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January 17, 2002

VIA U.S. MAIL and E-MAIL

Larry Elliott
Director, Office of Compensation Analysis and Support
National Institute for Occupational Safety and Health
4676 Columbia Parkway
Cincinnati OH 45226

Dear Mr. Elliott:

The Government Accountability Project respectfully submits the attached comments to NIOSH's proposed rules "Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000" (42 CFR Part 82) and "Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000" (42 CFR Part 81). We send these additional comments on each of the aforementioned rules with the intention of supplementing and correcting the errors of our original comments. We are grateful for your decision to reopen the comment period and allowing us the opportunity to submit these additional comments.

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA) is groundbreaking legislation. EEOICPA reverses the Department of Energy's history of denying compensation to the men and women who suffered injuries at a result of their exposures in our nation's atomic weapons facilities. We are dedicated to ensure that the administration and execution of the EEOICPA reflects its full congressional intent. It is our hope that these comments are helpful in your deliberations and we look forward to working with you in the future. If you have any questions or comments feel free to call Richard Miller at (413) 536-3858 or Frank Morales at (202) 408-0034 ext. 128.

Sincerely,

Louis Clark,
Executive Director

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COMMENTS OF THE GOVERNMENT ACCOUNTABILITY PROJECT

ON

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' PROPOSED RULE

"GUIDELINES FOR DETERMINING THE PROBABILITY OF CAUSATION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000" (42 CFR PART 81)

JANUARY 17, 2002

I. INTRODUCTION

A. Overview of the Government Accountability Project

The Government Accountability Project ("GAP") is a non-profit law firm and public interest organization that represents the interests of workers who have suffered retaliation for raising concerns about illegal or unethical conduct in the workplace. We advocate on behalf of groups of workers interested in the enforcement of safety and health standards and specific acts of individual whistleblowing. GAP has a nearly thirty-year history defending workers who raise health and safety concerns, either to an enforcement agency or as part of filing a claim for compensation. GAP has developed a program to track, educate, and advocate on issues related to the implementation of the Energy Employees Occupational Illness Compensation Program Act of 2000 ("EEOICPA"). GAP's Washington, D.C. office is located at 1612 K. St, NW, Suite 400, Washington, D.C. 20006. We can also be reached via fax at (202) 408-9855 or e-mail at gap1@erols.com.

B. Statement of Purpose

The purpose of these comments is to address our concerns about the National Institution for Occupational Safety and Health ("NIOSH") proposed regulations "Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000" (42 CFR Part 81). The EEOICPA is an essential first step to ensuring that

the men and women who dedicated their lives to the defense of our nation during the Cold War are adequately and equitably compensated for the injuries they suffered during their employment in Department of Energy ("DOE") and Department of Energy contractor facilities.

Section 3623 (c) of the EEOICPA requires the promulgation of guidelines for the purpose of determining whether a cancer sustained in the performance of duty "was at least as likely as not related to employment." Specifically, the EEOICPA states that such guidelines must:

(1) "be based on the radiation dose received by the employee... at such facility and the upper 99 percent confidence interval of the probability of causation in the radioepidemiological tables published under section 7(b) of the Orphan Drug Act;
(2) incorporate the methods established under subsection (d); and
(3) take into consideration the type of cancer, past health-related activities (such as smoking), information on the risk of developing radiation-related cancer from workplace exposure, and other relevant factors."

The President issued Executive Order 13179 "Providing Compensation to America's Nuclear Weapons Workers," which delegated the authority under Section 3623 (c) to the Department of Health and Human Services, which in return delegated their responsibility to NIOSH. The Executive Order requires that NIOSH promulgate regulations establishing "guidelines, pursuant to section 3623(c) of the [EEOICPA], to assess the likelihood that an individual with cancer sustained the cancer in the performance of duty at a Department of Energy facility or an atomic weapons employer facility, as defined by the [EEOICPA]."

II. THE PROPOSED REGULATION "GUIDELINES FOR DETERMINING THE PROBABILITY OF CAUSATION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000" (42 CFR PART 81).

A. Section 81.10 Use of Cancer Risk Assessment Models in NIOSH IREP.

NIOSH should modify the risk models in Interactive Radioepidemiological Program ("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 increasing age at exposure. NIOSH must modify the model for purposes of worker compensation to correct assumption that sensitivity to radiation decreases with age.

The National Cancer Institute 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. The Japanese exposure group comprises a range of ages from the very young to the elderly. The young are especially vulnerable to ionizing radiation when compared with adults; consequently, the slope tends to the negative.

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).

B. Section 81.11 Use of Uncertainty Analysis in NIOSH-IRE.

In the alternative, to the above proposal, NIOSH 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 U.S. nuclear workers raises uncertainty, if not serious doubts, about the validity of transporting risk estimates from the Life Span Study (LSS) to U.S. 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. This adjustment factor would allow for the fact that there is greater radiosensitivity of nuclear workers to ionizing radiation at older ages of exposure. Epidemiological literature for U.S. nuclear workers should be used to provide basis for developing such an age sensitivity uncertainty factor for use in the IREP model.

C. 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).

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 with associated uncertainty (e.g, 90% confidence bounds at 0.67 – 1.50).

D. 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.

E. Section 81.5 Use of Personal and Medical Information

NIOSH 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.

F. Section 81.6 Use of Radiation Dose Information

NIOSH needs to define the range of uncertainty distributions for radiation dose that will be used in determining probability of causation.

The Interim Draft Rule states that NIOSH will provide the Department of Labor 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. Will uncertainty estimates be provided to 90%, 95% or 99% for annual radiation dose estimates? We note that the EEOICPA applies the upper 99% confidence interval for determining the probability of causation. We believe that the same criteria (upper 99% confidence interval) should be used for radiation dose estimates when running IREP, except where the error, on average, is 6-10 times greater than the mean estimate when calculating the committed effective dose equivalent. In these cases, the workers should be placed, by NIOSH, in the Special Exposure Cohort because it is evident that it is not feasible to estimate dose with sufficient accuracy.

G. Section 81.4 Definitions of Terms Used in this Rule

The Interim Draft Rule definition of 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 the DOL has requested HHS to perform a dose reconstruction.*"

The addition of the italicized text requiring DOL to request 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. NIOSH needs to clarify its position on this matter.

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