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Sent: Tuesday, May 06, 2003 4:23 PM

To: niocindocket@cdc.gov

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Subject: AFL-CIO Comments

Friends--Attached please find the AFL-CIO's Comments on NIOSH's Notice of Proposed Rulemaking for the Special Exposure Cohort--Rob McGarrah

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Larry Elliott
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Dear Mr. Elliott:

SUBJECT: COMMENTS ON PROCEDURES FOR DESIGNATING CLASSES OF EMPLOYEES AS MEMBERS OF THE SPECIAL EXPOSURE COHORT UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

The AFL-CIO submits the following comments on behalf of all of the men and women, and their surviving family members, who worked in the service of their country during the Cold War at Atomic Energy Commission and Department of Energy sites and facilities.

We recognize the difficulties presented to NIOSH in crafting rules for designating classes of employees as members of the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. There is, however, only one standard that must apply: the plain language of the statute enacted by the Congress.

Section 3 626 (b) of the statute directs that "the members of a class of employees at a Department of Energy facility may be treated as members of the Special Exposure Cohort for purposes of the compensation program if the President, upon recommendation of the Advisory Board on Radiation and Worker Health, determines that--

> (1) it is not feasible to estimate with sufficient accuracy the radiation dose that the class received; and
> (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class."

Nearly three years after Congress enacted the Energy Employees Occupational Injury Compensation Program, NIOSH is finally getting around to establishing a process for the Special Exposure Cohort. Paul Montoya, who worked for 31 years at Los Alamos, put it this way:

"The reason I am here [before the Advisory Board on Radiation and Worker Health] is because the compensation program intended to help us is not working...Everyone's got their hand in the cookie jar," and the people who deserve the money aren't getting it because the claims process is too complex, Montoya said."[1]

[1] Albuquerque Journal (New Mexico), October 17, 2002.

There are two basic problems with these proposed regulations: first, NIOSH is limiting the list of specified cancers and second, it has not defined its terms consistent with the statute and Congressional intent with respect to the Special Exposure Cohort.

Limiting the List of 22 Specified Cancers

In §83.12 (b) (1) (iv), NIOSH says that when it finds it is not feasible to estimate dose with sufficient accuracy, NIOSH will then "determine" whether such finding "is limited to radiation doses incurred at certain tissue-specific cancer sites." Likewise, in §83.13 (b) (2) (iii), NIOSH proposes to identify tissue specific cancers for which it was not feasible to estimate dose with sufficient accuracy. Further, in 83.13 (c) (4), NIOSH may, in its report to the petitioner and Board, limit specified cancers to "a set of one or more types of cancers specified by NIOSH."

The AFL-CIO strongly oppose NIOSH's proposal to limit the number of specified cancers in a given Special Exposure Cohort, and urges the deletion of such authority from the three sections outlined in the previous paragraph.

NIOSH has no legal authority to reduce or limit the 22 specified cancers designated by EEOICPA for any members of any Special Exposure Cohort, including both those designated by Congress or those designated by the Secretary of HHS pursuant to EEOICPA §3626.

Indeed, the legislative history clearly delineates Congressional intent that a "fixed list" of specified cancers would serve as the basis for compensation for members of a Special Exposure Cohort, and not a variable list drawn up on a case-by-case basis at the discretion of the agency.

As specifically stated by Senator Bingaman in the *Congressional Record* for October 12, 2000 (Page S10377):

> "Once a group of workers was placed in the category [i.e., the Special Exposure Cohort], it would be eligible for compensation for a fixed list of radiation-related cancers." (Emphasis added)

NIOSH, by its own admission, has given considerable emphasis to comments submitted by the Health Physics Society.[2] Indeed, the Health Physics Society argues that there is no cancer risk from radiation doses below 10 REM and urges this as a threshold for setting a cutoff. We are troubled that NIOSH would adopt a policy recommendation that is founded on a scientific theory—a 10 REM threshold theory--which neither NIOSH, HHS nor the Advisory Board has adopted. Indeed, "no threshold" approaches are used in the NIOSH-IREP model. (Linear no-threshold and the linear quadratic no-threshold).

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[2] The Health Physics Society counts among its affiliate members numerous companies, including, EG&G (Idaho National Labs, Rocky Flats, Mound and Nevada Test Site), Nuclear Fuel Services (Erwin), Texas Instruments (Attleboro, MA), Battelle Northwest (Hanford) that are and were DOE contractors. They have a special interest in minimizing the number of SEC and other claimants under the Act. For a list of members See: Health Physics Journal.

