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Report to the Chairman, Committee on
Governmental Affairs, U.S. Senate

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NUCLEAR HEALTH AND SAFETY

Efforts to Strengthen DOE's Health and Epidemiology Programs



United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

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February 5, 1991

The Honorable John Glenn
Chairman, Committee on
Governmental Affairs
United States Senate

Dear Mr. Chairman:

Over the past several years, concern over the Department of Energy's (DOE) dual role of producing nuclear weapons and assessing the potential health hazards associated with operating its facilities has raised questions about DOE's ability to effectively manage its health and health effects (epidemiology) research programs. In March 1990 the Secretary of Energy announced several initiatives to address these concerns. These initiatives include, among others, the development of an occupational health and epidemiology program, the transfer of long-term health effects' studies to the Department of Health and Human Services (HHS), the establishment of an advisory committee to oversee DOE's environmental, safety, and health activities, and the design of a data base to store and retrieve health data. Specifically, you asked us to provide you with (1) a brief description of DOE's initiatives, including their status as of December 1990 and (2) our general observations on these initiatives.

Results in Brief

During the 1980s, several external reviews identified problems with DOE's management of its health-related programs. Among other things, these reviews pointed out that DOE had not effectively overseen its health programs, lacked credibility in its health effects research activities because it restricted public involvement and independent assessment of its research data, and did not standardize the collection of pertinent data on the health of its workers. Since March 1990 DOE has implemented the following initiatives, among others, to address these problems.

- DOE has consolidated its health programs to establish an Office of Health within its Office of Environment, Safety, and Health. This office will be responsible for providing, among other things, internal oversight of DOE's facilities to ensure adequate health protection of DOE's workers and residents of nearby communities. DOE plans to increase this office's staff from 26 to 86 personnel by fiscal year 1992. However, the current shortage of qualified staff may hinder DOE's ability to attract the staff required to perform all of this office's stated functions.

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- DOE is establishing an advisory committee in early 1991, composed of non-DOE members, to oversee DOE's environmental, safety, and health activities. As planned, this committee will serve in an advisory capacity without any formal authority to enforce its findings or recommendations.
- DOE has begun developing a comprehensive data base to consolidate previously collected worker health data and provide a repository for future data. And, for the first time, DOE plans to provide independent researchers access to this data so they can assess the validity of DOE's studies. This data base is expected to be operational by the end of fiscal year 1992.
- DOE has signed an agreement with HHS to transfer the management of DOE's long-term health effects research to HHS. A committee will be formed to oversee the implementation of this agreement.

DOE's recent initiatives are a positive step towards addressing the problems within its health and epidemiology programs. However, the success of these initiatives will likely depend on such things as DOE's ability to obtain the necessary resources and follow through on its commitment to allow the independent assessment of its activities.

Background

DOE's production of nuclear materials and weapons involves activities that pose potential health hazards. Some hazards are similar to those encountered in any other industrial setting. Others, such as exposure to radiation, are unique to the nuclear industry and can potentially affect the health of workers and the public. For instance, when radiation encounters human tissue it can damage the cell structure causing conditions such as burns, cancer, and various other illnesses.

DOE supports research for understanding the health effects associated with working at or living near its facilities. Historically, DOE has assessed the risks of exposure to potentially harmful materials partly through the conduct of epidemiologic studies.¹ DOE's epidemiology research program has primarily focused on the health effects of exposure to radiation on atomic bomb survivors and DOE nuclear workers. The results of DOE's worker studies have not conclusively shown whether there are detectable adverse effects from the exposure to low-levels of radiation.

¹ Epidemiology is the scientific study of disease among human populations. DOE's epidemiologic studies on its workers have used records—such as health, employment, and personnel records—to statistically analyze the risk factors for diseases in human populations.

Over the years, the management of DOE's epidemiology activities has been dispersed throughout the Department. However, the management of DOE's main epidemiologic activities during the past 8 years has been located largely within its headquarters Office of Energy Research under the direction of one epidemiologist. DOE's epidemiologic research activities have led to the publication of 340 articles in scientific journals. In addition to conducting epidemiology research on health effects, DOE has conducted occupational health-related programs within its Office of Environment, Safety, and Health. Specifically, DOE's health physics, industrial hygiene, and occupational medicine programs have been conducted to help detect, prevent, and treat illnesses and injury from occupational exposures and hazards.

Past Problems of DOE Health-Related Programs

Since the early 1980s, our work in this area, as well as other independent reviews, has identified problems with DOE's management of its epidemiology research and health programs. These problems include DOE's reluctance to (1) adequately fund the epidemiology program, (2) effectively oversee its health programs, (3) standardize the data collected at the various DOE facilities, (4) coordinate and communicate among the various health programs, (5) correct deficiencies in its radiological protection programs, and (6) establish credibility since it restricted public involvement and independent assessment of its health research data. DOE did little to formally address these problems; however, during 1989 congressional testimony, the Secretary of Energy acknowledged that DOE's epidemiology program was flawed because it was understaffed, lacked sufficient funding, and was buried deep within the departmental bureaucracy.

