To: Roxanne Summers

Dana A. Powers

From: Dana A. Powers

Subject: HEALTH EFFECTS OF LOW-LEVELS OF IONIZING RADIATION

Many thanks for the conference phone call on Friday and the revisions proposed by Shack and Kress to the draft letter on low-levels of ionizing radiation. Both have clarified much about the intention of the draft letter for me. I regret that I have to be such a 'pain' on this matter which is apparently far more transparent to other members of the Joint Subcommittee than it is to me.

The revised letter does not really address my original points that:

- radiation damage is more complicated than a simple dose-response relationship.
- if we are to recommend in this area, our recommendation should address the broad range of issues at stake rather than focusing on one narrow controversial topic, and
- it is unlikely that findings of unilateral examinations could be translated into revisions of the existing regulations.

But, I accept the idea at least in principle that a piecemeal approach to the subject may be appropriate. I feel, however, that the current draft letter does not accurately state the points and recommendations that the Joint Subcommittee wants ACRS and ACNW to endorse. Let me make some specific comments about the letter including editorial comments and perhaps my concerns will become apparent:

- paragraph 1: With regard to the last sentence in this paragraph, I do not know that the Commission wants to review and analyze the issue at all. In fact, I think it emerges toward the end of the letter that such a review and analysis is the actual recommendation that is being made.

- paragraph 3: In the last sentence of this paragraph the issues at hand are related to the emphasis on risk informed regulation. We should remember that in adopting a stance involving risk information the Commission did not abandon the concept of defense-in-depth. Their support of risk-based regulation is not especially strong as reflected by the "informed" term. In areas of great uncertainty such as the effects of low-level dose response relationships defense-in-depth may be a more useful guiding principle than risk. It is, in any case, not obvious to me that the Commission must use its resources to address the issue. Cannot an applicant propose rulemaking and defend a position seeking relief from burdens of the linear hypothesis?

- paragraph 4; line 6: "..... independent and special technical investigation....."
The letter does not indicate what the study is to be independent of. It would appear from the letter as now written that the NCRP study is to do exactly what is requested. I now know that it is this study and those who will conduct it that the letter objects to. The reasons for such objections are not ever stated. Similarly, later in the paragraph a call is made for impartial review. The letter does not say that it is believed that the proposed study by NCRP will not provide such an impartial review. I now know that this is in fact what is believed. The letter does not state or defend this view, so a reader may well think that the planned NCRP study is adequate.

- paragraph 5; line 3: I think this phrase should be reworded. Such an obviously biased phrase really detracts from a letter demanding an impartial examination of a subject.

- "..... any study to contribute to the testing of the model." I think what is meant here is "...results of any study being used to test the model."

- paragraph 6: Do you really mean that no healthy worker effect was detected in the study? If so, I would think it a very dubious study indeed. Perhaps what is meant is that the investigators were able to correct for the healthy worker effect.

- paragraph 6 -last sentence: This sounds remarkably like Lamarckian biology.

-paragraph 7: Why isn't the quote the last word on the subject? I prestigious group of experts has examined the data and hypotheses and published a conclusion it can defend. I know the authors of the letter don't think a full examination of the available data was conducted in an unbiased manner. But, the letter does not say this nor does it say why the experts are believed to be such bad guys. This leads me to think the authors just don't like the conclusion and they want to stack the supreme court with inexperienced people until they can get a vote that goes their way.

- paragraph 8 last sentence on page 4
The logic may not be correct but the conclusion may not be wrong. You are making a cost argument here and you don't present a basis for conclusion. Is it going to be cost-effective to go the route you plan? I think the proposed study is a waste of money because it can't result in the change of regulations. I know the regulations are a pain in the neck to follow, but I do not know that they are especially expensive to follow, nor do I Know that implementing changes with the heavy costs of retraining will be cheap. Ought we have something akin to a regulatory analysis to support our position?

- paragraph 8 on page 5:
Again, I call your attention to the fact that risk is not the only or even the most important basis for regulation. The current approach can be defended on the basis of defense-in-depth just as many other regulatory positions are defended.

