

June 4, 1999

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

Dear Chairman Jackson:

SUBJECT: LINEAR NO THRESHOLD HYPOTHESIS

The Linear No Threshold Hypothesis (LNTH), the current basis for setting radiation-protection standards worldwide, is vigorously challenged by many individuals as leading to exaggerated predictions of the adverse health consequences of low-level exposures. Use of the LNTH, it is argued, has resulted in unjustified levels of public fear concerning low-level radiation, unnecessarily large expenditures of (limited) public funds, and serious misconceptions with respect to the overall safety of nuclear power and use of nuclear materials. On the other hand, other distinguished scientists argue that there is insufficient scientific evidence to warrant a change from the LNTH.

Given the importance of these issues to waste isolation and decommissioning, the ACNW selected "Review of the Status of the LNTH" as one of its top first tier priority topics for 1999¹. Several Commissioners encouraged us to pursue this topic. On March 23–24, 1999, a working group meeting on this topic was held.

This letter report is based on material presented at that meeting, supplemented by comments from two expert consultants to the ACNW (Drs. Kimberly J. Kearfott and Otto G. Raabe) and from Dr. Dana A. Powers of the ACRS, on a review of a selection of published reports on the topic compiled by our staff, and on Committee deliberations and discussions. Our conclusions and recommendations are presented first, followed by a discussion of the basis for them.

¹Advisory Committee on Nuclear Waste 1999 Action Plan and Priority Issues, dated January 22, 1999.

Summary of Conclusions and Recommendations

1. The disagreements both inside and outside the scientific community over the evidence that either supports or contradicts the LNTH continue to be intense and polemical. Although strong supporting evidence for linearity of dose response for low levels of ionizing radiation is lacking, there is no scientific consensus that the LNTH has been discredited. Given this wide range of views, the ACNW is pleased that the chairman of the National Council on Radiation Protection and Measurements Subcommittee 1-6 (NCRP SC 1-6) agreed to give full consideration to the evidence and to diverse points of view presented during the working group meeting in revising the draft report from NCRP SC 1-6.
2. It appears to be impossible to determine from epidemiological studies whether protracted exposure to levels of ionizing radiation on the order of background radiation [i.e., several hundreds of millirem (mrem)] has any deleterious effect on a human population. The ACNW agrees with the assertion of the Health Physics Society that a 100-mrem standard for exposure ensures protection of public health and safety. Furthermore, we believe that collective doses should not be used in setting radiation protection standards.
3. A more complete understanding than is currently available about the fundamental mechanisms of cellular damage by radiation and about cellular repair mechanisms offers the potential for resolving questions about the dose-response relationship for low levels of ionizing radiation. To this end, the Department of Energy (DOE) has initiated a research program on the Biological Effects of Low Dose and Dose Rate Radiation. The NRC should monitor and participate in the activities of the DOE Biological and Environmental Research Advisory Committee.
4. The risks associated with exposures from waste-disposal and decommissioning activities are related to the ingestion of radionuclides that emit low linear energy transfer (LET)² radiation over long time periods. Data for such exposures are scarce. Research on these topics, which does not appear to be part of the DOE program on fundamental biological mechanisms, is needed. The NRC should support such work.

Basis for Conclusions and Recommendations

Trans-Science, the LNTH, and Risk-Informed Regulation

The ACNW is impressed with the characterization of the effects of low-level radiation provided by Weinberg³ in his 1972 paper. Weinberg suggested that the question, "What are the biological effects of low-level radiation insults from the environment?", is *trans-scientific*. In Weinberg's terms, a question is trans-scientific if it can be posed properly and rigorously within

²Radiation is classified as either high LET (linear energy transfer) or low LET. High LET is from high-energy neutrons and alpha particles. Low LET radiation is from gamma and beta rays.

