



# HEALTH PHYSICS SOCIETY

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*Specialists in Radiation Safety*

December 4, 2001

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**Subject:** Comments on the Notice of Proposed Rulemaking on Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000 as presented in 66 FR 50967 through 50978, October 5, 2001

Dear Sir or Madam:

The Health Physics Society (the Society) is an independent non-profit scientific organization of approximately 6000 professionals who specialize in radiation safety. The Society, in its role as the professional radiation safety organization, has some significant comments on the implementation of the Energy Employees Occupational Illness Compensation Program Act (the Act) and the guidelines for determining the probability of causation used to implement the Act. The Society appreciates the opportunity to participate in this rulemaking. As President of the Society, the following information is provided in response to the Federal Register Notice soliciting comments from interested organizations.

On May 2, 2001, then Society President Paul S. Rohwer provided Mr. L. J. Elliott, Acting Director of the National Institute of Occupation Safety and Health (NIOSH) Office of Compensation Analysis and Support, extensive comments and recommendations regarding the development of guidelines and promulgation of regulations covering: (1) probability of causation; (2) dose reconstruction; and (3) designation of Special Exposure Cohorts. I am enclosing, for reference, the recommendations and discussions of the items relating to probability of causation that were in the attachment to the May 2, 2001, letter. If the comments below do not refer to one of the HPS comments in the enclosure, the Society considers the rule has appropriately addressed the comment or the comment is not pertinent to this rule.

The proposed guidelines are to provide a method for determining whether individuals who are covered by the Act and who have a diagnosed cancer may have sustained that cancer from exposure to ionizing radiation in the performance of their duty at facilities covered by the Act. The October 5, 2001, Federal Register Notice identified some generic topics for comment. Society comments are provided within the context of some of these generic topics followed by additional comments that do not directly relate to one of the generic questions.

**1) Does the interim rule make appropriate use of current science and medicine for evaluating and quantifying cancer risks for DOE workers exposed to ionizing radiation in the performance of duty?**

The Society does not think the methods for determining the probability of causation in the proposed rule can be evaluated against current science at this time.

Society recommendations I.A.1, I.A.3, and I.A.6 in the enclosure relate to the issue of using *consensus* scientific knowledge that is subjected to an established independent peer review process using expert organizations such as the National Academies. The method promulgated at 42 CFR 81 for calculating the probability of causation is by use of a computer software program called the NIOSH Interactive RadioEpidemiological Program (NISOH-IREP). The basic computer program, IREP, is being developed in conjunction with a National Cancer Institute (NCI) and Centers for Disease Control and Prevention (CDC) project to update the 1985 NIH Radioepidemiological Tables. However, the IREP is still in draft form and has not been published as a peer reviewed product. The National Research Council (NRC) reviewed a draft report of the NCI-CDC Working Group to Revise the 1985 NIH Radioepidemiological Tables. The NRC review identified a number of concerns, recommendations, and suggestions regarding the proposed IREP and the underlying scientific methods it uses. Since IREP is still in draft form it is not clear if, or how, it ultimately will address the results of the NRC review.

Also of concern is the fact that the proposed rule includes provisions for NIOSH to change the risk models in IREP as it feels they are needed, without provisions for appropriate scientific peer review. Section III.H of the Notice of Proposed Rulemaking, 66 FR 50971, states NIOSH-IREP will be reviewed by the Advisory Board on Radiation and Worker Health. Discussion of Society recommendation I.A.2 of this letter's enclosure identifies a concern that since the members of the Advisory Board are selected to reflect a balance of scientific, medical, and worker perspectives the Board should consist of members with diverse levels and areas of expertise. Although this type of Board is well suited for general program oversight and review, it is not expected to be a scientific panel expert in methods for calculating probability of causation. Therefore, the computer program NISOH-IREP should be subjected to independent peer review by an expert scientific panel such as those formulated by the National Academies.

