as well as the development of estimates of past exposures to chemical and physical agents for future use in epidemiologic studies. Funding for activities conducted by NIOSH and NCEH under the MOU is provided by DOE.

Epidemiologic studies of workers often entail the comparison of the health status (usually defined as the presence of certain diseases or death from specific causes) of persons known to be exposed to the hazard under study (e.g. radiation or certain chemicals) with the health status of individuals not exposed to that hazard. Crucial to the conduct of such a study is the accurate characterization of the exposures experienced by all study participants. It is, of course, also important to have accurate information on other factors that might also be associated with the

disease under study. These factors, referred to as confounders, usually include exposures to other workplace hazards. In studies of workers, it is the exposure information that allows causal associations to be derived. The quantity and quality of available exposure information largely determine the strength of the associations drawn from the research. For this reason, it is imperative that full advantage be taken of all existing information.

To reconstruct past occupational exposures the following activities are typically performed:

1. Site visits - to obtain a general overview of site activities and records available.
2. Historical study
   + Records review and retrieval - to identify population demographics and exposure potential.
   + Coding, QA/QC - to transform data into a usable format and assure integrity of data.
   + Institutional memory - to obtain unrecorded knowledge from current and former worker or others knowledgeable about past operations.
   + Exposure assessment - to assign gradation of exposures to individuals/groups.
3. Mathematical modeling and simulations - to evaluate the utility if the exposure data and to compensate for missing data.
4. Measure present exposures - to augment historical exposure data and fill information gaps.
5. Multiple site comparisons - to examine consistency of exposures across sites.

Once past exposures have been estimated, epidemiologic analytic techniques are used to describe the disease experience of a population and to compare this with referent populations. Such analyses seek to document the presence or absence of a causal association between the disease(s) and exposures under study.

Multiple myeloma is a progressive, usually fatal, cancer of the blood-forming organs. There are over 12,000 new cases of multiple myeloma each year in the U.S.; therefore, the identification of a causal factor for this deadly cancer is of substantial public health interest. Previous epidemiologic evaluations at DOE facilities have suggested that multiple myeloma may be a consequence of exposure to ionizing radiation and/or chemicals present at those facilities.

In excess of 65 cases of multiple myeloma have occurred among workers at the K-25 facility since the plant began operation. On the surface, this appears to be a relatively large number of cases, compared with what one would expect in a population the size of the K-25 workforce. The K-25 workforce presents a unique research opportunity, both because of the apparently high number of multiple myeloma cases and because the facility has maintained exposure data of unusually high quality extending back to the plant's inception. In order to examine the possible work-related exposures that may have contributed to the occurrence of multiple myeloma to K-25 workers, an in-depth exploration of all records pertaining to radiologic and chemical hazards experienced by K-25 workers is essential.

NIOSH researchers have identified from the general literature a number of exposures that have been previously implicated as potentially causative agents in the development of multiple myeloma. Described in more detail in the study protocol, they are: internal and external ionizing radiation, metals (U, Ni, Cd, Pb, As, Cu, Cr), and solvents (benzene, carbon tetrachloride). Although the biological mechanisms in the development of multiple myeloma has not as yet been established, it is clear that several of the above chemicals, as well as fluoride, accumulate in the bone and therefore are suspect in causing hematopoietic diseases.

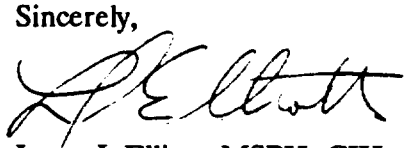
It has been NIOSH policy not to use classified information in the conduct of its epidemiologic research because it is contrary to DHHS philosophy which calls for research to be conducted openly, thus ensuring scientific integrity and public credibility. Studies utilizing classified information, where source data cannot be confirmed, have been a source of much criticism in the past (Attachment 3 [PSR]). In response to inquiries made by NIOSH as part of this investigation, K-25 personnel have determined that certain chemical and radiological information, some of which pertains to known or suspected risk factors of multiple myeloma, is classified and therefore not available for use in the exposure assessment portion of an unclassified epidemiologic study. Attachment 4 presents four data components which are currently deemed Confidential Restricted Data (CRD) and thus are not available for use in the study of K-25 workers (Attachment 4 [Confidential Memo date August 16, 1995]).

In order for NIOSH to accomplish its mission, we are requesting that all of the data related to worker exposures be declassified. If it is determined that portions of the data cannot be declassified, then we request that an encoding procedure be developed that will mask the identity of classified compounds or processes. This would allow the use of data in a non-identifiable form but would not impede proper scientific analyses.

It should be readily apparent from the discussion above that a timely resolution to this matter is required. Successful completion of this study using all relevant data may have important public health and economic benefit. The conduct and completion of the study as planned is dependent on the decision to declassify the data or establish a workable alternative that would allow the use of the data in an encoded fashion.

We have been informed that the Technical Evaluation Panel will meet in the near future to consider this request and provide a decision. It is understood that NIOSH representatives will attend this meeting to address any questions members of the Panel may have. Please contact me at (513) 841-4462 regarding the scheduling of this meeting or if additional information is needed. Your prompt attention to our request is appreciated.

Sincerely,



Larry J. Elliott, MSPH, CIH
Section Chief: Exposure Assessment
National Institute for Occupational
Safety and Health

Attachments:
1. List of Transferred Studies under MOU.
2. Memorandum of Understanding (MOU).
3. Physicians for Social Responsibility (PSR) Report.
4. Confidential Memo dated August 16, 1995.

cc w/ Attachments:
G. Marciante, DP-80
A. Quist
G. Peterson, DOE-HQ EH-62
C. Stachowiak, DOE K-25

Attachment 1

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ORAU

Health and Mortality Study. $2,817,000. (Includes $200K transferred to EH from NE for K-25 study)

1991 Non-malignant respiratory morbidity among workers in a uranium processing plant (Fernald).
1991 Mortality experience of workers in a uranium processing plant (I) (Fernald).
1991 Retrospective cohort mortality study of workers at the Oak Ridge Y-12 Plant (deaths through 1984).
1991 Mortality study of Y-12/UCC workers previously employed at Y-12/TEC.
1991 Mortality among workers at a uranium processing plant (Linde).
1991 Retrospective cohort mortality study of workers at the Oak Ridge National Laboratory (deaths through 1984).
1991 Oak Ridge facility comparison study (ORFCOM II), Phase I: WWII workers.
1991 Mortality study among welders in Oak Ridge facilities (deaths through 1984).
1991 Retrospective cohort mortality study of workers in the Savannah River Plant (deaths through 1985).
1991 Follow-up study of mortality and morbidity among DOE workers reported to have received ≥5 rem in a year.
1992 Case-control study of brain cancer among Oak Ridge workers.
1992 Oak Ridge facility comparison study (ORFCOM II), Phase II: The monitored workers and Phase III: All monitored and non-monitored workers (deaths through 1984).
1992 Study of mortality among chemical operators at all DOE plants in Oak Ridge.
1992 Retrospective cohort mortality study of workers in a uranium processing plant (Y-12).
1992 Case-control study of lung cancer deaths among workers at four uranium processing plants.
1992 Exploratory study of mortality among females employed at a uranium processing plant.
1992 Epidemiologic study of mortality among workers employed at the Oak Ridge Gaseous Diffusion Plant.
1992 Mortality experience of workers in a uranium processing plant (II) (Fernald) (deaths through 1984).
1992 K-25 Centrifuge workers study $200,000.
1993 Mortality among employees at Lawrence Livermore National Laboratory (LLNL).
1993 An epidemiologic study of mortality among workers at the Portsmouth Goodyear Atomic Corporation Gaseous Diffusion Plant.

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	1993	A study of mortality among workers at the Paducah Gaseous Diffusion Plant.
	1993	Mortality among workers at a uranium refining and processing plant (Mallinckrodt).
	1993	Mortality among short-term workers at the Oak Ridge Gaseous Diffusion Plant.
	Open	Case-control study of renal disease among workers at a uranium processing plant (Fernald).
ORO	1992	CDC/Fernald dose reconstruction. $6,100,000.
PNL		Statistical health effects studies. $295,000.
	1991	Hanford health and mortality study. Deaths through 1984 for all states and through 1989 for Washington State. Joint HEHF/PNL project.
	1992	Case-control study of childhood leukemia and non-Hodgkin's lymphoma and of late fetal deaths in populations around the Hanford Nuclear facility.
	1992	IARC combined analyses of cancer mortality among nuclear industry workers. IARC and DOE scientists are involved in analysis of health effects and occupational exposure to external sources of irradiation. Dr. Gilbert is the DOE contractor representative for this activity.
RL	1993	Hanford dose reconstruction - Support to PNL. $3,650,000.

