GUIDELINES FOR DETERMINING THE PROBABILITY OF CAUSATION UNDER THE U.S. ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

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Abstract

This paper presents the probability of causation guidelines [1] implemented under select provisions of the Energy Employees Occupational Illness Compensation Program Act of 2000 ("EEOICPA" or "Act") [2]. These guidelines are used to determine whether an individual with cancer shall be found, "at least as likely as not," to have sustained that cancer from exposure to ionizing radiation in the performance of duty for nuclear weapons production programs of the U.S. Department of Energy (DOE) and its predecessor agencies. These guidelines were developed by the U.S. Department of Health and Human Services' (HHS) National Institute for Occupational Safety and Health (NIOSH) and are applied by the U.S. Department of Labor (DOL), which is responsible for determining whether to award compensation to individuals seeking federal compensation under the Act.

1. Background

Under EEOICPA, a covered employee with cancer is eligible for compensation only if DOL determines that the cancer was "at least as likely as not" (a 50% or greater probability) caused by radiation doses incurred in the line of duty while working for DOE and/or an Atomic Weapons Employer. The HHS, NIOSH guidelines on probability of causation provide DOL with the procedure to make these determinations, and specify the information DOL will use. EEOICPA required the guidelines be based on the radiation dose received by the employee, incorporating dose reconstruction methods established by HHS, NIOSH and performed by NIOSH. Also, risk determinations were required to be based on the upper 99 percent "confidence interval" (credibility limit) of the probability of causation found in radioepidemiological tables published under section 7(b) of the Orphan Drug Act, and as such tables may be updated.

2. Discussion

Probability of causation as used in compensation programs is defined as an estimate of the probability or likelihood that the illness of an individual member of an exposed group was caused by the health hazard. Other terms for this concept include "assigned share" and "attributable risk percent." For these guidelines, the potential hazard is ionizing radiation to which U.S. nuclear weapons workers were exposed in the line of duty; the illnesses are specific types of cancer. The probability of causation (PC) is calculated as the risk of cancer attributable to radiation exposure (RadRisk) divided by the sum of the baseline risk of cancer to the general population (BasRisk) plus the risk attributable to the radiation exposure, then multiplied by 100 percent, as follows:

$$\frac{RadRisk}{RadRisk + BasRisk} x100\% \; = PC$$

This calculation provides a percentage estimate between 0 and 100 percent, where 0 would mean 0 likelihood that radiation caused the cancer and 100 would mean 100 percent probability that radiation caused the cancer.

In 1985, the U.S. National Institutes of Health developed a set of radioepidemiological tables [3]. The tables serve as a reference tool providing probability of causation estimates for individuals with cancer who were exposed to ionizing radiation. Use of the tables requires information about the person's radiation dose, gender, age of exposure, date of cancer diagnosis and other relevant factors. The tables have been used by the U.S. Department of Veterans Affairs (DVA) to make compensation decisions for veterans with cancer who were exposed in the line of duty to radiation from atomic weapon detonations. The primary source of data for the 1985 tables is research on cancer-related deaths occurring among Japanese atomic bomb survivors from World War II. The 1985 tables have been updated by the National Cancer Institute (NCI) and the Centres for Disease Control and Prevention to incorporate progress in research on the relationship between radiation and cancer risk as applicable for use in the DVA compensation program [4]. NIOSH has incorporated further modifications which are applicable for use of the radioepidemiological tables under EEOICPA [5].

A major scientific change achieved by these updates is the use of risk models developed from data on the occurrence of cancers (cases of illness) rather than the occurrence of cancer deaths among Japanese atomic bomb survivors. The risk models are further improved by being based on more current data as well. Many more cancers have been modelled in the revised radioepidemiological tables. The new risk models also take into account factors that modify the effect of radiation on cancer, related to the type of radiation dose, the amount of dose, and the timing of the dose.

A major technological change accompanying this update, which represents both a scientific and a practical improvement, is the production of a computer program for calculating probability of causation. This computer program, named the *Interactive RadioEpidemiological Program* (IREP), allows the user to apply the risk models directly to data on an individual employee. This makes it possible to calculate probability of causation using better quantitative methods than could be incorporated into printed tables. In particular, IREP allows the user to take into account uncertainty concerning the information being used to calculate probability of causation. There typically is uncertainty about the radiation dose levels to which a person has been exposed, as well as uncertainty in the science relating levels of dose received to levels of cancer risk observed in study populations. Accounting for uncertainty is important because it can have a large effect on the probability of causation estimates. The HHS, NIOSH guidelines and the NIOSH-IREP, as required by EEOICPA, use the upper 99 percent credibility limit to determine whether the cancers of employees are at least as likely as not caused by their radiation doses. This minimizes the possibility of denying compensation to claimants under EEOICPA for those employees with cancers likely to have been caused by radiation exposures.

