

Miller, Diane M.

From: Keith Dinger [keith.dinger@verizon.net]
Sent: Monday, May 05, 2003 3:10 PM
To: NIOCINDOCKET@CDC.GOV
Cc: Larry J. Elliott
Subject: Health Physics Society Comments on 42CFR83

On behalf of the Health Physics Society President, Dr. John Frazier, I am forwarding comments by the Society on the proposed rule for implementing the Special Exposure Cohort provisions of the Energy Employees Occupational Illness Compensation Program Act of 2000.

Please do not hesitate to contact me if you have any problems with, or questions regarding this submittal.

Sincerely,

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HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

May 6, 2003

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Subject: Comments on the Proposed Rule on the Procedure for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000 as presented in 68 FR 11294 through 11310, March 7, 2003

Dear Sir or Madam:

The Health Physics Society (the Society) is an independent, nonprofit scientific organization of approximately 5600 professionals who specialize in radiation safety. The Society, in its role as the professional radiation safety organization, has specialized expertise in issues related to the implementation of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). As the current President of the Society, I am pleased to provide comments on the proposed procedures, as contained in the referenced Federal Register, for designating classes of employees as members of the Special Exposure Cohort (SEC) under the Act. The Society appreciates the opportunity to participate in this rulemaking.

On August 26, 2002, the Society provided comments on the first proposed rule for designating classes of employees as members of the Special Exposure Cohort, which was presented in 67 FR 42962 through 42973, June 25, 2002. One of the Society recommendations in the August 26 letter was "that the definition of a Special Exposure Cohort be specific to the types of specified cancer that meet the 'likelihood' test for the potential exposures incurred by the cohort". This recommendation was based on the two fundamental principles that: (1) the procedures are based upon the most current consensus scientific knowledge; and, (2) that compensating members of a designated Special Exposure Cohort be fair. The Society is pleased that the latest proposed rule incorporates this recommendation.

Since publishing the latest proposed rule on March 7, 2003, it has become apparent that there are some stakeholders, or individuals, that have taken issue with the incorporation of the provision to allow specification of applicable cancer sites in the definition of newly designated members of the Special Exposure Cohort (see, for example, the discussion in the verbatim transcript of the meeting of the Advisory Board on Radiation and Worker Health [ABRWH] held on March 7, 2003, in Cincinnati, Ohio, starting at page 183, line 18). The discussion raises several issues about the interpretation of the enacting legislation, and one issue related to the science that forms the basis for the provision, i.e., the extent of scientific knowledge about the way radioactive materials, and their progeny (i.e., daughter products) are distributed and retained in the body once they have been inhaled or ingested. The discussion at the March 7 meeting regarding the scientific issue was based on an example presented to the ABRWH involving the inhalation of radon. However, the question asked in the discussion could be applicable to any radioactive material. The Society would like to provide an expanded comment on the scientific basis for this provision, since our previous letter and the example presented to the ABRWH did not address the details of the basis.

The crux of the concern is the reasonable question whether it is known what organs will be exposed following an intake (via inhalation or ingestion) of a particular radioactive material. To address this question, it is essential to emphasize that knowledge about which organs are exposed is insufficient information for determining the likelihood of causation. How much radiation dose the organs receive must also be determined, because the likelihood that an exposure can cause a disease in an organ depends on the radiation dose received (see, for example, the Society position statement "Compensation For Diseases That Might Be Caused By Radiation Must Consider The Dose", <http://hps.org/documents/Compensation.pdf>). One of the principal tenets of radiation toxicology is that biological effects occur where the radiation doses are the greatest. This conclusion has been borne out in decades of experimental animal studies and in the results of pertinent epidemiological studies.

The behavior of radioactive materials and their progeny in the body, and the radiation dose to organs resulting from that behavior, is a fundamental part of radiation toxicology, called internal dosimetry, a discipline of health physics that has been studied extensively for over 50 years. Knowledge gained in the large number of studies done since the early 1950's has resulted in a good understanding of the behavior of radioactive materials and their progeny in the body, and the resulting radiation doses to organs. This knowledge provides the basis for specifying which diseases fit in the definition of a Special Exposure Cohort. With this knowledge, it can be demonstrated that certain cancers are not "likely" to result from intake of a specified radioactive material because the radiation dose required to meet the "likelihood" test for those cancers is not reasonable without the presence of other more likely radiogenic disease or injury, which are naturally ranked by the magnitude of the radiation doses.