NIOSH bases its limitations by stating, "If NIOSH determines that it is not feasible to estimate radiation doses with sufficient accuracy, NIOSH will also determine whether such finding is limited to radiation doses at certain tissue-specific cancer sites, and hence limited to specific types of cancers."

While the concept that tissues differ in their sensitivity to radiation exposure and that some of this differential is related to the manner in which the radiation dose may or may not reach certain body tissues, the application of that principle to the Special Exposure Cohort is problematic. This scientific principle underlies the dose reconstruction and probability of causation procedures used for individual dose reconstruction. However, those claimants included in the special exposure cohorts will be individuals for whom dose cannot be reconstructed with sufficient accuracy and for whom the circumstances of their exposures may not be well described. Thus, it will often be very difficult to make any evaluation of their tissue specific doses necessary to make assumptions about which types of cancer should be included. Determining which cancers might be included and which ones should not may be very difficult and appear to be arbitrary.

It also appears that if enough information is available to determine that the tissue exposures are limited to only impact certain tissue types, often enough information should be known to complete a dose reconstruction for that individual.

Section 83.13: How will NIOSH evaluate petitions other than petitions by claimants covered under 83.14?

In section (b)(1)(i), the proposed rule states "Radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose that could have been incurred in plausible circumstances by any member of the class." The AFL-CIO has a number of concerns about this proposed approach.

This new gatekeeper criteria for Special Exposure Cohorts was apparently developed in response to comments submitted by the Health Physics Society in regards to the previous draft SEC regulations. In their comments, the Health Physics Society appropriately points out that health physicists rely on an estimate of the maximum radiation dose in order to protect exposed workers in situations where limited dose information is available and that often this estimate of maximum radiation dose is based on minimal information "about the source of radiation exposure and potential exposure conditions of the individual." The Health Physics Society also states that this so-called "upper bound" approach should permit the completion of a dose reconstruction for every individual claimant.

While the adoption of this approach by NIOSH has some merit, there are important limitations that must be recognized. The use of an "upper bound" for health protection purposes is usually done in a contemporaneous situation where the health physicist is attempting to estimate the "upper bound" based on their knowledge of the source and work situation. Dose reconstruction for this program is being done based on available historical records and recall.

Often the records go back over 50 years, and few (if any) individuals are available to recall the circumstances at the time of exposure.

The Congressional mandate for this program requires that the claimant be eligible for special exposure cohort status when it is not *feasible* to conduct a dose reconstruction with *sufficient accuracy*. Thus, it is not adequate just to be able to estimate an upper bound, but that upper bound or estimate of maximum dose must be evaluated for *sufficient accuracy* and for *feasibility*. NIOSH offers little guidance for either of those two parameters in the proposed regulation. Rather NIOSH proposes to rely on a case-by-case evaluation. While NIOSH may be correct that there is no simple method to evaluate sufficient accuracy or feasibility for these often complex dose reconstruction activities, a case by case approach risks the problem of significant inconsistencies in the way that different claims are adjudicated in this program. Moreover, in the absence of any guidance for this process, claimants may very well feel aggrieved or cheated by a process that appears arbitrary and is not transparent.

The claims in question are those where there will be very limited dose and process information and, therefore, will require the greatest degree of professional judgment on the part of the people conducting the dose reconstruction. For these professionals to perform these evaluations without guidance to a key question as to how *sufficiently accurate* the estimate of the maximum dose must be risks significant variability in the dose reconstruction activities for this group of cases.

Rather than rely just on a case-by-case approach, NIOSH should develop guidelines for dose reconstruction in these situations. For example, in the absence of individual dose records, NIOSH would utilize available source and work information to estimate the maximum dose for the claimant (not dissimilar to the current efficiency process). If that estimation process demonstrates a very low probability of causation and the NIOSH staff is certain that there were no other potential sources of radiation exposure, then that estimate of the maximum dose would suffice. However, on the other hand, if the estimate of the maximum dose was closer to 50% and there was uncertainty about other possible sources of radiation exposure in that work area and/or reasonable assumptions about the distribution of the dose around that estimate made a substantial difference in the calculated probability of causation, then NIOSH might determine that the dose could not be reconstructed with sufficient accuracy, and the claimant would be eligible for special exposure cohort status. Such a guidance document would indicate how different situations involving the availability of source and work information would be handled in evaluating these types of cases.