**2) Does the proposal appropriately and adequately address the need to ensure procedures under this rule remain current with advances in radiation health research?**

Section III.I of the Notice of Proposed Rulemaking, 66 FR 50971, states that substantive changes to NIOSH-IREP will be submitted to the Advisory Board on Radiation and Worker Health. The Society has the same concern as given above that the Advisory Board is not expected to be an expert scientific panel in the methods for calculating probability of causation and that any substantive changes should also be subjected to independent peer review by an expert scientific panel such as those formulated by the National Academies.

Provisions for review of changes to NIOSH-IREP should be included as a provision of the rule itself.

**3) Two additional comments not directly related to the generic topics.**

Section III.F of the Notice of Proposed Rulemaking, 66 FR 50969, states that none of the risk models explicitly accounts for exposure to other occupational, environmental, or dietary carcinogens. However, risk models do exist for occupational radiation exposure received from employment not covered by the Act and from therapeutic exposures to ionizing radiation, such as childhood x-ray treatment for tinea capitis or therapeutic radiation exposure for a cancer. Individuals receiving radiation exposures from sources not covered by the Act are at a greater risk of developing certain cancers than are the general public. This higher risk should be used as the baseline risk for the individual in the probability of causation calculation. Individuals usually know if they received occupational or therapeutic radiation exposures not covered by the Act and those associated risks should, therefore, be able to be ascertained. The proposed 42 CFR Part 81.5 should list occupational exposure in other than 42 CFR 81 covered work and therapeutic radiation treatments as personal and medical information to be provided to the Department of Labor. The calculation of probability of causation should account for individual's having an increased risk of cancer from these non-covered radiation exposures.

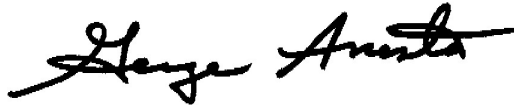
The NRC subcommittee that reviewed the draft report of the NCI-CDC Working Group expressed concern "about the problems with including so many cancer sites for which radiation associations have not been well established." The Society has the same concern. This concern for the lack of a well-established association allowing for the *quantification* of the radiation risk is the basis for recommendation II.A.2 in the enclosure to this letter. Section II.A.2 states that compensation should not be awarded for doses at which it is not known whether or not a risk exists. The establishment of a dose level below which compensation calculations need not be performed is also consistent with provisions of the interim rule 42 CFR Part 82.10(k)(2). This provision of the dose reconstruction rule recognizes there will be

conditions in which dose reconstruction need not be refined if it is clear, through worst-case assumptions, that it cannot be determined that the employee may have incurred a compensable level of radiation dose. The dose at which this provision is implemented will need to be based on the probability of causation calculation. Therefore, a dose below which the calculation is not performed will need to be determined and promulgated. The Society recommends 0.1 Sv (10 rem) for this dose level.

The Health Physics Society understands and appreciates the societal impetus of the Energy Employees Occupational Illness Compensation Act of 2000. We hope that the information provided in this letter is of use in this important effort.

Thank you for the opportunity to comment on the proposed rule.

Sincerely,

A handwritten signature in black ink, appearing to read "George Anastas", written in a cursive style.

George Anastas, President

Enclosure



# HEALTH PHYSICS SOCIETY

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*Specialists in Radiation Safety*

## EXCERPTS FROM THE HEALTH PHYSICS SOCIETY'S

Comments and Input to the  
National Institute for Occupational Safety and Health

On

Fundamental Principles for the Development of Guidelines and Promulgation of  
Regulations

in accordance with the

Energy Employees Occupational Illness Compensation Act (EEOICA) of 2000  
And  
Executive Order 13179\*

\* The entire Comments and Input document was an enclosure to a letter  
dated May 2, 2001, from Paul S. Rohwer to L. J. Elliott

