

AUG 2 2 1996

Mr. W. Roger Ney
National Council on Radiation Protection
and Measurements
7910 Woodmont Avenue, Suite 800
Bethesda, Maryland 20814

Dear Mr. Ney

Subject: Grant No. NRC-04-95-086

You are hereby given preliminary notice that it is the intent of the U.S. Nuclear Regulatory Commission to exercise the first two-year option under the subject grant in accordance with "Option to Extend the Term of the Grant", Attachment 1 to the Basic Agreement. This preliminary notice does not constitute an exercise of the option. The exercise of the option will be accomplished by modification to the subject grant.

Further, this preliminary notice does not commit the Government to an extension.

If you have any questions regarding this matter, please contact Ms. Shirley A. Crampton at (301) 415-6589.

Sincerely,

Elois J. Wiggins, Contracting Officer
Technical Acquisition Branch 2
Division of Contracts
Office of Administration

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Ally

August 20, 1996

C. Meinhold

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rates for estimating cancer risk for the general population after exposure to very low doses of ionizing radiation. In this regard, it also would be useful to learn the committee's views on how any uncertainties regarding the validity of the LNT assumption in the low dose range, and uncertainties with an assigned value for the dose rate reduction factor for human carcinogenesis, should be quantified or otherwise characterized. This NCRP report will provide valuable guidance to the NRC (and the rest of the regulatory community), provided Scientific Committee 1-6 can address each of these issues.

Finally, given the considerable scientific debate regarding the validity of the LNT assumption and the impact this assumption has on radiation risk assessment and risk management, the NRC's participation in this grant, as well as other related activities (e.g., the National Research Council's BEIR VII scoping study), was extensively reviewed. As part of this review, the NRC's Advisory Committee on Nuclear Waste (ACNW) recently expressed its interest and qualified support concerning the scientific committee's review of the LNT assumption. In a letter to Chairman Jackson, the ACNW endorsed the NCRP goal of critically evaluating data related to low dose health effects. However, the advisory committee also identified several issues about which it is concerned and requested that the enclosed letter be conveyed to the NCRP.

I look forward to the successful completion of this important endeavor.

Sincerely,

Original Signed by

David L. Morrison, Director
Office of Nuclear Regulatory Research

Enclosure: As stated

cc: CPaperiello, NMSS
PPomeroy, ACNW

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 20, 1996

Charles B. Meinhold, President
National Council on Radiation
Protection and Measurements
7910 Woodmont Ave., Suite 800
Bethesda, MD 20814-3095

SUBJECT: REFERENCE: GRANT NO. NRC 04-95-086

Dear Mr. Meinhold:

I would like to inform you of the intent of the U.S. Nuclear Regulatory Commission (NRC) to exercise its option to continue funding Grant No. NRC 04-95-086 entitled "Critical Evaluation of the Linear - No Threshold Assumption." Consequently, the option to incrementally fund Scientific Committee 1-6 at \$75,000.00 per year for the next 2 years is being processed.

Several national and international committees have recommended using the linear non-threshold (LNT) assumption as a conservative approach for regulating exposure to ionizing radiation. The LNT assumption continues to be used by various regulatory bodies in decision making on radiation protection. These decisions can have significant impacts on health and safety, and on the utilization of societal resources. However, as you and the members of Scientific Committee 1-6 are well aware, there is considerable divergence of opinion on how to estimate health risks that can result from exposure to very low doses of radiation (i.e., natural background radiation and additions of 1 to 100 millirem per year) as well as the validity of the LNT assumption for assessing radiation health risk at these doses. It is, therefore, important that every reasonable effort be made to ensure that regulatory decision making on radiation protection is based on the best scientific information available regarding the dose-risk relationship at doses and dose rates comparable to natural background levels. Therefore, I would like to encourage the NCRP and Scientific Committee 1-6 to expedite this project in order to publish an approved Council report as soon as possible.

