COMMITTEE ON RADIATION EPIDEMIOLOGICAL RESEARCH PROGRAMS

Progress Report

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I INTRODUCTION

The Committee on DoE Radiation Epidemiological Research Programs was originally established in response to the needs of the Office of Health and Environmental Research, Office of Energy Research in the Department of Energy (DoE). Following a reorganization of DoE health related programs in 1990, the committee now advises the Office of Epidemiology and Health Surveillance which is under the Assistant Secretary for Environment, Safety and Health. These administrative changes have not altered the committee concerns but have served to focus the committee's attention on helping DoE plan for an effective system of worker health surveillance as well as an epidemiologic research program.

The Department's epidemiological research program has been in a transitional phase which provides both opportunities and risks. Under the terms of a December 1990 Memorandum of Understanding with the Department of Health and Human Services (DHHS), DoE continues to fund a number of epidemiologic studies but their management has become the responsibility of the Centers for Disease Control (CDC), DHHS. The committee has served as a source of scientific advice during this transition period with special focus on the development of a Comprehensive Epidemiological Data Resource system. This system is being developed by the DoE to facilitate access by the scientific community to epidemiologic data on workers from the various DoE facilities.

II PROGRESS DURING THE REPORT PERIOD

The full committee had two meetings during this reporting period--June 24, 1991 and January 21-22, 1992. During the meeting of June 24, 1991, the committee discussed an article by Wing et. al. on cancer mortality in the Oak Ridge work force that appeared in the Journal of the American Medical Association (JAMA). In this article, Wing et. al. reported an increased leukemia incidence in workers who had received extremely low radiation doses. Seymour Jablon was invited to present his views in which he expressed his concern that the paper was somewhat misleading because confounding factors were not fully considered. He also mentioned that a letter to the JAMA by BEIR III and BEIR V committee members commenting on the Wing et. al. article had not been accepted for publication.

Dr. Robert Goldsmith, Director, Office of Epidemiology and Health Surveillance, DoE, presented a brief outline of his office's research priorities.

He also discussed the progress of the implementation of the Memorandum of Understanding (MOU) between the DoE and DHHS. Dr. Goldsmith indicated that the informal discussions that were being held between DoE and DHHS were progressing in a constructive fashion, although consultive committees to the respective DoE and DHHS Secretaries who were to oversee this task had not yet been appointed.

A report was made by the Comprehensive Epidemiologic Data Resource (CEDR) subcommittee. The subsequent discussion between committee members and the DoE staff concerned with CEDR development indicated that CEDR is an evolving concept and that its goals have changed since its inception. CEDR is now more of a repository than an interactive data collecting system. It was also noted that the data from the health surveillance system would not be on-line into CEDR, but would consist of a separate system, with annual summaries of the results of the surveillance being stored in CEDR.

The committee was further briefed on the Health Surveillance System planning that was in progress. An organizational meeting had been held that included the directors of health programs at various DoE facilities. Different facilities have had different methods for monitoring worker health and it will be necessary for the directors from the different facilities to agree on a common approach before a comprehensive surveillance system can be instituted.

The long-range research plans for OEHS were discussed in light of the Environmental, Safety, and Health Advisory Committee (ESHAC) that is being formed. This committee is to be appointed by the Secretary of Energy and will be selected from candidates nominated by state governments, scientific organizations, environmental groups, and industry associations. The OEHS will develop a research agenda with input from ESHAC; ESHAC will then prepare a research agenda for consideration by the Assistant Secretary for Environment, Safety, and Health.

Some of the OEHS near-term activities were also discussed during this meeting. In particular, activities concerning agreements between DoE and the states on epidemiologic studies and dose reconstructions were noted. Plans to replicate the Gardner study of the offspring of fathers exposed to radiation and to begin a pilot epidemiologic study of beryllium effects at Rocky Flats and Oak Ridge were discussed.

Items considered at the January 21-22, 1992, meeting included a report by the CEDR subcommittee, a review of activities of the OEHS, the status of the

health surveillance system (HSS), relative roles of DoE and CDC, state health agreements, and the function of this committee relative to the needs of OEHS.

The changes in the status of CEDR were discussed. In particular, the committee noted that there was no longer a movement toward a full-blown CEDR, but rather an emphasis on testing the capabilities of the preCEDR system. It was noted that there was a need for more management focus on CEDR. There was also a question of who would use CEDR other than those who currently have access.

The HSS has become a major focus of the OEHS. It is intended to become a system for real-time assessment of worker health. It is hoped that it might be used to identify hazardous conditions at DoE facilities. The lack of standardization among various DoE facilities remains a problem.

