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From: Inga Olson [olsoning@yahoo.com]
Sent: Tuesday, December 04, 2001 6:24 PM
To: NIOCINDOCKET@CDC.GOV
Subject: EEOICPA: Probability of Causation comments



NIOSH.doc



Dose
Reconstruction2.doc

Attached find two documents: 1) comments on Probability of Causation due today, and 2) comments on dose reconstruction submitted earlier, but referenced in today's comments.

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December 4, 2001

NIOSH Docket Office
Robert A. Taft Laboratories; M/S C34
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NIOSH Docket Officer:

RE: Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000; Notice of Proposed Rulemaking

We appreciate the opportunity to provide input to NIOSH on the EEOICPA "Probability of Causation" guidelines on behalf of Tri-Valley CAREs (Communities Against a Radioactive Environment), an organization started in 1983 by a group of neighbors and laboratory workers of the Lawrence Livermore National Laboratory (LLNL). We have a Technical Assistance Grant from the Environmental Protection Agency and represent the community's point of view on cleanup issues at LLNL. In addition, we have been providing assistance to current and former Department of Energy (DOE) employees, contractors, and subcontractors in California who are applying for compensation under the EEOICPA.

SPECIFIC COMMENTS ON "PROBABILITY OF CAUSATION" GUIDELINES

These comments are based on our direct experience with DOE workers, former workers, and the communities surrounding DOE facilities. This information is generally organized around the three questions provided in the Department of Health and Human Services (HHS) Notice of Proposed Rulemaking.

(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?

Human epidemiological evidence combined with track analysis has shown, by reasonable standards of biomedical proof, that there is no threshold dose of ionizing radiation with respect to induction of mutations (Gofman 1990). The same conclusion was reached by Britain's National Radiological Protection Board (NRPB 1995, p.68). Subsequently, work at the Brookhaven National Lab confirmed experimentally with DNA tests that complex chromosomal and DNA injuries are inducible by a single primary track of low LET radiation (Sutherland 2000). Meanwhile, a study on x-ray-induced breast cancer conducted by the National Cancer Institute provided additional

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human epidemiological evidence against any threshold dose (Doody 2000), since the estimated x-ray dose per exam was only 0.6 rad or cGy – a dose which causes an average of only one primary ionization track per cell-nucleus. There is no lower dose, at the DNA level, than one track. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR 1993) also has contributed to work that disproves the belief that a safe dose of ionizing radiation exists. This is also upheld by the National Academy of Sciences BEIR V report. The research results cited above pose legitimate questions about the validity of the currently accepted estimates that certain worker (and community) radiation exposures are safe and whether the exposure levels that were monitored and recorded at DOE facilities were adequate. We would like to see this body of knowledge considered by NIOSH staff.

The studies also raise questions about accidents such as the 1965 and 1970 tritium accidents at LLNL that released cumulatively 650,000 curies of tritium. Dr. John Gofman, the former head and founder of LLNL's biomedical department, estimated in 1987 that there was enough radiation released in these accidents to cause 60 deaths and 120 cancers. One problem is the employees (or community members) exposed to these accidental releases would not have all worn film badges. Furthermore, because of tritium's half-life of 12 years, a good deal of it is still existent today. This is one example of why we recommend a broad variety of methods for gathering information to determine dose including but not limited to: a review of worker's records to determine which groups of workers were at risk of high internal exposures and/or high lifetime exposures, use of air monitoring data including determining source term composition where necessary, and by inferring internal dose exposures from urine and lung-counting data. Further, we would like to see an independent auditing and oversight committee established with a strong scientific foundation and public and stakeholder credibility to address dose reconstruction. We support the Government Accountability Project's (GAP) and other industry experts' recommendation that NIOSH aggregate internal and external dose into annual committed dose equivalents in the IREP model from the date of exposure through the diagnosis of the illness.

We are concerned the decision to divide the lung cancer radiation estimate approximately in half for all workers who ever smoked will disqualify employees suffering from radiation-induced cancer. Even though radiation is not necessarily the only cause contributing to cases of radiation-induced cancer, many workers' cancers would not occur in the absence of radiation.

