Recent Activities and Actions of the Advisory Board on Radiation and Worker Health

Paul L. Ziemer, Ph.D., CHP

November 8, 2006 Meeting Veterans' Board on Dose Reconstruction Hampton, Virginia

Energy Employees Occupational Illness Compensation Program Act (EEOICPA)

- Public Law 106-398, enacted by Congress in 2000
- Became effective July 1, 2001
- Authorizes the President to carry out provisions of the Act
- Is intended to provide timely, uniform, and adequate compensation of covered employees (or survivors) who have suffered from illnesses incurred in the performance of duty for the Dept. of Energy and certain of its contractors and subcontractors

Energy Employees Occupational Illness Compensation Program Act (EEOICPA)

States that it is the sense of Congress that since World War II, many men and women have served in building the Nation's nuclear defense and, in the course of this work, have been exposed to beryllium, ionizing radiation, and other hazards unique to nuclear weapons production and testing.

Provides for \$150,000 in lump-sum compensation to workers who contracted certain diseases as a result of such exposures while working for the Department of Energy (DOE), its contractors, or subcontractors in the nuclear weapons industry.

Legislative Authority for the Advisory Board

- Part B of the Energy Employees Occupational Illness and Compensation Program Act (EEOICPA) authorizes the President to establish and appoint an Advisory Board on Radiation and Worker Health
- By Executive Order 13179 (December, 2000) the President designated responsibility of the Advisory Board to the Secretary of HHS

ROLE OF THE ADVISORY BOARD

The Board shall advise the Secretary of HHS

- 1. On the development of guidelines
 - for providing reasonable estimates of radiation doses received by individuals who seek assistance under the program (*dose reconstructions*)
 - for assessing the likelihood that an individual sustained cancer in the performance of duty at a DOE or weapons facility (*probability of causation*)

ROLE OF THE ADVISORY BOARD

The Board shall advise the Secretary of HHS2. On the scientific validity and quality of dose reconstruction efforts

 On whether there is a class of DOE employees for whom it is not feasible to estimate dose and whether there is a likelihood such dose may have endangered their health

Composition of the Advisory Board on Radiation and Worker Health

- Consists of no more than 20 members appointed by the President, who also designates the Chair
- Members shall include affected workers and their representatives, and representatives of the scientific and medical communities.

Current Membership (Nov. 2006) Advisory Board on Radiation and Worker Health

<u>Chair</u>

• Paul L. Ziemer, Ph.D., CHP, Professor Emeritus, Purdue Univ.

Designated Federal Official

• Lewis V. Wade, Ph. D., Distinguished Consultant, NIOSH, Centers for Disease Control and Prevention

Members

- Bradley P. Clawson, Senior Operator Nuclear Fuel Handling, Idaho National Engineering Laboratory
- Michael H. Gibson, Journeyman Electrician, Babcock & Wilcox of Ohio

- Mark Griffon, Health Physics Consultant, Creative Pollution Solutions, Inc. (NH)
- James E. Lockey, M.D, Professor, Univ. of Cincinnati, College of Medicine
- James Malcolm Melius, M.D., Ph.D., Director, New York State Laborers' Health and Safety Trust Fund
- Wanda I. Munn, Senior Nuclear Engineer (Retired), Richland, WA
- John W. Poston, Sr., Professor, Texas A & M Univ.
- Robert W. Presley, Nuclear Weapons Engineer, Oak Ridge, Tennessee (Retired)
- Genevieve S. Roessler, Ph.D., Professor Emeritus, University of Florida

Meetings of the ABRWH

- Frequency is determined by NIOSH and CDC and is based on agency needs.
- Since January, 2002, the Board has met 41 times, mainly face to face, but occasionally by teleconference.
- All meetings are open to the public(except where certain confidential material is being discussed) and include public comment periods.
- Transcripts are maintained of all meetings, as well as meeting minutes and executive summaries. All are posted on the NIOSH/OCAS web site.

