UNITED STATES ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM: ADJUDICATION OF RADIATION-RELATED CANCER CLAIMS UTILIZING DOSE RECONSTRUCTION AND PROBABILITY OF CAUSATION PROCEDURES.

L. J. Elliott, T. Katz, J. Neton, M. Schubauer-Berigan

The National Institute for Occupational Safety and Health (NIOSH), United States of America e-mail <u>liel@cdc.gov</u>.

Abstract

The United States (U.S.) nuclear weapons production workforce has recently been provided a compensation program, which covers claims concerning radiation-related cancer as determined by individual dose reconstruction and probability of causation guidelines. This paper provides information on the background, purpose, and implementation philosophy of this new compensation program. Companion papers describing the probability of causation and dose reconstruction guidelines for this program have also been submitted to the Conference.

1. Background

In October 2000 the United States' Congress passed the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), P.L. 106-398 §§ 3623(b) and (d-e) ¹. On December 7, 2000, the President issued E.O. 13179 assigning several policymaking and technical roles under EEOICPA to the U.S. Department of Health and Human Services (HHS), including promulgation of two regulations central to the adjudication of cancer-related claims.²

The first of these rules, 42 CFR Part 81, establishes guidelines 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.³ These "probability of causation" guidelines will be used for the adjudication of cancer claims by the U.S. Department of Labor (DOL), which has lead responsibility to administer this federal compensation program.

The second of these rules, 42 CFR Part 82, establishes the methods by which HHS will estimate the doses of radiation incurred by individual employees of nuclear weapons production programs. These methods of "dose reconstruction" will be used by the National Institute for Occupational Safety and Health (NIOSH), Centres for Disease Control and Prevention (CDC). NIOSH is named under EEOICPA to assist the Secretary of HHS to implement his responsibilities under the Act. NIOSH will provide the dose reconstruction results to claimants and to DOL, which will use the results to determine probability of causation. DOL, which has promulgated its administrative procedures under EEOICPA, will use the HHS regulation on probability of causation and the NIOSH generated dose reconstructions to adjudicate an estimated 40,000-50,000 cancer claims expected through FY 2005.

NIOSH obtained the views of a diverse cross-section of prominent scientific experts, program officials, and of representatives of the public who will be affected. The relevant scientific fields and compensation precedents have been thoroughly researched and applied with careful attention to the unique needs of this particular compensation program. The resulting interim rules are fair, reasonable, and grounded in the best available science. We also believe they

effectively and efficiently implement the directions and intent of Congress, as stated in EEOICPA.

2. Discussion

Approximately 650,000 nuclear weapons production workers have been employed by DOE and its principal contractors since the inception of these programs in the 1940s. In addition, as many as 100,000 workers may have been employed in production in the first decades of these programs by short-term contractors of DOE, referred to under EEOICPA as Atomic Weapons Employers. EEOICPA was enacted after research indicating associations between work-related exposures to potential hazards and elevated rates of cancers and other illnesses incurred by this workforce. As one of the remedies, EEOICPA mandated federal compensation including \$150,000 in lump-sum payments and the provision of medical coverage for surviving workers found to have incurred cancer, beryllium disease, or silicosis resulting from their service to the United States in nuclear weapons production.

The two HHS regulations provide a fair, reasonable, and science-based approach by which DOL would determine the probability of causation for cancer claims under EEOICPA and by which NIOSH would provide assistance by conducting dose reconstructions for individual cancer claimants. The regulations build upon methods used by the U.S. Defense Threat Reduction Agency (DTRA) and the U.S. Department of Veterans Affairs (DVA). These agencies, respectively, conduct dose reconstructions and determine probability of causation for cancer claims for Atomic Veterans – veterans and Department of Defense civilian employees exposed to radiation at nuclear test sites and during WWII. The HHS rules extend beyond these precedents as necessary to address the unique radiation exposure and disease experiences of nuclear weapons production workers and to implement the expressed directions of Congress in EEOICPA.

The probability of causation guidelines rely heavily upon the cancer risk models used by the DVA, called the "Radioepidemiological Tables." These cancer risk models were originally developed by a National Institutes of Health (NIH) committee and have been updated by a joint workgroup of the National Cancer Institute and CDC. The update takes the form of a computer program rather than a set of printed tables, and is called the Interactive Radioepidemiological Program, or IREP. NIOSH worked with the NCI to help bring the update to completion and add risk models for bone cancer and for lung cancer associated with exposure to radon. These additional cancer models address exposures uniquely incurred by nuclear weapons production workers. NIOSH independently incorporated additional changes with particular importance for claims under EEOICPA, such as risk models for skin cancers and adjustments to risk models to account for unique types of radiation exposures. These additional changes were produced in a unique version of IREP specifically intended for use by DOL in adjudicating claims under EEOICPA, and is identified as the NIOSH-IREP.

