

REPOSITORY Oak Ridge Operations (ORO)

COLLECTION Energy Programs Div. ER-11 ✓
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BOX No. Active Records Gathered from Human Radiation Exp. P.T.

FOLDER _____

B. Adams 490

B. Sleeman

~~J. Radloff~~

B. Seay

S. McCracken

✓ A. Chley

DOE

NEWS

NEWS MEDIA CONTACT:
Jeff Sherwood, 202/586-5806

FOR IMMEDIATE RELEASE
March 27, 1990

DOE BEGINS TO IMPLEMENT EPIDEMIOLOGY PANEL RECOMMENDATIONS

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Secretary of Energy James D. Watkins today received the final report from his independent advisory panel on epidemiological activities at the Department of Energy (DOE) and has issued six directives to begin to implement the panel's recommendations.

"I want to congratulate the panel and its chair, Kristine Gebbie, on the results of their intensive effort over the last six months," said Admiral Watkins. "I am pleased with the work of this panel. They have provided a forthright, hardhitting report. I share completely their sentiments that there should be a strong descriptive epidemiology program at the department, and that its functions should be consolidated within DOE into an occupational health program."

"The establishment of an occupational health program represents a major achievement toward my overall goal of strengthening the function of internal oversight in health protection," said Watkins. "There will be, for the first time, a single, definitive entity that is responsible for ensuring that line management is protecting the health of our employees and residents of nearby communities."

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"The panel's open deliberations and interim and draft final reports have permitted us to prepare timely action in anticipation of today's final report," said Watkins. "It is clear that certain recommendations can be implemented immediately. Accordingly, I have signed out today six Secretarial directives to the Assistant Secretary for Environment, Safety and Health."

The directives implement the following:

- o creation of an Office at the Deputy Assistant Secretary level which has functional responsibility for occupational health and epidemiology. This office will report to the Assistant Secretary for Environment, Safety and Health. This directive also calls for the Assistant Secretary to develop an implementation plan to provide for the initial consolidation of occupational health and epidemiologic activities.
- o development of a fully functional internal DOE epidemiology program that includes appropriate surveillance for the occurrence of occupational diseases and disabilities in worker populations. The program will be located in the new Office of Occupational Health.
- o establishment of an advisory committee to the Assistant Secretary for Environment, Safety and Health to monitor DOE occupational health and epidemiology programs as well as other issues before this office.
- o establishment of protocols and policies that ensure ready access to DOE epidemiologic data by researchers while balancing the need for protecting individual privacy.
- o examination, in detail, of each of the panel's more than 50 recommendations with an overall implementation strategy developed by June 30 and appropriate final actions taken by August 1.

The sixth directive calls for the development of a Memorandum of Understanding between DOE and the Department of Health and Human Services to establish an effective and credible external analytical epidemiology research program managed by HHS to support DOE's needs. Informal discussions with the Secretary of Health and Human Services indicate his willingness to provide this support.

(MORE)

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In describing this last initiative, Admiral Watkins said, "I agree with the panel's recommendation that the management of the department's long-term epidemiologic research be shifted to the Department of Health and Human Services. Although this type of research is interesting and serves a valuable purpose, it does not assist me in the day-to-day management of the department. Research of this nature is better suited for an agency that regularly addresses such issues. Such a shift will also enhance the credibility of the long-term research."

In order that valuable research not be interrupted, DOE anticipates that current epidemiologic laboratory research contracts will be continued, as recommended by the panel.

In June 1989, as part of a Ten-Point Initiative to move the department toward full accountability in the areas of environment, safety and health, Admiral Watkins announced the formation of an independent panel of experts to advise him on the restructuring of DOE's epidemiologic research activities. The Secretarial Panel for the Evaluation of Epidemiologic Research Activities for the Department of Energy (SPEERA), chaired by Kristine Gebbie, Secretary of Health for the state of Washington, is made up of nine highly respected public health professionals. Through site visits, public meetings, invited testimony and review of documents, the panel reviewed DOE's epidemiologic activities and prepared its report.

Copies of the DOE directives and the SPEERA report can be obtained by calling (202) 586-5575 or by writing to the: Department of Energy, Public Inquiries Branch, PA-5, Washington, D.C. 20585.

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The Secretary of Energy
Washington, DC 20585

March 27, 1990

MEMORANDUM FOR ACTING ASSISTANT SECRETARY FOR
ENVIRONMENT, SAFETY AND HEALTH

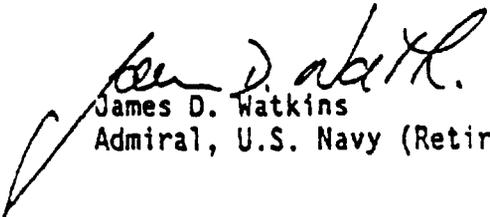
DIRECTOR, OFFICE OF ADMINISTRATION
AND HUMAN RESOURCE MANAGEMENT

SUBJECT: ESTABLISHMENT OF A CONSOLIDATED OFFICE RESPONSIBLE FOR
OCCUPATIONAL HEALTH AND EPIDEMIOLOGIC ACTIVITIES AT THE
DEPARTMENT OF ENERGY

On March 27, 1990, the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA) of the Department of Energy (DOE) presented to me its independent evaluation of the appropriateness, effectiveness, and overall quality of DOE epidemiologic and related occupational health activities. In response to the Panel's specific recommendations on the need for a fully consolidated organization within DOE for epidemiologic and occupational health activities, I hereby establish an Office of Health at the Deputy Assistant Secretary (DAS) level, which reports to the Assistant Secretary for Environment, Safety and Health (ASEH). In addition, I hereby direct that you take the following actions:

1. Immediately consolidate existing epidemiology staff and resources within DOE into this new office.
2. By May 1, 1990, present to me a coordinated implementation plan which shall:
 - a. Propose a mission and function statement detailing the responsibilities of the DAS office.
 - b. Propose a comprehensive staffing plan and resource requirements to support the DAS at the level needed to effectively perform the function as described in the mission and function statements, together with corresponding changes in other organizational units under the ASEH.
 - c. Develop and provide a detailed FY 1992 budget request to support the DAS and identify existing funds in FY 1990 and FY 1991 that may be reprogrammed to support program implementation and, if necessary, recommendations for supplemental funding in FY 1991.

In responding to this directive, the ASEH shall enlist any necessary expert assistants in occupational health and epidemiology administration to ensure the office is fully functional and contains requisite scientific talent.


James D. Watkins
Admiral, U.S. Navy (Retired)

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The Secretary of Energy
Washington, DC 20585

March 27, 1990

MEMORANDUM FOR ACTING ASSISTANT SECRETARY FOR
ENVIRONMENT, SAFETY AND HEALTH

SUBJECT: DESCRIPTIVE (INTERNAL DOE) EPIDEMIOLOGIC FUNCTIONS TO BE
PERFORMED BY THE DEPARTMENT OF ENERGY

On March 27, 1990, the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA) of the Department of Energy (DOE) presented to me its independent evaluation of the appropriateness, effectiveness, and overall quality of DOE epidemiologic and related occupational health activities. In response to the Panel's specific recommendations to ensure that the descriptive epidemiologic activities managed by the Office of Health in DOE are responsive to, and can effectively meet, the health and safety needs of DOE and contractor workers, I hereby direct that you take the following actions:

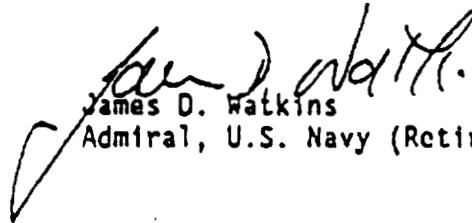
1. Develop an implementation plan which ensures the inclusion of appropriate surveillance for the occurrence of occupational diseases and disabilities in worker populations and to address valid local concerns over impacts from DOE activities. The ASEH shall:
 - a. Establish a comprehensive occupational health surveillance program to ensure the ongoing collection, maintenance, and interpretation of epidemiologic information on the workers at the Department's facilities.
 - b. Provide for the conduct of (DOE-managed) epidemiologic studies at DOE facilities, nearby communities, and other populations as needed. This may include the development of policies and procedures for funding studies by organizations outside of DOE.
 - c. Communicate results of epidemiologic studies to DOE management, the public, workers and worker unions, and operating contractors and their management.
 - d. Standardize methods for collecting epidemiologic data on DOE workers.
 - e. Continue development of the Comprehensive Epidemiologic Data Resource (CEDR) with guidance from the National Academy of Sciences Committee on DOE Epidemiological Research Programs.
 - f. Establish a system for conducting epidemiologic studies managed by the Office of Health.
 - g. Provide for peer review of epidemiologic studies managed by the Office of Health.

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- h. Ensure that ongoing retrospective mortality studies of DOE contractor workers continue to be supported pending the implementation of the Memorandum of Understanding with the Department of Health and Human Services.
2. Deliver the proposed implementation plan for these functions to me by June 30, 1990. Thereafter, provide me with quarterly reports on the status of these initiatives.


James D. Watkins
Admiral, U.S. Navy (Retired)

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The Secretary of Energy
Washington, DC 20585

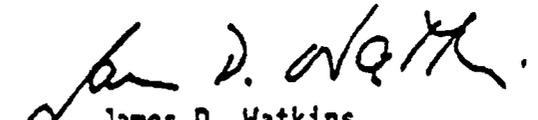
March 27, 1990

MEMORANDUM FOR ASSISTANT SECRETARY FOR
ENVIRONMENT, SAFETY AND HEALTH

SUBJECT: ESTABLISHMENT OF COMMITTEES TO PROVIDE OVERSIGHT
OF THE DOE EPIDEMIOLOGY PROGRAM

On March 27, 1990, the Secretarial Panel for the Evaluation of Epidemiologic Research Activities of the Department of Energy (DOE) presented to me its independent evaluation of the appropriateness, effectiveness and overall quality of DOE epidemiologic and related occupational health activities. In response to the Panel's recommendation for independent oversight of the DOE epidemiology program, I hereby direct that you take the following actions:

1. Provide me a recommendation on the establishment and composition of an independent group to advise the Office of Environment, Safety and Health concerning its mission. The charter of this group shall require that it periodically apprise the Secretary of Energy Advisory Board (SEAB) of its deliberations.
2. Provide me a recommendation, in consultation with the cognizant Program Secretarial Offices and Field Managers, on an approach for ensuring appropriate local participation in epidemiologic studies.
3. Provide a status report on the above actions by June 1, 1990.


