

**Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health**

**Fifth Meeting of the
Advisory Board on Radiation and Worker Health**

July 1-2, 2002

**Meeting Held at the Hyatt Regency Hotel
Denver, Colorado**

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**National Institute for Occupational Safety and Health
Advisory Board on Radiation Worker Health
Executive Summary of the Fourth Meeting
July 1-2, 2002**

The fifth meeting of the Advisory Board on Radiation Worker Health (ABRWH) was held on July 1-2, 2002, in Denver, Colorado. All the members were present. The Chair reported consideration by the White House Office of Personnel to appoint 1-2 additional members to the Board. The minutes of the previous meeting were approved and are available on the NIOSH Website, as are transcripts of the meetings. The process of the Office of Compensation Analysis and Support (OCAS) was outlined, as was the program status.

NIOSH OCAS Status Reported as of June 30, 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:	5264
Requests to DOE for radiation monitoring information	4451
Responses from DOE	2025
Dose reconstructions underway	127
Draft dose reconstruction reports completed	13
Requests to DOE for additional information	51
Phone interviews conducted	105
Claimant phone calls received	3140
Website contacts, generally responded to within 24 hours	~300
Finalized dose reconstructions sent to DOL	1

A **program status report** was provided by the OCAS (summarized in the above chart) and the Department of Labor (DOL). **NIOSH/OCAS** reported that the DHHS/DOE Memorandum of Understanding is close to completion and the dose reconstruction contract is hoped to be awarded by August. Certain deliverables are due within 30 days of startup and at least 8,000 cases are to be processed in the first year. It could take two years to address the 15,000 claims. To date, 8-10 site files have been compiled. Fortunately, the sites' different dosimetry methodologies also have some similarities. Department of Energy (DOE) and the Department of Health and Human Services (DHHS) have discussed deadlines for timely information provision.

The **DOL** program was outlined. Its benefits are: 1) payment of covered medical costs: lump sum of \$150,000 to the employee or eligible survivor; and 2) \$50,000 under the Radiation

Exposure Compensation Act (RECA), Section 5, to recipients who had previously qualified under RECA for \$100,000. Conditions covered are cancer, chronic beryllium disease (CBD), beryllium sensitivity, silicosis, and the illnesses under Section 5 of RECA. Four District offices and the national office administer the program. As of June 13, 29,651 claims were received, 3,531 approved and 1,277 denied; a positive recommended decision was sent to the adjudication board for 4,176 and a negative one for 3,262. About 5,300 cases are pending employment verification; NIOSH has received 4,914 for dose reconstruction. Payments were issued for 3,170 individual claims; total compensation payout to June 12, 2002, was \$237 million. There are 10,903 outstanding claims.

ABRWH discussion included that employees have had to find their own records to verify their employment. This seems to vary geographically and also pertains to the status of the DOE records retention process.

The ABRWH Dose Reconstruction Working Group reported on the results of two conference calls. Their charge is to develop options for the Board to review the scientific validity and quality of NIOSH dose estimation and dose reconstruction efforts. They discussed: 1) who would conduct the review, and favored a review panel of independent experts along with Board representation and Board oversight. The panel size, member composition, nature of the panel meetings, method of review case selection and protocols for review, potential tasks, type of case review, and how the reviews would be reported were discussed and are detailed in the minutes.

Board discussion addressed the criteria for review team membership and noted the importance of keeping the process moving quickly and efficiently, and of ensuring that all appropriate data are considered. The experience of the Department of Veterans Affairs (DVA) review panel could be informative, and beyond analysis of the data available, a case-control analysis of cases accepted or not would be interesting.

The implications of the small pool of relevant experts in the U.S. were discussed at several points in the meeting. Also noted was the difficulty for the Board to plan the reviews without having a case file, knowing the composition of the data or data sets, how many cases will require Q clearance, etc. After comprehensive discussion, the Working Group agreed to meet with the NIOSH staff in Cincinnati before the August meeting to develop a practical sense of what will need to be done.

Later in the meeting, NIOSH was requested to provide the Board members with copies of the most current IREP on a CD. However, NIOSH has decided to keep the current version on the Web, due to the legal implications if a claimant is advised of a possible determination that is based on a previous version and the problem of creating and distributing new CDs every time changes are made to the software. It was also explained that the feasibility of putting the tables online and even on CD is limited by the massive extent of the data involved. A table was offered of the 101 values from the newly analyzed data of the study (Thompson, 1994) that was the basis of IREP, and a smaller number of probabilities that go with that.

Discussion of the **Notice of Proposed Rulemaking for 42 CFR Part 83**, which addresses the Special Exposure Cohort (SEC), was the focus of this meeting.

Rule making under the EEOICPA is not necessary. In fact, DHHS intended to use the greater flexibility of guidelines rather than a rule, in view of the uncertainty involved. But legal case precedent exists that requirements of a certain specificity can be challenged if not issued as a rule, so the rule making was pursued.

The background of this document was provided and its components were reviewed. These included key technical issues of when estimating radiation doses with "sufficient accuracy" is not feasible and there is a "reasonable likelihood" that the radiation "endangered the health of the members of the class."

Also presented were the basis for a petition to form an SEC, the process of forming a class, the evaluation process, and the final definition of class(es). The rule also provides for the modification or cancellation of an added cohort upon new information.

In discussion, concern was expressed about the absence of criteria or guidelines with which to determine that the information is inadequate to do a dose reconstruction or to determine that a poor dose reconstruction was done. Such criteria were felt to be important to the transparency of the process and necessary to determine if there is enough available information to qualify a group as an SEC. While a "quality" dose reconstruction can be done within uncertainty, which is provided for, the question is whether the tools and information are in hand to define and to address all these parameters. NIOSH responded that part of that is in place to the extent possible through the NIOSH IREP program and process, which includes the Board's scrutiny.

Any suggestions to improve the method were welcomed, and later in the meeting, one was provided: clear triggers might help to determine a "reasonable estimate." This could be the reasonable uncertainty combined with the mean that is end-cancer specific. "Feasibility" could also perhaps be defined, clarifying the feasibility of time, resources, etc., spent to define a source term.

Further discussion about defining classes up front found this to be desirable but unlikely. A "class of one" defined in a dose reconstruction could be a starting point to determining others in the same situation who should be added to that class definition. Those who are on the borderline of having or not having a dose reconstruction are the cases that need to be reviewed with care. It was clarified that a worker need not have incurred a cancer to be part of the cohort, but could qualify to enter the SEC because s/he may have cancer. But a threshold of proof is required in the petition, and ultimately, the cancer must be diagnosed to receive compensation.

The time commitment for this Board was discussed. The OCAS anticipates 90 petitions per year to be addressed, all of which, by law, the Board must review.

Input to 42 CFR Part 83 began with a listing of potential comments:

- The advantages and disadvantages of individual dose reconstruction as way to generate SEC numbers, as opposed to an approach relying on group petitions.
- Guidance for a process if a dose reconstruction cannot be done.
- Origin and meaning of rule definitions; how special cohorts were created to begin with (perhaps to be the model to create new ones); clarification of who can bring a petition to NIOSH's attention.
- Provide the clarity/specificity of the presentation of the SEC given at this meeting.
- Clarify the rationale behind the table of values by latency/minimum dose to reach 50% PC to indicate health endangerment. This was provided later in the meeting.¹
- Clarify how classes of employees will be determined for an SEC; and that a proposal can proceed, but must be based on a commonality (e.g., lack of data or understanding of data for a group of people, most likely from a site); and clarify the tripping points that indicate an SEC is formed. Ensure that the criteria for entering the SEC are very clear. This must not become an automatic step in the petitioning process, but only activated when clear guidelines are met.

It was clarified that the SEC process does not evaluate individual workers, but a work activity/function (e.g., changing a filtration mechanism, not monitored, but recognized as a potentially sufficient exposure to cause cancer for class of workers.) The periods of importance are those for which there may be no monitoring records available. Affected workers can apply to be in that class who worked in that time period, facility, etc. While all those specific job functions cannot be defined, the commonalities can be. Once the class is established, the DOL is responsible for determining if the claimant fits in this class.

The Board began drafting these comments at this meeting for presentation at the next meeting, and for feedback at town meetings planned by NIOSH to vet this rule with the public. The public's views could be incorporated into the Board's opinion. At least one Board member will attend the public meetings, as possible, to take notes and report back to the Board.

¹ NIOSH decided to average the dose thresholds for both solid tissue and leukemia cancers. Given the incidence of solid cancers, the leukemia will have much more weight on an average. A table was provided of the PC values used (99% credibility limit), by disease latency, for the minimum dose to reach 50% PC. Its fixed inputs represented the median values of claims received to date, to demonstrate how this method would work, which would change with the actual data received. In the absence of other evidence about the class, the lowest latency, that for leukemia, would be used, as the most claimant-friendly alternative. The solid tumor cancer with the highest latency in this case is the thyroid. The average of the two dose levels produced a 5.25 threshold for health endangerment. Extremely low exposures would be capped at the maximum threshold dose. The petitioning group need not have leukemia or thyroid, in the cited case. This method establishes a threshold to be used as the bar to determine if radiation doses possibly as high as this or higher could have been received.

Public comment was provided by four individuals and is detailed in the minutes. The comments called for review panels with expert members of undisputed integrity, preferably who are known as critics of the DOE complex's errors. The workers' distrust must be addressed as well as their health effects, making the Board's role more important. A wish to reinstate the DOE's retention of historical records was reiterated.

A study of ~900 retired plant workers with known exposures >20 rem was outlined, which revealed previously unrecognized problems with the Rocky Flats dosimetry. Such DOE cohorts are probably mirrored throughout the nuclear industry. This makes the capture of the sites' unique information important, since their uniqueness makes interpolation between them difficult. Any ABRWH help to indicate a trigger inferring a special cohort will be welcomed. The NIOSH contract includes, as part of assembling the site profiles, gathering the knowledge of site "old-timers" to help indicate what data might be available.

Another comment called for a deadline for the provision of claimants' records needed to do their dose reconstruction. If not provided, the claimant should be allowed in the SEC by default. Also noted was worker experience supporting that people working side by side can develop different cancers.

Other comments questioned the SEC rule's endangerment level, set between leukemia and solid tumors; suggested that people appealing their dose reconstruction decisions be allowed to speak to this Board; agreement that "feasibility" should include NIOSH's inability to do a dose reconstruction when the necessary information is too long in being provided; and a call to clarify another equity issue: the apparent great disparity in the screening dose values used by the DVA in its adjudications versus the IREP values.

Representatives of **SENES Oak Ridge, Inc.** discussed the NIOSH-IREP risk models, uncertainty distributions and Monte Carlo analysis. SENES is the contractor helping to adapt the NCI-IREP to the NIOSH IREP and to make it more user-friendly on the Web. Technical presentations were provided on the role of uncertainty analysis in IREP, an integral component of moving from the measurement of past radiation exposure to the risk of resulting disease, and the calculation of the probability that the exposure caused the disease ("probability of causation" or PC). The basic calculation of PC in the IREP program was provided and explained, as was the use of probability distributions in calculating uncertainty. The IREP translates dose to disease to PC using a Monte Carlo simulation in which one value from each distribution is selected at random to produce a randomized outcome. This is repeated 2000 times to establish a central estimate.

Perhaps the most striking aspect of IREP is that it uses incidence-based data, as opposed to the traditional use of mortality data. IREP also has additional variable functions such as a bias correction factor. The program can be readily updated in the future, as needed. Several case examples of its use were provided.

The IREP also uses Radiation Effectiveness Factors (REFs) for different radiation types. This is

an evolution by SENES of the biological effectiveness (RBE) factors of the radiobiological literature. RBEs are based on the data from radiobiological animal model experiments; SENES created the REF as a more accurate term to the induction of cancer in humans. A thorough presentation was provided on how SENES developed the REFs, the sources of information used to develop them, and how they relate to the traditional set point values of RBEs.

The RBEs, REFs and related health outcomes to the following were described: fission neutrons and other energies, alpha particles, photons, and electrons. The low-energy Auger-emitting radionuclides (electron energies of ≤ 1.0 keV) have not yet been addressed, but since they can be incorporated directly into DNA, their RBE can be huge. If encountered, they would have to be examined by OCAS as a special case.

New research by SENES was done to estimate REF alone, primarily through the creation of hybrid distributions. One such hybrid distribution was based on the data of Thorotrast patients given thorium for medical treatment, resulting in doses of alpha particles to bone marrow, which over time produced an excess of leukemias; the data of the radium dial painters and other studies which showed no excess leukemias; and a distribution for fission neutrons.

Other work explored the weak evidence of an inverse dose-rate effect for both neutrons and alpha particles shown, in animal studies and radon studies of uranium miners. This refers to the phenomenon that occurs when the same total dose is delivered, but one at a fairly high dose rate and the other at a much lower dose rate. The latter's risk seems to increase slightly, a phenomenon sometimes referred to as a superlinear response.

The SENES work revealed that the REF for photons and electrons apply to all cancers equally and that the REF of alpha particles for leukemias and solid tumors involved an inverse dose effect in all cases. Exposures were always assumed to be chronic. For neutrons, separate distributions were done for leukemias and solid tumors and an energy-dependent REF. The biases in these calculations apply to where the cutoff is defined, but this is really more of a political/legal issue. Dr. Roessler applauded the science applied by SENES, and the honesty with which it was discussed.

Three case studies using NIOSH-IREP were presented and new additions to the software on the Website were described. Some calculations were demonstrated that were developed with 1,000 iterations; the DOL will do 2,000 for all their runs. Advanced features include an uncertainty distribution that can be defined by the user. Another improvement was the placement of two buttons on the welcome screen; one for the public to input their own data, and the other for the DOL claims examiners to use a pre-formatted input file prepared by NIOSH. The input file will contain pre-completed fields that help to reduce the possibility of entry errors.