³A. Weinberg, 1972. "Science and Trans-Science," *Minerva* 10:209-222.

the established scientific framework but cannot be answered by science, given current knowledge and techniques and given reasonable resources. The basic problem is that effects of low doses are so small that sample sizes required to discern an effect given natural variability are impossibly large. Charles Land, a biostatistician with the National Cancer Institute, reemphasized this conclusion at our working group meeting when he concluded that epidemiological studies cannot resolve the question of whether there is a threshold in the dose-response curve. Weinberg also noted a dilemma that follows from this observation when he stated: "Yet the regulator, by law, is expected to regulate even though science can hardly help him; this is the regulator's dilemma."⁴

The LNTH is an extrapolation from well-established health effects of high doses to very low doses [see the attached figure]. The LNTH offers a convenient, albeit potentially conservative, resolution to the regulator's dilemma. The controversy that continues to surround the LNTH stems from its roots in trans-science. Opponents of the LNTH point to evidence of no effects at low dose rates (really to the lack of evidence of any effect), and to some evidence for beneficial effects (hormesis). On the other hand, others argue that the LNTH underestimates effects⁵. There is no consensus among scientists, let alone an acceptance of a result by the public. Prospects are dim for coming to a resolution satisfactory to all constituencies in the near future. The challenge for the NRC will be to incorporate the risk-informed perspective into regulations, recognizing that the LNTH is simply a convenient assumption for expressing a potential risk.

The LNTH model can be used to calculate effects expected from very low exposure. The fact that these effects are hypothetical must be brought to the attention of stakeholders more effectively than it has in the past. Again, we can do no better than to quote Weinberg⁶. Commenting on the second report of the Committee on Biological Effects of Ionizing Radiation, BEIR-II, that 170 mrem per year over 30 years, if imposed on the entire U.S. population, would cause between 3,000 and 15,000 cancer deaths per year, Weinberg states: "I do not quarrel with the estimated upper limit—which amounts to one cancer per 2,500 man-rem, but I think that placing the lower limit at 3,000 rather than at zero is unjustified. Moreover, I think that it has caused great harm. The proper statement should have been that, at 170 mrems per year, we estimate the upper limit for the number of cancers to be 15,000 per year; the lower limit may be zero." Weinberg's suggestion, in order to avoid raising unnecessary alarm when reporting results of risk assessments, is to present (scientifically valid) estimates of health effects at high dose levels, but to present consequences of lower exposures (below 5,000 mrem) simply as the number of person-rem without trying to convert to numbers of latent cancers.

The ACNW agrees with Weinberg that much harm has been done in terms of public concern over the health effects of low levels of ionizing radiation by invoking the LNTH. The public is led to believe that small doses to large populations lead inevitably to large numbers of real cancers and real deaths. Examination of this issue indicates that these "realities" are no more than hypothetical estimates that have not been established scientifically. If NRC is to honor its

⁴ A. Weinberg, 1985. "The regulator's dilemma." *Issues in Science and Technology* 2:59-72.

⁵See, for example, J. W. Gofman, 1990. "Radiation-induced cancer from low-dose exposure: an independent analysis." Committee for Nuclear Responsibility, Inc., San Francisco, Ca.

⁶ Weinberg, 1985 *op.cit.*

commitments to provide clear and accurate information to the public, as stated in the NRC Strategic Plan, then it has an obligation to work to correct any public misunderstanding. The Committee agrees that a conservative approach is appropriate in protecting public health and safety, but direct application of the LNTH to waste isolation and decommissioning regulation, “just to be safe,” runs the risk of going beyond conservatism toward irresponsibility, given the very high stakes and costs (to the public) that are involved. The Committee believes that LNTH is an extremely important issue and will continue to push for strengthening of the NRC’s scientific basis for regulating low-dose exposures.

Unless and until fundamental biological scientific knowledge advances to the point at which the question of low-dose responses can be moved from the domain of trans-science to the domain of science, the best approach to regulation is to evaluate risk while recognizing uncertainty. Using the LNTH, the added risk of developing a fatal cancer over a 70-year period for a person exposed to 100 mrem per year over background radiation is calculated to be on the order of 10^{-5} per year. The risk may be much less than this, and may in fact be zero. Thus, we believe that a 100-mrem standard is realistically conservative in protecting public health and safety.

