Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health

Fourth Meeting of the Advisory Board on Radiation and Worker Health

May 2-3, 2002

Meeting Held at the Washington Court Hotel
Washington, D.C.

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The fourth meeting of the Advisory Board on Radiation Worker Health (ABRWH) was held on May 2-3, 2002, in Washington, D.C. All the members were present, including one new member. The Chair reported the DHHS Secretary's acknowledgment of the ABRWH's recommendations to date. The minutes of the previous three meetings were approved and are all available on the NIOSH Website. The process of the Office of Compensation Analysis and Support (OCAS) was outlined, as was the program status.

NIOSH OCAS Status Reported as of April 26, 2002	
Non-Special Exposure Cohort (SEC) cancer claims submitted to the Department of Energy (DOE) for verification	>15,000
Forwarded to NIOSH:	3634
Acknowledgment letters sent to claimants:	3391
Requests to DOE for radiation monitoring information/claimant advised Responses from DOE	2966 563
Requests to DOE for additional information	51
Phone interviews conducted	0

A demonstration was provided of the IREP system, and a draft version of its User's Guide was reviewed. The software has been so streamlined that only a half-dozen or so mouse clicks will be required by the DOL examiners to determine the compensability of a claim. Training on this software with DOL staff has already been conducted. Hard copy examples of the program materials (as of April 18, 2002) were provided, including the dose reconstruction telephone interview and the NIOSH/OCAS communications (letters/notices) to DOE and claimants during the process.

The publication of the final rules on dose reconstruction and probability of causation (PC) were announced. These allow the DOL's adjudication of all cancer claims not related to the Special Exposure Cohort (SEC). That rule will be published soon.

At several points of the meeting various members of the Board expressed dissatisfaction that the rapidity of the program development process to date had prevented the members from being integrated into its development and full vetting. That lack of participation was felt to weaken the members' full understanding of how the program's components connect and to jeopardize the Board's credibility, if perceived as only a rubber stamp to NIOSH work. The Board requested a discussion, in near-future meetings, of the context in which changes were made to indicate why one path was chosen rather than another.

NIOSH reassured the members on several points:

- The Chair noted the members' acceptance of NIOSH's use of the ICRP 60 model; that information on risk coefficients, dose rate factors, etc., was provided in general terms in past meetings; and the Interactive RadioEpidemolological Program (IREP) software used was tried out by the Board as it was developed.
- A document on the process of distilling the subject matter expert reviews is in preparation. NIOSH has provided the Board with ~75% of the expert reviews that prompted the changes reported, that had been available since January. Those not presented had been available only since the previous Monday. The IREP parallels the NCI IREP on which it was modeled, except for the customization needed to comply with the Energy Employees Occupational Injury Compensation Program Act (EEOICPA) to allow the calculation of PC for all radiogenic cancers. IREP also allows uncertainty to be incorporated into the dose, dose-response relationship and other factors. The differences between the two processes are only in risk and transfer coefficients as outlined at this meeting. NIOSH thought these discussions to be partly an artifact of the fact that both the NCI and NIOSH systems are being developed in parallel.

In discussion, the following was noted:

- The requirement for DOE to provide information within a certain number of days may be a metric this Board should examine.
- Secondary information may provide a different perspective on the personal dosimetry data files (e.g., bioassay data and site profiles). NIOSH will not finalize the dose reconstruction on a claim until convinced that all the information needed was received and considered. The site profiles will be developed concurrently with individual dose profiles. If denied, the claimant can petition for a new hearing and DOL can reopen a case at any time upon new information.
- The letters/information sent will be reviewed to ensure their clarity, particularly the sign-off letter. As communication materials are developed by the NIOSH Health Communication Specialist, they will be provided to the Board.

The comments received by NIOSH on the dose reconstruction and PC **final rules** were presented. These comments addressed the implementation issues or statutory requirements. The changes to the PC final rule added provisions on the process for updating NIOSH/IREP, to include addressing the risk of chemical-radiation interaction (when new data so allow), to notify and allow comment by the public and Board prior to any changes.

Changes to the dose reconstruction final rule included addition of a process for updating methods; a provision allowing NIOSH to review completed dose reconstructions on its own initiative; and clarified the following: 1) the processes involving the claimant (e.g., interviews could be iterative); 2) that NIOSH will use all relevant information; 3) that current ICRP models will be used, including the latest ICRP Radiation Weighting Factors; 4) how the Privacy Act affects availability of exposure records to the public; and 5) the procedures' use of a variety of old biomonitoring records.

A report was provided by Dr. Charles Land, of the National Cancer Institute (NCI), on the **revision of the 1985 NIH RadioEpidemiological Tables** by a workgroup representing NCI, CDC, and a contractor, SENES Oak Ridge, Inc. The 1985 report was based on the third Biological Effects of

Ionizing Radiation (BEIR III) report, and assumed that compensation claims could be adjudicated based on the probability of causation (PC) estimated from epidemiological data. It provided tables and algorithms for 13 cancers and uncertainty analyses. This new update was to bridge the gap between BEIR III and BEIR VII (in development), and includes new data from the atomic bomb survivor dosimetry study, the Radiation Effects Research Foundation (RERF) Tumor Registry, and methodological advances in computing power, modeling, and treatment of uncertainty.

The 2002 report uses incidence rather than mortality data, includes more sites and radon-associated lung cancer, uses computer programs rather than the tables, and emphasizes uncertainty distributions derived through Monte Carlo simulations. The Monte Carlo calculation samples each relevant factor 1000 times to produce a final distribution. The Workgroup developed statistical uncertainty distributions that were then transferred to the U.S. population. The challenges included Japanese/U.S. differences in dosimetry and baseline cancer rates, the latter of which were particularly relevant to stomach, liver, and prostate cancers. Those subjective uncertainties were adjusted based on expert judgement, except for breast cancer, for which the probability was split between additive and multiplicative distributions.

The few data available for ongoing low dose exposures required extrapolation through the use of a 1.0 Dose Rate Effectiveness Factor (DDREF). The excess relative risk per sievert (ERR/Sv) was evaluated with 1) a fitted linear dose-response coefficient; 2) a combination of dosimetry and population transfer factors; 3) the combined statistical and subjective uncertainty ("credibility") distribution in the adjusted risk estimate for all solid tumors combined; and 4) a credibility distribution for low-dose or chronic exposure and low dose-rate risk, using the transfer between populations, dosimetry error, and the DDREF.

Suggestions by an NAS/NRC review of the report were incorporated: grouping sites with few "exposed" cases (the Workgroup used <50); doing shared site modeling to estimate the modifying influences of age at exposure and those of age at diagnosis, and including estimates for radon-related lung cancer and non-melanoma skin cancer. NIOSH's initiatives also supplied:1) an adjustment to provide a smooth function of age at exposure and attained age; 2) development of uncertainty relative biological effectiveness (RBE) factors (still in review) for photons with energy of <250 keV, electrons, neutrons and alpha particle radiation other than radon; and 3) a separate NIOSH version of IREP to incorporate the EEOICPA administrative rules for application of the NCI/CDC report to the claims adjudication process.

A **summary of the modifications made to finalize NIOSH-IREP** was provided by Dr. Mary Schubauer-Berigan of NIOSH: 1) revision of risk coefficients for non-melanoma skin cancer and bone cancer; 2) modification of risk transfer functions for skin cancer and male breast cancer; 3) incorporation of an inverse dose-rate uncertainty distribution for alpha radiation exposures; 4) modification of the DDREF to more heavily weight a value of 1.0 for all solid cancers except breast and thyroid; 5) modification of uncertainty distributions for some RBE factors and for low-energy photons, x-rays, neutrons, and alpha particles.

Although the NIOSH and NCI versions of IREP agree very substantially, there are some differences. For example, NIOSH-IREP and NCI-IREP use different risk coefficients for malignant melanoma of

the skin and for male breast cancer. Some differences in application also were described, as well as potential future modifications, in accordance with the process that will be reviewed by the ABRWH. Comments will always be accepted on the IREP, which is the starting point for policy and science-based decisions.

Public comment, regularly requested, was received by one individual who requested a wish for more information about other agencies' role in the rule's development, particularly NCI. In response, the NIOSH staff indicated that except for one case in the PC rule, NCI was not involved. The ABRWH members were encouraged to stay focused on the Act's intent to meet the government's responsibility to address the sacrifices of Cold War veterans. The program must be properly constructed to ensure fair adjudication; the dose reconstruction criteria must compare equivalents (e.g., is the atomic bomb survivors' healthy survivor effect comparable to worker experience?) A comment at the last meeting about record keeping issues, particularly in light of the lifting of the records destruction moratorium at closed sites, was reiterated.

Regarding both **final rules and the ABRWH's role**, NIOSH was advised to speedily clarify for the public that it will have access to records; to prepare a clear explanation that the law requires use of the NCI tables as updated, which includes epidemiological study data; to include in the narrative the scientific reality when describing the intent of Congress; and to explain why the law addresses covered exposures as it does.

A **presentation of the legislative history behind the EEOICPA** (Energy Employees Occupational Injury Compensation Program Act) was provided by Dr. David Michaels. While serving as DOE Assistant Secretary of Environment, Safety, and Health, he was asked by the Secretary of Energy to address the DOE sites' problems related to sick workers. Dr. Michaels outlined the development of three proposals leading to the final solution.