Relative roles of CDC/NIOSH and OEHS were still being worked out. However, the MOU between DHHS and DoE specified development of a joint research agenda. Part of this process will involve ESHAC as noted above. The MOU assigned the responsibility for epidemiologic studies to CDC and CDC is supposed to finish ongoing studies as soon as possible. NIOSH has the responsibility for occupational studies. For example, the replication of the Gardner study will be undertaken by NIOSH; they will issue a request for proposal for this study.

Agreements have been reached with several states on topics such as registries for birth defects and cancer, and dose reconstruction activities. Other activities include construction of an inventory of records at DoE sites, management of the Uranium and Transuranic Registry, the radium dial painter studies, and the Radiation Effects Research Foundation.

The committee questioned its role and value to OEHS. Dr. Goldsmith reviewed the areas that he viewed as most valuable to his office. These included review and evaluation of research plans, advice on the CEDR and HSS, review of protocols for studies that DoE wishes to perform, and identification of research areas that they should be involved in. The response of the committee was very positive, particularly in regard to helping in the long-term planning process. This latter activity is seen by the committee as fitting better with the National Academy process than is day to day real time advice. The committee also felt that it would be beneficial to add expertise in molecular epidemiology (or molecular biology), and occupational medicine. Added expertise in industrial hygiene was also viewed as desirable.

In addition to the full committee meetings noted above, the CEDR subcommittee attended two meetings of the CEDR Group. The first meeting was held in Atlanta on April 9, 1991. Members of our subcommittee actively participated in the discussion, pointing out weaknesses and needs in the CEDR system. The CEDR subcommittee also attended a CEDR meeting at Lawrence Berkeley Laboratory in Berkeley, CA, in September, 1991. During this meeting, the subcommittee was able to try the system in the laboratory.

In response to the committee's feeling that additional expertise would be useful, two new members were added, Dr. William Bunn, Medical Director of Mobil International Services, and Dr. Jack Taylor, National Institute of Environmental Health Sciences. Dr. Bunn has extensive experience in both occupational medicine and epidemiology, while Dr. Taylor has performed both molecular biology and epidemiology studies. Two members of the committee requested removal due to other commitments and the changing needs of the committee. They are Drs. Jeffrey Star and Ian Higgins, both of whom made valuable contributions to the committee.

Because the emphasis of the committee during the coming year will be more on epidemiology and less on data systems, Dr. Behrman has been appointed as Vice-Chairman to replace Mr. Albert. Mr. Albert will remain as a member. Committee membership is now as follows: Dr. Richard D. Remington, Chairman, University of Iowa; Dr. Richard E. Behrman, Vice-Chairman, David & Lucile Packard Fdn.; Mr. Theodore Albert, U.S. Geological Survey (ret.), Savannah, GA; Dr. Judy A. Bean, University of Miami Medical School; Dr. William Bunn, Mobil Administrative Service; Dr. Mary L. Fleming, Eastern Kentucky University; Dr. Gordon M. Gerson, Gerson Information Systems; Dr. Maureen C. Hatch, Columbia University; Dr. William J. Schull, University of Texas; Dr. Jack Taylor, National Institute of Environmental Health Sciences; and Dr. Arthur C. Upton, New York University Medical Center.

III PROBLEMS ENCOUNTERED AND CORRECTIVE ACTIONS

Reorganization of epidemiologic research within DoE, and the signing of the Memorandum of Understanding with DHHS served to end a period of uncertainty concerning the relative roles of DoE and DHHS in epidemiologic research associated with DoE facilities. However, other questions concerning the design and implementation of CEDR, a long-term research agenda for OEHS, and the function of this committee have arisen. Changes made in the approach to CEDR by

utilizing the preCEDR system have helped to ameliorate concerns about the implementation of the full CEDR system. The construction of a long-term research agenda and the function of the committee are closely related. The role of the committee in providing advice on a long-term agenda is in keeping with the Academy's role and should provide a challenge to the committee as well as allowing the committee to provide the kinds of advice that will be most useful to the Department as new programs are developed.

IV PLANS FOR THE NEXT FUNDING PERIOD

In the next funding period, the committee will establish criteria for the evaluation and prioritization of research agenda items. It is felt that an evaluation system should be in place before detailed examination of current plans are performed. The committee will then review the research agenda that OEHS has constructed, evaluate the items, and prioritize those items. A similar process will be used as new research items are identified by the committee. The committee will also advise DoE about research priorities for the various epidemiologic studies being transferred to DHHS management. The committee will continue to examine the function of the CEDR system and provide advice concerning public access to occupational health data. While the committee recognizes that data security should not preclude public access to coded epidemiologic studies, it views the personal health information that is inherently part of a health surveillance program as particularly sensitive and thus requires extraordinary care to prevent unlawful disclosure.

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