Given the very large uncertainties associated with extrapolation to low doses (certainly doses any lower than 100 mrem), Weinberg’s suggestion of not calculating or reporting any health effects for low dose rates should be seriously considered. The fact that the available data are not sufficient to determine that a threshold exists in the dose-response relationship also carries the implication that the same data are equally insufficient to exclude the possibility that there is **no harmful effect** from doses on the order of 1,000 mrem per year.

The 1999 NCRP (Draft) Report

In 1996, the ACNW wrote a letter supporting the Commission’s planned funding of a review and analysis by the NCRP of the scientific evidence for the relationship between dose and response at low rates⁷. In that letter, we stressed the need for consideration of all studies that could relate to the LNTH, involvement of scientists who were not perceived to have built a career based on the LNTH, and independent review by an impartial entity with strong credentials in statistical analyses. The study referred to has been completed by the NCRP and the report is available in draft.

Dr. Arthur Upton, who chaired the NCRP SC 1-6, presented a summary of the draft report at our working group meeting. Dr. Upton briefly summarized much of the available evidence, from epidemiological studies to *in vitro* cell experiments, that was considered by his panel. The NCRP

position expressed in the draft report is that currently there is no evidence that

⁷ Letter from the ACNW to Chairman Jackson, July 10, 1996.

unambiguously leads to dismissal of the LNTH and that the prudent course is to accept the LNTH for regulation of exposures⁸.

Several people at the working group meeting took exception to the main conclusion of the draft NCRP report, that strong evidence for discrediting the LNTH does not exist. These opponents of the LNTH chided Dr. Upton for failing to take into account and to cite properly evidence that does not support the LNTH. For example, they claimed that the work of Cohen and of Luckey on hormesis was not cited, or was cited incompletely.

The Committee is not able to evaluate in detail the widely differing arguments presented on the LNTH and cannot decide which position is "correct."⁹ Dr. Upton did assure the working group meeting participants that the NCRP panel would consider all comments received on the draft when preparing the final version of the report. The Committee believes that concerns expressed by dissenters from the main position taken in the draft report during the revision process merit careful consideration.

The EDO's response to our July 1996 letter¹⁰ indicated that the NRC would conduct a comprehensive and critical review of the NCRP report before it was submitted to the full NCRP for approval. The ACNW was disappointed that this review was not presented. Presentation of the results of this "comprehensive and critical review by the NRC" to the working group would have added much to the working group session.

DOE Research Program

Marvin Frazier from the DOE presented a summary of plans for the new DOE research program on the Biological Effects of Low Dose and Dose Rate Radiation. The basis for supporting a large research effort at this time is that fundamental biological mechanisms can be elucidated because of the tremendous progress in the field over the last several decades, including research on the human genome.

There is widespread agreement that fundamental biological work, such as that to be funded by DOE, offers a chance to determine whether there are levels of radiation that are not injurious to humans. It is critical that the NRC keep abreast of developments in the research funded under this DOE program. We understand that there is a DOE Biological and Environmental Research Advisory Committee and that NRC participation on this committee might be possible. The NRC should be engaged in the activities of this Committee. Whether the NRC participates fully or as

⁸See also A. C. Upton, 1999. "The Linear-Nonthreshold Dose-Response Model: A Critical Appraisal, Radiation Protection in Medicine: Contemporary Issues." *Proceedings of the 35th Annual Meeting of the NCRP*, Bethesda, Md. pp. 9-31.

⁹ "At any stage, however, the boundary [between science and trans-science] is fuzzy, and much scientific controversy rages over deciding where it lies. One need only to read the violent exchange between Edward P. Radford and Harold H. Rossi over the risk of cancer from low levels of radiation to recognize that, where the facts are obscure, argument-even *ad hominem* argument-'blossoms.'" (Weinberg, 1985.) Thus, the failure to decide on which view is 'correct' simply reflects the trans-scientific nature of the question.

¹⁰ Letter from James M. Taylor to Paul W. Pomeroy, August 9, 1996.

an observer only, the staff should remain up to date on the work being done in this program.