Proposal #1: Provide equity by extending the coverage of the Federal Employee Compensation Act (FECA) for federal workers, to contractors injured on the job. This would provide a higher benefit cap than most state workers' compensation programs, cover all toxic-related occupational illnesses, and take DOE out of the process completely. This remedy was also extended to beryllium vendors that contracted with the Atomic Energy Commission (AEC). The remedy was exclusive; the compensated employee could not sue for damages.

The White House endorsed this proposal for chronic beryllium disease (CBD) claims and the National Economic Council began an interagency process to examine other conditions. During this time, a Paducah memo surfaced that appeared to prove deliberate neglect of occupational safety and health at the Paducah Gaseous Diffusion Plant (GDP). The legislation developed proposed CBD coverage and a separate cancer payment for the Paducah workers. The proposed legislation for CBD provided as an exclusive remedy FECA coverage for lost wages, first dollar prospective medical coverage, a $100,000 "liquidated damages" settlement, inclusion of vendor employees, and medical coverage for beryllium sensitization. Causation for RECA's listed cancers and bone cancer was provided for Paducah GDP workers. Radiation-exposed workers employed for at least one year before 1992 were covered. An alternative $100,000 lump sum payment was offered, with no medical coverage.

Proposal #2, based on public input, proposed a federal program to address unique nuclear worker situations. CBD (including sensitization) and cancer coverage would be administered by state-based programs; radiogenic cancer compensation was based on the radiogenic tables, embedded presumptions for certain radiosensitive cancers, and used the "as likely as not" language on dose-response. All three GDPs in the DOE complex were included. To eliminate the barriers of state compensation programs, DOE would provide direct federal compensation for conditions "unique to nuclear weapons production," and would work to eliminate barriers in the state compensation systems for the remainder of conditions. This approach also included smaller plants' "atomic weapons employers."

The resulting Thompson-Bingaman Bill followed this proposal, but mandated funding, added coverage for silicosis, and added the Amchitka site to the GDP plants, as well as the SEC and a mechanism to expand it. The benefit level was set at $200,000 or a wage loss option, plus medical coverage. The DOL was assigned as lead agency, with the assistance of DHHS and DOE. The House and Senate bills differed only on the benefit's nature/size and the lead agency (DOL or the Department of Justice (DOJ).

A Conference Committee compromise dropped the wage loss provision and the exclusive remedy stipulation, set the lump sum payment at $150,000, and identified no lead agency. Some coverage for silicosis was included provisionally (the President can remove it at any time). The RECA survivor definitions were used (adult children were not covered, a clause reversed in the later Defense Reauthorization Bill). Equity with DOE contractor employees was provided through another $50,000 payment to uranium miners, and an attorney fee limitation was set. A December, 2000, Executive Order assigned DOL the lead in this program and detailed the responsibilities of DHHS, DOE and DOJ.

ABRWH discussion included note of the concern expressed about the language in the "Sense of Congress" text, particularly the note that "98% of radiation-induced cancers in the nuclear weapons complex occurred at dose levels below the existing maximum threshold levels." A casual reader could erroneously assume that this applies to nuclear workers alone. Since most nuclear weapons workers were exposed to far less than the limits of exposure, Dr. Michaels said it may be true that 98% of the claimed outcomes are caused by less-than threshold limits. It was also clarified that this text arose from a DOE study investigating how many DOE employees who sought compensation for a radiogenic cancer would meet the doubling dose criteria.

The next meeting agenda should include development of a plan for the Board to review the quality of the dose reconstruction. A workgroup was formed to consider the related issues, develop an initial draft of options for this process, to report back to the full committee at the next meeting, and to keep the Board apprized as the Workgroup proceeds.

A complete list of the action items developed at this meeting are appended to the minutes.

National Institute for Occupational Safety and Health
Advisory Board on Radiation and Worker Health
Minutes of the Fourth Meeting
May 2-3, 2002

The fourth meeting of the Advisory Board on Radiation Worker Health (ABRWH, or the Board) was held at the Washington Court Hotel in Washington, D.C. on May 2-3, 2002. The deliberations of the Board and a complete transcript certified by a court reporter is available on the Internet along with the meeting minutes on the NIOSH/OCAS website (www.cdc.gov/niosh/ocas) when complete. The meeting was called by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH), the agency charged with administering the Board.

MAY 2, 2003

Attendance:

Members present were:
Paul L. Ziemer, Ph.D., Chair
Larry J. Elliott, M.S.P.H., C.I.H., 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., C.O.H.N.-S.
Mark A. Griffon
James M. Melius, M.D. Dr. P.H.
Wanda I. Munn
Robert W. Presley
Genevieve S. Roessler, Ph.D.

Federal agency representatives present were:

Armed Forces, Department of the Navy: Commander R.S. Thompson

Department of Energy (DOE): Josh Silverman, Jeff Eagan

Department of Health and Human Services (DHHS):
- Office of General Counsel: Mary Armstrong, Alice Kelley, Liz Homoki-Titus
- NIOSH: Fred Blosser, Larry Elliott, Tracy Gilbertson, Russ Henshaw, Cori Homer, Ted Katz, Jim Neton, Mary Schubauer-Berigan

Department of Labor (DOL): Jeffrey L. Kotsch, Mark Reinhalter

Environmental Protection Agency (EPA): Jerome Puskin

Members of the public who attended over the course of the meeting were:
Neil Barss, SAIC, McLean, VA
William M. Beckner, NCRP
Jim Blankenship, Atomic Trades Labor Council
Jeff Clemm, SAIC

Don Elisburg
Joe Fitzgerald, SAIC
Ray Green, court reporter, Atlanta, GA
Martin Mathamel, Washington, D.C.
Tim McAdams, Westat, Rockville, MD
Richard Miller, Government Accountability Project (GAP)
Frank Morales, GAP
Marie Murray, meeting recorder, Atlanta, GA
Louise S. Presley, Clinton, TN
Randy Rabinowitz, PACE International
Malia Rulon, Associated Press (AP)
Michael Schaeffer, Defense Threat Reduction Agency
Robert Tabor, Fernald Atomic Trade and Labor Council
Nancy Zuckerbrod, AP

Opening Comments:
Dr. Ziemer convened the meeting and called the meeting to order at 8:15 a.m., and welcomed new member Mr. Mark Griffon. Dr. Ziemer also reported that DHHS Secretary Thompson had acknowledged in writing the ABRWH's previous recommendations.

Dr. Kathleen Rest, NIOSH's Acting Director, welcomed the members and thanked them for their service to this important program. She announced the publication of the final rules on dose reconstruction and probability of causation (PC) in the *Federal Register.* This now allows the Department of Labor's (DOL) adjudication of all cancer claims not related to the Special Exposure Cohort (SEC). The draft SEC procedures, hoped to be ready for review at this meeting, are still in final review for publication. She looked forward to the Board's input on the processes of the SEC, dose reconstruction, and the software used, the Interactive RadioEpidemolological Program (IREP). The rapid development of the rules and these processes evidence DHHS/NIOSH' commitment to implementing this program as smoothly and efficiently as possible.

Discussion included:

- *The Board review of the entire program will be difficult without an understanding of how its components connect. Why was it not part of the guideline development process as well as their pre-finalization review? This also could have sped the process.* DHHS wished to ensure its own full understanding of the procedures internally, before putting them out for public comment. Dr. Rest reassured the Board that they were only weeks away from release.

Review/approval of the draft minutes of the January meeting and the February teleconference and meeting followed. Other than any editing comments, which were requested to be sent to Ms. Homer, these were accepted with the following corrections.

January 23-24, 2002 meeting minutes: Insert Dr. Andrade's name in the attendance list (page 1); insert ICRP "weighting" factors (page 24); change "jeopardized" to "enhanced (page 14); insert "a few hours or less" of exposure (page 3/5). Dr. Anderson made a **motion to accept the minutes with**

those edits. Dr. DeHart seconded the motion, which **passed unanimously.**

February 5, 2002 teleconference: Voice vote; **unanimously approved** with no corrections.

February 13-14, 2002 meeting: Voice vote, **unanimously approved** as written. No corrections were made, but the suggestions provided are listed on the action items table attached to this document. Dr. DeHart complimented the quality of these documents, which greatly helped to refresh his memory of the science and the discussions.

Program Status Report:
Mr. Elliott updated the Board on the status of claims received by NIOSH as of April 26:

NIOSH Statistics Reported as of April 26, 2002	
Non-Special Exposure Cohort (SEC) cancer claims submitted to the Department of Labor (DOL) for verification of eligibility	>15,000
Claims forwarded to NIOSH for Dose Reconstruction	3634
Acknowledgment letters sent to claimants by NIOSH	3391
Requests to DOE for radiation monitoring information Responses from DOE	2966 563
Dose Reconstructions underway Draft Dose Reconstruction Reports completed	75 6
Requests to DOE for additional information	51
Phone interviews conducted	55
Claimant visits to OCAS	1
Claimant phone calls received	1454

The OCAS claims process is as follows:

- The claims are forwarded from DOL to NIOSH in batches. A letter acknowledging receipt is sent to the claimants, detailing what they should expect and how to monitor the claim's progress. Samples of NIOSH communications were shared with the Board.
- Addressing each claim individually, NIOSH requests information from DOE to support the dose reconstruction, documents the cancer type, employment length, number of covered sites where the claimant worked and jobs held, and explores relevant NIOSH study information. Information requests to DOE are expected to quicken with the award of the dose reconstruction technical support contract next month. NIOSH is exploring ways to expedite those information requests, how to build site-specific profiles, and with DOE, evaluating how best to verify that no further information exists. These points will be included in the Memorandum of Understanding (MOU) now under negotiation. Aside from requesting further DOE data searches for those

claims with inadequate or incomplete information, NIOSH is also exploring secondary general information sources such the limits of detection for historical dosimetry practices (also applicable to the site profile) and coworker dosimetry data.

