Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health

Third Meeting of the
Advisory Board on Radiation and Worker Health

February 13-14, 2002

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

TABLE OF CONTENTS

Executive Summary of the Third Meeting 1/5

Minutes of the Third Meeting

FEBRUARY 13, 2002

Attendance 1
Opening Comments 2
Program Status Report 2
Status of ABRWH Recommendations 5
Status of Implementation of the Dose Reconstruction Rule 5
External Dose Reconstruction Guidelines 7
Implementation of Internal Dose Reconstruction and Guidelines 9
Public Comment 12
Review of Dose Reconstruction Rule 42 CFR 82 14

FEBRUARY 14, 2002

Administrative Issues 18
Discussion of Dose Reconstruction Rule 42 CFR 82 18
Rule Components; Motions 19
Discussion of Rule Questions 20
Public Comment 21
Closing Comments 22

National Institute for Occupational Safety and Health
Advisory Board on Radiation Worker Health
Executive Summary of the Third Meeting
February 13-14, 2002

At the third meeting of the Advisory Board on Radiation Worker Health (ABRWH) held on February 13-14, 2002, in Washington, D.C., approval of the draft minutes of the last meeting was deferred to the next meeting. A status report was provided on the **Office of Compensation Analysis and Support (OCAS) program** and the steps in the compensation process. Currently, >12,000 non-Special Exposure Cohort (SEC) cancer claims have been submitted to the U.S. Department of Energy (DOE) for verification before being sent to the National Institute for Occupational Safety and Health (NIOSH). NIOSH has received 419 phone calls. Methods of communication with claimants are being developed, as is a Website.

The Board expressed concern that the OCAS be adequately staffed to address the anticipated number of claims (10,000/year), and to ensure the completeness of the DOE records and the contractor's quality assurance. NIOSH provided reassurance on all points. Formation of an Advisory Board on Radiation and Worker Health (ABRWH) workgroup was anticipated to ensure that the dose reconstructions are appropriately done. NIOSH also reported on the development of guidelines for a petitioning process to expand the SEC. In a discussion of the selection of a dose reconstruction contractor, it was noted that the "request for proposals" calls for a plan to address how conflict of interest will be handled.

The Chair reported submission to the Secretary, Department of Health and Human Services (DHHS) of the **ABRWH recommendations** on the draft rule on Probability of Causation.

NIOSH staff members reported on the **status of the implementation of the dose reconstruction rule** was also reported in detail, with each aspect of the five major dose reconstruction steps outlined: 1) collection of existing information; 2) claimant or survivor and/or co-worker interviews; 3) evaluation of the completeness and adequacy of existing data; 4) calculation of the dose to the organ; and 5) report of dose reconstruction results.

The low dose and high dose processing strategies of the NIOSH Interactive RadioEpidemiological Program (IREP) system were described. Some time was spent discussing the dose reconstruction's methods for radon exposures, since there are no bioassay methods with which to measure radon. NIOSH reported that in general, it may be necessary to rely on source term analyses.

Discussion included queries about who interviews the claimants (NIOSH staff, initially, then the contractor); the information to be given to the employees beforehand; the development of a system to house the knowledge amassed and to ensure the completeness of information. Since the OCAS' program is restricted to radiation-related claims, NIOSH assumes that the Department

of Labor (DOL) and DOE's advocacy/outreach activities will recommend referral to state workers compensation programs of any claims involving non-radiological exposures.

The **guidelines for dose reconstruction of external exposures** were reviewed, both for those sites with, and those without, personnel monitoring data. The dose reconstruction elements include determination of external doses and their conversion to organ dose, uncertainty and distribution determination, and the interface with IREP. These guidelines, which include considerations relevant to the analysis of missed dose, environmental dose, and occupationally required medical dose were outlined. A rationale was presented for the assumption of a lognormal distribution for both missed and environmental dose, and occupational medical dose. The use of these data to calculate a conversion to organ dose in the IREP program was described. The primary factor considered in IREP is the dose to the target organ that may result in a primary cancer. Additional factors affecting conversion are the monitoring devices used, the energy of the emission, and the geometry of the exposure. A Monte Carlo analysis of each distribution will then be done to determine the uncertainty distribution for each dose. Those will then be added together to produce the organ dose. NIOSH also will consider changes in dosimetry over time, since improved dosimeter methodology reduced the amount of missed dose.

In discussion, NIOSH was advised to consult with experts in the field who have extensive archives of historical information from the DOE complex.

The **guidelines for and implementation of dose reconstruction of internal exposures** were also presented. The primary data sets used to determine internal dose are in-vivo bioassay measurements, incident reports, and measurements of airborne concentrations of radioactivity. The guidelines propose the use of the ICRP biokinetic models, which factors in routes of entry and elimination, transport of a radioisotope within the body, and the varying organ rates of absorption or excretion.

The dependency of date on acute intake analysis was explained. Nonetheless, the Board was reassured that, even assuming incorrect dates of exposure, modeling can achieve approximately the same total estimate of exposure. The quantity of intake can be determined from can be determined from a bioassay sample if the day of actual intake (as determined from incident reports); or, with limited or even missing sample information, follow-up sample measurements can be analyzed. Another method demonstrated how analysis of a chronic exposure can also be accomplished by viewing it as a series of acute exposures, thereby compensating even for missed dose. A comparison of complete and incomplete data, the latter using this method, demonstrated a very close parallel of results.

Discussion included:

- Latency and weighting factors are used to avoid including recent dose for materials that might have contributed to dose at the cancer site shortly before the diagnosis.
- The Memorandum of Understanding (MOU) to be established with DOE will specify

how classified data will be handled.

- NIOSH has considered taking bioassay samples as a quality check (a costly process) from retired individuals who may have had exposures.
- The term "conservative" in the rule is defined as applying the benefit of the doubt to the claimant in a worst-case scenario.
- The dose to the organs not included in the ICRP models will be developed by assigning the highest dose to the highest non-metabolically involved organ, as delivered by the volume of blood flowing through the organ, and then assigning that dose to the ICRP model. The impact of the uncertainty will be low because the dose will be lower than that to the metabolically involved organs by several orders of magnitude.
- To ensure the conservative approach integral to the intent of the Energy Employees Occupational Injury Compensation Program Act (EEOICPA), NIOSH can run multiple scenarios using an overestimate consistent with the data received. The impact of the assumptions on the outcome will have to be reviewed in every case, but especially for the middle group at 40-49% POC.

Public comment was received from representatives of the Institute for Policy Studies and the Government Accountability Project. The Institute for Policy Studies addressed the issues of conflict of interest; suggested a subcommittee to ensure quality of the work scope, spot checks of ongoing work, and addition of an ethicist to the Board's membership; review of extant information (e.g., 2001 work to establish an understanding of the mass balance flow of recycled uranium in the DOE complex; detail of the history of gaseous diffusion plants (GDP) done by the DOE Office of Occupational Safety and Health); and the need for the Board to look at the overall issues beyond the dose reconstruction outcomes.