James D. Watkins
Admiral, U.S. Navy (Retired)

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The Secretary of Energy
Washington, DC 20585

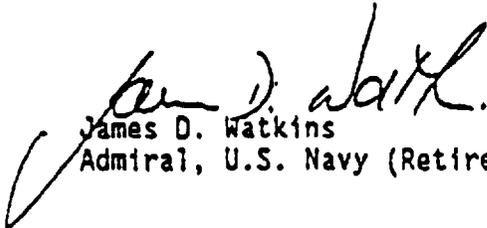
March 27, 1990

MEMORANDUM FOR ASSISTANT SECRETARY FOR
ENVIRONMENT, SAFETY AND HEALTH

SUBJECT: IMPROVED COMMUNICATION OF EPIDEMIOLOGIC INFORMATION WITHIN
THE DEPARTMENT OF ENERGY COMPLEX AND BETWEEN THE DEPARTMENT
AND THE PUBLIC

On March 27, 1990, the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA) of the Department of Energy (DOE) presented to me its independent evaluation of the appropriateness, effectiveness, and overall quality of DOE epidemiologic and related occupational health activities. The Panel emphasized that improved methods for sharing DOE epidemiologic information would enhance the credibility of the DOE epidemiologic program. Accordingly, I hereby direct that you take the following actions:

1. In consultation with the Epidemiologic Research Coordinating Committee (ERCC):
 - a. Develop, with the guidance of the National Academy of Sciences Committee on DOE Radiation Epidemiological Research Programs, a protocol governing the release of worker health and epidemiologic data to researchers and the general public. This protocol must properly balance the need for access to this data by the public with the need for protecting individual privacy.
 - b. Oversee the development of a mechanism for communicating epidemiologic results throughout all DOE elements. This information would be used by management and workers to evaluate existing operating procedures and policies to improve worker and public health and safety.
 - c. Report to me on the status of the above actions within 90 days of the issuance of this Directive.
2. Conduct negotiations on specific agreements with individual States concerning the release of death certificate information to DOE, its contractors, and other third parties. Report to me on the status of these negotiations within 90 days after the issuance of this Directive.


James D. Watkins
Admiral, U.S. Navy (Retired)

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The Secretary of Energy
Washington, DC 20585

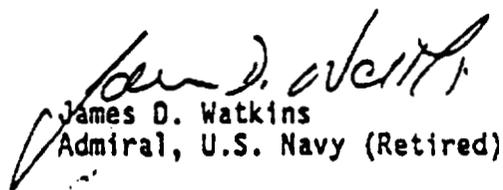
March 27, 1990

MEMORANDUM FOR ASSISTANT SECRETARY FOR
ENVIRONMENT, SAFETY AND HEALTH

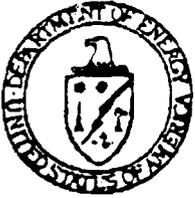
SUBJECT: ACTIONS TO ADDRESS EACH RECOMMENDATION OF THE SECRETARIAL PANEL
FOR THE EVALUATION OF EPIDEMIOLOGIC RESEARCH ACTIVITIES REPORT

On March 27, 1990, the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA) of the Department of Energy (DOE) presented to me its independent evaluation of the appropriateness, effectiveness, and overall quality of DOE epidemiologic and related occupational health activities. The SPEERA Report represents over 6 months of effort by recognized experts in their field and contains over 50 specific recommendations to improve the DOE occupational health and epidemiology program. I believe that DOE must carefully evaluate and consider all recommendations of the SPEERA Report. I hereby direct that you take the following actions:

1. By June 30, 1990, present to me an analysis paper and alternatives which examine, in detail, each of the recommendations of the SPEERA Report.
2. Ensure that any recommendations for future action as a result of the analysis have been fully coordinated with the Epidemiologic Research Coordinating Committee (ERCC).


James D. Watkins
Admiral, U.S. Navy (Retired)

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The Secretary of Energy
Washington, DC 20585

March 27, 1990

MEMORANDUM FOR ASSISTANT SECRETARY FOR DEFENSE PROGRAMS

GENERAL COUNSEL

ASSISTANT SECRETARY FOR NUCLEAR ENERGY

DIRECTOR OFFICE OF ENVIRONMENTAL RESTORATION AND WASTE
MANAGEMENT

ASSISTANT SECRETARY FOR ENVIRONMENT, SAFETY AND HEALTH

ACTING DIRECTOR, OFFICE OF ENERGY RESEARCH

SUBJECT: ESTABLISHMENT OF EPIDEMIOLOGIC RESEARCH FUNCTIONS TO BE
MANAGED EXTERNAL TO THE DEPARTMENT OF ENERGY

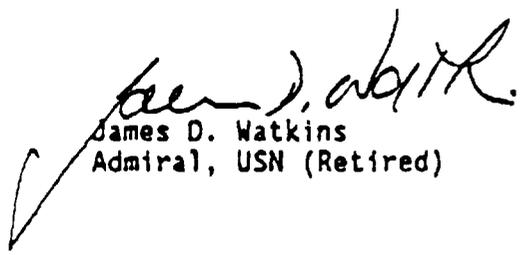
On March 27, 1990, the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA) of the Department of Energy (DOE) presented to me its independent evaluation of the appropriateness, effectiveness, and overall quality of DOE epidemiologic and related occupational health activities. In response to the Panel's recommendations relative to the need to implement an epidemiologic research function which is managed external to DOE, I hereby direct there be established, effective immediately, a Steering Committee, termed the Epidemiologic Research Coordinating Committee (ERCC), under the Chairmanship of the Assistant Secretary for Environment, Safety and Health (ASEH). Addressees are hereby appointed as members to the Steering Committee. The initial missions of the ERCC are to:

1. Direct negotiations with the Department of Health and Human Services (HHS) leading to a Memorandum of Understanding (MOU) for the management of an external program of analytical epidemiologic research activities funded by DOE.
2. Identify existing DOE-sponsored epidemiologic research studies to be managed by an organization outside of DOE and identify existing funding levels in FY 1990 and FY 1991 to continue support of these studies.
3. Identify programmatic and operational needs for epidemiologic activities to be directed by the new Office of Health.
4. Oversee all ongoing DOE analytical epidemiologic research including DOE-funded HHS-managed activities and other outside independent research efforts.

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In addition, I further direct that the ASEH take the following actions:

1. Provide to me by April 15, 1990, a Charter to formally establish the ERCC.
2. Immediately undertake, in coordination with the ERCC, negotiations for a MOU between DOE and HHS. Provide to me by April 30, 1990, a status report concerning the establishment of the MOU.
3. Propose, as part of the FY 1992 Internal Review Budget, necessary funding for external epidemiologic research. Include projected permanent funding levels for the program beyond FY 1992.


James D. Watkins
Admiral, USN (Retired)

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Adams

Report to the Secretary

**The Secretarial Panel
for the
Evaluation of Epidemiologic Research Activities
for the U.S. Department of Energy**

March 1990

1021677

**Secretarial Panel for the Evaluation of Epidemiologic Research Activities
for the Department of Energy**

Panel Members

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Mark Cullen, M.D.

Clark Heath, Jr., M.D.

Mark Rothstein, J.D.

Michael Silverstein, M.D., M.P.H.

Lee Stauffer, M.P.H.

Thomas Vernon, M.D.

Bailus Walker, Jr., Ph.D., M.P.H.

**Secretarial Panel for the Evaluation of Epidemiologic Research Activities
for the Department of Energy**

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Richard C. Weston, Health Policy Specialist

Frances D. Musgrove, Administrative Secretary

Helen L. Driscoll, Research Assistant

Robert S. Jackson, M.D., Consultant

Acknowledgments

The Secretarial Panel for the Evaluation of Epidemiologic Research was charged with providing the Secretary of Energy with an independent evaluation, which is transmitted in this report. The Panel wishes to acknowledge the valued assistance and insights gained from many sources.

The Department's senior staff, particularly in the Offices of the Secretary, Management and Administration, Energy Research, Defense Programs, and Environment, Safety, and Health provided effective administrative and efficient logistical support. Members of the Panel and their staff received security clearances at levels appropriate for access to every site and document that they requested. All requests from the Panel were honored by the Department of Energy.

Always unfailing in cooperation and diligent in response to inquiries was the Department's staff epidemiologist. Dr. Robert Goldsmith welcomed and supported the Panel and was always willing to assist, even on a moment's notice during the Panel's meetings.

The Panel was aided immeasurably by the cooperation of the Department's epidemiology contractors and investigators, the national laboratories, and the Department's operations contractors. The Panel benefited from the unique perspective of independent epidemiologic investigators, representatives of the work force in the Department's production facilities, community groups, and public interest organizations.

Although the Panel was charged with recommending measures that will ensure appropriate, effective, and quality epidemiologic activities, the Panel would be remiss if it failed to take note of the Department's long-standing emphasis on nuclear safety and its attention to collecting data on the exposure of workers to radiation and to monitoring the status of their health. It is remarkable that the Department and its predecessor agencies have sustained useful long-term epidemiologic studies for over four decades. More recently, the Department has supported dose reconstruction and other innovative epidemiologic studies in response to public concerns about the potential for adverse health effects in communities near weapons facilities.

Chartering an independent, outside panel and charging it to evaluate critically and to make unconstrained recommendations testifies to the Secretary's commitment to openness, to excellence, and to protecting public health. The Panel members thank the Secretary for this opportunity to work with the Department and to propose an approach for strengthening the protection of worker and public health.

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Executive Summary

In this report, the Panel makes recommendations to improve the quality of the epidemiology program and its value to the Department of Energy, its workers, and the communities near its facilities. This summary contains the Panel's major observations and recommendations.

Epidemiology provides a scientific evaluation of the health effects of worker and public exposures to potentially harmful materials. It uses health records, exposure records, environmental monitoring records, and personnel records to analyze health effects and to evaluate methods of protection and prevention. The Panel has distinguished between two types of epidemiology: descriptive epidemiology, which includes health surveillance; and analytic epidemiology, which tests hypotheses and often includes long-term research studies.

Over the years, epidemiologic activities have become scattered throughout the Department. Although the main epidemiologic research program is located within the Office of Energy Research; nevertheless, the Offices of Defense Programs and Nuclear Energy also conduct epidemiologic research. The Office of Environment, Safety, and Health is responsible for the data upon which analytic and descriptive epidemiologic research depends. There is no central coordination of epidemiologic data collected by the Department's site operations contractors.

Epidemiologic activities are inherently part of a comprehensive occupational and environmental health program. All the descriptive epidemiologic activities now scattered throughout the Department should be consolidated with the Department's other health and safety activities.

The Panel recommends that the Department establish a strong, comprehensive program by restructuring and expanding the current Office of Environment, Safety, and Health. This office should be restructured as the Office of Occupational and Environmental Health and Safety and continue to be directed by an Assistant Secretary. The office should contain a descriptive epidemiologic research component that includes a health surveillance system. When tightly linked with occupational and environmental health and safety activities, epidemiologic activities will give the Department another powerful tool to monitor day-to-day worker health, to measure the performance of health and safety activities, and to guide policy decisions.

A recurrent theme of witnesses at every meeting was a lack of credibility in the Department and its epidemiologic activities. The Panel believes that to restore public trust, to assure the highest scientific quality, and to assure the independence of investigators, the Department needs an independent system for managing its analytic epidemiologic research which can transcend changes in Departmental administrations. This can be achieved without statutory changes.