- Upon assembly of all information, a computer-assisted telephone interview (CATI) with the claimant is conducted. Completed draft dose reconstruction reports will be provided to six claimants next week. A follow-up phone call will explain it, and the claimant's completion of the OCAS-1 form to close the dose reconstruction process will be requested.
- Of the 1454 phone calls NIOSH has received, 140 were for general information and only ~670 related to actual claims. Most questions relate to claim status, NIOSH's receipt of dose data from DOE, and when the interview would be scheduled.

Discussion included:

- *The requirement for DOE to provide information within a certain number of days may be a metric this Board should examine. Is the data access formalized in the MOU?* That language is being developed now. The MOU language will attempt to establish the collaborative relationship and the method of verification that DOE has searched for all information.
- *Secondary information may provide a different perspective on the personal dosimetry data files (e.g., bioassay data and site profiles); its absence might require revisiting the claims upon new information provided later.* NIOSH will not finalize the dose reconstruction on a claim until convinced that all the information needed was received and considered. The site profiles will be developed concurrently with individual dose profiles.
- *Review the letters/information sent to ensure their clarity, particularly the sign-off letter.* Agreed. Multiple communication contacts include the first letter and brochure describing the program and the dose reconstruction process in lay terms. As the materials are developed by the NIOSH Health Communication Specialist, they will be provided to the Board.
- *What is the delay in awarding the dose reconstruction contract?* This is a competitive process in which the bidders' credentials are audited; a death in the contracting office slowed the process; and questions/responses are being generated to the proposals. Whether the conflict of interest component has been satisfactorily met cannot yet be confirmed.

Probability of Causation Final Rule:
Mr. Ted Katz summarized the changes made to the Probability of Causation (PC) rule, subsequent to review of comments received from 12 organizations and 24 individuals. Aside from the Board's recommendations (ABRWH review of any substantial procedural changes and notification of the public), these comments addressed:

- Peer review of the NIOSH-IREP in its development and updates.
- How chemical cancer risks will be addressed (e.g., whether this will include risk of occupational chemical carcinogens and their interaction with radiation, and how to address non-occupational chemical carcinogen exposures).
- NIOSH/IREP: a) Application of updates with new science/information to those claims already adjudicated under the previous IREP version; b) whether claimants will know the assumptions/formulae and what documentation will explain the results; c) IREP specifics such as risk models used, use of Japanese population study data, adjustments for smoking (felt to be

too high or too low).
- Theoretical/statutory-related comments (e.g., compensation for all claimants who received exposures, or to use a proportional benefit framework, or to use a radiation threshold PC measurement, particularly for rare cancers; or, rare cancers should be presumed to be radiation-related and have their uncertainty so addressed), or whether ICRP standards used for radiation protection and calculating PC should be synchronous.

The changes to the final rule:

- Added provisions on the process for updating NIOSH/IREP
- Changed the rule regarding IREP updates to provide an opportunity for pre-change public notice for Board and public review and comment and public notice of changes.
- Added a provision to allow NIOSH to update IREP to address the chemical-radiation interaction risk. These interactions were explored during rule drafting and this was raised in public comments. While the science and practicality do not currently support this inclusion in IREP, the rule now provides for the possibility that this could change.

In summary, most public comments addressed implementation issues or statutory requirements. The lack of comment on substantive policy decision suggests that the rule reasonably follows through on Congress' intent. The task now is to help the DOL with implementation.

Discussion included:

- *Is this rule subject to federal litigation, and is there any suggestion to date that this might occur?* Most regulations of substance are litigated at some point, but there is no indication that this is pending. Most want to see these rules implemented.
- *How will new science on the synergistic effects of chemical carcinogens and radiation affect future cases? Some such claims go to state workers compensation programs but are rarely awarded.* This will be done as possible in future, but there also is a practical concern of how DOL would use such information. Another provision, Subtitle D of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), covers assistance for people with state claims. Claimants can appeal a year after a claim is denied, but DOL can reopen a claim at any time based on new information.
- *How will future changes to the rule be made; how will the Board and public be notified?* The Board will review any substantial changes to the IREP first and the public will be notified via the Board meeting and FR notice.

Dose Reconstruction Final Rule:
Mr. Katz reported then on the comments received from 13 organizations and 23 individuals, which addressed all aspects of the dose reconstruction rule. These indicate clearly that a large education task will be required to make this program successful. Again, many issues related to implementation:

- Feasibility, precision, reliability of the information on which the dose reconstruction is based; use of efficiency measures.

- Claimants' role (ranging from overburdened to as fully involved as possible).
- Scope of covered exposures: x-rays, chemicals, non-occupational exposures to radiation.
- Selection of ICRP models other than those used in U.S. radiation protection programs.
- Use of DOE's dose record.
- Updating the scientific elements (in particular, paralleling the PC guidelines, what should be done with previous claims upon new scientific information).
- DOE involvement; use of oversight and peer-review (ABRWH role).
- The Board's incorporation as peer-reviewer of the scientific updates; clarification of several provisions (e.g., application of the Privacy Act to dose reconstruction records, procedures for NIOSH to conclude a dose reconstruction, use of current ICRP models).

The subsequent final rule changes were to:

- Add a process for updating methods.
- Add a provision allowing NIOSH to review completed dose reconstructions on its own initiative.
- Clarify the processes involving the claimant (e.g., interviews could be iterative).
- Clarify NIOSH's potential use of all relevant types of information (i.e., aside from those listed).
- Clarify the commitment to use current ICRP models.
- Remove Table 1 (ICRP Radiation Weighting Factors, and clarify that current factors will be used.
- Clarify application of the Privacy Act regarding availability of exposure records to the public.
- Clarify a variety of the procedures' use of old biomonitoring records (e.g., their disadvantages).

Discussion included a suggestion to, in future meetings, discuss specifics of the concerns expressed on implementation, now that the rules are fixed.

Report on Revision of the 1985 NIH RadioEpidemiological Tables:
Dr. Charles Land, of the National Cancer Institute (NCI), reported on the revision of the 1985 RadioEpidemiological Tables by a small workgroup consisting of himself and Dr. Ethel Gilbert of NCI; Dr. Jim Smith (administrative advisor, CDC); and Brian Thomas and Drs. Owen Hoffman and Iulian Apostoaei of SENES Oak Ridge, Inc.

The 1985 NIH report which presented the RadioEpidemiological tables was generated in response to a congressional mandate, which required periodic revisions. The 1985 report proceeded from the assumption that compensation claims could be adjudicated based on the probability of causation (PC), which could be calculated by dividing the excess risk by the baseline plus the excess risk (i.e., PC=ERR/1+ERR, with ERR representing the excess relative risk), as estimated from epidemiological data. A chapter of the report provided tables and algorithms for 13 cancers and another provided uncertainty analyses. An RBE >1.0 for x-rays was recognized by the committee but not addressed due to the lack of data.

The current/potential users of the report included the Department of Veterans' Affairs (DVA), to adjudicate compensation claims for radiation-induced cancer. The DVA commissioned the development of an approach, based on the 1985 tables, to screen out claims for which the upper 99%

credibility limit for PC was <50%. Other users were the Department of Defense (DOD) and now, the EEOICPA.

The DVA requested an update of the outdated 1985 table report, which was based largely on the 1980 third Biological Effects of Ionizing Radiation (BEIR) report. New information available offered longer follow-up, particularly the new dosimetry data on the atomic bomb survivors. The Radiation Effects Research Foundation (RERF) Tumor Registry provided more accurate and comprehensive incidence data. New inferences also had been made since BEIR III, and methodological advances included greater computing power, more flexible modeling, and much more sophisticated treatment of uncertainty.

This update was to be an interim update to bridge the gap between BEIR III and BEIR VII, which is still to be issued. The Workgroup used mainly atomic bomb survivor data and the original RERF incidence data, and emphasized uncertainty: statistical uncertainty based on the likelihood contours of fitted risk estimates. The treatment of other sources of uncertainty followed two NCRP reports written; Commentary #14 and Report #126.

The NAS Oversight Board for the 1985 report emphasized several points about PC: 1) its values pertain to populations rather than individuals; 2) they reflect the properties of the group to which the individual belongs; and 3) as a societal convention, it is agreed to assign the group's PC to the person as an "assigned share" (AS) or "attributable risk." Insurance companies work in the same manner. The oversight committee's argument was accepted by the NIH Workgroup but to avoid changing the terminology already in use, they chose to use the term "PC" rather than "AS."