The Government Accountability Project (GAP) warned against presuming the regularity of the dose record and provided several supporting rationales. The claimant may have to rely on memory and may have worked on a need-to-know basis, and the absence of the kind of detailed information developed in the GDP system report prevents determination of whether the systemic approach used at a site was proper or not, or whether the data has any basis.

The Board was advised to keep in mind the missed dose of unmonitored exposures, and not to be misled by the high degree of precision "tweaking" in the dose reconstructions done. An ABRWH recommendation to the Secretary was suggested on how to address the challenges of data gaps, as was a review of Fernald and Paducah studies' indication of the acceptability of internal and external dosimetry data. Finally, the issues of the SEC should be considered in parallel to this dose reconstruction rule, since policy questions are involved relating to the continuum between dose reconstruction and the inability to establish harm done in the absence of evidence.

The regularity of DOE's paper trail should not be expected. Large DOE sites could group their processes to determine those with measurements of a high degree of confidence. The workers in the other processes would fall within the SEC. Assessment of the processes of highest risk could assign a collective risk criterion. The best histories of radiation protection programs should be

gathered, to serve as the historical lens to define those posing the highest risk and to estimate their exposures. Finally, plans detailed in the RFP responses must be transparent regarding conflict of interest in order to ensure public confidence in this process.

The Board **reviewed dose reconstruction Rule 42 CFR 82** line by line. Comments and discussion occurred on the following points:

- NIOSH's address of accuracy of dose and reality of the workplace: Site profiles will be developed over time with accumulated data and be publically available for worker review. NIOSH will use data when satisfied that it accurately reflects the workplace. Changes to the guidelines and/or the technical basis documents resulting from interview or dose reconstruction information, or from ABRWH recommendations, can prompt previous POC determinations' review upon the worker's request.
- The anticipated process was described as three plans, in which "Plan A" uses the data in hand, "Plan B" involves a dose reconstruction using the source term, and "Plan C" allows revisions as necessary under the final rule. A "Plan D" also is needed, the criteria of which will address the SEC; and each succeeding plan level (A, B, C) will require more resources. At some point, the procedures to add to the SEC will have to be formed. Without knowing the borders of the continuum of these processes, the Board felt hard pressed to comment on the rule. NIOSH noted that this could be sent as a comment to the Secretary, including note of the cases in which NIOSH not only cannot do a dose reconstruction, but there also is evidence that there was a substantial exposure.
- DOE's certification of a completed records search is a written confirmation form, based on NIOSH's direction to search for types of records in all of the relevant archives. NIOSH also will do quality assurance through site visits to confirm that all available records have been found.
- The word "validated" can be open to interpretation, but those legal meanings have been left to the Office of General Counsel.
- In the presence of anomalies (e.g., when several sites' data indicate repetition of certain types of cancer and certain job functions), NIOSH would assess the significance of the dose, since a distinct internal dose at one site may not apply to another. The Board may wish to consider this in terms of its comments on sampling strategies in order to review completed dose reconstructions.
- The Board should discuss in future meetings how NIOSH will maintain the data, to allow application of past experience and, if necessary, to correct past errors in reconstructing doses. A NIOSH-DOL feedback loop for such potential reevaluations has already been discussed.
- Clarifications in the rule were suggested as follows: 1) Pointed out that NIOSH is not identifying causation; 2) Specify what information researchers could, or could not, receive in an identified data set under the Privacy Act; and 3) Make it clear that NIOSH will not seek permission from claimants or their survivors to release information.
- NIOSH will make available to the public the statistics on the number of claims, status, dose reconstructions completed, technical basis documents supporting implementation guidelines, etc.

- Codification of the ABRWH's role by moving language from the preamble and into the body of the rule was suggested.

The members were requested, for compensation purposes, to advise NIOSH of their time spent in preparing and participating in the conference call and in reviewing the technical guidelines. To allow the NIOSH staff time to address the public comments, Board comments, and technical peer comments to the two rule makings and promulgate final rules by April 2002, the Board agreed to meet next on May 1-2 or 2-3. Topics suggested are detailed in the Minutes.

In their final **discussion of dose reconstruction Rule 42 CFR 82**, the Board agreed on edits to the rule, which are detailed in development and final form in the Minutes. A summary of the comments officially approved will be sent in a letter to the Secretary, with the meeting agenda attached. They also crafted the following response to the rule's three questions:

> "Interim proposed rule 42 CFR, Part 82, makes appropriate use of current science in reconstruction of radiation dose scenarios to the extent practicable. The Board recognizes that if the efficient and expeditious consideration of claims is to be made, absolute precision is not possible. The methods proposed are intended to result in dose estimates favorable to the claimants and are appropriate to the occupational illness compensation program envisioned by EEOICPA.
>
> "The process for involving the claimant is fair and provides multiple opportunities for interaction with the involved agencies. Indeed, in cases where acceptably dependable personal exposure data do not exist, NIOSH will utilize other sources of information, as the basis for dose reconstruction. This approach unavoidably injects additional uncertainty into the calculation of dose. However, we view the proposed methods as being appropriate for the available information. There will be circumstances where NIOSH will not be able to estimate the dose with sufficient accuracy. Those circumstances need to be clarified in the implementation of the regulation and in the Boards review of NIOSH's dose reconstruction work. Groups whose exposure cannot be estimated with sufficient accuracy may be candidates for the Special Exposure Cohort."

NIOSH agreed to investigate whether the members of FACA committees, as opposed to federal agencies, can work both individually and as a group and in formulating predecisional drafts. In **public comment** it was asked, if DOE had calculated a dose higher than the IREP's, which number would be used for the claimant. It was noted that DOE did not calculate an annual internal dose before 1990, and that the DOE number will be a point number, while the NIOSH dose reconstruction number will be a distribution in a standard deviation. NIOSH will use their estimate, not DOE's, if a complete dose reconstruction is done. In addition, the IREP program's use of equivalent dose, and the weighting factors' use of a distribution, raises the uncertainty and therefore the claimant's chances of compensation.

The meeting then adjourned.

National Institute for Occupational Safety and Health
Advisory Board on Radiation Worker Health
Minutes of the Third Meeting
February 13-14, 2002

The National Institute for Occupational Safety and Health (NIOSH), Office of Compensation Analysis and Support (OCAS) convened the third meeting of the Advisory Board on Radiation Worker Health (ABRWH) on February 13-14, 2002, at the Washington Court Hotel, Washington, D.C. Verbatim transcripts are being taken and will be made available on the NIOSH/OCAS website (www.cdc.gov/niosh/ocas) when complete.

