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When separated from attachment, handle this letter as [redacted] UNCLASSIFIED

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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.

FILE CODE

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.

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.

scientific interpretation of the results for all 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.

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.

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.

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

By: James D. Watkins
Admiral, U.S. Navy (ret.)
Secretary

Date 12/19/90

DEPARTMENT OF HEALTH AND HUMAN SERVICES

By: Louis W. Sullivan, M.D.
Secretary

Date DEC 24 1990

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-

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.

terns 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-

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

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

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), 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

gators 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

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

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.

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.

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

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.)

tence 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 dam-

miologic 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

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]

verse 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.[56]

Risks of Nuclear Weapons Production. The present report summarizes that effort.

sions, will consider the extent to which that responsibility has been met.

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]

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]

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.