The PC value and its uncertainty summarize what is known and not known today about ER and ERR of cancer-caused radiation exposure. It is the best and most reasonable estimate that may also be relevant to an individual's claim, but it is not specific to that claim. Criticism of this approach was published by Sander Greenland, who found it a flawed concept subject to bias and unsuitable for adjudication for cancer compensation. Dr. Land considered this argument to be unpersuasive, noting that population characteristics are often used by organizations as a guide in making individual decisions (e.g., as in the use of life expectancy tables.)

The current report differs from the 1985 report in several ways:

1. Its use of incidence data, instead of mortality data.
2. Inclusion of more sites and groups of sites (28 versus 13), since this report was not restricted to sites only with proven association of cancer risk with radiation dose. This report addresses whether the *possibility* of causation is reasonable enough to award a claim. Some sites not significantly associated with radiation doses (e.g., pancreas, rectum, liver) also were included.
3. Inclusion of radon-associated lung cancer, based on the 1995 RECA report for the DOJ.
4. Use of computer programs rather than the tables.
5. More emphasis on uncertainty.
6. Reliance on Monte Carlo simulation to calculate most uncertainty distributions.

Dr. Land provided a graphical synopsis of the Workgroup's approach. They began with the

statistical uncertainty distribution for the atomic bomb survivors exposed to ~1 Sv, used as the basis of the assigned share PC calculation for members of that population. The example provided was sex-averaged ERR/Sv for all solid cancer combined, following exposure at age 30.

Dr. Land shared several line charts demonstrating the statistical uncertainty distributions. He began with a fitted linear dose-response coefficient for excess risk per unit of radiation dose, measured by age at and time after exposure for leukemia (excluding chronic lymphocytic leukemia – CLL). This demonstrated decreasing ERR with increasing age and time from exposure. Thyroid cancer differs, however, posing the greatest excess risk from radiation exposure at younger than older ages. In fact, the risk for adults is minimal.

These calculations were then transferred to the U.S. population. The challenges to this included the difference in dosimetry between the Japanese atomic bomb survivors and the U.S. population, as well as different baseline cancer rates (much higher in the U.S.), which has an unknown effect on radiation-related risk. While it is thought to be a difference of only a few percent for all solid cancers combined, it can differ by an order of magnitude for cancers of the stomach, liver, and prostate gland.

There are no definitive tools with which to adjust for that subjective uncertainty, since existing information is not as well quantified as the statistical uncertainty shown for leukemia and thyroid cancer. Therefore, expert judgment was used to estimate both the adjustments and their uncertainties.

For breast cancer, the outcome changed radically (by an order of magnitude) if the SEER registry data were used, versus the actual difference between U.S. and Japanese breast cancer rates. A chart represented the probability density function (PDF) of an "ignorant" uncertainty distribution resulting from the use of simple additive and multiplicative population transfer models for a linear exposure mixture. This showed a PDF of ~0.9 for both. In contrast, an "informed" uncertainty distribution for linear mixture showed a PDF of ~0.5. And for breast cancer, since data indicated more of an additive transfer function, the Workgroup split the probability between that of a simple and multiplicative distribution.

Extrapolating these estimates to exposures at low doses and low dose rates is hampered by the fact that the most informative epidemiological data on radiation-related risk that can be used pertain to single, acute, high dose exposures, while most compensation claims relate to ongoing low dose exposures. Low dose data also are far less informative about risk, which requires extrapolation.

Experimental studies focusing on biological effects other than human cancer suggest a lower risk per Sv at lower doses and dose rates than the risk at acute higher-dose exposures. A dose and dose rate effectiveness factor (DDREF) was developed to apply that extrapolation as needed. The International Council for Radiation Protection (ICRP) recommends a DDREF of 2.0 for doses <.2 Sv. However, since this showed no risk at a <1.0 DDREF, the Workgroup adjusted it to place more weight on the 1.0 DDREF and to allow some weight for the possibility that the risk may be greater at low doses. This produced a 0.01 probability at 0.5 DDREF and 0.04 probability at 0.7 DDREF. While the charted difference was not great, this allowed for some risk at low doses. A threshold

dose is charted as log uniform.

Dr. Land presented several graphs to illustrate the alterations in measuring ERR per sievert (ERR/Sv) when applying uncertainty factors, including:

1. A statistical uncertainty distribution for a fitted linear dose-response coefficient for ERR/Sv (e.g., a high-dose Atomic bomb survivor), which showed a perfect bell curve cresting at 0.65 ERR/Sv at a PDF of ~5.5.
2. A combination of dosimetry and population transfer factors, which showed a peak ~0.9 ERR/Sv at a PDF of ~1.6, with a long subsequent downward tail.
3. A statistical uncertainty distribution for low-dose or chronic exposure and low dose-rate risk, when applying the transfer between populations, the error in the dosimetry, and the DDREF. The chart reflected a radical shift leftward, showing a 0.2 ERR/Sv at a PDF of ~3.5. Dr. Land commented on the power of the DDREF used to considerably alter the outcome (e.g., it changed the 95% upper confidence limit from .76 to .56 for the ERR/Sv).

The Workgroup's product was reviewed by the NAS/NRC in May 2000. Their November 2000 report suggested a grouping of sites with few "exposed" cases (the Workgroup used <50), as well as shared site modeling to estimate the modifying influences of age at exposure and at diagnosis. They suggested including estimates for radon-related lung cancer and non-melanoma skin cancer. The BEIR VI model for radiation-related lung cancer is hard to apply to PC/AS since the risk curves rise and fall variably. However, the Workgroup found and used a dataset and the original data for the RECA report. The fact that non-melanoma skin cancer is not a reportable cancer in the U.S. presented a challenge in finding rates. But it is reportable in Japan, so they used atomic bomb survivor data.

While the Workgroup had no wish to be involved in the administrative outcomes of these analyses, the report was designed to provide the best possible analysis tolls based on current knowledge. While Dr. Land thought this report to be the best summation of the scientific uncertainties to date, he pointed out that what is done with it is up to NIOSH, DVA, and the other involved agencies.

In addition, NIOSH contributed to the development of the Workgroup's report:

- To minimize unreliable extrapolation with regard to exposure age and attained age in the default modeling of modification of ERR (1 Sv), the model was adjusted to provide a smooth function of age at exposure and attained age. This was more to the claimant's favor, although in general both the prior and new models fit equally well.
- NIOSH requested SENES to develop uncertainty RBEs for photons with energy <250 keV, electrons, neutrons and alpha particle radiation other than radon. These are still in review.
- A separate NIOSH version of IREP was created to incorporate the administrative rules for application of the NCI/CDC report to the claims adjudication process under EEOICPA. This also could serve as a model for a possible DVA version.

Discussion with Dr. Land included:

- *Radon is not used in this model, but is part of occupational exposures at some sites.* The Workgroup used exposure data and working level dose. We duplicated some of the RECA report tables and then modeled the ERR as a function of age at and time since last exposure. Working level months were taken to the 0.83 power, and the dependence on age of and time since last exposures was similar to that used for other cancers. This was not converted to dose, although the data relate to dose.
- *What was the rationale used to group the sites with <50 cases; biological, physiological, etc.?* To cite an example, an estimate cannot be done for miscellaneous digestive cancers, suggesting that they be approached as a group. They were grouped as most logical and most convenient. For example, a site-specific estimate could be done for urinary bladder cancer, but not for the rarer kidney and other urinary diseases presenting <50 cases, which were therefore grouped.
- *It was commented that the recent RERF Lifespan Study recommended a DDREF value of unity rather then a value of 2.0.* Yes, they do, because the epidemiologic data look linear and would use a DDREF of 1.0. But that is based on the linearity of the dose response; there is little evidence to suggest otherwise, if that is taken as the default. But this model uses experimental data, based on analogous systems such as chromosomal aberrations, mutations, etc. These data provide a clear curve, but they are not cancer data. The ICRP suggests using 2.0; the question then was how far beyond the official consensus the analysis should go. Their analysis has some probability at 1.0 and some at <1.0, and that movement makes a significant difference in the upper 99% of the uncertainty distribution.
- *Please explain your comment that the Monte Carlo calculation is not necessarily better, but is easier.* This calculation would be easy if all the distributions were log normal, but was difficult with the type in hand. The Monte Carlo method splits the factors and applies their distribution, then multiplies the various factors together 1000 times to produce a distribution. The computer technology was not present to allow this in the 1985 report, which was based completely on log normal probabilities. With today's computer technology, the problem now is with the upper 99th percentile, which is unstable without a large sample size; but with it, the calculation time is still lengthy and probably not possible to do on the Web.
- *Isn't the confidence improved/stabilized with by increasing the sample size?* Yes, but that still will take some time on the Web (e.g., 10 or more minutes), something for which people have little patience.

Summary of NIOSH-IREP:

Dr. Mary Schubauer-Berigan summarized the use of the NIOSH-IREP program under the PC final rule. EEOICPA requires calculation of PC using an "at least as likely as not" standard (>50% PC) at the upper 99th percentile of its uncertainty distribution. The PC is approximated by the calculation of assigned share.

The NIOSH-IREP software is based on the NCI-IREP program but was specifically adapted to implement the EEOICPA by allowing the calculation of PC for all radiogenic cancers. IREP allows uncertainty to be incorporated into the dose, dose-response relationship and other factors. Using those data, the upper 99th percentile PC then will be calculated by DOL.

