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Sent: Sunday, November 04, 2001 9:58 PM
To: niocindocket@cdc.gov
Subject: Probability of Causation



Probability.doc

To Whom It May Concern: Comments on the probability of causation rule are attached.

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November 4, 2001

Re: Comments – Probability of Causation, 42 CFR Part 81 Federal Register Vol. 66, No. 194, October 5, 2001

To Whom It May Concern:

The purpose of this letter is to comment on the proposal implementing provisions of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).¹ The proposed rule establishes methods for determining whether an individual with cancer can be found, “at least as likely as not,” to have sustained the disease from exposure to ionizing radiation while employed at a Department of Energy (DOE) facility. The following comments are intended to address the generic question raised in the October 5, 2001, Federal Register notice, to wit:

- (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?

I. The following general comments address the process in Section 81.10 to assess the likelihood of disease caused by exposure to radiation.

The risk models used by the Department of Veterans Affairs to estimate the probability of causation are not analogous to occupational exposures. The data used by the Department of Veterans Affairs to make compensation decisions for veterans with cancer was based on exposure to radiation from atomic weapons detonations.²

¹ Public Law 106-398

² The data relied on by the Department of Veterans Affairs was based on cancer related deaths occurring among Japanese atomic bomb survivors from World War II. Federal Register, October 5, 2001, page 50968.

Without addressing the inherent medical and statistical variations, from the layman's point of view, exposure from an atomic explosion is significantly different than radiation exposure in the workplace. The most apparent differences are as follows: (1) A blast results in a single concentrated burst of radioactivity. A workplace exposure is more likely to vary in intensity and type over the period of employment. (2) A blast results in an external exposure to radiation, whereas a workplace exposure may be external, internal or both. Internal exposures may result from the ingestion, inhalation or absorption of radioactive materials in the work environment. (3) Occupational exposures to radiation continue over the period of employment, whereas the exposure to multiple detonations is unlikely.

The probability of causation guidelines state that changes will be made to adapt the Department of Veterans Affairs risk models to meet the needs of the Department of Labor. It is unclear how or when the models will be changed. Does this mean that claims will be evaluated on a variable "standard?" If claims are evaluated on a variable standard, the process is arbitrary and capricious.

II. Probability of causation determinations depend on the dose reconstruction process

The process described in Section 81.6 to estimate the probability of causation requires the use of the dose reconstruction estimates prepared by the National Institute of Occupational Health and Safety (NIOSH).³ Dose reconstruction should not be used, however, when the employer⁴ was required to maintain exposure records. Dose reconstruction should not be used to impute doses when actual exposure records are now missing or incomplete.

If DOE, DOE's predecessors (AEC) or a contractor failed to maintain radiation exposure records or cannot now produce the records,⁵ the burden of proof on the actual level of exposure should shift from the claimant to DOE. This is reasonable because exposure records were required at the time and only DOE has privity of contract to compel the contractors to produce records. This is particularly important because the exposures are likely to be higher in the 1950s and 1960s, the period for which the records are missing or incomplete.⁶

³ See, EEOICPA Section 3623(d) and "Methods of Dose Reconstruction, Federal Register, October 5, 2001, page 50978.

⁴ Atomic Energy Commission, Department of Energy, or contractor.

⁵ The testimony elicited at site based public meetings includes numerous accounts of incidents when employees were directed to remove film badges, dosimeters and other monitoring badges when performing certain tasks. INEEL meeting on July 31, 2001. The document archives establish that DOE was aware of the deficiencies in the record keeping of exposures. Also, releases from accidents such as the SL-1 incident establish catastrophic exposures of indefinite duration which could not be monitored with available instruments and were not documented. Furthermore, interviews contained in the Human Radiation Experiments Documents archive establish numerous incidents of undocumented exposures, incomplete record keeping by contractors and the military.

⁶ The comments to the interim rule acknowledge that in the early years, records were primarily maintained for research on the health effects of exposure to radiation. Federal Register, Vol. 66, No. 194, page 50979.

If, in the absence of actual records, dose reconstruction is relied on to make a claim determination, the survivor/claimant should be given an opportunity and the necessary resources to make an independent technical review and evaluation of the dose reconstruction. The process of dose reconstruction requires a level of technical knowledge and skills exceeding the ability of most, if not all, survivor/claimants. Section 3631 of EEOICPA requires that claimants be provided with the necessary assistance to develop facts pertinent to a claim.

The dose reconstruction process includes an interview process which may require the survivor/claimant to assemble personnel records, exposure records and medical records. Although a survivor/claimant will have some personal information⁷ regarding the deceased employee, she may not have medical records before the final illness. During the 1950s and 1960s, most employees were not given copies of exposure and medical records. Survivor/claimants may not have documentation regarding illness, injuries or medical conditions during the period of employment. No process exists for survivor/claimants to develop full occupational histories, medical records or exposure records. Section 3631 of EEOICPA requires that claimants be provided with necessary assistance to develop facts pertinent to a claim.

The employee's personal medical records during the period of employment may be no longer available due to the passage of time, lapse of records retention periods, or the death of a treating physician during the period of employment. A survivor/claimant may be required to assemble personnel records, exposure records and medical records through Freedom of Information Act (FOIA) requests to DOE. The survivor/claimant cannot, however, obtain information directly from a contractor without initiating legal action to facilitate discovery because FOIA does not apply to a corporate entity.

The process in the proposed dose reconstruction rule does not provide the survivor/claimant with any resources, assistance or support to:

1. identify any relevant information on medical history;
2. confirm or supplement radiation information and medical treatment and monitoring;
3. differentiate between external and internal exposures and exposure sources;

The survivor/claimant must be given meaningful assistance in compiling medical information during the period of employment or the "reconstruction" effort will be incomplete, insufficient and unfair. Because the rule on the determination of the probability of causation is dependent on dose reconstruction, it is deficient for the same reasons.

⁷ Date of birth, social security number diagnosis of final illness, date of death, certificate of death, etc.

Please contact me during regular business hours at 801-468-2655 if you have any questions or require additional information.

Sincerely

Craig W. Anderson