The Panel recommends that the Department enter quickly into a Memorandum of Understanding with the Department of Health and Human

Services to manage the Department's analytic epidemiologic research. The Department of Energy would continue to allocate funds for analytic epidemiologic research and the Department of Health and Human Services would use its customary procedures for conducting scientific research, including peer review and open competition for research projects. This analytic research should be managed by one of the Department of Health and Human Services' epidemiologic research agencies.

The quality of epidemiologic research rests heavily on the quality of the data used. Many different programs -- industrial hygiene, health physics, environmental monitoring, and medical care -- have kept their records separately and in various formats. The Panel recommends that the Department identify a standard minimum set of data, including health and exposure data, necessary for epidemiologic research. These data should be standardized throughout the Department and collected routinely at all facilities.

Scientific quality and public credibility are related to the degree of openness with which data are collected, maintained, and analyzed. The Panel values the benefits that flow from allowing independent scientists to examine and re-examine data from different perspectives. Therefore, the Panel recommends that the Department take specific steps toward opening its epidemiologic data to scientific investigators; for example, requiring documentation about data preparation and assumptions; removing personal identifiers from data sets; and establishing new procedures for the timely release of data.

The Panel recommends that the Department make liberal use of committees to foster quality science, to assure independence of research, and to gain participation by outside experts and those who might be affected by the research.

The Department has an obligation to communicate epidemiologic findings to all affected people: workers, former workers, and communities. The Panel recommends that communications be prompt, direct, and understandable. People need to know the nature of studies and their results, whether the findings are good, bad, or inconclusive.

Beryllium disease is an occupational health risk and should be addressed by the Department's occupational health program and by the analytic epidemiologic research program managed by the Department of Health and Human Services. The Panel recommends that the Department use a liberal definition of exposure to identify workers throughout its complex who have been exposed to beryllium and who ought to be included in research studies. The Panel also recommends that the Department establish whether beryllium disease may have occurred at facilities other than Rocky Flats.

The Department of Energy has shown a continuing commitment to funding energy-related epidemiology. The recommendations in this report will require additional funds for epidemiologic activities. These would be new or re-allocated funds above those budgeted for epidemiology in the proposed Fiscal Year 1991 budget. The Panel recommends an additional \$4 million for health

surveillance and descriptive epidemiology and an additional \$11 million for analytic epidemiology.

The reader should put this summary in perspective by, at a minimum, reading "Introduction: Guiding Principles" to understand the beliefs that guided the Panel.

Introduction: Guiding Principles

The Panel members share many principles which have guided their deliberations. The recommendations for improving the Department's epidemiology program rest on a foundation of these guiding principles:

- Epidemiology is the study of the distribution and determinants of diseases in human populations. It involves: 1) the gathering of illness and exposure data; 2) the analysis of those data in order to reach conclusions about exposures to harmful materials and to make decisions about worker and public health; and 3) the communication of conclusions so that appropriate prevention, monitoring, and treatment measures are taken.
- Epidemiology is an integral part of a comprehensive occupational and environmental health program.
- The credibility of scientific research is essential and is directly dependent upon openness. The benefit -- credibility -- derived from maximum public access to health information greatly exceeds the risks of misuse or misunderstanding.
- To achieve credibility, epidemiology must be part of an institutional framework that is itself credible.
- The Panel values the benefits that flow from allowing independent scientists to examine and re-examine data from different perspectives. It also values the open scientific process in which competing ideas are considered and evaluated through the traditional practice of peer review. These processes are critical to the scientific validity of research and to the political and social acceptance of research conclusions.
- The Panel recognizes that the Department has two separate roles with regard to epidemiologic data: 1) it is the custodian of a publicly financed and unique data set; and 2) it is the sponsor (or financial supporter) of epidemiologic studies based on those data sets.
- The quality of epidemiologic research rests largely on the quality of data from medical surveillance, exposure monitoring, and environmental monitoring.
- Data which have genuine national security implications must be protected.
- An individual worker has a right to confidentiality about his or her workplace records. A worker's medical records must be protected from disclosure.

- The findings of any epidemiologic research must be reported fully and promptly to all who are affected.
- The public has a right to know about collective health experiences and risks to which they are exposed.
- Epidemiologic findings must be reported fully and promptly to policy makers so that findings are integrated into policy decisions.
- A commitment of adequate funding is necessary to achieve a comprehensive occupational health program and productive analytic epidemiologic research.

Chapter One: Origins of the Program

Epidemiology in the Office of Energy Research

The Department of Energy's main epidemiologic research program is now under the Office of Health and Environmental Research, which is located within the Office of Energy Research. Today's program evolved from the program established by the Atomic Energy Commission in 1948, shortly after the opening of the nuclear age. When the Atomic Energy Commission was abolished, its successor agencies -- first, the Energy Research and Development Administration (established in 1975) and then the Department of Energy (established in 1977) -- maintained the program.

The first epidemiologic research project -- a study of 110,000 people exposed to acute doses of ionizing radiation during the bombings of Hiroshima and Nagasaki -- began soon after World War II with joint funding from the United States and Japan. Originally titled the Atomic Bomb Casualty Commission and now the Radiation Effects Research Foundation, it continues to be a major international epidemiologic program which encompasses studies of health effects in bomb survivors and their offspring. These studies have provided the basis for much of what is known about the effects of external exposure to ionizing radiation and for the development of radiation protection standards. American participation in the Radiation Effects Research Foundation is now managed by the National Academy of Sciences with funds from the Department of Energy.

The Department's first epidemiologic activity with occupationally exposed populations continued earlier studies about ingestion of radium by watch dial painters. In the early 1960s the Department began retrospective epidemiologic investigations of weapons production workers at the Hanford facility exposed to low but chronic levels of external ionizing radiation. After 1978 this program was expanded to include workers at other Department facilities.

Other occupational epidemiologic work has included clinical, cytogenetic, and tissue studies of plutonium workers, a study of lung cancer in uranium miners, and an industry-wide investigation of mortality patterns in nuclear shipyard workers.

Until 1981 the Department's epidemiologic research focused principally on health effects from exposure to ionizing radiation, principally studies of atomic bomb survivors and Department contract workers. After 1981, however, the Department broadened the scope and added a study of oil shale workers and populations living near the oil shale production site and a study of coal gasification workers. In addition, the program began planning for a large data base for studies of populations exposed to environmental pollutants and for epidemiologic methodologies suitable for those studies.

Figure 1. Epidemiology Program Budget in the Office of Energy Research

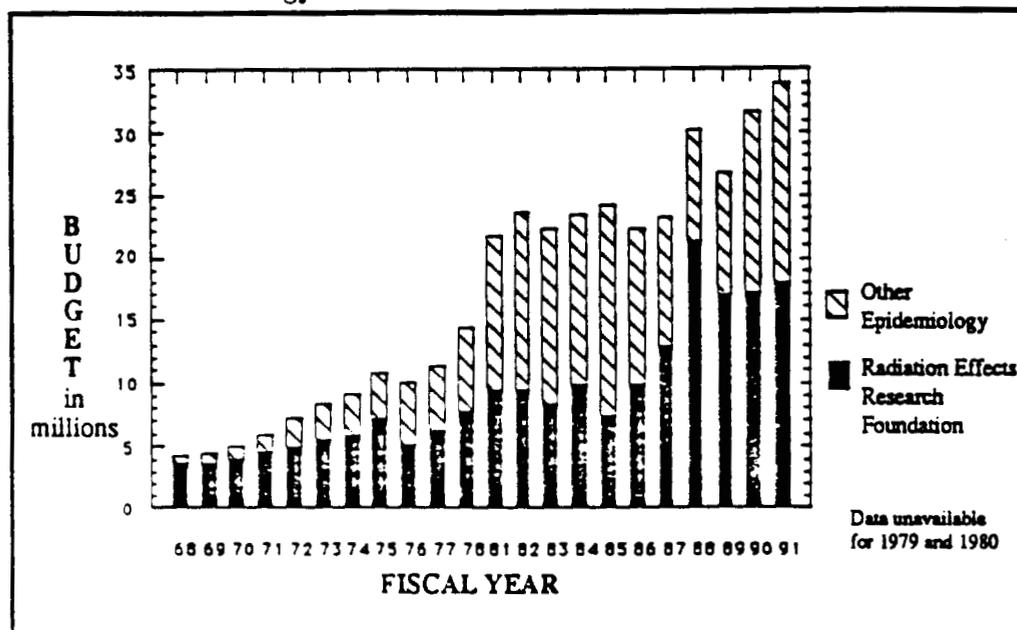


Figure 1 shows funding for epidemiology in the Office of Health and Environmental Research. Funding rose dramatically during the 1970s, remained relatively constant for most of the 1980s, and in the late 1980s approached the Department's proposed Fiscal Year 1991 level of \$34 million. Although increases appear substantial over the last two decades, support for the Radiation Effects Research Foundation, linked by international agreement to the value of the Japanese yen, constituted almost half of the Office of Health and Environmental Research's epidemiology budget and accounted for much of this rise. In a 1980 review of the epidemiology program, the National Academy of Sciences wrote:

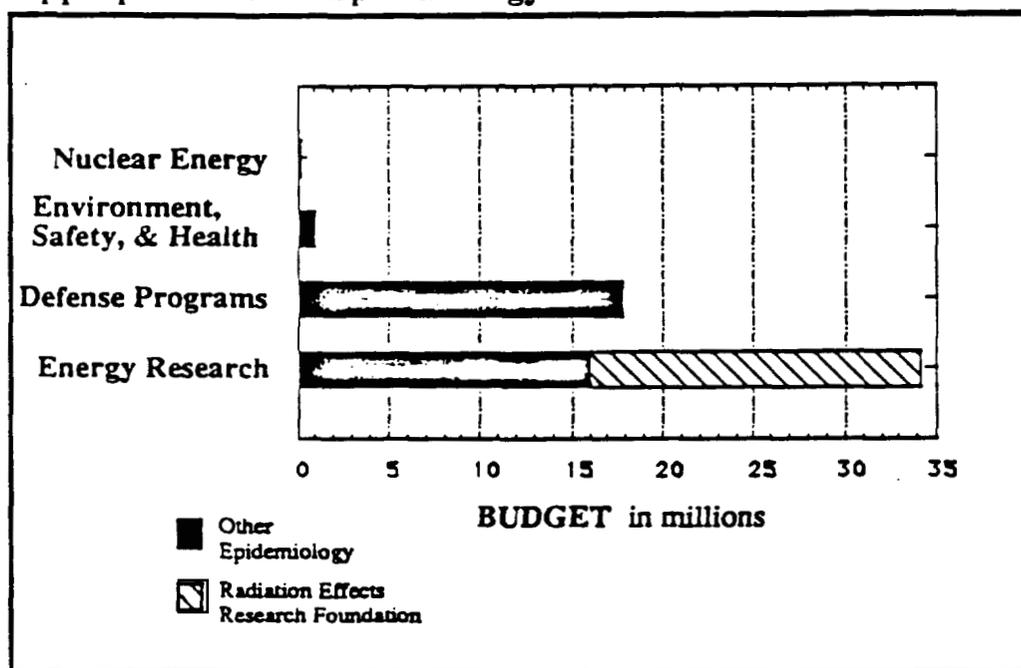
"The growth of the OHER [Office of Health and Environmental Research] budget for research on low-dose radiation effects in humans has been relatively slow in absolute terms over the last 10 years. Indeed, the increases in many projects have not kept up with the rise in the cost of living."

