Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health

First Meeting of the Advisory Board on Radiation and Worker Health

January 22-23, 2002

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National Institute for Occupational Safety and Health
Advisory Board on Radiation and Worker Health
Summary of the First Meeting
January 22-23, 2002

The first meeting of the Advisory Board on Radiation and Worker Health (ABRWH) was convened by the National Institute of Occupational Safety and Health (NIOSH) in Washington, D.C., on January 22-23, 2002. All the members were in attendance, as were representatives of several federal agencies and interested members of the public. Welcomes were extended to the members by the Deputy Secretary, Department of Health and Human Services (DHHS); the Acting Director of NIOSH, which is an agency of the Centers for Disease Control and Prevention within the Department of Health and Human Services (DHHS); and, the Director of the Office of Workers' Compensation Program (OWCP), Department of Labor (DOL).

Background:
The Energy Employees Occupational Illness Compensation Program Act (EEOICPA) was enacted to compensate the thousands of nuclear defense workers who Congress believes developed disabling or fatal illnesses as a result of exposure to beryllium, ionizing radiation, and other hazards unique to nuclear weapons production and testing. Its benefits also extend to those workers' survivors.

The ABRWH was established by the EEOICPA specifically to address workers who may have developed cancer from radiation exposure. The Board advises the Secretary of DHHS on: 1) the development of guidelines for determining the probability of causation (POC) for cancer-related claims; 2) the scientific validity and quality of the program's related dose reconstruction efforts. Upon the Secretary's request, the Board will also advise on whether there is a class of DOE employees who were exposed to radiation but whose dose is not feasible to estimate; and if so, whether there is reasonable likelihood that such radiation doses may have endangered their health. Specifically, the ABRWH will help form the rules and guidelines which will govern the POC determination and methodologies for the conduct of individual dose reconstructions for compensation claims from workers or their survivors.

The DOL estimates 80,000 claims will be filed in the first two years. Of the more than 18,000 claims already received, 2500 have received a decision (1570 final) and 1044 lump-sum payments have been issued to injured workers and their survivors. The necessary cooperative process of the DOL and DHHS to address the cases requiring a NIOSH dose reconstruction (1500 to date) was described. Another 1500 DOL dose reconstruction referrals to NIOSH are expected by April. The need to have the POC guideline in place by April has greatly abbreviated the ABRWH's timetable of work.

The EEOICPA program established a Special Exposure Cohort (defined by Congress) whereby claimants with a specified cancer will receive a lump sum payment if $150,000. The EEOICPA also provides medical care benefits coverage for work-related beryllium sensitivity, silicosis, and

cancer-related treatment and therapy. Uranium miners awarded $100,000 from the Radiation Employees Compensation Act (RECA) will receive an additional $50,000 to provide parity with EEOICPA. As the lead agency, the DOL will verify the disease diagnoses and employment by DOE or an atomic weapons facility to determine eligibility of a claim. The specific responsibilities of the DOE, DOL, and DHHS under the Executive Order were outlined.

Board Matters:
Briefings were provided on the composition and requirements of the Federal Advisory Committee Act (FACA), under which this Board is chartered, and on the administrative details of service on this Board. ABRWH operational guidelines were drafted and adopted at this meeting and are detailed in the minutes.

The members decided, regarding the ABRWH's responsibilities and operating procedures, that:

1. All members should participate in all deliberations, including the Chair. If necessary, a vote should be deferred to allow the Chair to get the viewpoint of absent members.
2. The meeting report must reflect all viewpoints expressed.
3. A quorum will be one-half the membership attending (physically or by telephone link), plus one.
4. Formal recommendations will be issued upon a majority vote of "eligible members" (those present, not recusing themselves or abstaining from a specific vote, or unavailable to participate in a given vote).
5. The board may form subcommittees and workgroups which may engage the assistance of outside technical experts.

In a **discussion of committee representativeness**, the members generally agreed that there is need for more balanced representation. A motion was proposed and passed in which the board recommended that the DHHS Secretary urge the President to provide balance to the board's membership by the addition of representation from production workers.

The **next ABRWH meeting** is scheduled for February 13-14, 2002, and tentatively for March 25-26, in Washington, D.C. Future meetings could be sited elsewhere. Possible agenda items include members' comments on the POC guidelines, evaluation of NIOSH dose reconstructions, and the SEC guidelines.

POC Rule:
The general background and technical aspects of the Probability of Causation (POC) Rule were presented and discussed. This rule guides the DOL's determination of whether a cancer was "at least as likely as not" caused by radiation arising from DOE employment. It is applicable to all non-SEC cancer claims and for SEC members with non-specified cancers. The related cancer risk models and uncertainties involved in producing an estimate were described.

The POC is based on a concept of "assigned share" or "attributable fraction", which is the proportion of disease in the population that would not have occurred without the exposure. The

EEOICPA requires a 50% POC after incorporating uncertainty. To determine the POC, NIOSH used the updated 1985 NIH RadioEpidemiologic Tables' Interactive RadioEpidemiological Program (IREP) and modified that for applicability to the nuclear weapons production workforce. The NIOSH-IREP modifications added cancer models for skin, bone, male breast, connective tissue, eye, non-thyroid endocrine, and "ill-defined" cancers; listed cancer models to use for claims where the primary cancer site is unknown; and developed operational smoking definitions for use in lung cancer models. The NIOSH-IREP may be updated, without requiring a rule change process, as new scientific information becomes available.

In calculating the POC, the DOL will use NIOSH's rule, the dose reconstruction result sent to them with a spreadsheet of detailed dosimetric information, and the NIOSH-IREP to generate results. A review and demonstration of the NIOSH-IREP software was provided. Variables used to demonstrate the calculation of various lung cancer POC estimates included chronic, long-term, 20- and 30-rem exposures to alpha radiation: smoking history; and the effect of changing formula elements such as standard deviation. NIOSH-IREP indicates the weight of computational changes with an importance analysis (e.g., absorbed dose, RBE, excess relative risk). Annual exposures received in a lifetime by a DOE employee are entered separately into the calculation. Particular issues related to running IREP and how they are addressed were outlined (e.g, the effect on POC estimate by claims with 2 or more primary cancers; or metastasized cancer with unknown primary site; unknown exposure type; and, the effect of gender, ethnicity and age at exposure).

Acute exposure was defined by the National Academy of Sciences (NAS) as a few hours or less of exposure; chronic dose would be more than a few hours, and could also relate to type of exposure. Mixed exposures (e.g, x-ray plus neutron) are handled independently and an excess relative risk is developed for each.

The general background and technical aspects of **the Dose Reconstruction Interim Final Rule** were presented and discussed. Dose reconstructions will be done for cancer claimants only, to estimate the radiation doses to unmonitored or inadequately monitored employees, or those with incomplete records. Employees found to have received high doses will not require extensive data collection and analysis, and the use of worst-case assumptions will be used for employees with low doses to determine if more extensive dose reconstruction is needed. Analysis with increased precision will be done for those claims that may be affected by such increased precision.

The compensation radiation dose reconstruction for the covered period of employment includes internal, external, and occupationally required medical exposures. An annual dose is required to estimate the POC; committed effective dose equivalent cannot be used. For external exposures, the concept of deep dose equivalent is not necessarily applicable, but the undetected and unmonitored doses are important factors. Uncertainty distributions associated with each radiation type will be used.

To achieve a level of efficiency, dose reconstructions using conservative estimates (benefit of

doubt to claimant) will be developed for the organ of interest; if a low POC (<30%) is produced, the dose reconstruction is considered complete given that no amount of further reconstruction would yield a decision to award. Conversely, under a conservative approach, a high POC (>50%) for exposure to one radiation types when the employee encountered several types would result in a limited reconstruction effort because the POC associated with all exposures would certainly support a decision to award. A POC in the middle range will spur a dose reconstruction using complete data and information, appropriate precision, and conservative estimates for all modes of irradiation, the doses of which are combined.

Public comment was solicited and is reported in detail in the meeting minutes. Broad topics addressed included balanced representation on the ABRWH and opportunities for public comments to the Board. Technical comments from the public for consideration included: 1) effect modification as well as bias and uncertainty; 2) linear or attenuated effects of chronic external radiation exposure; 3) examination of the Dose and Dose Rate Effect Factor (DDREF); 4) potential bias to outcomes stemming from a selection bias of atomic bomb survivors; 5) addressing the issue of RBE uncertainty and that of DOE's limited neutron dosimetry; 6) review of the technical issues and of NIOSH-IREP's use; and, 7) review of the anticipated release of IARC's massive international exposure study of DOE and nuclear reactor worker cohorts.

Technical guidelines for dose reconstruction methods for external dose and internal dose models were presented to the Board with more detail on each to be provided at the next meeting of the Board. The uncertainty distribution for external dose will be determined using Monte Carlo sampling from each of the dose component distributions, according to normal, lognormal, or triangular distributions as appropriate. For internal dose from radionuclides deposited inside the body through inhalation, ingestion, injection, or absorption through skin, ICRP 66 and ICRP 30 models will be used, and the Integrated Modules for Bioassay Analysis (IMBA) computer program. NIOSH will do site-specific facility profiles to identify measurement detection limits, determine exposure type and mode, characterize likelihood and effect of previous exposures, and physical characteristics of the source material. How acute and chronic dose will be differentiated was explained. A Memorandum of Understanding (MOU) between DHHS and DOE is being developed to ensure access to the needed data.

ABRWH Comments on the POC Guidelines included:

1. Many cancers go undiagnosed for many years. The uncertainty of the date of diagnosis is an acknowledged problem in the studies on which these guidelines are based.
2. To ensure that any substantive changes in the model (i.e., affecting the claim outcome) are proposed to the ABRWH before being effected, the committee recommends that such text be moved from the *Preamble* into the *Rule*. They also advised the inclusion of language that compensation determinations may change as a result of new science added into the modeling process used to determine the POC.
3. As best can be determined, the ABRWH found this rule to be appropriate for the DOE workforce on which it focuses, uses the best available science, and takes into account issues of uncertainty, and those parenthetical issues cited in the rule. This proposed rule

acknowledges that simple exposure to radiation does not automatically presume the development of disease. The best known current science informs the IREP process to reasonably define an appropriate method for translating experience gained in the veterans exposure calculations to this civilian nuclear worker program.

4. The members agreed that they had been able prior to this meeting to review the rules, supporting documentation, and public comments; and, at this meeting to receive technical presentations on the rules and question the technical foundation. The members generally agreed with NIOSH's approach as a sound framework, to the extent it is reflected in the regulations. However, the members strongly felt that they have not yet had time to study the issues and facts to provide definitive opinions, and will in future have to deal with particular details and issues such as were raised at this meeting. They looked forward to working with NIOSH, reviewing the comments, and pursuing the Board's role as defined in the EEOICPA.

A workgroup to develop the Board's comments was formed. It developed a draft to be compiled and e-mailed to the members the next day, and which would be discussed in a February 5, 2002, conference call to approve the comments to be forwarded to the DHHS Secretary.

National Institute for Occupational Safety and Health
Advisory Board on Radiation and Worker Health
Minutes of the First Meeting
January 22-23, 2002

The first meeting of the Advisory Board on Radiation and Worker Health (the committee) was convened by the National Institute of Occupational Safety and Health (NIOSH) at the Holiday Inn on the Hill, Washington, D.C., at 8:33 a.m. on January 22-23, 2002. Verbatim transcripts are being taken and will be made available on the NIOSH/OCAS website (www.cdc.gov/niosh/ocas) when complete.

