



HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

November 30, 1998

Dr. Martha A. Krebs, Director
Office of Science
U. S. Department of Energy
Forrestal Building
1000 Independence Avenue, S.W.
Washington, DC 20585

KEITH H. DINGER, CHP

President 1998 - 1999

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RE: HEALTH PHYSICS SOCIETY POLICY ON EXPENDITURE OF FUNDS FOR IONIZING RADIATION HEALTH EFFECTS STUDIES

Dear Dr. Krebs:

Enclosed is a policy recently adopted by the Health Physics Society's Board of Directors regarding expenditure of funds for ionizing radiation health effects studies. This policy is being provided to assist you in your responsibilities as manager of Department of Energy funds appropriated for health and environmental research and as the Department's Science and Technology Advisor.

As you may know, the Health Physics Society is a scientific organization of approximately 6000 professionals whose mission is to promote the practice of radiation safety. As President of the Society, it is my desire to make the extensive resources of the Society available to the Department of Energy to assist in the implementation and improvement of radiation safety. The enclosed policy statement is provided in our interest to offer you the Society's expertise on health effects studies.

I would greatly appreciate the opportunity to meet with you at a convenient time to further discuss this policy and other areas in which the Society may be of assistance to the Department of Energy. In the meantime, please contact me if you have questions about this, or any other issues.

Sincerely,

Keith H. Dinger, CHP

enclosure



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HEALTH PHYSICS SOCIETY POLICY ON EXPENDITURE OF FUNDS FOR IONIZING RADIATION HEALTH EFFECTS STUDIES

PREMISE:

1. Funding resources for studying the health effects of human exposure to ionizing radiation are limited.
2. The number of research and study activities related to studying and understanding the health effects of ionizing radiation exceeds the funding resources available.
3. The highest priority of funding work on ionizing radiation health effects should be work with a reasonable likelihood of defining, or significantly increasing the understanding of, the carcinogenic response in the range of occupational and public exposures.
4. A second priority of funding work on ionizing radiation health effects should be work assisting in the establishment of reasonable protection criteria which do not result in an inappropriate expenditure of public funds for purported protection. This is necessary for the period in which there is a lack of definitive knowledge or understanding of the dose response.
5. Epidemiological studies alone will not provide definitive evidence of the existence or non-existence of carcinogenic effects due to low dose or low dose-rate radiation.

RECOMMENDATIONS:

1. Do not fund epidemiological studies of exposed populations which have low statistical power and are unable to detect health effects with a reasonable statistical confidence (e.g., 90% or higher) based on the current risk estimates.
2. Do not fund epidemiological studies on populations for which there is insufficient data to properly control for known confounding factors, such as smoking history, exposure to other carcinogens, genetic pre-disposition, etc.
3. Support the continuation of the Life Span Studies of the Japanese Survivors but establish a multi-stakeholder body to provide peer review and alternative data analysis techniques for the RERF data analysis reports.

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4. Fund basic research in molecular biology directed at better understanding the mechanisms by which cancer is induced after exposure to ionizing radiation with a goal of identifying bio-markers unique to radiation-induced cancer.
5. Fund basic animal research that is directed at better understanding the mechanisms of radiation-induced cancer.
6. Fund work to establish a framework for determining a reasonable and safe dose level for public exposures. The treatment of uncertainties and statistical limitations of risk assessments must be such that continued reduction of quantitative dose limits below this level must be justified by scientific evidence else they may result in a net public harm when economic and societal factors are considered.

DISCUSSION:

The underlying scientific issue with the most impact on current radiation protection criteria development is the *assumption* that any radiation exposure above an absolute value of zero carries some risk of an adverse health effect and that the risk is directly proportional to the exposure (*i.e.*, the linear no threshold (LNT) hypothesis). This has become the dominant issue over the last decade as the focus of radiation protection standards and criteria has moved from the workplace to the general public. The impact of the current application of LNT to standards for the general public has resulted in real, or potential, large expenditures of money to be compliant with the idea of “protecting down to zero” dose. In addition, there is the real, or potential, result that beneficial uses of radiation and radioactivity may not be available for improving public health due to these regulatory positions and the public perceptions that arise from them.

As a scientific organization of professionals dedicated to the promotion of radiation safety, we are concerned that public funds not be inappropriately expended on hypothetical risks to the detriment of reducing real public risks. Therefore, the Society considers two priorities of research in support of improving radiation safety: (1) to better define and understand the response of the human organism as radiation exposure is reduced to levels in the occupational and environmental dose range; and, (2) to develop the scientific basis for implementing reasonable radiation safety standards while this low dose knowledge is being developed.