The probability of causation is estimated by dividing the relative risk (RR), minus one, by the RR (RR-1/RR) , or by the excess relative risk (ERR) divided by one plus the ERR (ERR/([1+ERR]).

The ERR is estimated from epidemiologic models of dose and cancer risk. Separate models were developed for each cancer or group of cancers. These models incorporate the statistical uncertainty about the RR estimates; the uncertainty associated with the exposures of the study population; uncertainty about the effects of confounding variables; uncertainty about the transfer of risk coefficients to other exposure scenarios and populations; and uncertainty associated with the claimant's exposure.

Modifications made to finalize the NIOSH-IREP include:

- Revision of risk coefficients for certain cancer models in NIOSH-IREP, addressing:
  - Non-melanoma skin cancer: new NCI-IREP models separate basal cell from squamous cell carcinoma. If the claimant's skin cancer cell type cannot be ascertained by DOL, the basal cell carcinoma (BCC) estimates are used.
  - Bone cancer: residual cancer risk coefficients are used, as recommended by NCI and subject matter experts.
  - Skin cancer and male breast cancer: a general uncertainty distribution is used that equally weights multiplicative and additive interactions, rather than favoring an additive model.
- An inverse dose-rate uncertainty distribution was incorporated for alpha radiation exposures.
- The dose and dose rate effectiveness factor (DDREF) was modified to more heavily weight a value of one for all solid cancers except breast and thyroid. For the latter, which had no values for distributions <1.0 in the draft IREP program, modifications shifted some of the distributions to allow for that.
- Upon expert consultation, some uncertainty distributions for some relative biological effectiveness (RBE) factors (now called "radiation weighting factors") were modified for:
  - Low-energy photons (small increase in the uncertainty distribution) and high-energy photons (slightly redefined to >250 keV).
  - X-rays, neutrons (slight increase in the central tendency and uncertainty distribution), and alpha particles (slight increase in RBE uncertainty distribution). A hybrid distribution was also weighted to the lower leukemia RBEs.

The final NIOSH-IREP is very similar to the NCI-IREP; its differences are to conform with the EEOICPA. These include the NIOSH-IREP's use of:

- Different risk coefficients for malignant melanoma. The NCI-IREP recommends no particular model. NIOSH-IREP uses the basal cell carcinoma (BCC) model because it: a) offers similar point estimates to the malignant melanoma model of the atomic bomb study; b) is supported by some evidence from nuclear worker studies; and c) the residual cancer model produces a lower estimate of risk per unit dose. This is consistent with policy used elsewhere to give the claimant the benefit of the doubt.
- Different risk coefficients for male breast cancer (MBC). The use of female breast cancer (FBC) risk coefficients was questioned. The NCI-IREP includes male breast cancer (MBC) in the residual category. The NIOSH-IREP uses FBC coefficients because MBC also appears to be hormonally related, and the residual cancer model produces generally lower risks per unit dose.
- Individual models are used for the "miscellaneous" categories by cancer type: connective tissue, eye, non-thyroid, endocrine, and "ill-defined" cancers.

- Differences in application include the NIOSH-IREP's use of an objective list of cancer models for claims in which the primary cancer site is unknown, its required use of two or more models for some leukemias, and operational smoking definitions for lung cancer models.

Potential future modifications resulting from new science include improvements in risk models or adjustments of uncertainties, using BEIR VII update of risk coefficients and input from epidemiological studies of nuclear workers; changes in dosimetry practices; adjustment for temporal changes in U.S. cancer rates; adjustments for radiosensitive sub-populations; adjustments for interactions with other workplace exposures.

In summary, the finalized NIOSH-IREP:

- Added several models to the software in response to comments by subject matter experts and the public: risk coefficients for bone/skin cancers; risk transfer functions for skin cancer and male breast cancer; and the adjustment of DDREF and RBE distributions.
- Justification of modifications are to be found in the final PC rule and final technical documentation of NIOSH-IREP.
- Documentation of NIOSH-IREP models and assumptions will be provided on line.
- Future modifications will be formalized and are subject to review and comment by the ABRWH.

Discussion included:

- *How are the expert consultations related to the Board's input? The Board will need to go into detail if it will address future modifications to this final model. There is a pattern of last-minute presentations for the Board's approval. The members repeatedly learn that expert review was solicited and changes were made, but does not see that science review, even though it is responsible for determining if those changes were appropriate. That cannot be done in the abstract.* The legislation mandates this Board's involvement in developing policies, not approving a final product, and its preamble states that the ABRWH will review the current IREP and is responsible to issue a review of it.
- Mr. Elliott reported the rush to put this in place to allow the DOL to begin adjudication. While the ABRWH did not see all the experts' comments, these are part of the documentation referred to by Dr. Schubauer-Berigan. In the next two weeks, the first batch of claims may be transmitted to DOL to adjudicate, using the IREP. The Board will be informed of and advise on any modifications. NIOSH understands the Board's discomfort at receiving information late, since NIOSH faces the same problem in making its own policy decisions. Such information is provided to the Board almost as soon as it exists. He reassured the Board that IREP was held apart from the rule, which is set, so that comments on IREP will always be accepted. It is the starting point for policy and science-based decisions.
- Dr. Ziemer found the calculation program of lesser interest than its underlying assumptions. He noted that the Board also had accepted use of the ICRP 60 model; that information on risk coefficients, dose rate factors, etc., was provided in general terms in past meetings; and that the IREP was tried out by the Board as it was developed.
- Dr. Schubauer-Berigan stated that the Board had received ~75% of the expert reviews, which

had been available since January. The RBE and DDREF reviews had been available only since the previous Monday. IREP uses the same DDREF as NCI's, a change from the draft, based on the desire to heavily weight it toward 1.0, part of NIOSH's more claimant-friendly approach. A document on the process of addressing the subject matter expert reviews is in preparation.

In other comments, the Board members commented on the following:

- There was general agreement that the Board can be more helpful to NIOSH if involved in the entire process. It not helpful to advise on a fait accomplis of a final document. To best conduct this process in the long term as part of the team, the Board should know up front the questions asked, literature reviewed, alternatives/options considered, etc. All portions of the process need to be known, to allow meaningful input on the route to be taken. Discomfort was expressed that changes were made without full vetting that includes the Board. There was uncertainty that these changes would be endorsed without more information on why they were made. While it is not an expert body, but an advisory panel, there are changes (e.g., DDREF, RBEs) that are important to this Board.
- It was hoped that this Board would not face the same fait accomplis with the SEC guidelines. It must not become a rubber stamp or have to rush through examining them. That would not be fair to the ABRWH, the claimants, or the congressional intent that set all this up.
- The difference was noted between advising that information is available as opposed to NIOSH distilling and providing it to the Board was noted.
- In near future meetings, discussion was desired on the context within which changes were made, why one path was chosen rather than another, etc. For example, were the DDREF changes made due to one recent study, or a compilation of many studies indicating the need to tend toward 1.0, or was this just a decision to be conservative? The Board needs to know the context of those change decisions, to either accept them comfortably or to question them, as outlined in the charter.
- Understanding the late-breaking nature of the information to date, the Board requested that NIOSH provide in advance the information to be discussed in the meeting, whenever it is available, either electronically or in hard copy, as long as this does not interrupt the agency's ability to bring all this to an operable point. While it is appropriate for the Board to ask for at least the rudiments of any changes to be made early on, there may be nothing to advise on until the agencies decide how they will deal with it.

Dr. Neton stated that the Act required NIOSH to use IREP or subsequent versions, although it allows modifications. It is almost certain that the DDREF and RBE distributions of NCI and NIOSH will not differ; NIOSH is essentially adopting the NCI IREP. NCI's RBEs are not finalized, but it was significant that Dr. Land had indicated his endorsement of them earlier in the day. The differences between the two processes are only in risk and transfer coefficients as outlined by Dr. Schubauer-Berigan. These discussions are partly an artifact of the fact that both systems are being developed in parallel. However, Dr. Ziemer noted a lack of clarity about which agency is deciding: is NCI accepting NIOSH's, or vice versa? The Board wishes to know why changes are being made, acknowledging this is happening in almost real time, and the basis/scientific context for Dr. Land's apparent endorsement.

Mr. Elliott summarized the Board's requests, that:

1. NIOSH send not only final information, but information as it is developed, electronically and by hard copy;
2. Identify with the committee what issues the members want to know about in more detail and what they wish to advise upon;
3. Provide the RBE and radiation weighting factors document in development;
4. Provide the subject matter expert comments not seen by the Board to date (perhaps an agenda item for the next meeting).

