Diana, Sherri A. (CDC/NIOSH/EID) (CTR)

From: Marvin Resnikoff
Sent: Thursday, November 08, 2001 11:04 AM
To: NIOSH Docket Office (CDC)
Subject: Comments on Proposed 42 CFR Parts 81 and 82
Attachments: HHS.doc

Dear Sir/Madam:
We wish to submit the attached comments on proposed rules 42 CFR Parts 81 and 82, guidelines for determining the probability of causation, and methods for radiation dose reconstruction, respectively. Questions can be addressed to Marvin Resnikoff, or sent to this email address.
Marvin Resnikoff

Comments on Regulations to implement the Energy Employees Compensation Program: Methods for Radiation Dose Reconstruction, and Guidelines for Determining the Probability of Causation

By
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Radioactive Waste Management Associates*
November 7, 2001

Since 1989, Radioactive Waste Management Associates has conducted dose reconstruction studies on behalf of plaintiffs in personal injury law cases. These cases involved disparate occupations such as uranium mining and milling, oil pipe cleaners, X-ray workers, lens polishers, and residents near a thorium processing plant and uranium mining and milling operations. In conducting this work, RWMA had to reconstruct radiation doses and estimate the likelihood that radiation caused cancer or genetic effects.

General Comments

In general, the methodology proposed by CDC/NIOSH is appropriate and errs on the side of the worker, but it places a high burden on the worker to prove his/her case. For certain occupations at certain facilities that were clearly at risk, CDC/NIOSH should be the party informing these past workers about the Energy Employees Compensation Program and sending compensation without any additional proof or effort on the worker's part. Where the basic data regarding air concentrations are lacking, the burden of proof should fall on CDC/NIOSH; CDC/NIOSH should prove that the work area was safe. As the proposed regulations are written, the burden is on workers to prove that he/she was injured, that is, that the work area was unsafe. Not having the basic data should not be a reason for denying compensation. Finally, for certain cancers and other diseases that are extremely rare, it is not clear why HHS should require workers to provide proof or should calculate radiation doses.

Specific Comments

Sec. 82.10 Dose Reconstruction Process

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If data are not available to assess internal and external doses, under the proposed regulations, this information will be passed to DOL who will deny compensation. This holds whether the former worker has been heavily exposed or not, just whether the basic data is available. This is unfair and a major defect in the proposed regulations. It is hard for us to imagine a situation where a rough approximation of radiation dose, at least a bounding dose, could not be calculated. This depends on the level of effort expended by NIOSH.

Occasionally, the necessary information may be classified, or the Freedom of Information Act office in the particular region may not release documents on a timely basis. It is not unusual for FOIA requesters, especially the Oak Ridge office, to wait 18 months before documents are released. Since these restrictions are imposed by the government, they should not work to the worker's disadvantage and loss of compensation. In cases upon which we have worked, if the defendant withholds information, they are penalized. Discovery must be unfettered.

Sec. 82.14 Information to be used

Under 82.14, NIOSH specifies the type of information that could be used in dose reconstructions. In addition to employment information, NIOSH will use worker monitoring data, internal monitoring data and monitoring program data. While the list of data is quite broad, except for employment information, none of this data may be available for some workers. In that case, rather than halt the evaluation process, we recommend that NIOSH borrow information from comparable work environments. E.g., if air concentrations at a specific uranium mine are not known, then air concentrations at another mine could be used, scaled according to radioactivity, and to tons per day. We mention air concentrations, because this parameter is the most difficult to determine (air volume samplers were not available in the early days) and may comprise the largest component of a worker's dose. If air concentrations for a specific work site are missing, NIOSH may have to investigate a comparable industrial process.

Further, all radionuclides in the air, including trace contaminants, must be identified and taken into account. E.g., radioactive particulates at the head end of gaseous diffusion plants where uranium is converted to hexafluoride form, may consist of uranium with trace concentrations of plutonium, neptunium and technetium. These trace concentrations are important for dose estimation.

We are concerned that NIOSH is only considering radioactive materials, using ICRP dose conversion factors. While we heartily approve of the use of ICRP-60, and encourage other federal agencies to follow NIOSH' lead, we encourage NIOSH to also include toxic

chemicals that are inhaled along with radioactive materials. If these toxic chemicals also induce cancer, the toxic chemical and radioactive risk should be added. How will the NIOSH-IREP software take this into account?

Some materials, such as uranium, pose a heavy metal risk in addition to a radioactive risk. This is not necessarily a cancer risk, but it is a health risk that should be compensated. In fact, for uranium, the heavy metal risk may be higher than the radioactive risk. The Nuclear Regulatory Commission assigns a more restrictive limit air concentration limit to uranium as a heavy metal than as a radioactive substance.

The toxic materials discussed above not only lead to cancer, but also to other diseases. For example, uranium as a heavy metal is related to health effects such as increased death rates due to the respiratory complications, kidney failure, and developmental and genetic effects. Other chemicals to which DOE workers were exposed may be related to many more diseases. Therefore, health effects other than cancer should also be taken into account for DOE workers and their estates. How will the NIOSH-IREP software take this into account?

Further, radiation is known to have hereditary effects. Hereditary effects are divided into effects *in utero*, which are health effects to the unborn due to irradiation of the pregnant mother, and genetic effects, which are effects of the offspring of a generation that received a radiation dose before the children were conceived. Genetic effects can be handed down many generations. The problem with these genetic effects is that they are very difficult to quantify, even though on a qualitative basis, we know that they exist. From this perspective, not only health effects in (ex)-DOE workers should be considered, but also health effects in their children and grandchildren. How will NIOSH compensate a worker or his estate for genetic effects?

81.10 Risk Assessment Models

The suggested changes to the risk models in IREP are welcomed. As more information is obtained from the study of Japanese bomb survivors, it is clear that statistically significant excess cancers are showing at lower dose levels. Further, recent data from Japan show that the dose rate effectiveness factor has been thoroughly discredited. This implies that the risk at lower dose rates and lower doses will generally be twice as great. We encourage NIOSH to review the latest RERF findings.

We remain concerned that NIOSH will take into account the role of non-radiation risk factors, such as smoking history, while also not taking into account toxic chemicals in the workplace that also give rise to cancer. In our view, the risk of developing specific

cancer from radioactive materials should be added to the risk of developing the same cancer from non-radioactive materials. This would be a balanced approach.

Further, the risk of developing non-cancer diseases should also be factored into the risk. How will the NIOSH-IREP software take this into account?