FEBRUARY 13, 2002

Attendance:

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

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

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

Department of Energy (DOE): Josh Silverman

Department of Health and Human Services (DHHS):
- Office of General Counsel: Mary Armstrong, Alice Kelley
- NIOSH: David Allen, Larry Elliott, Chris Ellison, Russ Henshaw, Liz Homoki-Titus, Cori Homer, Ted Katz, Jim Neton, Tim Taulbee, Twyla Saitow.

Department of Labor (DOL): Jeffrey L. Kotsch, Sonya Levine

Office of Management and Budget: Cristal Thomas

Members of the public present were:

Robert Alvarez, Institute for Policy Studies, Washington, D.C.
Neil Barss, SAIC, McLean, VA
Lynne Fairobent, ACR, Reston, VA
Mark Griffon, CPS/PACE, Salem, NH
Jeff Harper, Turner Harper, Washington, D.C.

W. E. Johnson, ATLC, Oak Ridge, TN
Justine Keye, ASSE
Martin Mathamel, Washington, D.C.
Tim McAdams, Westat, Rockville, MD
Richard Miller, GAP
Frank Morales, Government Accountability Project (GAP)
Frank Moran, Westat, Rockville, MD
Louise S. Presley, Clinton, TN
William D. Ulicuy, ATL International, Inc., Germantown, MD

Opening Comments:
Dr. Ziemer welcomed the members and convened the meeting at 8:30 a.m. He noted that the first agenda item was the review and approval of the draft Minutes of the last meeting. However, since they had not yet been reviewed and approved by NIOSH staff and the Chair, the approval of the Minutes was deferred to the next meeting.

Program Status Report:
Mr. Elliott indicated that the program status report was designed and intended to provide the ABRWH an understanding of the OCAS activities and a fuller context of how the Board's work was affected by the status of those activities. He outlined the work of each of the OCAS staff and a time line of each activity to date:

- March, 2001: Six NIOSH staff were reassigned to develop guidelines and policy regarding dose reconstructions and probability of causation (POC) and to draft the ABRWH charter.
- July, 2001: OCAS office was established in NIOSH with 22 full-time equivalent (FTE) staff, not all of whom have yet been appointed.
- August, 2001: ABRWH charter was signed.
- October, 2001: 1) Federal Register publication of Notice of Proposed Rulemaking for 42 CFR Part 81, Guidelines for Determining the Probability of Causation under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) -- opened a 30-day comment period; 2) publication of 42 CFR Part 82, Methods for Radiation Dose Reconstruction Under EEOICPA, an Interim Final Rule with request for public comments (this allowed dose reconstructions to begin while the rule is being finalized); 3) first batch of claims received from the Department of Labor (DOL) with verification of both employment and cancer diagnosis; 4) President Bush announces ABRWH appointments; 5) first batch of acknowledgment letters sent to claimants.
- November, 2001: 1) public comment period for Methods for Radiation Dose Reconstruction closed November 5, then reopened; will close again March 1, 2002; 2) first batch of requests for personnel monitoring data sent to DOE on November 27 to begin initial evaluation of dose reconstruction process for those claims.
- December, 2001: 1) public comment period for POC guidelines closed, then reopened; 2) first claim examined and interview conducted in an expedited process (claimant near death wanted to share his work history); 3) first batch of letters sent to claimants advising

that DOE had been queried about their work history regarding their claim.

- January 22-23, 2002: First ABRWH meeting.
- Currently, >12,000 non-Special Exposure Cohort (SEC) cancer claims have been submitted to DOE for verification before being sent to NIOSH.

Mr. Elliott outlined the steps of the process:

1. NIOSH receives the verified claim from DOL.
2. Letter is sent to claimant notifying them of NIOSH's receipt of the claim.
3. Evaluation of information needed; request for dose information (badge and bioassay data) is sent to DOE.
4. Claimant notified of requests to DOE.
5. DOE responds to information request.
6. Initial review (31 to date) of claimants' radiation monitoring information, in preparation for dose reconstruction.
7. Telephone interview conducted (one to date).
8. Requests for additional information sent to DOE (21 to date).
9. Dose reconstructions completed – none to date; NIOSH needs to finalize the s with the Board's assistance before a dose reconstruction can be completed.

At this meeting, more information on the dose reconstruction methodology will be provided to ensure a similar level of understanding of the process by all the members. To date, 419 claimant phone calls have been received, and one claimant visited the OCAS offices. The methods of communication with claimants are being developed. DOL claims/customer service procedures are being reviewed, and a Website on which claimants can check the status of their claim is being developed.

Amendments to the EEOICPA passed in the Defense Authorization Act, late in 2001, included a congressional requirement that NIOSH conduct and report on a residual contamination study of the atomic weapons employers. A status report on this study is due by June, 2002, and the final report is due in December, 2002, to Congress.

Questions and discussion with Mr. Elliott included:

- *Is the staffing adequate for the anticipated number of claims?* 8000 claims per year are anticipated and contractors will be engaged as needed. The proposals from potential contractors for the dose reconstruction work are due on February 20, 2002. The awarded contractor will do the bulk of the dose reconstruction work, and the different skills and staff needed in OCAS will be assessed over time. Additional support in OCAS can be requested.
- *Is the SEC being handled on a different track?* The policy guidelines for the SEC are in review by the Secretary, who will either finalize them or require us to go forward with a proposed rule.
- *Why does NIOSH need to go from DOL to DOE to conduct a dose reconstruction, why*

not have DOL ask DOE for dose data? NIOSH has the responsibility for conducting dose reconstructions and feels it is important to ask DOE for the information needed for a given claim, rather than have DOL seek information from DOE that may or may not be needed. NIOSH can utilize research data from pertinent NIOSH studies, and DOE is being impacted by information requests from many sources. NIOSH prefers to receive the claim and information on where the claimant worked and then to approach the DOE sites directly for the necessary information to complete a dose reconstruction.

