



National Institute for
Occupational Safety and Health
Centers for Disease Control
and Prevention (CDC)
200 Independence Avenue, SW
Washington, DC 20201

April 18, 2006

Donald G. Shalhoub, Esq.
Ombudsman for Part E of the Energy Employees
Occupational Illness Compensation Program Act
U.S. Department of Labor
200 Constitution Avenue, NW
Room N-2454
Washington, DC 20210

Dear Mr. Shalhoub:

This letter is in reference to your First Annual Report to Congress on Part E of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) amended, pursuant to 43 U.S.C. § 7385s-15(e) ("the Report"). In addition to documenting the number and types of complaints, grievances and requests for assistance received by your office, and assessing the most common difficulties encountered by claimants and potential claimants under Part E, the Report also raises several issues and comments related to U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH) activities under Part B of EEOICPA. NIOSH appreciates the opportunity to provide comments and clarification on Part B issues raised in the Report.

Section IV of the Report summarizes comments received regarding general statutory provisions of Part E. This Section indicates that two comments were received relative to Site Profiles developed by NIOSH to assist with completing radiation dose reconstructions under Part B. Section V of the Report summarizes comments received regarding the general regulatory provisions of Part E. This Section indicates that 28 comments were received concerning the dose reconstructions prepared by NIOSH for Part B claims.

In accordance with its responsibilities under EEOICPA, NIOSH has established through public rulemaking the scientific foundation that supports the adjudication of cancer-related claims. Radiation dose reconstruction is a scientific method used to estimate the radiation dose received by the specific organ(s) in which a worker developed cancer, particularly when radiation monitoring data are unavailable, incomplete, or of poor quality. Dose reconstruction is specifically called for by EEOICPA, 42 U.S.C. § 7384n(d), and is a widely-accepted technique used in the scientific community. NIOSH uses personal radiation exposure monitoring information whenever possible. This may include film badge readings, medical x-ray results, urine sample data and incident reports. If personal radiation exposure information

is lacking or incomplete, NIOSH may also use co-worker data, environmental exposure records, process records, technical documents, along with information obtained from interviews with workers or survivors to estimate radiation exposures.

To assist in completing dose reconstructions for a site, NIOSH frequently develops a Site Profile document for the site, a group of technical documents that describe the specific work site. Site Profile documents are regularly updated as information becomes available and used by health physicists to maintain consistency when completing dose reconstructions. Site Profile documents describe the physical characteristics of the site, the work processes employed, the types of material used, potential sources of radiation, and other details relevant to reconstructing radiation exposures at the facility.

Another type of technical document that NIOSH develops to assist in dose reconstruction is a Technical Information Bulletin (TIB), which contains information on specific technical issues or procedures for estimating radiation exposure. TIBs can add to or supplement Site Profile documents and may be site-specific or cover multiple sites. It is incorrect for the Report to state that either of these documents, site profiles or TIBs, are developed to “cover gaps” in claimants’ exposure histories.

EEOICPA specifically recognized that the process of estimating radiation doses would require dealing with uncertainties and limited data and thus required the program to establish methods for arriving at reasonable estimates of radiation dose in cases where employees were not monitored, were monitored inadequately, or whose records are missing or incomplete. In cases where radiation exposures in the workplace environment can not be fully characterized based on available data, default values based on reasonable scientific assumptions are used as substitutes. NIOSH addresses uncertainty about radiation dose levels by characterizing each annual dose estimate with a probability distribution that accounts for the uncertainty of the estimate. This information is used by DOL in the calculation of probability of causation. In this way, claimants receive the benefit of the doubt in cases where the actual radiation dose may have exceeded the best estimate calculated by NIOSH.

The Report states that claimants expressed concern about the use of Site Profile documents for dose reconstructions for “roving” workers. The concern expressed was that Site Profile documents covered only one portion of a facility and would thus result in unacceptably compromised dose reconstructions. However, a Site Profile document for a facility includes all information available to NIOSH that is relevant to dose reconstruction. If a worker moved throughout a facility and was not monitored at some or any of the locations, the dose reconstruction is completed assuming the worker consistently worked in the highest exposure area within the facility. This approach ensures that claimants receive the benefit of the doubt in cases where there is uncertainty.

The Report indicates that several claimants have suggested that the agency use a linear cancer risk model, such as the one outlined in the recent National Academy of Sciences study, rather

than a threshold model for demonstrating the effects of radiation. The cancer risk models used by NIOSH for dose reconstruction are and always have been linear models, not threshold models.