The Department now employs one epidemiologist, who works in the Office of Health and Environmental Research. This office is responsible for setting research priorities. However, contract investigators staff the projects, conduct the research, and publish the results. The Department's epidemiologic research activities have led to publication in peer-reviewed scientific journals of 340 articles in addition to the extensive literature from the Radiation Effects Research Foundation.

Epidemiologic Activities throughout the Department

Today epidemiologic activities are scattered throughout the Department. Departmental organizations and production contractors have often initiated research projects independently with only informal involvement of the established epidemiology program in the Office of Health and Environmental Research. Figure 2 shows the Department's overall request for appropriations for epidemiologic activities for Fiscal Year 1991.

Figure 2. Proposed Fiscal Year 1991 Appropriations for Epidemiology



The exposure and health data upon which epidemiologic research depends — including medical surveillance, exposure monitoring by industrial hygienists and health physicists, and environmental monitoring — are collected by programs located organizationally under the Assistant Secretary for Environment, Safety, and Health.

Environment, Safety, and Health, in addition to data collection, budgeted \$1 million for epidemiologic research in Fiscal Year 1990 and \$1 million in Fiscal Year 1991, primarily to support health physics research that emphasizes improving monitoring capability and dose measurement instrumentation and technology.

Defense Programs budgeted \$23 million for epidemiologic research in Fiscal Year

- Health effects studies, begun in 1954, of Marshall Islanders accidentally exposed to radioactive fallout from an atmospheric nuclear test at Bikini Atoll;
- Dose reconstruction studies from atmospheric testing at the Nevada Test Site before aboveground testing was banned in 1963;
- Health effects studies of residents near the Feed Materials Production Center at Fernald, Ohio;
- Morbidity and mortality registries of all current and retired Savannah River employees; and
- Studies associated with the Rocky Flats facility conducted under a Memorandum of Agreement with the State of Colorado.

Nuclear Energy budgeted \$300 thousand for epidemiologic research in Fiscal Year 1990 and \$200 thousand in Fiscal Year 1991. These funds include support for:

- Mortality studies of workers at the Portsmouth, Paducah, and Oak Ridge Gaseous Diffusion Plants.

Observations

- The Department manages its epidemiologic activities in an uncoordinated manner. The overall epidemiologic research agenda is not planned, data collection is not standardized, and peer review systems differ.
- Funding for epidemiologic research activities through the Office of Health and Environmental Research has experienced limited growth with the result that current projects move slowly and other important initiatives in epidemiology remain unfunded.
- Extensive reliance on contractor-based epidemiologic research is the prevailing practice in the Department's efforts to assess the human health effects of exposure to radiation and hazardous substances.

Chapter Two: Goals

Any effective organization needs well articulated and organized goals that permeate its policies, administration, and budget. A program is built around goals; and, in turn, they focus people's work.

Observations

- The Department's epidemiology program has not developed clear goals to communicate its purpose and direction. From testimony, the Panel found that health professionals, epidemiologists, workers, and people from communities nearby often appeared confused about the role and relationship of the epidemiology program to other Departmental programs.
- Persons associated with the epidemiology program presented their mission as derived from the authority to conduct health research as stated in the Atomic Energy Act. The Panel does not think that this broad mission statement represents sufficiently specific program management goals to direct the Department's epidemiology-related activities. The epidemiology program needs to develop program management goals to guide the way it carries out its responsibilities; including peer review, data collection, data access by other researchers, and communication to policy makers, workers, and communities.
- The role of epidemiologic research in delineating the health risks from nuclear energy and those from other energy producing sources is underrecognized. Moreover, the number of researchers educated and trained to conduct multi-disciplinary health research, such as epidemiology, is relatively small. The country will need a larger number of multi-disciplinary, post-graduate, investigators trained in health risk research.

Recommendations

The Panel recommends, at a minimum, the following goals for epidemiologic activities for the Department. These recommendations apply to the Department's contractors, as well.

- 2-1 Study the human health effects associated with energy production and technologies; and, where needed and appropriate, develop both retrospective and on-going epidemiologic data bases.
- 2-2 Involve workers and representatives of communities nearby in planning epidemiologic research.
- 2-3 Share health information with workers and with the communities nearby.
- 2-4 Establish a health surveillance system that provides timely and usable information about the health and safety effects of the Department's activities.

- 2-5 Study the health effects of the Department of Energy's activities on workers and on communities and use the findings of such research to set operational policies and practices.
- 2-6 Advance fundamental epidemiologic knowledge and scientific knowledge about the health effects of energy technologies; and develop new epidemiologic methodology, as needed.
- 2-7 Promote significant training and research opportunities for young investigators, particularly epidemiologists and biostatisticians, so that there will be enough researchers in the future prepared to do epidemiologic research.

Chapter Three: Organizational Placement of Epidemiologic Research

Two Major Concerns: Managing Health Risks and Achieving Credibility of Epidemiologic Research

The Panel has heard testimony calling for the transfer of the epidemiology program from the Department as a solution to a lack of trust by workers and the public alike. Yet merely transferring the program in total would overlook the facts that no employer can transfer its responsibility to protect worker and community health and that epidemiology has an integral role in protecting health. Thus, the Panel has identified two distinct problem areas of concern for the Department: 1) the Department lacks a comprehensive occupational and environmental health program; and 2) the Department's epidemiologic research results lack acceptance as credible by many of those who are most affected. Two new initiatives would address these concerns.

Firstly, the Department must establish a strong occupational and environmental health program which would include an operational safety program. To be effective, this program must hold a position of authority and visibility in the Department's organizational structure. Because epidemiology is a critically important tool in managing health risks, the occupational health program should include a descriptive epidemiology component. A descriptive epidemiology component would be capable of maintaining a high quality health surveillance system, identifying health problems within the Department's large industrial complex, providing the initial response to urgent worker or community concerns, and developing hypotheses to be examined in analytic epidemiologic studies.

Secondly, the Department must build credibility and trust in the results of its analytic epidemiologic research by establishing a new system for selecting and managing its epidemiologic research. The Department would allocate the funds for analytic epidemiologic research to a Federal agency that is primarily responsible for health and is involved with epidemiologic research. An advisory committee, comprised of representatives of interested parties, should play a major role to help set the research agenda, determine funding priorities, and guide a peer review system to select research proposals and to monitor the progress of funded studies. Research projects themselves would be managed by the primary investigators.

An Occupational and Environmental Health and Safety Program

The Department of Energy operates a large industrial complex and, as a major employer, must have in place a comprehensive occupational health program designed to prevent occupationally-related diseases, injuries, and premature deaths. This program must have the expertise to monitor workplace

exposures, evaluate those exposures in terms of workers' health, and develop corrective actions as may be required.

In addition to occupational health, the Department's environmental health program must be concerned about possible health effects of its facilities' operations on communities. No matter how efficient or well designed the production processes are, emissions and wastes may harbor materials hazardous to the health of the populations in surrounding communities.

Descriptive epidemiology, a component of a comprehensive occupational and environmental health program, centers on the surveillance of illness and exposure patterns. It describes trends of risk and disease. It is used to target resources for prompt intervention and prevention activities in affected populations. Such work provides information about who is getting diseases (person), where it is more or less common (place), when it is occurring (time), and what may cause it (exposure). Generally, descriptive epidemiology is not designed to test hypotheses, but it is often used to formulate causal hypotheses to be tested in analytic epidemiologic studies.

Descriptive epidemiology includes correlational studies, case reports, case series, and cross-sectional surveys:

Correlational (or ecologic) studies consider patterns of disease and risk exposure among populations. They provide data on populations rather than on individuals, are relatively quick and inexpensive, and use information already available;

Case reports document individual health problems and arise from a close link between clinical medicine and epidemiology. An astute clinician, perhaps a medical director at a Departmental site, may identify an unusual medical occurrence, feature of a disease, or patient history;

Case series are collections of individual case reports which occur within a fairly short period of time. Routine surveillance of accumulating case reports can suggest emerging or declining occupational diseases; and

Cross-sectional surveys are prevalence surveys which assess exposure and disease status simultaneously. They provide information about frequency and characteristics of both exposure and disease by furnishing a snapshot of a population's exposure and health experience at a specified time.

Observations

- Although the Department has built an operational safety program (which includes an industrial hygiene component) and a nuclear safety program (which includes a health physics component), leadership in occupational health is lacking. For example, neither the above health-related programs nor the medical program includes an epidemiologic component. In addition, these health-related activities are not linked as part of an occupational health program.

- The epidemiology program has insufficient influence on data collection; therefore, the data collected by industrial hygiene programs, health physics programs, and medical departments are often inadequate for epidemiologic analyses. While considerable attention has been devoted to reconstructing retrospective epidemiologic data sets for research purposes, very little coordinated effort has gone into developing continuing surveillance programs.
- Historically, the majority of the Department's epidemiologic research has focussed on long-term mortality studies. Epidemiologic research has not been optimally used to monitor day-to-day worker health, to identify the need for preventive or protective measures in the workplace, or to understand morbidity associated with the Department's activities.
- During site visits and hearings, the Panel observed that the Department lacks a strong compliance and enforcement mechanism for workplace health and safety standards. Even though the Department has taken a major step forward by changing the criterion for incentive fees from production performance to safety and health performance, this change alone will not correct the basic problem. It does not compel contractors to identify violations on a day-to-day basis and to correct them expeditiously.
- An occupational health program must include a strong medical presence; however, medical leadership is lacking. Medical directors at many sites view the Headquarters medical program as a distant advisory program. Additionally, the medical program's orders and procedures are out of date and have been mired in draft revisions for years.

Recommendations

- 3-1 The Department should establish a comprehensive occupational and environmental health and safety program by restructuring, expanding, and renaming the current Office of Environment, Safety, and Health. The Panel recommends that the office be named Office of Occupational and Environmental Health and Safety and continue to be directed by an Assistant Secretary. The major organizational components should include environmental health (including environmental monitoring), operational safety, and occupational health (including occupational medicine, industrial hygiene, health physics, and descriptive epidemiology). (See the organizational chart on page 23.)
- All the descriptive epidemiologic activities now scattered throughout the Department should be the responsibility of the Office of Occupational and Environmental Health and Safety.*
- 3-2 The Department should establish a descriptive epidemiology program as a key component of a comprehensive occupational and environmental health and safety program. This program would:

* This would include the management responsibility for medical surveillance for the Rongelap People of the Republic of the Marshall Islands. It would serve as the single Departmental voice on all Rongelap issues, including a review and decision about the Phase II Study, as authorized by the Compact of Free Association Act, P.L. 99-239.

