UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

SEP 7 1979

MEMORANDUM FOR: Scientific Review Group on Feasibility Planning Study

W. Mills, EPA
G. Simon, EPA
C. Silverman, BRH/HEW
F. Arsenault, NRC
K. Goller, NRC

FROM: Michael A. Parsont, Chief
Radiological Health Standards Branch, SD

SUBJECT: DRAFT OF THE SEPTEMBER 30 INTERIM REPORT TO CONGRESS ON THE EPIDEMIOLOGY FEASIBILITY PLANNING STUDY

Enclosed for your review and comment is a first cut draft of the FPS September 30, Report to Congress.

Since we are running close to the deadline, a meeting of the SRG has been scheduled at ~~9:30 AM~~ on September 11, 1979 in room 013 of NRC offices, 5650 Nicholson Lane, Rockville, Maryland.

If you are unable to attend, please inform me of your comments by phone. I can be reached at 443-5854.

Michael A. Parsont, Chief
Radiological Health Standards Branch
Office of Standards Development

Enclosure:
As stated

cc: G. Beebe, HEW
K. Bridboard, Md., NIOSH
W. Ellett, EPA
M. Shore, BRH/HEW
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T. Dorian, NRC
D. Rubinstein, NRC
R. Gustav, NRC
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H. Peterson, NRC

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INTERIM REPORT

ON

THE FEASIBILITY OF CONDUCTING EPIDEMIOLOGIC RESEARCH ON THE HEALTH EFFECTS OF LOW-LEVEL IONIZING RADIATION

Submitted by

USNRC and EPA

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INTRODUCTION

Publicity from claims of personal injury and the controversal results of several epidemiologic investigations in the recent past have led to intensified interest concerning the health effects of ionizing radiation.

In order to make competent judgements with respect to national policy on the use of radioactive materials, the Congress has sponsored extensive research in the area of biological effects of ionizing radiation through various governmental agencies.

Despite the extensive research and accompanying data there remains a need to examine the most appropriate methods and populations to be studied to provide accurate quantification of human radiation does-response at low levels of exposure. In addition, guidance is needed on the cost and time needed to perform such studies.

As one means to provide such guidance in P.L. 95-601, the Congress required that such studies be performed.

This report discusses the means by which the NRC and EPA has proceeded to fulfill the requirements of P.L. 95-601, and presents interim results of the study initiated as a result of this law. In addition is discussed the direction to be taken for completion of the study.

P.L. 95-601

Requirements for undertaking of radiation epidemiology studies were included in the Nuclear Regulatory Commission Appropriation Authorization for fiscal year 1978 (Public Law 95-601). The requirements of P.L. 95-601 are as follows:

(a) The Commission and the Environmental Protection Agency, in consultation with the Secretary of Health, Education, and Welfare, are authorized and directed to conduct preliminary planning and design studies for epidemiological research on the health effects of low-level ionizing radiation. In the conduct of such studies, the Commission and the Environmental Protection Agency shall consult with appropriate scientific organizations and Federal and State agencies.

(b) Within thirty days after the date of enactment of this section, the Commission and the Environmental Protection Agency shall submit to the Congress a memorandum of understanding to delineate their responsibilities in the conduct of the planning studies authorized by subsection (a) of this section.

(c) On or before April 1, 1979, the Commission and the Environmental Protection Agency shall submit a report to the Congress containing an assessment of the capabilities and research needs of such agencies in the area of health effects of low-level radiation.

(d) On or before September 30, 1979, the Commission and the Environmental Protection Agency, in consultation with the Secretary of Health, Education, and Welfare, shall submit a report to the Congress which includes a study of options for Federal epidemiological research on the health effects of low-level radiation, with evaluations of the

feasibility of such options. Such report shall be consistent with the findings of the assessment required by subsection (c) of this section.

(e) In carrying out the activities specified in subsections (c) and (d) such agencies shall:

(i) Cooperate with appropriate scientific organizations and agencies involved in related research, and

(ii) furnish copies of the reports required by those subsections to the organizations and agencies referred to in subsection (e)(i).

As required by paragraph (b), a Memorandum of Understanding (MOU) was executed between EPA and NRC delineating their responsibilities. This MOU became effective on January 18, 1979 and is reproduced as Appendix A.

As part of the MOU, a Scientific Review Group, (SRG), which included EPA, NRC, and HEW representatives, was established to oversee the conduct of an Epidemiology Feasibility/Planning Study to meet the requirements of paragraph (c). The general format and essential points of the project's workscope were developed during the meetings of the Scientific Review Group. The members of this Group are:

Dr. William Mills (Chairman)
Director, Office of Criteria and Standards
Office of Radiation Programs
Environmental Protection Agency

Dr. George Simon, Director
Health Effects Division
Office of Health and Ecological Effects Research
Environmental Protection Agency

Dr. Charlotte Silverman, Deputy Director
Division of Biological Effects
Bureau of Radiological Health
Food and Drug Administration
Department of Health, Education, and Welfare

Mr. Karl Goller, Director
Division of Siting, Health and Safeguards Standards
Office of Standards Development
Nuclear Regulatory Commission

Dr. Frank Arsenault, Director
Division of Safeguards, Fuel Cycle, and Environmental Research
Office of Nuclear Regulatory Research
Nuclear Regulatory Commission

The Scientific Review Group was assisted by the participation of the following individuals:

Dr. Shlomo Yaniv, Technical Assistant to Dr. Arsenault.