Subsequently, **NCI input** was provided by telephone link with Dr. Charles Land. Dr. Land generated the original NCI-IREP upon which this program is based. He explained the questioned divergence of the estimated dose values used by the DVA (CIRRPC) and NIOSH/OCAS. The CIRRPC used the medians of the point estimates developed by the 1985

NIH committee. These assumed, except for breast and thyroid cancer, a linear quadratic dose response. The higher calculated CIRRPC product was intentional, to qualify as many cases as possible that would then be evaluated more stringently.

In **ABRWH administrative** details, the public input meetings on the SEC Rule were scheduled for the week of July 23-25 (Amhurst, New York and Cincinnati, OH); and the week of August 5 (Richland, WA and Espanola NM). The Dose Reconstruction Working Group will meet in Cincinnati on August 13-14 (half day) and the Board will meet on August 14 (half day) and 15. The next Board meeting will be on October 15-16, but it was noted that the 14th is a federal holiday which affects staff; the alternate date is November 18-19. It will likely be held close to the Los Alamos site.

Regarding **membership**, almost all the Board members' terms expire in August, which the White House is expected to extend. The members retain their seat until replaced. Additional **public comment** urged consideration of additional data such as worker epidemiology studies and of whether the model adequately accounts for the uncertainties related to age at exposure.

The **Workgroup Report on SEC Rulemaking** advised clarification of the rule's purpose, what triggers the rule, and what the Board's related role is. Specific advice was offered to:

1. Explain clearly, up front in the rule and if desired in the preamble, that establishing or petitioning for an SEC status is not necessarily a next step to seek remedy if the Secretary determines that a particular group or case does not meet 50% PC criteria. It is not an appeal process.
2. Be clear how an SEC might be constructed. As written, the language seems to leave the onus on the individual to petition for such status, almost forcing the belief that this is the final recourse. The NIOSH contractor should bear some responsibility to note, in the course of dose reconstructions, any commonality of situations found (e.g. of activity or potential of missed doses) and report that back to DHHS/NIOSH. The individual might not be aware of these commonalities.
3. New information in itself should trigger examination of potential SEC status.
4. The Board should remain informed and involved in successful SEC petitions without participating in the details. Even more important, the Board should be informed of decisions to *not* pursue an SEC and some of the details related to that.
5. Claimants should not petition the Board directly. That would make this an adjudicative Board, not its role; that clause should be stricken that from the rule.

Specific areas of the rule were reviewed and discussed with NIOSH and its General Counsel. The Board's advice will be put into formal text for review at the next meeting.

The **Dose Reconstruction Workgroup Recommendations** regarding the dose reconstruction reviews were provided. The rationale for each is provided in the minutes.

1. *Convene a review panel* of independent experts with Board representation and Board

oversight, composed of two groups (each with 1 expert and 2 board members). Identify 4-6 experts to be available as needed.

2. *ABRWH case selection.* The Board should select the cases for review, preferably a stratified sampling of cases based on site, claims awarded and denied, and cases for which dose could not be reconstructed. The first 10 cases which are completed should be assessed by the panel.
3. *ABRWH scope/protocol.* The Board should establish the scope of work and the protocols for the panel. The scope should include the panel's assessment of the dose reconstruction methods, whether or not the reconstruction of dose provides a 'reasonable estimate' of the dose (at least as needed to determine eligibility); whether or not the assumptions (individual case and multiple case assumptions) made for dose reconstruction are credible; and whether or not the data from DOE or other sources are of sufficient quality necessary to obtain a 'reasonable estimate' of dose.

Discussion included some uneasiness about the scope of work described, although the workgroup's intention was appreciated. However, NIOSH liked the proposal. This kind of recommendation is needed to get the support necessary for the Board to begin its review of dose reconstructions. It was suggested that NIOSH be able to refer a claims-related technical difficulty or dispute to this Board, while still keeping it out of the process, to help support the credibility of the process. NIOSH will consider this and discuss it with the OGC. A **motion to adopt the working group's recommendations** was passed.

**Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
Advisory Board on Radiation Worker Health**

**Records of the Fifth Meeting
July 1-2, 2002**

The fourth meeting of the **Advisory Board on Radiation Worker Health** (ABRWH, or the Board) was held at the Hyatt Regency Hotel in Denver, Colorado, on July 1-2, 2002. The deliberations of the Board and a complete transcript certified by a court reporter are available on the Internet along with the meeting minutes. 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.

JULY 1, 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:

Department of Energy (DOE): Robert W. Bistline, Sonya Levine

Department of Health and Human Services (DHHS):

- Office of General Counsel: Mary Armstrong, Liz Homoki-Titus
- NIOSH: Larry Elliott, Russ Henshaw, Cori Homer, Ted Katz, Jim Neton, David Sundin

Department of Labor (DOL): Jeff Kotsch, Robert Manzanares

Presenters to the Board or members of the public who attended over the course of the meeting were:

F. Owen Hoffman, SENES Oak Ridge, Inc., Oak Ridge, TN

Sylvia Keating, PACE, Denver, Co

David C. Kocher, SENES

Ray Malito, Energy Employee Resource Center, Westminster, CO

Richard Miller, Government Accountability Project, Washington, D.C.

Louise A. Presley, Clinton, TN
Phillip Schofield, L.A. POWs, Espanola, NM
Robert G. Tabor, Fernald Atomic Trades and Labor Counsel, Harrison, OH
Brian A. Thomas, SENES
Joseph F. Tinney, SAIC, McLean, VA

Opening Comments

Chair Dr. Paul Ziemer convened the meeting at 8:29 a.m. He announced that the White House Office of Personnel is considering making 1-2 additional appointments to the Board.

Review of the Minutes

The minutes of the last meeting were reviewed. Ms. Munn requested that the summary (page 1/5) replace the word “hazard” with “jeopardize” or “compromise.” Dr. Roessler complimented the minutes for their conciseness and ease of reading. **Mr. Presley moved to approve the minutes** with that one edit and Dr. DeHart seconded the motion. The minutes were unanimously approved.

Program Status Report

Mr. David Sundin, Deputy Director of NIOSH’s Office of Compensation and Support (OCAS) and Mr. Robert Manzanares, of the Department of Labor (DOL) Denver district office, provided an overview of the program and its status.

NIOSH/OCAS Update

Mr. Sundin reported the OCAS status as of June 30, the end of their third quarter of this fiscal year (FY). To NIOSH’s understanding, the DOL received ~15,000 non-SEC cancer claims, for which they are verifying employment and diagnosis. As of the previous week, they had transferred 5264 claims to NIOSH for dose reconstruction. Batches of claims are received by NIOSH each week, and that receipt is confirmed to the claimant. The claim is logged in, and electronic and paper records are maintained. The DOL cover sheet identifies the sites applicable to the claimant, and pertinent NIOSH information is identified. Requests for radiation exposure information for the claimant’s time periods are requested, to be delivered in a timely manner. NIOSH continues to explore ways to build site-specific profiles, to expedite information, and to verify that no further information exists. The Memorandum of Understanding and its guidelines for this DHHS/DOE collaboration under the EEOICPA is close to completion.

In the last quarter, responses to requests for information have improved. Accurate and complete information is needed for dose reconstruction; if inadequate, additional information is requested. Once the information has been received and evaluated, an interview with the claimant is conducted. The dose reconstruction is then completed based on all the foregoing information. A telephone call to the claimant explains the report and its findings, and the claimant’s approval of the OCAS-1 form is requested to move the claim to the DOL for determination of the probability of causation (PC). A comprehensive administrative record of all the documents used in the dose reconstruction, all correspondence with the claimant, and the input file for the NIOSH IREP software is then sent to the DOL. A substantial contract to execute this exhaustive process will

be issued. The procurement process to accomplish this is almost complete.

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Phone interviews conducted	105
Claimant phone calls received	3140
Website contacts, generally responded to within 24 hours	~300
Finalized dose reconstructions sent to DOL	1

Discussion included:

- *What response has there been to the telephone interviews?* Good information and feedback is being received from energy employees. They receive the questionnaire ~1 week before the call. NIOSH follow-up calls are made to coworkers of deceased claimants to elaborate on the survivors' memories. These also have netted some good information. The calls average ~1 hour to a maximum so far to well over 4 hours. For interviews involving classified information (only two to date), employees with Q clearances are interviewed in a DOE facility and the interview notes are reviewed by a classification officer.
- *If the dose reconstruction contract is awarded in late July, and considering the start up time, what is the timetable to catch up the backlog of dose reconstructions?* NIOSH's limited staff will conduct the dose reconstructions until the contractor is in place, and the scope of work calls for a very ambitious startup period. The high priority is to ensure a short learning curve; certain deliverables are specified within 30 days of startup. The contractor will have sufficient surge capacity to handle the backlog. The contract specifies the processing of 8,000 cases in the first year, but NIOSH can request that volume to be increased as able. It could take two years to address the 15,000 claims. The limiting step will be getting adequate information to complete the dose reconstructions for each claimant.
- *Basic questions to be pursued include: who recorded the dosimeter readings, historically?; who kept the records and how?; were they transferred from plant to plant with the employee?; if the employee thought they were sick from radiation and questioned that, could they get those records?; are records kept the same way at all DOE plants, or are there any*

differences between the contractors and the DOE plants? Once a few dose reconstructions are complete, a review of the lessons learned will be done and applied to the remaining cases. Many of those details are being collected in the site histories. To date, 8-10 site files have been compiled and are on the NIOSH Intranet (not yet available to the public). Much of this is also documented in the individual dose reconstruction. In early Atomic Energy Commission (AEC) days, the individual labs developed their own dosimetry schemas. While there is not one single methodology for the entire DOE complex, there are similarities between sites.

- Ms. Gadola appreciated all the work that has been done, and NIOSH/OCAS' desire to give accurate information. She noted that the challenges involve historical staffs who were not adequately trained, records lost or altered, and lapses of memory among some of the people who were directly involved. It is important for this Board to question and examine this, and she appreciated the difficulty of obtaining accurate scientific information.
- *Perhaps the MOU should have two schedules: one for routine responses with available records, and one for finding harder to find records, or determining if they exist. A deadline may be necessary to avoid backing up the whole process.* This has been a major point of discussions on the MOU. Both agencies share a commitment to timely satisfaction of requests, while acknowledging that there will be difficult ones. The development of the MOU has had value of itself as each party learns about the other.

DOL Status Report

Mr. Robert Manzanares, District Director for the DOL Denver Energy Compensation District Office, welcomed the Board and outlined the DOL program. It provides compensation to persons who became ill due to work at DOE-operated facilities or those operated by its vendors, contractors, and subcontractors. The EEOICPA was enacted to provide efficient, uniform and adequate compensation to individual safety and health conditions. The benefits are as follows:

- Payment of covered medical costs: lump sum of \$150,000 to the employee or their eligible survivor.
- \$50,000 benefit paid to the Radiation Exposure Compensation Act (RECA) Section 5 recipients, in addition to the \$100,000 they qualified for under RECA.
- Conditions covered are cancer, chronic beryllium disease (CBD), beryllium sensitivity, silicosis, and the illnesses under Section 5 of RECA.

The administration of the program involves the national office, four district offices (Seattle, Denver, Cleveland, Jacksonville), and the Final Adjudication Branch (FAB). The participants in the claims process are DOL, NIOSH, the medical providers, the Social Security Administration (SSA) for verification of employment, the claimants or their survivors, corporate entities (again for employment verification), DOE, and the Department of Justice (DOJ).

Mr. Manzanares outlined the number and types of claims received as of June 13, 2002:

- Claims received: 29,651 (19,080 for cancer; 1,019 for beryllium sensitivity; 1,010 for CBD; 534 for silicosis, 3,512 RECA claims, and 4,496 other claims.)
- 3,531 claims were approved, 1,277 denied.
- Processed with recommended decision to the FAB: 4,176 approved, 3,262 denied.

- Cases awaiting employment verification: 5,346
- Cases sent to NIOSH for dose reconstruction: 4,914
- Payments issued: 3170 individual cases, including 1,200 RECA claims
- Total compensation payout to June 12, 2002: \$237 million.
- Outstanding claims: 10,903
- As of June 14, 2002, overall claim acceptance is 73% and 27% for denials. Most of the accepted cases pertain to the additional RECA benefits.

Discussion included:

- *Why is it, as reported by claimants, that those employed 20-30 years have had to go through their own personal files to verify their employment and send that to DOL?* This seems to vary geographically according to where the claimant worked, but DOE explains this as an outcome of the records retention process. If the employer does not have that primary information, the employee's secondary or tertiary information can be used to verify that they were on site (e.g., newspaper clippings about a process the person was involved in), or SSA records. If the affidavit can be established by any of these methods, DOL will find for the claimant. All sites are having these problems, but NIOSH also is finding records that DOL was told did not exist there.
- *What is the rate of claims received?* This varies by district office. In Denver, they have ~4,400 claims in house. Before March, they received ~300-400 a week, which has now dropped to <100 claims/week.

Dose Reconstruction Workgroup Report

Mr. Mark Griffon, Chair of the Dose Reconstruction Workgroup, reported. The workgroup members are himself, Dr. Roessler, Dr. DeHart, Mr. Presley, Mr. Espinosa and Dr. Neton as the NIOSH representative. They have held two conference calls. The minutes from the first call were distributed; the second call was held the previous week and would be reported on this day. Good discussions on the issues led to some recommendations; other issues need more discussion before recommending.

