



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

June 20, 1996

MEMORANDUM TO: Bill M. Morris, Director
Division of Regulatory Applications
Office of Nuclear Regulatory Research

THRU: John E. Glenn, Chief *John E. Glenn*
Radiation Protection and Health
Effects Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

FROM: *JKR* Alan K. Roecklein, Project Manager
Radiation Protection and Health
Effects Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

SUBJECT: REQUEST TO INCREMENTALLY FUND A PROJECT (NO CHANGE IN SCOPE)

I recommend that you approve notification of the NCRP of our intention to approve a planned 2-year option as per the attached contractual action for Job Code G6590, Critical Evaluation of the Linear-No Threshold Assumption. My recommendation is based on the following:

No work scope changes are needed to the last contract/work order.

The research completed thus far is of sufficiently high quality to proceed. The NCRP is on schedule with meeting the conditions for continuing with the project. A list of the selected committee members was provided on schedule and the membership is considered by the NRC staff to be a sufficiently diverse representation from the expertise needed to complete this task. Quarterly progress reports have been received and the committee's final full voting response will be received and assessed before funds for years 2 and 3 are committed (see Attachment 3). This preliminary notification of NRC intent is required to be made prior to termination of the first year (9/30/96).

The subject of this grant continues to be of great current interest and is a significant part of the technical basis for NRC regulations.

A/69

B. Morris

2

The outgoing work is sufficiently within budget and on schedule to continue.

- the funding is consistent with spending plan in 189
- the allocated funding has not been exceeded
- the interim deliverables have been received on schedule

Attachments:

- Part 1 of Grant
- NCRP Technical Proposal
- Attachment 3 - Conditions
for Containing Grant Year 2 and 3

June 20, 1996

B. Morris

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Distribution: [g:\roeck\g6590.fnd]
JEGlenn/RPHEB rf
File Center

*See previous concurrence

Office	RPHEB:DRA	RPHEB:DRA	D:DRA:RES
Name	ARoecklein*	JGlenne	BMorris gm
Date	6/3/96	6/10/96	6/11/96
Distribution	Yes/No	Yes/No	Yes/No

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B. Morris

2

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Office	RPHEB:DRA	RPHEB:DRA	D:DRA:RES
Name	<i>ASE</i>	JGlenn	BMorris
Date	<i>6/3</i> /96	<i>1</i> /96	<i>1</i> /96
Distribution	Yes/No	Yes/No	Yes/No

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(File Code No.) _____

Date: August 22, 1995

PART I

U.S. Nuclear Regulatory Commission : 1. RFAA Number: RES-95-086
Request for Assistance Action (RFAA) : 2. RFAA Revision No.:
: 3. Assistance Control No.:

Instructions: This form is to be used :
for Federal Assistance :
requests to include :
grants and cooperative :
agreements :
: 4. Type of Action Requested (check
: and complete as appropriate)
: [X] Execute a Grant to NCRP
: [] Execute a Cooperative Agreement
: [] Execute a Modification to a Grant
: Grant No.: Grantee
: _____
: [] Execute a Modification to a
: Cooperative Agreement
: Coop Agree No.: Cooperator
: _____

5. Title and Brief Description of Work (50 Word Summary)

Critical Evaluation of the Linear - No Threshold Assumption

RES Document I.D. No.: RES-C95-501

6. Attachments (Specify)

1. Proposal from NCRP
2. Evaluation
3. Delimiters for placing this grant
4. Cost Considerations
5. FAB Approval memo

7. Funding

a. B&R Number <u>56015224015</u>	b. JOB CODE <u>G6590</u>	c. APPN Number(s) <u>31X0200.560</u>	d. BOC <u>4110</u>
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e. FUNDS AVAILABILITY: This certifies that funds in the amount of \$ 75,000.00 are available for obligation in the current budget for the described work.

8. SIGNATURE OF CERTIFYING OFFICIAL

DATE SIGNED

Cecelia E. Johnson-Storsey
 Norma M. Price, RES Certifying Official
 Financial Management Branch, FMPAS/RES

8/21/95

9. PROJECT OFFICER'S NAME:

MAIL STOP:

TELEPHONE NO.:

Charleen RaddatzT-9-C24415-6215

10. REMARKS:

DC is requested to award a grant to NCRP for one year with one two-year option at \$75K per year. Att. 3 should be incorporated into the grant. If all of the provisions in this attachment are not agreed upon by NCRP in their entirety, the grant shall not be awarded. In addition, the two-year option must be approved by the FAB at the end of the first year of the grant before the option can proceed.

Marianne Riggs, 415-5822, is the RES administrative contact for this RFAA. Please place Ms. Riggs on distribution for this grant.

The RES Document I.D. No., RES-C95-501, must be placed on all documents related to this RFAA.

