

NEW EVIDENCE

EXHIBIT K

FEDERAL REGISTER / VOL. 67, NO. 85, MAY 2, 2002 / RULES AND REGULATIONS - PAGE 22300-II. SUMMARY OF PUBLIC COMMENTS – B. COMPENSABILITY

Federal Register/Vol.67, No. 85, May 2, 2002 / Rules and Regulations – Page 22300-II. Summary of Public Comments – B... Compensability – This states in part: “Various comments relating to the use of these guidelines were received. Specifically, HHS received comments on: awarding compensation based upon a proportional level of probability of causation; the use of the upper 99 percent confidence limit to estimate probability of causation; awarding compensation for employees who incurred radiation doses within regulated radiation safety limits; automatically qualifying employees who incurred doses in excess of the maximum allowable radiation dose under Atomic Energy Commission regulations; waiving dose reconstruction and probability of causation for employees with rare cancers; and automatically compensating employees for whom DOE is unwilling or unable to provide employment records. The development and use of these guidelines for determining compensability and the benefit structure are statutorily mandated and therefore these comments were not adopted.”

According to Dose Reconstruction Overview of the NIOSH Report of Dose Reconstruction approved by NIOSH April 1, 2004 and sent to me in letter dated April 19, 2004 from Mr. Larry J. Elliott, “The Department of Labor (DOL) has verified that [redacted] worked at the Mathieson Chemical Company from 1949 through 1979 and

No dosimetry or bioassay records for [redacted] related to Mathieson Chemical’s work for the Atomic Energy Commission, one of the predecessor agencies of the present Department of Energy), could be found. Mathieson Chemical Company performed work for the AEC between 1951 and 1953. The primary source of information used for this dose reconstruction was the document “Technical Information Bulletin: Technical Basis for Estimating the Maximum Plausible Dose to Workers at Atomic Weapons Employer Facilities” prepared for the EEOICPA project.” No other records were provided. The absence of records and the lack of known activities clearly show that dose reconstruction is not feasible.

Attachment:

- (1) Federal Register / Vol. 67, No. 85, May 2, 2002 / Rules and Regulations – Page 22300-II.

An initial version of the NIOSH-IREP Operating Guide is available to the public online on the NIOSH homepage at: [www.cdc.gov/niosh/ocas/ocosirep/html](http://www.cdc.gov/niosh/ocas/ocosirep/html). The public can obtain printed copies by contacting NIOSH at its toll-free telephone information service: 1-800-35-NIOSH (1-800-356-4674).

## II. Summary of Public Comments

On October 5, 2001, HHS proposed guidelines for determining probability of causation under EEOICPA (42 CFR 81; see 66 FR 50967). HHS initially solicited public comments from October 5 to December 4, 2001. The public comment period was reopened subsequently from January 17, 2002 to January 23, 2002 for public comments, and from January 17, 2002 to February 6, 2002, for comments from the Advisory Board on Radiation and Worker Health (67 FR 2397).

HHS received comments from 12 organizations and 24 individuals. Organizations commenting included several labor unions representing DOE workers, a community based organization, an administrative office of the University of California, several DOE contractors, and several federal agencies. A summary of these comments and HHS responses is provided below. These are organized by general topical area.

### A. Appropriateness of Adopting Compensation Policy Used for Atomic Veterans

One commenter requested explanation of the appropriateness of adapting existing compensation policy for atomic veterans to a compensation program for nuclear weapons workers. The comment appears to question whether this existing policy for atomic veterans is an appropriate starting point from which to develop compensation policy under EEOICPA. In the notice of proposed rulemaking, HHS had solicited public comment on whether it had appropriately adapted compensation policy for atomic veterans to meet the needs of this workforce, which has a substantially different occupational and radiation exposure experience.