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* The year shown in the second column represents the estimated completion date of the initial or updated analysis. In general, this represents completion of a manuscript or submission of a study for scientific peer-review. "Open" implies that the work is on-going, a start date has not been assigned, or additional funding has not been provided.

Attachment 2

MEMORANDUM OF UNDERSTANDING

BETWEEN
DEPARTMENT OF ENERGY
AND
DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. Background

The Secretary of Energy established an advisory committee to make recommendations on strengthening the Department of Energy's (DOE) epidemiologic research activities. This advisory committee—the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA)—recommended that DOE enter into a Memorandum of Understanding (MOU) with the Department of Health and Human Services (HHS) to manage and conduct analytic epidemiologic research (studies which test hypotheses). The Panel also recommended that DOE conduct descriptive epidemiologic studies, e.g., occupational health surveillance. The Secretary of Energy agreed with the Panel's recommendations and has requested that HHS enter into an MOU to implement them.

II. Purpose

This MOU sets forth the guidelines for coordination between DOE and HHS to carry out the recommendations of the SPEERA for the management and conduct of energy-related analytic epidemiologic health research by HHS.[1] This includes the authority, resources, and responsibility for the design, implementation, analysis, and scientific interpretation of analytic epidemiologic studies of the following populations: workers at DOE facilities; residents of communities in the vicinity of DOE facilities; other persons potentially exposed to radiation; and persons exposed to potential hazards resulting from non-nuclear energy production and use. This agreement is not meant to affect existing MOUs and Interagency Agreements (IA) between DOE and HHS or to preclude DOE and HHS agencies from entering into MOUs or IAs for other purposes.

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[1]This agreement does not apply to activities and facilities covered under Executive Order 12344 (42 USC 7158 note).

III. Authorities

A. The Department of Health and Human Services/Public Health Service/Centers for Disease Control has legislative authority under Section 301(a) of the Public Health Service Act (42 U.S.C. Section 241) and under the Occupational Safety and Health Act [29 U.S.C. Section 669(a)] to conduct research into the health effects of a broad range of environmental and occupational hazards and to cooperate with other appropriate authorities in the conduct of such research.

B. The DOE may enter into agreements with HHS for the management of epidemiologic research pursuant to Section 103 (3) and 103 (11) of the Energy Reorganization Act of 1974 [42 U.S.C. Sections 5813 (3) and 5813 (11)]; The Economy Act of 1932 as amended (31 U.S.C. Section 1535); and DOE Order 1280.1, MEMORANDUMS OF UNDERSTANDING, of 9-20-85.

IV. DOE Responsibilities

A. Access to DOE Data Sources

DOE will provide HHS with access to data and other documents that may be pertinent to the management and conduct of analytic epidemiologic studies and programs, including data on occupational and community exposures, and environmental releases.

DOE will solicit input from HHS on the development and maintenance of the Comprehensive Epidemiologic Data Resource (CEDR) and the selection of data to include in CEDR.

DOE will allow HHS personnel, contractors, and grantees with appropriate security clearances access to all DOE and DOE-owned, contractor-operated facilities for the purpose of independently reviewing or collecting any health or environmental information or samples that HHS determines are necessary for conducting analytic epidemiologic research.

To the extent that existing regulations, Privacy Act routine uses, or agreements with its own contractors preclude disclosure of data held by DOE or its contractors to HHS, or subsequent use by HHS under section V.G., below, DOE will amend the regulations and routine uses, and renegotiate the agreements, so as to permit such disclosure and use.

E. Office of Management and Budget/Congressional Submissions

For FY 1992, DOE will forward to the Office of Management and Budget (OMB) for inclusion in the President's Budget a request for resources necessary to support the conduct of the aforementioned studies and programs.

F. Official Point of Contact

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

Name: Paul L. Ziemer, Ph.D.
Title: Assistant Secretary for Environment, Safety and Health
Address: U.S. Department of Energy, Washington, DC 20585
Telephone: (202) 586-6151

V. HHS Responsibilities

A. HHS Advisory Committee

HHS will establish an Advisory Committee to provide advice to the Secretary of HHS in setting the research agenda and in conducting the research program. Members of the Advisory Committee will consist of representatives selected by the Secretary of HHS from non-federal employees and will include research scientists, public health officials, representatives of public interest groups, and representatives of affected parties (e.g., workers, community residents). Both HHS and DOE will have nonvoting members on this Committee.

This HHS Advisory Committee will have an open channel of communication with the DOE's Advisory Committee which will be established to advise DOE's Assistant Secretary, Environment, Safety and Health, on the conduct of its environmental, health, and safety programs.

B. Committee Representation

Representative(s) of HHS will serve as non-voting member(s) of the DOE Advisory Committee which will provide direction, oversight, and evaluation to the DOE's Office of Environment, Safety and Health.

Additionally, there exist currently DOE-funded host State health agreements. For these existing and future agreements, HHS representatives will provide technical and public health assistance to the host States, including participating on the Technical Review/Oversight Committees at the request of the host States. DHHS' role in future analytic epidemiologic studies conducted through States will be discussed by DOE with HHS prior to negotiations of their agreement with States.

C. Establishing the Research Agenda

The HHS Advisory Committee will provide advice and recommendations to HHS on establishing the research agenda. All energy-related analytic epidemiologic health studies proposed by DOE and HHS will be submitted to the HHS Advisory Committee. The HHS Advisory Committee will take into consideration information and proposals provided by DOE and its Advisory Committee as well as information and proposals from other agencies and organizations. HHS will then establish the research agenda and develop a research plan.

HHS will provide DOE the research plan for review and comment. The HHS research plan will be revised each fiscal year to incorporate changes in the research agenda and to reflect changes in available resources.

All DOE initiated analytic epidemiologic research projects, including dose reconstruction and exposure assessment studies essential for conducting these epidemiologic studies, would be offered first to HHS for consideration. However, DOE may conduct through alternate means an analytic epidemiologic study that it referred to HHS if the HHS Advisory Committee has recommended the study but HHS has chosen not to include it in its research agenda. Funding for such will come from a DOE source separate from that funding level set aside for HHS-managed studies to be conducted under this MOU.

D. Conducting Research Activities

HHS will have sole responsibility for the design, conduct, analysis and scientific interpretation of the results for all transferred studies beginning at the time of transfer and for all future studies and programs covered under this MOU. HHS agrees to initially continue existing DOE grants and contracts listed in Appendix A. However, HHS will review all existing grants and contracts and continue, expand, or discontinue the projects based on this evaluation. This initial evaluation of current research activities and inclusion of those studies on a defined research agenda shall proceed with the advice of the HHS Advisory Committee and shall adhere to the principles specified in Section V.C. of this MOU.

HHS will decide which studies will be performed intramurally and which will move to open competition for all extramural research. HHS will develop a schedule for determining when continuing programs will be recompeted. HHS has the discretion to begin new intramural or extramural research consistent with the approved research agenda and resource availability.

E. HHS Data Sources

HHS will be responsible for the management of all data collected by HHS scientists, including data obtained from DOE. HHS will have access to all DOE and DOE-owned, contractor-operated facilities for the purpose of independently reviewing or collecting any health or environmental information or samples that HHS determines are necessary for conducting the analytic epidemiologic research consistent with the approved agenda.

F. Procedures for Conducting Research

HHS will employ established HHS peer review procedures for awarding research grants and contracts. These mechanisms include open competition, peer review, a competitive system for project renewals, and quality assurance for research in progress. The National Laboratories would be eligible to compete in this process along with other applicants to the extent permitted by law and DOE policies.

Intramural research will be conducted in accordance with established mechanisms for assuring scientific peer review. After coordination with DOE, HHS will prepare and submit the necessary information collection proposals to OMB under the Paperwork Reduction Act. Representatives of populations being studied shall be included in review panels which will be established as appropriate for studies conducted under this MOU. These panels will allow for public comment on the design and conduct of all studies. Results of the studies will be communicated directly to the Secretary of DOE and HHS and openly communicated to all interested parties. Notification of workers will be performed through existing HHS procedures and coordinated through DOE if the workers are from DOE or DOE owned, contractor-operated facilities.

G. Classification of Documents and Security Clearances

As soon as possible following the effective date of this MOU, HHS personnel with appropriate security clearances will participate in a DOE classification review of documents and data necessary for HHS to conduct the studies and programs described herein. HHS will complete all necessary paperwork for appropriate security clearances for its personnel so that they may examine classified documents and enter DOE and DOE-owned, contractor-operated facilities.