The risk models developed by NCI and CDC for the NCI-IREP provide the primary basis for developing guidelines for estimating probability of causation under EEOICPA. They directly address 33 cancers and most types of radiation exposure relevant to employees covered by EEOICPA. These models take into account the employee's cancer type, year of birth, year of cancer diagnosis, and exposure information such as years of exposure, as well as the dose received from gamma radiation, x rays, alpha radiation, beta radiation, and neutrons during each year. The risk model for lung cancer takes into account smoking history as well. None of the risk models explicitly accounts for exposure to other occupational, environmental, or dietary carcinogens. It was not feasible to develop models accounting for these factors due to limited information from existing research studies. Moreover, HHS and DOL could not consistently or efficiently obtain the data required to make use of such models.

IREP models do not specifically include cancers as defined in their early stages: carcinoma in situ (CIS). These lesions are becoming more frequently diagnosed, as the use of cancer screening tools, such as mammography, have increased in the general population. The risk factors and treatment for CIS are frequently similar to those for malignant neoplasms, and, while controversial, there is growing evidence that CIS represents the earliest detectable phase of malignancy. Therefore, for determining compensation under EEOICPA, CIS will be treated as a malignant neoplasm of the specified site.

Cancers identified by their secondary sites (sites to which a malignant cancer has spread), when the primary site is unknown, raise another issue for the application of IREP. This situation will most commonly arise when death certificate information is the primary source of a cancer diagnosis. It is accepted in medicine that cancer-causing agents such as ionizing radiation produce primary cancers. This means, in a case in which the primary site of cancer is unknown, the primary site must be established by inference to estimate probability of causation.

HHS has established such assignments in these guidelines, based on an evaluation of the relationship between primary and secondary cancer sites using the National Centre for Health Statistics (NCHS) Mortality Database for years 1995-1997. Because national cancer incidence databases (e.g., the National Cancer Institute's Surveillance, Epidemiology and End Results program) do not contain information about sites of metastasis, the NCHS database is the best available data source at this time to assign the primary site(s) most likely to have caused the spread of cancer to a known secondary site. For each secondary cancer, the set of primary cancers producing approximately 75% of that secondary cancer among the U.S. population was identified (males and females were considered separately). The final assignment of a primary cancer site for an individual claim will be determined by DOL on a case-by-case basis, as the site among possible primary sites which results in the highest probability of causation estimate.

Claimants diagnosed with two or more primary cancers also raise a special issue for determining probability of causation. Even under the assumption that the biological mechanisms by which each cancer is caused are unrelated, uncertainty estimates about the level of radiation delivered to each cancer site will be related. The consequence has simple but important implications; instead of determining the probability that each cancer was caused by radiation, DOL performs an additional statistical procedure using IREP to determine the probability of causation for each cancer and then the probability for both cancers combined. This will be important to the claimant because it will determine a higher probability of causation than would be determined for either cancer individually.

Some employees covered by EEOICPA were substantially exposed to radon and other sources of high linear energy transfer (LET) radiation. This type of radiation exposure has unique properties affecting cancer risk, specifically an inverse dose-rate effect for high-LET radiation exposures. This effect means at any particular dose level, especially higher dose levels, a dose of high LET radiation incurred gradually over time is more likely to cause cancer than the same total dose incurred quickly or at once. A substantial body of research supports this finding, including studies of uranium miners, patients exposed to bone-seeking radium alpha particles, and research on the cancer effects of high LET radiation in animals. Because high-LET radiation is an important type of radiation exposure among employees covered by EEOICPA, NIOSH has modified IREP to include uncertainty associated with the assumption of an inverse dose-rate effect for these exposures. Also, using epidemiologic evidence on the lung carcinogenicity of radon exposures, a lung cancer model for radon exposures is incorporated into the NIOSH-IREP. The data source for this model is the analysis conducted by the federal Radiation Exposure Compensation Act Committee.

The DOE workforce has also been exposed to various types of neutron energies, which is frequently documented in the worker's dosimetry records. The relative biological effectiveness (RBE) of radiation exposure, a factor in cancer risk models that accounts for the differing level of cancer risk associated with different forms of radiation, varies as a function of neutron energy. This variation in RBE related to differing neutron energy is accounted for in the NIOSH version of IREP.

References

[1] "Probability of Causation Guidelines Under the Energy Employees Occupational Illness Compensation Program Act of 2000" proposed for promulgation at 42 CFR 81 (66 FR 50967), October 5, (2001).

[2] The Energy Employees Occupational Illness Compensation Program Act, Public Law 106-398, 114 Stat. 1654, 1654A-1231 (October 30, 2000), enacted as Title XXXVI of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001.

[3] National Institutes of Health (NIH). Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables. NIH Publication No. 85-2748. (1985) 355 pp.

[4] National Cancer Institute (NCI). Draft Report of the NCI-CDC Working Group to Revise the 1985 NIH Radioepidemiological Tables (2000).

[5] NIOSH-Interactive RadioEpidemiological Program Documentation - DRAFT, DHHS, National Institute for Occupational Safety and Health, Cincinnati, Ohio (2001) 63 pp.