The Workgroup's charge was to develop options for the Board to review the scientific validity and quality of NIOSH dose estimation and dose reconstruction efforts. The issues discussed were:

1. Who would conduct the review: this was the area of most agreement. The workgroup favored a review panel of independent experts along with Board representation and Board oversight. The related issues discussed included:
 - The selection of individual experts, a contractor, or a consortium (e.g., of several contractors). Whatever panel makeup is chosen, the members must have the expertise to review a wide variety of cases, must have the credibility to do objective work (perhaps being "outside the box" to be objective about model assumptions, etc.), and must consider conflict of interest.
 - The size of the panel and availability of independent experts (it is a limited pool of expertise): The NAS Committee for Review of VA cases has nine individuals and may be

- too large.
- Selection of the experts (who/how): the Board should determine the membership of the panel and the selection process (competitive bid, sole source, diversity, range of expertise, etc.), and NIOSH awards the contracts to individuals or companies.
 - The nature of the panel meetings (i.e., should they be public?): the panel would report a summary of the case reviews to the Board on a periodic basis. The Board has the ultimate responsibility for the reviews and to report to the public.
2. How would cases be selected: the Board would select the cases for review. A stratified sample of cases is necessary, which might include the following variables: site, exposure type, cancer type, time period (1950s, 1960s, etc.), and others.
 - ▶ The number of cases: the overall case load should be more than the 2.5% that the NAS VA review team is reviewing, which would equate to ~100 cases of 4,000 overall. Due to the need to do a stratified sample, the percent would be greater than 2.5% for a NIOSH case review.
 3. Protocols used for review; who would establish them: the Board should establish the panel protocol. The scope of work for the NAS review of VA dose reconstructions was examined, and potential tasks for scope of work and type of review were discussed.
 - Potential tasks: the panel should determine whether or not: 1) the reconstruction of dose is accurate (at least as needed to determine eligibility); 2) the assumptions (individual case assumptions and assumptions applicable to multiple cases) made for dose reconstruction are credible and sufficient to determine eligibility; whether data from DOE or other sources are accurate and whether the estimate of dose is a “reasonable estimate,” as stated in the statute.
 - Type of case review: from simplest to most complex, this would include: a) initial review of case/calculations; b) more comprehensive review to determine the quality of the data NIOSH considered in the review; c) review to determine if all necessary data were provided by DOE or other sources. This is an important point due to DOE records destruction. This remains difficult due to the challenge of determining that “all” information was retrieved, if the definition of “all” remains unclear.
 4. How the reviews would be reported: the panel would first report back to the Board with panel reviews/reports of panel activities. That report and all relevant policies and procedures should be made available to the public in a de-identified format.

The Workgroup agreed to meet later to fine-tune three areas discussed for specific recommendations: the makeup of the panel, the selection of the cases, and the scope of work.

Discussion included much appreciation of the Working Group’s work. There seemed to be general agreement that the panel review should begin immediately:

Other comments included:

- *What would happen if this panel were to find a potential shortcoming/disagreement with a dose reconstruction activity, even if only for a single individual, or the manner in which the dose reconstruction is conducted?* This will have to be addressed at some point.

- Criteria for the review team membership could be: a) no more than two relevant independent experts (i.e., familiar with dosimetry at a particular site); b) at least one or maybe two Board members to be members of that team, as long as they have no relevant conflict; and c) allow them to conduct at least two reviews at two separate sites. In the first experience, they will learn what is important, the types of records that need to be considered, etc. It would be tragic to lose that experience without going to another site, with its own approaches, to allow comparison of apples to apples between sites. The idea was supported of smaller teams to review cases from several sites (not site-specific). The process should be kept moving quickly and efficiently while building competence/expertise. The importance of ensuring that all the appropriate data are considered was noted. This will be even more important to claimants, especially with the SEC. A process to get to that information is needed, such as access to people at a site to confirm that NIOSH got all the information available. This also would help the credibility of the overall process. It may have to be done separately from the review panel, but it should still be linked to that.
- A quick start-up is important, and the Board's activity increasingly will focus on these reviews. Enable Board members to rotate among the panels, or assign them to one or two. The experience of the VA review panel could be helpful. Beyond an analysis of the data available, it would be interesting to do a case-control analysis to explore what claims are or are not accepted; and to compare cases (one with data, one a similar case without data, etc.) to see if all systems were checked for both to ensure completeness. The validation process could be done by the contractors, but a protocol for data collection, analysis, etc., is still needed.
- Avoid using the term "accuracy" of data; that cannot be determined from 50 year-old data, although its quality, quantity, and source could be assessed. But Dr. Ziemer stated that if NIOSH can access the site's calibration information to establish some level of accuracy within a confidence range, perhaps this could be done.
- Keep the panels small.
- There was some concern expressed about the stratification mentioned. While some degree of stratification might be necessary, being too specific and identifying too many strata should be avoided. While the number or percent of cases may be something to examine more carefully, some other type of randomness might serve as well.
- Identifying well-qualified people for these panels is a real problem. Consider expanding the pool, and perhaps a greater degree of objectivity, by involving qualified individuals from abroad (e.g., the U.K. or France).
- Will the 2.5% population provide adequate power? Check the likelihood to detect the degree of problems and errors made. Another idea might be to just review a certain percentage of claims denied and appealed.
- *If a flaw is found in the dose reconstruction, or in the quality of a review, how is this handled?* If case is denied in the adjudication, appealed, and reviewed by the Board, it would be returned to NIOSH for re-evaluation, in which case NIOSH could ask DOL to reopen the case based on new information. Such specifics are in the implementation guidelines, not in the regulation itself, but the regulation is written broadly enough to accommodate this process. Or, a dose reconstruction finding in dispute could be presented to the Board before the final adjudication process.

- The comment was made, and often repeated in the course of the meeting, of the difficulty for the Board to plan without having a case file, knowing the composition of the data or data sets, how many cases will require Q clearance, etc. NIOSH was asked to assemble dummy case files to help the Board estimate the mass of information the members will be responsible for reviewing. This would be a challenge, requiring staff to redact every page of potential 400-500 pages, but Mr. Elliott said it could be done, perhaps using de-identified case files. Another option would be to have the working group review an actual case and report back to the full Board on the probable magnitude of the effort; or just to have the working group visit the NIOSH staff in Cincinnati to develop a sense of what will need to be done. Ultimately, the members agreed to the latter, which was scheduled later in the meeting. Mr. Elliott offered to facilitate whatever action the Board finds to be most helpful.
- The panels could be composed of a fixed number of experts with the members rotating between them. A common file also could be reviewed across groups to calibrate between them. There was agreement that the members schedules could be better facilitated and potential conflicts of interest better avoided by having two panels that could exchange experts.
- The VA review group is led by Dr. John Till, but Mr. Griffon could not contact him. Other NAS team members could not be too specific about their protocols and the NAS Website only describes the general scope of work. However, that work is a one-time review that is not completed, which in itself would discourage the sharing of information yet, and it also differs from this Board's ongoing process. However, it might be helpful to hear a description of how the VA reviews dose reconstructions, perhaps during the Cincinnati site visit.

Adding to the SEC Notice of Proposed Rulemaking

The Notice of Proposed Rulemaking for 42 CFR, Part 83, which addresses the Special Exposure Cohort, was published on June 25, 2002 and is open for public comment to August 26, 2002. Mr. Ted Katz, of NIOSH, provided the document, its background, and aspects of addressing this cohort.

Background. The cohort was established by the Energy Employees Occupational Injury Compensation Program Act (EEOICPA), 42 USC 73841(14). In that, Congress designated four facilities/sites at which compensation was awarded presumptively to employees with 22 ("specified") cancers, under limited conditions. The SEC cohort need not have their doses individually reconstructed. If it is one of the 22, their cancer cases are presumed to be caused by work at the site. If other than those 22, they can seek a dose reconstruction from NIOSH.

Adding to the cohort. Congress recognized that a similar presumption-based claims adjudication may be necessary for other cancer claimants. Congress authorized the President to add to the cohort, a responsibility he delegated to the DHHS Secretary. The statutory requirements to guide the President/Secretary in adding classes to the SEC cohort identified two criteria: 1) not feasible to estimate radiation doses with "sufficient accuracy" and 2) a "reasonable likelihood" these radiation doses "endangered the health" of the class. These are key technical issues to evaluate, if a class should be added.

The claims process is to: 1) consider petitions by classes of employees and 2) obtain the advice of the Board as to whether the class should be added. The final decision to add a class to the SEC is effective after 180 days, unless Congress decides otherwise.

Mr. Katz outlined the considerations related to the key statutory issues:

- *Sufficient accuracy*: sufficient for what? Recognizing that there is a difference between accuracy and precision, the case focuses on precision. But there is no universal standard for precision, so the standards for precision meet specific needs. The practical answer is “sufficient to enable fair adjudication of claims.”
- *Dose estimation*. Standard proposed: “Can NIOSH complete dose reconstructions using 42 CFR 82 methods?” If NIOSH can, the dose estimates will be succinct and accurate. But three sub-questions beg an answer: can the dose distribution be reasonably estimated? If not, can the upper limit of the dose be reasonably established?; and if so, is it below or above a compensable level?
- *Non-feasibility*. When is dose reconstruction “unfeasible”? This is determined case-by-case. It will be put before the Board for review of the logic of why a dose reconstruction could not be done. The following limitations, when occurring together, could prevent a dose reconstruction: 1) lack of personal or area monitoring records for radiation exposure; 2) insufficient information on the radiation source; and 3) work processes involved in radiation sources that are unknown or that could result in a hazardous dose.
- *Endangered the health*: Membership in the SEC is only for claims involving “specified cancers.” There is no other health endpoint.
- *Reasonable likelihood*: There is no standard definition, but the NIOSH-IREP was designed to evaluate the likelihood (PC) under EEOICPA. The statute sets a 99th percentile credibility limit, and the IREP applies the benefit of the doubt with respect to unknown variables affecting likelihood. This is appropriate since the IREP does not address individuals, but a class, which involves different issues. The variables that affect likelihood include: cancer type/site; radiation type, dose and dose parameters; cancer latency; age at exposure and cancer diagnosis; other demographic variables, smoking history (only for lung cancer), etc. NIOSH will attend to the profile of the class in assigning these variables.

Mr. Katz commented as an example that two variables, selection of cancer type and latency, are important in determining causation. The rule instructs that the the cancer caused at the lowest dose, depending on the radiation exposure, be chosen for use in the NIOSH-IREP. When dealing with internal versus external dose, the external dose will usually result in leukemia being identified as the most radiogenic cancer. But it can have a phenomenally low dose threshold, such as 1.5 rem, meaning that nearly every proposed class would qualify for the cohort.

A balance is needed between individuals in the class and the class as a whole. The threshold for a class as a whole requires judgement. Should a rare cancer be applied as a measure to a class? Probably not -- the chances are that, in a class of 100, there will be no incident cases. So NIOSH proposed splitting the difference: taking an average between the radiation dose threshold for leukemia and that for the most radiogenic solid tissue tumor. But latency works in the opposite

directions for these two cancers. Leukemia has low latency; being a disease that emerges relatively soon after exposure, it is more likely caused by that exposure. With solid cancer tumors, generally speaking, a much longer latency increases the probability that the cancer was caused by the exposure.

Mr. Katz presented a chart of PC values (99% credibility limit) by latency, charting the minimum dose required to reach 50% PC: long latency for solid tissue, short latency for leukemia. Technical difficulties during his presentation prevented him from explaining this in detail, but that was done on the following day (see Clarification of IREP Threshold Rationale).

The key process goals to evaluate claims are to: 1) establish an evaluation process that is public, thorough, and fair; 2) to ensure the timely consideration of claims; and 3) to involve the claimants. The groups who can petition are covered employees and/or their survivors, and unions that represent the employees.

The basis for petition is the following: 1) When NIOSH is unable to complete dose reconstruction for a member of the proposed class; and/or 2) other substantial grounds exist for believing that others in the class may meet the requirements for being added to the cohort. In the initial considerations of the petition, definitive proof is not needed, but it should demonstrate a substantial effort to show that the dose reconstruction would be an unlikely possibility. NIOSH would have to define the class and determine what records are available.

Considering a class involves several steps. Once the petitioners present a substantial basis for the petition, NIOSH will provide a petition form, will inform petitioners of unmet requirements, and will assist them in completing the form. DHHS will notify petitioners if it recommends the petition not be evaluated. The Board will advise DHHS before it decides not to evaluate a petition, and DHHS will notify petitioners of that.

The evaluation process is as follows. DHHS selects petitions to be evaluated with the advice of the Board; NIOSH evaluates the petition and reports the results to the Board and the petitioners. According to the DHHS definition of the class(es) – these could be separate or combined groups. The Board evaluates the petition and advises DHHS, with opportunity for petitioner involvement as well. DHHS receives the recommendations and their basis and reports to the petitioners, who may contest that decision within 30 days. DHHS publishes and reports the final decisions and reports an affirmative decision to Congress, which is effective after 180 days. Congress can expedite or deny the petition.

The outcome of this evaluation process is to provide the final definition of class(es) and the final decision(s) to add or exclude groups in those class(es), and it provides a technical basis for those decision(s). There is also provision in the rule to cancel or modify an added cohort if information permitting dose reconstruction becomes available. The cancellation procedures are comparable to procedures to add a class to the cohort.