## I. GENERAL PROCESS

- A. Proposed **Fundamental Principles** for the general process of developing guidelines and promulgating regulations under the EEOICA:
1. Guidelines and regulations should be founded upon, and consistent with the most current consensus scientific knowledge.
  2. The Advisory Board on Radiation and Worker Health (the Board) should establish an expert working committee for each of the technical issues under its jurisdiction (i.e., probability of causation, dose reconstruction, and Special Exposure Cohort designation) to:
    - a. advise the Board on the most current consensus scientific knowledge related to their technical area of responsibility, and
    - b. draft guidelines and regulations for Board action based on the current consensus scientific knowledge and directions from the Board.
  3. Guidelines and regulations should be subject to an established independent peer review process using expert organizations such as the National Academies.
  4. Development of guidelines and promulgation of regulations should be accomplished in an open, inclusive, and democratic process.
  5. Regulations should be established in accordance with the provisions of the Administrative Procedures Act.
  6. Guidelines and regulations should include provisions for periodic review of the current consensus scientific knowledge to evaluate if the guidelines or regulations need to be changed to reflect more current knowledge and to evaluate if previous claim decisions need to be re-addressed.
  7. Guidelines and regulations should include provisions for an appropriate appeals process by claimants.

## B. Discussion:

1. With regard to proposed fundamental principle I.A.1 above, the EEOICA (Sec. 3611 (b)) establishes that the purpose of the compensation program is to provide for compensation of employees and, where applicable, survivors of employees suffering from illnesses incurred by the employees in the performance of duty for the Department of Energy and certain of its contractors and subcontractors. The likelihood that a specific illness in an individual was incurred due to the performance of their duty, as opposed to a non-occupational etiology, is a determination that must be made by scientific and medical experts based on the most current knowledge about the association of an individual's workplace exposure and the disease. Because cancer is such a prevalent disease, studies of the association of workplace exposures as a cause of cancer in a workforce are difficult to perform and are open to divergent interpretation of results. The scientific community addresses the issue of differing study results through the "peer review" process with "consensus scientific committee" determinations. Therefore, the purpose of the EEOICA can only be achieved if current consensus scientific knowledge is used as the foundation for the guidelines and regulations implementing the Act. The Health Physics Society (HPS) has a formal position statement titled "Compensation For Diseases That Might Be Caused By Radiation Must Consider The Dose." The last paragraph of the position statement titled "Compensation Programs" provides the HPS position that "If the reason [for a compensation program] is compensation for a disease or injury caused by exposure to an agent, like radiation, *then the best scientific and medical knowledge, including dose-response considerations* should support the likelihood that the compensated disease could be caused by the measured or reconstructed exposure" (emphasis added). A copy of the position statement is attached.
2. With regard to proposed fundamental principle I.A.2 above, the EEOICA (Sec. 3624 (a) (2)) directs that the composition of the Board reflect a balance of scientific, medical, and worker perspectives. This, with the fact the members are at a Presidential appointment level, will result in a Board with members of diverse levels and areas of expertise. In order for all members of the Board to have an appreciation for the details of the scientific issues involved in each of the related but different technical areas for which they have responsibility, they should have the assistance of expert technical committees to do the "drafting and ground work" for their review and subsequent "big picture" discussion and decision making. The EEOICA (Sec. 3624 (c)) provides for a staff for the Board to facilitate the work of the Board. Although staff is necessary, the expertise of those developing the proposed guidelines and regulations that are considered by the Board should be established through the appointment of expert working committees appointed by the Board.

3. With regard to proposed fundamental principle I.A.3 above, in January 2000 the U. S. General Accounting Office (GAO) reported to the Senate Committee on Veterans' Affairs the results of their review of the validity of dose reconstruction as a tool for determining veterans' eligibility for benefits (GAO/HEHS-00-32). One of the conclusions of this report was that "an independent review process . . . could mitigate concerns about the integrity of the program." We believe this conclusion can be applied to each of the technical areas of responsibility for the Board, i.e., probability of causation, dose reconstruction, and designation of Special Exposure Cohorts. The independent review should be accomplished by expert organizations charged with scientific reviews, such as the National Academies.
4. With regard to proposed fundamental principle I.A.7 above, an appropriate appeals process incorporates provisions to accomplish two purposes. These are to: (1) accommodate consideration of information an aggrieved claimant feels was not correct, or not correctly considered; and, (2) limit the process such that, while protecting the rights and interests of all workers the administration and processing is not overly burdensome on either the claimant or the compensation system.
5. All other proposed fundamental principles above are considered to be self-explanatory.