- paragraph 8 last line on page 5
I believe this is the real recommendation - re-examine the regulatory model.

- paragraph 10 "...create an independent body..." What is this? Are we recommending the creation of a whole new commission? In the current budgetary environment you will get nowhere with this. I think there is an Executive Order that now limits the creation of independent bodies. I still do not see why the NCRP study cannot be counted on to do everything that is requested in the letter. In fact, they seem to have done it based on the quote earlier in the letter. If new evidence has just recently come to light they may want to re-evaluate their position.

- paragraph 10 on page 6: lines 5 6
The sentence seems to imply that anyone with an expertise in dose-response relationships is ipso facto biased. I for one cannot say this is accurate. I do not know how you adjudicate between the supposed biases and well-founded, firmly held, defensible positions. The additional expertise being proposed here needs to be better defended so it is not attacked as "court-stacking." Is it, in fact, true that past examinations of the data did not include assessments of the data quality? I would be stunned if this were the case. It seems to me that all these studies get scrutinized in great detail for errors in design and statistical analysis.

- paragraph 11 point (a):
This recommendation seems to say put any old stray dog on the panel as long as he can claim to not have any expertise in dose-response relationships!" I might take it also to mean that anyone who advocates LNT must be excluded as well. As to point (b), is it true that there was no expertise in statistics among those involved in past examinations of the issue? I would be surprised.

- paragraph 12 "...these studies..." Is there to be more than one study?

- paragraph 6: I believe the anecdotal citation of a few studies is inconsistent with a call to examine all the data. Furthermore, citation of the particular studies may make the readers think a bias exists among the authors of the letter.

I hope my comments are of some use in developing a letter that can be finalized. I regret that right now I don't think I can formulate specific language on the issue because I'm just not persuaded of the draft position. Even if the position is entirely correct, I'm not sure its worthwhile to try to remedy the situation this way.

FAX COVER SHEET

PRIORITY: HIGH MEDIUM ROUTINE

DATE: 5/18/96
TIME: 10:41 PM
PAGES INCLUDING COVER:

TO: B. John Garrick @ FAX 714 833 2085
Noel Dudley @ FAX 301 415 5589
cc: Roxanne Summers

FROM: MARTIN J. STEINDLER

Phone (H) 708 241 3750[4]
Phone (O) 708 252 4314
Fax (O) 708 252 5528
FAX.....(H) 708 241 3750*

MESSAGE:

Noel, John;

Regarding version 'Final Draft 1B, 5/17/96' of the Health Effects letter faxed to me by Noel, please note the following.

1. Page 4, perhaps the terms 'logic' might be better 'conclusion'. The softening of the sentence is ok but there is a loss of 'punch'.

2. Page 5, 1st full para.: I don't understand why 'scientifically-based' has been removed. The term 'appropriate' could very well refer to one that is incorrect but conservative, which is exactly what we now have and want to reexamine. I urge retention of what was there but I won't object absolutely if this is all that stands in the way of getting the letter out.

The rest of the changes are ok but strike me as not substantive. I urge that any future messages be handled in accord with information left with Rich Major or John Garrick, regarding where and how I can be reached.

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4 Address is 1524 Chicago Ave, Downers Grove IL 60515-3450. Fax number is the same as the phone number.

* No unattended reception. Call and talk to us before sending.

3/24/96

FAX TO John Larkins
CC TO ACRS/ACNW Joint Subcommittee Members (JTL - please provide copies of this memo to the members)
Roxanne Summers
FROM JCC
SUBJECT 3/26/96 ACRS/ACNW Joint Subcommittee Meeting

Because of another commitment I have decided to conserve your budget by not attending the 3/26/96 ACRS/ACNW Joint Subcommittee Meeting. Additionally as a short timer on ACRS (my term ends on 5/30/96) I won't be around to participate in the on-going deliberations of low-level radiation health effects a subject dear to my heart. I have full confidence that the members of the Joint Subcommittee will come to an appropriate position on this issue without my presence at the meeting.