- *How do you know if the records DOE provides are complete (all that they have)?* To test the veracity of DOE information, NIOSH's methodology includes a detailed request for the type of information NIOSH feels is necessary. Progressive steps are taken to develop the case file. In-house data is checked. Initially, DOE is asked for badge and bioassay data for a claim. Information and data to fill gaps, group-based exposure data, and general site-specific information is then requested as necessary. NIOSH has, through its research program experience with DOE sites, a clear understanding of the data and information which should be available at a given site to support dose reconstruction efforts. NIOSH has Q-cleared staff to pursue classified information. DOE and NIOSH are working on a Memorandum of Understanding (MOU) to ensure NIOSH's access to the needed information.
- *What is the expected timetable for the MOU?* Absent complete information, that is hard to predict. NIOSH hopes in April to report further on when the MOU will be in place.
- *The contractor must be objective; who selects the contractor?* This is done according to government procurement standards. A technical review team (composed of NIOSH staff) and a business review team will review the proposals. An evaluation guide is prepared to review and rank the proposals on a point basis. The award negotiations are done by the program and the procurement office. NIOSH staff will provide oversight by conducting blind dose reconstruction spot checks and the ABRWH has a responsibility to review completed dose reconstructions for quality.
  - Dr. Roessler commented that the contractor's quality assurance must be ensured, in addition to the ABRWH's review of the dose reconstructions, and noted that NIOSH's staff seems insufficient. Dr. Ziemer anticipated the need for the ABRWH to establish a workgroup to ensure the dose reconstructions are appropriately done.
- *Are the 20% of cases received from DOE, that involve additional interaction or more information, a startup activity or will that continue?* This is an evolving process; it is still too early to interpret how many cases will require more information from the sites. For example, some sites sent cumulative dose information rather than individual dose information, misunderstanding what was desired. NIOSH is evaluating work loads by site.
- *Will the SEC be broadened?* Guidelines for a petition to do so are being developed.
- *How will a conflict of interest by the contractor be handled?* The Request for Proposal (RFP) calls for a plan to address that. The proposals will be reviewed and negotiated with the awardee.
- *The claims process presents a complex tracking problem, coupled with time lines. How will NIOSH monitor the track of a claim, including determining when alternate exposure*

records should be requested/investigated? NIOSH requests a response or report from DOE within 60 days. Completed requests for information for a given claim are provided to NIOSH by DOE whether the entire batch is complete or not.

- *Does DOE have resources to support this work?* The Office of Worker Advocacy (OWA) was established and funded to address these issues. Major field sites have been funded and OWA is in regular communication with the sites to facilitate this program, which is a new process for them. The OWA is working with the sites, NIOSH, and DOL to retrieve the needed information.
- *Are the telephone calls asking about claim status?* Yes, and the are also asking when a decision can be expected. The Website has a page now to detail the number of claims in-house and where they are in the process. The number of calls is expected to decline when claimants can access their status through the Website.

Status of ABRWH Recommendations:

Dr. Ziemer reported that the ABRWH recommendations had been sent to Secretary Thompson on February 6, 2002. These were developed at the last meeting, refined and unanimously accepted in the
February 5, 2002 conference call. He reported some debate on how the public should be involved in this process. For this particular document, it appeared that one group had access to the wording while others did not. Consideration is needed on how to make documents universally available to the public to allow everyone the opportunity to review and comment.

Board discussion noted that all drafts and comment should be posted on the Website as they are received, and announced at the meeting, along with the public's comments. Mr. Elliott said that this was possible. And, since the Board's discussions need to be conducted in a public forum, he asked that he and
Ms. Homer be copied on all e-mails, which they will post on the Website. Arrangements also need to be made for members of the public without Web access and to accommodate telephoned requests.

Status of Implementation of the Dose Reconstruction Rule:

Dr. Jim Neton outlined the five major steps of dose reconstructions: 1) collection of existing information (if personnel monitoring information alone allows dose reconstruction that will be sufficient); 2) claimant interview (a computer-aided telephone interview) or an interview of survivor and/or co-workers; 3) evaluation of the completeness and adequacy of existing data (very little atomic weapons employer (AWE) personnel data are anticipated); 4) calculation of the dose to the organ (including discussion of the related software programs and development), and 5) report of dose reconstruction results.

Program documentation includes four important aspects: 1) receipt of case files (all received to date have been scanned and made electronic or PDF files and easily downloaded to any computer); 2) implementation guidelines (the Board's comments on this document were requested) were drafted to be more specific and detailed than the guidelines in 42 CFR, Part 82; 3) technical basis documents (to address unusual scenarios) are more detailed and specific than

the guidelines; and, 4) procedures (a step-by-step approach on how each part of the , guidelines, or technical basis document is to be completed).

The *low-dose processing strategy* begins conservatively for a person with a low external dose profile, using available monitoring data and doing an initial evaluation using worst-case assumptions. When cases result in a very low estimated POC, the dose construction is considered complete; if not, as is expected for cases, more information is sought and more detailed analyses are performed.

The *high-dose processing strategy* is similar to low dose in that if a POC is determined to be greater than 50%, based upon the available monitoring data, the dose reconstruction is concluded. Less determinate results are analyzed further and more definitive information sought. The organ of interest for possible internal exposure is determined, and evaluation is performed on selected data (e.g., the highest internal dose or that of a single intake) in a conservative overestimation of the total dose. In cases where the dose reconstruction is still indeterminate, more complete analysis of the case is done. NIOSH is developing tools that will be useful to the dose reconstruction process, tools which focus on cancer type, organ of interest, and the extremes of POC. Dr. Neton provided two examples of this approach.

He also spent some time discussing the dose reconstructions to be done for radon. These will be unique since there are no bioassay methods to measure radon. The dose reconstruction is based on exposure measurements (air concentration), not on a dose. The POC analysis uses risk values drawn from the studies of U.S. uranium miners. The calculation must address differences in natural background levels between different geographic regions. Poor monitoring records are anticipated, but some air concentration measurements are available to factor into the analysis. Fortunately, only a few sites were affected by radon, among them the Fernald and Mallincrodt sites.

Atomic weapons employers are somewhat unique in terms of the periods of covered employment versus those of covered exposures. A NIOSH study is in process to evaluate the residual contamination that might have been left at AWEs after DOE operations ceased. Due to the expected limited availability of personnel monitoring data it may be necessary to rely heavily on source term analyses at the AWEs.

Discussion included:

- *Will these data be placed in an analytic database? If data on some diseases such as leukemia fall into a special group, that could create classes of exposures such that all exposures over a certain level will be automatically covered by the EEOICPA.* Yes.
- *Who interviews the claimants?* Initially, NIOSH staff; then a contractor once in place. This is part of the request for contract specifications. Emergency approval under the Paperwork Reduction Act has been granted by the Office of Management and Budget (OMB) to develop the interview scripts. They will be placed on the Website when approved and copies will be supplied to the Board.

