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From: PACE [paceport@zoomnet.net]
Sent: Wednesday, December 05, 2001 1:51 AM
To: NIOCINDOCKET@CDC.GOV
Subject: PC COMMENTS

Mr. Larry Elliott:

Attached are PACE comments. Hard copy will be provided.

Also, we will provide comments on the IREP model.

Also, I would be very interested in doing an alpha review of the internal dose program that Tony James et al are customizing for NIOSH.

Thanks very much,

Mark Griffon
PACE HP Consultant

PACE Comments on NIOSH Proposed Dose Reconstruction Regulations: 42 CFR Part 82: Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000

The Paper, Allied-Industrial, Chemical and Energy Workers International Union (PACE) represents 320,000 workers nationwide in oil, chemical, pulp, paper, auto parts and nuclear industries. We represent workers at eleven (11) Department of Energy sites in the nuclear complex and workers at a number of current and former beryllium and other atomic weapons suppliers. PACE also represents tens of thousands of former workers potentially affected by this proposed rule. The NIOSH Proposed Regulations on determination of the Probability of Causation will be critical in determining the outcome of cancer claims filed under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICP). Thus, PACE wants to ensure that workers or former workers who file claims for radiation-related cancers are afforded an accurate and comprehensive assessment of their risk. To this end we are providing the following comments regarding the proposed rule.

Response to questions under the "Comments Invited" section.

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?

We believe several revisions are needed with regard to current science and medicine including but not limited to the following:

a) The model should be modified to reflect the radiation exposure and disease experiences of workers covered under EEOICPA which differ from experiences of the Japanese atomic bomb survivor cohort. Specifically, the IREP model assumes an inverse relationship between age at exposure and sensitivity to radiation, in contrast to recent occupational epidemiological studies that indicate the opposite pattern of association.
b) We have concerns about the use of early bioassay data for the determination of the temporal distribution of dose since IREP requires annual doses. Early bioassay data sometimes is considered obsolete and insufficient by present day standards (18).
c) The Japanese Atomic Bomb Survivor study may not appropriately adjust for a healthy survivor effect which would result in biasing risk estimates toward the null.
d) We have concerns about incorporating modifications in the model without scientific review of the proposals. For example, the RBE distributions presented in Table 7 are referenced to an Internal Report (Kocher, October 2001). While the application of the RBE distributions may be appropriate we are concerned that the review was not adequate.
e) While there is a great deal of focus on the variation in effect estimates by specific radiation types (and energy ranges), there is little discussion about how this will be applied in practice to workers with limited historical radiation dosimetry records. This may present problems even for external radiation exposures since IREP models expect dose by energy range.
f) The model does not include several nuclides which were significant exposures at some DOE sites including protons and other accelerator produced particles.

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?

As was stated above we feel that the model should be modified to reflect the radiation exposure and disease experiences of workers covered under EEOICPA which differ from experiences of the Japanese atomic bomb survivor cohort. We are currently reviewing the model and comparing it to the previous 1985 NIH tables to see what effects the modifications in the approach have on the outcome and will provide more specific comments on the IREP-NIOSH computer model in the future.

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

While it is clear that NIOSH intends on keeping procedures current with advances in radiation health research we feel that NIOSH must establish a peer review process for "radiation health research" which will be used to modify the model.

Specific Comments on the Regulation:

1. Section 81.10 (Use of Cancer Risk Assessment Models in NIOSH IREP) should be modified to change the risk models in IREP to reflect the radiation exposure and disease experiences of workers covered under EEOICPA which differ from experiences of the Japanese atomic bomb survivor cohort.

The IREP Model, as modified by NIOSH, fails to account for the fact that worker epidemiology at Department of Energy nuclear weapons facilities indicates increasing sensitivity to ionizing radiation with age at exposure. These results contrast with the atomic bomb survivor cohort with respect to the age and sensitivity to ionizing radiation. NIOSH must modify the model for purposes of worker compensation.