In 1989 the Secretary of Energy established a panel of experts, commonly referred to as the Secretarial Panel for the Evaluation of Epidemiologic Research Activities, to evaluate, among other things, the effectiveness of DOE's epidemiology research activities. This panel issued a report, in March 1990, that identified problems similar to those found by the previous reviewers. Moreover, the report contained over 50 recommendations for DOE to improve its occupational health and epidemiology program, including the transfer of DOE's management of its long-term studies to HHS. (See app. I.)

DOE's Initiatives to Restructure Its Health Programs

In response to recommendations made by the expert panel in its 1990 report, the Secretary of Energy announced his intentions to consolidate and strengthen the various departmental health and epidemiology activities. At that time, he (1) established an Office of Health to conduct a comprehensive DOE occupational health and epidemiology program, (2) directed the establishment of an advisory committee to provide external advice, and (3) established policies to better ensure access to DOE's epidemiology data by independent researchers. Furthermore, he directed the development of a memorandum of understanding between DOE and HHS to transfer the management of DOE's long-term health effects research from DOE to HHS. (See app. II.)

Office of Health

On March 27, 1990, the Office of Health was established to consolidate and strengthen the Department's health activities. This office, at the deputy assistant secretary level within the Office of Environment, Safety, and Health, consolidates health physics, industrial hygiene, occupational medicine, and descriptive epidemiology studies to create an overall occupational health program.² The office also develops the respective standards and policies as well as provides internal oversight of DOE's operations of the facilities. By consolidating these offices, DOE intends to facilitate communication among the various health-related offices, elevate the importance of health programs within DOE, and minimize duplication of efforts while standardizing the collection of health data.

The office also plans to develop an occupational health surveillance system at all DOE sites. The principal component of this surveillance system will be the collection of health-related data on current DOE workers. The data can then be used to help ensure the prompt detection of hazards to human health. The design of the occupational health surveillance system is projected to be completed by the end of fiscal year 1992.

The Office of Health will require additional staff to carry out these functions. DOE plans to increase this office's professional staff from 26 to 86 personnel by fiscal year 1992. However, according to DOE officials, the competing demands from industry and other federal agencies for the

²Descriptive epidemiology studies analyze health data to "quickly" identify, through the surveillance of illness and exposure patterns, adverse trends (hypotheses) in the health of workers. These trends will then be studied in more depth during long-term epidemiology studies.

same type of qualified staff may hinder DOE's efforts in attracting qualified staff. Consequently, if DOE does not obtain such staff, it may not be able to perform all of its stated functions.

Advisory Committee

DOE is establishing an advisory committee to oversee its environmental, safety, and health activities. The committee, termed the Environment, Safety, and Health Advisory Committee, is intended to provide DOE with a broad representation of non-DOE participants, including public health officials and workers, to (1) obtain public comment on its activities; (2) lend credibility to its actions; and (3) provide a balanced and unbiased assessment of the mission and direction of the Office of Environment, Safety, and Health.

As planned, the Environment, Safety, and Health Advisory Committee will serve in an advisory capacity without any formal ability to enforce its findings or recommendations. Specific details concerning the activities of the advisory committee are still being developed; however, the committee's activities are intended to be conducted in accordance with the Federal Advisory Committee Act which provides for public attendance at its meetings.

DOE's Actions to Consolidate and Release Data to Outside Researchers

During the past 45 years, various DOE facilities have been collecting employee health-related data that are useful for epidemiology studies on their workers. These records were not collected in a standardized manner nor centralized so comprehensive assessments could be made. However, since 1989 DOE has been developing a data base to put into one place the various types of collected data on human health. This data base system, termed the Comprehensive Epidemiologic Data Resource, is being designed, in part, to provide independent researchers access to the collected data so they can assess the validity of DOE's studies. The data base will include data collected during previous and ongoing studies, related death data from the state(s), and future data collected for epidemiologic research studies.³

Originally, DOE was planning to survey its facilities to determine the availability of data that would be useful for epidemiologic research. However, DOE officials now contend that it would be more appropriate

³In collecting and storing this data, DOE recognizes the need to prevent the improper disclosure of the identity of the individual workers to the users of this data base. Therefore, DOE has identified various options to limit the ability of the user to ascertain the identity of the individual.

for the researchers managing the studies to collect the pertinent data since they will determine the scope of the research. Once this information is collected by the researchers, it will then be stored in DOE's comprehensive data base.