Dr. Michael Parsont, Chief
Radiological Health Standards Branch
Office of Standards Development
Nuclear Regulatory Commission

Mr. Thomas Dorian, Attorney
Office of the Executive Legal Director
Nuclear Regulatory Commission

Dr. David Rubinstein, Statistician
Applied Statistics Branch

Office of Management and Planning Analysis

Nuclear Regulatory Commission

Dr. William Ellett, Chief

Bioeffects Branch

Office of Radiation Programs

Environmental Protection Agency

Dr. Gilbert Beebe

Clinical Epidemiology Branch

National Cancer Institute

National Institutes of Health

Department of Health, Education, and Welfare

In accordance with paragraph (e)(i) copies of the workscope were circulated to other governmental agencies and a meeting was held on January 12, 1979 with representatives of the Veterans Administration, Department of Defense and the Department of Energy at NRC for further review of the workscope. (See Attachment.

The finalized Request for Proposal (RFP), which incorporated the workscope developed by the Scientific Review Group, was prepared by the five-member Source Evaluation Panel, and approved by the Scientific Review Group. Four NRC representatives and one from EPA constituted the Source Evaluation Panel, whose task was to evaluate all proposals submitted in response to the RFP. The Request for Proposal was issued on February 12, 1979 following notice in the Commerce Business Daily on January 31, 1979. Over 140 Requests for Proposal were sent to both requestors and others who had shown previous interest in NRC-funded similar projects. On February 27, 1979, a Preproposal Conference was held at the NRC office in Silver Spring, Md. to provide

information on the preparation of proposals, and to answer questions from potential offerors regarding the solicitation.

The closing date for submittal of proposals was March 20, 1979, and evaluation of the four proposals received was completed on March 29th. Proposals were evaluated on the basis of both organizational capabilities and technical approach, including a demonstrated understanding of the objectives of the work-scope; the proposed approach to locating, obtaining and evaluating data sources; and the application of epidemiologic, statistical, radiation dosimetry and radiobiological principles. Some potential offerors indicated that proposals might have been submitted if the winning offeror were not excluded from participating in possible NRC-funded follow-up studies. Following review of initial proposals, discussions with each of the four offerors were held on April 17-18, 1979 to provide guidance for submission of "best and final" offers. These were reviewed by the Source Evaluation Panel, and the panel's recommendation was made to the Director of the Office of Standards Development, NRC in early May for final choice. Following approval by the Commission, the contract was awarded on July 2, 1979 to Systemedics, Inc. of Reading, Massachusetts.

Senate Bill S. 562, the NRC Appropriations Authorization for Fiscal Year 1980, would amend Public Law 95-601 to add a specific requirement for the feasibility/planning study to include workers at the Three Mile Island Nuclear Station who received or will receive radiation doses from the accident which occurred on March 28, 1979, and from subsequent decontamination efforts. This Act would also extend the date for the feasibility study report from September 30, 1979 to March 1, 1980. Modification of the Scope-of-Work for the contract to perform the Feasibility/Planning Study has already been made to include the Three Mile Island worker population.

STUDY OVERVIEW

In order to provide the Congress with options for Federal epidemiologic research on the health effects of low-level ionizing radiation and evaluations of the feasibility of such options, the study will provide a comprehensive list of populations that might be suitable for study, prioritized by their ability to provide unextrapolated dose-response data on the health effects of low-level ionizing radiation. Factors such as data availability, validity and reliability, sample size and statistical power, as well as cost and time constraints will be considered.

The study is divided into two phases; the first ~~being~~ designed to generate a working list of potentially suitable populations, and the second to evaluate these populations in detail with respect to the above factors. Appendix ___ contains a report on the results of the first phase. During Phase II, the contractor will pare down the extensive list of potential study populations presented in that report through an examination of existing data on each population. This Phase will be completed by September 30, 1979.

PROGRESS TO DATE

The workscope for the first phase of the Feasibility/Planning Study comprises four specific tasks. Of these, the identification and preliminary analysis of potential study populations is the most important. However, the other three tasks provide a systematic basis for determining the feasibility of studying these populations epidemiologically. Thus, the report on Phase I activities (Appendix) deliniates the strengths and limitations of various epidemiologic methods for evaluating the health effects of exposure to low-level ionizing radiation, in addition to listing potential study populations. Since Phase I did not involve any field work, sufficient data were lacking for an in-depth feasibility evaluation. In Phase II, however, information will be gathered that will allow the convergence of methodological considerations with data availability, population size and range of exposures.

As discussed in Appendix ___, 173 potential study populations were identified in Phase I. Nineteen of these were determined, from available data, to be infeasible for study because of insufficient sample size or exposure data. Most promising among the remaining 154 potential study populations are occupational groups involved in the following aspects of the nuclear fuel cycle: Mining, milling and refining, and operation of reactors. Many of these workers are already included in the Department of Energy's Health and Mortality Study. In addition to these occupationally-exposed groups, a few populations exposed to diagnostic or theraputic irradation appear suitable for study, based on information gathered in Phase I. These groups include cardiac catherization patients, persons with lumbar spine examinations, and patients given I^{131} therapy. Environmentally exposed populations including nuclear power plant communities and residents of high fallout areas, while unlikely to provide information on dose-response relationships, may nonetheless provide data to

determine if there is any health effect from exposure to low-level ionizing radiation. Several international populations also seem particularly promising.

Work on Phase II has already begun, with meetings of the contractor's Independent Review Panel held to evaluate the results of Phase I and recommend approaches to fulfilling the requirements of Phase II. The panel's tasks were to determine if any potential study populations had been missed and assess the usefulness and validity of the criteria used to determine feasibility. In addition, since the number of populations to be considered initially in Phase II is rather large, due in part to the inclusion of medically-exposed groups with low doses to some organs, the panel has suggested methods to pare down the list developed in Phase I. An interim report on the progress of Phase II will be submitted to the NRC shortly.

We will continue to provide the Congress with copies of pertinent reports on the progress of the study. We are also available to discuss any aspect of the project as needed.