JANUARY 22, 2002

ATTENDANCE:

Members present were:
Paul L. Ziemer, Ph.D., Chair
Larry J. Elliott, Executive Secretary
Henry A. Anderson M.D.
Antonio Andrade, Ph.D.
Roy L. DeHart, M.D., M.P.H.
Richard L. Espinosa
Sally L. Gadola, M.S., R.N., COHN-S
James M. Melius, M..D. Dr.P.H.
Wanda I. Munn
Robert W. Presley
Genevieve S. Roessler, Ph.D.

Federal agency representatives attending over the course of the meeting were:

Agency for Toxic Substance and Disease Registry (ATSDR): Robert Spengler

Department of Health and Human Services (DHHS):

- Office of the Secretary: Claude Allen, Lance Leggit
- Office of General Counsel: Mary Armstrong, Elizabeth Homoki-Titus, and Alice Kelley
- Centers for Disease Control and Prevention (CDC): Frances DePeyster and Helen Kuykendall
- National Institute for Occupational Safety and Health (NIOSH): Mary Schubauer-Berigan, Grady Calhoun, Allison Davis, Martha DiMuzio, Russ Henshaw, Nichole Herbert, Corrine Homer, Ted Katz, Jim Neton, Kathleen Rest, David Sundin, David Utterback, and Trudi Zimmerman

Department of Defense (DOD): D.M. Schaeffer

Department of Energy (DOE): Josh Silverman

Department of Labor (DOL): Shelby Hallmark, Peter M. Turcic, Jeffry L. Kotsch, Sonya Levine, Jeffrey L. Nesvet, Rose Toufexis,

Members of the public present were:
Neil Barss, SAIC, McLean, VA
Mike Gibson, PACE International Union, S-4200
Jordan Baravy, AFL-CIO, Washington, D.C.
Dan Burnfield, DNFSB, Washington, D.C.
James Ellenberger, PACE International Union
Joseph Fitzgerald, SAIC, Germantown, MD
Mark Griffon, CPS, New Hampshire
Jeff Hill, ATLC - ORNL., Ten Mile, TN
Charles Land, National Cancer Institute
James L. Liverman, DNFSB, Washington, D.C.
Fay Martin, LOC/CAP, Oak Ridge, TN
John Mauro, Sanford Cohen & Associates, Red Bank, NJ
Richard Miller, Government Accountability Project (GAP), Washington, D.C.
Frank Morales, GAP, Washington, D.C.
David Michaels, George Washington University School of Public health
Marie Murray, Recorder, Atlanta, GA
Kim Newsome, Nancy Lee & Associates, Atlanta, GA
Grace Leeds Papte
David Richardson, University of North Carolina/Chapel Hill
Roger Shaw, McCarter & English, Newark, NJ
Robert G. Tabor, Fernald Atomic Trades and Labor Council, Harrison, OH
Lowell Ungar, Office of Sen. T. Harkin

FACA Orientation:
Ms. Helen Kuykendall, of CDC's Office of Committee Management, provided an overview of the purpose/requirements of the Federal Advisory Committee Act (FACA), Public Law 92-463, enacted in October 1972. FACA was established to create and operate advisory committees by the Executive Branch of the federal government, and to: 1) enhance accountability of the advisory committees to the public, 2) protect against undue influence of special interests, and 3) reduce wasteful expenditures of public funds. FACA committees provide a vehicle for the provision to the government of consensus advice or recommendations on issues or policies.

This particular committee, the Advisory Board on Radiation and Worker Health (ABRWH), was mandated by Congress to advise the President on: 1) the development of guidelines for determining the probability of causation (POC) for cancer-related claims; 2) the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; 3) the feasibility of adding classes to the Special Exposure Cohort; and 4) other matters related to radiation and worker health in DOE facilities considered appropriate by the President.

Ms. Kuykendall outlined the governing authorities of and requirements under the FACA. The

latter include a charter, balanced membership (points of view represented), public access, maintenance of detailed minutes of each meeting, and availability of all committee documents to the public for as long as the committee exists.

Board composition/structure: The members of the Board are appointed as Special Government Employees, requiring compliance with conflict of interest statutes. The members serve for overlapping terms of up to four years, in this case one year. The Committee membership includes a Designated Federal Official (DFO), a Chair, and members, whose responsibilities as special government employees were outlined. The latter includes their service as private citizens, appointed based on expertise of value to the committee's objectives, who serve without compensation for 130 days or less per year. The members render personal opinion only, and are legally accountable for ethical issues, particularly those involving financial interests. All details on FACA and committee membership are available at the General Services Administration Website (www.GSA.gov/committeemanagement). Subsequently, ABRWH members viewed a video of the history of the government's use of advisory committees.

Opening Comments/Welcome to the Board:
Board welcomes were provided by representatives of the U.S. Department Health and Human Services (DHHS), the U.S. National Institute for Occupational Safety and Health (NIOSH), and the U.S. Department of Labor (DOL).

Mr. Claude Allen, Deputy Secretary, Department of Health and Human Services, on behalf of the Secretary of DHHS, welcomed the Board members and thanked them for their commitment and skills to the challenging responsibilities of the Board. Mr. Allen expressed the need for the Board's service to this compensation program and this Administration. He thanked the board members for their willingness to aid workers and their survivors. He noted that DHHS, DOL, and DOE are working cooperatively together and are giving serious attention to this compensation program. Mr. Allen briefly noted the topic areas where the Secretary of DHHS expected the Board to provide advice. He indicated that the Board could expect the full support of DHHS in accomplishing its tasks.

Dr. Kathleen Rest, Acting Director of NIOSH, recognized the commitment entailed in the members' contributions to this effort to ensure timely uniform and adequate compensation to the men and women who sustained injuries when working in the U.S. nuclear program. The Energy Employee Compensation Program Act named NIOSH to assist DHHS in carrying out its duties under the Act because of NIOSH's established integrity and scientific expertise. NIOSH's tasks include crafting new policies to implement the program and to build a new program to effect the implementation. The NIOSH will have the lead in carrying out DHHS' responsibilities under this Act.

Involvement in a compensation program is a new role for NIOSH, although its expertise from many years of epidemiologic research on DOE workers' health risks provides a firm foundation. To date, NIOSH's accomplishments include:

- Establishment of the Office of Compensation Analysis and Support, under Mr. Elliott's direction;
- Arranging its staffing with technical and scientific teams and support staff;
- Establishing records facilities, systems and procedures for dose reconstruction;
- Publishing a Notice of Proposed Rulemaking on Probability of Causation (POC);
- Publishing an Interim Final Rule on Methods for Dose Reconstruction;
- Establishing a Website;
- Establishing software systems to calculate POC and internal dose estimation;
- Issuing a Request for Proposal (RFP) for dose reconstruction;
- Appointing physicians as members of the DOE Office of Worker Advocacy's medical panels; and,
- Staffing/funding this advisory board.

The NIOSH goal for the Energy Employee Occupational Illness Compensation Act (EEOICPA) is to establish DHHS policies/decisions that are fair to the workers, their survivors, and which are practical and grounded in good science. With the assistance and advice from the ABRWH, NIOSH and DHHS will achieve a dose reconstruction program capable of meeting those high standards and meeting the DOL claimants' needs. Dr. Rest pledged to work collaboratively with the Board and the other agencies to effect this program.

Mr. Shelby Hallmark, Director of the DOL Office of Workers' Compensation Program (OWCP), noted the advisory board's unique opportunity to address 3-4 cabinet-level government departments. The Department of Labor is responsible to receive and adjudicate claims, and so is very interested in this Board's effectiveness and speed in facilitating that role. The OWCP will issue lump sum payments, medical benefits, provide an administrative appeal process for declined claims, and work with the Department of Justice to defend their decisions in courts if pursued to that extent by aggrieved claimants. Proceeding with the thousands of claims already received is stalled until DHHS completes the Probability of Causation Rule. He anticipated this advisory board's review and comment on that, as well as the processes necessary to add classes of workers to the Special Exposure Cohort.

The DOL accomplishments to date include:

- Publishing a final interim regulation in May 2001, which allowed the claims process to begin;
- Establishing a benefit claims program;
- Hiring 150 federal employees both regionally and in Washington, D.C.;
- With DOE, establishing ten Resource Centers at major DOE weapons sites since July 2001; and,
- Conducting outreach in town hall meetings and through those resource centers to inform the public about the program.

Already, more than 18,000 claims have been received. The DOL has the authority to take many of these through the complete process. Those claims come from those of the Special Exposure Cohort (who have cancers specified as presumptive); those with silicosis; and those defined under the Radiation Exposure Compensation Act (RECA). To date, 2,500 claims have received a decision, of which 1,570 are final decisions; and 1,044 lump-sum payments have been issued to injured workers and their survivors. Mr. Hallmark termed this a good beginning.

Those cases requiring a NIOSH dose reconstruction will require interaction/cooperation between the DOL and DHHS, involving the following steps:

- The DOL receives/screens a claim from a DOE worker with cancer, or a survivor of an energy employee who died of cancer, and verifies the eligibility of the claim;
- A claim verified as eligible is referred to NIOSH for dose reconstruction;
- NIOSH conducts and completes the dose reconstruction and sends the claim with dose reconstruction back to the DOL;
- the DOL adjudicates the claim based on the dose reconstruction and the DHHS POC regulation.
- If the claimant objects to DOL's determination based on the dose reconstruction, the case may be returned DHHS for reconsideration.

To date, Mr. Hallmark reported good working relationships and coordination between the DOL/OWCP and DHHS. He appreciated in particular DHHS' work to assemble their regulations and procedures with which to proceed. DOL has already referred 1,500 cases requiring dose reconstruction to NIOSH. Another 1,500 will probably be advanced by April, when NIOSH is committed to have the POC guideline in place. Finally, on behalf of the nuclear workers who suffered these exposures and deserve the Board's best efforts, he also thanked them for their service.

Discussion included:

- The ten resource centers established with DOE are at Paducah, Kentucky; Hanford, Washington; Las Vegas, Nevada; Rocky Flats, Colorado; Oak Ridge, Tennessee; Savannah River, South Carolina; Los Alamos, New Mexico; the Idaho National Environmental and Engineering Laboratory, Idaho; Portsmouth, Ohio; and Anchorage, Alaska. Traveling resource center meetings also have been held in Los Angeles, California; Buffalo, New York; Reading and western Pennsylvania; and the Amarillo, Texas (Pantex) area.
- About 80,000 claims are expected in the first two years, which seems high based on what has been received to date. However, this is a continuing program, so people will become eligible over time, and Congress had just broadened the definition of "survivor" (e.g., allowing formerly disallowed "adult children") and addressed how tort claims can proceed under the EEOICPA program.
- The lump sum payment is $150,000, or $50,000 supplements to the RECA compensation

program to provide parity for the latter's covered uranium miners' $100,000 awards.
- The OWCP pays for medical care for those energy employees found to have beryllium sensitivity, silicosis, or cancer.