Furthermore, in the NCRP's original project proposal, the possibility was raised that the scientific committee might be able to provide definitive guidance on specific radiation protection assumptions at low dose. Based on their review of all the relevant information (e.g., cellular and molecular studies on mutagenesis, carcinogenesis, and DNA repair mechanisms; studies addressing the carcinogenic effects of low dose radiation on laboratory animals and humans; and studies addressing the potentially beneficial effects of low dose radiation exposure), the NRC would welcome and encourage Scientific Committee 1-6 to discuss whether or not the LNT assumption can be used appropriately in radiation risk assessment and radiation risk management at doses and dose rates comparable to natural background radiation levels. The NRC also would welcome the committee's opinion on what numerical value should be assigned as the risk reduction factor for low dose and low dose



UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON NUCLEAR WASTE
WASHINGTON, D.C. 20555

July 10, 1996

The Honorable Shirley Ann Jackson
Chairman
U.S. Nuclear Regulatory Commission
Washington DC 20555-0001

Dear Chairman Jackson:

SUBJECT: HEALTH EFFECTS OF LOW LEVELS OF IONIZING RADIATION

The health effects of ionizing radiation are central to many of the regulations that are promulgated by the Nuclear Regulatory Commission (NRC). The validity of the linear- no threshold (LNT) dose-response relationships in the area of low doses and low dose rates has been questioned. This letter supports the Commission's present course of action of a review and analysis by the National Council on Radiation Protection and Measurements (NCRP) leading to an evaluation of this important issue.

Our discussion and recommendations concerning this subject derive from the first meeting of the Joint Subcommittee of the Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on Nuclear Waste (ACNW) held on March 26, 1996. Presentations were made by members of the NRC staff, including the visiting medical fellow, and representatives from institutions and agencies such as the NCRP, the Health Physics Society, and the Massachusetts Emergency Management Agency. Written comments were also received from the public.

Most national and international scientific committees dealing with the subject take the view that the safest approach to regulation is one that relies on the LNT model of response to doses of ionizing radiation. This model holds that the ill health effects observed at high doses and high dose rates (mainly among atomic bomb survivors) can be extrapolated linearly to low doses and low dose rates, down to the smallest doses. The NRC staff prepares regulations on the basis of this model. One of the basic questions in this field is whether the LNT model is valid at the low doses and rates normally encountered in many of the regulatory domains. The increasing emphasis placed by the Commission on risk-informed regulation makes it imperative that the actual health risk of low levels of ionizing radiation be assessed accurately.

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The NRC is currently funding a contract with the NCRP to make a critical evaluation of the LNT assumption. The ACNW has not reached conclusions on the validity of the LNT model, and will continue to study the matter. We see the NCRP study as an opportunity to obtain an independent review of the data and their quality.

The presence of unavoidable background radiation and the need for very large samples have made it difficult in the past to obtain definitive data on the validity of the LNT model. As with all small-effects phenomena, the quality of the data and the statistical interpretation of the results govern the ability of any study to contribute to the testing of the model. However, investigators in the field have recently been able to account for the effect of such confounding factors such as variation in background radiation. Some studies in the United States, as well as in China, Sweden, Poland, and Canada, have arrived at conclusions that do not support the LNT model. Other research concludes that it is likely that at least a threshold or perhaps a corresponding zero equivalent point with beneficial risk decrements (hormesis) exists at lower doses.

A notable example of the latter is a ten-year study by Johns Hopkins University of U.S. nuclear shipyard workers which, we were told, showed lower mortality, no increase in malignancies among workers exposed to radiation when compared to those who were not exposed, and no "healthy worker effect." This study may be particularly significant since the investigators were looking for evidence to support the LNT model. Another study, of Canadian women patients in tuberculosis sanitariums who underwent repeated fluoroscopy to monitor response to therapy, is used frequently to show the validity of the LNT model, but examination of data at lower doses shows significant beneficial effects. The 1994 report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) contains an extensive appendix detailing cellular repair mechanisms (called "adaptive response mechanisms") that could contribute to an explanation of a threshold, or, if such cellular responses were stimulated by low doses of radiation, to an explanation of beneficial effects.