Congress determined the veteran's compensation policy as a starting point for HHS. It did so by requiring the determination of probability of causation based on radiation doses and the use of the NIH Radioepidemiological Tables, and by requiring that the cancer covered in a claim be determined to be "at least as likely as not" caused by radiation doses incurred in the performance of duty, based on the upper 99 percent credibility limit. These are

defining features of compensation policy for atomic veterans.

The public should also recognize that the Radioepidemiological Tables required years to initially develop and then additional years to update (the update is not completed). Without this critical, highly sophisticated element developed for the veterans' program, it would not have been possible to establish and implement a policy for nuclear weapons workers in a timely fashion.

HHS adapted these policies for nuclear weapons workers through two prominent measures, discussed in the notice of proposed rulemaking and below. HHS included provisions to allow NIOSH to adapt the cancer risk models in the latest version of the NIH Radioepidemiological Tables to reflect the unique radiation exposure experience of nuclear weapons workers. And HHS established transparent, objective procedures for DOL to handle a variety of circumstances in which various information relevant to determining probability of causation will be unknown. The majority of comments received on this rule suggest most commenters view as appropriate the measures HHS has taken to adapt existing compensation policy to this new program.

### B. Compensability

Various comments relating to the use of these guidelines were received. Specifically, HHS received comments on: awarding compensation based upon a proportional level of probability of causation; the use of the upper 99 percent confidence limit to estimate probability of causation; awarding compensation for employees who incurred radiation doses within regulated radiation safety limits; automatically qualifying employees who incurred doses in excess of the maximum allowable radiation dose under Atomic Energy Commission regulations; waiving dose reconstruction and probability of causation for employees with rare cancers; and automatically compensating employees for whom DOE is unwilling or unable to provide employment records.

The development and use of these guidelines for determining compensability and the benefit structure are statutorily mandated and therefore these comments were not adopted.

One commenter suggested prohibiting the use of probability of causation findings as proof of fault in litigation. This suggestion was not adopted because prohibiting the use of probability of causation findings for litigation purposes is not authorized by

the statute. However, because these findings will be based on NIOSH dose reconstructions, which will not always produce complete or best estimates of the actual doses received by an individual,<sup>14</sup> HHS does not believe these findings should be used for any purpose other than the adjudication of claims under EEOICPA.

### C. Need for Peer Review

Several commenters recommended that HHS obtain peer review of the cancer risk models that comprise NIOSH-IREP, and of changes to NIOSH-IREP, as it is updated based on progress in the underlying sciences. Several commenters recognized that the Advisory Board on Radiation and Worker Health is intended by HHS as one means of obtaining such peer review, but the commenters raised concerns about whether the Board would have sufficient expertise for this purpose.

HHS recognizes the importance of peer review. Consequently, as indicated above, the National Cancer Institute obtained peer review of IREP by the National Research Council. NCI and NIOSH have made modifications in IREP consistent with this peer review. NIOSH has also obtained peer-review by independent subject matter experts of changes developed by NIOSH to adapt IREP to the experience of nuclear weapons workers. These peer-reviews are posted on the NIOSH website and are also available to the public by request.

In addition, the Advisory Board on Radiation and Worker Health will be reviewing the cancer risk models in NIOSH-IREP, as indicated above and in the notice of proposed rulemaking. Contrary to the public comments noted above, HHS finds the Board has appropriate expertise for such a review, including eminent physicians and scientists from the field of health physics. Moreover, the Board maintains the option to commission additional independent scientists to participate in the Board's review. HHS also has the option to obtain additional peer reviews by the National Academy of Sciences, as recommended by some commenters.

In response to comments recommending peer review and to the recommendations of the Advisory Board on Radiation and Worker Health discussed below, HHS has added a new requirement to this rule to affirm the commitment of HHS to involve the

<sup>14</sup> For explanation of these possible limitations of NIOSH dose reconstructions, see the discussion under "II. Summary of Public Comments: A. Purpose of the Rule" in the preamble of 42 CFR Part 82 (the HHS dose reconstruction rule).