OGC Briefing:
After a brief break, Ms. Mary Armstrong, Senior Attorney, Office of General Counsel (OGC)/DHHS, assigned to NIOSH, requested that any questions about conflict of interest be directed to Mr. Elliott, and discussed the rulemaking process. NIOSH has issued an interim final rule on the Dose Reconstruction Rule and has issued a Notice of Proposed Rule Making on POC. The statute requires this Board to advise on the proposed POC rule making, which will be used by the DOL to adjudicate cancer-related claims. NIOSH has also requested the Board's review and comment on the Interim Final Rule on Dose Reconstruction. These reviews must be conducted expeditiously in order for the rules to be finalized by April; adjudication of cancer claims by DOL cannot be finalized until the POC rule is established. A transcript of this meeting will go into the public record for both rule makings. NIOSH has made no final decisions as yet, awaiting this advisory board and the public's input during the comment period.

Discussion included:

- The comment period does not include the next advisory board meeting. NIOSH hopes to finalize and promulgate the rule in April after its review of the public's, and the Advisory Board's comments, completion of the DHHS clearance process, etc.
- The final rule will not have the comments and NIOSH's responses attached as appendices, but will address them generally in the Rule's preamble.

Review of the EEOICPA:
Mr. Larry Elliott reviewed the Executive Order and Charter of this advisory board. He reported NIOSH's reopening, the previous week, of the comment period for the rules on dose reconstruction and POC, in order to allow this board and the public to provide comments. The deadline for individual public comments is January 23, 2002, and for the Board's consensus comments, February 6, 2002. Dr. Anderson asked why such pressure was placed on the Board. He commented that the intended December meeting was canceled in order to finish processing the Board's paperwork, and that the value of any advice given would be proportional to the time allotted to it. Mr. Elliott indicated the Board had advance preparation by reviewing the rules and supporting documentation, public comments, and subject matter expert comments prior this meeting. He also commented about the need for timely response to claimants and indicated NIOSH's commitment to support the Board and do the best possible job in the time given.

EEOICPA Background. In passing the EEOICPA, it was the sense of Congress that thousands of nuclear defense workers have paid a high price for their service by developing disabling or fatal illnesses as a result of exposure to beryllium, ionizing radiation, and other hazards unique to nuclear weapons production and testing. Long latency periods, the uniqueness of the hazards to which workers were exposed, and inadequate exposure data have prevented these workers from

obtaining state Workers' Compensation benefits for health effects incurred in the performance of duty for Department of Energy (DOE) and its contractors and subcontractors (including Atomic Weapons Employers).

This advisory board is specifically concerned with those workers who may have sustained cancer due to radiation exposure (not chemicals or other exposures) in the performance of their duty. Those workers in the Special Exposure Cohort (SEC) are covered for 22 specified cancers. Employment by DOE or an atomic weapons facility will be verified, as well as a diagnosis of the specified cancers, and the claim will be awarded. DOE, DOL, and DHHS each have specific responsibilities designated under the Executive Order.

Agency Responsibilities Under the EEOICPA:
The Department of Labor is in charge of the administration of the program (determining eligibility and adjudicating claims); establishing program administration regulations; ensuring that claim forms are available; and, developing information materials in coordination with DOE and DHHS to assist the claim process.

The Department of Health and Human Services leads in establishing the regulation and guidelines for the POC, as well as, the regulation on methods for the dose reconstruction; conducting individual dose reconstructions for verified cancer claims; considering/issuing determinations on petitions by classes of employees to be included in the SEC; appointing members to the DOE Physician Panels; and providing staff and administrative support for this advisory board (ABRWH).

The Department of Energy has the responsibility of providing DHHS and the ABRWH with assistance and access to all relevant information on worker exposures when needed to carry out the committee's duties. On the request of the DOL or DHHS, DOE will require its contractors, subcontractors, or designated beryllium vendor to provide information relevant to a claim; they will identify and notify potentially eligible individuals of the compensation program; designate atomic weapons employers and additions to the list of covered facilities and designated beryllium vendors; negotiate agreements with states to assist DOE contract employees filing state Workers' Compensation claims; provide annual reports on the workers advocacy program regarding claims-related statistics; and publish in the Federal Register a list of atomic weapons employer facilities, DOE employer facilities, and facilities owned and operated by beryllium vendors.

The Attorney General is responsible for: 1) notifying claimants of their approval of Radiation Exposure Compensation Act (RECA) claims by the Department of Justice (DOJ) and availability of supplemental compensation under EEOICPA; 2) identifying and notifying eligible uranium workers or their survivors of the availability of supplemental compensation under EEOICPA; and 3) upon request from DOL, providing the information needed to adjudicate the claim of a covered uranium employee under EEOICPA.

The ABRWH shall be appointed by the President and advise the Secretary of DHHS on:

1) establishing the guidelines on determining the POC; 2) the scientific validity and quality of dose reconstruction; and 3) petitions to add classes of workers to the SEC.

The ABRWH charter addresses the composition of the Board, its meetings, the members' compensation, the required reports and its termination date. An annual report will be prepared of the committee's activities.

The Secretary of DHHS is especially interested in the Board's review and comment on the POC rule and asks the Board to focus on the following three general questions raised in *Section I. Comments Invited* of the rule:

1. Does the proposal make appropriate use of current science and medicine for evaluating and quantifying cancer risks for DOE workers exposed to ionizing radiation in the performance of duty?
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?
3. Does the proposal appropriately and adequately address the need to ensure that procedures under this rule remain current with advances in radiation health research?

The Dose Reconstruction rule has similar general questions raised in *Section I. Comments Invited* of the rule:

1. Does the proposal make appropriate use of current science and medicine for conducting dose reconstructions to be used in an occupational illness compensation program?
2. Does the interim rule appropriately balance the potential precision of dose reconstructions and the necessary efficiency of the dose reconstruction process?

3. Does the interim rule implement an appropriate process for involving the claimant in the dose reconstruction?

These, and any other questions the Board feels pertinent, should be addressed in its advice to the Secretary, DHHS.

Board Responsibilities/Operating Procedures:
Dr. Ziemer asked the members to consider and discuss several issues regarding how the Board should operate and function.

1. What constitutes a quorum? He suggested use of Roberts Rules, which allows a majority (50% plus one: in this case, 6) conclusion while still allowing the minority to be heard.
2. What constitutes consensus? Would five members in agreement suffice? Should it be two-thirds (7 votes) rather than 50% (6)? Is it a fixed number, or a fixed percentage of those present?

3. Shall the committee use subcommittees (subset of the advisory committee, appointed by the Chair with the Committee's agreement) and workgroups (can include outside experts) to do its work?
4. How shall public comment be obtained in order to allow views to be expressed and considered?

Ms. Kuykendall explained that FACA does not define a quorum, but the DHHS policy manual does, and defines a quorum as being 50% plus one of the members. The General Services Administration (GSA) regulations refer to consensus as a "common viewpoint."

Discussion included the following, prior to the formation of a workgroup (consisting of Drs./Ms. DeHart, Andrade, Munn, Gadola, and Ziemer) to draft operating procedures for the Board:

- This is not an expert, but an advisory, committee, with major medical and scientific gaps in its membership in consideration of its responsibilities, noted Dr. DeHart. Mr. Elliott stated NIOSH's willingness to provide administrative and technical support, as well as supply outside expertise as requested.
- Mr. Presley commented that consensus and quorum issues include the likelihood that there probably will be times some members have to recuse themselves. Mr. Elliott remarked that, the Advisory Board will address general issues regarding the rules which would not require members to recuse themselves. However, since they will also provide advice on specific dose reconstructions and SEC petitions, some members may have to recuse themselves from discussions and votes on site-specific or claim-specific matters.
- The Board is small and will address an intense work schedule. Those setting up the meetings should try to have as many members as possible able to attend. The agenda should be very specific to ensure that those who can contribute to the discussion or have great interest in it can be present.
- Consensus should be explored often to avoid time spent discussing issues of common agreement. It could consist of: 1) a simple majority (6); two-thirds majority (7 members).
- The public perception of "consensus" is unanimity. One member advised dropping that term; whatever word is used, it must be ensured that all viewpoints are reflected in the discussion report.
- Voting: All members should participate in all deliberations; if necessary a vote should be deferred until the Chair can get the viewpoint of absent members. The one person missing may be the most knowledgeable on a topic area. The Chair's vote was considered important, and he was asked not to abstain in general.
- The meeting report must reflect all viewpoints expressed.
- Some members may not be able to vote (or feel unqualified to do so, e.g., on a technical question). Use a simple definition of quorum and require a majority vote on any issue (e.g., with 7 members present, and 2 abstaining, 5 will vote, and 3 votes would carry the motion.) Another option: set up a one-hour teleconference after a meeting to resolve an issue.

Probability of Causation Rule 42 CFR, Part 81:
Mr. Ted Katz of NIOSH provided a general background on the formation of the Probability of Causation (POC) Rules, followed by Dr. Mary Schubauer-Berigan on the technical aspects.

General Background:
Mr. Katz discussed the purpose of the DHHS guidelines, the basics involved in determining POC, the requirements of the EEOICPA, and the goals of the Rule.

Purpose. The EEOICPA requires the DOL to determine whether a cancer was "at least as likely as not" caused by radiation exposure arising from DOE employment, and requires the DOL to make these determinations using these guidelines. This requirement applies to all non-SEC claims for employees with cancer, as well as to members of the SEC with non-specified cancers

Basics of determining cause. The scientific basis and mathematics used to produce an estimate of probability include: cancer risk models, requiring knowledge of the relationship between radiation dose and the frequency of a specific cancer, and factors that affect this relationship; radiation dose estimates for the claimant; a policy for addressing uncertainty; and policies for addressing unknowns.

Uncertainty. There are no methods available to prove for certain whether a cancer was caused by a person's radiation dose. The EEOICPA uses a rule of thumb to decide causation (i.e., "at least as likely as not,"or a greater than 50% chance). But the uncertainty involved in the cancer risk models and the dose estimates results in a range of estimates of causation of varying likelihood, with a "central tendency" rather than a single point estimate. The question in policy formation is, how certain should the estimates be? Can the uncertainty be reduced by tending to the extremes rather than the central tendency? The question is important, especially since this application will pertain to people's lives. That is, the answer will determine whether an individual's claim is awarded or not.

Addressing Unknowns. In many cases, the employee's primary cancer will not be known because it will have metastasized. There is not always a single, best cancer model available for each cancer type; some cancers have to be considered as a group in a risk model to achieve a higher degree of certainty for rare cancers. Public comments have indicated this to be a matter of concern. The policy question is, therefore, how can the DOL make fair, objective decisions in the absence of a single best scientific answer? For example, in using the only two leukemia models available, the higher probability result will be used; or, all the likely cancers to result from the cited exposure will be examined and that with the highest probability will be used.

The EEOICPA requires that the employee's possible radiation doses be estimated by DHHS, to enable the DOL to determine whether a case was "at least as likely as not" caused by radiation. In determining probability of causation, the DOL will also take into account other risk factors as feasible (e.g., smoking) and use the RadioEpidemiologic tables and the upper 99% credibility limit. Probability of causation will be used to address all types of cancer (not just those specified

for the SEC). EEOICPA also requires this advisory board's advice in establishing these guidelines.

EEOICPA goals are to:

- Make use of the best available science;
- Ensure that the claimants receive the benefit of the doubt;
- Establish procedures that DOE can apply objectively and consistently for every claim; and
- Make those procedures as transparent as possible for the public through these objective criteria.