The specification of cancer sites in the definition of a Special Exposure Cohort is just as relevant as specifying the facilities, or job functions in the definition. The specified cancer sites are associated with the exposed organs that justify the designation of an *Exposure* cohort.

The concept that certain cancers are not likely in the absence of other disease or injury can be illustrated with an example. The Department of Energy's Office of Oversight Environment, Safety, and Health issued an assessment of the radiological hazards at the Paducah, Kentucky, gaseous diffusion plant in February 2000 (Phase II Independent Investigation of the Paducah Gaseous Diffusion Plant Environment, Safety, and Health Practices 1952 – 1990). The report cited that the transuranic element Neptunium-237 was present at Paducah from 1953 to 1957 without having been detected and that "The personnel exposure pathway of principal concern was the inhalation of particulate material contaminated with neptunium". The behavior and resulting dose from inhalation of neptunium is described in ICRP Publication 71 (Age-dependent Doses to Members of the Public from Intake of Radionuclides: Part 4 Inhalation Dose Coefficients; CD version)." Dose coefficients give the amount of dose to an organ per quantity intake and are given for 25 specific organs. Examining the dose coefficients (radiation dose per unit intake) for organ and tissue doses from inhalation of Neptunium-237 shows that the coefficients range by a factor of approximately 800 from the highest exposed organ, the bone surface, to the lowest exposed organs. One of the organs with the lowest radiation dose coefficient, which is associated with a high "natural" cancer rate, is the thyroid. In a group of workers exposed to Neptunium-237, what is the "likelihood" the neptunium would result in a thyroid cancer with no other cancers or disease symptoms? The radiation dose necessary to result in the EEOICPA definition of "more likely than not" (i.e., a 50% probability of causation (PC) at the 99% upper uncertainty level) for thyroid cancer depends on the specific conditions of work, age, and exposure. Calculations of PC, using the NIOSH-IREP for example, results in approximately 20 cSv or more required to reach the compensable level. However, there may be scenarios that would result in a lower radiation dose; so for demonstration purposes let's assume it would take 10 cSv to the thyroid to conclude the dose may have caused the thyroid cancer. The dose coefficients tell us that any intake, which was presumably unmonitored or not able to be estimated, that would deliver 10 cSv to the thyroid would also deliver approximately 8000 cSv to the bone surface, and approximately 200 cSv each to the red bone marrow, lungs, and liver. Probabilities of causation (PC's) for the radiation doses to these organs calculate to over 90% for each of them, with bone cancer having a PC greater than 99%. Based on this it can be concluded that it is very unlikely that an individual in a cohort exposed to unmonitored airborne concentrations of Neptunium-237 would contract thyroid cancer from this exposure before contracting bone cancer, leukemia, or liver cancer.

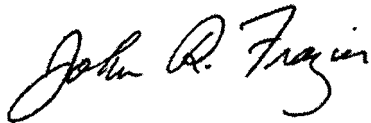
In conclusion, the current scientific knowledge allows us to answer the question whether it is likely a certain cancer can be caused by an exposure condition without the presence of other disease or injury for either an internal or external exposure scenario. This scientific knowledge should be used to specify the *exposure* part of a Special Exposure Cohort in order to ensure fairness.

Unfairness can occur if persons with exposures meeting the dose reconstruction criteria of 42CFR82, which disqualifies them for consideration as an SEC, have doses and diseases that are not compensable because the probability of causation does not establish "likelihood" while similarly exposed and diseased persons in an SEC are compensated. Additionally, payment of compensation for specified cancers that cannot meet the "likelihood" test of a 50% probability of causation is not consistent with consensus science.

The Health Physics Society understands and appreciates the societal impetus for the Energy Employees Occupational Illness Compensation Act of 2000 and strives to support the Act while maintaining sound science in public policy. 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, reading "John R. Frazier". The signature is written in a cursive style with a large, sweeping initial "J".

John R. Frazier, Ph.D., CHP
President