- *What information will be given to the employees beforehand?* The interview questions will be provided, and general information about what NIOSH is seeking. NIOSH will explain the process as the interview goes on, addressing the exposures individually. The interviewer will review the file with all collected data (DOE, etc.) before the interview itself. Good interviewing skills will be required; for example the claimant may state that a badge was not worn, forgetting that temporary badges were issued monthly at some facilities. More than one interview can be done per claim (for example, with sick claimant survivors), and interview methods will have to be flexible.
- *The items listed by NIOSH to be examined involve a wide range; how will the knowledge base be built and the completeness of information ensured?* The process will not be efficient in the beginning, as a sense is developed of whether all the information needed is in hand. All the data will be placed on a system that can be accessed directly and modeled for dose reconstructions on other claims.
- *Be sure to get the multiple sites at which person worked.* That will be gained from the claim forms filed, the person's employment file records, and the interview information. Everyone will be interviewed, even those with exposures high enough to warrant a claim. But the complexity of the interviews will depend on the number of sites at which the person worked and on the exposures. The point of the interview is to include the claimant in the process, and obtain as much information is possible to establish an accurate dose.
- *Will the program refer a claimant whose cancer was caused, not by radiation, but by other exposures in the working environment, to file a state unemployment compensation claim?* NIOSH assumes that the DOL and the DOE state outreach activities will recommend referral to state workers compensation. The OCAS dose reconstruction program is restricted to radiation exposure and cancer-related claims.

External Dose Reconstruction Guidelines:

Mr. Tim Taulbee, health physicist with the OCAS, reviewed the implementation guidelines for external dose reconstruction. Two types of dose reconstructions address those sites with personnel monitoring data (dosimetry, missed dose, environmental and occupational dose), and those sites without such data. The latter is compensated for by use of co-worker, air monitoring survey data, source term data, and data on radiological control limits. The dose reconstruction elements include determination of external doses that are converted to organ dose, with uncertainty and distribution determined, and then interfaced with the IREP. Similar doses are defined as all readings greater than 0. Early readings were taken in milliRoentgen (mR), and later converted to millirem (mrem).

Missed dose resulted from such factors as the limits of detection (LOD), frequency of badge exchanges (now quarterly, but up to weekly in the past), and the number of badges recorded as zero (i.e., due to an administrative policy to not record measurements greater than 30 mrem). A missed dose calculation assumes a lognormal distribution, with the geometric mean calculated by the number of zero dosimeter measurements, times the limit of detection, divided by two, to produce a central estimate.

The rationale for choosing a lognormal distribution is based on data indicating that individuals' doses as a whole over their entire work history tends to reflect a lognormal distribution. The number of dosimeters which have results recorded as less than the LOD, times the LOD, produces the upper 95% bound of the estimated missed dose. The rationale for using a normal distribution for the dosimeter dose is that laboratory measurements generally include a predicted range of uncertainty and tend to follow a normal distribution for a particular year. The literature also supports a normal distribution for missed doses.

Environmental dose (mostly from stack emissions in an ambient environment) is calculated by a general equation that includes the number of months spent in the area, the average monthly dose rate for the year of interest, and an occupancy factor (i.e., the percent of time spent on site), again assuming a lognormal dose distribution.

Occupational medical dose stemmed from medical monitoring on-site; for example uranium workers were provided yearly chest x-rays as a condition of employment for monitoring purposes. Current x-ray doses are orders of magnitude lower, but in the early years, diagnostic x-ray doses could be very significant, depending on the medical monitoring device and the frequency of the monitoring. The calculation factors in the number of screening exams in the calendar year and the type of diagnostic x-ray procedure. The medical monitoring dose is not automatically added into the calculation unless it pertains to the cancer site of interest.

DOE work was typically supported by written procedures. Procedures were documented, but not necessarily at all sites. Smaller sites may be missing much of these procedural data, necessitating extrapolation from larger facilities. There may be a wide range in x-ray doses due to such differences as the filtration of the beam and the film speeds used. It was emphasized that the radiation doses being discussed here were not from therapeutic radiation (e.g., medical diagnosis and treatment), but procedures required to hold the job. In general, these are not as complex to calculate as they may seem; their importance only pertains to those persons whose claims may be borderline.

NIOSH may seek additional information from the DOE site, for example, from medical files that may not have been provided with the case information provided by the DOL. Older documents can also provide such other factors as the LOD of the time and methods used, which frequently were adopted by other sites.

Conversion to Organ Dose. The primary factor considered in IREP is the dose to the target organ that may result in a primary cancer. Additional factors affecting conversion are:

1. Monitoring device: film or thermoluminescent detector (TLD).
2. Energy of the emission (as recommended by ICRP 74, integrating the measurement curve to produce an average dose conversion factor [DCF] for the energy band from the lowest to highest DCF).
3. Exposure geometry: to determine the likeliest dose conversion factor (DCF), NIOSH uses a weighted approach based on the information in hand about the job, and/or

information gathered in the interview about the hazards encountered. For example, to determine the exposure of a person working in a glove box, a 90% anterior/posterior exposure would be calculated and then changed to a 10% rotational geometry to calculate the worker's exposure while walking around the worksite.

A triangular distribution is used, considering the lowest to highest DCF for the energy band of interest and the likeliest DCF, to calculate the DCF and determine the central tendency. A Monte Carlo analysis of each distribution will then be used to determine the uncertainty distribution for each dose (missed, environmental, medical) and dose conversion to mrem. Adding them together will produce the organ dose (e.g., bone marrow). NIOSH also will consider changes in dosimetry over time, since improved methods of containment and dosimeters reduced the incidence of missed dose over time.

Once the central estimate and the uncertainty distribution has been developed through Monte Carlo analysis. A goodness of fit test will be applied to determine the most probable distribution type. For external dose, the Monte Carlo developed uncertainty distribution is usually either a normal or a log normal distribution.

Discussion included:

- *In the early periods, and even today, certain neutron energies were not easily detected by dosimeters. That was known at the time as well, and algorithms were used to correct for that in the dose record, based on the source terms present. Is NIOSH automatically assuming that some neutron dose was missed, or are those algorithms being used?* NIOSH allows for this site-by-site according to a site's calibration procedures.
- NIOSH was advised to consult with experts in the field who have extensive archives of historical information from the DOE complex, such as Paul Frame and Ron Kathren.

Implementation of Internal Dose Reconstruction and Guidelines:
After lunch, Mr. David Allen, health physicist with the OCAS, outlined the methods by which intake and dose are calculated in the dose reconstruction. The primary data used to determine internal dose is that from in-vivo and bioassay measurements (urinalysis, fecal, and breath samples); incident reports, airborne concentration of radioactivity (samples of breathing zone or general air; estimates from contamination levels or dispersible source inventory). Bioassay data are frequently archived, is directly related to the individual's intake, are traceable, and are more likely retrievable.

NIOSH will use the ICRP's biokinetic models, which describes different routes of entry to and elimination from the body, and the transport of a radioisotope within the body, as well as the rates of various organs to absorb or expel the radiation. The model can be used to extrapolate when exposures over a period of time occurred. In principle, a rate intake (e.g., a constant) can be assigned to model this mathematically with differential equations.

Analysis of an acute intake is date dependent. The quantity of intake can be determined from a

bioassay sample only if the day of the actual intake is known, this date can be found through incident reports. Another method used in the presence of limited information, or even missing samples, is to analyze follow-up samples. Even assuming incorrect dates of exposure, the modeling can achieve essentially the same total estimate of exposure.