In addition to radioactive hazards, it is clear from the nature of work done at nuclear weapons plants that many workers are exposed to or are at risk of exposure to non-radioactive hazardous materials such as acids, organic solvents, fluoroine and fluorides, and heavy metals. This information should be collected and included, where available, under "other relevant factors" for HHS to consider as further justification to compensate workers due to occupational illness.

(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?

Tri-Valley CAREs responded on October 31, 2001 to HHS's request for comments regarding "Dose Reconstruction." We will reiterate two key points that were made in more detail in that "Dose Reconstruction" document (which is attached for your convenience), and that also respond to question two above:

- 1) The bias built into the dose reconstruction tables that cancer risk decreases with age has been empirically rebuked, and the tables should be adjusted accordingly.
- 2) The dose and dose rate effectiveness factor (DDREF) should be 1 not 2.

Another point not made previously in the "Dose Reconstruction" document addresses the determination of what is a "reasonable" dose. We concur with the suggestion made by GAP in consultation with other experts that the IREP model should be modified to apply the upper 95% or 99% confidence interval of the dose estimate instead of the average (mean) dose. In addition, if the uncertainties are large (i.e., the 99% confidence interval is 6-10 times greater than the average), NIOSH could flag this claimant as a candidate for the special exposure cohort. This will prevent claimants from being denied compensation based on HHS' inability to estimate dose. Furthermore, we support utilizing special exposure cohorts for claimants with extremely rare cancers or other diseases, where their employment was clearly the most likely causal factor in contracting their disease.

Next, with reference to question #2, we wish to add some recommendations concerning policy issues related to workers' eligibility for this program:

1. Nuclear weapons production cannot take place without support staff. The employees of the nuclear laundries, i.e., the Interstate Nuclear Services in Pleasanton, CA are not eligible for the federal compensation payment and medical care. These employees should be made eligible.
2. Radiation does not stop at the fence line of the nuclear facility. Members of the community that surround DOE facilities who have been made ill due to toxic chemical and radiation releases should be eligible to apply for compensation under this program.
3. If a person is murdered, whether it be by knife or gun, the weapon is incidental to the deceased person or family members. Similarly, any hazardous substance, whether it

be radiation, metal, or toxic chemical, that causes the work-related illness or death of a nuclear employee, should be a part of this compensation program. Conversely, if radiation at work causes illness but not cancer, the illness should also be covered.

The two examples below suggest modifications are needed to the policy and method of notifying potential claimants.

1. We have been told by EEOICPA claimants, who receive retirement benefits from LLNL as a result of their deceased spouses' employment, that they were not notified by the Lab about the EEOICPA. They, fortunately, found out about it through other means. This indicates that there may be many people, with whom DOE nuclear facilities have a direct relationship as a result of retirement or other compensation matters, who have not submitted claims because they have not been informed about this Act.
2. We have been informed by the daughter of a LLNL employee who died of cancer that when her mother approached the Lab in the past to obtain her deceased husband's records because she believed his illness and death were work-related, she was told that employee's personnel files are shredded at death. Several other people who the employee worked with had also died of cancer and the families had initiated a legal action which they eventually abandoned because of their inability to obtain records. These people are unwilling to file an EEOICPA claim because they feel it is useless.

This evidence suggests that there needs to be more assurance in communications to potential claimants that their claims will be handled sympathetically, and unlike the past. It also suggests that communications to DOE employees or former employees should be handled by an agency other than DOE or accountability measures should be built into communications so that it will be certain that the entire potential pool of claimants are being notified appropriately.

Finally, rather than having compensation funds for this program compete with other funding needs, DOE should set aside federal funds to pay workers' claims. These funds should be in addition to those currently allocated to contracts, and DOE should seek supplemental appropriations for this purpose if necessary.

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

It is now evident that low-energy beta particles are considerably more mutagenic per rad or cGy of exposure than recognized in 1987 (Straume 1995; Gofman 1999) – perhaps by a factor of four or five. As new knowledge such as this about radiation-induced illness is

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understood, it is important to ensure that no statute of limitations prevents claimants from filing for compensation based on new information. Nor should a statute of limitation prevent an employee from filing a claim, if that claimant must wait for information to be declassified or for a delay due to filing for information under the Freedom of Information Act.