Discussion included:

- The cancellation of cohorts is only applicable to those added after the law was passed.
- *Can a denied individual claim return as a class petition?* The individual decision can be appealed, and if denied, could return as class, but only if information can be provided that was not previously available to show the dose reconstruction was wrong. The federal rule states that the “petitioners statement (i.e., of exposure) now becomes a matter of fact, which it would not have been earlier,” but records will still have to support that, specific about the sources, exposure, etc.
- There are no guidelines established with which to determine that the information is inadequate to do a dose reconstruction; the rule is based on nebulous case-by-case method. Having enough information to indicate a “reasonable likelihood” to support a dose reconstruction for this class, but not to meet criteria for individual dose reconstruction, creates a murky situation.
 - ▶ Decisions vary about who qualifies in a class and the scientific decisions are variable since there are less supportive data. There is no certainty that any scheme can determine that a poor dose reconstruction was done. The absence of criteria prevents drawing a line between a “bad” dose reconstruction and acknowledging insufficient information to do a dose reconstruction, and now a third parameter indicates an area in between, without any criteria.
 - ▶ Criteria must be established to indicate that a quality dose reconstruction cannot be done. Without that, transparency is poor and the process is unfair to claimants. Those criteria also are needed to determine if there is enough available information to qualify a group as an SEC, to judge the effort NIOSH has exerted, etc. Cases will differ, but guidelines are needed to make the program work fairly.
- On the other hand, a “quality” dose reconstruction can be done within uncertainty. While the large uncertainty that may cause some to call a dose reconstruction “poor,” whatever data exist (e.g., calibration methods, limits of detection, etc.) are reflected in the uncertainty, which actually helps the claimant. The foregoing points would apply to a situation of virtually no dose information, but some knowledge by a source (e.g., a worker knowing of a 10 μCi exposure when no film badges were worn) can help to determine the upper boundaries without any dosimetry and monitoring data. The question is whether the tools and information are in hand to define all these parameters and to address them.
- Mr. Katz responded that part of that is in place to the extent possible. The rule fairly clearly states, in addressing feasible likelihood, how the NIOSH IREP will be used. Determination of whether radiation could have exceeded a threshold is a subjective judgement, but is open to scrutiny by to the Board to decide if the subjectivity is reasonable. Any suggestions to improve the method will be welcome
- *What would you anticipate as a hypothetical group that is not now a part of the system? Can we define those persons in order to define a class and slot claims as they come in, rather than having to go through a dose reconstruction (e.g., those in unmonitored and unreconstructible accidents or events that could have delivered a significant dose for the selected cancers). And, if a cancer other than of the 22 designated for the SEC is in question, that would be compensated based on exposure.* Defining classes up front is desirable, but not likely. In some critical instances, monitoring exists to allow dose reconstruction, but not in others. *In that case, you could have “classes” of one, whose dose*

could not be reconstructed while the other could. But you can reconstruct a person's dose by using co-workers' data. A "class of one" could be a starting point to determine if others are in the same situation as that individual and thus should be added to that class definition. The original definition is not necessarily the final one.

- *So, in the current special cohorts, no one need have their dose reconstructed?* No. The rule is explicit that, if the cancer is not one of the 22 specified, a dose reconstruction is required. NIOSH has received requests for dose reconstructions from those who have the 22 cancers and are in the SEC. To some extent, fairness does not enter into these considerations, since Congress set the 22 conditions and the sites included, even though work at other sites was similar or even worse than those included.
- *So, if these are classes of one person whose dose cannot be reconstructed, a reasonable likelihood calculation is done, and if they pass that and have one of the 22 cancers, they are compensated. But how would one fine-tune who is in the class? For example, having data for person B but not for person A could take a long time to sort out and delay compensation for many years.* The dose reconstructions done also will look at co-workers, which in itself will help to create parameters of a class. If more information is found in working on class parameters, the nonqualifying person acts as a sentinel that there may be a group that should be added to the SEC.
- People on the borderline of having or not having a dose reconstruction done are those of concern for review, since they pose major implications for a large class as well as persons with marginal dose reconstructions. A process is needed to ensure they are the ones reviewed with care. They are probably a sizable proportion of the 15,000 claims, but would be hard to identify without criteria.
- *Is there any concept of the time commitment involved for this Board?* In some respects, the final rule will bear on that. Currently, the OCAS anticipates that 90 petitions per year will be received, mostly due to the inability to do a complete dose reconstruction. By law, the Board must review all of them. NIOSH also has heard from several entities interested in filing petitions for construction workers across the complex or at specific sites (e.g., Rocky Flats, Los Alamos, Oak Ridge, and the army ammunition plant in Iowa), who are unsure that NIOSH can do a dose reconstruction, although NIOSH may disagree.
- *Could we go with an interim rule with a sunset clause to reduce that speculation?* Yes, but that would create more problems if the petitions addressed have to be revisited after the Secretary's final rule decision.
- *When will NIOSH announce its plan to hold stakeholder meetings?* The details are not settled, but there will be four local meetings held at the sites most likely to submit petitions (perhaps Hanford, Los Alamos, the New York/Pennsylvania/Buffalo area, and Savannah River; Rocky Flats, Fernald, or Oak Ridge have also been mentioned. The plan is to conduct them within 45 days of the comment period; the end of July, beginning of August.
- *There is a difference between guidelines and policy. Does this need to be done by rulemaking/formal regulation?* Rule making under the EEOICPA is not necessary. In fact, DHHS intended to use the greater flexibility of guidelines rather than a rule, in view of the uncertainty involved. But NIOSH lawyers advised that this needs to be a rule, based on case precedent that requirements of certain specificity can be challenged if not issued as a rule. This also ensures a public process that could be bypassed by a guideline, although NIOSH

was planning on that anyway.

- There is no difference between an interim or final rule in terms of the way they bind DHHS, but a step would be saved by issuing an interim final rule (as long as it stays within the original rule's scope) in that only a second comment period would be required before the final rule is issued.

Continued Discussion of 42 CFR, Part 83

After lunch, Dr. Ziemer asked for discussion of potential comments on the technical and scientific issues to be addressed, procedural issues, questions identified by the Board that need to be answered, and whether the Board would like to make an overarching statement about the rulemaking (i.e., specifics of how the process could be approved).

Issues to be discussed were identified by the members:

Dr. Melius: This rulemaking emphasizes individual dose reconstruction as a way to generate SEC numbers, as opposed to an approach relying on group petitions. So, 1) we should discuss the advantages and disadvantages of both approaches, which are complementary to some extent; and 2) discuss the lack of any definition of when a dose reconstruction cannot be done.

Ms. Gadola: Discuss 1) the definitions and why some things are stated as they are. For example, "ill effects" are related to radiation and cancer, and silicosis and beryllium; so why are some areas, which appear to have more cases of silicosis, not considered a special cohort?; 2) how the special cohort was determined to begin with; that may suggest how new classes should be added. Based on their data, NIOSH could be in the best position to determine that criteria exist for an SEC. Although the law precludes a SEC if a dose reconstruction can be done, submission of a group of claims with certain type of cancer that cannot be proven to be connected may still indicate something to be addressed. And, 3) discuss who can bring a petition to NIOSH's attention, other than the union (e.g., groups such as local healthcare providers and retiree organizations).

- Mr. Katz responded that the rule limits petitions to be submitted by employees, their survivors, or unions, and no others. Other parties could serve as an expert on the request of a single employee, but they may only assist the petitioners, not petition themselves.
- *Can we as a Board recommend a group as an SEC?* Not under this rule. The Board can recommend to the DHHS Secretary, but the proposed SEC procedures have the Board's recommendation coming in after NIOSH's initial evaluation of a petition.
- *Depending on the application form, will an individual or more likely, their survivor, need expert help to apply for SEC status?* Section 83.9 sets out the framework; there is no hurdle for a survivor other than stating that NIOSH could not do a dose reconstruction and the dead individual was an employee. The OCAS evaluates similar co-workers' records to see how many could have a dose reconstruction done, and then determines the probability of an incurred dose that could cause specified cancers.
- *How does one get into a class?* *Everyone will belong to some class.* NIOSH has to assign the person to a class, after defining the class' parameters beyond that individual (a class of

individuals for which a dose reconstruction cannot be done), and determine if the exposure is such that certain cancers could be caused.

Dr. Andrade: Acknowledging that this is proposed legislation, he remained ill at ease with its contents.

1. It lacks the clarity/specificity of Mr. Katz's presentation. For example, it should state that one might be considered for an SEC upon discovery of new documentation about an individual or group of individuals.
2. The table is arbitrary (e.g., using leukemia versus solid tumor and latency periods as a comparison to find the lowest dose), especially for a case where a dose reconstruction could not be done due to a lack of dose information. Rather than using science to set a level at which an SEC would be formed, the process seems contrived. The probability is small that many groups of workers will have so little known about them.
3. But, presuming that such groups do exist, make the legislation very clear that a proposal can proceed, but must be based on a commonality of a lack of data or understanding of data for a group of people, most likely from a site, who might have been doing work for which no records were kept.
4. He had no objection to codifying the guidance, but stressed that the criteria for entering the SEC must be very clear. Clear guidelines should be established, such as a group of individuals for whom lack of information is common (e.g., common to a site or type of work). As written, the regulation is unclear and incomplete.

Dr. Melius: Discuss how classes of employees will be determined for an SEC; and 2) the endangerment criteria just discussed by Dr. Andrade, along with the issues of latency, type of tumor, etc.

Dr. Ziemer: This Board advises the Secretary if there is a special class of employees for whom a dose reconstruction cannot be done but is likely to have been exposed to a radiation dose. It is unclear how the Board would go about establishing that, whether within or without this rulemaking.

- *Section 83.14 (e) states that at the Secretary's discretion, other factors may be considered or other procedures may be employed that are not detailed in this rule, when deemed necessary.* This text was left deliberately vague to leave room for the Secretary's decisions in view of future unknowns that might need to be addressed. But any measures taken would be done in public view with full involvement of the Board.

The Board agreed to begin drafting some comments at this meeting for presentation at the next meeting and to allow public comment at the town meetings that could be incorporated into the Board's expressed opinion. The public comments (those written and those transcribed from the public meetings) will be posted on the NIOSH Website. NIOSH desires the Board's recommendations before finishing its consideration and response to those comments.

- *Are the 90 petitions expected to come from individuals?* Yes, in general, mostly due to an inability to reconstruct individual doses. But then it's a question of how many other individuals are in that same boat, and then trying to define that class. That is why NIOSH is regarding the individual dose reconstructions as a sentinel. There could be commonality at a site.
- *When do you close it out?* The data are not boundless that will determine the scope of a class pertaining to a specific group of individuals.
- *What is the workload/timetable involved in complete evaluation of those 90 petitions?* That has not been estimated.
- *Is there a provision that a worker need not have incurred a cancer to be part of the cohort, but could qualify to enter the SEC because s/he might develop cancer?* Yes, but some effort is required to file the petition, and the cancer must be diagnosed to receive compensation.

Dr. Neton summarized that the SEC does not evaluate individual workers, but a work activity/function (e.g., changing a filtration mechanism, not monitored, but recognized as a potentially sufficient exposure to cause cancer for class of workers.) The periods of importance are those in which there may be no monitoring records available for the worker. Then those workers can apply to be in that class which worked in that time period, facility, etc. It is impossible to define all those job functions, but it is possible to define the commonality. Once the class is established, the DOL is responsible for determining if the claimant fits in this class.

- *Perhaps this Board is getting ahead of itself and missing the total picture. The table provided (informational requirements for petitions) delineates what is needed to be part of an SEC. These discussions seem to be sub-classes of the table's information. Would any case come before this Board due to the Secretary's decision, not what was in the individual's file?* No, there are two phases: DHHS will evaluate the petition in full. Then, if DHHS thought the petition not worth evaluating, the Board would review that decision and recommend its agreement or disagreement. But once DHHS evaluates a petition, the Board oversees that.
- *Ms. Gadola: Presumably, NIOSH can capture enough information to indicate similarities even if a dose reconstruction cannot be done. But how would Paducah and Oak Ridge workers with similar experiences, for example, know about each other? That supports NIOSH as likely the first to recognize an SEC group, as opposed to an individual's memory. But while that helps clarify how many might be in a group, standards are needed to clarify how they are to be included. Section 83.5 (c) of the rule requires that the workers be at the same facility to be in a single class, although separate classes can be very similar between facilities.*
- *Dr. Andrade: This and all other criteria need to be moved up front in the document as opposed to being scattered throughout.*
- *Mr. Griffon: What was your thought process in defining factors such as "reasonable estimate?" Potential triggers could be used. Reasonable estimate in DR might pertain to the size of the standard error, for example. But, since a higher SE in DR gives the benefit of the doubt to the claimant, that seemed to NIOSH to not be a good enough reason to rule out DR and trigger SEC status. The logic, therefore, was that if the dose reconstruction*

could be done fairly, the claimants are being treated fairly. The “reasonable estimate” in terms of SEC was created to address claimants who do not have a dose reconstruction as a remedy. Dr. Neton added that the estimate could be unbounded on the upper end, producing a level sufficiently high to have caused cancer; but this would prevent establishing it with any certainty.

- Mr. Griffon reported he has considered potential quantitative triggers, although he was not yet ready to present his work. He expressed his concern, from the claimant’s perspective, that the absence of clear triggers could prompt cynicism of “once again I just missed the hurdle; surprise, surprise.” A “trigger” is, hypothetically, how to determine a reasonable estimate. It could be the reasonable uncertainty combined with the mean that is end-cancer specific. One possibility could be to compare the sigma values on either side and then to those of IREP for PC. He also thought that “feasibility” could be defined to some extent, in terms of the feasibility of time, resources, etc., required to define a source term (e.g., to characterize a dump site for a small cohort).

In discussion, Dr. Neton was unsure that triggers could be used since they are specific to individuals; assigning one that could apply to every individual would not be possible. But, Mr. Griffon rejoined, it may be possible for a “reasonable estimate.”

- Ms. Munn stated the certainty, no matter what threshold of dose or event is chosen, that some people who do not pass the cutoff will continue to feel mistreated. The only response is to do the best job possible based on the best science available, and not to be swayed by the fact that some people will be unhappy with whatever decision is made.

After a short break, the Board agreed on the following:

- To defer the agenda item of discussing the dose reconstruction review process until the working group discussed it later that evening.
- To craft an ABRWH response to the SEC Rulemaking in draft form, preparing a semi-final document by mid-August that could be edited or appended in view of the public comments received. The comments and meeting transcripts will be put on the Website as soon as possible after receipt. The draft recommendations for word-smithing this rule for clarification (e.g., its philosophy, what it intends to accomplish, the idea of commonality, etc.) will be done sooner rather than later and finalized later by telephone conference or a face-to-face meeting. Dr. Andrade and Ms. Munn offered to help Dr. Ziemer draft those preliminary comments.
- As possible, one Board member should attend the public meetings to take notes and provide feedback to the Board.

Public comment was provided by four individuals.

Robert G. Tabor, of the Fernald Atomic Trades and Labor Council, stressed the importance of the integrity of the dose reconstruction review process. Workers were told in the past that the risk was minimal, which was not the case. The studies by Arjun Makhijani and John Till, and the information that emerged from some of the lawsuits indicate that data collection processes

could be in some doubt. Determination of the risks by statistics, probabilities, and estimates, is a inexact, “mushy” kind of process. Not only the effects to workers, but also the workers’ persistent distrust, must be addressed. Since many of the panel reviewers will be people paid by the government in the past and perhaps present, the Board’s role becomes more important.