Status of NIOSH Program Office of Compensation Analysis and Support

Overall Claim Information (as of Aug. 31, 2006)

- 22.316 cases have been referred to NIOSH for dose reconstruction
- 16,822 (75%) have been return to DOL
 - Cases submitted with a DR report 14,731
 - Cases pulled from DR by DOL 661
 - Cases pulled from DR for SEC 1,255
 - Cases administratively closed
 175
- 5,494 (25%) cases remain at NIOSH for dose reconstruction

Summary of Completed Dose Reconstructions (as of August 31, 2006)

Of the 14, 731 dose reconstructions sent back to DOL for final adjudication:

3,982 (27%) cases had a PoC > 50%

• 10. 749 (73%) cases had a PoC < 50%

How does NIOSH Carry Out Dose Reconstuctions ?

- Individual worker monitoring data: If complete and adequate, individual dosimeter readings and bioassay are given highest priority
 - Default values based on reasonable scientific assumptions used if individual data inadequate
 - Worst case assumptions may be used to provide benefit of a doubt (claimant favorable)
- <u>Workplace area monitoring data:</u> Used if individual monitoring data not available
 - May use monitoring results for groups of workers with comparable activities and relationships
- <u>Process description information:</u> Quantity and composition of rad material, chemical form, particle size distribution, containment...

What are the Components of the Reconstructed Dose?

- 1. The measured doses
- 2. Missed dose (resulting from null readings)
- Missing dose (periods where dosimetry is missing)
- Occupational medical exposures (i.e. mandatory x-rays as condition of employment)

What Value from the PoC Distribution is Used?

- The NIOSH guidelines, as required by the EEOICPA Law, use the upper 99 percent credibility limit to determine whether the cancer of an employee is as likely as not caused by the radiation exposure.
- This is intended to minimize the possibility of denying compensation to claimants with cancer that may have been caused by ionizing radiation.

What is the Special Exposure Cohort?

- The SEC was established by the Act and allows eligible claims to be compensated without the completion of a radiation dose reconstruction or determination of the probability of causation. To qualify for compensation under the SEC, a covered employee must have at least one of 22 "specified cancers" and worked for a specified period of time at one of the SEC work sites.
- Initially the SEC included the Paducah, Portsmouth, and Oak Ridge gaseous diffusion plants and the Amchitka Island Nuclear Explosion Site.

Adding Additional Classes to the SEC

- In addition to establishing the SEC, Congress allowed for additional classes of employees to be added to the SEC.
- The responsibility for adding classes of employees to the SEC was assigned to the Secretary of Health and Human Services (HHS).
- HHS used rulemaking procedures to establish a process for HHS to make decisions on whether to add classes of employees to the SEC.
- NIOSH/OCAS is responsible for collecting and evaluating petitions for consideration by the Secretary of HHS when determining whether or not to add groups of employees (classes) to the SEC.
- The ABRWH is required to review the NIOSH/OCAS evaluation and provide a recommendation to the Secretary of HHS.

Requirements for Adding a Class to the SEC

- HHS finds that it is not feasible to estimate the radiation doses of a class of employees with sufficient accuracy
- There is a reasonable likelihood that such radiation doses may have endangered the health of members of the class

What is Sufficient Accuracy?

- Radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the <u>maximum</u> <u>radiation dose</u>, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class, or
- If NIOSH has established that it has access to sufficient information to estimate doses to members of the class more precisely than an estimate of maximum radiation dose.

Cancers Included in the SEC Rules

- Bone cancer
- Renal cancers
- Leukemia (other than chronic lymphocytic leukemia) provided the onset of the disease was at least two years after first exposure
- Lung cancer
- The following diseases provided onset was at least five years after first exposure:
 - Multiple myeloma
 - Lymphomas (other than Hodgkin's disease)
 - Primary cancer of the Bile ducts, Brain, Breast, Colon, Esophagus, Gall bladder, Liver, Ovary, Pancreas, Pharynx, Salivary gland, Small intestine, Stomach, Thyroid, Urinary bladder

Status of SEC Petitions Office of Compensation Analysis and Support (as of September 11, 2006)

- Petitions Received: 60
- Administratively closed by NIOSH: 24
- Petitions in the qualification process: 13
- Petitions for which NIOSH evaluation reports are in development: 6
- Petitions under Board review: 6
- Petitions that ABRWH has recommended and HHS has approved for SEC status: 10
- Petitions approved by HHS & ABRWH but not added to SEC: 1