H. Use and Disclosure of Information

Establishment of Privacy Act Systems

HHS will establish the necessary Privacy Act systems of records for information provided to HHS by DOE (or will include such information in existing systems). Before integrating DOE data into a HHS system of records, HHS will consult DOE about provisions of the system notice, including the routine uses, applicable to the DOE data in the system. Before establishing a new system of records for DOE data, HHS will consult DOE about the provisions of the system notice, including the routine uses.

Disclosure of Information to the Public Generally

Information provided to HHS under this agreement that is requested by the public under the Freedom of Information Act shall be made available by HHS in accordance with the Act, 5 U.S.C. Section 552 and implementing regulations, 45 C.F.R. Part 5. In making decisions about disclosure, HHS will consult DOE about any information provided by DOE and identified in advance by DOE as warranting such consultation.

Disclosure of Personally-Identifiable Information for Research Purposes

As provided under applicable laws, HHS will not use or disclose any personally-identifiable information obtained from DOE or its contractors except for research purposes. HHS will not use information in identifiable form to make any determination about the rights, benefits, or privileges of any individual. HHS will use and disclose this information in accord with agreements under which the personally-identifiable information was obtained by DOE or its contractors provided this is consistent with applicable law. Subject to applicable law and such agreements, HHS will provide this information to DOE's Comprehensive Epidemiologic Data Resource (CEDR) data base and otherwise may disclose this information outside HHS for research to persons or entities it deems qualified, after consultation with DOE and in accord with the provisions for disclosure in HHS Privacy Act notices. HHS shall notify DOE of any efforts on the part of anyone to obtain or use personally-identifiable information for purposes other than research and shall use and take appropriate steps to prevent improper disclosure. HHS will assist DOE as necessary in renegotiating (as required by section IV.A., above) any agreements that preclude disclosure to HHS of data held by DOE or its contractors.

I. Release of Data from Completed Studies

HHS will promptly disseminate results obtained through research covered by this MOU to the populations being studied. Public access, including DOE access, to data in HHS epidemiologic studies will be governed by applicable Federal laws and HHS implementing regulations. After HHS epidemiologic studies have been completed and reported, study data will be made available to the public and to CEDR without personal identifiers subject to the provisions of Sections V.G. and V.H. above.

J. Reports to DOE

HHS will report its progress to DOE on a quarterly basis for the first year of this MOU. After the first year, DOE and HHS will evaluate the reporting needs and determine the frequency of future reporting.

K. Responsible Official

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

Name: William L. Roper, M.D., M.P.H.
Title: Director, Centers for Disease Control
Address: 1600 Clifton Road, N.E., Atlanta, GA
Telephone: (404) 639-3291 (FTS 236-3291)

VI. Implementation of MOU

The Secretaries of DOE and HHS will appoint a task force to oversee and assist in implementing this MOU, including transfer of the analytic epidemiologic research programs listed in Appendix A. This task force will be appointed for one year and will report to the Secretaries at the end of its term. The task force will consist of staff from DOE and HHS.

VII. Resources

DOE will provide and transfer resources to HHS for the purpose of managing the DOE energy-related analytic epidemiologic research program. The funding and full-time equivalent (FTE) employment levels will be determined annually by agreement between designated agency official points of contact for this MOU (for DOE, see Section IV.F.; for HHS, see Section V.K.) For FY 1991, funding for this program will be $14,145,000 for grants and contracts and $2,855,000 and 25 FTEs for program operations, and for FY 1992, program levels will be $14,725,000 for grants and contracts and $6,200,000 and 44 FTEs for program operations. Upon mutual agreement, resource levels may be amended at any time during the fiscal year, however in the event that HHS incurs extraordinary expenses as a result of DOE's action to amend or constrain this MOU, HHS will be entitled to reimbursement for these expenses upon demonstration that additional and extraordinary costs were necessarily incurred. A copy of the signed agreement can be used by DOE as the basis for DOE to request the allocation of FTEs to HHS to carry out the terms of this agreement.

The details of the levels of support to be furnished by DOE to HHS will be developed annually through a single interagency agreement. HHS will provide to DOE a description and justification for funding and FTE resource requirements for submission to OMB and Congress for the studies and programs described under this MOU. These submissions will be provided by HHS to DOE in a timeframe agreed upon that is consistent with DOE's budget cycle.

HHS will not accept responsibility for specific studies or undertake new programs unless the mutually agreed level of resources is sufficient to achieve the intended goals and objectives. If equipment is procured in order to provide service under this MOU, HHS will retain title to the equipment.

Any requirement for the payment or obligation of funds by DOE established by the terms of this Agreement shall be subject to the availability of appropriated funds.

For the purposes of studies conducted by HHS or its grantees and contractors, HHS will prepare the necessary information collection proposals for OMB approval under the Paperwork Reduction Act. These proposals will be submitted by HHS to OMB. In the event that OMB fails to approve the information collection or allow adequate burden hours, HHS will be under no obligation to undertake or complete individual studies but will advise DOE and work with DOE to secure OMB approval which may result in necessary modification of reporting requirements.

VIII. Duration of Agreement

This agreement is effective when signed by both parties, shall initially remain in effect through FY 1995 unless amended by mutual written consent of both parties. The agreement is to be renewed annually thereafter by written mutual agreement. There is every intention to continue this agreement over the long-term.

IX. Modification or Cancellation

This agreement, or any of its specific provisions, may be revised by signature approval of both of the parties signatory hereto, or their respective designees.

Cancellation of the agreement may be accomplished only at the expiration of 90-day advanced notification by either party.

DEPARTMENT OF ENERGY	DEPARTMENT OF HEALTH AND HUMAN SERVICES
By: James D. Watkins Admiral, U.S. Navy (ret.) Secretary	By: Louis W. Sullivan, M.D. Secretary
Date 12/19/90	Date DEC 24 1990

EXECUTIVE SUMMARY

A Critical Review of the Department of Energy's Epidemiologic Research

THE U.S. NUCLEAR weapons industry is now approaching its 50th year—a half-century of experience that has cumulatively involved more than a half-million workers. In the years since the Manhattan Project began, some nuclear weapons workers have been exposed to internal and/or external ionizing radiation in doses that are high by any standard. Much larger numbers of these workers have been exposed to low-dose, low-rate external and/or internal ionizing radiation. During those years there were also numerous releases of radioactive and other toxic materials—some accidental, some deliberate—into the air, soil and groundwater of unsuspecting populations living near the nuclear weapons research, production and testing sites. The profound environmental contamination created by the nuclear weapons complex, revealed only within the last few years, after decades of official denial, has become a national scandal.

Yet today there is far less knowledge of the health risks to workers, and far less certainty in the estimates of risk that do exist, than might have been expected from this vast body of experience. There is evidence of environmental contamination at most, if not all, nuclear weapons sites. But even less is known about the impact of weapons complex contamination on the health of surrounding communities. The protection of workers and the public, as well as scientific understanding of the biological effects of low-dose ionizing radiation, has therefore suffered immeasurably.

A Wall of Secrecy

From the first days of the Manhattan Project onwards, the Department of Energy (DOE) and its predecessor agencies, the Atomic Energy Commission (AEC) and the Energy Research and Development Administration (ERDA), have been responsible both for the *creation* of threats to health and safety consequent to their work and for *protection* against those hazards. There is an inescapable conflict between the goals of nuclear weapons production and those of public, occupational and environmental health.

Historically, the DOE, its predecessors, and associated agencies such as the Transuranium Registry, have operated behind a wall of secrecy. They had a virtual monopoly on the collection and analysis of data on the radiation exposures and health outcomes of the nuclear weapons workforce and on radioactive and toxic releases from weapons facilities. In the name of "national security," access to these data was generally denied to scientists not directly employed by the AEC/ERDA/DOE and their contractors. The scientific community—and the public—knew little beyond what the agencies chose to publish, in a policy that violated the fundamental principle of free and open scientific inquiry.

For the first two decades of nuclear weapons production, although measurement of radiation exposures (of some, not all) of the workers was ongoing, the government failed to initiate research adequate to establish the effects of exposures on health. The first adequate epidemiologic study was initiated in the mid-1960s, and it produced disturbing indications of excess risks of several types of cancer. These study findings were disputed, and their authors were denied further access to the nuclear weapons workforce health data. From that time on, even as the nuclear weapons complex grew enormously and epidemiologic research expanded, the AEC/ERDA/DOE repeatedly maintained that the necessary health and safety precautions were in effect at all facilities, that their nuclear operations were safe, that there rarely had been serious accidents, that few significant radioactive or toxic releases to the environment had occurred, and that there was no imminent threat to the health of the workforce or the public.