The NCI Radioepidemiology tables and the NIOSH-IREP Model both assume an inverse relationship between age at exposure and sensitivity to radiation, in contrast to recent occupational epidemiological studies that indicate the opposite pattern of association. This trend in the IREP Model is derived from the atomic bomb survivor data, where data is used from Japanese survivors who were exposed from very young ages to old age. The young are especially vulnerable to ionizing radiation when compared with adults; consequently, the slope tends to the negative.

However, with respect to workers compensation, we are examining the variation in sensitivity to the effects of ionizing radiation only in adult ages (e.g., age 18+ years). Studies of U.S. radiation workers suggest that older adults are more vulnerable to the cancer causing effects of ionizing radiation than young adults (1). Several epidemiological studies (including worker studies) suggest that sensitivity to the carcinogenic effects of radiation may increase in adulthood with older ages at exposure (suggesting a non-linear trend in sensitivity across the lifespan) (2-6). This age-sensitivity relationship is indicated at studies at multiple nuclear facilities in Oak Ridge, Rocketdyne, Hanford, and encompasses all types of cancer. Moreover, most studies of other chemical and physical hazards find a similar pattern of increasing vulnerability to hazards in later life.(7-8)

2. In the alternative, Section 81.11 (Use of Uncertainty Analysis in NIOSH-IREP) must, at a minimum, establish a factor that accounts for the potential for increased sensitivity to radiation with increasing age at exposure for U.S. nuclear workers.

The evidence from the occupational cohort studies of US nuclear workers raises uncertainty, if not serious doubts, about the validity of transporting risk estimates from the Life Span Study (LSS) to US nuclear worker populations specifically with respect to variation in radiation effects with age at exposure.

Expert opinion and recommendations from David Richardson at the University of North Carolina call for the development of an adjustment factor to account for uncertainty in risk estimates with age at exposure to allow for the fact that there is greater radiosensitivity of nuclear workers to ionizing radiation at older ages of exposure. Epidemiologic literature for US nuclear workers should be used to provide basis for developing such an age sensitivity uncertainty factor for use in the IREP model.

3. The use of a DDREF of 2 in the NIOSH IREP model is not supported in the most recent literature and should be replaced with a DDREF of 1.

The NIOSH IREP model assumes that the effectiveness of radiation in causing cancers decreases at low doses (except for an uncertainty factor included by NIOSH for high LET exposures). For all other chronic exposures, the IREP model specifies a dose and dose-rate effectiveness factor (DDREF) with a value that is distributed around 2, even though analyses of the atomic bomb survivor data (which are the quantitative basis for these tables) suggest that there is no reduction in effectiveness at causing cancer at low doses (indicating a DDREF of 1). DDREF is defined in Section 81.4(b).

Epidemiological analyses of atomic bomb survivors do not support the conclusion that the dose-response relationship for solid cancers departs from linearity (that is, the atomic bomb survivor study does not support a DDREF greater than unity for solid cancers).(9, 10) Analyses of leukemia among atomic bomb survivors have been interpreted as supporting a DDREF greater than unity, although there is substantial uncertainty in estimates of the excess relative risk for leukemia in the low dose range of the Life Span Study (LSS) data; and, when broader groups of solid cancers are examined there is strong evidence of linearity. Evidence from studies of chromosomal damage and animal experimentation (often evaluating non-cancer outcomes) is of questionable relevance to radiation-induced cancer in humans. Epidemiological studies of populations other than the Japanese atomic bomb survivors offer minimal support for a DDREF greater than unity. Studies of breast cancers among tuberculosis patients who were exposed to multiple chest fluoroscopies, for example, have been considered in evaluations of the effect fractionation of low-LET radiation doses. There is no evidence in these studies of a reduction in breast cancer risk with protracted exposure.(11) Some have argued that a lack of a dose-related excess of lung cancer among tuberculosis patients suggests a DDREF greater than unity for that cause of death (12); however, necrosis and surgical removal of lung tissue among tuberculosis patients (related to risk of lung cancer and duration of treatment) precludes any clear interpretation of dose, or dose-rate, effects on lung cancer. (13)

NIOSH also assumes in its model that it will be able to estimate on an annual basis the amount of high LET dose and low LET dose and apply a different DDREF. First, historical data will not be available in many cases to separate high LET doses from low LET doses, because the radiation dose will be reported in Sv. Second, individuals will have internal doses of a combination of high and low LET radionuclides with various biological half lives, and it will be difficult, if not impossible, to assign values between high LET and low LET doses in these cases. Finally, there simply may not be data to determine whether individuals encountered certain exposures, such as the unmonitored neutron exposures (slow cooker effect) discovered by NIOSH at Portsmouth from "freeze ups" in the uranium enrichment cascade. In this case, what DDREF should be assigned, if the benefit of the doubt is to be given to workers.

