PURDUE UNIVERSITY

SCHOOL OF
HEALTH SCIENCES

April 30, 2001

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Dear Mr. Elliott:

In response to your letter of April 6, 2001, I am pleased to provide some comments relating to the responsibilities of the Advisory Board on Radiation and Worker Health. In doing so, I must emphasize that my comments are very preliminary in nature and are made in the absence of complete information pertaining to the subject.

1. Concerning the promulgation of regulations for use by the Department of Labor and by NIOSH:
    - The "probability of causation" issue, while conceptually sound, has some serious aspects and pitfalls that must be addressed. Development of probability of causation values is very dependent on the dose-effect model(s) used and upon the assumptions made concerning the role of radiation as a cancer-causing or cancer-promoting agent. Use of this approach requires a careful evaluation of both the reliability of and variations in risk coefficients for development of cancer due to radiation exposure. In addition, risks for other carcinogenic agents, and for natural causes for the particular individual must be taken into account. Among the current issues for which there is not agreement in scientific circles is the matter of the "linear-no-threshold" (LNT) model on the dose-effect relationship. The issue of whether or not there is a threshold dose below which there is no effect is critical to the matter. It is not an issue that is likely to be resolved by epidemiological studies, nor is it likely to be resolved within the time frame of implementation of the current regulations. It should also be noted that the idea of attributing cancer solely to

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radiation exposure in the absence of information on other exposures to carcinogenic agents that the individual has incurred would be inappropriate. Other agents that would have to be considered and addressed include

- Cigarette smoking
- Chemical carcinogens
- Biohazards
- Natural radioactivity and radiation (e.g., radon gas)

- A key issue that must be addressed is finding a fair way of sorting valid claims from invalid claims. Basically this is the matter of a claimant being able to show that it is more likely than not that his/her health effect was caused by radiation. A probability of causation (PC) value below 0.5 implies that is more likely than not that an effect was not caused by radiation. Thus, use of PC values below 0.5 to establish compensation must rely completely on hypothetical models to calculate odds for low doses at which effects have not been actually observed experimentally. From a legal point of view it would probably be better to use relative risk (RR) as the tool for establishing a claim. RR has already been used successfully in the case law of many courts. It requires a determination of the dose to the individual and a determination of the scientifically observed RR for individuals who have received that dose. If the RR is greater than 2.0, then it is more likely than not that the health effect was caused by the agent in question (radiation).

- Dose reconstruction, although critical to the assignment of past doses, is inherently an inexact science. It is vary dependent on the mathematical models and assumptions used and is thus subject to great uncertainties. Indeed, it would not be surprising for the uncertainties to be as great as an order of magnitude in some cases. Finding an appropriate approach for addressing this uncertainty in the regulatory framework will be challenge. In Great Britain, where a probability of causation scheme is used to reimburse for radiation-linked diseases, "generosity factors" factors are used to account for such uncertainties. These are generally applied in a manner that will favor the claimants.

2. Estimation of doses incurred by individual claimants.
   - Claimants who have been monitored in the past (e.g., radiation workers) can be expected to have doses that are known to within about $\pm$ 20%, depending on the exposure conditions involved. For individuals for whom doses are reconstructed from secondary information, the uncertainties will undoubtedly be much greater as suggested in item 1, above. In either case, it will be

important to identify and estimate the uncertainties when assigning individual dose values.

- The estimation of doses through dose reconstruction methods has been evolving over several years. For certain scenarios, there are well-accepted models that can be applied, and these should be used consistently whenever possible. In general it will be important to identify and standardize the methodologies that will be used to carry out dose reconstructions at various facilities and locations.

- Since dose reconstruction models typically are based on standard assumptions concerning personal characteristics and eating habits, adjustments may need to be made when applying the models to specific individuals for purposes of estimating dose.

3. Establishing a process to decide whether additional classes of workers should be included:
    - In item 1, above, I indicated that there indeed could be other agents in the workplace that could adversely impact on worker health. One example is beryllium, exposure to which has already been identified and is being dealt with legislatively. Because the cause-effect issues of this agent are clear-cut, it is one that can be addressed in a straightforward manner. Unfortunately, most other chemical, physical, biological, and radiological agents do not present such clear relationships, especially at low doses. Long-term dose-effect responses are not always well known, and the associated health effects are often difficult to distinguish from normal background effects or normal incidence rates. Unless there are cases similar to the beryllium case where the dose-effect responses are clear, it would seem to be premature to add additional classes of workers at this time.

    - Epidemiological studies and occupational health surveillance should be emphasized and supported in cases where suspect agents are in use. Decisions on adding additional worker classes must be based on scientific evidence and not on speculation. The National Occupational Health Agenda (NORA) might be a potential route for identifying worker classes that are experiencing elevated rates of long-term health effects. Appropriate studies on these groups could then be directed toward isolating and identifying potential associations with suspect agents.

These comments are brief, and I would be happy to expand on them in much more detail if needed. There is a substantial body of literature on the topics of probability of causation, the linear-no-threshold model, and dose reconstruction. The Advisory Board on Radiation and Worker Health will need to review and be familiar with this body of literature as it prepares to address the guidelines and regulations associated with the Energy Employees Occupational Illness Compensation Act.

Thank you for the opportunity to provide these comments. They represent my personal views, and none of the statements herein are endorsed by or represent the positions of Purdue University or its officers.

Sincerely,

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