His site, Fernald, was not part of the SEC originally, but they dealt with the same materials as the SEC sites and ran different but comparable processes. He advised “looking at things from the front end” rather than waiting to see if commonalities emerge, to ensure that claimants don’t die in the interim. The data accumulated must also be comparable. He was not convinced that the data of the a-bomb survivor studies apply to what workers were exposed to in the nuclear network. All the relevant studies should be reviewed to ensure all the information is considered.

Finally, he reminded the Board again about record keeping issues, especially important with site closings. He wished the Board could recommend, to whatever agency might be pertinent, to reinstate the historical record retention.

Dr. Robert Bistline, of the Rocky Flats DOE Field Office, has done internal dosimetry there for 36 years (for the past 7 years as a DOE employee, but prior to that as a contractor.) He began a study in 1980 of ~900 retired plant workers with known depositions of plutonium or with exposures >20 rem, and recognized problems with the Rocky Flats dosimetry. He now heads DOE’s oversight of internal dosimetry, occupational medicine, and beryllium exposure. He will appreciate any clarification the Board can provide about the SEC criteria.

Rocky Flats is seriously considering special cohorts in several areas. For example, there was no lung counting capability before 1964, and current retirees’ bioassays during their employment indicated no exposures. But at least one 92-year-old retiree has extensive plutonium deposition in his lung. And before 1957, only 18 people at Rocky Flats had ever been given neutron dosimeters. While he is making progress in re-reading some films, some personnel have no data at all. Such DOE cohorts are of concern, and are probably mirrored throughout the nuclear industry and DOE complex. Capturing the unique information that is lacking at sites is important. NIOSH is trying to do that, and he encouraged any contribution possible such as from the planned stakeholders meetings.

Calculating the exposures of the 1950s and 1960s is almost impossible, and many sites are dealing with that issue. The uniqueness of these facilities makes interpolation between them difficult. For example, exposure to insoluble plutonium cannot be well interpolated between workers, even those working side by side – one might have had a minor tear in his glove and been exposed, while the other did not. Dr. Bistline again expressed his appreciation of any clarification the Board can give to help sites decide if special cohorts are worth pursuing.

Discussion included:

- *Can you reconstruct doses from present lung counts?* Among some, but many are no longer living or are not part of this particular cohort recall, so many have never had lung counts.
- *Is the follow-up assay only for lung counts, or others as well?* Urinalysis and lung count.

Some of the Rocky Flats workers were exposed to high-fired plutonium oxide, and autopsies were done on ~120 former workers. One, who was involved in the 1965 fire, had a burden of 222 nanocuries of plutonium and 48 nanocuries of americium in his lungs and lymph nodes. The rest (soft tissue, bones, etc.) were measured at <10 nCi – and this autopsy was performed at almost 20 years post-exposure.

- *This is precisely the type of case that would be considered for SEC status because new information came to light on an activity engaging people for many years. Have you tried ultra sensitive techniques such as mass spectrometry?* No.
- *Were there a significant number of excess lung or other related cancers that could be identified with exposure?* Not really, but there was insufficient follow-up to determine that. Follow-up of some of the workers at Rocky Flats and Los Alamos who were exposed in the 1950s/1960 showed that many of them are still living. The man with the second highest reading from the fire exposure cited above just died at age 87, from complications of surgery. Ms. Munn noted that this reflects the experience of most of the “Pu club.”
- *NIOSH should consider gathering a group of old-timer experts, at least at major sites, to help advise about the data that might be available.* Current NIOSH staff are insufficient to do that, but the contractor’s statement of work includes that as part of assembling the site profiles. And, as the interviews are being conducted with the claimants, they are directing NIOSH to others.

Philip Schofield, a former Los Alamos worker for 21 years, expressed concerns about the SEC. The petitioner must have positive evidence that the records needed to do dose reconstruction do not exist. If they have done all they can to access those records and been denied them, they should be allowed in the SEC by default within a reasonable time. He, himself, has been asking for his exposure records for six months; the contractor should have a deadline to provide them. When the records are missing or not supplied, the burden of proof should shift to NIOSH and DOL rather than the petitioner. He also agreed that people working side by side can develop different cancers. A clear criterion point of qualification is needed. Relying on dosimeters is unwise, since they could be biased toward gamma but not neutron exposure, or vice versa. Exposure records will not reflect these things. There also are special classes to consider, such as guards who might be exposed to plutonium, uranium, and various forms of americium all in the same shift. How can those doses be reconstructed accurately enough to reflect their true exposures?

Dr. Andrade asked, when he requested his exposure records, if that was for this program alone or just for himself? Mr. Schofield answered “both” and reported a strong distrust of the Los Alamos DOE among workers. The site nurse had given him a file documenting his radiation poisoning (with hair falling out, skin turning red, etc.), but the same file the doctor held a week later now “no longer exists.”

Mr. Richard Miller, of the Government Accountability Project in Washington, D.C., thanked NIOSH staff for presenting the proposed SEC rule in Washington the previous week. This is heart of EEOICPA; during the legislative process, hearing after hearing revealed the absence of data; the question is, what to do in that case? If that lack is the government’s or contractor’s

fault, this involves a powerful equity issue, beyond the issues of science. That is why the SEC exists.

Mr. Miller asked why the SEC rule set the endangerment level between leukemia and solid tumors. He related the story of Joe Garcia, who worked in the ‘hot dump’ at Area G at Los Alamos, and has leukemia and has had a bone marrow transfer. He is incapacitated, although alive, but there are very little data to support his exposure. If the dump becomes a candidate for SEC status, and Mr. Garcia is the lead petitioner, he cannot reach the required dose, he does not meet the criteria. That involves an equity question. The statute does not make exceptions, for example, to include people with leukemia but without the feasibility to estimate dose. Perhaps only a few people so affected have rare cancers, but individually their risk is 100%. There’s no legal authority to set up such cutoffs. It was done arbitrarily and does not look “right” to claimants. According to Mr. Miller, NIOSH does not seem to care if people “fall through the cracks.”

He suggested that those unsatisfied with how the dose reconstructions are done be asked to speak to this Board. The adjudicators will only review if the analysis is reasonable; they will not investigate what the dose should have been as opposed to what was used. This should be a safety valve for people if they feel boxed in. The law (Section 3623, Subpart D2) includes the notion of having a feedback mechanism in the dose reconstruction’s rulemaking and guidelines, and that must not be left out when the Board finalizes its report.

The definition of “feasibility” should account for some reasonable amount of time past which too long has transpired to get any reasonable information (e.g., requested data are not received for months, or are so incomplete as to not be useful). There needs to be an outer bound of time at which NIOSH says it cannot do the dose reconstruction, in order to ensure that the claimants are not “left holding the bag.”

He referenced as a process issue from the last meeting: the difference between the 1988 screening dose information from the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) as compared to IREP. A chart of the former screening dose values used by the DVA in its adjudications of leukemias and esophageal cancer were far lower compared to the IREP values. Clearly different eligibility compensation between the two programs was reflected. The GAP asked NIOSH to explain this differential. They also asked for the baseline risk data used in the IREP #1, and the ERR per sievert for these cancers which would allow them to crosswalk the discrepancy. Dr. Land had outlined the source of this difference, something worth the committee’s discussion. Other than that, the equity question of different compensation levels begs discussion.

Finally, he referred to previously-expressed GAP concerns about conflict of interest by the contractor selected. Whoever is chosen will depend on the DOE for their income, so it is important that the panel members selected to assist the Board in its review process have no contract with the DOE. Since in his opinion only a handful of individuals in the U.S. fit the category of unimpeachable integrity, he urged that someone like them be found to ensure a

credible NIOSH process. He also suggested selection of critics of the system, to have the benefit of their advice during the process rather than their criticism later. This would put NIOSH in a much stronger position to defend SEC decisions later.

With no further comment, the formal meeting was adjourned at 4:20 p.m. and reconvened at 8:30 a.m. on the following morning.

JULY 2, 2002

SENES Presentations: NIOSH-IREP Risk Models, Uncertainty Distributions and Monte Carlo Analysis

Presentations were provided by SENES Oak Ridge staff, Dr. Owen Hoffman, Mr. Brian Thomas, and Dr. David Kocher, on the NIOSH-IREP risk models, uncertainty distributions and Monte Carlo analysis. Dr. Charles Land, of the NCI, who collaborated in this work to adapt the NCI-IREP to the NIOSH approach, and the previous work to update the 1985 NCI models, also participated by telephone link.

The Role of Uncertainty Analysis in IREP

Dr. Owen Hoffman described SENES' work with NIOSH to make the NCI's Interactive RadioEpidemiological Program (IREP) more transparent to the members of the public as they use the IREP on the Web. He explained that estimation of the probability that past exposure to radiation caused a diagnosed cancer is based on the measurement of organ-specific exposure, its translation to risk of resulting disease, consideration of the uncertainty related to both those two steps, and then using that result to calculate the probability that the exposure caused the disease ("probability of causation" [PC]). Essentially, the probability of causation is the product of the risk from radiation added to the risk from all other sources, divided into the basic risk from radiation alone.

A concept related to PC is that of "Assigned Share," but they differ. AS is a population attribute and is measurable. It is the fraction of disease in a heterogenous population that would not have occurred in the absence of exposure, among people sharing the same exposure category (e.g., dose, gender, age at exposure, age at diagnosis, time between exposure, and onset of disease, etc.) PC, on the other hand, is simply the weight of evidence that an individual's cancer could have been caused by some specified exposure.

The basic calculation of PC in the IREP program is to divide the excess relative risk (ERR) by itself plus one, or $ERR/ERR+1$. This simple equation includes several considerations:

1. In epidemiological terms, $ERR + 1$ is known as the relative risk. The equation's excess relative risk divided by relative risk equals probability of causation.
2. The excess relative risk is a product of the risk coefficient, which is the excess relative risk per unit of dose in sieverts, times the dose.
3. The uncertainty in the risk coefficient times the uncertainty in dose produces the uncertainty in the excess relative risk.
4. Therefore, the uncertainty of the PC is just a function of the uncertainty in the calculated

excess relative risk.

IREP is the state of the art in calculating uncertainty and in calculating the risk from radiation or any hazardous substance. It is probably the most extensive use of full quantitative uncertainty analysis and risk assessment to date. Uncertainty is considered using probability distributions, which factor in:

- The organ equivalent dose, which is defined by the person doing the dose reconstruction.
- The original relative excess risk per unit dose in the Japanese atomic bomb survivors (which includes the statistical uncertainty in the original dose response as defined by age at time of exposure, gender, etc.), and bias from random and systematic errors in the dosimetry used in the epidemiologic analysis.
- The models chosen to extrapolate the risk to the U.S. (i.e., which account for the differences in cancer incidence rates between the Japanese and U.S. populations).
- The radiation effectiveness of exposure to radiation types other than high energy gamma rays. High energy gamma rays are what the Japanese survivor data are primarily based on. Now, though, we're looking at low energy gamma (x-rays) and beta (tritium); alpha particles, and neutrons.
- Extrapolation of a-bomb survivors data to low doses and low dose rates. The Dose and Dose Rate Effectiveness Factor (DDREF) is used to calculate both acute and chronic exposures to low LET radiation. But in an acute scenario, it is only used for acute exposures from 2-20 centisieverts. A small possibility for an inverse dose rate effect considered for both low and high linear energy transfer radiation implies that the DDREF may be superlinear, or <1.0 .

IREP's probability distributions are used to represent uncertainty, mostly of subjective states of knowledge, not of variables associated with an experimental design or repetitive observations. Probability distributions that describe stochastic variability from random observations in an experiment must obey the laws of nature. Normal and lognormal distributions most commonly are produced by such experiments. State of knowledge distributions can be any shape to represent the space within which the true but unknown value is likely to occur. In the case of IREP, distribution functions are used that are discrete, continuous, and hybrid. IREP combines various sets to represent the state of knowledge within a probability distribution.

Dr. Hoffman provided as an example a bar chart of the current IREP distribution of DDREF for solid tumors (except for breast and thyroid cancer, whose risk for radiogenic cancer is linear.) The chart demonstrated a primary weight assigned to values between 1.0 and 3. At 1.0, there is complete linearity between health effects seen at high acute exposures and those occurring at low doses and low dose rates. The higher the value of the DDREF, the more the risk is adjusted downward and suppressed, inferring that exposure to chronic doses will give a lower risk.

The calculation, translating dose to disease to PC, is done in the IREP using a Monte Carlo simulation. All of the uncertain inputs are entered as probability distributions, and one value from each distribution is selected at random to produce a randomized outcome. The sampling is repeated 2,000 times to establish a central estimate (in the presented case, a 95% confidence

interval). This was shown on a progressing line chart, on which the upper 99th percentile mandated by the EEOICPA law was delineated. That high percentile is used for decision-making and claim adjudication, in order to give the benefit of the doubt to those who were exposed.

Dr. Hoffman emphasized that the latter benefit stems from Congress' selection of the 99th percentile, not from the development of the IREP methodology. IREP only represents the quantitative state of knowledge, aided by the collective expert judgment of its developers, which itself is subject to peer review.

IREP can be readily updated in future. It also allows additional sources of uncertainty to be considered, given adequate justification and a written rationale. Additional variable functions, like a bias correction factor that is uncertain, can be adjusted in their central value and width of uncertainty in the estimate of the final ERR. The default built into IREP for additional uncertainty is a lognormal distribution with a geometric mean of 1.0 and a geometric standard deviation of 1.0. Thus, it has no present effect on the final calculation of the PC. It could be adjusted, however. Such an adjustment could stem from an individual's higher-than-normal background rates of cancer, updates in radiogenic cancer risk for certain disease end points, or other new information on worker populations.