Scientific/Technical basis for POC Rules: 42 CFR, Part 81:
Dr. Mary Schubauer-Berigan, of NIOSH's Health-Related Energy Research Branch (HERB), explained that Probability of Causation is based on a concept of "assigned share" (or in epidemiology, "attributable fraction"): the proportion of disease in the population that would not have occurred without the exposure. This is more applicable to populations than to individuals. POC is approximated by the calculation of assigned share. It allows the incorporation of uncertainty in dose, dose-response relationship, and other factors that modify risk. The EEOICPA requires a 50% POC after incorporation of uncertainty. While the POC method has been criticized by some, it is the only method available to use for this compensation program at this time.

The estimate of POC is derived by dividing the risk from radiation exposure by sum of the background risk and the risk from radiation exposure (or, ERR÷1+ERR = RR-1÷RR), where the relative risk is the relative risk of cancer at a given dose level, compared to a similar unexposed population at a specified age, sex, age at exposure, time since exposure, etc.

Relative risk (RR) is estimated from epidemiologic models of dose and cancer risk. Separate models may be produced for each cancer type or similar groups of cancers, and "transfer" the relative risks from the exposed population to the claimant population. The models also may incorporate uncertainty:

- Statistical uncertainty about the relative risk estimates;
- Uncertainty about exposure of study population;
- Uncertainty about the effects of confounding variables;
- Uncertainty in transfer of risk coefficients to other exposure scenarios and populations; and
- Uncertainty associated with the exposure of the claimant.

Precedent for the use of POC: Department of Veterans Affairs:

- The National Institutes of Health (NIH) developed the RadioEpidemiologic tables in 1985 that modeled risk for 12 different cancers using primarily external radiation dose with no adjustment for dose-rate effects; linear-quadratic dose responses were assumed for all but breast and thyroid cancers. These tables were based on epidemiologic analyses of the atomic bomb survivors and studies bone cancers in patients injected with radium 224. The NIH 1985 methods were reviewed by the National Academy of Sciences (NAS). The tables incorporated a constant relative risk model (except for leukemia and bone cancer), and transferred the risk additively to the U.S. population.
- The limitations of the NIH 1985 Tables included a poor ability to assess POC from high-LET dose, and they incorporated uncertainty rather crudely. The use of the Tables were difficult and require knowledge and experience to implement. Expert judgement is frequently used to supplement the consultations on claims. The Tables were meant to be updated every few years.
- The Tables are, however, a good fit to the dose scenario for "atomic veterans" and have served the Veterans' Affairs (VA) program very well. The VA currently processes 300-400 claims per year.

NCI Update of IREP Tables:
New data on cancer incidence among the Japanese atomic bomb survivors through 1987 and improved computational methods prompted an update of the NCI 1985 RadioEpidemiologic tables. This resulted in improved risk modeling from the atomic bomb survivor data and incorporation of detailed uncertainty analysis. Also, this included development of a computer software program for calculating the POC, the Interactive RadioEpidemiological Program (IREP). As of the NAS review of November, 2000, the changes made were to increase the number of modeled cancer sites (now 33 in all); elimination of the radium-224 bone cancer model and the radon-lung cancer models; more detailed uncertainty analysis; addition of dose-rate adjustment factors for low-LET radiation and addition of radiation quality factors for high-LET risk estimation. However, they were still directed toward the "atomic veterans" compensation program. The NIH changes are still in review at NCI.

Development of the NIOSH-IREP:
The limitations of the NCI IREP in application to DOE workers were described by Dr. Schubauer-Berigan:

- The absence of radon and lung cancer models or dose-rate adjustment factors, and highly uncertain RBE values for bone marrow and other cancer sites;
- The absence of cancer models for skin, bone, male breast, and others;
- The fact that the models were unlikely to result in compensable claims for some cancers that were demonstrably elevated in the DOE workforce, suggesting that the Japanese data should be supplemented with the results of other studies;
- The lack of consideration of temporal changes in U.S. cancer rates. (The NCI program is

more relevant for current claims than for cancers occurring in the past);
- The absence of guidelines on how to handle metastatic cancers with an unknown primary site; and
- The absence of methods to estimate POC for multiple primary cancers.

The strategy for the development of POC to meet the EEOICPA needs was to:

- Use existing NCI methodology where appropriate (including modifications to address NAS panel review comments);
- Identify short-term versus long-term solutions to limitations;
- Work with NCI and contractors to address some limitations (incorporated radon/lung cancer models, RBE factors, and Dose and Dose Rate Effect Factor (DDREF) distributions for all radiation types experienced by DOE workers);
- Finalize the software development of the IREP to incorporate these modifications and generate a NIOSH-IREP; and
- Remain involved in developing long-term modifications addressing limitations for DOE workers.

Modifications made for NIOSH-IREP included:

- Addition of the cancer models needed: skin, bone, male breast, connective tissue, eye, non-thyroid endocrine, and "ill-defined" cancers (a grouping of cancers for which no cancer-specific models existed);
- Addition of the radon in the lung cancer model;
- Provision for various radiation exposure types through separate RBE and dose-rate adjustment factors in the NIOSH-IREP;
- No inclusion at this time of chronic lymphocytic leukemia (CLL) due to the absence of qualitative evidence of causation or of quantitative models with which to estimate risk;
- Adjustment for temporal changes in background U.S. cancer rates;
- Development of an objective list of cancer models to use for claims where the primary cancer site is unknown; and
- Development of operational smoking definitions for use in lung cancer models.

The future of POC calculation under EEOICPA includes periodic updates resulting from new scientific information, Advisory Board's recommended changes, and review of public and scientific expert comments.

Future modifications resulting from new scientific information may include:

- Possible long-term changes: improved risk models or reduced uncertainties (BEIR VII update of risk coefficients; input from epidemiologic studies of DOE workers);
- Changes in dosimetry practices;
- Adjustment for radiosensitive sub-populations; and/or

- Adjustments for interactions with other workplace exposures.

Discussion included:

What would be the magnitude of the effect of temporal changes in cancer incidence? The extent of that contribution to the POC estimate would need to be examined through modeling, which has not been done for that specifically.

Have any of the ongoing DOE epidemiologic studies indicated any increased relative risk? It is difficult to generalize without going into specific details of the exposure scenario. Workers exposed to higher levels of radiation are expected to have higher levels of risk. Some studies have found larger increases than that expected for specific cancers; others found either no or smaller elevations of risk.

Congress picked the 99% confidence level, but the claims of individuals with a cancer with little literature on it will be enhanced due to a large range of uncertainty, raising the upper bound. This is a valid point, also raised by the NAS panel. The NIH's grouping of cancers was one attempted resolution to avoid these extremely high uncertainty estimates for very rare cancers.

Please elaborate on the operational smoking parameters used in lung cancer models. The definitions from the 1985 NIH tables were used. However the definition of a "non-smoker" was modified to a lifetime smoking experience of less than 100 cigarettes. The DOL is instructed to inquire about smoking habits up to 5 years before the cancer diagnosis.

What other carcinogens are considered? Modifiers of radiation induced cancer that are incorporated in the NIOSH-IREP include: aging, gender (cancer risks differ for each), and skin pigmentation (only for skin cancer models which reflects the varying risk of seen in background incidence rates according to race). ***Chemicals?*** EEOICPA is limited to radiation risk. If a chemical exposure modifies that risk (increases or decreases), it would be considered, but there are insufficient data on any chemicals to this point except for smoking/radon and lung cancer.

What excess cancers were found in DOE workers? DOE worker studies indicate elevations in multiple myeloma levels in some cohorts and brain cancer in the Rocky Flats cohort. NIOSH can provide the references to that work.

IREP Review and Demonstration:
Mr. Russ Henshaw, M.S., of NIOSH's Office of Compensation Analysis and Support (OCAS), outlined NIOSH's Interactive RadioEpidemiological Program (NIOSH-IREP). This is a Web-based, interactive software program that estimates the probability that an individual's cancer was caused by occupational exposure to radiation. It incorporates probability distributions for uncertainties associated with risk models and assumptions. The NCI methodology is used where appropriate, with increased applicability under EEOICPA provisions for exposures and risks of DOE employees and contract workers.

The IREP is intended to be as user-friendly as possible. Its primary goal is to produce the best possible estimate of causation given the current state of knowledge. Due to uncertainty factors, it will give the benefit of the doubt to the claimants. It does so by calculating the POC by using the "as likely as not" standard (greater than 50% POC, based on the upper 99% credibility limit (confidence interval)). IREP addresses all the cancer types needed under the EEOICPA by incorporating appropriate risk models. The calculation process is intended to be as open and understandable as possible, and self-documenting as it includes online model details for the user.

The information needed to estimate POC includes: gender, years of birth and cancer diagnosis; type of cancer (primary organ site, ICD-9 code); ethnicity (for skin cancer); smoking history (lung cancer) equivalent organ dose (cSv); year(s) of exposure(s); exposure rate (acute or chronic); radiation type and range; organ dose and distribution parameters. In the case of more than 1 primary cancer, each cancer is calculated individually. The results of each are combined in a calculation to determine the overall POC.

Demonstration of the NIOSH-IREP Web page. Mr. Henshaw pointed out the online documentation and help files, and navigated through the NIOSH-IREP screens from entering data through to output. The NIOSH-IREP Web address is http://216.82.51.38/irep_niosh/, or it can be accessed through the cdc.gov/niosh Website, through the OCAS web page. He subsequently calculated POC 1) for a hypothetical male with lung cancer and a chronic, long-term, 20 rem (and subsequently 30-rem) exposure to alpha radiation.

Discussion included:

What is the menu for smoking history? Never smoked; former smoker; current smoker (number per day); more than 19 cigarettes, 20-39 cigarettes ; 40+ cigarettes per day, currently.

Where will the exposure data required by IREP (e.g., exposure year, rate, radiation type, organ dose (cSv) come from? DOE records, NIOSH in-house research information/data, and from interviews with the claimant or co-workers of the energy employee. The NIOSH health physicists will also provide data from the dose reconstruction for DOL to use in the NIOSH-IREP. However, since the energy employee or general public will not know all of these components, drop-down menus of parameter options are provided.

In the case analyzed, the individual's claim was not compensable, producing only a 43.2% POC of lung cancer in the 99th percentile. But further analysis, using the same dose but changing the standard deviation from lognormal to 5.0, changed the result to a 77% POC. This demonstrated the program's achievement of Congress' intent to provide the benefit of the doubt to the claimant in terms of addressing the bounds of uncertainty. Subsequently, with the same dose and GSD, the number of cigarettes smoked per day was changed: 10-19/day produced a POC of 59.1%; 40+/day produced a POC of 57.94%.

NIOSH designed an importance analysis to indicate the weight of the changes in the

computation, considering absorbed dose, RBE, and excess relative risk (taken from epidemiologic models), which were outlined by Dr. Schubauer-Berigan. The number of exposures received by a life-long DOE employee are entered separately, by year, into the calculation.

Special Issues in Running IREP in EEOICPA:
Dr, Schubauer-Berigan reviewed several issues related to NIOSH-IREP use, and provided examples of how each is addressed:

- Claims for which more than one NIOSH-IREP run is needed, such as for 2 or more primary cancers, leukemia (and effects of age at exposure), and metastasized cancer with an unknown primary site.
- Effect of specifying exposure type (chronic versus acute) when that is unknown. In the absence of data, when there may only be the workers' recollection of their activities, the highest POC is assumed, even though chronic dose tends to lead to a lower POC.
- Effects of gender, ethnicity, and age at exposure on the POC estimate while holding exposure constant.

