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From: john abbotts [abbotts@u.washington.edu]
Sent: Tuesday, December 04, 2001 4:27 PM
To: niocindocket@cdc.gov
Cc: bill griffith; timothy takaro
Subject: comments, guidelines for probability of causation



probcoms.doc

Dear NIOSH Docket Officers:

Please accept the attached Word file containing comments on the guidelines for determining causation under the Energy Employees Compensation Act

[RIN 0920-ZA01].

We are submitting these comments electronically to meet today's deadline for submission. We also plan to send via postal mail a paper copy, signed by Dr. Takaro, for the formal record.

We appreciate the opportunity to submit comments.

Yours truly,
John Abbotts

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This message from:

John Abbotts

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December 4, 2001

NIOSH Docket Office
Robert A. Taft Laboratories
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4676 Columbia Parkway
Cincinnati, OH 45226
email to: niocindocket@cdc.gov

Re: Comments on Guidelines for Determining the Probability of Causation Under the Energy
Employees Occupational Illness Compensation Program Act of 2000
RIN 0920-ZA01
Comments invited by 66 FR 50967, October 5, 2001

Dear NIOSH Docket Officers:

We appreciate the opportunity to comment on the subject proposed rulemaking. We also appreciate the Institute's practice of making applicable documents available through its web pages, which facilitates the ability to comment for persons geographically distant from Washington, D.C. Please accept the attached written comments; contributors to these comments are: Timothy Takaro, MD, MPH; William C Griffith, Ph.D; and John Abbotts, Ph.D. The commenters are faculty (T.T.) and staff affiliated with the University of Washington, whose research has been supported in part by DOE. However, responsibility for these comments lies with the contributors as individuals. The views expressed have not been endorsed by the University, the State of Washington, nor the Department of Energy. Please feel free to contact me at 206-616-7458 on any matter related to these comments.

Sincerely,

[original signed]
Timothy K. Takaro, M.D., MPH
University of Washington
4225 Roosevelt Way NE
Suite 100
Seattle, Washington 98105

Comments on Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000 (Compensation Act)
Comments invited by 66 FR 50967, October 5, 2001

We investigators and staff at the University of Washington have practical experience with the occupational hazards and health concerns of the Hanford workforce through work with the U.S. Department of Energy (DOE) Former Worker Medical Monitoring Program and other health related projects at DOE's Hanford site. Radiation risk is a paramount concern for these workers. With the enactment of the Compensation Act of 2000, there is a widespread expectation in this population that those with cancers "on the list" are likely to be compensated for their cancer through this Act. Based upon records of external dosimetry (PNNL databases REX and REMS) it seems likely that very few Hanford workers with cancer will qualify for compensation based upon the NIOSH Interactive Radio-Epidemiologic Program (IREP). This situation will produce significant dissatisfaction with the Program and the Federal response to former Secretary Richardson's admission that work hazards at USDOE facilities during the cold war harmed the workforce. The sense of injustice is further exacerbated by the Compensation Act's establishment of Special Exposure Cohorts (SECs). Similar to the situation with U.S. Atomic Veterans, members of SECs are not required to meet the strict radiation dose and causation components of the Compensation Act. HHS should address this problem by the active establishment of additional cohorts based upon the same criteria used for the SECs already defined.

Under the Compensation Act, employees meet requirements for the Special Exposure Cohort if they were exposed to ionizing radiation during designated times at specified gaseous diffusion plants, or as part of duties related to specified nuclear tests at Amchitka Island. The Compensation Act allows the Secretary of HHS to designate additional SEC classes, and the preamble to the proposed rule states that procedures for adding classes to the SEC are to be developed by HHS (66 FR 50968).

The SEC provision seems to establish a two-tier system for compensation: Once an employee is designated a member of the SEC, then compensation can be expected for specified cancers, contracted after beginning employment with DOE or a DOE contractor. For other energy employees, requirements appear more demanding: employee dose must be determined or reconstructed, and then the probability of causation must be established. It seems likely under this two-tier system that compensation will occur more frequently for workers designated as members of the Special Exposure Cohort. We recognize that HHS is constrained by the provisions of the law, but a likely outcome will be pressure on the Department to expand the Special Exposure Cohort.

If the compensation system is to be viewed as equitable, then the procedures for adding classes to the SEC should incorporate scientific criteria for causation no more stringent than those applicable to the SEC classes already designated by the Compensation Act. We note that studies sponsored and/or conducted by HHS/NIOSH could develop epidemiological data that may allow comparisons between the current SEC classes and cohorts at other sites across the DOE complex. The two-tier compensation system also suggests that the Department of Labor should maintain records on the frequency of compensation for workers applying under the SEC or non-SEC categories, and inform the Congress of any differences between those categories.

The compensation program should address all exposures during work for the USDOE that might have contributed to a cancer, e.g. nickel or chromium for lung cancer or trichloroethylene for liver cancer. While IREP reduces the radiation contribution in lung cancer for smoking, there is

no mechanism for increasing the risk from DOE work from non-radiation exposures. In most cases, this is an effect that is likely to be multiplicative because of differing biological mechanisms [Chekoway, Pierce, Crawford-Brown. Research Methods in Occupational Epidemiology. Oxford University Press, New York, pages 318-321, 1989]. Additionally, the smoking contribution to risk unfairly uses an additive model where most epidemiologists apply multiplicative models for smoking and radiation as discussed in detail by comments on this proposed regulation made by the Center to Protect Workers' Rights.

The current proposal is deficient in ignoring the difficulties faced by workers who have incomplete dose records (similar to the problems faced by SEC Amchitka Test Site workers). Particularly for sub-contractors and construction workers, important unexpected exposures occurred in non-routine operations. Many of these exposures are unrecorded. Some workers report removing their badges when entering radiation zones in order to avoid "burning out" their badge. In short, for many workers the DOE records of radiation exposure (much less records of other occupational carcinogen exposures) do not account for all of the risk faced by the worker. HHS could address these deficiencies by actively opening additional special cohorts to workers who can show they have work periods with likely exposure that are not a part of their dose record.

With regard to the details of the proposed rules, the calculation of the probability of causation is an involved model for which expert judgment must be applied in many steps. Based on the preamble to the proposed rules, it appears that a process of peer review will be used to review the assumptions made along the way. In order for this process to be equitable there should be a document describing the peer review process, including a description of how others can contribute to the peer review process.

The peer review process should not just include a review of the model and the method of calculation of the probability of causation, but should also include a review of how the model is applied to assure that it is being used in a correct and equitable manner. The criteria for compensation involve looking at the 99th percentile of the probability of causation. Using an extreme value such as the 99th percentile might mean that in the application of the program, most of the people being compensated would be those whose doses were the most uncertain and not those with the highest doses.