Dr. Hoffman provided an example of a person exposed at age 24 and diagnosed with thyroid cancer at age 60. His thyroid exposure was 15 cGy (or 15 cSv, which is an identical measurement for low LET radiation to high energy gammas). A modest uncertainty of a GSD of 1.4 (a factor of ~2 either side of the central estimate) was applied. The central estimate shows only ~12% PC. The upper 95th percentile (often used for decision making) at <40% PC, would still not be compensable. The upper 99th percentile used by EEOICPA, however, would be compensable.

As opposed to the traditional mortality data, IREP is the first program to use incidence-based data directly. Dr. Hoffman outlined the sources of data sets used by NIOSH-IREP. Those original epidemiological estimates are adjusted (by ERR/Sv) for errors in the Japanese dosimetry, to transfer the risk from the Japanese population to that of the U.S. population (model and background rate uncertainties). Further adjustments for low dose and dose-rate effectiveness factors were done, and the final ERR/Sv can be adjusted using a user- or claimant-justifiable uncertainty factor.

Additional slides:

Dr. Hoffman followed the development of the quantification of radiogenic cancer risk from the original National Council on Radiation Protection (NCRP) Report 126 to the development of the NCI IREP. Early reports distributed the cancer risk of solid tumors other than cancers of the breast and thyroid in a range of 1.0 to 5.0 for DDREF with a peak value at 2.0. The EPA in 1999 allowed for a DDREF of 1.0 to >5.0, but with very small weights given to values greater than 5. The bulk of the distribution, however, lies between 1 and 2. Now, as a result of the DR at Rocky Flats (Grogan, *et al*, 2000), we have what is basically the NCRP distribution, but with small

probabilities factored in for values between .2 and 1. No DDREF is used for leukemia, however, since it follows a linear quadratic relationship with the risk of low chronic exposures lower by about a factor of two than for high acute exposures.

Discussion included:

- *Why use the DDREF for the solid tumors and the linear quadratic for leukemia, when they are essentially the same?* The far better-developed data for leukemia clearly show a linear quadratic relationship. That is not so for the ERR of solid tumors; the model is more linear than anything else.
- *Analysis of the Hiroshima data showed some superlinearity; did they recommend a separate distribution for the DDREF value?* No, they did not recommend at all, but only presented data. The reference is the cancer mortality paper by Pierce, et. al. published in Radiation Research (1996; 146:1-27.)
- *Now that the Hanford thyroid study is complete, will that impact the adjustment of the geometric mean in IREP?* IREP can be adjusted to the latest state of knowledge as needed. The Hanford final report was very recent and not yet read by Dr. Hoffman. His bias, based on the previous Hanford Thyroid Disease study report, was that it was underpowered to distinguish the signal from the noise, and may have underestimated the high end of the distribution and overestimated the low end.
- *As epidemiologic studies emerge, how will IREP be validated and adjusted?* The design makes it amenable to frequent updates, and each new information is a form of validation. A problem might arise if new knowledge indicates that a person who was previously awarded compensation was in fact not eligible. An advantage of having IREP on the Web is that it can be updated in one place, and that update is available to the world, as opposed to putting it on a CD and having to generate thousands of new CDs every time there's an update.
- *What model serves as the baseline for IREP?* The 1994 Thompson, *et al*, study. But the NCI re-analyzed that data, so mapping directly from that study is no longer possible. Over time, the health physics community has used other data than those from the Japanese survivor studies to calculate these risk coefficients. But the main focus in IREP has been on the Japanese data, except for thyroid and the radon cohort studies. A major update to IREP would be to include more data from other studies such as worker studies and their outcomes.

Radiation Effectiveness Factors (REFs) for Different Radiation Types

Dr. David Kocher then addressed the risk of radiation types other than high energy gamma, which is used as the reference radiation (i.e., a defined REF of "1.") Research to date has addressed neutrons, photons, electrons, alpha particles, etc., but not yet the very high energy neutrons. These factors have not been expressed in terms of uncertainty. For radiation protection purposes, set point values are used, but uncertainty must be factored in for individual doses. IREP is the first time that uncertainty has been thoroughly factored into a human health risk assessment in a broad approach.

Sources of information. Dr. Kocher commented that the ICRP has not released information to explain why they selected the point values they did (e.g., a value of 20 for alpha particles). Dr. Kocher's 77-page report is posted on the NIOSH Web site. The report explains the thought

process that SENES followed to develop uncertainty distributions for these different factors. He invited feedback to any areas that could be improved.

The sources of information used are in the radiobiological literature on the relative biological effectiveness (RBE) of different radiation types. The term “RBE,” strictly applied, refers only to the results of specific radiobiological studies that were conducted under controlled conditions. Thus, SENES created a new term, Radiation Effectiveness Factor (REF), to apply to the induction of cancer in humans, the values of which are derived from evaluations of RBEs and from other data. They consulted the articles published by experts who have analyzed data on RBEs (International Commission on Radiation Units, the NCRP, the U.K.’s NRPB, the ICRP, CIRRPC, EPA, and the work of Straume and Carsten on tritium). SENES also obtained input from 2 rounds of external peer reviews. Recent primary literature was used in a limited fashion.

Cancer risk/solid tumors. Dr. Kocher presented several equations with which they estimated the cancer risk for solid tumors and leukemias. For the former, the risk from photons, electrons, and alpha particles is the REF (adjusting for the radiation dose and dose rate) times the risk coefficient from the a-bomb data (high energy gamma rays with an RBE of 1.0), which is sometimes affected by the DDREF, times the dose. Neutron radiation is more hazardous because it produces various kinds of secondary radiation, and it is very complicated in terms of how it interacts with human tissue. The cancer risks for leukemias are linear quadratic, but are linear for everything else. The NCI’s Dr. Charles Land used these values.

The radiation protection field conducts calculations to control doses. The radiation protection value for both neutrons and alpha particles, according to the ICRU, is 25, whereas the ICRP assumes a value of 20. However, the substantiation for those values has never been explained.

Cancer risk, leukemias. The literature offered evidence that the RBEs for both alphas and neutrons are different for leukemias and solid tumors. In general, the RBEs are lower for leukemias than for solid tumors.

Neutrons (other energies.) This area involves the subjective states of knowledge distributions referenced earlier by Dr. Hoffman. SENES assumed that these REF distributions should have three properties: 1) They are not less biologically effective than high-energy gammas (a lower bound of 1.0); 2) the median is reduced by a factor of 2 or 4 compared with fission neutrons – but those data are pretty shaky, so, 3) they reduced the upper confidence limit by a factor of less than 2 or 4 compared with fission neutrons.

This essentially captures the state of knowledge about these other energies, which admittedly is not good.

Alpha particles: Alpha distributions, of all radiation types, are the most subject to adjustment by further study and review. For solid tumors, we assumed a lognormal distribution where 95% of the values were in the interval from 3 - 80, and with a median of 15. It’s possible that this median may be too low. We’re on thinner ice with regard to alpha particles and leukemia,

because the available data are sparse and conflicting. The main problem is how to estimate the dose to radiosensitive cells in bone marrow. The uncertainty of the dosimetry makes distinguishing between that and the biological effectiveness of alpha particles difficult.

Dr. Kocher decided to ignore the dosimetry problem, leaving that to the dosimetry field, and estimate the REF alone, assuming a hybrid distribution of REF_L :

1. Thorotrast patients were given thorium for medical treatment, which meant fairly high doses of alpha particles to bone marrow, producing over time an excess of leukemias. But the problem with this analysis was that Thorotrast is given in a colloidal suspension. The alpha particle exposures to DOE workers were not in colloids, so the applicability of this experience to a DOE worker is questionable. For this data, SENES applied a lognormal distribution with a 95% CI of 1.0, 15, and granted it a 50% weight.
2. The radium dial painters study showed no excess leukemias, but no confidence interval was ever published for that study, just a central estimate. The uncertainties in these populations need to be analyzed. Leukemias tend to emerge early after exposure, and there was some question as to whether they were followed-up early enough to detect those. However, the ICRP dosimetry model would predict the increase to occur. That it did not could be due to very low RBEs or a dosimetry problem. (Dr. Kocher suspected the latter.) SENES granted these data a 25% weight to a value of 1.
3. So, SENES then developed a hybrid distribution of the REF_L , applying different weights to these different and often contradictory pieces of evidence. They applied a 50% weight to the Thorotrast data (based on dosimetry to the right target cells), a 25% weight to the absence of excess leukemias in other human populations; and a 25% weight to the distribution for fission neutrons. However, Dr. Kocher acknowledged the weakness of this distribution due to the contradictory data and problems with dosimetry. An area of potential research is animal studies on alpha particles and leukemia. The hybrid distribution showed a spike at the 25% weight, at the value of 1, and long tails for the other two weighted values, which were lognormal distributions. This also can be plotted as a cumulative probability distribution rather than a frequency distribution.

Inverse dose effect. As mentioned by Dr. Hoffman, there is weak evidence of an inverse dose-rate effect for both neutrons and alpha particles, demonstrated in animal studies and radon studies of uranium miners. This refers to the phenomenon that occurs when the same total dose is delivered, but one at a fairly high dose rate and the other at a much lower dose rate. The latter's risk seems to increase slightly. To account for this, SENES applied a small correction to the REFs for chronic exposures to neutrons (sometimes chronic) and alpha particles (always chronic). They created a discrete distribution applying most weight to the 1.0 value and successively smaller weights to the values of 1.5, 2.0 and 3.0. Average corrections of 1.4 for neutrons and 1.2 for alpha particles were applied. The inverse dose rate effect for alpha particles for solid tumors produced another lognormal distribution, but more skewed to the left than before. They began with a lognormal distribution from 3 to 80. Adjusting for the inverse dose-rate effect raised this from 3.4 to 100, with a few straggling values >100. The resulting median of 18 is comparable to the standard ICRP assumption of 20, since all exposures to alpha particles are chronic.

Another approach might be to begin with something other than a lognormal distribution to raise the median somewhat. But, Dr. Kocher commented, this was all based on judgement, not data. Much work is needed in this area. He felt that if this REF is applied to the standard ICRP dosimetry models, the leukemia risk may be overestimated. But the severity of the dosimetry problems prevents any definitive knowledge about alpha particles and leukemias, and those must be rectified first.

Photons. To this point, the distributions for neutrons and alpha particles encompassed the ICRP model results, although the REF's broad range of uncertainty was different. But for photons, things changed. The ICRU 40 publication stated clear evidence that x-rays are twice as effective as gamma rays in causing stochastic effects. But this was never adopted by the ICRP, which assumed that biological effectiveness of any photon energy is the same. In this case, the SENES team agreed with the ICRU.

There are few studies of the biological effectiveness of x-rays, but there are data on particular endpoints in humans. At this point, Dr. Ziemer pointed out that most x-rays are a third less energetic than the energy range Dr. Kocher cited in the calculation of 30-250 keV. Dr. Kocher explained that the data all lie in the first two-thirds of the curve, and so demonstrate the ICRU's statement that lower energy x-rays and higher energy gamma rays have an RBE_L range from 1.5 to ~4. Other studies have also indirectly inferred the RBE_L for x-rays, producing a range of ~1.5 to 3.1.

There also are data in humans in studies of thyroid cancer among children given x-rays for medical treatments, where the 95th percentile CI ranged from an RBE of .2 up to 4. There are other data sets, but none demonstrating either the presence or absence of a difference between x-rays and gamma rays. But, since the central estimates clustered near 1 and 2, without any outliers, SENES thought that more weight could be applied to this.

Again, SENES developed a hybrid distribution of REF_L . The evidence from the nonhuman studies was sufficiently compelling to apply a 75% weight to a lognormal distribution between 1 and 5 and a 25% weight to 1.0 (inferring no difference in humans). The resulting 95% CI ranged from 1.0 to 4.7 and produced a median of 1.9. To apply these data for a very limited range of X-ray energies to 30 and 250 keV, they accepted the ICRU calculation with a mean of ~30, and arbitrarily assigned a cutoff point of 250 keV. The curve showed the biological effectiveness beginning to rise from <30 keV, which they assumed to be a correct curve. Because of that, they increased the previous distribution by a triangular distribution at ≤ 30 keV, the mean curve of which rose to 1.3. The biological effectiveness increased more at <30 keV. This resulted in a probability distribution for the lowest energy photons, with a median of about 2.4. Interestingly, research into breast cancer in women resulted in the use of very low energy X-rays, and their results agreed with the ICRU curve. However, Dr. Kocher is unaware of any data to describe this problem.

Electrons. Only tritium beta particles have been studied, producing RBEs for many stochastic endpoints and biological systems. The ICRP today sets the RBE for tritium beta particles at 1.0,

but this assumption is contradicted by other data. So SENES used the existing data, with an RBE ranging from 1-2 at the low end to 6 at the high end. Assuming a lognormal distribution, the 95% CI ranged from 1.2 to 5, with a median of 2.4. The historical median in the literature is 2.3. This demonstrates a clear effect that the ICRP lacks in their model.

One problem is that these energy levels of beta particles are very low (4.7 to 15 keV), but they do show a clear effect. This is of particular interest to this Board, since the compensation claims are almost certain to include tritium exposures. The levels are so low that SENES wondered if there would be an intermediate electron energy range where the biological effectiveness would be lower than that for tritium beta particles, but still >1.0 . They concluded that from 15-60 keVs, there should be an increase. However, Dr. Kocher doubted that many <60 keV exposures would be encountered in the OCAS program, except perhaps for carbon 14.

Finally, he noted that SENES did not address the low-energy Auger-emitting radionuclides (electron energies of ≤ 1.0 keV). Some of these can be incorporated directly into DNA, so their RBE can be huge. If any of those are encountered, they would have to be examined as a special case.