Discussion included:

- *It would be unlikely to find any occupational exposure with similar total exposures, aside from accidents, to those of the Japanese atom bomb survivors. Should such a factor be applied?* The justification does not stem from the Japanese survivor data. Recent data indicating essentially the same risk regardless of dose rate negates comparison of the two (worker-Japanese) exposure scenarios. The NAS review panel defined an acute dose as a period of hours of exposure. Many committees have addressed the dose rate effectiveness factors, but NIOSH-IREP addresses the operating definition for this particular application, in which, for example, a person who wore a badge for 30 days could be assumed to have received their total dose all in one 8-hour day.
- *Does the definition of "chronic" exposure relate to the claimant's and types of exposure?* Yes, type of exposure. In most cases, alpha exposure is considered chronic; there are no plausible acute alpha exposures. Neutron exposure, as a high LET emitter, could also be a chronic dose. The same exposure on a badge could be found to be chronic for neutrons and acute for gamma exposures. Treatment of acute versus chronic variables of dose is one risk of putting this software out in the public domain; there is no guarantee that the energy employee (claimant) will calculate the same result as the DOL analysts.

Dose Reconstruction Rule 42 CFR, Part 82:
Mr. Katz provided a background presentation on the radiation dose reconstruction methods of the Interim Final Rule, and Dr. James Neton provided an overview of the technical approach.

General Background:
Mr. Katz discussed the purpose of the DHHS guidelines, the basics involved in determining

POC, the requirements of the EEOICPA. and the goals of the Interim Final Rule.

The purposes of the guidelines are: 1) to establish dose reconstruction methods that NIOSH will use to estimate the radiation doses incurred by employees; 2) to indicate how dose estimates will be used by DOL to determine probability of causation for cancer claims; and 3) to emphasize that NIOSH will conduct dose reconstructions for cancer claimants only; dose reconstruction and estimation for research or compliance is done differently.

The EEOICPA's requirements are that the dose reconstruction methods must be applied for employees who were not monitored, who were monitored inadequately, or who had incomplete dose records. In practical terms, these methods will be applied for all claims. The Board will independently review these methods and verify a sample of dose reconstructions.

The Basics of determining cause. The scientific basis and mathematics used to produce an estimate rely on a hierarchy of data that starts with personal monitoring data and extends to area monitoring, process information, and source-term information. The key issues involved are the completeness and adequacy of data. These issues which will be addressed by using all sources of data. Interviews of employees (and co-workers when necessary) will be conducted to identify and fill data gaps and help interpret data. The best science and ICRP models will be used to ensure state-of-the-art internal dosimetry. A full accounting will be provided to the claimant of the methods, data, and assumptions used. If the claimant is dissatisfied with the finding and feels the NIOSH dose reconstruction was not conducted according to these methods, the claimant can seek review through DOL.

Mr. Katz outlined how NIOSH will balance the needs for precision and efficiency. Both are necessary in view of the more than 12,000 claims requiring dose reconstructions already submitted to DOL, and in view of Congress' emphasis on the need for timely claims decisions. The dose reconstruction process is intended to permit claims decisions, not achieve precision. For that reason, those employees determined to have received high doses will not require extensive data collection and analysis; those employees with low doses will receive the benefit of the doubt through the use of worst-case assumptions in estimating POC; and increased precision will be effected for those claims that appear could be affected by such increased precision.

In the event that NIOSH cannot complete a dose reconstruction, an SEC petition process can be followed. However, since the specified cancer list limits the compensation eligibility by SEC members, individuals who have cancer not on the specified list and for whom a dose reconstruction can not be done will have no recourse for compensation in this program. DHHS is now developing the SEC procedures.

Dr. Jim Neton, the OCAS Health Science Administrator, described the differences in the definition of dose in compensation and regulatory (DOE compliance) interpretations. The compensation dose evaluation is limited only to the covered period of employment; specifically the compensation dose time period is from the date of first exposure to the date of cancer

diagnosis. It includes internal, external, and occupationally required medical exposure sources of radiation. An annual dose is required to estimate the POC; the committed effective dose equivalent concept is not applicable. For external exposures, the concept of deep dose equivalent is not necessarily applicable, but the undetected dose is an important factor. Uncertainty distributions can be used and advantage can be taken of recent scientific developments.

The technical approach used in the Interim Final Rule:

- Evaluate all doses of record for data quality shortcomings: assess the capability of external dosimetry programs over time; assess the quality of radiochemical techniques for bioassay samples.
- Evaluate the potential for undetected dose (missed dose for external exposure standard by LOD/2; the minimum detectable internal dose based on bioassay program capability).
- Use the recommendations established by national and international organizations (ICRP 66 lung model for inhalation exposures; more recent ICRP recycling models adopted for internal dose estimates; ICRP 74 model used for external dose evaluation).
- Preferentially use individual monitoring data, if available, and of sufficient quality.
- As necessary, use area air dosimeters, radiation survey, and air sampling data to augment individual monitoring data.
- If no individual monitoring data are available, use that available on source term, process information, etc.

The types of information that will contribute to this process include claimant interviews, dosimetry, *in vivo* exam results, incident investigation reports, biosampling data, source term characterization data, monitoring data, and general process descriptions.

Strivingto achieve efficiency, the dose reconstruction aspect of claim processing will be conducted with a specific strategy. The processing strategy is to begin simply and conservatively, using the available monitoring data and using the worst-case assumptions when doing initial evaluations.

Dr. Neton shared a dose reconstruction flow diagram, and described the efficiency strategy with various examples. Beginning with the organ of interest and the most probable mode of exposure (e.g., uranium would involve internal exposure), and for a claim with an estimated low likelihood of compensation a dose evaluation and reconstruction would be done using worst case assumptions and combining all possible doses. Based on that reconstruction, if the estimated probability of causation is still low, the dose reconstruction would be considered complete and the claim returned to DOL.

If the likelihood of compensation is estimated to be high, dose reconstruction would be initially done using a conservatively low estimate of exposure. If that produces a high likelihood for compensation, the dose reconstruction would be complete and the claim returned to DOL. However, if the likelihood is low, a dose reconstruction would be done using conservatively low

estimates for the other modes of irradiation and the doses would be combined. If this effort results in a high likelihood, the dose reconstruction would be considered complete. If not, a dose reconstruction would be done using complete data and information. Dr. Neton outlined an example of a simple case of internal exposure to plutonium, indicated by bioassay sample analysis.

For those claims anticipated to be in the middle of the two examples (i.e., likelihood that a calculated POC would be under but close to 50%), a full and complete dose reconstruction effort using all available information and worst case scenarios would be conducted.

The duration of the dose reconstructions would be variable (days to months) depending on the complexity the individual claims. Cases with extensive internal exposure are expected to be the most complex, and additional time could be required for previously unexamined locations/processes.

Finally, Dr. Neton reported the status of NIOSH's readiness to conduct these dose reconstructions:

- The first draft of implementation guidelines is complete;
- The NIOSH-DOE Memorandum of Understanding is in process of negotiation;
- Information on DOE personnel monitoring has been requested for claims received at NIOSH;
- NIOSH is investigating records available at DOE facilities (Oak Ridge and Hanford).
- A computer data base is in development; and
- A request for contract for technical assistance to conduct the dose reconstructions is in procurement. The NIOSH staff is too small to handle all the dose reconstructions for this program.

Discussion included the following exchanges:

- *The new models could produce numbers differing from the agency's dose of record and cause problems for the claimant (i.e., by producing lower dose estimates or higher dose estimates than reported to them by DOE).* Most of the doses will probably not match; most DOE programs did not calculate an internal dose over the time period being examined under the EEOICPA. NIOSH will not be making one-to-one comparisons to the dose in the records, but will use dose from the records as a starting point for dose reconstruction. NIOSH-IREP allows use of the ICRP 60 weighting factors, and samples over the entire distribution of a weighting factor, not providing a point estimate for the radiation weighting factor. Explaining the dose reconstruction process, outcome and report to the claimant will require a considerable communication effort.

Public Comment:
Richard Miller, Government Accountability Project (GAP). The GAP has tracked the

implementation of this legislation, and noted several unintended consequences:

1. The statute is clear (Section 3624) in calling for consultation to ensure a balanced membership of the Advisory Board. GAP feels that is not achieved in the composition of this Presidentially-appointed board, particularly in its under-representation of labor. Only Mr. Espinosa seems to qualify to represent this perspective, which the law intended to benefit as the group with the least power. While that under-representation may not affect the outcome, GAP feels it is an obvious imbalance. GAP has communicated this opinion to the President.

2. GAP has learned that only two entities appear likely to bid to execute the dose reconstruction work, SAIC and the Oak Ridge Associated Universities (ORAU). The legislation specifically barred DOE from doing this work, since the dose reconstruction should not be done by the agency responsible for the exposure nor the same person who did the previous radiation monitoring work. He did grant that NIOSH has a "crisp paragraph" on its Website stating that applicants with such conflict of interest would be precluded from performing dose reconstructions. The problem is that there is a small pool of highly-qualified individuals with the expertise required. Therefore, clear parameters of "do's" and "do not's" are needed, such as not allowing the involvement of contractors who are witnesses for DOE in litigation. What can be done to raise confidence in a system in which great irregularities were cited in DOE's own field hearings, such as those by Dr. Michaels. The contracting process needs to overcome those irregularities.

David Richardson, Department of Epidemiology, University of North Carolina, Chapel Hill. Dr. Richardson has worked on studies of DOE workers at multiple DOE facilities. He appreciated NIOSH's work to date in engaging a cutting edge approach and clearly making an effort to consider issues of both bias and uncertainty. He offered several suggestions:

1. Move beyond the focus on bias uncertainty to effect modification (e.g., age of exposure). Under the current tables, dose history, ERR and POC tend to be constant or to decline with older age at exposure. In contrast, a number of studies of U.S. nuclear workers show an opposite pattern of larger relative risk and excess rates of cancer with age (age 20, beginning work, to 65, retiring). He cited studies of the Hanford and Oak Ridge cohorts, a multi-facility study of multiple myeloma incidence with older age of exposure, that was associated with increased risk; and the Rocketdyne study done by the University of California. This indicates a conflict between the evidence of the atomic bomb studies, which are the basis of the radiological tables, and the exposure conditions of DOE workers.
2. Another interesting issue involves the confounder not only of smoking but also of the other chemicals encountered in a lifetime of work in the DOE complex. That inconsistency is recognized in the literature in the uncertainty of additive and multiplicative effects, age of exposure, dose, etc. Since the literature is inconsistent about

the effects of these various exposures, the average span estimate is more uncertain.

3. An issue needing at least clarification, if not more exploration, is whether the external radiation exposure, treated as acute (with a DDREF of 1.0) infers that the effect of a chronic exposure is attenuated. If, as assumed by IREP, any annual dose is substantially <20 rem/year and the DDREF is ≥1.0, a worker's dose will be divided by a factor of 2 to 5 to be at the lower end of the distribution. But recent evidence from the RERF report of the Lifespan study indicates that there is no departure from linearity, making a DDREF of 2 to 5 invalid. Animal studies of low-level exposures, where the end point is rarely cancer incidence, need to be reviewed, as this poses implications to the benefit of the worker.

Roger Shaw, Carter and English, Limited also advised the ABRWH to examine the DDREF. The ICRP and other expert organizations support a DDREF for low-LET exposures of 4-5; and many national/international bodies support using a Dose Rate Effect Factor (DREF). He pointed out that a DREF of 2.0 lowers the risk by a factor of 2, and that "acute" is not defined as a short period of time such as months. He anticipated, when the workers begin to use NIOSH-IREP online to calculate their own doses, that differences will emerge (e.g., by changing the constant from a standard deviation). He strongly supported Congress' intent to give the worker the benefit of the doubt, and thought that reasonably possible to be done without adding even further uncertainty to the large amount inherently in the data.