Analysis of a chronic exposure can be accomplished by treating it as a series of acute exposures. An example compared an acute exposure with the same quantity of exposure spread out (e.g., over 30 days). Mr. Allen shared a sample of data on a charted excretion curve of Pu-239, demonstrating a data differential of less than 10% on day 20 and less than 2% on day 30. Since the excretion curve of Pu-239 is a constant, the analyst is able to enter a series of estimated intakes to try to match the measurement data in hand.

Missed Dose. Mr. Allen then shared an example again demonstrating that, even with missing data (e.g., due to an exposure below detectable limits), an accurate reconstruction can be developed when correlated with subsequent samples. For example, considering the case of an individual whose first detectable sample was 31,000 pCi. If we assume a detection limit of 0.0020 picoCuries (pCi), and an undetected chronic exposure of 87 pCi per day for 152 days prior to the first detectable sample, which we add 13,000 pCi of intake. The real intake is thus 44,000 pCi rather than 31,000 pCi. However, adding a missed dose and reevaluating later intake estimates still produces a similar end result (but with a 5.5% error, rather than 7%). Mr. Allen's conclusion was that, with a series of good sample results, there is no need to add a missed dose that occurred prior to detectable samples unless very fine refinement is required. The example demonstrated that there is no missed dose for years after detectable samples. If the predicted values are detectable, no missed dose needs to be added.

Discussion included:

- *If there is a long-lived material in the body, are NIOSH calculations truncated to avoid including materials that might have contributed dose to the cancer site shortly prior to the diagnosis?* No, the calculations include dose for the period from exposure to date of diagnosis. However, since IREP examines the latency, recent dose probably would have no effect; the weighting factor used would address that.
- *Will you be routinely asking DOE for incident reports?* That will be done if any information from the interview that augments DOE information indicates a need for incident reports. If, for example, an incident report is received without any available supporting monitoring records, that information can still be used (e.g., an estimate of airborne contamination factors could be analyzed).
- *If the incident files did not include bioassay data, or the incident file was archived, those data could be more difficult to get.* Nonetheless, as long as there is some information available of detectable measurements, the exposure can be calculated. Other sources also will be explored, such as air sampling data, co-worker or data, etc.; there is no one formula to address all possible scenarios. Noting that this would seem to be important to the individual claimant, Dr. Melius requested a presentation on this at some point in the future.

- *How will you handle classified data?* This will be addressed in the MOU to be established with DOE. NIOSH staff with Q-clearances will review the data. If the data's clearance level prevents its use, NIOSH will seek declassification. If that is not possible, methods will be needed to involve a judge who would deal with classified information issues.
- *Has either NIOSH or DOE considered taking bioassay samples from retired individuals who may have had exposures?* That has been considered. With more sophisticated methods, more accurate clearance data could be obtained on the workers, but this is costly (several thousand dollars per process). While this could perhaps be done to check the dose reconstruction work, no decision has yet been made.
- *A referenced paper mentioned the use of resuspension factors, such that "with limited information, conservative default factors would be used." What might be the agreed-upon default values?* NIOSH most likely would go to the tables and use the research factors listed there. This will be done on an ad hoc basis. But as stated, "conservative" is defined as applying the benefit of the doubt to the claimant in a worst-case scenario.
- *A more formal analysis is needed than the illustrative examples provided, to define when certain parameters or assumptions may be necessary (e.g., a sensitivity analysis). And, are you prioritizing your areas of effort to ensure the best use of resources in terms of the cases addressed? This seems to be a challenge, since in many cases NIOSH may not know until the end of the analysis whether the technical work done would appreciably change the dose or the POC.* NIOSH is taking the steps one at a time. Technical basis documents will be developed in collaboration with the contractor, based on the lessons learned from the claims analyses as time goes on, to demonstrate how these inform subsequent analyses. The effort put into refining the risk estimates could provide a large payoff, since some of the models (e.g., bone cancer) have a large enough uncertainty range, making absolute precision unnecessary (e.g., regarding the internal dose).
- *How will you develop dose to those organs not included in the ICRP models and the uncertainty associated with that?* That is acknowledged as a potential problem. Since some of these organs are not radiosensitive, there are little data, and ICRP could not deal with them well. If they are not radiosensitive, the risk factor should be a little bit higher. But in some cases, the uncertainty of the risk factor may make the uncertainty of the dose almost irrelevant. NIOSH will enter the upper bound of the best estimate of the dose to IREP, and incorporate either a large uncertainty or a constant for the dose. If both indicate similar compensation eligibility, the uncertainty of the dose need not be refined further. The concept at this point is to assign the highest dose to the highest non-metabolically involved organ (e.g., for plutonium, liver, skeleton, lung and gonads) as delivered by the volume of blood flowing through the organ, and that would be the dose assigned to the ICRP model.
- *Does the fact that extended sensitivity analysis will matter little to the outcome alter in any way NIOSH's response to EEOICPA's intent to be conservative in doing these estimates? That is, would Monte Carlo analyses have to be done until there is sufficient data to indicate which elements are most predictive of an outcome? And how will you know if you do need more data, until that point?* There will be technical basis documents developed, and NIOSH can run multiple scenarios using an overestimate consistent with

the data received. But it is agreed that the parameters will have to be reviewed in every case to see how much difference the assumptions make, especially for the middle group at 40-49% POC. The contributions to that result by the input parameters received from DOL and by the risk model will be the areas of most focus by NIOSH.

Public Comment:

Mr. Bob Alvarez, of the Institute for Policy Studies, Washington D.C., addressed several issues. The work done by the DOE workforce was for national security purposes, and in some cases people were consciously put at risk. With the government as a liable party, it is important for this Board to address these issues. Related to that, he suggested several concepts for consideration:

1. However the dose reconstruction contractor is chosen, an ABRWH subcommittee should be formed, whose membership would include workers. It should be provided the resources needed to hire technical consultants to conduct quality assurance on the work scope, spot checking ongoing work, and reviewing the general approach taken. This subcommittee would report to the full committee itself, which also would spot check. This would add a layer of quality and build the public trust that is important to this process.
2. Once the dose reconstruction issues are addressed and the Special Exposure Cohort (SEC) issues are approached, the Board should consider the circumstances that led to the enactment of EEOICPA. These involve not just issues of dose response, but social policy and how science forms that, which pertains to the redress of past wrongs. In particular, a memo from the Paducah plant was cited. It revealed the site's duplicity in not releasing damaging exposure information, and refusing even to allow postmortems, due to anxiety that this would cause trouble with the unions. He suggested the addition of an ethicist to the Board membership to help sort out these issues.
3. In March 2001, an attempt was made to establish an understanding of the mass balance flow of recycled uranium in the DOE complex, but that work was discontinued by the new administration. Although incomplete, the study documents provide important insights. About 200 million tons of uranium was recycled in the weapons complex, going through several sites and off-site contractors. The Hanford site's report noted that the tank farm phosphate extraction process was done with excessive levels of plutonium, sufficiently excessive that they did not meet Oak Ridge's acceptance levels. The material then was sent to Cleveland, where the workers conducted the process which brought the plutonium levels down to an acceptable level for Oak Ridge. The Board must attempt to examine those worker issues. As the ABRWH considers those processes, they should keep in mind that some of the flow sheets detailing those exposures are still missing, and could indicate those who could have been affected.
4. More work needs to be done, such as the very useful mass balance study and the history of GDPs done by the DOE Office of Occupational Safety and Health. While the dose reconstruction gives part of the image, overall issues still require examination, such as the evidence of workers deliberately put a risk and the kinds of jobs that may constitute high risk from an SEC point of view (e.g., those handling uranyl nitrate in Hanford's caltrate

process). Reports on recycled uranium note that there were no limits to exposure to neptunium, etc.; and each site had its own way of measuring, leaving big questions about inventory discrepancies.

Mr. Richard Miller, of the Government Accountability Project (GAP), commented that NIOSH's guidance for internal and external exposure dose reconstruction presumes the regularity of the dose record, unless the interview with the claimant or something else casts doubt on that for the contractor. He recalled the history of radiation protection programs done by Bob Alvarez, et al, in cooperation with site unions. The 375 interviews detailed in three reports indicate a spotty history of radiation protection. For example, the Monday morning urinalysis done after a weekend of beer drinking that had washed out the worker system did not indicate the levels potentially present later in the week (e.g., in workers without any personal protective equipment who beat bags of neptunium to release the dust). There are no records with which to reconstruct those doses. He also noted that if that information is not made public or reported electronically, and if the employee has no access to DOE records and NIOSH has no indication that such records exist, what is there to advance this work?

He defined DOE itself as the largest impediment to, as well as opportunity for, data access. If the contractor cannot seriously explore records and the worker has to go from memory (and some worked for years on a need-to-know basis), the necessary information may remain forever unknown. While the report on the gaseous diffusion plants lays out the irregularities of the entire system, it is still true that most sites lack that kind of detailed history. Without that the claimants will not be able to say if the systemic approach used was proper or not, bringing into question whether the data has any basis.

A mandatory bioassay program was not instituted at Paducah until the 1970s. The first voluntary bioassay monitoring program for transuranics was not instituted there until 1992, and not made mandatory until several years later. And, although the neptunium amounts in any given ton of uranium measured later by a contractor were found to be low (a few ppm/ton), it was also found that it preferentially accumulated and deposited on certain pieces of equipment. Only when the equipment was disassembled (e.g., for maintenance work) would a person be exposed to less than a 55% concentration of neptunium-237. There was no radiation protection plan implying that the paper trail was not designed to assess such a risk.

Therefore, Mr. Miller recommended that the Board keep in mind the missed dose of unmonitored exposures and not be misled by the high degree of precision "tweaking" in the dose reconstructions done. Even three years before the story about Paducah was exposed to the Washington Post, the Paducah workers themselves could not have provided this information.

He suggested an ABRWH recommendation to the Secretary regarding how to address the challenges of data gaps, ranging from well-run programs down to coverups. The issues discussed at this meeting also should be a factor of the questionnaires developed for the dose reconstruction interviews. He cited a study of the Mound facility where exposures stemmed from the failure of the radiation protection program. The records, when recovered for dose reconstruction, were so

contaminated they had to first be copied. He also suggested to a review of Dr. Arjun Makhijani's studies at Fernald or Mr. Mark Griffon's work with the University of Utah on the Paducah site, to judge whether the paper record on internal and external dosimetry should be accepted. He shared a photo (of a worker stamping a uranium bar held between his legs, with his dosimetry badge clipped at top front of his overalls), and rhetorically asked how to capture the badges' ability to measure such workday exposures.

Finally, he commented on his own difficulty as an outsider to figure out how the dose reconstruction rule will fit in with the SEC considerations. He felt that those issues must be considered in the current deliberation on the rule, since they involve policy questions in the continuum between dose reconstruction and the inability to establish the harm done due to the absence of evidence.

Mr. Miller was asked how the ABRWH should handle the unknown; should everyone be a member of the SEC? He responded with two questions: 1) should regularity be expected in DOE's paper trail? According to their own assessments, he thought not. Then, 2) what kind of information should be amassed on the sites? The large sites could group some of their processes to determine which ones' measurements provided a high degree of confidence, and the workers in the other processes would fall within the SEC. Those of highest risk would be assessed and assigned a collective risk criterion – which, he noted, Congress essentially did in establishing the SEC.

He added that perhaps the most thoughtful method would be to gather the best histories of radiation protection programs, as done for the three GDPs. They could be used as a guide, the historical lens with which to define those processes of highest risk and to estimate their exposures. Finally, he noted that this legislation was created to cure coverups. And, regarding conflict of interest issues, he stated that the minimum criteria for determining conflict of interest are still unknown, but will be part of the RFP response evaluations. It will be essential that the bidders plans are transparent regarding conflict of interest in order to ensure public confidence in this process. NIOSH can impose that transparency, although that is not specifically stated in the RFP.

Review of Dose Reconstruction Rule 42 CFR 82:
The Board members subsequently conducted a line-by-line review of the dose reconstruction rule 42 CFR 82. Comments and discussion occurred on the following sections:

82-2: Basics of Dose Reconstruction

How will NIOSH address the accuracy of the dose, and how can it address the reality of the workplace? The rule references data "found to be complete and adequate..." NIOSH will use data when convinced that it is reflective of the workplace. Site profiles will be developed and will be publicly available documents, such that workers who disagree can report their experience. The experience of the dose reconstructions underway at Mound and Rocky Flats will be useful, and NIOSH hopes that the interviews also will establish other factors that may not be evident in

the records. The members' suggestions were welcomed on how to improve the procedures in that regard. All reported information will be incorporated to the site profiles which will be built over time. While an individual's dose reconstruction report will not be public information, the relevant findings of the dose reconstruction report will be without personal identifiers.

Can changes be effected after the interview, for example, if an employee subsequently remembers a dose differently? Yes. Changes can stem from the interviews, the result of the dose reconstructions, changes in information guidelines and/or the technical basis documents, or changes effected by the ABRWH. It was noted that the latter is addressed in the preamble of the rule. The Board may wish to move that language into the rule itself.