- Define a minimum epidemiologic data set and play a key role in standardizing the medical and exposure surveillance data collection systems throughout the Departmental complex so that data are easily usable for epidemiologic research;
- Establish and implement a system of routine surveillance which evaluates these medical and exposure data in an effort to identify problems as early as possible;
- Investigate urgent and immediate problems detected by the surveillance system; for example, the investigation of a report of increased incidents of respiratory disease at a work site. Investigate other problems suspected by managers, workers, and communities; for example, an initial review to determine the value and feasibility of a radiation dose reconstruction project. (The Panel cites as a model the epidemic response activities conducted by the Epidemiology Program Office of the Centers for Disease Control.);
- Support and maintain the Department's data sets for epidemiologic research and provide documentation and liaison for using these data sets;
- Communicate with the Secretary of Energy, contractors, workers, and the public about health issues detected by surveillance or special studies; and recommend epidemiologic research that should be undertaken or supported;
- Provide support to appropriate agencies for special disease registries important to the Department; such as cancer and birth defects registries; and
- Assure that Departmental managers and policy makers understand the results of epidemiologic research and apply preventive or protective measures throughout its operations.

3-3 At the Assistant Secretary level, a steering committee should provide direction, oversight, and evaluation to the Department's Office of Occupational and Environmental Health and Safety. The Assistant Secretary should appoint members from nominations submitted by interested parties: workers, communities adjacent to the Department's plants, academic disciplines (occupational health, epidemiology, public health), State health departments, Federal health agencies, and medical directors. The steering committee's major functions would include:

- Identifying major concerns about the Department's activities as they relate to health, safety, and environmental health;
- Setting the descriptive epidemiology agenda;
- Ranking priorities for the occupational and environmental health and safety program;

- Ensuring the integration of medical care, occupational safety and health, industrial hygiene, health physics, surveillance systems, and epidemiology;
 - Providing advice about program policies;
 - Evaluating the adequacy of the occupational and environmental health and safety program;
 - Reviewing the adequacy of occupational and environmental health and safety standards in light of the descriptive and analytic epidemiologic findings;
 - Reporting annually to the Secretary and the Assistant Secretary; and
 - Convening or sponsoring public meetings to collect and disseminate information.
- 3-4 A new system should be established to require that the Department's operating contractors comply with the Occupational Safety and Health Administration's standards and regulations. At a minimum it should provide for the following: inspectors fully trained in conducting inspections for compliance with Occupational Safety and Health Administration standards; the assessment of penalties, including monetary fines against contractors; an administrative appeals process; and a quality control system for auditing the inspection and enforcement process.
- This compliance system should be achieved by bringing the Department's facilities and contractors under the authority of the Occupational Safety and Health Administration or an organizationally independent system equivalent in standards, inspections, penalties, and appeals.
- 3-5 Senior staff in the Office of Occupational and Environmental Health and Safety should include people professionally trained in the fields of occupational health and public health. The Medical Director should have expertise in occupational medicine and public health.
- 3-6 The Department may find a need to supplement its health surveillance system with contractors. In working with such contractors, the Department should exercise initiative and leadership by writing and enforcing clear program plans and procedures, and by using competitive selection processes.

Quality Assurance and Peer Review

Observations

- The Panel saw few written policies and procedures by which the epidemiology program could guide itself.

- The current process for selecting research projects often appears arbitrary and ill-defined. It lacks a clear cycle of proposals and awards; and it lacks a formal system of peer review.
- Epidemiologic research can take many years to complete and a timetable for results is often hard to predict. Still, the epidemiology program appears to have few procedures for evaluating the progress of projects and for setting timetables for completing projects.
- The Department has only one staff epidemiologist to manage an extensive program. Staff from contractor organizations, such as national laboratories, are used as the Department's own staff. This situation leads to the impression that the contractors' epidemiologists, not the Department itself, control the program.

Recommendations

- 3-7 Program managers for descriptive epidemiology should write policies and procedures, including those for:
- Data requirements, data collection practices, and assurance of the quality of all surveillance data;
 - Protocols for notifying employees, former employees, and other affected people about study results;
 - Policies and procedures for data access, including access to information from death certificates;
 - Confidentiality agreements concerning individual medical and workplace records;
 - Quality assurance controls for each descriptive epidemiologic study;
 - Coordination with all interested parties; Federal, State, and local; and
 - Roles of committees such as the Assistant Secretary's Steering Committee for Occupational and Environmental Health and Safety.
- 3-8 Quality control plans for descriptive epidemiologic activities should include mid-course objectives, quality indicators (for example, the percentage of data that are error-free), and a method for including those people who are being studied in all phases of the study -- from study design to information dissemination.
- 3-9 Each descriptive epidemiologic project should have direct input from the population being studied and from local health officials. A project- or study-specific advisory committee is part of a quality control plan; it assures that those who are being studied have direct input and that the study's results are communicated to those who are affected.

The Role for Committees

The Panel recommends that the Department make liberal use of committees to foster quality science, to assure independence of research, and to gain participation by outside experts and those who might be affected by the research. Committee members should represent all interested parties, be recommended by the groups they represent, and be appointed by the Department of Energy.

Observations

- Often workers and communities are not fully enough involved or informed to understand the time required to do epidemiologic studies, to grasp the meaning of the findings, or to trust the outcomes.
- Workers and communities do not feel included in the making of policy decisions that affect them. The Department has missed opportunities to garner information from workers about hazards in the workplace.
- The Department has missed opportunities to consider varied viewpoints and bolster credibility. It can make more frequent and forceful use of peer review committees and other panels of reputable outsiders to give advice about data access, research methodology, research project selection, program policy, and other critical issues.
- The Department's epidemiologic research results are usually published in peer-reviewed journals but with only occasional efforts to communicate research findings to workers and the public.
- Although the Department and its contractors have made efforts to communicate to workers, those attempts are not yet adequate or effective. The Panel did not observe a consistent process for informing the public, State and local officials, and workers at some of the Department's facilities about the Department's activities in their communities and its response to their environmental and health concerns.

Recommendations

- 3-10 At the Secretarial level, the Secretary of Energy Advisory Board (SEAB), was recently established to "advise the Secretary on the research, development, energy, and national defense responsibilities, activities and operations of the Department." This panel should include a public health policy professional to review and advise the Secretary about the broad impact on public health of the Department's activities.
- 3-11 At the community level, each Department of Energy site should establish a committee to provide interaction among interested parties. Members should represent the community, scientists, workers, local health officers, and management. Its purpose would be to:

- Discuss health, safety, and environmental issues;
 - Identify research needs; and
 - Disseminate information about on-going research activities and the results of research.
- 3-12 Each facility should establish a health and safety committee that represents workers and management in equal numbers. Workers, whether organized in unions or not, should select their own representatives. These committees should have full access to all information about health and safety at the facility.

An Epidemiologic Research Program

A recurrent theme of witnesses at every meeting has been a lack of credibility in the Department's epidemiologic activities. The Panel believes that to restore public trust, to assure the highest scientific quality, and to assure the independence of investigators, the Department needs an independent system for managing its analytic epidemiologic research. This can be achieved without any statutory changes.

Analytic epidemiologic studies are designed to test causal hypotheses. Most of the epidemiology and human health effects studies currently supported by the Department are of this type. The worker retrospective cohort studies are especially time-consuming and expensive because they involve following large numbers of individuals over several decades. The current radiation worker studies, in particular, investigate the effects of sustained occupational exposures to low levels of radiation. The outcomes of concern are rare (usually cancer) and the latency periods are long and variable.

Observations

- The Department of Energy 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. Because the Department's role is to promote energy production, there is an inherent potential conflict between immediate production goals and health and safety goals.
- Most of the scientists conducting epidemiologic research for the Department are employees of the Department's major long-term contractors. The Department, through its relationships 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 is 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.

Recommendations

- 3-13 The Department should enter quickly into a Memorandum of Understanding with the Department of Health and Human Services to manage the Department's analytic epidemiologic research.* This analytic research should be managed by one of the Department of Health and Human Services' epidemiologic research agencies. The Memorandum of Understanding should cover the following elements:
- The Department of Energy would continue to budget for analytic epidemiology, with the funds to be allocated to the Department of Health and Human Services.
 - Current grants and contracts would be continued. Research-in-progress would become subject to the Department of Health and Human Services' regular monitoring process and would move toward open competition for grants and contracts. There would be a transition to a competitive system for project renewals and for add-on studies.
 - The Department of Health and Human Services would use its usual methods to set the research agenda, provide for peer review of research proposals, provide quality assurance for research-in-progress, and provide access to data.
 - Several communication channels between the Department of Energy and the Department of Health and Human Services would be established to share information about surveillance data, research findings, and policy implications. Information sharing would be routine and frequent.
 - The Department of Health and Human Services would adopt a method of notifying workers and communities promptly and effectively of results of studies which could affect them.
 - The Department of Health and Human Services would establish an advisory committee for the Department of Energy's analytic epidemiologic research. Such an advisory committee could serve as a vehicle for public comment. Its members would represent all affected parties; including workers, communities, academicians, public health officials, and public interest groups.

* The Panel heard no adverse testimony about the Department's arm's length relationship to the Radiation Effects Research Foundation through the National Academy of Sciences. Therefore the Panel makes no recommendation for relocating this activity to the Department of Health and Human Services.