With no further discussion, the meeting adjourned for the day at 5:07 p.m.

JANUARY 23, 2002

Administrative Overview:
This Advisory Board is DHHS's only Presidential appointed committee. Ms. Corinne Homer, of NIOSH's Committee Management Office, outlined the administrative details provided for the Board members: preparation of personnel actions as Special Government Employees, arrange/prepare travel and vouchers for travel expenses, request salary reimbursement, meeting planning, and committee support. She requested that the members provide, before leaving, an estimate of the hours spent in preparation for this meeting. Staff points of contact pertinent to this meeting are Nichole Herbert for travel and vouchers (513) 841-4498, and Ms. Homer for issues of salary, personnel, administration, travel and vouchers (404) 498-2529.

Board Work Schedule:
The next is meeting scheduled for February 13-14, 2002, and March 25-2, 2002, was tentatively selected for the subsequent meeting. The goal is to finalize the rules by April. Mr. Elliott hoped to be able to send the Board's comments on the POC guidelines to the Secretary by February 6th. The goal is to finalize the rules by April so claims can be decided. The SEC petitioning procedures should be available for Board review in late April or May. NIOSH will have to have completed several dose reconstructions before the Board is engaged in its reviewing responsibility. Those possibly could be reviewed at some point around July. A teleconference

will be held on February 5, 2002, from 10 a.m. to noon, Eastern time, to finalize the discussions of this meeting and agree on the Board's comments on the POC rule. Ms. Homer will request the required notice be posted in the Federal Register.

Dr. Ziemer reported the suggestion that other meeting location sites than Washington, D.C., be considered, to enable site visits and/or to make the Board available to the interested public. When asked their opinion, the members' comments included:

- While the site visits are wise to allow public input, the public may well ask a site-specific question the committee is not yet prepared to answer. The members need to get comfortable with their work first.
- DOE offices at Oak Ridge and Hanford have indicated their willingness to arrange site visits.
- In deference to the west coast members, the meetings should not be held exclusively on the east coast.
- There was **consensus to meet in Washington, D.C., in both February and March.**

Adoption of Committee Operational Guidelines:
The ad hoc workgroup assembled on the previous day reported on their development of Operational Guidelines for the ABRWH:

1. The Board shall implement the DHHS/GSA definition of a quorum regarding the minimum number of members required to attend (physically or by phone) in order to conduct a formal meeting. A quorum shall be comprised of one half the membership plus one.
2. The Board shall issue formal recommendations on specific matters to DHHS/NIOSH only after a majority opinion has been reached through voting by "eligible members". If, despite every reasonable effort, members cannot be present in person or telephonically to vote, the majority will be determined on the number of eligible voting members present. Eligible members are defined as those who a) have not been required to recuse themselves from participating in discussions regarding the issue at hand; b) those who have not abstained from a specific vote, or, c) those who may not be available to participate in a given vote. All reasonable efforts shall be made by NIOSH/OCAS to obtain the vote (or notification of recusal or abstention from a vote) from any member who may not be able to be present either by telephone or in person.
3. The Board can form subcommittees and workgroups, at the discretion of the Chair and Executive Secretary. These groups may invite the participation of outside technical experts to assist in their discussions.

Dr. DeHart moved to adopt the operational guidelines and Mr. Presley seconded the motion.

In discussion, Dr. Melius offered a friendly amendment to modify #1 such that every attempt will be made to ensure that all the board members are available to be present, rather than to simply

seek a quorum. With general agreement to that change, the members **unanimously approved** the motion.

Working Session on POC Comments:
Dr. Ziemer suggested that the Board members form three workgroups to address each of the questions asked by DHHS, and the comments in response received to date. Dr. Melius requested that the materials to be discussed be brought to future meetings, especially voluminous paper copies.

Mr. Elliott reported that the scientific peer review comments had focused on the NIOSH-IREP and the associated risk models. Two other comments received pertained to the dose reconstruction documentation for RBEs that are used in the NIOSH-IREP, which would not apply directly to this POC rule. The staff expertise available to the members at this meeting included Dr. Schubauer-Berigan (research epidemiology); Mr. Henshaw (epidemiology); Mr. Katz (policy implications); Dr. Neton and Dr. Calhoun (health physics). And, in the audience, Dr. Richardson had commented as a subject matter expert, and Mr. Josh Silverman of DOE was available to discuss the intent of Congress. Mr. Dave Sundin reported that only two comments had been received since the rulemaking was reopened, and should be posted on the Website soon. Copies of those comments were distributed.

Initial discussion included:

- *How easy will it be to make changes to update the NIOSH-IREP, or will a rule amendment process be required (e.g., public comment).* Changes to NIOSH-IREP are separate from this rule and will be brought before this board. No substantive modifications to NIOSH-IREP have been suggested for discussion at this meeting.
- *Are there plans for regular review of claims that could be affected by changes to NIOSH-IREP and require retrospective re-review?* This has been discussed; a method is needed to avoid constant changes, such as clear criteria that are necessary to modify NIOSH-IREP. Future meeting agendas could include briefings on the NIOSH-IREP background to facilitate any future changes. Also suggested was providing background on the EEOICPA law itself.
- The Interim Rule references the 1985 RadioEpidemiologic tables, which are updated from time to time. The NCI justification for the development of the new software program could be distributed, but the justification of the tables' update has not yet been published.
- The members requested a copy of the DVA policy to see how it was adapted for this application. The NAS review of the IREP and the Government Accounting Office (GAO) report review were offered, but there was no document that would allow a line-by-line comparison. For that reason, the Board decided to conduct a paragraph-by-paragraph review by the of Probability of Causation Guidelines, according to the three questions indicated and the applicability of the methods. The background was skipped under the assumption that the members had read that. They proceeded to page 50974,

Part 81.

Page 50974, Part 81

Question #1: Does the proposal make appropriate use of current science and medicine for evaluating and quantifying cancer risks for DOE workers exposed to ionizing radiation in the performance of duty?

81.0 Background.

- *What methods/guidelines were used to establish the Special Exposure Cohort?* The SEC was established by Congress to include the three Gaseous Diffusion Plants (GDP – Paducah, Kentucky; Portsmouth, Ohio; and K-25, Tennessee); and Amchitka, Alaska workforce. A 1960s memo at Paducah noted that ~600 workers should be tested with a new bioassay for neptunium, but that this would probably result in a union request for hazard pay, and so the bioassay was never used. And the Radiation Exposure Compensation Act (RECA), which addressed those affected (by living downwind of releases, uranium miners, and Nevada Test Site research participants) included categories of near-site residents who were not otherwise covered. To be comparable with RECA and arrange for lump sum compensation for people missed by such gaps, Congress established the SEC within EEOICPA.

81-1. No questions/comment.

81-2. No questions/comments.

Subpart B: Definitions:
There is no defining time to indicate employment; how is that considered in calculations? Employment is verified by DOL before the claim goes to NIOSH, and the DOL also verifies diagnosis through death certificate or physician report. SEC workers must have worked 250 days; the overall cohort has no minimum.

Is the dose over time considered in calculating exposure? Yes, from first employment through time of diagnosis.

How are RBEs defined? ICRP 60 radiation weighting factors are used. The paper by David Kocher *et al* applied the RBE for high-energy photons. In doing the dose reconstructions, the ICRP-60 weighting factors are used to report a dose similar to that which the worker was exposed to, with uncertainty factors. However, when the NIOSH-IREP is run, those weighting factors are removed and the Kocher RBEs are applied with their uncertainty distributions. Although there are differences, this is comparable to the reality of the exposure in most cases.

Does the NIOSH-IREP weighting factor produce a weighted average? No; it is calculated as is done with any uncertainty in the NIOSH-IREP program, with a Monte Carlo approach that samples the distribution. That allows a sampling of the overall uncertainty, since the RBEs do not offer any constant uncertainty.

What comments on the linearity (page 50975) of low dose have been received? Ones similar to Dr. Richardson's the previous day, and in fact, the NAS panel also reviewed such issues with the NCI -IREP report on application of DDREF. Based on the growing literature domestically and internationally, NIOSH leaned toward giving a greater weight to a DDREF of 1.0, and they worked with NCI to adapt their model to the NIOSH-IREP software. It includes a small probability of inverse dose rate effects and that the DDREF is less than 1.0. However, there is no software available to do the modifications necessary to incorporate the possibility of enhanced susceptibility at older ages of exposure, as mentioned by Dr. Richardson.

Are the 22 cancers listed based on various sources of radiation? The list was established by Congress. But this list applies only to the SEC and has no relevance to the dose reconstructions that the NIOSH-IREP is to facilitate. The 22 cancers were adopted from the RECA list.

How is the prostate handled in the dose reconstruction, since its degeneration is a normal process in males? The prostate is addressed in the NIOSH-IREP software cancer models. That dose calculation would be applied to the models derived from A-bomb data. Although prostate cancer is one not shown elevated in those studies, however, due to the range of uncertainty and with enough dose it conceivably could be compensated.

Subpart C, Section 81.5:

How will race and ethnicity be covered? The categories in skin cancer models are based on traditional definitions. There are no incidence data for cancers of these classifications. The NIOSH-IREP divides the claimants' self-identified race/ethnicity by Hispanic/non-Hispanic; African American, Asian, or Pacific Islander. Since the risk is related to melanin in the skin, the NIOSH-IREP program assesses variances in background incidence rate to transfer the risk to the various population groups. The calculation for a person self-identifying as multi-ethnic, the calculation should be done for each race. In that case, the higher value would be used.

To establish the credibility of a diagnosis, are latency periods determined in the initial screening and/or used in NIOSH-IREP? The software addresses this and each cancer risk model adjusts for latency. Some cancers such as leukemia have different latency periods. The DOL program requires that a cancer in the SEC group occur five years after initial employment.

Is only the exposure that logically contributed toward the cancer of interest considered? The program inputs doses throughout the entire period and does Monte Carlo calculations of possible latencies. Those exposures which occurred within the latency period are not included in the risk assessment.

Smoking is also a risk for upper respiratory infections, bladder cancer, etc.: will those be considered? This was discussed with NCI. A decision on those other outcomes was tabled to future versions of NIOSH-IREP when justified by scientific advances.

Many cancers go undiagnosed for many years. The uncertainty of the doses is accounted for, but what about that for the date of diagnosis? That is an important point and an acknowledged problem in general among the studies on which these guidelines are based. However, except for rapidly progressing cancers such as leukemia, whose risk rises steeply right after exposure and then declines, the delayed diagnosis may work on the claimant's behalf, by lengthening the boundary dates of their doses. This is another area lacking analyses to resolve such questions.

81.6, Use of Radiation Dose Information:
Are mixed exposures (e.g, x-ray, neutron) calculated independently and then merged? Yes, all exposures to that person are entered and an excess relative risk is developed for each, then combined to produce the probability of causation estimate.

Subpart B, Risk model POC estimate requirements:

81.10:
How will changes to the model be handled over time? Any substantive changes (i.e., that affect the claim outcome) to the NIOSH-IREP will be proposed to this advisory board before being effected. The ABRWH will be advised and comment sought prior to publication of any substantive changes to the rules.

