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Sent: Tuesday, December 04, 2001 2:59 PM
To: NIOSH Docket
Subject: Comments on Guidelines for determining causation under EEOICPA

comments on probability of cau...

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As recorded in Federal Register 66(194): 50967-50978 dated October 5, 2001, The Building and Construction Trades Department, AFL-CIO submits the attached comments on the Guidelines for Determining Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000.

The attached document is in a Word Perfect format. Please contact Trish Quinn at 301-495-8521 if there is a transmission problem.
Thank you.

COMMENTS ON

Notice of Proposed Rule Making

Guidelines for Determining Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000

Federal Register 66(194): 50967-50978, October 5, 2001

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Submitted via email to **NIOCINDOCKET@CDC.GOV**
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The Energy Employees Occupational Illness Compensation Program Act (EEOICPA) requires the promulgation of regulations to be used in determining if an individual energy employee's cancer was caused by radiation exposures experienced at DOE facilities. We commend NIOSH for its efforts to create a model which is sensitive to the difference between community exposures from atomic bombs and occupational exposures of workers, as well as its cautious application of the model to individual workers. At the same time, we believe there is room for improvement.

In its announcement, NIOSH invites comments on three main issues, which we will address below.

(1) Does the proposal 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?
(2) Does the proposal appropriately adapt compensation policy as it has been applied for the compensation of veterans with radiation exposure from atomic bombs to compensation policy for radiation-exposed nuclear weapons production workers?
(3) Does the proposal appropriately and adequately address the need to ensure procedures under this rule remain current with advances in radiation health research?

Appropriate Use of Current Science

NIOSH has applied a probability of causation (PC) model that is conceptually simple. Selected references which address the strengths and limitations of the probability of causation approach to compensation are listed at the end of this report. We commend NIOSH for many of the adjustments it has made to existing probability of causation models for radiation exposure. At the same time, there are a number of important limitations to this approach that are not addressed in the notice.

In many ways, NIOSH has created a design which can best be described as an oxymoron. One part of the oxymoron stems from the Act's requirement for an "all or nothing" approach to compensation with the threshold being a probability of causation (PC)of 50% or more. In other words, it must be "at least as likely as not" (50% or greater probability) that any individual's cancer is due to ionizing radiation exposures experienced in the performance of duty at nuclear weapons production programs.

The other part of the oxymoron is created by the conceptual approach proposed by NIOSH for determining PC. NIOSH proposes to apply the epidemiologic principle of attributable risk percent or etiologic fraction. The attributable risk model is, of course, designed to "assign shares" of risk (Legakos and Mosteller, 1986); yet NIOSH will use it to assign "all or none" of the risk. While NIOSH has taken precautions in light of this problem, it can lead to inequities in which we will address below.

In NIOSH's conceptual framework, epidemiologic data are used to determine the relative risk (RR) and the exposure-response pattern by type of radiation for any cancer site. Both the cancer relative risks and the estimates of exposure have substantial uncertainty associated with them; therefore, NIOSH will take these into account by use of the Interactive Radio Epidemiology Program (IREP) which incorporates uncertainty models. Compensation decisions are then based on the 99 percent confidence interval for the probability of causation, based on models of uncertainty. Use of the 99 percent upper confidence interval is appropriate. Likewise NIOSH proposes to add several additional cancer sites to those contained in the NIH radioepidemiological tables, which is another improvement intended to better consider exposures and risks faced by weapons facility workers.

Potential Inequities

We think an approach based on "assigned share" according to Lagakos and Mosteller (1986) may lead to more equitable compensation decisions where the probability of causation is substantial but less than 50%, which is the case for most radiation exposures.

As a minimum, NIOSH needs to fully document its PC decisions, including the extent to which it considered interactions of exposures, when finalizing its PC findings, and it should furnish this documentation to the claimant.

a. NIOSH's Model Ignores the Complexity of Mixed Exposures

Greenland (1999) points out that rate fraction, as listed in the NIOSH notice, will underestimate the probability of causation when an exposure accelerates the disease occurrence. The all-or-nothing approach based on a probability of causation of at least 50% also ignores the fact that many radiation exposures may be a "substantial contributing factor" in the cause of a given cancer while not achieving a probability of causation to 50% or more. Parascandola (1998) points to the inherent unfairness of the all-or-nothing approach for cancers where the exposure substantially increases the risk — although less than double.