The use of the estimate of the maximum radiation dose for dose reconstruction as described here also conflicts with the proposed use of this value in the dose reconstruction regulations as an "efficiency" tool, at 42 CFR Part 82.10(k)(3). That part of the dose reconstruction rule states:

> "Worst case assumptions will be employed under condition 2 [which allows completing a dose reconstruction with worst case estimates] to limit further research and analysis only for claims

> which it is evident that further research and analysis will not produce a compensable level of radiation dose [a dose producing a P of C >50% or greater], because using worst case assumptions it can be determined that the employee could not have incurred a compensable level of radiation dose.

In the dose reconstruction rule, if the "efficiency" estimate of the maximum radiation dose is above 50% for the appropriate probability of causation calculation, then a more comprehensive and thorough dose reconstruction is attempted. Under that regulation, presumably if the dose reconstruction were not feasible to complete, then the case would be eligible for inclusion in the SEC.

According to these proposed regulations, for that same case, NIOSH would use the estimate of the maximum dose to calculate the probability of causation and presumably compensate the individual. Alternatively, NIOSH could determine under the dose reconstruction regulation that the dose reconstruction was not feasible to complete but the estimate of the maximum dose would not be used for calculating the probability of causation (this appears to be the approach intended in the dose reconstruction regulation). Then it is unclear where this claimant would fall – the claimant would not be eligible for the SEC but their claim would also be denied, and apparently they would not have any recourse to pursue a claim or cohort status.

Therefore, the AFL-CIO recommends that NIOSH reexamine the proposed approach to dose reconstruction and special exposure cohort designation and that guidelines addressing feasibility and sufficient accuracy be developed. These guidelines should be developed within a reasonable time period after the promulgation of the regulation and should be submitted to the Board for review. Appropriate changes should be made in the regulation to indicate the planned development of these guidelines and the process for their development. Appropriate changes in the dose reconstruction regulations should be made to address the potential conflict between the two sets of regulations that could leave some claimants ineligible for either individual dose reconstruction or special exposure cohort status.

Time Limits

In its comments on the initial proposed procedures for adding workers to the SEC, the AFL-CIO suggested NIOSH set a time limit for completing individual dose reconstruction. If dose could not be reconstructed within a certain time frame, the affected employee or group of employees should be added to the SEC on the ground that dose reconstruction is not feasible. In its revised proposal, NIOSH agrees in principle with this position, 68 ***Fed. Reg.*** 11296. Nevertheless, its revised procedures do not set any time limit because, NIOSH claims, the dose reconstruction process is just starting and it is too soon to impose time limits.

In 2000, Congress told employees seeking compensation for radiation-induced cancer that their claims would be processed expeditiously and that long delayed compensation finally would

be forthcoming. Three years have passed since Congress made that promise to DOE contract workers. Yet, in that time virtually no workers with cancer, other than those employed at gaseous diffusion plants, have received compensation. These delays are the direct result of the slow pace of NIOSH dose reconstructions. The proposed procedures effectively enshrine this slow pace into the program. By refusing to establish a time limit on individual dose reconstruction, NIOSH ensures that sick employees and their families will continue to bear the burden of delay. Enough time has passed for NIOSH to get its program up and running. The procedures should presume that inclusion in the SEC is appropriate because NIOSH cannot feasibly estimate radiation dose for any dose reconstruction not completed within six months from receipt of a claim (or in the case of pending applications, six months from the date of the final rules).

Section 83.5

NIOSH needs to correct the following errors in the definitions:

In section 83.5(c) NIOSH has defined facility as a singular term rather than plural (i.e., facilities) term. There are several reasons why this should be defined as a plural term.

i. A DOE site may contain many facilities and most construction workers are not limited to a single facility.
ii. Many DOE workers move from DOE site to DOE site. These may be the most heavily exposed workers, engaged in repair and maintenance, clean-up or decommissioning activities.
iii. In the Act, Congress accepted that SECs might span several DOE sites, as in the case of the Gaseous Diffusion Plants at Oak Ridge, Paducah and Portsmouth.
iv. Reasonable statutory construction does not require defining facility in singular terms. Cumulative exposure at various sites within the DOE Complex is a reasonable interpretation of the statute for the benefit of claimants, including those who were engaged in construction activities.

Sincerely,

Robert E. McGarrah, Jr.

Coordinator for Workers' Compensation