Due to concern that this could be bypassed if not codified in the rules, Dr. Andrade moved and Dr. Melius seconded **to insert the language of the Preamble (page 50971, paragraph two), beginning "substantive changes..." directly into the Rule, and that the advisory board submit as a comment on this ruling that language should be included on the probability or possibility that compensation determinations may change as a result of new science being added into the modeling process used to determine the POC.**

In discussion, caution was advised in using the wording "level of compensation;" a preference for "the awarding of compensation" was expressed. However, it was also noted that the language just moved from 50971 also implies an effect to the compensation.

Are claims potentially affected by new scientific information automatically reconsidered retroactively? The DOL Interim Final Rule allows both the claimant and the DOL a time period to reopen a claim based on new information.

Vote: The members, including the Chair, voted unanimously to approve the motion.

81.11, Use of Uncertainty Analysis in NIOSH-IREP:

Is the use of acute exposure for photons a default position, or can chronic exposures be used? This pertains more to dose reconstruction, but acute exposure is used unless information is available that indicates otherwise. This is not a NIOSH-IREP default, but it is handled in the technical guidelines for dose reconstruction. The DDREF is for exposures <20 rem, and would not be affected by being applied to acute exposure. Dr. Charles Land of the NCI developed the methods (documented in NCI's revised IREP software) whereby at some theoretical low dose (0.03 to 0.20 Sv), the chronic DDREF factor is applied, but it is sampled from a distribution of possible low doses.

Subpart E: Guidelines to Estimate POC:

81.20: No questions/comments.

81.21:
Since carcinoma found in situ is likely to be treated and perhaps cured, why is it included? Improved screening methods have resulted in more cancers detected in situ. A policy decision was made that distinguishing between *in situ* and early metastatic cancer would essentially punish those who are screened, and the policy was set in favor of the claimant. Also, for breast cancer, for example, the *in situ* risk factor is equal to that of early stage breast cancer. Additionally, a cancer victim (*in situ*, malignant, or metastized) may be found eligible for medical benefits for the therapy and treatment of the cancer if the POC is greater than 50%.

81.22, General Guidelines for Use of NIOSH - IREP:
Who actually calculates the POC; DOL or NIOSH? DOL will, using NIOSH's rule and the dose reconstruction results sent to them, with a spreadsheet of detailed dosimetric information. They will use the NIOSH-IREP to generate the POC results.

81.23, Guidelines for Cancers of Unknown Primary Cancer Site:
This section includes Table 1 of the listed secondary cancers and the ICD-9 codes of likely primary cancers. The process for selection (use of the highest probability for adjudicating the claim) was already discussed by the committee.

81.24, Guidelines for Leukemia. No questions/comments.

81.25, Guidelines for Claims Including Two or More Primary Cancers:
Are there ways to determine independent cancer risks? Yes, for two or more primary cancers a risk estimate is made for each; these are considered independent probabilities for the purposes of the calculation. This does not refer to secondary cancers arising from a primary one, but two different primary cancers (e.g., colon and skin).

Is the time relationship of the two cancers involved? For example, 20 years after surviving an early skin cancer, colon cancer is developed, as opposed to having them simultaneously? There is no "statute of limitations" in this regard; this could apply to primary cancers that occur decades

apart. Although only one lump sum payment is provided, the causes for each claimed disease have to be determined for payment of medical benefits.

81.30, Non-Radiogenic Cancers:
Is there any research indicating other kinds of cancer that may be non radiogenic? Some tissues are more sensitive than others, but there is no known tissue un-responsive to radiation.

Will changes in the ICD, and updating of the tables require another rule process? Technical non-substantive changes can be made without going through the rule making process. The risk models also are in ICD-9 codes, and the program does not require use of the most current ICD codes.

Question #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?

Question #3. Does the proposal appropriately and adequately address the need to ensure that procedures under this rule remain current with advances in radiation health research?

Mr. Katz noted that Question #3 could pertain to the use of independent expert judgement to reconcile issues/contradictions. This is allowed in the DVA guideline but not be done in the quantitative NIOSH process.

Public Comment:
Robert G. Tabor, Fernald Atomic Trades and Labor Council, worked as a millwright for 21 years at the Fernald site. He was a labor representative for 17 years and had been to every site in the operating nuclear network except Pinellas and Pantex. He welcomed the creation of the ABRWH. He asked two questions:

1. What impact would new methodologies/techniques/practices used to make POC claims decisions have on previous cases determined negatively with a lesser methodology, and what would be done with borderline cases? (This was addressed previously.)
2. The board's performance would be optimized by more labor representation, especially of the production facility workers who will probably generate the most claims and could provide very helpful input. He suggested, aside from scientific data, consideration of: a) operational experiences which may have an important role in decision making (For example, exposures to some parts of the body may not appear significant on a dosimeter, but may cause metastases that would not otherwise occur.); and, b) the lifting of record destruction moratoriums, particularly at closure sites, may present an issue in the claims determinations.

Faye Martin, Local Oversight Committee/Citizen Advisory Panel Oak Ridge was also a member of the Subcommittee on Community Awareness (SCA), and a consultant to Advisory Committee

on Energy-Related Epidemiologic Research (ACERER). She asked if the ABRWH would have a similar citizens group to work with. She also reported questions raised as to whether $150,000 is sufficient compensation for the suffering caused. There should be a opportunity for such issues to be raised. Mr. Elliott noted that board responsibilities are clearly defined. The public and workers are welcome at the Board's meetings, comment periods are provided for in each meeting agenda, and there are no plans or need to incorporate a citizen's advisory group to this Board.

Dr. Richardson noted the IREP's base on the decades-long Japanese atomic bomb survivor studies (the Life Span Study), and commented that study participants are needed who reflect the susceptibility of the general population to the same exposures. Several papers have tried to explore whether a selection among atomic bomb survivors (of 5 or more years) in the high-dose areas could bias the outcomes. The high-dose survivors could be a robust group with selective survivorship; and the experience of survivors at lower doses may be more applicable to this compensation program. He cited relevant studies published in *Radiation Research* and the Stuart, 1990 study published in *Environmental Health Perspectives*, as well as the Little and Charles study published in *Health Physics*, 1990,Vol 99.

A National Council on Radiation Protection (NCRP) paper also explores the sources of uncertainty in radiation risk estimates coming from estimated doses in the Life Span Study, which were modeled based on survey self-reports. It also devotes a section to epidemiologic uncertainties, which recognizes the aspect of selective survivorship as an issue. The study concluded that the dose estimates of the Life Span Study are probably biased, although in a small way. Dr. Richardson recommended consideration of two issues:

1. The remaining non-quantification of a recognized source of small (perhaps ~10%) downward bias and its related uncertainty. He suggested consulting the NCRP's Document 126 on bias/uncertainty and selective survival. Publications have questioned if in fact the Life Span Study doses may be biased downward due to selective survivorship. Since people with higher doses tend to be healthier than those with lower doses, that could be evidence of selective survivorship in that population..
2. He provided comments on the dose reconstruction rule. The rule does not address one issue related to the RBE of neutrons that is important, due to: a) the relative biological effectiveness factor; and b) uncertainty acknowledged internationally about the RBEs. In addition, DOE neutron dosimetry was limited for a long period, involving review of x-rays. That makes both the dose and the RBE uncertain.

Roger Shaw, of McCarter and English, identified himself as a Cold War veteran of the DOE complex. He recommended review of the technical issues and of IREP's use, including the process of claims applications. New studies may offer new risk coefficient basis: the Life Span Study, DOE studies, and a study to be published late in 2002 from the International Agency for Research on Cancer (IARC). The latter involves DOE and nuclear reactor worker cohorts in 16 countries (Germany dropped out since they could not produce their data on time). It is the largest

study of nuclear workers in the world (involving ~600.000 workers), most of whom received low-LET exposures, and which delineates, for example, neutron and internal exposure doses. That cohort could answer some of the problems involved in using the Japanese survivor data. He also noted the use of an inverse DDREF for alpha radiation (i.e., increasing the risk) by a factor of four for internal dose, while using a DREF of ~1.0 for external exposure.

Jim Ellenberger, PACE International Union, has been involved in union work over a long time, including work with the AFL-CIO union in enacting this legislation. The failure to appoint this board within the mandated 120 days slowed this process, which is being followed with great interest by the workers. The Act requires a balance of scientific, medical, and labor representation.

PACE, the single largest union in the DOE complex, tried unsuccessfully to work with the administration to place production workers on this board. On the other hand, the DOE created an advisory committee to the Office of Worker Advocacy, established by this Act. It was established a year ago to advise the Secretary of Energy in addressing issues relevant to DOE's responsibilities under EEOICPA. He serves on that committee, which includes very distinguished experts on workers compensation. That committee realized early on that is membership was unbalanced due to a lack of contractor representation, so the Secretary of Energy appointed those representatives. As they proceeded with their work, they realized an additional representation need, of the insurance industry, and have recommended to include those interests. He agreed that broadening the representation on this committee would strengthen it and raise the public's trust.

The Board then adjourned for lunch, after which Dr. Ziemer expressed for the record the committee's appreciation of the work of Ms. Cori Homer, Ms. Nichole Herbert and Ms. Martha Denuzio in facilitating the logistics of this meeting so well.

Discussion of Committee Membership Representation:
The committee members generally agreed that there is need for more balanced representation on its membership, as commented at this meeting

Dr. DeHart moved that the board recommend that the Secretary of DHHS urge the President to provide balance to the board's membership by the addition of another nuclear industry worker. Dr. Andrade seconded the motion.

In discussion, the following points were made:

- Mr. Presley, Ms. Munn, and Dr. Andrade related their careers' progression and focus, as support to their own perception of themselves as nuclear workers, not management. Counting them, the board primarily consisted of nuclear workers.
- However, it was also agreed that this question relates to the perception of workers as labor, but not organized versus non-organized labor. The motion seeks representation for

workers in those portions of the DOE complex that had single-function missions (e.g., the GDPs, or those doing only plutonium or uranium production). Mr. Espinosa is a good representative of the current laboratories (e.g., Lawrence Livermore or Los Alamos) where the staff addresses a spectrum of work and trades. A representative from older facilities now going into shutdown mode would be prudent in terms of the history of the complex.

Vote: Nine members voted in favor of the motion, and Ms. Munn abstained. The motion passed.

ABRWH Responses to the Rules' Three Questions:

Question #1:

- Dr. Melius: The program needs to move on and not delay people from getting the compensation they deserve.
- Dr. DeHart: Agreed, but to give some *indication of the activity underway, state that the Board* has been able to review the documentation and had technical presentations, and was able to question the technical format.
- Dr. Melius: State the *ABRWH's general agreement with NIOSH's approach as a sound framework, to the extent it is reflected in the regulations. However, the members strongly felt that they have not yet had time to study the issues and facts to provide definitive opinions, and will have in future to deal with particular details and issues such as were raised at this meeting.*
- Dr. Anderson: Add that the ABRWH *looks forward to working with NIOSH, reviewing the comments, and pursuing the committee's role as defined in the rule.*

The Board members agreed to craft a formal statement. Mr. Elliott appreciated these comments for the Secretary's information, which were expected to be general with regard to the rule. NIOSH will bring back the NIOSH-IREP to the Board with modifications made based on the comments received. He expected that the ABRWH would become more comfortable with details of the NIOSH-IREP and the dose reconstruction technical guidelines.