We think this concern should be particularly great in the instance of applying the model to worker populations who are exposed to a large number of different agents which can interact in the carcinogenic process. The fact is that we know very little about the interaction of radiation and other exposures. The data on the population of bomb casualty survivors, which NIOSH relies on, provides no information on exposures other than radiation (and smoking). There is a lack of biological models on the interaction of radiation with other carcinogenic agents. Therefore, it is not possible to say whether a person's cancer might have been caused y the addition of the radiation exposure, even if the dose received was less than the 50% required by the model that NIOSH is applying.

b. NIOSH's Adjustment for Smoking in Lung Cancer is Unreasonable

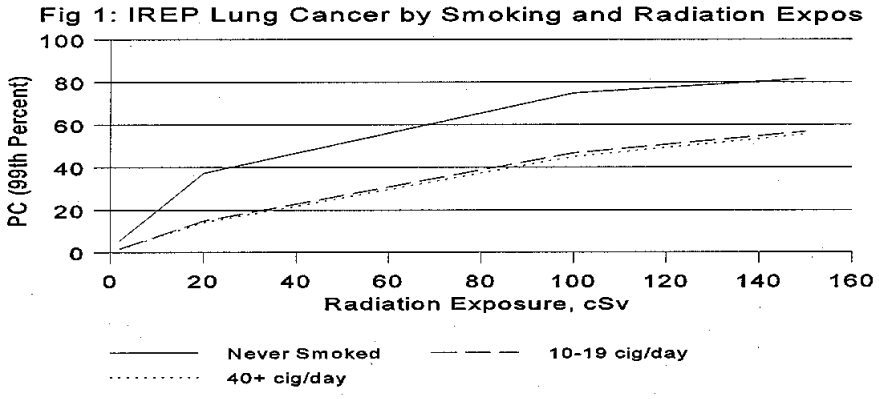
The lung cancer risk model and the proposed adjustment of the probability of causation for smoking presents yet another conceptual problem with the probability of causation approach. Under NIOSH's current model, a smoker would need to have 2-3 times more radiation exposure than a non-smoker to qualify for compensation. This suggests that smokers are significantly more resistant to the biological effects of radiation than non-smokers, but NIOSH does not present any data in support of such a finding; nor do such data exist in the published literature. Clearly, DOE did not deny smokers employment and the opportunity for radiation exposure; yet the net effect of this adjustment is to deny smokers an equal right to compensation for radiation exposure.

Only when radiation and smoking have a multiplicative joint effect would the simple probability of causation formula be correct (Checkoway et al., 1989). Since the biologically appropriate risk model for the combined effects of smoking and radiation exposure is not known, use of a multiplicative model would appear desirable. With a multiplicative model, the risk due to radiation exposure would not depend on smoking status (Checkoway et al., 1989), thus no adjustment for smoking would be needed.

We have performed some preliminary tests of the NIOSH IREP program to examine the effects of the proposed smoking adjustment for lung cancer. The default example worker in the draft IREP (male, date of birth 1950, exposure in 1970, and diagnosed with lung cancer in 1990) was tested using the lung cancer model, the general exposure scenario, and system default variances. Various combinations to smoking status and radiation exposure were run in the model (see Fig. 1).

These preliminary analyses suggest that the smoking adjustment in the IREP model for a worker currently smoking ½ to 1 pack per day is very close to that for a worker smoking more than 2 packs per day. A worker considered to be a moderate smoker (i.e. 10-19 cig/day) would require approximately 2.5 times the radiation exposure as a never smoker to achieve a probability of causation of 50% or more. This is an unreasonable penalty for smoking and would result in many workers not getting justly compensated.

This is a major issue for the construction work force. In the Hanford Building Trades Medical Screening Program, for instance, 76.4% of workers are current or former smokers. The adjustment for smoking would penalize these workers to the point where virtually none would receive compensation for lung cancer. It is not appropriate.



Adaption of Compensation Policy from Atomic Bomb Veterans

NIOSH has not documented why it is required to "adapt compensation policy as it has been applied for the compensation of veterans with radiation exposure from atomic bombs to compensation policy for radiation-exposed nuclear weapons production workers." We find no reference to such a requirement in the Act, or in the President's Executive Order, or in the DOL Interim Final Regulations.