On a related matter, we believe it is important to proactively develop a procedure for a covered employee (or a member of his/her family) who was denied compensation after dose reconstruction to later be included as a member of a new special exposure cohort, if they meet requirements for inclusion. Also, a process needs to be created to evaluate and recommend expanding the special exposure cohort after receiving input from a petitioner or a recommendation from NIOSH.

A final issue we would like to address that is related to advances in radiation health research applies to the children and grandchildren of nuclear workers. In our work at Tri-Valley CAREs we are now beginning to see some children of nuclear workers who may have health problems associated with the occupational exposure of their parents. For this reason, we believe it is important to include language in the guidelines that takes into account health and genetic effects to children and grandchildren of nuclear workers.

ADDITIONAL COMMENTS ABOUT HHS TECHNICAL AND POLICYMAKING ROLES

HHS has a role in staffing the Advisory Board on Radiation and Worker Health. We are concerned that this Board may be compromised by appointing members who financially, politically, or in other ways have a conflict of interest in their relationship to DOE. We hope that this issue will be investigated and that members with such conflicts will not remain on the Board. Not only is avoiding conflict of interest issues paramount in the Act and Executive Order, but a balance among the members was also emphasized. We would like to see the preponderance of members from the medical and science fields vs engineering. We also believe it is very important to have a strong contingent of affected nuclear workers on the committee.

In addition, no individual or company should be placed in the position of reviewing, re-estimating or needing to critique her/his current or former dosimetry work. If there is a potential liability associated with radiation exposure or if the individual or company has been retained by DOE or its contractors to serve as experts in ongoing litigation that involves radiation, these individuals or companies should not receive contracts to perform dose estimates for NIOSH. These two recommendations involving conflict of interest, in our opinion, are consistent with the Federal Advisory Committee Act (FACA) and the written intention of the law as passed by Congress and stated in the Executive Order of the President.

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Finally, regarding HHS role with DOE in appointing physicians panels, we hope that you will support physicians panels use of a uniform standard to evaluate medical causality in order to determine whether it is as likely as not that a worker's medical condition was caused, aggravated, or accelerated by the worker's exposure to toxic substances at one or more DOE, contractor, or subcontractor facility.

Your time and consideration are greatly appreciated. We provide these thoughts in the spirit of cooperation and with a shared goal of providing a responsible program to DOE employees, former employees, and their survivors who have become ill or died as a result of their loyal and committed work in the nuclear weapons development industry for our country.

If you have questions or need more information, please call at 925-443-7148.

Respectfully,

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cc Senators Barbara Boxer and Dianne Feinstein
Representatives Ellen Tauscher, Barbara Lee, Fortney "Pete" Stark, Richard
Pombo, George Miller, and Robert Matsui
Secretary of Energy, Spencer Abraham
Deputy Secretary Robert G. Card
Acting Assistant Secretary Steven Cary

October 31, 2001

NIOSH Docket Office,
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National Institute of Occupational Safety and Health

Re: Tri-Valley CAREs comments on EEOICPA dose reconstruction

Tri-Valley CAREs (Communities Against a Radioactive Environment) was started in 1983 by a group of neighbors and laboratory workers of the Lawrence Livermore National Laboratory. We wish to submit the following information as part of the Department of Labor's (DOL) formal comment period regarding how dose reconstructions will be done.

We strongly advocate for the integration of stakeholder and worker input throughout all stages of dose reconstruction because conditions in and between facilities can vary so significantly, as can the interaction of radiation with the worker's body. Worker and stakeholder input can help to customize what is measured and how it is measured to ensure a higher level of dose reconstruction accuracy as opposed to standardized measurements based on inadequate data. For instance, worker input could describe how their exposure was due to carrying "hot" materials on their left side, yet their dose badges were always pinned to their right pocket and, therefore, may not have recorded the exposure.