Although there were criticisms and inquiries during the 1970s, the wall of secrecy did not really begin to crumble until 1986, when a cascade of investigations by other government agencies, scientific and congressional oversight committees and investigative journal-

ists revealed records of past accidents, melted fuel, radioactive contamination, and violations of safe operating procedures. Major environmental and safety violations, and evidence of widespread contamination, were found at almost every major DOE facility. The agency admitted that it had been "imbued with a dedication to the production of nuclear weapons without a real sensitivity for protecting the environment." Our concerns about the DOE's epidemiologic studies—the bulwark of its assertions that there was no serious excess risk to nuclear weapons workers—intensified.

PSR's Physicians Task Force on the Health Risks of Nuclear Weapons Production

In response to growing concerns about the DOE's weapons complex, Physicians for Social Responsibility formed a Task Force of physicians, epidemiologists and other scientists, both from within and outside PSR membership. This Task Force had three mandates:

1. to examine the AEC/ERDA/DOE record of epidemiologic studies of health, safety and environmental issues in the nuclear weapons production complex, and to identify and explore problems of medical and public health concern;

2. to review DOE management policies and evaluate the conduct of promised reforms; and

3. to make recommendations to the medical and scientific communities and to the general public on the management, activities, proposed reconfiguration and "cleanup" of the complex.

The present report addresses the first of these objectives.

Methods and Objectives

Over the past 30 months, the Task Force constructed a relevant bibliography of AEC/ERDA/DOE sponsored or contracted epidemiologic publications, developed and applied a standardized protocol for review, and critically analyzed 124 published AEC/ERDA/DOE epidemiologic studies on nuclear weapons workers. We reviewed related scientific publications and controversies on the biologic effects of low-dose ionizing radiation and considered their implications for the DOE workforce. We examined the work of earlier investigations of DOE epidemiologic research by independent committees and panels. The Task Force also assessed the adequacy of recent policy changes in the control and conduct of research. This report summarizes the Task Force's findings and its epidemiologic and public policy recommendations for the future.

The Task Force did not attempt a formal meta-analysis of the published AEC/ERDA/DOE epidemiologic work or prepare a report on all the methodological, analytic and interpretive issues raised by each publication. Instead, it undertook a search for overall *patterns* in this research—the systematic patterns that might be found in its methodologies, its procedures for acquiring and recording basic surveillance data, its inclusions or exclusions of data, its selection of problems for study, and its modes of inference, interpretation and emphasis in reaching conclusions. This is a search for generic or systematic strengths and faults in the way the entire process of epidemiologic investigation has been designed and conducted by the DOE and its predecessor agencies. The objective was to reach a judgment on a central issue: the adequacy of the DOE program in relation to the goals of worker and public health protection, and in relation to the development of further scientific knowledge of the effects on human health of low-level ionizing radiation. The Task Force focused on studies of workers in the nuclear weapons complex. The intended audience of its report is an informed general public.

Major Findings of the Task Force Review

The Task Force reviews identified five major patterns or problem areas in the AEC/ERDA/DOE epidemiologic studies of the nuclear weapons workforce, involving:

1. the accuracy and reliability of radiation dosimetry, the measurement and recording of exposures;

2. the coverage of the nuclear weapons workforce and of plant and laboratory sites by the studies;

3. the length of follow-up to determine the health outcomes of cohorts of nuclear workers;

4. the consequences of the "healthy worker" effect, and of the focus on deaths rather than on disease incidence; and

5. the reliance on tests of statistical significance in the interpretation of studies necessarily involving relatively small numbers of subjects, and the resulting pattern of interpreting as benign—or dismissing—findings of excess cancer mortality.

Radiation Dosimetry

There appear to be major inaccuracies, and serious questions as to consistency and reliability, in the measurement and recording of the radiation exposures of nuclear weapons complex workers. Yet these are essential elements on which occupational epidemiology studies depend. Methods of collecting and recording expo-

sure data on employees at different sites, or within sites over time, have varied widely. In the earlier years only a fraction of the workers were monitored, and there was serious risk of under-reporting exposures. At some sites, for many workers, it is impossible to distinguish between unmonitored years and years with a zero dose. At other sites, a zero dose was recorded for any exposure below the threshold of film badges. In one case spurious "correction factors" were invented to lower exposure figures and give some workers a "negative radiation dose," something that does not exist in nature. One research team has concluded that there is "no constant relationship between recorded doses . . . and actual doses." At five important DOE sites, no radiation exposure data are available for epidemiologic studies; at others, computerization of exposure data and linkage to individual workers are years out of date. The great majority of published DOE studies do not present any individual-specific exposure data, thereby limiting the analyses of health effects and raising the possibility of misclassification bias (mixing exposed and unexposed workers together, which would dilute the estimated effect). The worse the data, the harder it is to compare workers with higher radiation exposures to those with lower or no exposures, the only proper method of analysis. There is also a pervasive lack of data on workers' medical irradiation histories, smoking and other factors which could distort or confuse findings.

The published DOE epidemiologic studies cover only a relative handful of the 76 nuclear weapons research, production and testing sites.

Coverage of the Workforce and of DOE Sites

Of the cumulative total of approximately 600,000 nuclear weapons workers, large numbers are not represented in published DOE studies. From 1947 to 1978 at some sites, no exposure data were kept on the employees of subcontractors. Data on thousands of workers are incomplete. By 1990, only 250,000 workers were represented in computerized databases. At one site involved in a study of all workers exposed to 5 rem of external radiation in any one year, records are so confused that the true number of workers exposed at that level may be three times greater than the number included in the study, and the number exposed at 4 to 5 rem (many of whom may in fact have had higher exposures) is ten times greater. The published DOE epidemiologic studies cover only a relative handful of the 76 nuclear weapons research, production and testing sites. Because DOE sites vary in the industrial processes they employ, and average radiation exposures vary widely at different sites, the published research findings may have overlooked some serious hazards to health.

Length of Follow-up of Worker Cohorts

There have been long and inexplicable delays in gathering death data on many nuclear weapons plant workers, and the information is typically out of date by five to seven years or more. This is reflected by the limited length of follow-up reported in many studies. For most nuclear weapons workers covered by the published studies, follow-up is far short of the period required before many forms of cancer, especially solid tumors, appear. Such studies are therefore radically incomplete, and the reported absence of significant findings may constitute a false reassurance. These deficiencies are more serious in view of a few recent studies finding more cancer deaths during extended follow-up periods. It is noteworthy that those more recent DOE studies which cover longer time periods tend to report higher cancer mortality rates and more findings that are statistically significant.

The "Healthy Worker" Effect and the Lack of Morbidity Data

Many of the benign or dismissive interpretations of excess cancer risk in nuclear weapons workers as compared to the general population—interpretations that are consistently found in DOE-sponsored studies—give insufficient weight to the "healthy worker effect," which predicts *lower* risks of disease for workers. The workforce almost always has low mortality in comparison to the population at large, since the latter includes many more people at high risk of poor health, who are too sick to work, who lack good medical care, who have lower average socioeconomic status and higher rates of smoking, etc. Years of research has taught that overall death rates, and death rates from specific diseases such as cancer, will be lower among workers than in the general population. For example, any comparative increase in death rates for cancer among workers runs counter to expectations and calls for further investigation and follow-up. Despite widespread knowledge of the healthy worker effect, studies that are subject to this form of bias continue to be conducted; the majority of published DOE studies are plagued by this problem.

While some of the DOE's published studies may acknowledge the healthy worker effect, they rarely regard excess, but not statistically significant, worker death rates as warning signals. Instead, they tend to

effects in the nuclear workforce, permitting at best the selective and limited release of such information. These data thus became the virtual monopoly of an agency with the inherently conflicting missions of increasing weapons production and protecting worker and public health. This facilitated the dismissal or denial of health findings that might be alarming and the withholding, for decades of information on both accidental and deliberate radiation and other toxic releases to the environment. Perhaps most damaging of all was the violation of basic principles of unfettered scientific investigation. Secrecy is totally inappropriate in investigations of health and safety.

While there is no reason to question the integrity of individual DOE-sponsored epidemiologic researchers, there is evidence extending over many decades of intermittent administrative attempts by the AEC/ERDA/DOE to suppress evidence suggesting health risks, to intimidate some epidemiologic and environmental investigators, and to highlight reassuring findings while downplaying or denying risks. The DOE epidemiology program has not been operated as a publicly funded program with public accountability.