Dr. Kocher summarized the work SENES had done:

- Photons: Created separate distributions ($REF_L > 1$) at a distribution (E) is <30 keV, and $E = 30-250$ keV. This applies to all cancers equally and is based on x-ray data.
- Electrons: Created a single distribution for tritium beta particles, which assumes an application up to 15 keV. This applies to all cancers, and is similar to a distribution for <30 keV photons.
- Since these first two points tie together, Dr. Kocher was fairly confident about them.
- Alpha particles: Separate distributions for leukemias and solid tumors. This is the shakiest part of their analysis. It applies at all energies in radioactive decay. An inverse dose effect was applied in all cases; exposures were always assumed to be chronic.
- Neutrons: Separate distributions for leukemias and solid tumors and an energy-dependent REF (five energy bins, three sets of distributions; inverse dose-rate effect applied to chronic exposure).

Discussion included:

- Dr. Ziemer commented that the SENES staff appeared to have performed their work with the intent of letting the science speak for itself. If there are biases in the calculations, they apply to where the cutoff is defined, and this becomes primarily a political/legal issue.
- Dr. Roessler applauded the science applied, and the honesty with which it was discussed. Her only advice was to make it clear that the 50% weight applied to the Thorotrast patients is based on more than one study; it is based on literature review as well.

Results of Case Studies Using the IREP

Mr. Brian Thomas outlined the IREP's use as applied to three case studies and described additions to the software now on the Website, such as a new "view model details" button. The latter includes additional calculation buttons to show the ERR/Sv used for the case being run;

then the ERR/Sv after adjustment for dosimetry errors; that after the values are transferred to the U.S. population and after adjustment by the DDREF; and last, the final ERR. His presentation focused on demonstrating that two people exposed in the same way might not have the same probability of causation.

He demonstrated calculations that were developed with 1,000 iterations of the data; DOL will do 2,000 for all their runs. First, he outlined the required model inputs: the individual's gender, year of birth, and the year diagnosed with a particular cancer. A pull-down feature provides 32 cancer models to use, including a category called "other and ill-defined sites." Other entries include lung cancer and smoking history, and ethnic origin if the person has skin cancer. Advanced features include an uncertainty distribution that can be defined by the user. Another improvement was the placement of two buttons on the welcome screen; one for the public to input their own data, and the other for the DOL claims examiners to use a pre-formatted input file prepared by NIOSH containing pre-completed fields. This can help to reduce the possibility of entry errors.

Mr. Thomas demonstrated the NIOSH-IREP software with three cases. The example to show dependence on age at exposure was a woman aged 20 and at age 40 at first exposure who is diagnosed with liver cancer at age 50; smoking history was demonstrated through a male exposed at age 20, diagnosed with lung cancer at age 50, in two scenarios (never smoked and smoked 1-2 packs/day) and exposed to 50 cSv. The final example, of time since exposure, was based on non-smoking individuals exposed at age 20; one develops lung cancer at age 25, the other at age 35; both received 50 cSv of radiation. The example demonstrated that the person who developed the cancer earlier had a lower probability of causation.

Discussion included:

- The Analytica program, on which the model's version 5.2 was run, was used for its superior presentation of the IREP to the public as opposed to Fortran code or Excel spreadsheets. NIOSH decided to place this on the Web rather than on CDs, since more people are familiar with a web browser than with Analytica. Placing IREP on the Web also better ensures that the latest program is used. A description of the desirable features of Analytica and how they were translated to the current version was provided.
- As of this day, the model's risk coefficients are viewable and available for use on the Web.

NCI Input. At this point, Dr. Ziemer asked if there were any questions for Dr. Land, who was standing by at NCI to respond by telephone if needed. Dr. Land generated the original NCI IREP upon which this program is based. The Board comments and questions were as follows:

- Mr. Griffon commented that the ERR/Sv need not necessarily be on the Web version. But ERR/Sv is case-specific, putting the onus on him to plug in individual variables to see how each is handled. Frustratingly, he knew that such a table already exists, but is not on the site; for review purposes, a CD containing comprehensive tables would provide the needed transparency and would be easier to work with.
- Dr. Hoffman shared a spreadsheet just received by e-mail from Dr. Land to explain the difference between the two DVA (CIRRPC) and IREP values. Mr. Griffon found the

spreadsheet to be helpful, demonstrating how the ERR per sievert values were transferred from the Japanese population, and the other factors affecting that result in the final values of IREP ERR/Sv.

Dr. Land explained that the table presents the median values for the statistical uncertainty distributions and a correction for the uncertainty introduced by the dose reconstruction (.82). The DDREF is applied to it, except for thyroid, and the median value is then multiplied by a transfer factor, which depends on the extent of the baseline risks (i.e., if they are higher or lower in Japan). The product is the median of the IREP, which is presented in appendix table E-2. The NIH 85 medians used were the point estimates developed by the 1985 NIH committee. They assumed, except for breast and thyroid cancers, a quadratic dose response. CIRRPC replaces, and acts in much the same way as the DDREF correction used in the present. While it lacks the uncertainty, it can correct for what it would be if the dose response were linear. The baseline factor is for 10% of the U.S. population (i.e., the lowest 10% of counties), and is used as a multiplying factor. Multiplying the uncertainty and the baseline factors together results in a factor of ~5 and therefore the much higher median value in the CIRRPC product. But it is intended to be higher, to let in as many cases as possible that would then be evaluated more stringently. In summary, the factors were intended to boost the values, and the transfer between populations in the NIH model was assumed to be additive, which means that the coefficients for a disease such as stomach cancer will be higher than if a multiplicative transformation was used. And for something like breast cancer, where the U.S. has higher rates than Japan, it would make the excess relative risk lower.

Public comment was solicited, with no response forthcoming.

ABRWH Administration

Meeting schedules

Public meetings. Pending completion of the logistics, public input meetings on the SEC Rule will be held the week of July 23-25 in Amhurst, New York and in Cincinnati; and during the week of August 5 in Richland, WA and Espanola NM.

Working Group. The Dose Reconstruction Working Group will meet in Cincinnati on August 13-14 (half day). They will meet with Dr. Neton and some of his staff, review some case studies, CD ROMs of data, etc., to prepare for the dose reconstruction reviews. There may be some overlap between the working group's and Board's meeting, and the working group may continue working on Friday, August 16, if needed.

Board -- August meeting. The Board meeting will be held on Wednesday (half day) and Thursday, August 14-15. The agenda will include finalization of the comments on the SEC rule and perhaps include input on the oversight of dose reconstructions, since the workgroup will have a better feel for that. The only outside speaker would be the DTRA (VA) on the afternoon of August 14.

The *October meeting* is tentatively scheduled for October 15-16. Noting that the 14th is a federal holiday that affects staff; the alternate date is November 18-19. Since the agenda will probably include review of the first dose reconstructions, it might be better to meet in November. It is important that this group go to New Mexico to follow up on the Los Alamos outreach done by Mr. Espinosa.

Membership. Mr. Elliott noted that almost all the members' terms expire in August. The White House is expected to extend those memberships, and the members retain their seat until replaced.

Public comment was solicited. Mr. Miller, of the GAP, noted the issue raised by Dr. Hoffman about the adaptability of the model. Except for radon, the IREP model does not account for many of the other studies done. He urged the Board, as it proceeds, to explore how those might fit into the program. He specifically suggested examination at a later date of worker epidemiology studies and whether the model adequately accounts for the uncertainties related to age at exposure. Finally, claims have already been filed related to the Los Alamos accelerator and Mesa facilities, which involve different energy and radiation exposures. He asked if those dose reconstructions could be done, or if those persons would be candidates for a special cohort.

Discussion included:

- Dr. Neton was unconvinced that the unusual particles of the accelerator program would be the predominant exposure at that site, and noted that these workers are monitored. Since the population of personnel that would be exposed to such particles is so small, they would be addressed individually, with extremely conservative values applied to their calculation. If the number affected appeared to grow, NIOSH would commission a study in anticipation of a potential full-blown dose reconstruction.
- Mr. Miller stated that monitoring devices for those particles were only developed in the last 20 years, posing problems for exposures prior to ~1980. However, Dr. Andrade noted that accelerator exposures mostly involve secondary gammas. The highest exposure level would be to staff irradiated by the direct beam or a scatter of it. After that, exposures would come from decay products from target areas or where portions of misaligned beams might have hit. The exposures run the gamut of beta and gammas emitters; anything produced by energetic particles (e.g., protons, electrons, heavy ions).
- Mr. Schofield noted that workers have to be above-average in health. This healthy worker effect introduces a definite bias and needs to be considered by the Board.

Discussion of SENES Presentation

Mr. Griffon requested that all the Board members be provided with copies of the most current IREP on a CD. Mr. Elliott reiterated NIOSH's decision to keep the current version on the Web. There are legal implications if a claimant is advised of what their determination might be, and the advice is incorrectly based on a previous version. Mr. Griffon asked, then, that the online model include some of the tables to avoid the need to regenerate work already done. Whether on the Web or a CD, the Board needs to be able to conduct an adequate review, and there is no technical barrier to placing the tables on the Web. Dr. Melius urged that this be settled, with the Office of General Counsel present to explain the barriers at the next meeting, if necessary.

Later in the meeting, Mr. Thomas explained that the feasibility of putting the tables online, and even on CD, is limited by the extent of the data involved. For example, in addition to the cancer groups, there are the data on age at exposure (70 rows), attained age (80 rows) and then the uncertainties associated with the 5th, 10th, 50th, 90th, and 95th percentiles. Combined, these pose four dimensions that would have to be on the Web. However, he could provide a table of the 101 values from the newly analyzed Thompson data and a smaller number of probabilities that go with that. Mr. Griffon said that this table would be satisfactory. He and Mr. Thomas agreed to develop that together.

Clarification of IREP Threshold Rationale

Mr. Katz referred to Dr. Andrade's expression of concern on the previous day about the apparently arbitrary use of a threshold for health endangerment and the use of an averaging threshold that uses solid tumors and leukemia as a basis, to create a threshold for cases of external exposures. He explained how this threshold was developed.

He began with the conceptual basis. In the absence of data with which to do a dose reconstruction (i.e., for an SEC), NIOSH knew that subjective judgements of dose levels would probably have to be made. To begin from a threshold with which no claimant would take issue, they selected the most radiogenic cancers that would result from exposure to determine the minimum (threshold) dose level. For external exposures, this would be leukemia; for internal, it would be the relevant 22 cancers.

Review of this approach produced the following comments:

- Using leukemia to determine the threshold for external radiation could result in a trigger as low as 1 rem, which would be hard for anyone to accept as a health endangerment for a class.
- Another view was that the mission is to characterize health endangerment that is representative for the class, not a conceptual, most vulnerable member. To do that, a perfectly representative threshold would require a weighted average for all cancers potentially related to the cancer resulting from the exposure, weighted again by incidence rates. So the more prevalent in the population, the more weight would be averaged in.

However, NIOSH did not think that to be feasible. They would be working with expected values for an unknown dose that could be higher or lower, essentially entailing a subjective judgement to which yet another subjective threshold would be applied. In addition, they still wanted to be more claimant friendly.

The practical solution derived was to average the dose thresholds for both solid tissue and leukemia cancers. Given the incidence of solid cancers, the leukemia will have much more weight on an average. Mr. Katz provided a table of the PC values used (99% credibility limit) by latency, for the minimum dose to reach 50% PC. Its fixed inputs represented the median values of claims received to date, to demonstrate how this method would work. It would vary according to the data associated with each proposed new class. So, in the absence of other

evidence about the class, the lowest latency, leukemia, would be used, the most claimant-friendly alternative. In the case provided, the most radiosensitive of the leukemias (CML) was used with a 1.5 rem dose. The solid tumor cancer with the highest latency in this case was the thyroid, with a dose level of nine. The average of 1.5 and 9 produces a 5.25 rem threshold for health endangerment. For extremely low exposures, for example, as a component of a dose reconstruction for which there is insufficient information, the exposure would be capped at the maximum threshold dose.

In the ensuing discussion, it was noted that the petitioning group need not have leukemia or thyroid, in the cited case. This method establishes a threshold to be used as the bar to determine if radiation doses possibly as high as this or higher could cause disease.

Workgroup Report on Rulemaking 42CFR, Part 83

Dr. Andrade presented the draft proposed wording changes developed by the workgroup on the previous evening. The intent of the members (Dr. Anderson, Ms. Munn, Dr. Ziemer) was to:

1. Explain clearly, up front in the rule and if desired in the preamble, that establishing or petitioning for an SEC status is not necessarily a next step to seek remedy if the Secretary determines that a particular group or case does not meet 50% PC criteria. It is not an appeal process.
2. In 83.1 (Purpose of the Procedures), the goal is to be clear about how a SEC might be constructed. As written, the language seems to leave the onus on the individual to petition for such status, almost forcing the belief that this is the final recourse. The working group felt that NIOSH's contractor should bear some responsibility to note, in the course of dose reconstructions, any commonality of situations found (e.g. of activity, of potential of missed doses) and to report that back to DHHS/NIOSH. The individual might not have been aware that such commonalities existed.
3. New information can come to light at any part of this process, such as noted in Dr. Bistline's presentation on Rocky Flats the previous day. That in itself should trigger examination of potential SEC status.
4. The workgroup felt that many of the procedures described under 83.2 (how cancer claimants are affected by the procedures) relate to how the Board would become involved in reviewing DHHS decisions to create an SEC. The Board should remain involved (be informed) without participating in the details of successful SEC petitions. On the other hand, it is more important that the Board be informed of decisions to *not* pursue an SEC and some of the details related to that.
5. The Board does not want people to petition the Board directly. That would make this an adjudicative Board, not its role; that clause should be stricken that from the text.

In summary, the workgroup advised clarification of the rule's purpose, what triggers the rule, and what the Board's related role is.

Dr. Ziemer provided the specific edits developed by the workgroup:

- 83.1 It appears that "a cohort" exists now, to which new classes of employees can be added.
The document does not address NIOSH as being able to develop a new class based on its

own findings of fact (e.g., people at a facility who were unaware of doses they received). *NIOSH response:* Part of the dose reconstruction report advises the claimant of the SEC and the materials needed to submit the petition. But the interpretation of EEOICPA was that the starting process to create a class was a petition by a class, although there is no language barring the President (through DHHS) to do that.