## II. PROBABILITY OF CAUSATION

- A. Proposed **Fundamental Principles** for developing guidelines and promulgating regulations to be used to assess the probability that a claimant's cancer was caused by his or her occupational exposure to radiation:
  1. The probability that a claimant's cancer was caused by his or her occupational exposure to radiation must consider the person's radiation dose.
  2. Probability of causation determinations should only be made where the person's occupational exposure exceeds some minimum value below which there is no known risk of cancer causation in populations exposed below this value. This value should be approximately 0.1 Sv (10 rem).



## B. Discussion:

1. With regard to proposed fundamental principle II.A.1 above, the attached HPS position statement "Compensation For Diseases That Might Be Caused By Radiation Must Consider The Dose" sufficiently discusses this principle. This principle is incorporated into the requirements in the EEOICA (Sec. 3623 (c) (3) (A)) which states the "guidelines [for making the determination an individual sustained a cancer in the performance of duty] shall be based on the radiation dose received by the employee (or a group of employees performing similar work) at such facility. . ." It should be noted that the HPS position statement does not specifically state how an individual's dose should be used in consideration of determining if a cancer is occupationally related (i.e., how to calculate or use a probability of causation) with the exception of the establishment of a minimum value for calculating a probability, which is our second fundamental principle.
2. With regard to proposed fundamental principle II.A.2 above, the HPS position statement on compensation states "there should be no compensation for persons whose lifetime doses are less than approximately 0.1 Sv (10 rem)." This position is explained in the following, which is taken from the position statement. "This relationship of increasing likelihood of disease with increasing dose has only been observed for doses greater than approximately 0.1 Sv. The likelihood of radiation-induced disease below this level, if it exists at all, is so small that it is not measurable, it is not a matter of scientific fact, and it can only be estimated utilizing hypothetical mathematical dose-response models."

The HPS position regarding a value below which compensation should not be paid is based on its position statement titled "Radiation Risk In Perspective." A copy of this position statement is attached. This statement contains the HPS position that "In accordance with current knowledge of radiation health risks, the Health Physics Society recommends against quantitative estimation of health risks below an individual dose of 5 rem in one year or a lifetime dose of 10 rem in addition to background radiation." The position statement sufficiently discusses the rational for this position.

The EEOICA (Sec. 3623 (c) (3) (A)) refers to the use of the radio-epidemiological tables published under the Orphan Drug Act in determining the likelihood an individual's cancer is related to their employment. These radio-epidemiological tables use the scientific knowledge regarding the relationship of cancer induction and radiation exposure obtained from studies where this relationship is observable, i.e., at doses greater than approximately 10 rem. They then *extrapolate* that relationship to doses below 10 rem where the relationship cannot be observed, but where it can only be estimated using hypothetical mathematical dose-response models. This extrapolation is an

example of a quantitative estimation of health risks below 10 rem with which the HPS does not agree.

3. In summary, incorporation of fundamental principles I.A.1, II.A.1, and II.A.2 results in a proposal that the probability of causation use the current scientific knowledge of radiation health effects to calculate an individual's probability of causation using the individual's dose, provided that dose is above an established value below which compensation should not be provided. The establishment of the minimum value for which compensation should be provided could be refined using our scientific knowledge to establish an organ dose value for each type of cancer, in lieu of a general "whole body equivalent" dose. When an individual's dose is greater than the minimum value for compensation, the HPS does not have a position on the specific method of calculating a probability of causation, or how to use this calculation to determine if the dose was "at least as likely as not" to have caused the cancer (EEOICA Sec. 3623 (b)). This should be the subject of study and recommendation by an expert technical committee formed as recommended by proposed fundamental principle I.A.2.