Recommendations

In summary, the Task Force believes the findings of DOE-sponsored epidemiologic studies offer no firm basis for the repeatedly expressed official position that the health of workers and the public has been fully protected and that there are no excess risks of disease and death in the nuclear weapons workforce. There is a steadily growing body of troubling and disturbing findings which are not definitive but which call for urgent, expanded and independent investigation. We conclude that the AEC/ERDA/DOE epidemiology program is seriously flawed, inadequate in scope and pace of work, underfunded in relation to the studies that are needed, and burdened by an intrinsic conflict of interest and the public's recognition of that conflict.

On the basis of its review, the Task Force makes the following recommendations:

*1. **Establish a new Office of Radiation and Toxins Health Assessments.*** The involvement of the Department of Energy (DOE) in the supervision of epidemiologic research activities on its workforce and on the health and environmental effects on surrounding communities should be ended completely and definitively. In its place, an aggressive and coordinated investigatory process to assess weapons complex-related occupational and environmental health effects should be established. This should be accomplished by statute, through a new Congressionally-mandated Radiation and Toxins Health Assessment Office within the Department of Health and Human Services (HHS) or the Environmental Protection Agency (EPA), superseding the present DOE-HHS Memorandum of Understanding.

*2. **Provide greater direction and coordination of health and environmental assessments in and around the nuclear weapons complex.*** The new Office should direct, coordinate, and initiate comprehensive occupational and environmental health assessments at weapons complex facilities. It should coordinate ongoing and future efforts with the DOE, other HHS offices and institutes, the Environmental Protection Agency (EPA) and state health departments on all matters of potential public health impacts of these facilities. The goal would be to evaluate the possibility and extent of occupational and off-site health effects, develop health-based occupational safety and environmental cleanup priorities, and address worker and community health concerns.

*3. **Ensure worker and public participation.*** A primary task of the new Office should be to develop and implement a process for identifying worker and community concerns regarding potential health impacts and to obtain broad and meaningful involvement of independent scientists and the public in the health assessments. Such a process should involve oversight and periodic program review by non-governmental panels of qualified independent scientists and representatives of DOE workers and surrounding communities.

Each epidemiologic project should have direct input from the population being studied—workers and/or residents of nearby communities—at every phase from the planning of research, the dissemination of information about ongoing research activities, and the communication of the study's results. As the Secretarial Panel for the Evaluation of the Epidemiologic Research Activities pointed out, workers and the public have a right to know about collective health experiences and risks to which they are exposed.

*4. **Implement a uniform, system-wide radiation data collection.*** The new Office should take steps to assure that a uniform system-wide instrumentation for external and internal radiation dose measurement, and standardized protocols, methods and forms for dose recording, data entry and storage are rapidly implemented throughout the weapons complex, in compliance with the 1989 National Academy of Science recommendation that "data collected within the complex should be comprehensive, accessible and comparable."

*5. **Implement a detailed employee health information system.*** The new Office should take steps to assure that the DOE fully implements the detailed employee health information system promised in 1990, and currently limited to a small pilot program, with special attention

dismiss them as likely due to chance, even in the many cases in which the number of workers under study is so small that statistical significance would be difficult to achieve unless the excess of observed over expected deaths was extreme. Nuclear weapons workers and the public alike may be falsely reassured by the DOE's emphasis, in repeated statements, that total death rates and cancer death rates among nuclear weapons plant workers are usually lower than in the U.S. population at large.

There are, however, alternative ways of examining the data, though they are not reflected in DOE studies. Comparisons of Standardized Mortality Ratios (SMRs) for cancer among nuclear weapons plant workers with the SMRs for other diseases or for total deaths may suggest excess cancer risks. (An illustrative example is presented in Table 2, Appendix F.) If specific data on radiation exposures of workers were available, more sophisticated analyses of this type would be possible.

A second problem is presented by the almost exclusive reliance of the DOE studies on death rather than illness, mortality rather than morbidity, as the health outcome examined. Mortality studies are admittedly cheaper and easier than studies of disease incidence. Yet many adverse health outcomes can be ascertained far sooner during life; mortality studies eliminate from consideration virtually all adverse health effects which may be related to radiation exposure but which will not or have not yet caused death. This is especially true in the case of cancer; many cancers are now treatable, and some curable, and if life is prolonged or the disease cured, mortality studies of nuclear plant workers will not give a true picture of the frequency with which cancer appears in this group. Furthermore, because of the way in which death certificate information is frequently coded, cancer deaths may be miscounted or falsely attributed to some other disease category.

"Statistical Significance" and Fragments of Knowledge

"All too often," one researcher has noted, "investigators disregard a positive association between exposure and disease . . . because the finding is not statistically significant . . . . A consequence is that negative findings can be guaranteed simply by doing studies of small populations or by stratifying data so finely that it becomes impossible to obtain 'statistically significant findings' unless an extremely strong exposure effect is present." Another has pointed out that "a small insensitive study may rule out very strong effects."

Repeatedly, our reviewers described studies in which DOE investigators have dismissed findings because they were not statistically significant even if more than the expected numbers of total cancer deaths, or deaths from specific cancers, had occurred. Often the numbers in any one study were too small to test for meaningful effects. Consequently, the interpretations in these studies are unduly shaded toward reassurance rather than toward vigorous, inquisitive exploration of clues, recognition of potential "sentinel" events or warnings, and growing magnitudes of effect over time. Careful follow-up of such leads and other methods of analysis of the same data can yield important findings that would otherwise not come to light but may be vital.

The Task Force summarized reported trends or suggestions of excess rates of cancer (typically mortality rates) associated with working in the nuclear weapons industry at 14 sites, 11 in the U.S. and three in the U.K. (See Table 1.) We identified findings where there was either a standardized mortality or incidence ratio over one (and the occurrence of at least 5 cases), or a standardized ratio that was significantly higher than expected, or a statistically significant increase in cancer with increased radiation exposure.

Table 1 shows an increase in deaths from all lymphatic and hematopoietic cancers, non-Hodgkins lymphoma, brain and central nervous system cancer, prostate cancer and lung cancer in five or more of the populations. In addition, there were four sites with increases in bladder cancer deaths. These findings, in our view, do not justify a policy of underinterpretation, reassurance or premature dismissal.

The epidemiologic research on the nuclear weapons industry lends itself to meta-analysis, a method involving the aggregation of results from similar but independent studies. The lack of statistical power associated with studying one small group of workers can be overcome by combining the results from several other studies. Meta-analyses may thus produce findings which were not apparent in any of the individual studies. Two recent meta-analyses have been published by non-DOE investigators. One combined the results of seven previously published DOE and U.K. studies (only four DOE studies had sufficiently specific radiation dose data to be included) and identified a 50 to 80 percent increased risk of leukemia mortality among higher-exposed workers; the other found a consistent 15 percent excess risk of brain cancer among 8 of 10 nuclear weapons plant worker cohorts compared with the U.S. general population. DOE researchers have begun to conduct studies pooling data from different sites, but continue to conclude that there is not "clear evidence of adverse effects of low-level radiation by external exposure."

Secrecy, Monopoly and Power

From the earliest moments of the development of the nuclear weapons production complex, secrecy has been the most dominant and unvarying characteristic of the process. "National security" has been invoked to justify secrecy not only for the design of weapons, the processes of manufacture and the results of testing but also for the data on radiation exposure and health

to the real-time recording of morbidity data (while protecting employee confidentiality). This will serve as an early-warning system for detecting changes in worker health and will facilitate epidemiologic studies of morbidity to supplement the present focus on mortality studies.

6. Establish a National Registry of Nuclear Weapons Production and Cleanup Workers. A national registry of nuclear weapons production and "cleanup" workers should be established immediately and maintained prospectively, in cooperation with the Social Security Administration, national and state death and cancer registries and other appropriate agencies to facilitate the monitoring of these cohorts throughout their lifetimes. It is essential that this recommendation (and the two previous recommendations) apply to the employees of contractors and sub-contractors, who may currently be omitted from surveillance, as well as the employees of the DOE itself. Contractors and subcontractors should be bound by the same regulations and the same protocols for data collection and recording that apply to the DOE.

While it is beyond the immediate purview of our study, we note that the inclusion in this registry of workers in commercial nuclear power plants and nuclear shipyard workers would extend the umbrella of surveillance and, by substantially increasing cohort size, facilitate scientific investigation of the health effects of low-dose ionizing radiation.

7. Update data and conduct follow-up studies. Priority should be given to (a) updating, computerizing and linking radiation dosimetry, mortality and other data—now often many years out of date at a number of DOE facilities—and to (b) studies which "re-visit" worker cohorts to extend the follow-up periods, in view of recent studies which suggest excess cancer mortality (and longer than expected latency periods) after longer follow-up.