I have reviewed the impressive stack of paper on low-level radiation health effects that Roxanne put together for the meeting. I believe now as I have believed for the 40+ years that I have been associated with the nuclear power industry that the nuclear establishment has created an unwarranted fear of man-made ionizing radiation on the part of the general public with the "linear, no threshold" effects/dose hypothesis. This has resulted in a tremendous financial and health effects cost to society not only with respect to the utilization of nuclear power but in the use of all forms of nuclear technology.

There appears to be considerable technical bases for the March, 1996 Health Physics Society's recommendation "... against quantitative estimation of health risk below an individual dose of 5 rem in one year or a lifetime dose of 10 rem in addition to background radiation." However the proponents of this position were given a number of clearly valid challenges by W. K. Sinclair (See p. 5 of Attachment 15 to Roxanne's memo). Of his several questions I was particularly intrigued by his question regarding the usefulness of a threshold of a very low value of dose in actual radiation protection practice. I believe that we have an answer to this challenge as it concerns the regulation of nuclear power plants.

The last ¶ of Mary Goldman's comments (see Attachment 18 to Roxanne's memo) seem to me to be an especially cogent summary of where we are and where we should be going.

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> Let's stop debating what we believe and hope for and put the linear no-threshold hypothesis to sound solid scientific scrutiny and objective testing. It's time for innovative research! We need to do a complete review of the available data and as well employ our newer molecular tools in unique research to better understand the radiation carcinogenesis process."

I don't believe that the NRC can change its regulatory approach (at least politically if not legally) until the NCRP (and the ICRP?) changes its radiation protection philosophy with respect to low doses of radiation. Attachment 24 to Roxanne's memo is a proposal to the NRC from the NCRP dated 2/10/95 (over a year ago) to produce a report entitled "Critical Evaluation of the Linear-No threshold Assumptions." The estimated cost of this three year study is $225k a drop in the bucket relative to the RES budget. We need to know what action has been taken by the staff with regard to this proposal. It seems to me that this is an obvious first step in dealing with this issue although I can imagine that there are staff people that might see this as a threat to their empires.

Finally, I believe that the Committees either individually or jointly should recommend to the Commission that the agency develop a proactive strategy to settle the question of the health effects of low level radiation exposure. This would be wholly consistent with this Commission's stated policy that NRC regulations should be risk informed.

BEIR VII "SCOPING STUDY"
Draft Work Scope
May 2, 1996

BACKGROUND

Since publication of the 1990 BEIR V Committee report, "Health Effects of Exposure to Low Levels of Ionizing Radiation," new information has become available ~~on the Japanese atomic bomb survivors and other~~ regarding cohorts exposed to ionizing radiation at low doses and dose rates. Studies at the molecular and cellular level have ~~pointed the way towards~~ contributed to a better understanding of carcinogenesis and may eventually lead to an improved basis for estimating radiation risks at low doses and dose rates. In addition, there is new information on the effects of low-level radiation in producing risk decrements of both mortality and cancer, and other non-cancer effects ~~other than cancer~~.

To be credible, it is critical that federal radiation protection measures and risk assessments be based on the best current science. Although the emergence of new epidemiological data and progress in understanding the biological basis for carcinogenesis is expected to continue in coming years, an ~~update~~ extension of BEIR V may be desirable at this time. Before proceeding with a full-scale National Academy (BEIR VII) review and analysis aimed at updating the existing state of understanding and quantification of risks from low dose, low-LET radiation, it would be advantageous to conduct a preliminary study that would examine the range of potential issues that could be addressed, along with an assessment of the usefulness of available sources of new information in order to define the most useful scope for BEIR VII.