Because this is a new policy, we are not prepared to comment on its appropriateness. We find it somewhat surprising, however, that NIOSH has made this decision, given its expertise in the area of occupational carcinogenesis. Clearly there are big differences in the types of exposures that workers experience and the types that veterans experience. We think workers are exposed to a

much larger number of carcinogenic agents, and at much higher doses, than the Veterans. Workers are also exposed under different policy circumstances. People who enroll in the uniformed services accept a number of risks that workers don't accept as part of a civilian employment contract, and as a result there are a number of policies that apply to uniformed services that do not generally apply to civilian employment (e.g. paid retirement after 20 years of service).

We think it is incumbent upon NIOSH (1) to show why it has concluded that there should be conformity with compensation policy for veterans; and (2) to describe the advantages and disadvantages of applying this policy to workers in the atomic weapons facilities.

Incorporating Advances in Science

NIOSH has anticipated a wide range of scientific improvements in its model and has provided for procedures to incorporate such improvements. In addition to the areas where new findings may arise we would add the important of new knowledge about biological models on the interactions of radiation with other workplace exposures.

Additional Comments

While NIOSH is asking for comments on this proposed rule by itself, it must be noted that this rule stands in a context with two other rules.

Radiation Dose Reconstruction

NIOSH has proposed methods for dose reconstruction (66FR194:50978). The PC model is only as useful as the data that are sued to determine risk. As long as dose ascertainment remains uncertain, the outcomes of PC will remain uncertain. We represent workers employed mostly intermittently on DOE sites, and when employed they are in the employment of sub-contractors. We have reason to believe that in many instances (perhaps the majority of our members) the dose records will be highly deficient for three reasons:

- There are no records or there are only partial records.
- The records that do exist are deficient.
- Subcontractor workers were frequently engaged in work with potential for very high peak, and relatively short-term exposures, and the likelihood of such exposures not being captured adequately in the dose record systems is very great.

For these reasons, we urge that NIOSH exercise a greater degree of caution than it might otherwise, in concluding that it is in possession of complete and accurate dose records on these workers.

DOL Interim Final Regulation

Claims will be adjudicated by DOL under its Interim Final Regulation (66FR102:28948). This gives rise to concerns about two areas of coordination which the NIOSH PC rule does not speak to.

a. Documentation of PC Finding

While DOL is ultimately responsible for making decisions about whether a claimant's illness was caused by radiation as defined in the Act, the NIOSH PC finding is a very important part of the DOL consideration. Yet, nowhere in the DOL rule nor in the NIOSH rule is there a clear statement about how NIOSH is to document the basis for its findings when it sends them to DOL. It is therefore uncertain, at best, whether there will be sufficient documentation presented to DOL so that a claimant may review and contest a NIOSH PC finding. As noted above, NIOSH's PC finding is in effect an "all or nothing" finding, and it will have a significant impact on the Final Adjudication of the claim. Therefore, we believe that NIOSH needs to set out clearly in this rule how it will document its PC findings, in such a way that the documentation can be used to fully evaluate the adequacy of the NIOSH PC finding.

NIOSH needs to add a section to the proposed regulation stating the kind of documentation it must include with its findings.

b. Reconsideration of Decisions in Light of New Science

NIOSH has made clear that there are many areas where future scientific knowledge may enhance its PC model, and has provided a framework for updating it in the future. Such updates could have an effect on compensation decisions that have already been made, and should therefore have retroactive effect.

However, under DOL's Interim Final Regulations for adjudicating claims (66FR102:28948) a final decision on a claim is generally not subject to reconsideration. This final decision appears to apply to claims for which NIOSH has provided the dose reconstruction. Clearly, if NIOSH obtains new scientific evidence, and modifies its models in such a way that it would affect PC findings made in the past, the claimants with such PC findings who had been denied compensation because of deficiencies in NIOSH's model, should be notified of this change, and be given an opportunity to having the claim reconsidered. This places a burden on NIOSH to maintain records of the individuals for whom PC findings have been made, in such a way that these individuals can be identified and notified in the future.

The proposed regulation should include a procedure for reconsidering claims in light of new science that impacts of PC decisions.

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