8. Improve research methods. To the fullest extent permitted by the flawed radiation dosimetry procedures and incomplete worker coverage of past decades of DOE epidemiologic research, further studies of the nuclear weapons workforce should: a) present individual-specific radiation dose data; b) include all workers at potential risk; and c) differentiate the experiences of workers with longer length of employment (and presumably length of exposure) and higher cumulative doses from the experiences of those with shorter lengths of employment and those with lower or no doses. Pooling the data on these categories of workers tends to dilute the exposed fraction of the study members, biasing the results downward from any actual radiation effect and causing observed results to understate the actual risk.

Where possible, dose reconstruction should be understood to include and specify external, internal and organ doses. Since nuclides are not uniformly distributed within the body, use should be made of standard-man models developed by the International Commission on Radiological Protection. Greater use should be made of surrogate indicators, such as the number of urine tests for internal exposure, to stratify workers by risk of exposure. Data on medical irradiation, background radiation, smoking and other lifestyle factors should be collected and utilized.

9. Enhance environmental monitoring for site-specific health investigations. There is at present no coherent strategy for adequate investigation of the possible health effects in all the communities exposed to off-site radioactive or other toxins released from the nuclear weapons complex. Large-area studies, especially when used to measure death rates, are far too insensitive. If good prospective epidemiologic studies of populations near weapons facilities are to be undertaken, an effort must be made to estimate levels of exposure. The establishment of accurate environmental monitoring networks in every such community is necessary to permit good dose measurement. Only site-specific investigations based on such data can properly evaluate possible links between environmental contamination from the weapons complex and health effects in a particular community. Such off-site monitoring and off-site investigations should be coordinated and directed by the proposed Radiation and Toxins Health Assessment Office.

10. Provide complete and unrestricted access to data. Complete and unqualified access to DOE and contractor records, and to all other relevant epidemiologic data, must be guaranteed both to HHS and subsequently, and in a timely fashion, to independent, nongovernmental scientific researchers, with no restraint on publication or presentation of findings other than the normal processes of peer review.

11. Improve the link between research findings and occupational safety programs. Systems should be developed to assure rapid transmission and communication of relevant research findings to those DOE and contractor officials, including in-plant physicians, health physicists, managers and administrators, with responsibility for occupational health and safety.

12. Expand the budget and resources for radiation and toxins health research. Congress should mandate a substantially expanded budget for weapons complex-related epidemiologic, occupational and environmental research. Substantial additional numbers of highly qualified epidemiologists, biostatisticians, specialists in occupational and environmental health and other

scientists will be needed to assure competent and adequate study both of the existing nuclear weapons workforce and of the workers who will be involved in the long and potentially dangerous cleanup effort. Adequate funding from the DOE's "050" defense production accounts should be used to support the new Office of Radiation and Toxins Health Assessment, an expanded staff of researchers, and the costs of studies covering all potentially exposed workers and off-site populations at all facilities.

*13. **Fully fund and implement improved CEDR Program.*** Adequate funding should be provided for a Comprehensive Epidemiologic Data Resource that will be available to all scientists, with the assurance that *all* relevant data from the nuclear weapons production complex and its planned health surveillance system will be entered.

*14. **Enhance the regulatory power of OSHA and EPA throughout the weapons complex.*** While on-line, in-plant responsibility for occupational health and safety programs might remain with DOE and its contractors, statutory provision should be made and funds provided for rigorous oversight by the Occupational Safety and Health Administration (OSHA) and EPA. Those agencies should be given the power to impose fines or, when necessary, shut down operations at the DOE facilities that violate occupational and environmental standards or otherwise pose an unacceptable public health threat.

Legislative action is required to assure that all relevant OSHA and EPA regulations are applied to the DOE's weapons complex at least as vigorously as they are applied to private industry. In view of the risks, and the record, the defense of sovereign immunity by the DOE and its contractors should be waived.

*15. **Consider the health and environmental impacts of continued nuclear weapons activities.*** Any proposal to resume production of nuclear weapons should incorporate a complete review of the associated hazards to the health and safety of workers and nearby communities. The putative benefits of such weapons should be weighed against the associated risks and hazards.

data on radiation and toxic releases, and on workers' exposures and health. Thus, independent scientific studies of illness and deaths in potentially affected workers and nearby communities were impossible.

The Development of Epidemiologic Studies

Occupational and public health in the weapons plants were the responsibility of the DOE and its predecessors, the Atomic Energy Commission (AEC) and the Energy Research and Development Administration (ERDA), directly and through their contractors, as part of a process of internal regulation, surveillance and scientific study. One essential element of this effort was epidemiologic study. This involves: (1) the precise and continuous definition and measurement of radiation and other toxic exposures; (2) careful and long-term measurement of the distribution of illness and death in worker (and surrounding community) populations; (3) meticulous comparison with the health outcomes of less-exposed or unexposed individuals. This is the most certain (if imperfect) route to the identification of previously unknown risks, the more precise quantification of those that are known, the design of protective measures, and the recognition of clues to the biological and environmental modes of action of the radiation and other toxins involved.

Causal relationships between exposure and disease may be inferred if the data on exposure doses are precise, if other potentially confounding risk factors such as smoking are measured and adjusted for, if follow-up on health status is accurate and long enough to detect diseases which may have a long-delayed onset or latency period, and if the cohorts (the groups of exposed people studied) are large enough to permit secure tests of statistical significance. Additionally, dose-response calculations, a measure of the risk associated with intensity and duration of exposure, may be made. Even when all of these conditions cannot be fully met, as is often the case in epidemiologic studies, findings of excess disease and death may constitute signals of serious possible danger and indicate the need, at the least, for additional studies and for consideration of measures to reduce permissible exposure levels.

Shortly after the end of World War II, the Atomic Energy Commission initiated extensive research into the health effects of radiation by supporting the Atomic Bomb Casualty Commission (reorganized in 1975 as a binational U.S.-Japanese venture, the Radiation Effects Research Foundation [RERF]) to explore the carcinogenic and other consequences of the (primarily acute, high-dose) exposures among Japanese survivors of the Hiroshima and Nagasaki bombings.[9] That effort has continued to the present; since 1945, approximately half of total radiation research expenditures by the DOE and its predecessor agencies have gone to RERF and half to studies of the (primarily low-dose and cumulative) radiation exposures and their consequences among nuclear weapons workers.

Although the measurement of workers' radiation exposures began in the earliest years of the Manhattan Project, the planning and conduct of large-scale epidemiologic studies of the workforce was not built prospectively into the initial stages of the development and growth of the government's nuclear weapons complex, nor was this effort a prominent feature of the early decades of research, production and testing. Not until the mid-1960s, with the award of a contract to Dr. Thomas Mancuso and his colleagues at the University of Pittsburgh for studies at Hanford, Oak Ridge National Laboratory, and the Y-12 Plant and K-25 gaseous diffusion plant at Oak Ridge, was any major effort undertaken in the analysis of radiation exposures and health outcomes in the nuclear weapons workforce. However, when preliminary (and controversial) reports from the Mancuso team suggested a significant increase in cancer risk estimates over then-current beliefs, the Mancuso contract was abruptly cancelled. Epidemiologic research was transferred and confined to the agency's own laboratories (thus raising the real possibility of conflict of interest) and divided among them, rather than conducted as an integrated effort. In the decades since, large numbers of scientists have been employed, either directly by the DOE or through contracts with a limited number of laboratories and universities which the DOE selected and directly supervised, and a large body of epidemiologic work was undertaken and published.[10]

Secrecy and DOE Epidemiology

Just as the wall of secrecy shielded all other aspects of the nuclear weapons program, these epidemiologic and related scientific studies were not subject to the usual conventions of open scientific or academic inquiry. While several scientific advisory committees intermittently consulted with or reviewed DOE epidemiology, the "culture of secrecy" permeating the entire nuclear weapons complex kept this work from outside scrutiny.

This meant that AEC/ERDA/DOE and contractor epidemiologists formulated their overall research plans, designed and organized their studies, decided which data to collect, made choices of measurement and monitoring techniques and instruments, and analyzed and interpreted their data as part of "an enterprise that has operated in secrecy for decades, without any independent oversight or meaningful public scrutiny."[11] While some results from many of the affected or potentially affected sites have been published in the open scientific literature, meeting the test of peer review, the basic data sets are still not generally available to independent researchers, and it is unclear how many studies were done but have never been released to the public.