PROPOSED PLAN OF ACTION

The Board on Radiation Effects Research will organize a small expert panel to investigate what issues a BEIR VII study might usefully address in depth. The scoping study should address each of the issues/areas outlined below and any others the panel deems relevant. In conducting its review, the panel should consider the current availability of data not evaluated by the BEIR V committee and the expectation of significant additional data during the period of the BEIR VII review. The panel should provide a final letter report that: (1) recommends which of these issues could profitably be addressed in depth in a BEIR VII study, (2) provides a basis for these recommendations, (3) lists primary sources of data that might be used, (4) assesses whether or not a detailed analysis of each issue could have a significant effect on the quantification or validity of radiation risk estimates, and (5) indicates what scientific disciplines would be required to adequately address each of the

OUTLINE OF AREAS TO BE ADDRESSED IN SCOPING STUDY

In considering issues to be addressed in future BEIR studies, the panel should at least review the following:

1. Cancer risk estimation at low doses

The form of the low dose response ~~below~~ in the dose range directly accessible to human epidemiological studies, including the evidence for or against linearity and thresholds ~~at or near background levels of exposure~~

Adjustments to organ-specific risk estimates at low dose rates, e.g. as expressed by a Dose Rate Effectiveness Factor (DREF)

Significance-or nonsignificance- of "hormetic effects," i.e., risk decrements in human populations resulting from enhanced prevention, repair, or removal of DNA damage in the exposed biosystem.[1] ~~(e.g., adaptive response, immune system stimulation) to the dose response for cancer induction~~

2. Numerical risk estimation

Alternative biologically based[2] models for projecting radiation-induced cancer risks in the U.S. population, for workers and the general population

Quantification of uncertainties in radiation risk estimates

Resolution of claimed inconsistencies in risk estimates derived from different epidemiological studies

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[1] UNSCEAR 1994 Annex B contains a discussion of various mechanisms for adaptive responses, such as, prevention by increased radical detoxification (page 205), repair by activated genes and their enzyme products (page 199), removal by apoptosis (pages 199, 208), and immune system changes (page 206).

[2] The following biologically based models include both the normal very high background of intrinsic metabolic mutations (2.4×10^5/cell/day) and the adaptive responses of the biosystem to radiation.

- A Cytodynamic Two-Stage Model that Predicts Radon Hormesis (Decreased, then Increased Lung-Cancer Risk vs. Exposure, Dr. Kenneth T. Bogen, Lawrence Livermore National Laboratory, University of California, February, 1996
- The meaning of the α-Term in the Dose-Risk Function for Late Radiation Effects, Ludwig E. Feinendegen, Medical Department, Brookhaven National Laboratory, Upton, NY, and US Department of Energy, Washington, DC

3. Existence of sensitive subgroups

Genetic predisposition to radiogenic cancer

Role of other agents that modify the effect of radiation when that agent is administered for this purpose

Risks from prenatal exposures

In reviewing these and other issues, the sources of data considered should include (but not be limited to) the following:

- Japanese atomic bomb survivors data

  Cancer incidence and mortality data available subsequent to BEIR V analysis with emphasis on exposures at low doses and dose rates

  Dependence of risk on cancer site, age at exposure, age at observation, time since exposure, gender, city, and dose

  New dosimetric information, particularly pertaining to neutron doses at Hiroshima ~~on risk estimates applicable to elevated environmental exposures~~

  Evidence pertaining to possible low level radiation induction of noncancer effects (mortality, genetic, teratological, cardiova... er, cataracts, etc.) ~~by radiation~~

- Other epidemiological low level data that has been cited as a basis for risk estimation at low levels of exposure

  Medically irradiated cohorts

  Populations exposed to chronic doses: (1) groups exposed in the former Soviet Union, (2) nuclear workers in the U.S. and other countries, and (3) other population groups for which studies have been reported (e.g., residents of high background areas).

  Evidence for carcinogenicity of I-131

- Laboratory studies pertaining to mechanisms of radiation carcinogenesis

  Occurrence of various types of DNA damage produced by radiation and intrinsic normal metabolism.

  Efficiency of biosystem in prevention, repair, and removal of DNA damage and its functional dependence on dose and dose rate

  Importance of specific gene changes caused by radiation or other agents in carcinogenesis

Influence of cell cycle on radiation-induced cellular changes and repa

[illegible] issues can be profitably addressed, the panel shall also [illegible] relevant reviews conducted by BNS(EAR, NRPB, ICRP, NCRP, and [illegible] prioritize [illegible] the issuance of BEIR V. Should the panel recommend that it is not appropriate to evaluate specific issues at this time, the report should, if possible, indicate what additional data would be needed to make such an evaluation appropriate.