Dr. Melius and Dr. Andrade repeated that the process must be clarified. It is not clear that the worker just has to affirm they want to be part of the class. NIOSH might already be advising them of this, but it is wise to add an extra line to make it clear that if some evidence arises, there is a possibility that they could be part of a cohort, and they might want to petition.

- Mr. Elliott stated that the burden is on NIOSH, not the contractor, to monitor the results of the dose reconstructions, observe where dose reconstructions are only marginally possible, determine what that means for that potential class, and to procure an affirmation from an individual in this class.

83.5 To the text on employees at a similar facility, include the similarity of time periods in the definition. This also refers to only one facility, which does not address itinerant workers who moved from facility to facility.

NIOSH response: The legislation defines classes as being at “a facility,” which is why separate petitions are needed for different facilities. Dr. Neton added that, for example, radiation technologists go from facility to facility, but are difficult to group because of their different exposures. However, they could be part of the facility cohort.

- ▶ But the impact could be their cumulative exposure across facilities, with could be hard to reconstruct. It could be that only one exposure gets them in the class that could not be reconstructed, but the exposure would have to be high enough.
- ▶ Maintenance and construction workers moved from facility to facility. Some were told they were working in areas not requiring a monitoring badge, where later they needed. They could be a cohort, but they would have to be linked to some facility. The question is, how to define “facility?”
- ▶ Recommendation: Follow up with the OGC to ensure that these workers are not excluded because of the definition of “facility.” Oak Ridge, for example, had a prime contractor overseeing several facilities, but they were changed several times and records are almost nil.
- ▶ Exposures are very individual, but the individual needs to know what is happening to determine if they might be in a cohort. Other than the unions, only NIOSH is in a position to define that commonality. This could lead to suspicion that NIOSH is covering up because the individual cannot know if they’re in a special class.
- ▶ So, make it clear that everyone whose dose cannot be reconstructed just has to mail this back to NIOSH, and be clear that NIOSH will accept the application. It would also be helpful to publish in unidentified form the characteristics of a defined class, for those sites where a dose reconstruction cannot be completed.
- ▶ Insert a line or two to note, once a class is established and the criteria are released to the Federal Register, that NIOSH may do notification outreach based on information from coworkers at the original plant.

NIOSH response: A notification component is worth considering. Other coworkers may be found who may or may not have applied/have cancer, to whom proactive outreach could be done.

- 83.1 Add to the Purpose of the Procedures a statement of what it is not; specifically, it is not an appeal process.
- 83.10 Rules for this Board. The Board should not be involved in the day-to-day process of the program, or be in the loop too early. E.g., 83.10, Subpart B2, discusses that this Board will review the recommendation to turn down petitions that do not meet the requirements. That is a staff function; they already do not meet the requirements, so why should the Board review it? *NIOSH response:* This was inserted to reassure the claimants, as noted in the EEOICPA, that they can appeal to the Board to consider their class, but DHHS has the prerogative to decide before advancing it to the Board.
- 83.10.C NIOSH “.. will present the petitions for evaluation to the Board...” Mr. Elliott explained that this was inserted in case the Board wished to weigh in on a specific plan. The workgroup interpreted this to mean that these are the petitions that NIOSH intends to evaluate and to hear NIOSH’s intended plan. Clarify that:
- ▶ This is not where the Board evaluates them, but where NIOSH presents its evaluation package.
 - ▶ If something is missing in the application, NIOSH will get back to the applicant and give them the 30 days to respond.
- 83.13 “The Board will review the petition and NIOSH’s evaluation at a meeting to which the petitioners are invited to present their views and evidence.” This increases the perception of the Board as part of a formal adjudication process. The workgroup asked if was necessary to invite petitioners to these meetings, or if it would just apply to cases involving major issues. If in fact 90 cases will be reviewed, this will take a great deal of time, and the Secretary makes the decision, not the Board.
- ▶ *NIOSH response:* Mr. Katz related NIOSH’s expectation that the petitioner will want to come, especially in response to a negative report. NIOSH thought they should have an opportunity to do so without NIOSH keeping them at arm’s length.
 - ▶ The question is, who does the petition go to? The Board, or to the Secretary, as the President’s designee? The language of the law states that the petitions are addressed to the Board, which advises the Secretary.

Ms. Mary Armstrong, NIOSH’s Senior Attorney, understood the concern about turning the Board’s meeting into a hearing. The Secretary makes the final determination upon advice of the Board, but it is unclear whether the Board petition is to start that process. These are public meetings, which the public can attend and at which they can make a public comment. The OGC will look at the text to ensure the meeting does not turn into a hearing. That will require clarification of the text about presenting evidence.

Dr. Ziemer asked for volunteers to put this advice into formal text for review at the next meeting, and for any further input to be provided to him. The workgroup to formalize the Board's recommendations is Ms. Gadola, Dr. Anderson, Ms. Munn, Mr. Presley and Dr. Ziemer. Mr. Elliott commented that the working group products could be exchanged on the Website, since they have to remain public.

Dose Reconstruction Workgroup Recommendations

Mr. Griffon provided the recommendations on the dose reconstruction review.

Independent panel. Working group recommends having a review panel with independent experts along with Board representation and Board oversight. The Working group proposes that the panel be composed of two groups (each group consisting of 1 expert (contractor) and 2 board members). The workgroup recommends that 4-6 experts be identified and available on an as-needed basis. The groups within the panel will work separately however, as a control the groups will be asked to assess some number of the same cases.

Rationale: The 4-6 extra experts are needed due to a potential need to rotate subgroups or the need for certain expertise at certain sites. The two groups were proposed initially to enable a scale-up to the number of cases the Board will be reviewing. More may be needed, but the pool of experts may be limited.

Case Selection. The Workgroup recommends that the Board should select the cases for review. The workgroup recommends a stratified sampling of cases based on the following parameters: site (weighted based on # of claims / site), awarded claims, denied claims, and cases for which dose could not be reconstructed. The Workgroup also recommends that the first 10 cases which are completed be assessed by the panel.

Rationale: The weighting based on the number of claims per site may be revisited because that number is not yet known. They also considered the idea of having an appeals process, perhaps a sample from the group of people who appellants. In addition, the first ten cases received are likely to be simpler cases that are awarded, providing a good place for the panel to start.

Ms. Armstrong advised against getting involved in appeals, an adjudication process. She suggested instead that the Board sample rejected appeals on a de-identified basis.

Scope/protocol. The Workgroup recommends that the Board establish the scope of work and the protocols for the panel. The workgroup recommends that the scope include the following:

1. The panel should assess the methods for dose reconstruction.
2. The panel should determine whether or not the reconstruction of dose provides a 'reasonable estimate' of the dose (at least as needed to determine eligibility).
3. The panel should determine whether or not the assumptions (individual case assumptions and assumptions applicable to multiple cases) made for dose reconstruction are credible.
4. The panel should determine whether or not the data from DOE or other sources are of sufficient quality necessary to obtain a 'reasonable estimate' of dose.

Dr. Ziemer noted that this recommendation came to the full Board (not to the Secretary, although he could be informed), as a recommended procedure for the Board's use in proceeding with its work. It could be viewed as a starting procedure and, if adopted, could be modified at any time.

Dr. Melius **moved to adopt the working group's recommendations**, recognizing that there will likely be changes. This is a good vehicle with which to begin until the contractors are in place, to understanding the parameters of the review and to begin in August. Since the recommendation was from a subgroup, there was no need for second to the motion.

Discussion included:

- Ms. Munn appreciated what the working group intended, but was concerned at the extent of this scope. It could be translated to require the work of two full time employees for the next two years. Any search for "outside consultants" could fall on the Board or again on the already heavily-burdened staff. She thought that earlier discussions had focused on the overview of a small number of cases with a couple of experts and perhaps a Board member or two.
- Mr. Elliott understood that, but liked the proposal. NIOSH needs this to get the support necessary for the Board to begin its review of dose reconstructions. The proposal specifies an appropriate amount of resources and can be modified as needed. He agreed that the first ten cases may be the "low hanging fruit," but they may not be representative and they may include extremes, both awards and denials. And in fact, the denied applications can meet the workgroup's interest in reviewing the appeals process without stepping into adjudicatory process. In addition, the random sampling could reveal some contentious cases, because the administrative record will have all the communications therein.
- Regarding Ms. Munn's question of who will find the experts, the workgroup thought that to be an important Board task, although it is NIOSH's role to contract with them. And, regarding the amount of work and staff support needed, that will not be known until the workgroup has reviewed the protocols at NIOSH.
- Dr. Melius thought that NIOSH should be able to refer a technical difficulty or dispute related to a claim to this Board, while keeping them out of the process, which also would help to support the credibility of the process. Mr. Elliott responded that this merits NIOSH's consideration and discussion, and agreed that the Board's mission is to review completed dose reconstructions. NIOSH will discuss this and ask the OGC's advice.

Dr. DeHart called the question of the adoption of the working group's recommendation. With unanimous approval, **the procedure was adopted**. Mr. Elliott added comment that engaging expert consultants involves procurement issues, on which NIOSH will work together with the Board. Then, with no further comment, the meeting adjourned at 3:58 p.m.

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

/s/

Paul Ziemer, Ph.D, Chair

9/4/2002

Date

ATTACHMENTS

Draft Agenda
Advisory Board on Radiation and Worker Health
Hyatt Regency Denver
1750 Welton Street
Denver, Colorado 80202
(303) 295-1234
July 1-2, 2002

Monday - July 1, 2002

8:00 a.m. - 8:30 a.m.	Registration and Welcome	Dr. Paul Ziemer, Chair Mr. Larry Elliott, Executive Secretary
8:30 a.m. - 9:00 a.m.	Review and Approval of	Dr. Paul Ziemer, Chair Draft Minutes
9:00 a.m. - 9:30 a.m.	Program Status Report	Mr. David Sundin, Deputy Director, OCAS
9:30 a.m. - 10:30 a.m. Report	Dose Reconstruction Workgroup	Mr. Mark Griffon, Workgroup Chair
10:30 a.m. - 10:45 a.m	Break	
10:45 a.m. - 11:15 a.m.	Special Exposure Cohort Petitioning NPRM	Mr. Ted Katz, NIOSH
11:15 a.m. - 12:00 p.m.	Board Discussion - Special Exposure Cohort Petitioning NPRM	
12:00 p.m. - 1:00 p.m.	Lunch	
1:00 p.m. - 2:30 p.m.	Board Discussion - Special Exposure Cohort Petitioning NPRM	
2:30 p.m. - 2:45 p.m.	Break	
2:45 p.m. - 3:45 p.m.	Board Discussion - Dose Reconstruction Review Process	
3:45 p.m. - 4:30 p.m.	Board Discussion - Special Exposure Cohort NPRM	
4:30 p.m.- 5:30 p.m.	Public Comment Period	
5:30 p.m.	Adjourn	

Agenda items are subject to change as priorities dictate.

Draft Agenda
Advisory Board on Radiation and Worker Health
Hyatt Regency Denver
1750 Welton Street
Denver, Colorado 80202
(303) 295-1234
July 1-2, 2002

Tuesday - July 2, 2002

8:00 a.m. - 8:30 a.m.	Registration and Welcome	Dr. Paul Ziemer, Chair Mr. Larry Elliott, Executive Secretary
8:30 a.m. - 9:30 a.m.	NIOSH-IREP Risk Models, Uncertainty Distributions and Monte Carlo Analysis	Dr. Owen Hoffman and Mr. Brian Thomas, <i>SENES</i> Oak Ridge, Inc.
9:30 a.m. - 10:30 a.m.	Radiation Effectiveness Factors (REF)	Dr. David Kocher, <i>SENES</i> Oak Ridge, Inc.
10:30 a.m. -10:45 a.m.	Break	
10:45 a.m. - 11:45 a.m.	Board Discussion - NIOSH-IREP Technical Documentation, Subject Matter Expert Comments, and Radiation Effectiveness Factors paper.	
11:45 a.m. - 12:00 p.m.	Public Comment Period and/or Board Discussion	
12:00 p.m. - 1:30 p.m.	Lunch	
1:30 p.m. - 2:30 p.m.	Board Discussion - Special Exposure Cohort NPRM	
2:30 p.m. - 2:45 p.m.	Break	
2:45 p.m. - 4:00 p.m.	Board Discussion -	
4:00 p.m. - 4:30 p.m.	Administrative Housekeeping and Board Work Schedule	Ms. Cori Homer, NIOSH Dr. Paul Ziemer, Chair Mr. Larry Elliott, Executive Secretary
4:30 p.m. - 5:00	Public Comment Period	
5:00 p.m.	Adjourn	

Agenda Items are subject to change as priorities dictate.

Attachment #2: Dose Reconstruction Review Workgroup Recommendations

Independent Panel

Workgroup recommends having a review panel with independent experts along with Board representation and Board oversight. The Workgroup proposes that the panel be composed of two groups (each group consisting of 1 expert (contractor) and 2 board members). The workgroup recommends that 4-6 experts be identified and available on an as needed basis.

The groups within the panel will work separately however, as a control the groups will be asked to assess some number of the same cases.

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Workgroup recommends that the Board should select the cases for review. The workgroup recommends a stratified sampling of cases based on the following parameters: site (weighted based on # of claims/site), awarded claims, denied claims, and cases for which dose could not be reconstructed. Workgroup also recommends that the first 10 cases which are completed be assessed by the panel.

Scope and Protocol

Workgroup recommends that the Board establish the scope of work and the protocols for the panel. The workgroup recommends that the scope include the following:

- Panel should assess the methods for dose reconstruction.
- Panel should determine whether or not the reconstruction of dose provides a ‘reasonable estimate’ of the dose (at least as needed to determine eligibility).
- Panel should determine whether or not the assumptions (individual case assumptions and assumptions applicable to multiple cases) made for dose reconstruction are credible.
- Panel should determine whether or not the data from DOE or other source is of sufficient quality necessary to obtain a ‘reasonable estimate’ of dose.