Not wishing to micro-manage the staff but to still attend to the broader issues of how this law is administered nationally, and to provide the Board with a comfort level on how the final product is developed, Dr. Ziemer suggested the members identify the IREP issues of concern and explore whether experts from other fields raised similar issues. The following topics were suggested:

- Discussion and agreement on a process on how this Board functions, generically,
- Discuss at the next meeting individual IREP concerns, or have NIOSH representatives discuss the changes and important factors.
- Schedule informational discussions in future, even before a document is developed in draft form.
- Discuss the process on how the Board will review the dose reconstructions done.
- Keep in mind long-range issues such as age at exposure, due to public and expert comments received.
- With this list, explore any other pertinent issues on which NIOSH could prepare presentations.
- Assume transparency of the IREP model, especially since it is on the Internet. The Monte Carlo process is mysterious to most, particularly how the Monte Carlo uncertainty analysis is done.
- Clarify how the cancer grouping was done.
- Provide copies of the technical reviewers' comments and notify the members when things are placed on the Web.
- Provide more details of the models used in IREP, including raw data. (Dr. Schubauer-Berigan reported that the version on the Web has some model details but stops at the ERR per sievert coefficients. NIOSH is working with NCI on this, but until that version is finalized, it cannot be posted. However, NIOSH's intention is that the documentation will be at least as transparent as that used for version 2.1).
- Present the questions or opinions the experts and NCI had about IREP themselves, or what they would like it to include, in terms of components of what the IREP program addresses. The varied representation of this Board and other experts available could perhaps be helpful.

Presentation of the IREP Users Guide:
Mr. Russ Henshaw presented the IREP User's Guide which was developed by SENES Oak Ridge, Inc. He, Brian Thomas, and Jeff Kotsch of DOL had just returned from training DOL staff around the country on the IREP's use. The example provided at this meeting and in the

training program only used 500 iterations; DOL will use 2000. He demonstrated this on the Internet. The User's Guide also provides a glossary.

Since the last demonstration for the Board, the changes included creation of an input file which, when sent to DOL, will automatically fill every input point of the software. (However, data can still be entered if desired.) For most claims, DOL examiners need only execute about a half-dozen mouse clicks to produce a PC calculation for adjudication purposes. The resulting output file contains an abstract of all the information from the input file and the PC results are delineated by the first, fifth, fiftieth, ninety-fifth and ninety-ninth percentiles. The claim demonstrated was compensable, producing a >55% PC.

SENES Oak Ridge is currently developing a feature which will allow the automatic calculation of PC for claims involving multiple primary cancers, avoiding the need to plug individual results into a mathematical equation. DOL will receive separate input files for each run for unknown primary cancers. Multiple software runs may also be needed for claims in which PC falls between 45-50%. To allow the DOL examiner to run it again, a "generate new random seed" button was added, which generates a number between one and one million. The DOL examiner will simply change the random sample size and run the calculation again. SENES developed the software with the goal of making it as simple as possible, and DOL is pleased so far.

Discussion included:

- *Information need not be entered about the distributions anymore?* Yes, the input file will provide all the information relevant to the claims. The input file was shown that had been downloaded in the presentation, a spreadsheet holding all the information gathered by NIOSH: gender, exposure, DOE site, etc. Most distributions are log normal or perhaps constant, but there are portions of the pull-down menu that allow adjustment of the dose distribution.
- *How is chronic exposure handed?* A mouse click can adjust the exposure parameter from acute (the default) to chronic.
- *This will be on the Web page for the claimant; is there concern that they may get a different result? Do you give them the data file?* No. An exact copy of the spread sheet is part of their dose reconstruction report, so they can enter those data themselves if they want to check for correctness. All changes were made with the DOL claims examiner in mind. Once they reach the PC results step, they save the file as an HTML-only file to prevent any changes in the formatting.
- *Has NIOSH done any sets of examples (e.g., in the way Dr. Land compared the IREP to the old epidemiologic tables by age, exposure scenarios, etc.)?* The difference between the NCI-IREP and NIOSH-IREP is that the latter allows input about variations in dose distribution, making a direct comparison of the two difficult. But the NAS review panel expanded Dr. Land's comparison, which will be in its final report. NIOSH did not feel the need to do more than that. NIOSH's primary approach also has been to use the latest scientific information, which is not necessarily always to claimant's benefit. If the ICRP 60 model provides a lower PC than the old one, NIOSH will not use the old one to consistently favor the claimant. The same models will be used for all. But if NIOSH has information that is not definitive, the raw data will be used.
- Dr. Ziemer encouraged NIOSH to ensure that terms used in the S.I. system of units are

Dr. Anderson noted that the *Federal Register* responses frequently indicate the responding person's or organization's name, which often helps to understand the response. Mr. Katz reported NIOSH's decision to favor brevity by excluding that, and Dr. Ziemer noted that an individual's comments also sometimes are accorded less weight. Nonetheless, Dr. Melius agreed that this would be enlightening, and asked that the individual respondents' names be added in future. With no further comment, the meeting recessed at 4:20 p.m.

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Upon reconvening at 8:44 a.m. the next morning, Dr. Ziemer reviewed the work schedule and topics discussed the previous day. Mr. Katz reported that the SEC materials were expected to the ready in about two weeks, and would be then be followed by a 60-day comment period.

The next meeting was scheduled for July 1-2, 2002. Potential sites meeting locations and their related sites were suggested: Seattle (Hanford), Denver (Rocky Flats), Cincinnati (Fernald, Portsmouth), and Chicago (Argonne National Laboratory). NIOSH staff will check on the related logistics.

Continued Discussion on Final Rules/ABRWH Role:
Dr. Ziemer reviewed the final rules and the members commented on the following components:

Part 81: Probability of Causation Rule

Page 22, staff response to public comments (applicable to both rules): Since doses and exposures differ between the groups, NIOSH should have ready a clear explanation that the law requires use of the NCI tables as updated, which includes the epidemiological study data. The narrative describing the intent of Congress also needs to address the scientific reality.

Need for peer review: the ABRWH's expertise. Dr. Roessler appreciated the text indicating the Board's ability to solicit expertise in its discussions, and thus provides a way to deal with any questions about the Board's expertise. Mr. Elliott stated that NIOSH would handle such consultations through a "fee-for-service" mechanism.

Covered exposures. Similar to the page 22/staff response to the public, supply the reason the law is the way it is. An informational presentation from NIOSH was requested on the state of the art on synergistic effects.

Radiation dose threshold for calculating PC. Dr. Roessler appreciated the several paragraphs explaining both threshold and uncertainty, particularly regarding the grouping of rare cancers, concepts which are both controversial areas.

Technical elements of IREP. Updates on almost all these subjects have already been requested by the Board. Age at exposure was added, including the healthy survivor effect.

Cancer diagnosis by ICD-9 (page 82). It was noted that ICD-10 is now available.

grammatically correct when printed in the NIOSH-IREP User's Guide or in other documents.

Continued Discussion, Agenda Topics:
Mr. Elliott agreed to generate a table of the topic suggestions noted by recorder in the meeting, which will include the topic's status. He reviewed the topics proposed to date in the previous meeting minutes and responded to them, after which more topics were added. These are itemized on a chart attached to this document.

Public Comment:
Mr. Richard Miller, of the Government Accountability Project (GAP), commented that the preamble of the PC rule indicates a disproportionate role by NCI in answering questions from the public or experts. For example, the question of what to do about the age of exposure debate seems to have to be done through NCI. Since the NCI model applies to the Atomic Veterans Program as well as this program, the Veterans Program would also need to be modified. Modification would require an interagency process. It seemed clear to him that this is not just a NIOSH rule, since it involves other arms of DHHS and perhaps more. He wished to see intra-agency communications between NCI and other involved agencies described on the Web page or elsewhere, to understand what each communicated to the other to result in what was being described on this day. Mr. Katz responded that he was unsure what could be shared, but was willing to do whatever was possible. The agencies who received/responded to comments (DHHS, DOL, DOE, DOJ, and OMB and the Defense Threat Reduction Agency) provided comment. NCI was not in that loop.

Mr. Miller said he was startled and confused, in reading the preamble, by the specific comments about PC, and rather than finding NIOSH describing this as insufficient evidence or weight of evidence, he read NCI's view on this. He asked NCI's role in this, particularly with regard to making policy decisions on this model. Mr. Katz responded that there were a very few instances with this rule in which NCI is discussed. In most cases, the EEOICPA and DVA populations are similar and there is no scientific reason to discriminate between them. But there is only one case in the PC rule where that was not so, and consensus was desired on how to deal with that scientific issue.
Mr. Miller noted distinctions, though, in the epidemiology studies (e.g., of the effects of a single blast exposure at a test site versus long-term chronic exposure at an oxide facility to a worker with inadequate protection), and noted that the *Federal Register* referenced studies on the effect of degree of exposure (e.g., to someone age 40 versus younger). The extent that NCI will play a role in determining what is good for this population should be transparent, whether conveyed by memos, e-mail, etc., to allow insight for those out of government on how conclusions travel from one part to another. Reading the preamble and just guessing what might be happening is difficult; those conversations should be on the record.

Closing Discussion:
Dr. Ziemer asked if the Board wished to discuss the SEC (e.g., issues to be addressed, and changes in the rule) despite lack of the draft document. The Board decided not to discuss issues surrounding the SEC procedures. The did wish to read through the Final Rules and comment. However, they noted the lack of a redlined/strike out document made it too difficult to see the changes. The members agreed to review it after the meeting. Mr. Katz pointed out that the preamble summary in each rule indicates the changes made to each section.

Part 82: Dose Reconstruction Rule

Who receives dose reconstructions. Dr. Anderson noted the need, in view of aggressive cancers, to determine the claimant's cancer stage in order to determine when to interview as part of the dose reconstruction. Mr. Elliott reported that NIOSH has a "compassionate category" to address this.