The other important innovation of the HHS probability of causation guidelines is to implement systematic objective procedures for handling claims with unusual characteristics. This is essential to achieve consistent and efficiently rendered decisions, particularly because of the high claims volume expected. The principal example of this innovation is the handling of claims for secondary cancers, when the primary site of cancer cannot be identified in available records. DVA handles these on an ad-hoc basis by a program expert making case-by-case judgments for assigning the primary site of cancer. The HHS regulation provides DOL with an objective procedure for making such decisions. Other types of claims that involve unusual

characteristics requiring such procedures include those involving certain cancers for which we lack a single, optimal cancer risk model, and claims involving multiple primary cancers.

The HHS regulation on dose reconstruction uses methods similar to those applied by DTRA. These methods are based on standard approaches of this research field but achieve efficiency by substituting scientific, reasonable, and fair assumptions in the place of extensive data collection. The trade-off of reduced precision of dose estimates for increased processing efficiency is essential for an effective compensation program, since claimants cannot await the months to years of data collection that a dose reconstruction might otherwise require, if conducted for the purpose of research. NIOSH methods include measures to achieve additional efficiency, because the data collection burden and expected volume of claims under EEOICPA are far greater than those experienced by DTRA. Thus, the NIOSH methods also include a triage approach to husband resources for claims in which increased precision of the results is important and to speed the conclusion of dose reconstructions for claims whose outcomes would not be affected by increased precision.

The other important innovation of the HHS dose reconstruction rule is the systematic inclusion of the claimant in the dose reconstruction process. The claimant is essential as an informational resource, because of the greater complexity of radiation exposures and the variability of radiation safety practices and records, compared with the situation for Atomic Veterans. DTRA indicated strong support for such an approach. While DTRA only involves claimants on an ad hoc basis, they find this involvement to be critical to establish the trust and understanding of the claimants. Establishing trust and understanding are particularly important with respect to nuclear weapons production workers because of their widespread distrust of DOE in matters concerning occupational radiation exposures and health.

Of final note on the content of the HHS rules, both include provisions that allow NIOSH to update scientific elements of the guidelines and methods without the promulgation of revised rules. These are necessary to allow the compensation program to remain current with important advances in science that affect either probability of causation determinations or dose reconstructions. Any updates of either HHS regulation proposed by NIOSH would be published for public comment and obtain the review of the Advisory Board on Radiation and Worker Health.

Prior to drafting the regulations, NIOSH obtained the individual views of experts, directly affected individuals, and interested parties. These included DOE contractors, organized labor representatives of nuclear weapons production employees, the employees themselves, federal agencies and their contractors involved in the compensation program for Atomic Veterans, experts in health physics and cancer research, and the federal agencies involved in implementing EEOICPA. NIOSH expected the HHS rules to be received as consistent with mainstream views from each of these perspectives.

HHS has reviewed budget projections related to the promulgation and implementation of these two HHS rules. The most substantial costs will be incurred in conducting the HHS program of dose reconstructions. We expect at some point these regulations may face legal challenges based on procedural and substantive grounds. Legal challenges are unlikely to occur before DOL renders final decisions denying cancer claims for which dose reconstructions were conducted. This will likely be late summer or early fall of 2002. Before then, DOL must review and verify eligibility of claims, request dose reconstructions from NIOSH for qualified claims, obtain completed dose reconstructions from NIOSH, calculate probability of causation, issue

recommended decisions to claimants, respond to requests by claimants for administrative review of recommended decisions (including obtaining NIOSH reviews of completed dose reconstructions), and render final decisions. This period before final denials are rendered provides reasonable opportunity for the Advisory Board on Radiation and Worker Health to conduct its technical review of the probability of causation guidelines and its evaluation of the quality of dose reconstructions.

References

- [1] 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.
 - Executive Order 13179, Providing Compensation to America's Nuclear Weapons Workers (65 FR 77487), December 7, (2000).
 - 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).
- [4] Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000, proposed for promulgation at 42 CFR 82 (see 66 FR 50978), October 5, (2001).