Our knowledge of the health effects of ionizing radiation on humans has come from extensive study using *in-vitro* cellular studies, animal studies, and epidemiological studies of exposed human populations. The latter have included studies of populations exposed at high dose/high dose-rates and occupationally and environmentally exposed populations at low dose/low dose-rates. Our current risk estimates for low dose, low dose-rate exposures are primarily derived from

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extrapolation of results of the high dose, high dose-rate epidemiological studies. Most important among these is the Life Span Study of the Japanese survivors of the atomic bombings in Hiroshima and Nagasaki, which continues to be the main source of information. Studies of occupationally and environmentally exposed populations have been performed for the last two decades but have provided very little additional scientific knowledge regarding actual human response to low doses of radiation. In addition to the inherent statistical limitations that are a function of the randomness of the health effect of concern (*i.e.*, induction of cancer) and its rate of natural occurrence, these low dose/low dose-rate studies suffer from insufficient data on many potential factors that can, and do, confound the results.

Studies of these occupationally and environmentally exposed populations do serve some purpose. For example, they are useful in addressing allegations of adverse health effects in the population and in demonstrating a concern for the health of the exposed people. However, unless they are sufficiently powerful, they do not add to the scientific knowledge of low dose effects.

Therefore, we make recommendations one and two above.

The continuation of the Japanese Life Span Studies is very important as we enter the years where cancers are more likely to develop, if caused by the bombings, and as the last half of the cohort approaches the end of its lifespan. However, as important as these studies have been, there is scientific debate on the interpretation of the data provided by the research organization performing the study, the Radiation Effects Research Foundation (RERF). There have been peer reviewed publications demonstrating that alternate methods of analyzing the Japanese data lead to different conclusions about the risks extrapolated to the low dose/low dose-rate region. For example, the BEIR VII phase-1 report states that in the majority of radiobiologic observations after photon irradiation, dependence on dose is found to be curvilinear, which stands in contrast to reported solid cancer results from the atomic bomb survivor studies. This apparent contradiction would be resolved if reevaluations of neutron exposures at Hiroshima indicated a sufficient high-LET component to the Hiroshima doses, particularly in the lower photon dose range. The BEIR VII phase-1 report observes that one possible outcome of the reevaluation of neutron exposures at Hiroshima could be "... a vanishing linear component for photons but a substantial quadratic component ...", and that "... the solid-cancer data from Hiroshima could cease to be proof of a finite risk coefficient for photons." These alternate data analysis methods should be given due consideration. This is consistent with the recommendations of the BEIR VII phase-1 Committee report.

Therefore, we make recommendation three above.

The field of research identified as having the greatest potential for providing an understanding of the relationship between radiation exposure and cancer is the area of bio-medical research. The

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BEIR VII phase-1 Committee, the Wingspread Conference Report, and the ATSDR Draft Report for Toxicological Profile for Ionizing Radiation all, for example, identify the need to perform basic research on bio-markers that are unique to radiation exposure.

Therefore, we make recommendation four above.

The BEIR VII phase-1 Committee report also identifies the potential for valuable understanding of the mechanism of radiation induced cancer from animal studies currently in progress. There also appears to be much that can be learned from animal studies already conducted, but not yet summarized.

Therefore, we make recommendation five above.

Research dedicated to quantifying the human response to radiation at low doses and low dose-rates will probably take years to produce conclusive results. In the meantime, it is important that current knowledge be used judiciously to set radiation protection standards. Our current knowledge recognizes the feasibility that at low doses there may be: some adverse risk down to zero; a physical threshold below which there is no risk; or, a level below which there may be beneficial effects. These are the physiological possibilities which present the possibility that continually reducing dose towards zero may at some point no longer be protective. However, a greater risk in continually reducing dose limits is that associated with expending scarce resources, including large sums of money, to accomplish the task. The money expended in the public arena on protective measures is limited. Choices have to be made as to where to spend the money for obtaining the most benefit to public health. If the money is spent in the wrong place, public health has been harmed because other more pressing public health areas with greater “benefit per dollar spent” may not receive funding or receive reduced funding. Therefore, there is a lower range of exposure levels where we do not know if we are doing good, or harm, taking economical and societal considerations into account. It is important to establish this level on the basis of scientific knowledge, and not formally regulate into that area where we don’t know if good or harm is being done. Work on establishing this “statistical threshold” should be done to provide a method for knowing what is a reasonable level for regulations.

Therefore, we make recommendation number six above.

It is recognized that many other areas of research contribute to our knowledge base and nothing in these recommendations is intended to subvert those efforts. Rather these recommendations are intended to provide guidance on the areas of research that clearly should, and should not, be funded for the stated purpose of researching the health effects of exposure to ionizing radiation.

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