SEC submissions are Administratively Closed for one of the following 3 reasons:

- The submissions do not meet the petition requirements outlined in 42 CFR 83, § 83.9
- The facility in the submission is already a member of the SEC
- Petitioner(s) voluntarily withdrew the submission

- HHS decisions/ABRWH recommendations made to add classes to the SEC: 10
 - Mallinckrodt (2): 1942 to 1948 and 1949 to 1957
 - Iowa Army Ammunition Plant (2): 1949 to 1974 and May 1948 to March 1949
 - Y-12 Plant (2): Mar 1943 to Dec 1947 and January 1948 to December 1957
 - Linde Ceramics : Oct 1, 1942 to Oct 31,1947
 - Ames Laboratory : January 1, 1942 thru December 31, 1955
 - PPG: 1946 thru 1962
 - NTS: January 27, 1951 thru December 31, 1962

- 6 petition evaluation reports currently under review by the Advisory Board:
 - Rocky Flats
 - Oak Ridge Institute for Nuclear Studies
 - Chapman Valve
 - Blockson Chemical
 - Oak Ridge Thermal Diffusion Plant (S-50)
 - Los Alamos National Lab, Radioactive Lanthanum workers
- 6 petition evaluation reports in process by NIOSH
 - Feed Materials Production Center
 - Monsanto Chemical Co.
 - General Atomics
 - Los Alamos National Laboratory
 - Bethlehem Steel
 - Harshaw Chemical

- 13 current requests to add a class to the SEC are in the qualification process
 - Hanford (2)
 - Nuclear Materials and Equipment Corp.
 - Nuclear Metals, Inc. (2)
 - Sandia National Laboratory (Livermore)
 - Sandia National Laboratory
 - Y-12 (Oak Ridge) (2)
 - NTS
 - Pantex
 - Dow Chemical

Cases Impacted by Additions of SEC Classes (as of September 11, 2006)

1,435 claims sent to DOL for class member status determination and claim adjudication

•	Mallinckrodt (1942 to 1948):	95
•	IAAP (Mar 1949 to 1974):	338
•	Y-12 (Mar 1943 to Dec 1947):	342
•	IAAP Radiographers (May 1948 to Mar 1949):	1
•	Mallinckrodt (1949 to 1957):	56
•	Linde Ceramics (Oct 1, 1942 thru Oct 31, 1947):	44
•	NTS (Jan 27, 1951 thru Dec 31, 1962):	332
•	PPG (1946 thru 1962):	47
•	Ames Lab (1942 thru 1954)	21
•	Y-12 (1948 to 1957)	159

Advisory Board Accomplishments

- Review and comment on proposed Rulemaking for 42 CFR 81 (*Probability of Causation* Rule)
- Review and comment on proposed Rulemaking for 42 CFR 82 (*Dose Reconstruction* Rule)
- Review and comment on proposed Rulemaking for 42 CFR 83 (Special Exposure Cohort Rule)
- Establish methodology for reviewing and assessing scientific validity of completed DRs
- Conduct review of 100 randomly chosen final dose reconstructions (20 more currently in process)
- Establish methodology for reviewing and assessing Site Profiles (Technical Basis Documents)
- Establish methodology for assessing SEC petition evaluations
- Review and make recommendations on 10 SEC petitions

Contractor Support for the Board

- To assist the Board in carrying out its responsibility to advise the Secretary of HHS on the scientific validity and quality of the dose reconstructions, the Board has contracted with SC&A for assistance in reviewing completed dose reconstructions and site profiles that are used in the DR process
- The reviews ("audits") are the responsibility of the Board. SC&A provides input to assist the Board in carrying out this responsibility
- The contractor has also been tasked to assist the Board in reviewing NIOSH & ORAU procedures and to assist in the review of certain SEC petitions

Tasks assigned to SC&A

- Task Order 1: Site Profile Reviews
- Task Order 2: Case Tracking
- Task Order 3: Review of Dose Reconstruction Procedures and Methods
- Task Order 4: Individual Dose Reconstruction Reviews
- Task Order 5: SEC Petition Evaluation Reviews