Research Needs Beyond the DOE Program

Exposure of populations to radiation from decommissioning and waste-disposal activities would result from internal deposition of radionuclides at low doses over protracted time periods. [This differs, for example, from the largely external (and high dose) radiation suffered by humans exposed to nuclear explosions.] There is limited information available on the response of whole organisms (laboratory animals) to protracted doses of internally deposited radionuclides. Evidence that is available is cited by those who deem the LNTH untenable and overly conservative for risk assessments. For example, animal studies on bone cancer induced by ^{226}Ra indicate a nonlinear dose-response and long induction periods.¹¹ When the lifespan of the animal is taken into account, there is an effective threshold in the dose-response curve in that, although cell damage does occur, the time required for induction of a cancer is longer than the lifespan of the animal.

The DOE program does not appear to include work on whole-organism responses to internally deposited, protracted, low doses of specific radionuclides that are of greatest importance in assessing the risks associated with decommissioning and the disposal of radioactive wastes. Such research is needed, and support for it should be a priority for the NRC.

Concluding Remarks

The controversy surrounding the LNTH is likely to continue for years to come. There is hope that evidence from *in vitro* experiments on mechanisms for damaging DNA will be reconciled with *in vivo* whole-organism (studies that include a full range of repair and adaptation mechanisms) and will lay the controversy to rest. In the meantime, we believe that a reasonably conservative regulatory approach is to set 100 mrem per year as a dose rate that is protective of public health and safety.

Sincerely,

/s/

B. John Garrick
Chairman

Attachment: Figure 1

¹¹Raabe, et al., Health Physics Vol. 44, Suppl. 1, pp 33-48, 1983, with Steven A. Book and Norris J. Parks.

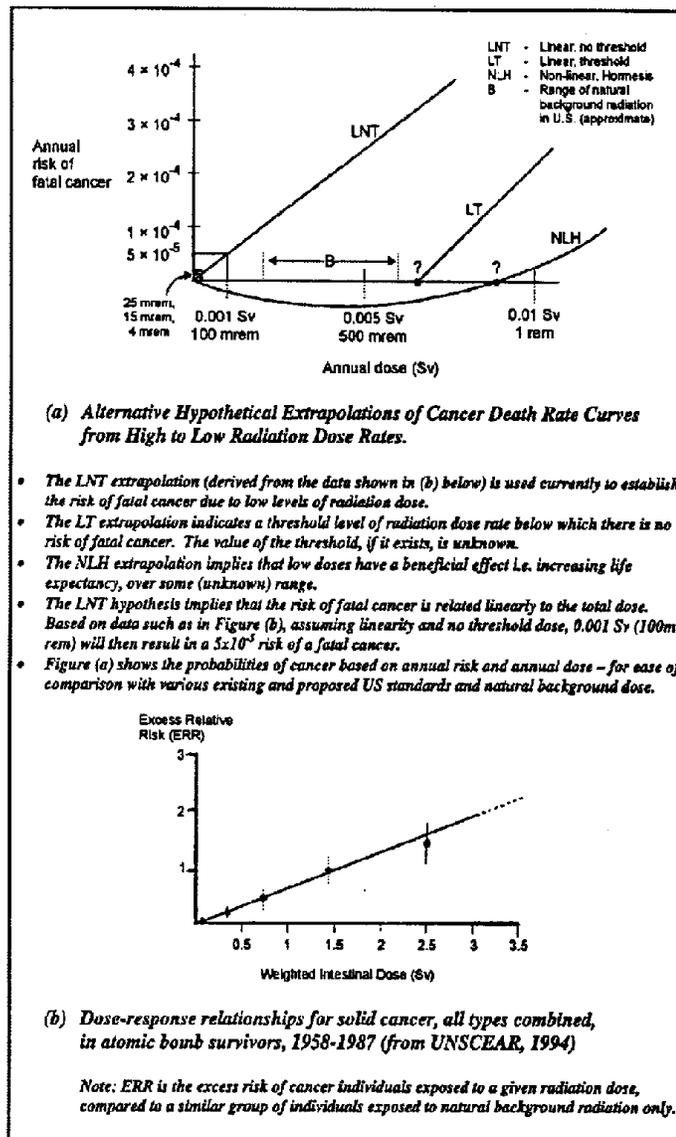


Figure 1