In contrast, some of the public comments received by the Subcommittee suggested that the LNT model underestimates the harmful effects of low doses of radiation. Also NCRP Report No. 121, "Principles and Application of Collective Dose in Radiation Protection," issued November 1995 and discussed with the Joint Subcommittee at its March 26, 1996 meeting, finds that "from the point of view of the scientific bases of collective doses for radiation protection purposes, it is prudent to assume the effect per unit dose in the low-dose region following single acute exposures or low-dose fractions is a linear response."

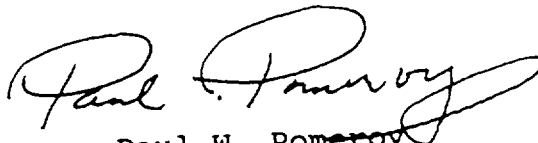
In the face of conflicting views, the general belief of the national and international committees dealing with the matter has been that using the LNT model for regulatory purposes is a safe and conservative approach and, if there is error, it is on the side of enhanced protection. However, if there is a health benefit at low doses, this logic is incorrect. Even if there is no evident health benefit, there are significant societal costs associated with this conservatism that could be avoided or reduced if a threshold level could be established below which no harm occurs. A basic principle of risk-informed regulation is to prevent a situation in which scarce resources are misspent to avoid negligible risks, while significant risks remain unattended for want of resources to deal with them. Owing to the potentially significant costs of the present conservatism, we conclude that a reexamination of the regulatory model is appropriate.

It is obvious that agreement on an appropriate dose-response model is made more difficult by the differing voices on this subject within the scientific community and those outside of this community, including regulators, policy makers, and members of the public. The first task required to reach such an agreement is an impartial review of the data and their quality in the face of the extensive application of the LNT model in regulations and scientific opinion.

We recommend that the need for special attention be conveyed to the NCRP regarding its study. Such attention should include: (1) assurance that the study includes scientists other than those who are "recognized experts" with a reputation built on the LNT model, (2) an evaluation of the data by an entity with expertise in statistics or information science, but no prior position on LNT - such as the National Institute of Standards and Technology (NIST) as well as the NCRP study committee, and (3) consideration of essentially all studies that could relate to the LNT.

The Committee strongly believes in the NCRP goal of critically evaluating data related to low dose health effects. We will follow the program through interaction with NRC's Office of Research and will report to the Commission on the study and its implications.

Sincerely,



Paul W. Pomeroy
Chairman

7/31/96
11:52:57 AM

Nuclear Regulatory Commission
Office of Nuclear Regulatory Research
Advance Procurement Plan for FY 1997

Page : 1

JOB CODE: G6590

TITLE: CRITICAL EVAL OF LINEAR THRESHOLD-NCRP

Division of Regulatory Applications

Program Manager: Roecklein, Alan K.

Phone: 415-6223

OBJECTIVE: To review all available research data and evaluate if the current linear-no-threshold hypothesis can be or should be challenged. Determine if a threshold exists, below which radiation is not harmful or is potentially beneficial. Determine if the relationship between dose and risk should be extrapolated in a linear fashion from high dose high dose rate epidemiology results.

REGULATORY USE: If a dose threshold exists, below which, there is no discernible harm from radiation exposure, then dose limits for workers and members of the public should be raised to some fraction of that value. The effect of such a change in NRC regulatory philosophy could save licensees, the government and the US economy billions of dollars in decommissioning, rad waste management and radiation protection costs.

WORK SCOPE: Convene a group of internationally renowned experts.

Meet 3 times per year

Develop a balloted NCRP report on the appropriateness of the existing linear-no-threshold hypothesis.

FUNDING (\$1000):	<u>Prior Year</u> <u>Obligations</u>	<u>FY97</u>	<u>FY98</u>	<u>FY99</u>	<u>FY00</u>	<u>FY01</u>	<u>Total</u> <u>Project</u> <u>Cost</u>
	150	75	0	0	0	0	225

PROCUREMENT METHOD : Non-Educational Grant.

THIS ACTION:

RFPA NUMBER: Not Available

GRANTEE: National Council on Radiation Protection GRANT NO: 95-086

FUNDING PERIOD: Jan,1997 through Sep,1997

PERIOD OF PERFORMANCE: Oct,1995 through Sep,1997