Funding to support the development of this comprehensive data base has been fragmented. For example, during fiscal year 1990, funding from various DOE programs were used to support the comprehensive data base program. Moreover, DOE's fiscal year 1991 budget request does not specifically designate funding for this project but rather includes it as part of another program activity. According to DOE officials, this program should be operational by the end of fiscal year 1992 at an estimated developmental cost of about \$3 million.

HHS Role in Conducting DOE Studies

As reported by DOE's panel of experts, DOE lacked credibility in its epidemiology activities, in part, because it restricted public involvement and independent assessment of its research data. To restore public trust, DOE has entered into, as recommended by the panel, a memorandum of understanding with HHS to manage and conduct DOE's analytical epidemiology research.⁴ Under this agreement, HHS will be responsible for conducting analytical studies of (1) workers at DOE facilities, (2) residents of communities in the vicinity of DOE facilities, (3) other persons potentially exposed to radiation, and (4) persons exposed to potential hazards resulting from non-nuclear energy production. The health research program to be managed by HHS will also include DOE's ongoing analytical studies (the majority of DOE's current health effects research) and future epidemiology health studies.⁵ DOE and HHS plan to form a committee for a year to oversee the implementation of this agreement.

HHS plans to establish a new advisory committee to recommend the type of research that should be undertaken. Under current plans, DOE will have a non-voting representative(s) on this HHS committee. DOE's Environment, Safety, and Health Advisory Committee will also be able to communicate and propose analytical epidemiology studies to the HHS

⁴Analytical epidemiology studies are designed to test whether the trends (hypotheses), identified by DOE's occupational health surveillance program and other non-occupational studies, are valid. Analytical epidemiology studies are often long-term in nature.

⁵HHS has agreed to initially continue existing DOE grants and contracts; however, HHS plans to review all existing grants and contracts to determine whether each project should continue or whether the scope should be changed.

committee. The HHS committee will then assess these proposals for inclusion in its recommendation for the research agenda. HHS will make the final determination on which analytical studies will be conducted.

DOE plans to provide HHS with funds to manage the analytical epidemiology research. Under this agreement, DOE will transfer approximately \$17 million to HHS in fiscal year 1991 for the management of the ongoing studies as well as for new research.

Observations on DOE's Initiatives

We believe that DOE's consolidation of its health programs and the transfer of its studies to HHS, in concept, provide a credible framework for overseeing the health of its workers and nearby communities. Because of the lack of outside involvement in DOE's past operations, it is encouraging to see that the current initiatives involve public oversight and independent assessment. Moreover, we believe that the consolidation of DOE's health programs into one central office should strengthen DOE's efforts in overseeing how line management is carrying out its health responsibilities. However, results from our previous work and those from other independent reviews in the environmental, safety, and health area lead us to make several observations concerning issues that could have an impact on the success of DOE's current health initiatives.

First, the success of DOE's occupational health and epidemiology program will likely depend on the availability of technically qualified staff. According to the Secretary of Energy, DOE has not been effective in overseeing its health and epidemiology research, in part, because of the lack of adequate staff. According to DOE officials, there has been and continues to be a shortage of the qualified staff that DOE will need to carry out the functions of its Office of Health. Furthermore, competing demands for qualified staff may hinder DOE's efforts in attracting them. The competition is not just limited to private industry working in these areas; the competition extends to other organizations within the federal government as well as within DOE. For example, DOE will have to compete with HHS for the same type of qualified personnel that HHS needs to carry out DOE's long-term epidemiology studies. Consequently, the positive concept of the new emphasis on health within DOE cannot, in itself, ensure the effective management and oversight that is required.

Second, the development of a comprehensive data base system will likely require DOE's commitment to continued funding for this program. As mentioned earlier, funds from various other DOE programs were used

to support this program in fiscal year 1990, while no funds were specifically designated for the program in fiscal year 1991. Consequently, funding for the program could easily be diverted if DOE's commitment to this program is lessened. However, DOE officials stated that they are committed to providing funds to develop and maintain this system. This commitment will be an important factor in ensuring that an effective system is developed and maintained to serve as a national data repository for researchers to use when conducting epidemiologic research.

Third, the effectiveness of the Environment, Safety, and Health Advisory Committee, particularly how DOE responds to its recommendations, could be a key aspect in establishing public trust in DOE's ability to protect the health of its workers and nearby communities. Historically, DOE has been remiss in correcting the problems identified during previous reviews of its health-related programs. Consequently, its credibility has suffered. Because the newly established advisory committee will be, according to its charter, "solely advisory," DOE's commitment to addressing the advisory committee's recommendations/findings will directly affect its ability to restore public trust and reestablish credibility.