The Secretarial Panel for the Evaluation of Epidemiologic Research Activities

In the summer of 1989, the DOE faced a major erosion of its credibility in epidemiologic research. Congress was considering transferring responsibility for such research from the DOE to an independent federal health agency. To counter growing criticism, Energy Secretary Watkins formed the Secretarial Panel for the Evaluation of Epidemiologic Research Activities of the Department of Energy (SPEERA). The Panel's membership included academic experts in public and environmental health, state health officials, epidemiologists and legal experts.

The SPEERA was charged with providing "an independent evaluation of the DOE's epidemiology program and the appropriateness, effectiveness, and overall quality of DOE's epidemiologic research activities."[28] It was asked to investigate many aspects of the DOE's epidemiologic program, including:

- the goals and objectives;
- the management and reporting structure;
- quality control mechanisms, including standards for data, archiving, and access; and
- the utility and feasibility of transferring the epidemiologic research to another entity.[29]

From September, 1989 through March, 1990, the SPEERA held a series of meetings, public hearings, and DOE site visits. The SPEERA's final report characterized DOE epidemiologic research program as lacking central coordination, and recommended consolidation of the research activities and opening up the research field to other federal health agencies, independent researchers, and the public.

To achieve this, the SPEERA urged that the DOE's scattered epidemiologic activities be unified in one office. It recommended that the DOE negotiate a Memorandum of Understanding (MoU) with the Department of Health and Human Services (HHS), under which HHS would manage the DOE's analytic epidemiologic research. It also urged standardization of the basic data and improvements in its quality and availability,[30] and called for increasing the dissemination of data through the creation of a Comprehensive Epidemiologic Data Repository (CEDR)[31] open to independent scientists.

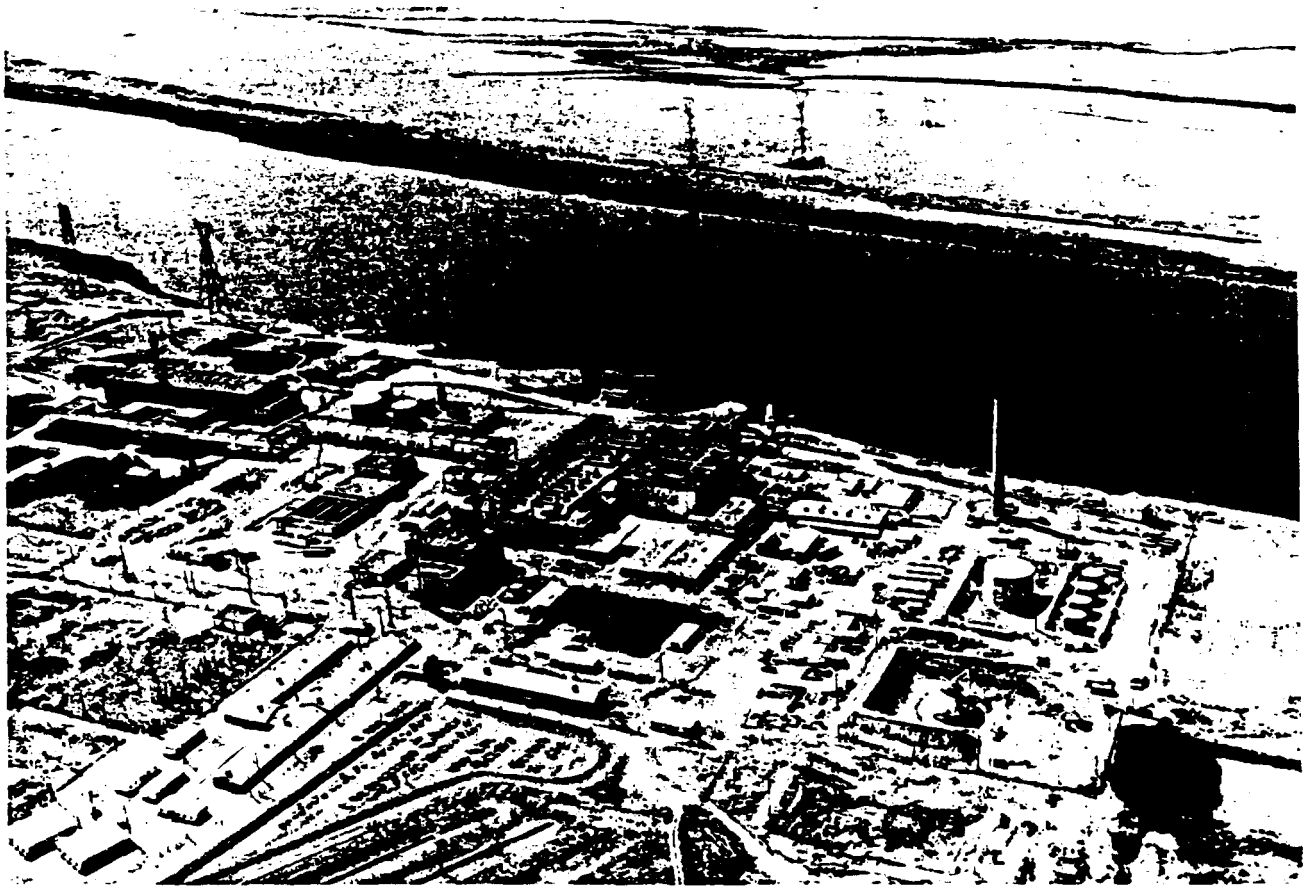
The SPEERA's Findings and Recommendations

The Panel stressed that restoring public trust and assuring high scientific quality required that the Department develop "an independent system for managing its analytic epidemiologic research."[32]

This recommendation was based on the following SPEERA findings:

- The DOE has shown a continuing commitment to funding energy-related epidemiology.
- There are limits to how well an organization can study itself without facing conflict of interest issues.
- Most of the scientists conducting epidemiologic research for the Department are employees of the Department's major long-term contractors. The Department, through its relationship with contractors, has made it difficult for researchers outside of the system to conduct studies.
- The Panel heard testimony accusing the Department and its contractors of attempting to influence epidemiologic findings inappropriately. The Panel also heard testimony from people who believe that there is a conscious effort not to influence the studies. The Panel decided it was not in a position to judge; however, the fact that the question of influence has arisen requires that it be addressed.
- There has not been open competition for epidemiologic research projects. Open competition helps assure a strong research program.
- In many cases the research interests of current primary contractors appear to set the epidemiologic research agenda. In its relationships with contractors, the Department's epidemiology program appears to lack leadership.[17]

In light of these findings the Panel recommended the enactment of the MoU between the DOE and HHS. In its view, such an MoU could include provisions for the DOE to continue to fund the studies taken over by HHS, and current grants and contracts would continue to be executed by the original parties. Thus, primary DOE epidemiology contractors would continue to carry out much of the research in progress. However, HHS would use "its usual methods to set the research agenda, provide for peer review of research proposals, provide quality assurance for research-in-progress and provide access to data."[34] (See page 55 for further discussion.)



The Hanford facility includes reactors like the N-Reactor pictured here, which was used to produce plutonium. PHOTOGRAPH COURTESY OF THE U.S. DEPARTMENT OF ENERGY

production reactors at Hanford and Savannah River were completely shutdown. The Purex plutonium-extraction plant at Hanford suspended operations in December of that year. Rocky Flats Plant plutonium operations were suspended in November, 1989, six months after it was raided by FBI agents searching for documentary evidence of regulatory violations. The Fernald facility's production operations were suspended in October, 1990. A Union of Concerned Scientists report labelled the weapons complex experience a "catastrophe" and summarized it as follows:

> Driven by excessive demands for new nuclear weapons in the early 1980s, plagued by declining in-house expertise and dependence on the questionable competence and good faith of contractors, protected by pervasive secrecy from the discipline of public and congressional oversight, and immune from the environmental, health and safety regulations that control private industrial activities, the weapons complex suddenly collapsed in the second half of the 1980s and now lies in shambles.[59]

Loss of Credibility and the Need for Review

After 40 years of assurances that no threats to the health of community residents and workers had ever occurred, the credibility of the government was damaged beyond repair by this series of revelations. Even Energy Secretary James D. Watkins openly admitted that the weapons complex had been "cloaked in secrecy and imbued with a dedication to the production of nuclear weapons without a real sensitivity for protecting the environment."[60] Similarly, the revelations intensified skeptical questioning of the DOE's epidemiologic studies, the bulwark of its assertions that there was no serious excess risk to nuclear complex workers. As Watkins' Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA) noted after a nation-wide series of hearings:

> A recurrent theme of witnesses at every meeting has been a lack of credibility in the Department's epidemiologic activities . . . there are limits to how well an organization can study itself without facing conflict of interest issues.[61]

The SPEERA focused primarily on the processes and organization of the DOE's epidemiologic efforts. Given the constraints of secrecy, only two relatively independent and reasonably comprehensive reviews of the AEC/ERDA/DOE/contractor epidemiologic record had ever been conducted, though many specific criticisms of individual studies had been published in the scientific literature. (In 1980, a review of DOE

explosive "single-shell" high-level nuclear waste storage tanks and other major hazards within the plant, and of contamination of the Columbia River and groundwater reservoirs was followed by a DOE admission that hundreds of thousands of curies of radioactive I-131 had been released to the atmosphere during the 1940s and 1950s, with the possible exposure of up to 13,000 children, some of them to doses as high as 70 rads.[35-40]

Widespread environmental contamination, dangerous reactor accidents and a threat of explosions in waste storage tanks were also identified at the Savannah River Site.[41-44] At Mound,[45] in Miamisburg, Ohio, investigators discovered that a pipe carrying high-level waste burst, and plutonium seeped into irrigation canals and water supplies for several years afterward. Contamination was extensively documented at Oak Ridge,[46,47] the Nevada Test Site,[48] the Pantex plant,[49] the Idaho National Engineering Laboratory and Lawrence Livermore National Laboratory in California. A conservative preliminary estimate of the cost of "cleanup," a task expected to take decades and generate new potential health risks, exceeds $100 billion.[50]

By the spring of 1988, all of the DOE's nuclear

Office of Technology Assessment's Report on the Environmental Legacy of Nuclear Weapons Production

Congress asked its Office of Technology Assessment (OTA) to evaluate what is known about the contamination and public health problems at the Nuclear Weapons Complex and to investigate technological and other approaches to solutions. In February of 1991, OTA released its final report, *Complex Cleanup*.[51] The report includes an analysis of research on the health effects of the DOE weapons complex on off-site populations and observations on basic problems in the organization and conduct of DOE epidemiologic research.

Complex Cleanup questions the DOE's claim that current contamination from weapons production poses "no immediate threat" and no "near-term risk" to public health. The authors conclude that such claims are "largely unsubstantiated" and "also somewhat misleading."[52]

The OTA report explains that the DOE's effort to survey site contamination is critical in determining the health risks of weapons production. *Complex Cleanup* concludes that in this process crucial public health concerns have not been investigated adequately.[53] Responsibility for conducting site-specific studies is scattered throughout several federal and state agencies, and such efforts are under-funded. Important health objectives may be slipping through the cracks because there is no single agency or coordinating body responsible for this work.[54]

The OTA report reinforces many of the Secretarial Panel for Evaluation of Epidemiologic Research Activities (SPEERA) findings, noting that basic structural problems are at the heart of the DOE's failure to adopt a health-based approach to cleanup of the Weapons Complex. *Complex Cleanup* points out that the "DOE has recognized that its current organizational structure for investigating possible off-site health impacts of the nuclear weapons sites is in need of improvement."[55]

Complex Cleanup reports that DOE research has been kept away from open scrutiny. Those in charge of the DOE have not fostered adequate health research, in part, because there is an inherent conflict of interest between their primary mission of weapons production and their simultaneous responsibility to protect worker and community health. The OTA points out that under the DOE's proposed reorganization of its health research program:

> [No] 'unsolicited proposals' would be funded by the [DOE] Office of Health. How such arrangements would differ from present practice of arranging for scientists at the DOE national laboratories to conduct the bulk of DOE-funded epidemiologic studies is not discussed.[56]

In examining the process of determining off-site health effects, the OTA report finds that:

> Available studies do not afford a comprehensive survey of contamination present throughout the Weapons Complex; information about toxic chemicals is especially lacking. Nor is reliable information available regarding human exposure routes and dose range.[57]

The OTA attributes this problem to the DOE's lack of an aggressive health research agenda. They find that public health concerns are still not being investigated adequately by the DOE or other government agencies. *Complex Cleanup* concludes that:

> Published reports and available data can neither demonstrate nor rule out the possibility that adverse health effects have occurred or will occur . . . . Investigations beyond those already completed will be necessary to pursue questions about the occurrence of off-site health effects and to produce the information required to identify the most pressing cleanup priorities.[58]

research on human health effects of low doses of ionizing radiation was prepared by a Committee of the National Research Council, National Academy of Sciences. In 1984, a review of the epidemiology program was prepared by a subcommittee of the Health and Environmental Research Advisory Committee (HERAC) to DOE. These reviews are summarized and discussed briefly in Appendix D.) No overall evaluation of the DOE epidemiologic record, however, has ever been released in a form available to the general public.

In 1988, Physicians for Social Responsibility undertook an effort to meet that need as part of the overall mandate of its Physicians Task Force on the Health Risks of Nuclear Weapons Production. The present report summarizes that effort.

While most of its work focused on the analysis of DOE-sponsored epidemiologic studies published during the last several decades, the Task Force has also made assessments of recent policy changes. In 1989, Admiral Watkins told the Senate Committee on Governmental Affairs:

> As an employer, DOE has a moral and ethical responsibility to monitor the health of its workers in an effort to ensure that all potential harmful aspects of the work environment are controlled .... Epidemiologic surveys of our work force represent a key element of our programmatic efforts to successfully meet this obligation.[62]

Subsequent sections of this report, and its conclusions, will consider the extent to which that responsibility has been met.

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Attachment 4

DEPARTMENT OF ENERGY DECLASSIFICATION REVIEW
1ST REVIEW-DATE: 09-08-95
AUTHORITY: ☐OC ☐ADC ☐ADD
NAME: [redacted]
2ND REVIEW-DATE: 10/6/95
AUTHORITY: ADD
NAME: [redacted]
DETERMINATION (CIRCLE NUMBER)
1. CLASSIFICATION RETAINED
2. CLASSIFICATION CHANGED TO:
3. CONTAINS NO DOE CLASSIFIED
4. COORDINATE WITH:
5. CLASSIFICATION CANCELLED
6. CLASSIFIED INFO BRACKETED
7. OTHER (SPECIFY): 2 pages

Sanitized by NN-523 on 2/5/98

August 16, 1995

SUBJECT: PROPOSAL FOR DECLASSIFICATION OF CERTAIN GASEOUS DIFFUSION ENRICHMENT INFORMATION. (U)

The National Institute for Occupational Safety and Health is presently investigating health issues at the Gaseous Diffusion Plants that involve information that is classified, restricted data. The NIOSH policy requires them to conduct their studies unclassified, and with unclassified information. It is possible, but much less desirable, to use information that is encoded in such a way as to protect the specific classified information, and to have a classified key to the encoding as a classified appendix to their report.

This request is intended to state the specific information that is required, and the way the information will be used. The investigation covers any occupational exposure to a list of specific chemicals, and will require any data that are relevant to the exposures.

1) The chemicals of concern consist of two groups. The first group are taken from the open literature about the gaseous diffusion plants. These are:

NICKEL	COPPER	ARSENIC	CADMIUM
MERCURY	URANIUM	FLUORINE	CARBON TETRACHLORIDE
ACETONE	PERCHLORETHYLENE		PCB'S

The classified compounds include:

DELETED DELETED

A less desirable but possible alternative to naming the chemicals would be to encode the names by using terms like "Particulate A, Particulate B, and Chemical A, Chemical B." This approach would require the use of a classified appendix with the decoding information in it.

2) The monitoring results that are used for dose calculation would include volumetric concentrations of specific materials.

A less desirable form of the data would be an encoding of dosages into "High, Medium, or Low" ranges, with the decoding of the ranges given in a classified appendix.

3) The monitoring data should be identified by the building and department numbers to be correlated with worker exposure. It would be very useful to include job titles.

A less desirable approach would be to identify buildings as "Building A, Building B."

[redacted]

8/17/95

4) The time of acquisition of the monitoring data is needed, including the time of day, the day of the week, month and year. The intent is to identify trends.

[redacted]

[redacted]IAL

5) The sampling duration and volume are required.

6) Supporting comments on individual operations and tasks. It is important to include notes about any protective equipment or measures used in particular areas, as these would have a mitigating effect on the calculated doses. Examples of task descriptions would be: transfer of powder from one drum to another, welding, cleaning or degreasing.

7) Indication of generic job tasks, e.g. Welder, painter.

8) The data presentation will be tabular to indicate relationships between cases of multiple myeloma and exposures either internal or external versus cases of no-multiple myeloma and exposures either internal or external.