

September 1, 1998

SECY-98-206

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: NATIONAL ACADEMY OF SCIENCES/NATIONAL RESEARCH COUNCIL
GRANT TO FUND THE BIOLOGICAL EFFECTS OF IONIZATION RADIATION
STUDY NUMBER VII (BEIR VII)

PURPOSE:

To request Commission approval by negative consent for the staff to partially fund the subject grant proposal (Attachment 1).

BACKGROUND:

The staff forwarded SECY-95-249, dated October 3, 1995, containing a joint Nuclear Regulatory Commission/Environmental Protection Agency (EPA) "White Paper on Risk Harmonization" and "Risk Harmonization Recommendations of the Interagency Steering Committee on Radiation Standards" (ISCORS). General Risk Management Recommendation #3 proposed the initiation of a comprehensive review of the risk associated with ionizing radiation by the National Academy of Sciences/National Research Council (NAS) as Committee VII of the Biological Effects of Ionizing Radiation (BEIR VII). The staff estimated that NRC's portion of the BEIR VII funding would be \$100,000 per year for 3 years and 0.5 full-time equivalent per year for 3 years.

In a Staff Requirements Memorandum, dated November 29, 1995, the Commission approved the joint NRC/EPA Recommendations on Risk Harmonization, and directed the staff to "provide the Commission with an explanation of how the results of the BEIR VII study will be factored into the risk harmonization effort, and in particular, into the schedule for the issuance or reconsideration of any Federal Guidance document." The staff response to the Commission, dated March 11, 1996, indicated that the BEIR VII report could have a variety of implications for Federal guidance on radiation protection. For example, it could affect the recommended annual dose limit for members of the general public (currently 100 mrem per year), or it could affect the

Contact:
E.V. Holahan, RES
415-6272

recommendation that doses from individual sources be limited to a fraction of the public dose limit.

In a Staff Requirements Memorandum, dated April 2, 1996, the Commission approved the staff's recommendation to proceed with BEIR VII as expeditiously as the availability of financial resources and new scientific information will permit, and directed the staff, on completion of BEIR VII, to "provide recommendations to the Commission regarding the implications of BEIR VII for NRC regulations, for Federal guidance, and for risk harmonization."

A task group from the ISCORS Risk Harmonization subcommittee (EPA, DOE, and NRC) jointly drafted the BEIR VII work scope with two phases. This work scope became the basis on which the NAS prepared their project proposal to establish a committee to reassess the health risks related to exposure to low-level ionizing radiation. In the first phase, the committee would collect and evaluate data published since the 1990 BEIR V report to determine whether sufficient new information is available to warrant a comprehensive reassessment of health risks related to low-level radiation exposure and define the most productive scope, goals and objectives for the comprehensive reassessment (phase 2). The NAS proposal was reviewed and approved by the ISCORS task group members. EPA awarded a \$230K grant to NAS to initiate a 12 month feasibility study (phase 1) beginning in September 1996.

The BEIR VII phase-1 committee convened its first meeting, March 26, 1997, to reassess the health risks related to exposure to low-level ionizing radiation. The committee evaluated the scientific literature pertinent to the biologic and health effects of low-level ionizing radiation and convened a scientific workshop, July 21-22, 1997, to assess the impact of biology on risk assessment. Based on their review, the committee submitted to the EPA a letter report, dated January 21, 1998, that stated that sufficient information has become available since the 1990 BEIR V report to warrant a comprehensive reassessment of health risks in a BEIR VII phase-2 study. The committee recommended issues that could be addressed in a BEIR VII study, provided justification for those recommendations, listed primary sources of data that might be used, assessed whether a detailed analysis of particular issues could have a significant effect on radiation risk estimates, and indicated what scientific disciplines should be represented in order for a committee to address the key issues adequately in a phase-2 study. The committee's recommendations are discussed in greater detail in a report entitled *Health Effects of Exposure to Low Levels of Ionizing Radiation: Time for Reassessment?* (Attachment 2).