Finally, the success in implementing the memorandum of understanding between DOE and HHS will likely depend on the level of funding that DOE provides to HHS for managing these studies. As pointed out by the Secretarial Panel for the Evaluation of Epidemiologic Research Activities, a commitment of adequate funding is necessary to achieve a "productive" analytical research program. Furthermore, since the transfer of the management of these programs will go through a transitional phase, close coordination between the two agencies will be an important factor in helping to minimize inefficiencies. We believe that a continuing commitment and effective dialogue with HHS will provide greater assurance to DOE's workers and the residents of nearby communities that useful epidemiological studies are being conducted to help determine the risks associated with DOE's operations.

Scope and Methodology

To gather information on DOE's initiatives, we interviewed officials at DOE and HHS headquarters and reviewed pertinent documents, including congressional testimony, Secretary of Energy Notices, DOE orders, and memoranda and correspondence. We also reviewed the transcripts of the Secretarial Panel for the Evaluation of Epidemiologic Research Activities hearings and supporting documents as well as interviewed DOE contractor personnel involved with DOE's health research program.

Furthermore, to develop an overall perspective on the potential implications of DOE's current initiatives, we relied on our previous work in the environmental, safety, and health area as well as other independent reviews. We conducted our work from July 1990 through November 1990 in accordance with generally accepted government auditing standards.

We discussed the factual contents of this report with agency officials and incorporated their views as appropriate. In general, they agreed with the factual information presented. As requested, we did not obtain official agency comments on this report. Unless you publicly announce its contents earlier, we plan no further distribution of this report for 30 days from the date of this letter. At that time, we will send copies to the appropriate congressional committees; the Secretary of Energy; the Secretary of Health and Human Services; and the Director, Office of Management and Budget. We will also make copies available to others upon request.

If you have any questions, please contact me at (202) 275-1441. Major contributors to this report are listed in appendix III.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Victor S. Rezendes". The signature is stylized with a large, looped "V" and a cursive "Rezendes".

Victor S. Rezendes
Director, Energy Issues

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Abbreviations

CEDR	Comprehensive Epidemiologic Data Resource
DOE	Department of Energy
GAO	General Accounting Office
HHS	Health and Human Services
RCED	Resources, Community, and Economic Development Division
SPEERA	Secretarial Panel for the Evaluation of Epidemiologic Research Activities

Reviews of DOE's Health Programs

Since the early 1980s, several independent reviews have identified problems with DOE's management of its epidemiology research and health programs. A common theme of these reviews revealed DOE's failure to effectively oversee its health programs, establish credibility in its research activities, and standardize and coordinate the collection of pertinent data on the health of its workers. DOE did little to formally address these problems; however, the Secretary of Energy, during 1989, acknowledged that the program was flawed because it was understaffed, lacked sufficient funding, and was buried deep within the departmental bureaucracy. In March 1990 he announced several initiatives, in response to recommendations made by a DOE-appointed panel of experts, to restructure and strengthen DOE's health programs.

Program Shortfalls Identified in the Past

In 1984 reviewers from the DOE Health and Environmental Research Advisory Committee reported concerns in DOE's epidemiology research program.¹ The committee concluded that the credibility of DOE's epidemiology program suffered because it did not competitively bid its studies, allow external review of its programs, and allow independent researchers access to its health-related data. Furthermore, the committee disclosed that continuous funding needed to be provided to develop a data base to store all the health data. They also reported that the working relationships between DOE's epidemiology program and various other DOE health programs (e.g., health physics and industrial hygiene) needed to be strengthened to ensure that their records, which would become part of the data base, were standardized and designed to meet the needs for epidemiologic research.

Since the early 1980s, we also have reported on DOE's safety and health programs. In 1981 we reported that DOE's oversight of its radiological and non-radiological workplace conditions needed to be improved to ensure that workers at DOE's nuclear plants were provided with better protection from safety and health hazards.² In 1985, and again in 1988, we reported on DOE's safety and health programs at specific DOE facilities. Within these reports, we stated that (1) radiological monitoring

¹Review of the Office of Health and Environmental Research Program: Epidemiology (Sept. 1984).

²Better Oversight Needed for Safety and Health Activities at DOE's Nuclear Facilities (GAO/EMD-81-108, Aug. 4, 1981).

guides were not always followed, (2) management did not provide adequate attention to safety and health programs, and (3) improvements were needed in radiological protection programs.³

Despite the findings, DOE did little to formally address these problems primarily because management did not take the necessary action to correct them. However, during 1989 congressional testimony, the newly appointed Secretary of Energy publicly acknowledged that DOE's epidemiology health effects research program was flawed because it was understaffed, lacked sufficient funding, and was buried deep within the departmental bureaucracy. In late 1989 similar problems were reported by the National Research Council.⁴ Moreover, the Council reported that DOE's vagueness and secrecy regarding releases of radioactivity and the extent of environmental contamination at DOE facilities contributed significantly to a public lack of confidence in DOE's concern about risks to human health.