We suggest that worker participation be coordinated through cooperation with the union(s) and by using both one-on-one interviews and open meetings. Workers should be able to provide an affidavit to NIOSH based on their knowledge and that is part of the administrative record. Where significant data gaps exist for an individual, we hope that NIOSH will group workers based on job categories, department or building information to assist in dose estimation. Air monitoring data, dose badge re-reading, neutron exposures, isotopes and ionizing radiations, radiation surveys, work practices, co-located worker exposure data should all be considered in reconstructing the dose.

Past DOE conflict of interest problems would be detrimental if they resurface in implementation of the current legislation. For that reason we recommend that individuals or companies not be placed in the position of reviewing, re-estimating or needing to

critique their current or former radiation dosimetry work. If there is a potential liability associated with radiation exposure or if the individual or company has been retained by
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the DOE or its contractors to serve as experts in ongoing litigation that involves radiation, these individuals or companies should not receive contracts to perform dose estimates for NIOSH.

The revised radioepidemiological tables and the supporting interactive computer program (IREP) should be modified to address weaknesses. The tables need to be tailored to better account for the experiences of workers in the nuclear weapons complex. We suggest tailoring tables to include results of epidemiological studies of workers so that the tables reflect low-dose exposures typically received over a working lifetime and internal exposure to alpha particles—the largest sources of radiation dose at many DOE sites.

There are assumptions built into the IREP model that need to be adjusted to truly reflect the atomic bomb survivor data and the conditions at DOE nuclear facilities. One assumption in the IREP model—the effectiveness of radiation at causing cancers decreases at low doses—needs to be changed. In the analyses of the atomic bomb survivor data—the quantitative basis for the tables—atomic bomb survivor data suggests that there is no reduction in effectiveness at causing solid cancers at low doses. In addition, the epidemiological tables are applied to workers who were exposed to alpha and neutron radiation typical at the DOE facilities, not just gamma radiation, which was typically the type of radiation exposure that atomic bomb survivors received. These incorrect assumptions cause the IREP model to be programmed with a dose and dose-rate effectiveness factor (DDREF) value that is distributed around 2 and which is too high for solid cancers.

National Research Council studies published in the National Academy Press in 1999 of exposure to alpha-radiation among miners suggest an inverse exposure rate effect (that is, radiation effects were of larger magnitude when doses were accrued at lower dose rates). Also, an International Agency Research on cancer study published in 2000 concluded that there is no evidence of a reduction in effectiveness of neutrons at low dose or low dose rates, and that effects may be larger for neutron doses accrued at lower rates.

A 1997 study by the National Council on Radiation Protection and Measurements suggests that the simple inflation of all doses by a fixed correction factor is an inadequate assumption about the distribution of measurement error. The study suggests that further investigation of measurement techniques for evaluating the contribution of the neutron component of dose in each city, and at varied distances, is needed to understand the error distribution.

The decision to divide the lung cancer radiation risk estimate approximately in half for all workers who ever smoked should be questioned. We recommend that NIOSH apply the

multiplicative approach for all cancers. The assumption that a multiplicative relative risk model is valid has been argued in much of the literature on radiation effects.

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Furthermore, the multiplicative model would give the benefit of the doubt to the claimant in a situation where there is scientific uncertainty

The assumption built into the current radioepidemiological tables is that the probability that an adult worker's cancer was caused by radiation tends to be lower for workers exposed at older ages than younger ages. Recent occupational epidemiological studies, however, indicate the opposite is true. Richardson and Hoffman report in the *Occupational Medicine: State of the Art Reviews 2001* that older adults are more vulnerable to the cancer causing effects of ionizing radiation than young adults. The work of Kaplan and Haan in the 1999 *Annual Review of Public Health* and the work of Cohen in *Cancer* published in 1994 find a similar pattern of increasing vulnerability in later life in most studies of other chemical and physical hazards.

We hope that the recommendations and suggestions above will influence how dose reconstruction will be done, the assumptions built into the radioepidemiological tables, and the IREP model. Without these revisions we believe that many sick nuclear workers will be denied compensation in direct conflict with the goals and objectives of the Energy Employees Occupational Injury Compensation Program Act.

We appreciate the opportunity to provide our comments.

Sincerely,

Marylia Kelley
Executive Director

MK:pao