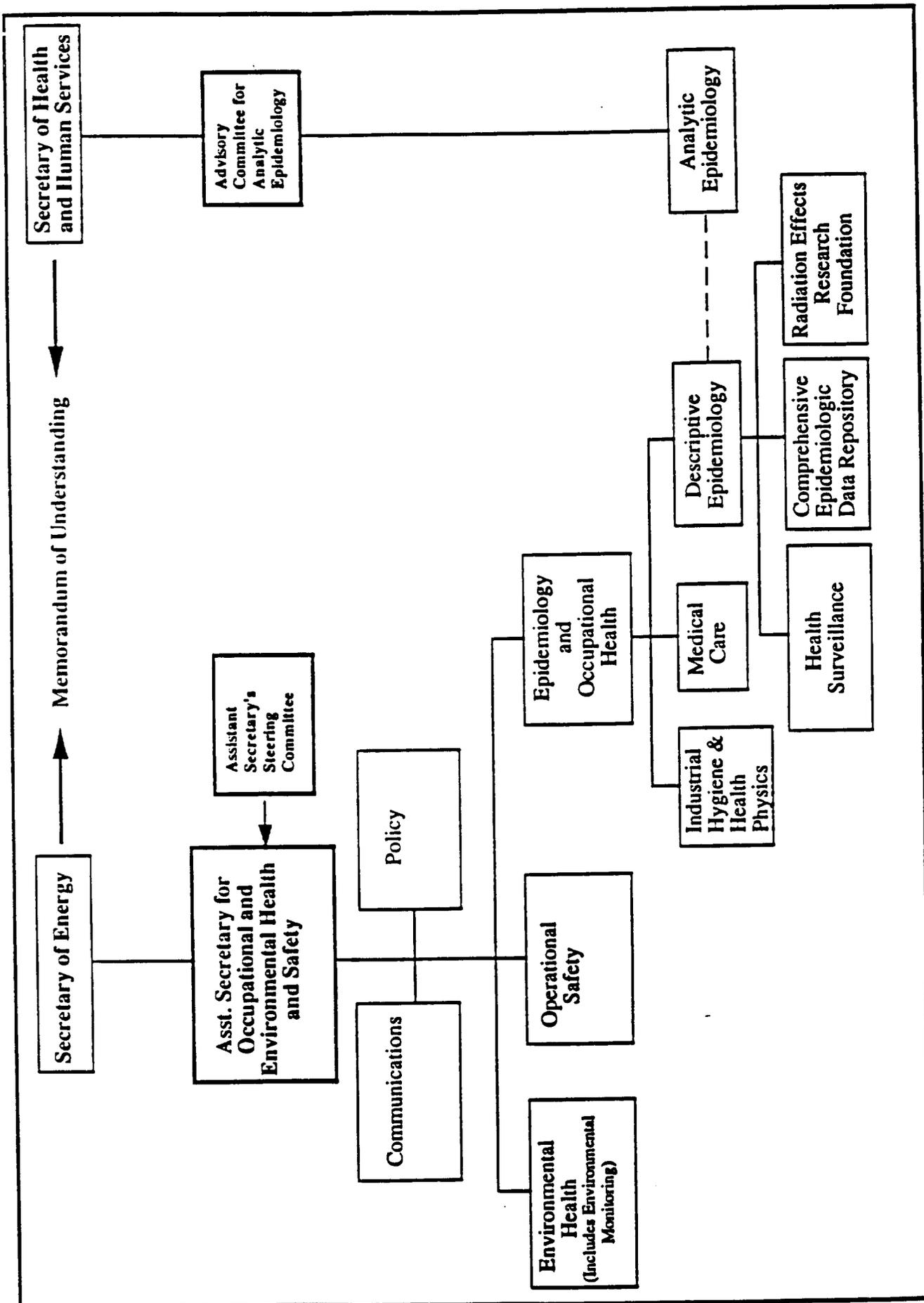
Use of Contract Scientists

Observations

- The Department of Energy's epidemiology program has relied extensively on national laboratory contractors, resulting in allegations of conflict of interest.
- Valuable long-term epidemiologic studies are in progress under contracts with the Department of Energy.
- The relationships between the Department and its major long-term contractors are such that the distinctions between them often are blurred.

Recommendation

- 3-14 National laboratories have valuable expertise and experience conducting energy-related analytic epidemiologic research and therefore should be allowed and encouraged to compete for future projects. If necessary, steps should be taken to assure that they are able to compete for analytic research projects directed by the Department of Health and Human Services.
- 3-15 Long-term epidemiologic studies supported by the Department of Energy should not be arbitrarily discontinued, or the primary investigators arbitrarily changed, as a result of the new management of analytic epidemiologic research by the Department of Health and Human Services.



This chart illustrates two new initiatives: 1) establishing an occupational health program (that includes descriptive epidemiology) within the Department of Energy; and 2) establishing an analytic epidemiologic research program funded by the Energy Department and conducted by the Department of Health and Human Services.

Chapter Four: Data Management

The quality of epidemiologic research rests heavily on the quality of the data used; including information about health status, exposures (radiation, chemical, and mechanical), and environmental monitoring.

Collection and Maintenance

For most of its history, the Department has collected health information not for epidemiologic research but to help identify safety problems. Many different programs -- industrial hygiene, health physics, environmental monitoring, and medical care -- have kept their records separately and in various formats.

Observations

- The records that epidemiologists need -- health records, exposure records, environmental monitoring records, personnel placement records -- are maintained differently throughout the Departmental complex. Building an epidemiologic data files from these inconsistent records is problematical and time-consuming.
- The Department has not built a data set that is primarily intended for epidemiologic research. Therefore, it has not been easy to adopt existing data sets for epidemiologic purposes.
- Researchers have found that assembling data for epidemiologic research is fraught with problems, both practical and scientific, that are exceedingly time-consuming.
- There may be significant limitations to the utility of retrospective data. The recommendations here are primarily prospective in nature.

Recommendations

- 4-1 A standard minimum set of data necessary for epidemiologic research should be defined by the Assistant Secretary for Occupational and Environmental Health and Safety with oversight from the Assistant Secretary's Steering Committee. In defining this data set, the Assistant Secretary should include data that will be valuable for workplace surveillance and analytic epidemiologic research. It should be consistent with the requirements of the Comprehensive Epidemiologic Data Resource.
- 4-2 The standard minimum set of epidemiologic data should be collected routinely at all facilities throughout the Departmental complex. If reasonable, retrospective data should also be included in this data set.
- 4-3 The Assistant Secretary for Occupational and Environmental Health and Safety should serve as caretaker of the epidemiologic data collection system. This includes the responsibility for quality assurance safeguards.

Data Access

Scientific quality and public credibility are related to the degree of openness with which data are collected, maintained, and analyzed. The risk of misuse of data is more than outweighed by the benefits of credibility and quality that result from the availability of information. The Panel values the benefits that flow from allowing independent scientists to examine and re-examine data from different perspectives. These processes are critical to the scientific validity and quality of research and critical to the political and social acceptance of research conclusions.

Observations

- Researchers independent of the Department and its contractors have not been able to obtain data. Many times, the reason given for withholding data has been to protect the data from inappropriate analysis which, in turn, might lead to incorrect conclusions and cause people to be unduly alarmed.
- Other reasons given for withholding data have been that data sets are too complex to understand without primary investigators spending considerable time explaining them and that data are not yet verified. Thus, the investigators would be delayed from finishing their studies.
- The databases that have been built for epidemiologic research are highly complex and cannot be readily understood without substantial explanation. Preparation of adequate documentation has not been a condition of the Department's contracts with researchers.
- The credibility of epidemiologic studies rests on the ability of other scientists to verify the analyses, replicate the findings of the initial investigators, and analyze the same data sets from different viewpoints.
- As a public agency, the Department has a responsibility to promote openness and sharing of its health data, balanced by its responsibility to maintain rights of privacy of current and former workers.
- Few, if any, breaches of confidentiality were brought to the attention of the Panel; however, fears about breaches of confidentiality often dominated public testimony about data access.
- The Panel has heard various reasonable views about when a researcher should release the data set he or she has created for a study. Traditionally, data are most often released at the time a peer-reviewed journal accepts the results for publication.
- Many Federal and State agencies, such as the National Center for Health Statistics, the Bureau of the Census, the Health Care Financing Administration, the National Institute for Occupational Safety and Health, and the National Institute of Environmental Health Sciences routinely make available to the public health data sets which were collected at public expense. These data sets vary widely in their nature, complexity, and

intended uses so that interagency and interdata comparisons are not made easily. Policies about the time of data release vary.

Recommendations

- 4-4 Confidentiality protection must be provided for any data which contain personal identifiers.
- 4-5 Data collected by a public institution with public money are a public resource and public property. Nevertheless, the Panel respects the traditional practice of allowing the investigator who produces the data a reasonable time to analyze and publish those data. The specific circumstances associated with a request for data or the status of a research project may affect the appropriate time for release of data, but data must not be restricted indefinitely. The Assistant Secretary's Steering Committee for Occupational and Environmental Health and Safety should set guidelines for when the data in question must be released.
- 4-6 At the local level, thoroughly de-identified descriptive epidemiologic data sets should be available so that workers and communities can obtain information conveniently.
- 4-7 Each study should include explanatory information that enables other researchers to reconstruct the study; for example, documentation for assumptions about data assembly and analytic methodology.

The Department's Response to the Three Mile Island Public Health Fund Request

Recommendation

- 4-8 The Department should adopt a policy of maximum possible openness with regard to releasing data to the Three Mile Island Public Health Fund. Full documentation should accompany the data. In addition, the Department (or its contractor) should provide reasonable and appropriate assistance necessary to render the data usable for study. This release should be subject only to the following limitations:
 - Confidentiality protection must be provided for any data which contain personal identifiers; and
 - Those final files created by any individual contractor for a specific study, which are under active analysis for the purpose of publication (and which may therefore be subject to proprietary considerations), may be withheld for a reasonable time to complete the study.

The Panel advises that these limitations be construed narrowly. In implementing this recommendation, the Department should facilitate access to death certificate information because of its importance to the research.

A Comprehensive Epidemiologic Data Repository

The Department is in a unique position to make a valuable contribution to science and to health protection for workers and nearby communities by creating a large general purpose data repository.

Observations

- The Department has started a comprehensive epidemiologic database, Comprehensive Epidemiologic Data Resource. Within the Departmental complex, there are many different expectations about what this database is and what it is intended to do.
- The Panel recognizes that designing a comprehensive epidemiologic database is a complicated matter.
- The central focus of a comprehensive epidemiologic data repository should be on the workers from the Department's facilities.
- A standardized comprehensive epidemiologic data repository would be especially valuable for researchers studying current and future workers. It could be developed prospectively without many of the problems researchers now face as they attempt to reconstruct and link incomplete records from the past for use in retrospective studies.
- The majority of the Department's epidemiologic research has been mortality studies. A comprehensive epidemiologic database might make needed morbidity studies easier to conduct.
- The majority of research has been on health effects of radiation. A comprehensive epidemiologic data repository would make studies of other exposures easier to conduct.
- This important project may attract research workers from multiple disciplines into an area which needs more attention.

Recommendations

- 4-9 All interested researchers should have full access to a basic health data set that has full protection against the identification of individuals. The Department should establish such a database with procedures for public access.
- 4-10 Before the Department continues to develop the Comprehensive Epidemiologic Data Resource, it should establish, under the guidance of the National Academy of Sciences, a clear statement of intended goals and uses. Other needed steps are to: identify users, evaluate feasibility, distinguish retrospective and prospective data assembly issues, and set policies. Work on a project of this magnitude should not be undertaken in haste; rather, the project should be planned in a step by step fashion.

4-11 Role of the National Academy of Sciences' Committee on Radiation and Epidemiological Research Programs:

The National Academy's Committee offers a strong and valuable resource of independent scientists capable of addressing a variety of technical issues. The Committee should direct the design and implementation of the Comprehensive Epidemiologic Data Resource. Some of the committee's major functions would include: to study the project's feasibility and alternative approaches, to set its policies, to oversee its plan and design, and to establish quality review procedures.

4-12 Data collection for a comprehensive epidemiologic research database should be standardized throughout all the Department's facilities.

4-13 The descriptive epidemiology program should serve as liaison with all groups that provide data to and use data from a comprehensive epidemiologic research database.