The Secretary of Energy Established a Panel to Evaluate Program Effectiveness

To correct the problems within DOE's health programs, the Secretary of Energy in 1989 established a panel of experts, commonly referred to as the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA), to evaluate, among other things, the effectiveness of DOE's epidemiology research activities. After reviewing documents and hearing testimony from various interested parties, the panel issued a final report, in March 1990, that identified problems similar to those found by the previous independent reviews.⁵ Among other things, SPEERA reported the following:

- DOE's health programs (e.g., health physics, industrial hygiene, and occupational medical programs) lacked leadership. For example, neither the health-related programs nor the occupational medical program were linked as part of a coordinated health program. The panel contended that such disciplines should be consolidated and provided with authority and visibility in DOE's organizational structure.

³Environment, Safety, and Health: Environment and Workers Could Be Better Protected at Ohio Defense Plants (GAO/RCED-86-61, Dec. 13, 1985) and Nuclear Health and Safety: Summary of Major Problems at DOE's Rocky Flats Plant (GAO/RCED-89-53BR, Oct. 27, 1988).

⁴The Nuclear Weapons Complex: Management for Health, Safety, and the Environment (National Academy Press, Dec. 1989).

⁵Report to the Secretary: The Secretarial Panel for the Evaluation of Epidemiologic Research Activities for the U.S. Department of Energy (March 1990).

- DOE's epidemiology activities lacked credibility. This lack of credibility was because DOE had not (1) effectively managed its epidemiologic research, (2) allowed public involvement and independent review of its research data, and (3) systematically communicated study findings to its workers or nearby communities. To restore public credibility, the panel recommended entering into a memorandum of understanding with HHS to manage DOE's analytical epidemiologic research program. The panel also recommended that DOE establish an advisory committee composed of outside experts and other interested parties to oversee DOE's health activities.
- DOE's employee health-related records were maintained differently throughout the complex and were not collected in a standardized manner. The panel also reported that it is unknown whether the health data are of any use for epidemiology research. Therefore, the panel recommended that a standard set of health records be collected routinely and stored in a central data base.
- DOE's epidemiology programs were understaffed and lacked adequate funding. For example, headquarters assigned only one epidemiologist to manage the program, and low-level funding for this program precluded the expansion of its research agenda. The panel estimated that the costs of acquiring additional professional staff and the development of a health surveillance program, coupled with the broadening of DOE's health effects research, may require as much as \$15 million more than the proposed fiscal year 1991 DOE budget for epidemiology research.

SPEERA's report contained over 50 recommendations for DOE to improve its occupational health and epidemiology program, including the transfer of DOE's management of its long-term studies to HHS. On the same day that SPEERA issued its report, the Secretary of Energy announced several directives designed to develop a health program that is responsible for ensuring that the managers of its facilities are protecting the health of its workers and residents of nearby communities. These directives and their related initiatives are discussed in appendix II.