The Report indicates that some claimants expressed concerns related to the burden of retrieving employment and medical exposure records. To address this, DOL and NIOSH systematically collect employment and radiation exposure information from the Department of Energy (DOE), former employers and contractors, the Social Security Administration and other sources. Most of the information used by NIOSH in dose reconstruction is gathered from sources other than the claimants. Furthermore, the NIOSH records retrieval process often identifies additional employment history and relevant medical or incident information missing when a claim is provided to NIOSH by DOL. NIOSH provides all claimants *the opportunity* to participate in a voluntary interview and supply information potentially relevant to dose reconstruction. There is no penalty for not providing information and claimants are in no way required to provide any documents as part of the dose reconstruction process. Claimants are given the opportunity to verify that the information obtained and being used in the dose reconstruction is both accurate and complete to the best of their knowledge.

The Report indicated that commenters were concerned that employment at multiple covered facilities is not always reflected in the reports of dose reconstructions completed under Part B. There are two potential reasons for some employment history provided by claimants to not be included in the dose reconstruction estimate. This may occur if it is evident from a partial dose estimate (a limited dose reconstruction that may not include evaluating exposure from all covered facilities) that the estimated cumulative dose is sufficient to qualify the claimant for compensation. Use of this efficiency process by NIOSH completing dose reconstructions would account for the fact that employment at multiple covered facilities is not always reflected in dose reconstructions. Another reason that some claimed employment may not be included in NIOSH dose reconstructions is that DOL determines what is or is not covered employment; therefore, NIOSH can only include employment that has been verified by DOL. If there is new information that changes the covered employment determination, it is a matter that DOL and the claimant would have to correct. If DOL certifies other employment as being covered by the program, NIOSH would complete another dose reconstruction using the new information. This often occurs with multiple cancers as well, the coverage determinations by DOL being the basis of information used by NIOSH for dose reconstructions.

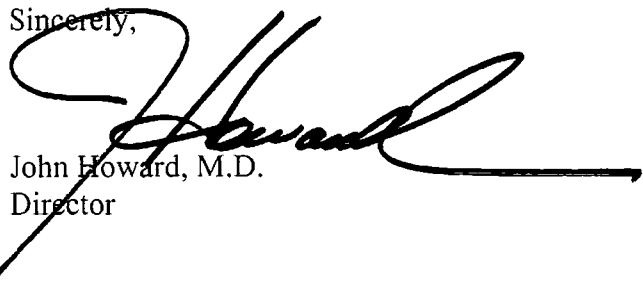
The Report indicated that claimants have expressed concerns that information claimants provided to NIOSH regarding work history is sometimes not accounted for in NIOSH dose reconstructions and that documentation used to conduct the dose reconstruction is not provided. This is an inaccurate perception. When NIOSH sends the final dose reconstruction report for to DOL for final adjudication, NIOSH also sends the input file for the NIOSH-Interactive RadioEpidemiological Program (IREP), any information used in developing the dose reconstruction, copies of all correspondence related to the claim, any radiation exposure information received from DOE, and the case file materials received from DOL.

Page 4 - Donald G. Shalhoub, Esq.

There also appears to be some confusion related to the OCAS-1 form provided with the draft dose reconstruction report. NIOSH sends the OCAS-1 form to all claimants before returning the case to DOL for decision. The form is not a waiver: signing the form does not mean that the claimant agrees with the results of the dose reconstruction. The purpose of signing the OCAS-1 form is to confirm that the claimant is not aware of additional relevant information to share with NIOSH at the time the form is signed. NIOSH does not send the completed dose reconstruction report to DOL for a final decision without the signed OCAS-1 form. It is strongly encouraged that claimants sign and return the form within 60 days of receiving it. According to the established procedures, if the form is not signed and returned within 60 days, and the claimant has not informed NIOSH that they have any additional information for dose reconstruction or need more time to gather such information, NIOSH may administratively close the dose reconstruction. This means the final dose reconstruction report will not be sent to DOL for adjudication. If the claimant provides new information or a signed OCAS-1, the dose reconstruction will be re-opened or submitted to DOL, respectively.

We hope the information and clarifications regarding Part B issues provided in this letter will be of assistance in evaluating the concerns expressed by Part E claimants in your report.

Sincerely,

A handwritten signature in black ink, appearing to read "Howard", with a long horizontal stroke extending to the right.

John Howard, M.D.
Director