Given the epidemiological findings of linearity in the atomic bomb survivor study, which is used as the quantitative basis for the risk estimates in these tables, there is little support for the decision to divide risk estimates by a factor of approximately 2 for purposes of compensation. Further, there is great practical difficulty in obtaining sufficient data to segregate high LET from low LET exposures. We therefore recommend that the DDREF should either be equal to 1.0, or follow a distribution centered around 1.0.

4. Clarification is needed with respect to whether the model has been corrected for a "healthy survivor effect" of the atomic bomb survivor cohort.

The model does not appear to account for underestimation of radiation dose response effect in the atomic bomb survivor Life San Study due to the healthy survivor effect. The GAP comments filed with NIOSH in June 2001 noted:

> "A number of recent studies have concluded that there is convincing evidence that mortality following the bombings of Hiroshima and Nagasaki left a select group of healthy survivors. These analyses of radiation effects clearly pertain to a highly select population. Furthermore, there is evidence that this selection was dose-related, such that people in the high dose categories were more select than people in lower dose categories. Overall mortality rates, for example, in the first 15 years after the bombing, are negatively associated with dose.(15) Such a pattern is consistent with a healthy survivor effect in the cohort, and would lead to a downward bias in radiation risk estimates.(16,17) "

Furthermore, A-bomb survivors' exposures to fallout and irradiated structures is an additional source of underestimation of dose-response in the LSS because these doses would have been relatively more important for distant survivors (with low flash doses) than for survivors closest to the hypocenter at the time of the bombing. We recommend that NIOSH develop and include a correction factor for these sources of bias and associated uncertainty, (14) as it appears that the rulemaking and IREP do not address these issues.

5. Section 81.5 (Use of Personal and Medical Information) Needs to Allow for Affidavits When Specific Medical Data is Not Available to Support a Claim

Certain medical data, particularly for survivor claims, is not going to be available to all claimants, because the covered worker's physician is no longer in practice, hospitals have closed, or records have been discarded because time frames for records retention have passed under state law. For this reason, NIOSH should specify (1) the minimum records required to run the IREP model; and (2) define which data can be supplied in affidavit form, as opposed to medical records, when such records are not available from any sources.

6. **Section 81.6 (Use of Radiation Dose Information) Needs to Define the Range of Uncertainty Distributions for Radiation Dose that Will be Used in Determining Probability of Causation. MARK TO REVIEW**

The Interim Draft Rule states that NIOSH will provide DOL with annual dose estimates for each year in which a dose was incurred, together with uncertainty distributions associated with each dose estimate. Please provide more prescriptive guidance in this rule with respect to the range of estimates that will be used in the IREP model. Specific guidance on the method for determining the appropriate distribution for a given dose estimate must be established by NIOSH. How will NIOSH determine if an individual annual dose estimate is "sufficiently accurate" for purposes of the Special Exposure Cohort clause of the statute.

7. **Section 81.4 (Definitions of Terms Used in this Rule)**

The Interim Draft Rule defines a covered employee imposes an added requirement beyond that prescribed by EEOICPA. It states: "For purposes of this rule, an individual who is or was an employee of DOE, a DOE contractor or subcontractor, and for whom DOL has requested HHS to perform a dose reconstruction."

The addition of the underlined text requiring DOL to require a dose reconstruction precludes the possibility that a claimant, on behalf of a covered employee, could request a dose reconstruction even though DOL fails to make such a request. Please clarify.

Section IIIA.(2) uses the phrase "certain individuals with cancer" but does not define it.

Citations to Comments of GAP

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