DOE's Initiatives to Restructure Its Health Programs

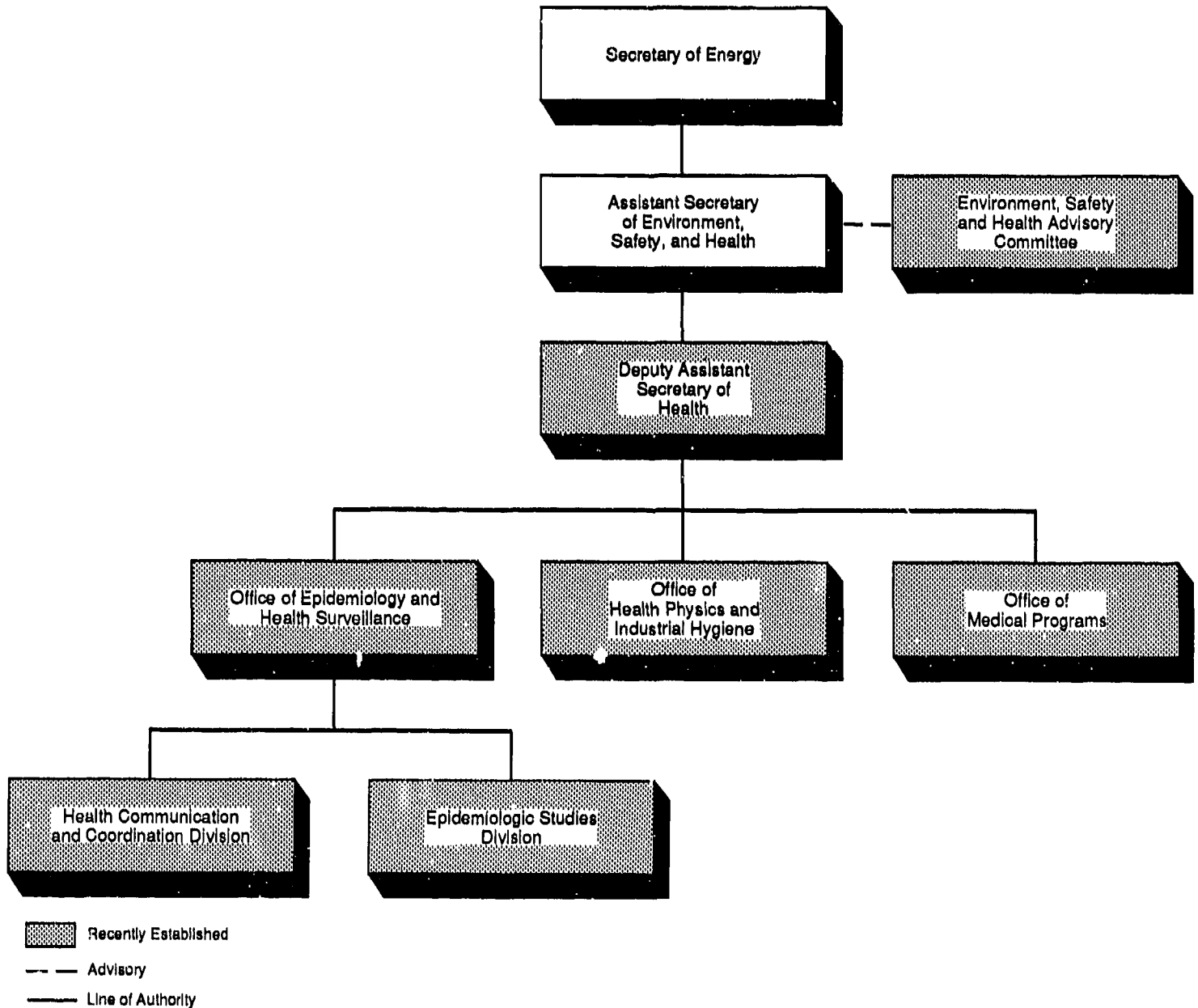
In response to the recommendations that the SPEERA panel made, the Secretary of Energy (1) established an Office of Health to conduct a comprehensive DOE occupational health and epidemiology program, (2) directed the establishment of an advisory committee to provide external advice, and (3) established policies that better ensure access to DOE's epidemiology data by independent researchers. Furthermore, he directed the development of a memorandum of understanding between DOE and HHS to transfer management of DOE's long-term health effects research to HHS. As of December 1990, each of these initiatives was in various stages of implementation.

DOE's Office of Health

On March 27, 1990, DOE established the Office of Health, at the deputy assistant secretary level within its Office of Environment, Safety, and Health, to develop an occupational health and epidemiology program. The establishment of such a program, according to the Secretary of Energy, will provide "... 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." Specifically, this office has consolidated DOE's health activities (e.g., industrial hygiene, health physics, occupational medicine, and epidemiology) into one central office to (1) facilitate communication among these various health-related offices, (2) elevate the importance of health programs within the Department, and (3) minimize duplication of efforts while standardizing the collection of health data.

As depicted in figure II.1, the Office of Health is currently comprised of three suboffices—the Offices of Health Physics and Industrial Hygiene, Medical Programs, and Epidemiology and Health Surveillance. The Office of Health Physics and Industrial Hygiene consolidated various health programs that already existed within the Office of Environment, Safety, and Health and is responsible for ensuring that managers of the facilities carry out effective worker radiological and industrial hygiene protection programs. Under current plans, the Office of Medical Programs, formed from an existing office within the Office of Environment, Safety, and Health, will be given more authority and staff to strengthen and elevate its importance within DOE's hierarchy. The Office of Medical Programs will be responsible for protecting the physical and mental health of DOE's workers as well as providing internal oversight of the contractor's occupational medicine programs.

Figure II.1: Organization of DOE's Health-Related Activities



The remaining suboffice, called the Office of Epidemiology and Health Surveillance, assumed responsibility for the epidemiology research program which was dispersed throughout the Department. Specifically, this

office, comprised of an Epidemiologic Studies Division and a Health Communication and Coordination Division, will be responsible for (1) developing and managing an occupational health surveillance system;¹ (2) standardizing health data collection; (3) conducting quick response epidemiology studies; (4) developing a system to provide independent access to epidemiology data; and (5) communicating the results of epidemiology studies to DOE management, workers, operating contractors, and the public.

A main objective of the Office of Epidemiology and Health Surveillance will be to develop an occupational health surveillance program at each of DOE's sites. To accomplish this task, DOE will request representatives from organized labor, workers, and the public to actively participate in the programs' development. The principal components of this health surveillance system will be the collection of health-related data on current DOE workers. The data can then be used to help ensure the prompt detection of hazards to human health. Under current plans, the health surveillance program is expected to be fully designed by the end of fiscal year 1992 since it will take sometime to actually develop and implement the program to meet the needs of DOE and its workers. To conduct studies of the communities near DOE facilities, DOE proposes to establish "Health Agreements" with the state health departments to undertake these studies using DOE funds. Another element of this office will be to communicate the results of epidemiology studies to the population being studied. In doing so, DOE plans to develop a program designed to communicate directly to the public through mechanisms such as newsletters and reports.