11. SIGNATURE - Selecting Official or Representative

DATE SIGNED

SIGNED: *Bill m. morri*
 NAME: Frank A. Costanzi
 TITLE: Deputy Director
 DIV: Division of Regulatory Applications
 OFFICE: Office of Nuclear Regulatory Research

8/21/95

Proposal
To
U.S. Nuclear Regulatory Commission
to produce an NCRP report on the
Critical Evaluation of the Linear— No Threshold Assumption

April 1, 1995 to March 31, 1998

National Council on Radiation Protection and Measurements

7910 Woodmont Avenue, Suite 800

Bethesda, Maryland 20814

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TECHNICAL PROPOSAL SUMMARY

Submitted by: National Council on Radiation Protection and
Measurements
7910 Woodmont Avenue, Suite 800
Bethesda, Maryland 20814

Type of Organization: A non-government, not-for-profit, congressionally
chartered, public service, scientific and educational
organization

Principal Investigator: Charles B. Meinhold, President
National Council on Radiation Protection and
Measurements
7910 Woodmont Avenue, Suite 800
Bethesda, Maryland 20814

Telephone: (301) 657-2652

Cost: \$225,000, \$75,000 per year for
three years

Institutional Administrator: W. Roger Ney

Institutional Financial
Officer: W. Roger Ney

Date of Submission: February 10, 1995

Objective¹

The objective is to make a critical scientific assessment of all biological studies of the effects of ionizing radiation, and radiobiological theory of effects, in the low-dose and dose-rate region, *e.g.*, less than approximately 200 mSv and 10 mSv h⁻¹ and then to summarize these effects.

¹The NCRP is imminently qualified to perform this study as it has among its membership national experts in many fields to carry out its broad program in radiation protection and it can assemble the best scientific minds of national stature to serve on the committee to perform this assessment. In addition, the NCRP has the responsibility to meet the objectives of this study as given in its charter, see page seven. No other organization in the United States has this specific responsibility in its charter.

Rationale/Task²

Those responsible for establishing limits of radiation exposure for radiation protection purposes have assumed that at the low levels of dose relevant to radiation protection activities, the response of humans, as far as cancer induction or hereditary effects is concerned, is linear with no threshold. It has always been recognized, however, that this is an assumption and not a fact directly demonstrated by human epidemiological data nor uniformly supported by other biological data or theory.

Because the assumption of linearity plays such a vital role in our systems of radiation protection, both as a means of employing information available from human exposures at high doses and from a practical standpoint in facilitating exposure control, a critical examination of the scientific support, or lack thereof, for the assumption is warranted. The report to be prepared is aimed as such an examination.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) has published two reports of particular relevance to this examination. Annex E of their 1993 report (UNSCEAR, 1993) reviews mechanisms of radiation carcinogenesis at low dose and low-dose rate. Their 1994 report (UNSCEAR, 1994) contains a section on low-dose epidemiology and a section on adaptive response. These reports, particularly the 1994 report,

² A study by the NCRP addressing this subject is timely in that there is considerable discussion taking place currently in the radiation protection community on adaptive response and radiation effects in general at low dose. This committee is not expected to specifically address risk estimates such as those derived from the survivors of Hiroshima and Nagasaki nor are they expected to specifically address the uncertainties in those estimates. However, the committee will perform a thorough assessment of the available information on radiation effects at low dose.

have raised questions of hormesis to the level of in-depth scientific analysis and will form an important aspect of the committee's reference material. The committee will also review the experimental data and the radiobiological theories of scientists who have varying opinions and theories on the response of biological systems to ionizing radiation in the low dose region.

It may be possible that definitive guidance on specific radiation protection assumptions at low dose could result, but a detailed exposition of what is known about the subject will, in and of itself, prove to be of major importance to all who have responsibilities that relate to radiation protection.

With the availability of funding, the NCRP will establish a scientific committee of national experts to conduct this assessment. It is anticipated that such a scientific committee would be comprised of recognized individuals with expertise in the scientific areas such as biophysics, genetics, DNA repair, experimental animal oncogenesis, dosimetry, radiation epidemiology, as well as operational radiation protection. It is anticipated that an additional 10 to 15 scientists with diverse opinion on the effects of ionizing radiation at low dose will be asked to present their views to the committee and to, therefore, serve as consultants to the committee. The consultants would not regularly attend meetings, but would most likely attend one meeting and have the opportunity to review the committee's report as it is developed. It may be effective to conduct a one or one and one-half day seminar where the consultants would be invited to present their views to the committee.

Such a committee would be expected to meet six to eight times during a three year period. The estimated cost of travel and secretariat support for such a committee is \$75,000 annually. (A detailed budget will be provided on request).

PROVISIONS FOR PLACING A GRANT WITH NCRP
ENTITLED, "CRITICAL EVALUATION OF THE LINEAR - NO THRESHOLD ASSUMPTION"

The following terms and conditions are incorporated into this grant:

1. NCRP will provide the NRC with a list of the committee members of Scientific Committee 1.6 within 30 days after the first meeting.
2. NCRP will provide quarterly progress reports with as much detail as possible. An outline of the Committee's final full voting report will be included in the third quarterly report.
3. The final product of this grant will be a full voting report and not a commentary.