4-14 The Department should allow access to a comprehensive epidemiologic database under guidelines which recognize that it is intended for public use without a review of the investigator's qualifications or protocol. Requests for information beyond the basic data set may require some minimal level of review. Individuals whose request for data are denied should have an opportunity to appeal the decision.

Chapter Five: Communication

Epidemiology provides a scientific approach to the evaluation of the Department of Energy's occupational and environmental health and safety program. The analysis and interpretation of data generated by this approach should be communicated to all those affected: workers, former workers, residents of communities in close proximity to the Department's facilities, and other people in similar circumstances.

Communication within the Department

Testimony suggests that the Department neither systematically incorporates epidemiologic findings into its policy deliberations nor systematically circulates information about epidemiologic findings to operating contractors and workers.

Observations

- The epidemiology program has considered itself primarily a research program; its findings are disseminated in the traditional scientific manner -- through peer-reviewed professional journals. The program has not been used for quality control of the Department's worker and community health protection and, therefore, its findings are not systematically communicated to the Department's policy makers.
- Communications are often stifled or slowed by complex bureaucratic channels and by concerns about legal liability, national security, and production costs.
- The Department's highest level policy makers do not have timely information from epidemiologic surveillance and epidemiologic studies to consider during policy discussions.

Recommendations

- 5-1 The Assistant Secretary's steering committee (See 3-3) should assure that the Department includes epidemiologic research findings in its policy decisions. The Assistant Secretary's steering committee should issue at least annual reports that identify health-related policy issues and make specific recommendations.
- 5-2 The descriptive epidemiology program should publish an annual progress report to keep site managers informed about studies being conducted throughout the Departmental complex.
- 5-3 The Assistant Secretary for Occupational and Environmental Health and Safety should assure that there are adequate information loops to communicate critical findings from either health surveillance or epidemiologic studies quickly throughout the Departmental complex.

Informing Communities and Interest Groups

Most epidemiologists realize their ethical responsibility to publish the results of their studies in peer-reviewed scientific journals. The Department's epidemiologic research has been reported in 340 articles published in peer-reviewed scientific journals. However, these journals are directed at scientists. Further efforts are needed to meet the communications needs of workers and the general public.

Observations

- Testimony from representatives of communities near the Department's plants makes it clear that the residents often understand little about epidemiologic and environmental studies related to operations at the plants.
- In public hearings around the country, the Panel heard from individuals and organizations representing many views. Many shared the perception that the Department is hostile to any outside expression of concern about the health effects of nuclear weapons production. Witnesses further testified that when outsiders questioned the Department's assumptions and practices, its response was often to assume a defensive stance.

Recommendations

- 5-4 Efforts to communicate the results of epidemiologic studies would be most successful when pursued in the context of a risk communication program in the Office of Occupational and Environmental Health and Safety. This program should study and understand the concerns of communities and workers and develop activities that would contribute to their knowledge and involvement in health and safety programs.
- 5-5 Study-specific advisory committees (See 3-9) should function as varied and knowledgeable teams of educators. These committees should function from the early stage of study design through the information dissemination stage. As one model of such a committee, the Panel cites the Technical Steering Panel for the Hanford Dose Reconstruction Project.
- 5-6 Before and after each study by the descriptive epidemiology group, the investigators should hold a conference with workers, managers, and affected citizens. The Panel cites conferences held by the National Institute for Occupational Safety and Health as a model.
- 5-7 The Department should recognize the importance of a positive stance toward people who have genuine concerns about health hazards. A productive posture would recognize disagreement where it exists but would also pursue practical solutions to the questions that vex substantial segments of the American public. In some situations, the Department may need to use an ombudsman or facilitator to improve communication.

- 5-8 Communication should be prompt, direct, and understandable. Whenever possible, the best way to tell people news about themselves is directly and in person. It is important that they understand what is said so that they are neither inappropriately frightened nor inappropriately reassured. They need to know the nature of epidemiologic studies and their results, whether the findings are good, bad, or inconclusive.

Coordinating with Federal, State, and Local Agencies

Observations

- State and local health officials have public health responsibilities that often mirror those of Federal officials. State and local officials, however, have much closer contact with communities, including persons who are included in studies sponsored by the Department. Clearly, State and local officials have an interest in the Department's activities.
- Several Federal agencies conduct or support epidemiologic studies on the effects of ionizing radiation. The Federal committee coordinating this effort is the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC).^{*} The Department of Energy is an active participant in this committee.
- Many Federal agencies are responsible for more general epidemiologic research; and many Federal agencies are responsible for occupational health and safety, public health, and disease control. Some of these agencies are: the Centers for Disease Control's National Institute for Occupational Safety and Health and Center for Environmental Health and Injury Control; the Occupational Safety and Health Administration; and the National Institutes of Health's National Institute of Environmental Health Sciences and National Cancer Institute.

Recommendations

- 5-9 The Department should make greater use of the broad range of health expertise and experience which resides at every level of government. State governments should participate on three committees: the Secretary of Energy Advisory Board; the advisory committee established under the Memorandum of Understanding with the Department of Health and Human Services; and the Assistant Secretary's Steering Committee for Occupational and Environmental Health and Safety. State and local health officials, who have unique knowledge about local concerns, should participate on study-specific advisory committees (See 3-9) and on Department of Energy site committees (See 3-11).
- 5-10 The Department should enter into Memoranda of Agreement with States that address subjects such as: sharing death certificate information, sharing the

^{*} CIRRPC is chartered through the Federal Coordinating Council for Science, Engineering and Technology, Office of Science and Technology Policy, Executive Office of the President.

Department's dosimetry data, and sharing data to develop disease registries. Federal policies and State laws can make information sharing difficult; therefore, negotiations for agreements should begin now so that information can flow smoothly in the future.

- 5-11 Throughout the Department's occupational and environmental health and safety activities, the Department should regularly seek the expertise of other federal agencies.

Chapter Six: Beryllium

Beryllium disease is an occupational health risk; therefore, many of the Panel's earlier observations and recommendations apply to this chapter as well.

Beryllium metal is used in many of the Department's manufacturing plants. Beryllium disease may result when tiny beryllium particles become deposited in the lungs.

The severity of the disease varies. In some cases, both the clinical and pathological findings are minimal when diagnosed, and the disease does not progress. In other cases, the disease progresses to severe respiratory impairment and death. Latent periods between initial exposure and first appearance of beryllium disease are usually long and variable.

Treatment may reduce the symptoms and improve the outcome. It appears that early diagnosis and removal from exposure increases the probability of a favorable outcome. Lymphocyte transformation testing, a blood test under development, may prove increasingly useful for detecting subclinical beryllium disease.

Beryllium is also a suspect human carcinogen.

Request to the Panel

The Secretary has asked the Panel to undertake the following:

- 1) Evaluate the appropriateness of the beryllium studies that are currently associated with the Department of Energy;
- 2) Recommend measures whereby those studies could either be expanded to include the universe of the Department's beryllium workers or initiate new studies that will accomplish this goal; and
- 3) Recommend the role and structure of an appropriate oversight function that will ensure that these studies are conducted in a useful and credible manner.

Observations

- Current research on beryllium disease is being conducted by the National Institute for Occupational Safety and Health and the National Jewish Center for Immunology and Respiratory Medicine. These studies are neither funded nor conducted by the Department of Energy.

- A recent epidemiologic study of Rocky Flats workers identified 12 cases of beryllium disease. Thousands of current and former workers are potentially at risk of beryllium disease; for example, approximately 2,000 workers were exposed to beryllium at the Oak Ridge Y-12 plant and 1,300 workers at the Rocky Flats plant.
- The Panel has heard conflicting views about dose response to beryllium. At least one recent study suggests that there is no relationship between the amount of exposure and the risk of developing disease.
- The extent of the beryllium problem is difficult to quantify because the Department has no reliable system of records for identifying all workers who may have been exposed to beryllium. For example, records may identify a worker as a machinist, but not identify that he or she was machining beryllium; therefore, that worker may not be recognized as having been exposed to beryllium.
- There is no uniform definition of what constitutes exposure to beryllium. For example, the Panel heard that a few day's work with beryllium does not constitute exposure; whereas others have indicated that ever being in the presence of beryllium may represent exposure.

Recommendations

- 6-1 The current research being conducted by the National Institute for Occupational Safety and Health and the National Jewish Center for Immunology and Respiratory Medicine seems to be appropriate. However, these studies are not sufficient. The Department should establish whether there is beryllium disease comparable to that at Rocky Flats at other Departmental facilities.
- 6-2 The Department should use a liberal definition of exposure to identify workers throughout the complex who have been exposed to beryllium and who ought to be included in research studies.
- 6-3 The Department should address beryllium disease both within the Department's occupational health program and within the analytic epidemiologic research program that the Panel recommends be managed under the Memorandum of Understanding with the Department of Health and Human Services.
- 6-4 The Department should fund a range of research projects related to beryllium disease, such as: environmental and personal risk factors for beryllium sensitization and disease; exposure reconstruction efforts with diagnostic sampling to confirm or refute the absence of dose-response for beryllium disease; natural history of subclinical disease and sensitization; the appropriate length of time between screenings; streamlining and automating the lymphocyte transformation test; and establishing laboratory comparability.

Chapter Seven: Resources

The Panel recognizes that its recommendations will require new or re-allocated funds. The general cost estimates identified here are consistent with those contained in the Panel's Interim Report.

Observations

- The Department's existing occupational health program (including health surveillance and descriptive epidemiology) lacks comprehensiveness and coordination. The Department is understaffed at the policy level in this program area.
- The majority of the Department's epidemiologic research agenda focuses on assessing health risks from low levels of radiation. The Department's employees, those of its contractors, and nearby communities are potentially exposed to a much broader range of health risks. Many questions about non-nuclear energy related risks (for example, toxic chemicals and beryllium) should be addressed. All sources of energy and the risks associated with their use are important areas for study.
- Expenditures for epidemiologic research are not centrally controlled or coordinated. All of the following Departmental organizations budget for epidemiology: Energy Research; Environment, Safety, and Health; Defense Programs; and Nuclear Energy.

Recommendations

- 7-1 The Department should fund a health surveillance and descriptive epidemiology program that can function as an integral part of an occupational health program. Funding should enable stronger program management and more multi-disciplinary depth; for example, physicians trained in occupational medicine and public health (supported by clinical staffs at plants), epidemiologists, biostatisticians, data managers skilled in large computerized data sets, industrial hygienists, safety specialists, toxicologists, and health physicists. See recommendation 3-2 for a description of the program.

Increase over proposed Fiscal Year 1991 budget: This new effort will require funds for a professional staff of 12 to 16 and funds to support day-to-day surveillance, data management, hazard analyses, data collection, descriptive epidemiology, and support for the Assistant Secretary's Steering Committee. (See recommendation 3-3.)

Funds for the descriptive epidemiology program under the Assistant Secretary for Occupational and Environmental Health and Safety are recommended at \$4.0 million* over the proposed Fiscal Year 1991 budget.