The Office of Health will require additional staff to carry out these new functions. DOE plans to increase this office's professional staff from 26 to 86 personnel by fiscal year 1992. Specifically, the proposed staffing levels for the Office of Health for fiscal year 1991 through fiscal year 1992 are 69 and 86, respectively. According to DOE officials, the current shortage of qualified staff and competing demands for them from industry and other federal agencies may hinder DOE's efforts in attracting qualified staff. For example, DOE will have to compete with HHS for the same type of qualified personnel that HHS needs to manage DOE's long-term epidemiology studies. Even though the mission and responsibilities of the office are approved, according to the Acting DOE Deputy Assistant Secretary for Health, without the necessary staff the

¹DOE's epidemiology program assumed the leadership role in developing a health surveillance system in 1983 for the testing of surveillance methods and procedures.

office will not be able to perform all of the assigned functions. The functions will then have to be phased in as the additional staff is hired and trained. Consequently, if DOE does not obtain the qualified staff, it may not be able to perform all of its stated functions.

DOE Advisory Committee and Local Participation

DOE is establishing a committee of 12 experts to advise and oversee DOE's management of its environmental, safety, and health programs. As recommended by SPEERA, DOE needed to establish an advisory committee to oversee its safety and health activities since its credibility has suffered from its reluctance to allow independent oversight of its operations. DOE responded to this recommendation by establishing the Environment, Safety, and Health Advisory Committee to provide DOE with broad representation, including public health officials, workers, and a non-voting HHS representative(s) to (1) obtain public comment on its activities; (2) lend credibility to its actions; and (3) provide a balanced and unbiased assessment and oversight of the mission and direction of the Office of Environment, Safety, and Health. The Secretary of Energy will select the committee members from nominations provided by groups outside of DOE (e.g., trade unions and public health officials). DOE will also provide funding and support staff to the committee. The committee is anticipated to be operational in early 1991.

The committee, when staffed, will provide oversight and evaluation of DOE's environmental, safety, and health programs. Specifically, its primary functions will include recommending and advising DOE on the (1) need for revised environmental, safety, and health standards; (2) guidelines for the release of health surveillance data; (3) research agenda for the epidemiology program; and (4) appropriate policy for specific programs. The committee will report to the Assistant Secretary for Environment, Safety, and Health. According to DOE officials and the committee's charter, the committee is expected to meet about three times a year and will serve in an advisory capacity without any formal ability to enforce its findings and recommendations. Specific details concerning the activities of this advisory committee are still being developed; however, the committee's activities are intended to be conducted in accordance with the Federal Advisory Committee Act which provides for public attendance at and participation in the committees' meetings.

DOE also plans to solicit local participation in its research agenda for descriptive studies from public groups. Under current planning, committees will be formed at DOE facilities where studies are being conducted. These groups will have direct input into the design of these studies.

Because these committees will represent the public being studied, it will allow DOE to directly communicate the studies' results to the affected populations. As yet, only two such local committees, at DOE's Hanford and Rocky Flats facilities, have been formed.

DOE Program to Standardize and Release Its Data

During the past 45 years, various DOE facilities have been collecting, through their health programs, health-related data on their employees. These data—health, exposure, environmental monitoring, and personnel records—are required for researchers to conduct epidemiology studies on DOE's workers. The primary purpose for collecting these data was not for epidemiologic research but for the health and safety of DOE's employees. However, no uniform method has been developed for collecting or analyzing the data. Only recently has there been an effort to link together the data files that exist at the various DOE facilities.

Since 1989, DOE has been developing a data base to put into one place the various types of collected data relating to human health. This data base system, termed the Comprehensive Epidemiologic Data Resource (CEDR), is being designed, in part, to provide independent researchers access to the collected data so they can assess the validity of DOE's past studies and any future studies that may be undertaken. The data base will include data collected during previous and ongoing studies, related death data from the state(s), and future data collected for epidemiologic research studies.² By allowing independent assessment, according to the Acting Director of the Office of Epidemiology and Health Surveillance, DOE believes it will enhance the credibility of the research it conducted in the past as well as for future research.

During late 1989, DOE established the Epidemiology Research Task Force to oversee, among other things, the development of the CEDR program.³ The task force, in pursuing its objectives, established a steering group to coordinate the development of the program and several ad hoc working groups to carry out specific tasks. These ad hoc groups were to recommend a method for standardizing the collected data and the design of the supporting computer system. As a first measure to standardize the

²In collecting and storing this data, DOE recognizes the need to prevent the improper disclosure of the identity of the individual workers to the users of this data base. Therefore, DOE has identified various options to limit the ability of the user to ascertain the identity of the individual.