Use of information:

- This raises the issue of data access. The faster NIOSH clarifies for the public that NIOSH will have access to records, the better.
- Page 31, top: A claimant comments on the burden of proof and that "most of the parameters relate to information held by NIOSH" suggests that NIOSH will have much of this data, when in fact DOE has it. DOE's provision of all information may involve more than personal dosimetry. While NIOSH has the lead, there is a dependence on DOE's cooperation. Mr. Elliott clarified that this text was specifically written in response to the comment, to make it clear that NIOSH is responsible to assemble the case information file, not the claimant. The resources to administer the program are guaranteed through DOL appropriations that are apportioned to NIOSH according to its work plan and budget. DOE is responsible to provide the records, using their own resources.
- *How can the ABRWH expedite this process?* The Board's vigilance, expressed concern, and continued observation of the process is very helpful. No intervention currently can speed the execution of the MOU; that process is within the DHHS now.

Use of ICRP models. Dr. Roessler found this section to be particularly well written, making it possible to defend the position that the best science is being used in the process. But the fact that individual cases may require decisions made by the dose reconstruction team emphasizes the need for ABRWH to establish how an independent review would be done.

Reviews of methods used in completed dose reconstruction. Dr. Ziemer related the comment on page 59 to Dr. Roessler's comment. The rule should require the Board to do an independent review of a sample of the dose reconstructions, with the Board to determine the procedures of the dose reconstruction.

Mr. Griffon asked if any listing had been developed of substantial changes made to the regulation itself. Mr. Katz responded that only the use of the current ICRP models was altered and Table 1 with weighting factors was removed. Mr. Elliott added note that the preamble to the final rule requires less background than did the drafts.

Presentation of EEOICPA Background:
Dr. David Michaels, of the George Washington University School of Public Health, outlined the legislative history behind the EEOICPA. He thanked Dr. Ziemer (who like Dr. Michaels is also a former DOE Assistant Secretary) for his work, and the Board members for their willingness to serve. He provided the historical context for the enactment of the Energy Employees Occupational Injury Compensation Program Act (EEOICPA).

In 1998, when Dr. Michaels became the DOE Assistant Secretary, the common perception of many of the sick workers at DOE sites was of toxic exposures as the cause. This was not unreasonable, considering their work with toxic materials, the secrecy of the processes, and DOE's lack of credibility. The latter stemmed from its dispute of claims, uncompensated cases of chronic beryllium disease (CBD) in the Colorado Rocky Flats site; a proliferation of expensive, no-win lawsuits; and anti-worker compensation policies. For example, the Pantex contractor's beryllium screening program encouraged workers to file compensation claims, which were all rejected, a common occurrence at DOE sites even when DOE acknowledged the cause. DOE Secretary Richardson asked Dr. Michaels to address these problems within a month of his arrival.

Proposal #1:

The resulting initial proposal was to provide equity by extending the coverage of the Federal Employee Compensation Act (FECA) for federal workers, to contractors injured on the job. Four advantages of this were that: 1) most state workers' compensation programs capped benefits at two-thirds of the state median, while FECA's was higher, a two-thirds to three-quarters of the federal median; 2) this covered all toxic-related occupational illnesses and 3) took DOE out of the process completely; and 4) this remedy also was extended to beryllium vendors that contracted with the AEC. The latter had sent industrial hygienists to sites that had been closed down for over 10 years. The dozens of employees affected had no employer left in place to compensate them. The disadvantage was that this was an exclusive remedy; the compensated employee could not sue for damages thereafter.

The White House immediately approved this proposal for chronic beryllium disease claims and requested that legislation to be developed. The National Economic Council (NEC, the domestic equivalent of the National Security Council) examined conditions other than CBD in an interagency process involving DOE, DOL, DHHS, EPA, NRC, and NASA.

During this time, the Paducah allegations of deliberate suppression of known exposures surfaced. A *Qui Tam* suit was filed alleging multiple environmental safety and health violations by DOE, principally from transuranic contamination of recycled uranium. An uncovered 1960 memo about environmental safety and health at Paducah related that neptunium 237 was found in reclaimed feed materials provided by the Hanford site. The workers were supposed to wear special face masks, but were not controlled too closely. Np-237 was detected in their urine, but not consistently. It went on to note that ~300 Paducah employees should be checked, but the site hesitated to proceed with this intensive study because of the union's potential use of this as an excuse for hazard pay. The memo was filed in the 1960s and the exposures were kept secret.

The legislation developed proposed CBD coverage and a separate cancer payment for the Paducah workers.

- The initial legislative component for CBD provided FECA coverage for lost wages, prospective medical coverage, a $100,000 "liquidated damages" settlement, inclusion of vendor employees, and medical coverage for beryllium sensitization. Again, this was offered as an exclusive remedy.

- The Paducah component for the Gaseous Diffusion Plant (GDP) workers was modeled on the Radiation Exposure Compensation Act (RECA). It presumed causation for the cancers listed under RECA, and added bone cancer as well in view of the transuranic exposures. Radiation-exposed workers employed for at least one year before 1992 were covered. Alternatively, a $100,000 lump sum payment was offered, with no medical coverage.

Proposal #2:

Meetings around the country to vet the initial proposal produced a second administration proposal: a federal program to address unique nuclear worker situations. CBD (including sensitization) and cancer coverage were provided as before, administered by a state-based program. Radiogenic cancer compensation was modeled on the exiting DVA "Atomic Veterans Program," which was based on the radiogenic tables. The Paducah proposal was expanded to include all three GDPs in the DOE complex, all of which had poor radiation protection. A DOE-based program for all other conditions (to eliminate the barriers of state compensation programs) would provide direct federal compensation for conditions "unique to nuclear weapons" production, and DOE worked to eliminate barriers in the state compensation systems for the remainder of conditions. This approach was based on a program at the Fernald, Ohio, site, where nationally recognized experts reviewed compensation claim cases and recommended on compensation. The proposed program also included smaller plants' "atomic weapons employers" and recommended compensation.

The general idea was to parallel demonstrably successful federal programs in place. Of these, the "Atomic Veteran" cancer compensation program was a model. It compensated veterans with cancer who had been exposed to radiation from AEC/DOE products. It included exposures in Japan, from the Nevada Test Site, and even from Hanford releases. This was a "science-based" model with PC estimated through use of NCI's RadioEpidemiological tables. Presumptions are embedded for certain radiosensitive cancers. The benefit of the doubt is provided to the veteran's claim through use of the "as likely as not" language on dose-response.

The proposal was sent to Congress, resulting in the Thompson-Bingaman bill, which was similar to the administration's second proposal. The differences included mandatory funding (in response to the RECA debacle where compensation was acknowledged, but RECA was not funded to pay the $100,000). This mandatory funding also was applied to RECA, at $400 million in 2002. The bill also added coverage for silicosis caused by digging underground holes for detonations without adequate protection. The SEC was provided for, to include the three GDP plants and the Amchitka site, and a mechanism to expand the SEC was proposed. The benefit level was set at $200,000 or a wage loss option, plus medical coverage. The DOL was assigned as lead agency, with the assistance of DHHS and DOE. Strong local interest led to strong congressional support.

The program, part of the 2001 Defense Authorization Bill, was adopted by a large margin in the Senate, and the House bill added a Sense of the House Resolution. The differences between the two bills included the nature and size of the benefit and designation of the lead agency (DOL by the Senate – lump sum or lost wages, and medical coverage; versus the House's designation of a DOJ lead, which administers RECA, offering a lump sum payment without medical coverage).

Outcome: A Conference Committee compromise was written that dropped the wage loss provision and the exclusive remedy stipulation. The lump sum payment was set at $150,000 and no lead agency was identified. Some coverage for silicosis was included provisionally (the President can remove it at any time). The RECA survivor definitions were used (adult children were not covered, a clause reversed in the later Defense Reauthorization Bill). Under RECA, equity with DOE contractor employees was provided through another $50,000 payment to uranium miners, and an attorney fee limitation was set.

An Executive Order signed on December 7, 2000, basically returned to the Thompson-Bingaman model for agency roles and responsibilities. DOL was assigned as the lead agency, and the responsibilities of DHHS, DOE and DOJ were detailed. (Dr. Michaels applauded the "phenomenal job" done by DHHS/NIOSH in developing the rules). An Interagency Workgroup was also established, with representation by DHHS, DOL, DOE, DOJ, OMB, and the NEC.

Finally, this Act was amended in the 2002 Defense bill, to clarify survivor definitions, increase the attorney fee limit, change certain litigation-related provisions, and to direct NIOSH to study the effects of residual contamination. The resulting program is a network of pieces of programs that were already working well, that were cobbled together with compromises and a few new approaches. In short, it is a combined product of scientific, historical, and political forces.