- 7-2 Additional funds should be allocated to support analytical epidemiology that will be managed by the Department of Health and Human Services. (See recommendation 3-13.) Many of the studies the Department is currently supporting are in this category. Many current studies need to be strengthened, particularly in the area of data collection. Areas for further research need to be identified.

Increase over proposed Fiscal Year 1991 budget: Funds to strengthen and broaden epidemiologic research; \$11.0 million** over the proposed Fiscal Year 1991 budget.

- 7-3 The Steering Committee for the Assistant Secretary for Occupational and Environmental Health and Safety should help develop more accurate cost estimates for the descriptive epidemiology program, including costs for risk communication programs and disease registries. Similarly, more accurate cost estimates for the analytical epidemiology program should be developed in collaboration with the advisory committee established for the management of analytical epidemiology under the Memorandum of Understanding with the Department of Health and Human Services.
- 7-4 Any epidemiology project funded by the Department (for example, by Defense Programs, Nuclear Energy, Operations Offices, and others) should be coordinated through the Assistant Secretary for Occupational and Environmental Health and Safety. To the extent that any component of the Department can justify separate fiscal support for epidemiologic activities,*** the funds should be channeled through either the descriptive epidemiology program or the mechanisms established under the Memorandum of Understanding with the Department of Health and Human Services.

* This includes the \$0.5 million for program management that the Panel recommended in its Interim Report and \$3.5 million of the \$7.5 million the Panel recommended for broadening epidemiologic research into new areas.

** This includes the \$7.0 million for strengthening current research that the Panel recommended in its Interim Report and \$4.0 million of \$7.5 million that the Panel recommended for broadening epidemiologic research into new areas.

*** For example, the Defense Program's funding of medical surveillance for the people of Rongelap Atoll in the Marshall Islands.

Appendices

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Appendix A

DEPARTMENT OF ENERGY

CHARTER

SECRETARIAL PANEL FOR THE EVALUATION OF EPIDEMIOLOGIC RESEARCH ACTIVITIES OF THE DEPARTMENT OF ENERGY

1. Committee's Official Designation:

Secretarial Panel for the Evaluation of Epidemiologic Research Activities of the Department of Energy

2. Committee's Objectives and Scope of Activities and Duties

The Secretarial Panel for the Evaluation of Epidemiologic Research Activities of the Department of Energy (SPEERA) will provide to the Secretary an independent evaluation of the Department of Energy's (DOE) epidemiology program and the appropriateness, effectiveness, and overall quality of DOE's epidemiologic research activities.

The SPEERA will examine the following aspects of DOE's epidemiologic research activities and recommend measures to the Secretary that will ensure that these activities are appropriate, effective, and represent excellence:

- a. The goals and objectives of the epidemiologic research program (the Program).
- b. The management and reporting structure of the Program.
- c. The full-time-equivalents (FTE's) and budget resources allocated to the Program (both internally to the DOE and externally to contractors).
- d. The use of contract scientists for ongoing and special projects.
- e. The quality control mechanisms in the Program, including data completeness and accuracy, and data management (archiving and access).
- f. The utility and feasibility of transferring the epidemiologic research function, including the necessary data, to another entity.
- g. Maintenance and access to related records such as exposure incident files, materials standards records and facilities design information belonging to the DOE or its contractors.

- h. Current and proposed mechanisms for determining epidemiologic data release policies including controls on "raw" data, "work in progress," and completed analysis.
- i. Current and proposed mechanisms for the storage of DOE epidemiologic data, including the establishment of a comprehensive data repository.
- j. DOE's response to the data related request of the Three Mile Island Public Health Fund.
- k. The long term role of the National Academy of Sciences "Committee on Radiation and Epidemiological Research Programs."
- l. Other areas related to the Program as determined.

3. Issuance of an Interim and a Final Report:

The Panel shall submit an interim and a final report to the Secretary of Energy.

4. Time Period Necessary for the Committee to Carry Out Its Purpose:

The Panel is expected to complete its purpose within 10 months.

5. Official to Whom This Committee Reports:

The Panel will report to the Secretary of Energy.

6. Agency Responsible for Providing Necessary Support for This Committee:

The Department of Energy shall provide the Panel with such administrative services, funds, facilities, staff, and other support services as may be necessary for the performance of its functions.

7. A Description of Duties for Which the Committee is Responsible:

The duties of the Panel are solely advisory and are fully stated in paragraph 2 above.

8. Estimated Annual Operating Costs in Dollars and Person-Years:

The estimated operating costs are \$750,000 and 7.5 person-years. This estimate covers salaries for the support staff to the Panel; the salaries of any consultants, including Federal employees who may be detailed from another agency to assist the Panel; travel expenses; per diem in lieu of subsistence for panel members; supplies; facilities; and other services as may be necessary in support of the Panel's functions.

9. Estimated Number and Frequency of Committee Meetings:

The Panel is expected to meet approximately six (6) times, or as determined by the Secretary.

10. Committee's Termination Date (If Less Than Two Years From The Date of Establishment or Renewal):

The Panel is expected to terminate no later than May 31, 1990.

11. Subcommittees:

To facilitate the functioning of the Panel, subpanels may be formed. The objectives of the subpanels are to make recommendations to the SPEERA with respect to matters concerning the DOE plans and programs which are related to the objectives and scope of the SPEERA. The subpanels shall be comprised of such members of the SPEERA as may be determined by the Chairperson.

12. Members:

Committee members shall be appointed by the Secretary of Energy. Members shall be distinguished individuals who have experience in the areas of public health, occupational health, epidemiology, research standards, ethical and legal aspects of medical research, organized labor, and other areas as necessary to achieve a fairly balanced membership. The approximate number of members is seven.

13. Chairperson:

The Chairperson shall be appointed by the Secretary of Energy.

This Charter for the Advisory Committee named above is hereby approved on:

Date: August 1, 1989

Howard H. Raiken
Advisory Committee Management Officer

Date Filed: August 1, 1989

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Appendix B

PANEL MEETING SCHEDULE

Date	Subject	Site
<u>1989</u>		
September 12-13	Meeting/Public Hearing	Washington,DC
October 26-27	Meeting/Public Hearing	Chicago, IL
November 13-14	Meeting/Public Hearing	Denver, CO
November 15	Site Visit	Rocky Flats, Denver, CO
December 20-21	Site Visit	Hanford, Richland,WA
December 27	Site Visit	Los Alamos,NM
December 28-29	Meeting/Public Hearing	Albuquerque,NM
<u>1990</u>		
January 9-10	Site Visit	Oak Ridge, TN
January 17-18	Meeting/Public Hearing	Cincinnati, OH
January 19	Site Visit	Feed Materials Production Center, Fernald, OH
February 21	Site Visit	Savannah River Plant, Aiken, SC
February 22-23	Meeting/Public Hearing	Columbia, SC
March 12-13	Meeting/Public Hearing	Washington, DC

Appendix C

Background Information and Reference Materials

The Panel's work included: 14 days of public meetings in 7 cities around the country;
6 visits to Department of Energy sites;
177 people who presented testimony; and
Thousands of pages of reference material, as follows.

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Total Items: 120

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Appendix D

Biographical Information

Secretarial Panel for the Evaluation of Epidemiologic Research Activities of the Department of Energy

Kristine Gebbie, M.N., of Washington, is Chairperson of the Secretary's Panel. She is Secretary of Health, Department of Health, for the State of Washington. In addition, she is an Adjunct Associate Professor at Oregon Health Science University and a member of the Institute of Medicine's AIDS Oversight Committee. She was Administrator of the Oregon Health Division and a member of the Presidential Commission on the Human Immunodeficiency Virus Epidemic. She has been president of the Association of State and Territorial Health Officials.

Molly Joel Coye, M.D., of Maryland, is Associate Professor and Head of the Division of Public Health at Johns Hopkins University School of Hygiene and Public Health. She serves on the National Environmental Sciences Advisory Council for the National Institutes of Health and as co-chair of the AIDS Advisory Committee for the U.S. Public Health Service. She was New Jersey Commissioner of Health and she has served on National Academy of Sciences' committees addressing occupational and environmental health matters. She is the author of numerous publications on occupational health subjects.

Mark Cullen, M.D., of Connecticut, is Associate Professor of Medicine and Epidemiology at Yale University School of Medicine and Director of the Yale-New Haven Occupational Medicine Program. He is a member of the United Automobile Workers/General Motors Occupational Health Advisory Board and the author of numerous publications on the subject of occupational diseases.

Clark Heath, Jr., M.D., of Georgia, is Vice President for Epidemiology and Statistics, American Cancer Society. He was Director of South Carolina's Bureau of Preventive Health Services and Director of the Chronic Disease Division of the Bureau of Epidemiology at the Centers for Disease Control. He has served on advisory committees for the World Health Organization, the National Institute for Occupational Safety and Health, and the National Academy of Science.

Mark Rothstein, J.D., of Texas, is Professor of Law and Director of the Health Law Institute at the University of Houston Law Center. He is on the Board of Advisors of the Southwest Center for Occupational Health and Safety and on the Executive Committee of the Institute for Health Policy Education and Research at the University of Texas Health Science Center. He is the author of numerous publications on medical legal issues and has served on committees for the Office of Technology Assessment of the U.S. Congress and the National Academy of Sciences. He is an editorial reviewer for the *Journal of the American Medical Association*, the *Journal of Legal Medicine*, and *Trial*.

Michael Silverstein, M.D., of Michigan, is Assistant Director of the Health and Safety Department, United Automobile Workers. He is Adjunct Professor of Occupational Medicine at the University of Michigan School of Public Health. He serves on the Advisory Committee for the New York State Environmental Disease Surveillance Program and is a member of the editorial board for the *Journal of Occupational Medicine*.

Lee Stauffer, M.P.H., of Minnesota, is Associate Professor at the School of Public Health at the University of Minnesota and a 1989 recipient of the Public Health Achievement Award from the Minnesota Public Health Association. He was chairman of the Task Force on Safe Drinking Water for Minnesota's Department of Health and Dean of the School of Public Health at the University of Minnesota. He is a Fellow of the American Public Health Association.

Thomas Vernon, M.D., of Colorado, is Executive Director of the Colorado Department of Health. He is Associate Clinical Professor for the Department of Internal Medicine and Preventive Medicine at the University of Colorado Health Sciences Center. He is past-president of the Association of State and Territorial Health Officials, and he served as Epidemiologist Consultant for the U.S. Agency for International Development and as State Epidemiologist for the Colorado Department of Health.

Bailus Walker, Jr., Ph.D, M.P.H., of New York, is Professor of Environmental Health and Toxicology at State University of New York at Albany. He was Commissioner of Public Health for Massachusetts and State Director of Public Health for Michigan. He is past-president of the American Public Health Association and a member of the National Academy of Sciences Committee on Enhancing the Practice of Occupational and Environmental Medicine. He is a contributing editor for the *New England Journal of Medicine* and a member of the Study Group on Cancer Prevention/Control for the National Cancer Institute.