³DOE established the Epidemiology Research Task Force to coordinate the Secretary of Energy's initiatives to (1) have SPEERA evaluate DOE's epidemiology programs, (2) provide scientific advice of its programs by the National Academy of Sciences, (3) allow independent access to DOE's epidemiology data, and (4) develop CEDR.

data, an ad hoc group began to design a survey of DOE facilities to determine the availability of data that would be useful for epidemiologic research. Also, other working groups began assessing the types of variables that are required to conduct epidemiology research. In August 1990 the steering committee and the ad hoc groups were disbanded except for the information systems working group—charged with recommending the design of the CEDR computer system—and the dosimetry working group. According to the Acting Director of Epidemiology and Health Surveillance, DOE decided to disband the committee and other working groups because (1) the working groups tasks were completed; (2) DOE's Office of Health has designated a program manager to develop this program; and (3) the Environment, Safety, and Health Advisory Committee and the National Academy of Sciences will provide the "steering" for developing the CEDR program. Moreover, DOE decided not to survey its sites because it will not be managing the studies for which the data will be used. Furthermore, DOE contends that it would be more appropriate for the HHS researchers managing the studies to collect the pertinent data since they will determine the scope of the research.

During fiscal year 1990, funding from various other DOE programs was used to support the CEDR program. Moreover, DOE's fiscal year 1991 budget does not specifically designate funding for this project but rather includes it as part of another program activity. Consequently, funding for the program could be easily diverted if DOE's commitment to this program lessened. Furthermore, as written by two former DOE contractor employees involved with this program, "without this financial commitment, contractors cannot hire the staff needed . . . and the project will be delayed." DOE intends to specifically designate funds for this program in the fiscal year 1992 budget. According to DOE officials, this program should be operational by the end of fiscal year 1992 at an estimated developmental cost of about \$3 million. This amount does not include the future funding that will be needed to operate and maintain the system.

HHS to Manage a Major Portion of DOE's Epidemiology Research Activities

In recent years, legislative and public concern has centered on DOE's objectivity in producing nuclear weapons while assessing the health risks associated with operating its facilities. Moreover, SPEERA concluded that ". . . to restore public credibility, to assure the highest scientific quality, and to assure the independence of investigators, the Department [DOE] needed an independent system for managing its long-term epidemiologic studies." Therefore, to address SPEERA's recommendation, DOE has entered into a memorandum of understanding with HHS to

manage and conduct analytical epidemiology research for DOE. A task force, with staff from HHS and DOE, will be appointed for 1 year to oversee and assist in the implementation of this memorandum of understanding.

As outlined in the memorandum of understanding, HHS will be responsible for conducting and managing epidemiology studies for DOE. Specifically, HHS will manage analytical studies of (1) workers at DOE facilities, (2) residents of communities in the vicinity of DOE facilities, (3) other persons potentially exposed to radiation, and (4) persons exposed to potential hazards resulting from non-nuclear energy production. HHS's Centers for Disease Control will be the lead agency in managing this research. HHS will also manage DOE's ongoing analytical studies (the majority of DOE's current health effects research) and future epidemiology health studies that may result from DOE's descriptive epidemiology program.⁴ HHS has agreed to initially continue existing DOE grants and contracts; however, HHS plans to review all existing grants and contracts to determine whether each project should continue or whether its scope should be changed.

HHS plans to establish a new advisory committee and institute a peer review system to manage these studies. HHS plans to establish a new advisory committee, composed of non-federal parties including a non-voting DOE representative(s), to recommend a research agenda on analytical studies to HHS. DOE's Environment, Safety, and Health Advisory Committee will also be able to propose analytical epidemiology studies to the HHS advisory committee to include in its recommendation for the research agenda. HHS will make the final determination on the types of analytical studies that will be conducted. In awarding grants and contracts for the studies identified in the research agenda, HHS plans to employ its existing mechanisms such as a competitive system for project renewals, open competition, peer review, and quality assurance for research in progress.

DOE plans to transfer resources (funds and full-time equivalent employment levels) to HHS to manage the analytical epidemiology research program. The funds can be used to manage the studies and support staffing levels. Under the terms of the memorandum of understanding, DOE will transfer approximately \$17 million to HHS in fiscal year 1991 for the management of ongoing studies as well as for new research. However,

⁴Programs that HHS will manage include, among others, the health and mortality studies and Hanford's Dose Reconstruction study.

**Appendix II
DOE's Initiatives to Restructure Its
Health Programs**

HHS will not undertake any new studies unless adequate resources are available. The level of DOE funding for HHS to manage the analytical epidemiology program will be determined annually through interagency agreements.