Question #3:

- Dr. Melius: Combine this question with #1, adding some text to confirm that there is a level of adequacy with which the Board is comfortable.
- Dr. Anderson: Strengthen this to clarify the Board's role, such as by moving that definition into the rule, as done for NIOSH-IREP earlier in the day.

Question #2:

- Dr. Ziemer: Include a phrase that states *"As best we can determine, this rule appears to be appropriate for the DOE workforce for whom it's focused."*
- Dr. Melius: *NIOSH considered a number of factors in which DOE differs from the workforce covered by the DVA program, and has taken them into account: uncertainty issues, scientific issues, and the parenthetical issues cited in the rule.*
- Ms. Munn suggested a still further focus: *There is an enormous difference in the categories of compensations covered by this ruling. In some cases, the Atomic Veterans Act required primarily that they were there, had one of the specified cancers, and were therefore compensated. This proposed rule is an effort to face the reality that simple exposure to radiation does not automatically presume the development of disease. The excellent efforts of NIOSH staff and their subject matter experts in bringing the best known current science to the IREP process has, in our opinion, been quite reasonable in defining an appropriate method for translating experience gained in the veterans exposure calculations to this civilian nuclear worker proposal.* It seemed appropriate and wise to her that this distinction be made and to applaud NIOSH for the effort to identify and reduce the uncertainty in making these kinds of decisions.
- Ms. Gadola suggested noting it was the intent of Congress, through the EEOICPA, to address the needs of Cold War veterans and those who worked in nuclear plants, as well as to address the related scientific and technical aspects.

A workgroup to develop these responses was formed by Dr. Ziemer, Dr. Melius, Dr. Roessler, Dr. Anderson, and Ms. Munn. They developed a draft which Dr. Melius agreed to compile and to e-mail to all the members on the following morning. The members were asked to review and provide feedback for the final wording to be shared in the **February 5, 2002, conference call to be held from 1:00-3:00 p.m, for the purpose of approving the recommendations to be forwarded to the DHHS Secretary.**

Technical Guidelines for Dose Reconstruction:
Dr. Neton reviewed the technical guidelines developed to date for dose reconstruction. He defined external dose as that received from radiation sources outside the body, whether a deep dose or a skin dose. The three primary sources of external dose are gamma and x-ray radiation, neutrons, and beta particles. Alpha radiation is not a source of external exposure.

For compensation purposes, external dose is defined in four components: dosimeter dose (D_d), missed dose (D_M), occupational environmental dose (D_E -- workers not monitored in the plants but in its general vicinity, such as stack emissions with photons that may irradiate workers); and occupationally derived medical dose (D_{OM}). The total dose is the sum of those four types.

Measured Dose. The measurement information hierarchy of external exposure data is as follows: individual personal dosimeter (film badge or thermoluminescent dosimeters – TLD), pocket ionization chambers, group dosimeters, area monitoring data (ambient area surveys), and

radiation source terms. Dr. Neton provided examples of external dosimetry data for a Hanford worker's dose for each of the 12 months of 1951, with an estimated laboratory uncertainty of 14 mrem, as well as the bell shaped distributional curve of that dosimetry.

Missed dose. This is important in past measurements due to frequent exchange of dosimeters (i.e., weekly) and relatively high limit of detection (LOD, at >0.30 mSv). The current programs miss only <0.4 mrem/year. If a facility recorded what they thought was a missed dose, the claimant will be interviewed, and their input will be accepted if the claim seems reasonable.

Missed dose estimation is important in view of compliance-based monitoring. It can be significant when there is a frequent exchange of dosimeters. (With a weekly exchange frequency, and an LOD of 0.30 mSv, the maximum missed dose would be 15.6 mSv. Dr. Neton then discussed NIOSH's approach to modeling missed dose by applying a log-normal uncertainty distribution to the LOD/2.

Environmental Dose is defined as an unmonitored dose received onsite, typically from stack emissions. It can be significant in the early years during the green fuel runs, high production periods, etc. For some groups of workers such as construction workers in non-radiological areas, this may be the primary exposure. Dr. Neton shared a map of the Hanford reservation's ambient beta and gamma radiation distribution around the site in May1947.

Occupational medical monitoring dose came from the medical x-ray monitoring conducted at most large DOE sites as a condition of employment. This exposure can be significant, depending on the type of medical monitoring device and frequency of the examinations. X-ray radiation to the red bone marrow in some workers was estimated to be 800mrem after a photofluorographic examination.

Conversion to Organ Dose: ICRP74 methodology will be used to convert measured dose, either ambient deep dose, or deep dose equivalent. Factors affecting the conversion include target organ (primary cancer), monitoring device (film or TLD), energy of the emission, and exposure geometry. Dr. Neton shared a chart of the geometry of the exposure (front to back, etc.) and those relationships to energy effects.

The exposure geometry can vary significantly depending on job function: for example, a drum storage warehouse laborer would receive mostly isotropic exposure; a glove box or fume hood worker would receive them in an anterior-to-posterior orientation; and a reactor worker would receive exposures in a combination of anterior-posterior and rotationally geometrics.

The final dose uncertainty distribution will be determined using Monte Carlo sampling from each of the dose component distributions and the associated dose conversion factor uncertainty: dosimeter dose (normal distribution), missed and environmental doses (lognormal distributions), and dose conversion factor (triangular distribution).

Internal dose is received from radionuclides deposited inside the body, through four primary routes of entry: inhalation, ingestion, injection, and absorption through skin. Internal dose is most significant for alpha emitters. Radon exposure is evaluated using working level months (WLM). The internal dose calculation is done in steps: intake, transfer throughout the body, and excretions. It is based on certain ICRP models: (inhalation; ICRP 66; specific biokinetic models; ICRP 56, 67 and 69; and ICRP 30 for all others).

Analytic Models: Dr. Neton shared a general model for an internally deposited contaminant. While it is difficult to calculate the dose to organs not intrinsically irradiated (e.g., the prostate), it can be estimated by the volume of the blood transferred in these organs. The dose probably will be small, but can be documented in future.

Dr. Neton then described the ICRP 66 lung model, developed in 1994 and the current state of the art for inhalation exposure. The 1979 ICRP 30 model, the basis for ICRP 66, has two models still in use by the DOE and NRC: a gastrointestinal (GI) model, and a bone model. The absorption values specific to the GI model for specific isotopes have been updated in more recent ICRP publications.

Integrated Modules for Bioassay Analysis (IMBA) Computer Program. Dr. Neton described this new program, which is not yet used in the U.S. A beta version was developed for NIOSH by ACJ and Associates with the National Radiation Protection Board in England. It calculates internal dose based on ingestion, inhalation, or injection (wound/skin absorption) intake scenarios and includes compensation program-specific features. He shared a program screen. The software can calculate an annual fractional dose to multiple organs per case.

Important features of the IMBA computer program include that it models acute or chronic exposures; can modify absorption and aerosol parameters; allows input of single or multiple bioassay samples; and that it currently supports four types of bioassay samples: whole or partial body count, lung, urinary excretion, and fecal excretion. NIOSH hopes to have the production version available in the next month or so, to be ready for the April onset of POC calculations.

The IMBA outputs include total intake by picaCuries (pCi), Becquerels (Bq), and micrograms (μg); committed effective dose equivalent and the CDE to each of 36 organs; effective dose each year (or total) over a specified period of time; and dose to each organ, each year (or total) over a specified period of time

Reconstruction requires detective work related to the bioassay sample. NIOSH will do site-specific facility profiles to determine the detection limits for the measurements. They will also determine exposure type (acute/chronic), exposure mode (inhalation, ingestion, injection), effect of previous intakes on the results; estimates of the date that an intake occurred; and the physical characteristics of the source material.

The data used to determine dose include bioassay data: *in vivo*, urinalysis, fecal and breath samples (few are available, but will be used as possible); incident reports; and airborne radioactivity concentration (breathing zone or general area air samples, estimates from contamination levels or from dispersible source inventories).

How do you differentiate between acute and chronic dose for intake? Chronic dose would be sustained in urinalysis over time, whereas acute would be indicated by a measurement that drops off. Elements such as plutonium, which stays in the body for lifetime, would be considered a chronic exposure to the date of diagnosis. Iodine is also considered chronic, despite its half-life of a few days. Acute is defined as an exposure of only a few hours; chronic is defined as more than a few hours.

Missed dose could be a dose that was received without producing a detectable bioassay sample. Missed dose from urinalysis may be high but the upper limit could be set by in-vivo analysis. The dose has to be correlated with subsequent samples and all available data, and the dose will differ between facilities and time periods. The solubility of inhaled aerosols is a major factor in missed dose. Pure Class S material can cause a missed dose to the lungs resulting in a >50% POC without producing a positive bioassay. In many facilities, the solubility of the material is really a mixture of two classes. For example, Class M can be a small contributor to dose, but a large contributor to bioassay.

Dr. Neton provided an example of internal dose reconstruction using an underestimation approach, another using the conservative (overestimation) approach, and another using air monitoring data.

For input parameters using the ICRP 60 methodology, are Monte Carlo distributions used to select particle solubility or size? No. The upper end of Monte Carlo samplings are used to ensure the worst case scenario is considered, without having to run the entire simulation. This strategy is similar to an ICRP 26 study methodology, assuming Y class material and one micron type particle size, but using the ICRP 66 methodology, which factors S class solubility and a 5μ particle size default.

In discussing the potential intake from estimated air concentration, Dr. Neton reported skepticism about the respirator protection factor (RPF) of the early years, unless air samples recorded already considered the RPF. If recorded, NIOSH will evaluate if that was appropriate.

The *Source Term Estimate* is an estimation of airborne concentration without air samplers. An example was shared of machiners grinding uranium dioxide pellets by hand in a hood. The bracketing estimate calculation for such a worker resulted in a calculated exposure of 5×10^{-8} μCi/ml averaged over one hour.

Who will be doing this? There is no question about NIOSH' science, but how about the contractor and other aspects of whoever is doing these calculations? NIOSH means to

document as much as possible how this process runs through guidelines and procedures, but where information is lacking or not ascertainable, the default will be to a conservative approach. Initially, NIOSH will examine every dose reconstruction performed by the contractor. NIOSH will also conduct quality assurance analysis of the contractor efforts and compare it to the contractor's results.

Issues unclear in the current documentation include what will be the documentation/communication procedures for draft results of the claims determination process, particularly in cases of incomplete data? Two issues relate to this, this Board's oversight responsibilities and the appearance of conflict of interest by some of the parties involved. That is a good point and will be an object of NIOSH's attention. The claimants will receive a copy of the technical report, with a-2 page summary of the work/analyses done, including the associated limitations and issues. They also will receive a copy of the interview report and the information received by NIOSH from DOE. The claimant has the right to review the entire case file, and will be made aware of any information that was not available. Section 82.26 provides some detail of what information might be included, if not all; but this particular rule could bear clarification about how these issues will be communicated.

Is there a formal agreement in place with DOE to get the needed data? A Memorandum of Understanding (MOU) is being developed now.

Public Comment:
Public comment was solicited at the end of the meeting; there was no response. Then, with Dr. Ziemer's and Mr. Elliott's thanks to the staff, the public for their comments, and the board members, and the latter's thanks for Dr. Ziemer's chairing, the meeting adjourned at 3:44 p.m.

I certify that, to the best of my knowledge, the foregoing Minutes are accurate and complete.

Paul L. Ziemer, Ph.D., Chair

May 10 2002
Date