Discussion with Dr. Michaels included:

- *Frequent concern has been expressed about the language in the "Sense of Congress" text. How did that arise?* Congressional aides developed it to reflect the feeling of the members who supported this program. It is not meant to describe specific actions, but to reflect the intent behind it.
- *Why is there an attorney fee, since this is not a worker compensation-type program?* Under RECA, the attorney gets 2% of the settlement and 10% if there is an appeal. This bill allowed 2% to be applied to the $150,000 lump sum provision. The percentage acknowledges that an appeal constitutes more work by the attorney, and DOL wanted to ensure compensation high enough to interest a good lawyer. This is not a consistent system; in this case, the RECA component required that.
- *Please comment on the SEC's two criteria, when it is not feasible to estimate radiation doses, but it is feasible that the radiation dose could have produced effects.* Normally, legislative language is drafted multiple times, but this one was done in one sitting. Since many reported disbelief of their dose records, Congress took the GDP approach and threw on the ABRWH the responsibility to figure out how and who to compensate.
- *The Sense of Congress statements, even though not part of the Bill, are very misleading, especially to the public. For example, item 6 of the Bill has two sentences. One states that linking exposure to development of occupational disease is difficult, but that scientific evidence supports that beryllium dust vapors can cause CBD and CBD sensitivity. There is no dispute with that, but there is with the second sentence. It states that "98% of radiation-induced cancers in the nuclear weapons complex occurred at dose levels below the existing maximum threshold levels." If applied to the general population, that is probably accurate, but the casual reader will assume it applies to the nuclear workers alone, which is very misleading; and as*

part of the law, this becomes more than a casual misstatement. Most workers in the nuclear weapons complex were not exposed to anywhere near the limits of exposure, so it may be true that 98% of the claimed outcomes are associated with less than the threshold limits. Hundreds of thousands were exposed to low doses. But aside from that, Dr. Michaels' own review of the interagency review of the Thompson-Bingamen bill showed that no one ever discussed the Sense of Congress findings. Only what the agencies were being told to do was reviewed.

Dr. Ziemer commented that this was pertinent to Congress, but also to the concerns voiced about the public's perception. The ABRWH may wish to comment on that at some point. Mr. Miller reported that GAP had developed language to amend that part of the law, and would appreciate the Board's comment on that language.

Those whose claims are denied will undoubtedly question the accuracy of the dose, regardless of the science used to develop it. Do you think that the strong scientific support for the SEC will continue? Dr. Michaels was confident that the dose reconstruction and PC modules, if properly explained to workers, will show that even with an inaccuracy in their individual dose, they will be compensated if they are anywhere close to the cutoff. And those who are victims of egregious site exposures and/or poor record keeping have the SEC route as an option, and record searches will go beyond individual dosimetry.

Were there any criteria in mind when provision for "reasonable likelihood that radiation dose may have endangered" a person was created (e.g., epidemiological study)? Dr. Michaels responded with his estimation that the framers crafted that as the best they could develop in the time they had, and assumed that experts would be available to follow up.

How will conflict of interest be handled when the contract is let for dose reconstruction, considering that this involves a small qualified professional community, including this Board itself and the potential contractors? This pertains to credibility of the process. NIOSH didn't ask for input before the RFA was issued, but the Board needs to see the plan. Mr. Elliott responded that this is a procurement issue; the contract will have a conflict of interest plan agreed upon by NIOSH and the proposer. The Board will not have an opportunity to advise on it, but can evaluate and comment on it.

NIOSH also was advised, when considering tracking total number of claims received by DOL, etc., to also consider such additional factors as kinds of cancers, a template for an update report, how often statistics will be generated and put on the Web, etc; and track any quality control issues (e.g., number of days from receipt to issuance of the acknowledgment letter, to adjudication, etc.)

Public Comment:
Mr. Richard Miller agreed to the concern expressed about the Sense of Congress finding, noting that neither the administration nor the public was involved in the Conference Committee process. However, he was able to provide some context to the text, which refers to the doubling dose. He reported that Dr. Tara O'Toole, successor to Dr. Ziemer at DOE, had commissioned a study of the epidemiology of the DOE complex and the experience of the workers' compensation system. This was the work that noted the likelihood that only 1%-2% of individuals in the DOE complex who

sought compensation for a radiogenic cancer could meet the doubling dose criteria, depending on the calculation of death or incidence. Therefore, 98% of all occupationally-derived cancers will fall below the doubling dose, which is also below the legal threshold of state compensation systems.

Mr. Robert Tabor, a Fernald facility millwright since 1981, stated his appreciation that the government was finally addressing these DOE workers' issues. He urged the Board and NIOSH to do "the right thing right the first time," to be maximally efficient. He encouraged the members to stay focused on the Act's intent to meet the government's resulting responsibility to address the sacrifices of Cold War veterans. Specifically, he challenged the ABRWH to ensure that the program is properly constructed, especially for evaluation of the dose reconstructions, to ensure fair adjudication. He expressed concern that the criteria for dose reconstruction may not compare equivalents (e.g, past statistics developed from the atomic bomb survivors involve the healthy survivor effect, which may not be comparable to worker experience). In 1981, respiratory and personal protective equipment were not mandatory, and skin coating with black/green oxide was common at Fernald. Inhalation exposures were common, well before the science to monitor that was in place. Mr. Taber has seen many coworkers die in recent years. He stated that the workers will be vocal if they suspect that the program is not being well applied, especially as regards the SEC. Finally, he reminded the Board of his comments at the last meeting about record keeping issues, particularly in light of the lifting of the records destruction moratorium at closed sites. He also had some concern that the Fernald site was not included in the SEC and said that he will track this in the future.

Closing comments:
To proceed with the Board's legislative mandate to review the quality of the dose reconstruction, the July agenda should include development of a plan to accomplish that. This cannot be done in a single meeting. A workgroup was formed to consider the related issues (e.g., how to evaluate the data sets; how to review the dose reconstruction process itself and how much of the case load to review; status of getting data retrieval itself, etc.). The Dose Reconstruction Workgroup members are Mr. Griffon, who agreed to serve as its Chair, Dr. Roessler, Mr. Espinosa, Dr. DeHart, and Mr. Presley.

The Dose Reconstruction Workgroup's charge is to: 1) develop an initial draft of options for a process through which the ABRWH can meet its obligation to review the quality of NIOSH's dose reconstruction efforts; 2) report back to the full committee at the next meeting; and 3) keep the Board apprised as the Workgroup proceeds. The Workgroup also will discuss such related issues as the need to consider the Privacy Act in this review process. Between the issues of confidentiality and the members' role as special government employees, the specific cases should be reviewed by the Board in a non-open forum, after which the results could be discussed in an open forum.

With no further comment, Mr. Elliott and Dr. Ziemer thanked all in attendance for their participation and adjourned the meeting at 11:42 a.m.

I hereby confirm that these Minutes are accurate to the best of my knowledge.

Paul Ziemer, Ph.D., Chair

7/4/02
Date

NIOSH/ABRWH Action and Topic Items

Date	NIOSH Action item(s)	Status
2/2002	Experts to present (action needed by Board members: clarify whom, on what?	Clarified at 5/02 meeting
	Provide program history/background, particularly as applied to the SEC	Dr. Michaels presented 5/02
	Discuss IREP issues	5/02 Dr. Lamb presented; further list developed
5/2002	The next meeting was scheduled for July 1-2, 2002.	
	Add, to the beginning of past minutes and to future minutes, that "A court reporter transcribed the deliberations of the Board and a complete transcript is available on the Internet."	Done as of the May 2002 minutes
	Maintain a "to do" list of meeting topics	Begun 5/02
	E-mail members of Website documents postings	
	Present the state of the art on synergistic effects	
	Provide copies of the technical reviewers' comments	
	Provide name/affiliation of commenting responders	
	Provide more IREP model details to the Board, including raw data	
	Present the questions and opinions about, or what else the experts and NCI would like IREP to include	
	Overview presentation by the Office of General Counsel (OGC) of what ABRWH can and cannot tell the claimants.	
	Explain the records request process; will the dose reconstruction contractor have direct access on site? How will the kinds of records that are relevant be decided, and how will they be pursued?	

Date	NIOSH Action item(s)	Status
	Address access to information from DOE sites: * If no MOU by next meeting, update status of information needed/received, etc.; the extent work required by NIOSH to get the information available, etc. * When MOU is in place, discuss records missing or unavailable; how far NIOSH should go into the search; how the applicant will be assured that the search was complete.	
	Describe what criteria determine information insufficient to award a claim.	
	Identify research gaps and how this Board can help fill them.	
	Present the plans to publish this process as well as results such as number of cancers identified. Can results also be analyzed by site or geographic area?	

Date	ABRWH Action Items	Status
2/02	Discuss the statutes/language regarding ABRWH future role; it is vague if not misleading	Clarification needed for NIOSH
5/2002	Comment on the public's perception of the misleading character of the Sense of the Congress statement.	
	Discuss how ABRWH will review the quality of the dose reconstructions.	
	Discuss using as a metric DOE's requirement to provide information within a certain number of days	

Date Raised	Meeting Discussion Topics	Date Discussed
5/2002	Concerns expressed on implementation of the final rules	
	Agreement on a process on how this Board functions, generically.	
	Individual IREP concerns, or have NIOSH representatives discuss the changes and important factors	
	The ABRWH's process to review completed dose reconstructions.	
	Pertinence of long-range issues such as age at exposure, DDREF and RBE, and explore any others on which NIOSH could prepare presentations	
	The transparency of the IREP model and the Monte Carlo analysis process	
	How the cancer grouping was done.	
	How conflict of interest will be handled by the dose reconstruction contract.	