EPA forwarded to NRC, DOE, and DOD a draft proposal for the BEIR VII phase-2 study on May 27, 1998. NRC comments were provided to NAS on June 9, 1998. The final NAS proposal is to establish a committee of approximately 15 persons to: conduct a comprehensive review of relevant epidemiologic data related to risk from exposure to low-doses of low-LET radiation, define and establish principles on which quantitative epidemiological analyses can be based, assess the current status and relevance to risk models of biologic data and models of carcinogenesis, consider problems that might exist in determining doses to target cells, and consider recent evidence regarding genetic effects not related to cancer. A major goal of the BEIR VII phase-2 study will be to better quantify and characterize the uncertainties associated with risk estimates and to produce the most realistic estimates of uncertainties. The committee will produce a consensus report that contains

conclusions and recommendations regarding the health risks related to exposure to ionizing radiation.

DISCUSSION:

The BEIR VII phase-1 committee concluded that sufficient information has become available since publication of the BEIR V in 1990 that makes this an "opportune time" to proceed with BEIR VII phase-2. For example, information published since the BEIR V report has prompted renewed questioning of the postulated linear nonthreshold dose-response relationship at low levels of exposure such as natural background or very small incremental doses above natural background. This dose response relationship has provided the scientific basis on which federal agencies have developed regulatory standards and advisory recommendations for over thirty years. The BEIR VII study, in part, will be aimed at updating the assessment of risks related to low-dose, low-LET radiation and exploring all that is known regarding the biologic processes determining those risks. Furthermore, the results of the BEIR VII study may enable NRC and EPA to bridge several risk management differences that might not otherwise be resolved without the NAS' independent scientific review.

One disadvantage of initiating phase-2 now is that several potentially important studies may not be completed in time to be fully considered by the BEIR VII committee. For example, the NAS recently reactivated its Committee on Dosimetry to review and possibly revise DS86, the dosimetry system on which individual doses for the Japanese atomic-bomb survivors and current cancer mortality risk estimates are based. Although the results of the reevaluation will not be available for several years, revision of the dosimetry system could significantly change the current risk coefficients for fatal cancer. The NAS staff for BEIR VII recognize the potential implications of a revised DS86 dosimetry system and are willing to delay publication of the final BEIR VII report if such a delay is warranted.

The NRC staff believe the NAS proposal is responsive to the NRC's desire to initiate a comprehensive review of the health effects associated with exposure to low-dose, low-dose rate ionizing radiation and to obtain realistic risk estimates for carcinogenic and noncarcinogenic health effects. NRC staff and other members of the BEIR VII task group also recognize that additional health effects data and a more complete understanding of the cellular and molecular response to radiation exposure may be acquired in the next few years. However, it may be beneficial to at least evaluate the information that is available since publication of BEIR V eight years ago, and we may gain useful information from an NAS review of these publications. Therefore, Mr. Dennis O'Connor announced at the June 1998 ISCORS meeting that EPA plans to award a grant to NAS during FY 98 to initiate the BEIR VII phase-2 study. Since the BEIR VII phase-2 study could prompt EPA to move forward on finalizing Federal Guidance on exposure of the general public, the staff believes it is prudent for NRC to co-fund the BEIR VII study to ensure that the Commission's concerns are adequately addressed by the NAS committee.

RESOURCES:

The duration of the proposed grant is 3 years. The estimated cost is about \$1,195K. The costs by fiscal year are projected as: \$376.4K in year 1, \$385.6K in year 2, and \$433K in year 3. The planned NRC contribution to the project is \$100K per year for each of the three years beginning in FY 98 and will be re-programmed from existing funds. EPA will provide the remaining funding, either alone or in conjunction with the Department of Energy, the Department of Defense, and the Department of Health and Human Services via interagency agreement.

COORDINATION:

The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

RECOMMENDATION:

The staff recommends that the Commission approve, by negative consent, the partial funding of the BEIR VII grant proposal as discussed above.

Staff requests action within 10 days as the staff intends to use FY 98 funding for the first year's funding. Action will not be taken until the SRM is received. We consider this action to be within the delegated authority of the EDO.

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