How will you state that the data is incomplete or inadequate (if so), but is all that is available and, therefore, is all that was used? The data have to be complete and sufficiently adequate to conduct dose reconstruction. That does not mean all evidence must be in hand, just enough to make an unbiased determination about exposure. The exposure could be approached from source term analyses based upon the operations, to produce a bracketing dose estimate for each individual. In the absence of single point estimates, a dose distribution could be developed (e.g., between 1-10 rem) which then would be input to the IREP program. Section II, "Final Rule," sets up the process by which dose reconstructions completed under the interim final review rule will be reviewed and revised as necessary to conform with any substantive changes that might be included in the final rule.

So Plan A is a scenario with data in hand; Plan B is that of a dose reconstruction using the source term; Plan C is to revise as necessary under the final rule. Consideration is also needed for a Plan D, the criteria of which will address the SEC. NIOSH and the Board are proceeding into dose reconstruction using Plan B. But the process of doing so (and its efficiency) remains unknown, which makes it difficult to address these questions, and with each plan level (A, B, C), more resources are required. At some point, the effort will have to be stopped and the claimants placed in an SEC. The question is, how much effort the ABRWH wants to put into this part of the rule. The Board needs to have some concept of where the continuum is going in order to comment on the rule. Those remarks could be sent as a comment to the Secretary, including that not only can NIOSH not do a dose reconstruction, but that is there evidence that there was a substantial exposure.

Dr. Ziemer drew the members' attention again to the three questions related to 42 CFR Part 82:

1. Does the interim role make appropriate use of current science for conducting dose reconstructions to be used in the occupational illness compensation program question?
2. Does the into room role appropriately bellows the potential precision of dose reconstructions and the necessary efficiency of the dose reconstruction process?
3. Does the interim role implement an appropriate response for involving the claimant in the dose reconstruction?

There was no response to his request for further comments on this section or those up to 82.10 H.

82.10 H: What does the DOE certification of completed records searches consist of? The written confirmation form stating that DOE has searched for all types of records requested in all of the relevant archives. The rule also specifies that NIOSH will visit sites, as necessary, for quality assurance to confirm that all available records have been found.

Can there be a cross-inventory of internal NIOSH records from work on sites that may supplement DOE information, in order to find people who might otherwise be lost in the record search? Employment verification is a DOL responsibility and can use NIOSH records for that purpose, if needed. They also can use other records beyond the DOE information to do this, such as Social Security and Internal Revenue Service records.

Aside from unemployment records, have independent records been considered such as those of state regulatory agencies that may have monitoring records (e.g., Nuclear Regulatory Commission (NRC), the unions, or the contracting laboratories)? The NRC used contractors to monitor the source term. Typically, those monitoring results were not sent to the NRC. Records from union files can be used, as necessary.

82.11 I: Are there existing default values? Those of the ICRP 66, etc., are cited rather than stated in the rule.

82.1 J: The word "validated" can be open to interpretation. The legal meanings have been left to the Office of General Counsel.

82.1 K and I: If data of several sites indicate that certain types of cancer seem to appear from certain job functions, can that information be used to determine the validity of the dose reconstruction? One would hope that this work could contribute to the overall knowledge. This was discussed by the OCAS teams. NIOSH would look for those types of anomalies and assess the significance of the dose, since a distinct internal dose at one site may not apply to another. The ABRWH may wish to consider this in terms of its comments on sampling strategies.

The Board should discuss in future meetings how NIOSH will maintain the data. The data system is needed to be in place to allow application of past experience, and if necessary to correct past errors in reconstructing doses. NIOSH has already spoken with DOL about a feedback loop for such potential
re-evaluations.

What if the risk (coefficient) of the cancer changes, rather than the dose, so as the affect the IREP calculation? NIOSH is only taking the dose reconstruction far enough to provide an answer about the claimant in question, not the exact individual dose. NIOSH can make modifications to risk models in the NIOSH-IREP if the science supports such changes and the ABRWH recommends the merit of such modification.

82.1 M – O: There was some discussion that this section's 60-day deadline to sign form OCAS-1 seemed to end what had previously been an interactive process. Survivors of the claimant may

need a longer time to locate appropriate information. Clarification was suggested of 1) the text's intent to simply give the claimants or their survivors 60 days to decide to whether or not to sign the form; 2) the related intercommunication; and 3) two relevant situations: the need to close the process when the dose reconstruction does not support the claim, versus the need to provide more time to a survivor trying to find the information needed, without leaving the process open-ended. However, it was agreed that the wording's use of "may close" not "must close" after 60 days indicates a prerogative, not a mandate. Along with Section O's statement that this can be reopened, the Board was satisfied to retain the current language.

Section 82.11: Is determination of a high dose considered a reconstruction, since this section indicates that every claim will have a dose reconstruction? Yes.

82.12 C:
It is hard to imagine that a dose reconstruction could not be done, at least within confidence brackets. Yes, but this may be true in rare cases, especially in the early days when material might have been processed (resulting in high doses) in a situation where there was no monitoring, little process information, and no contamination surveys to determine loose contamination of airborne transuranics. Such workers would be candidates for an SEC.

82.28: Important medical literature could be generated from the studies, but NIOSH must be clear through publication that it is not identifying causation. And, it would be appropriate to add to the last sentence "without the worker's permission." Since this benefit accrues to the individual, the statute should at least offer them the opportunity to decline. The Privacy Act controls how information with personal identification may be disseminated. Under this Section, Item B allows researchers supported by a NIOSH source (grant, cooperative agreement) who have a protocol approved by their Internal Review Board (IRB) to be supplied with identifiable data. Researchers so interested, but without NIOSH funding, would have to approach NIOSH for a de-identified data set. NIOSH agreed that this needs to be rewritten to more clearly indicate that NIOSH-funded researchers could get that set, and those who could not. This particular provision is present because the EEOICPA itself required making general information available to researchers and members of the public who would not come under the umbrella of the Privacy Act. There is an exception to the Privacy Act, in which an individual can waive their rights under the Privacy Act. However, NIOSH does wish to make it clear that they will not seek permission from the claimants or their survivors to release data.

There were no further comments by the Board on the proposed rule. Subsequent discussion included the following:

- NIOSH will make available to the public the statistics on the number of claims, status, dose reconstructions completed, awards vs. non-awards, technical basis documents supporting implementation guidelines, and other appropriate summary information.
- Codification of the ABRWH 's role by moving it out of the preamble was suggested.

The members agreed to make notes later that evening on answers to the three questions and to

add other points desired, for discussion in the morning. With no further comment, the meeting adjourned at
4:50 p.m.

FEBRUARY 14, 2002

Administrative Issues
Ms. Homer addressed issues regarding the board members pay and travel vouchering.

Mr. Elliott suggested that the March meeting be postponed. It was unlikely that the SEC procedures would be ready for review by that time. And, although the members could discuss how to conduct their review of the dose reconstructions, that work probably would not begin until early in the fall.

Dr. Ziemer noted the staff's immediate need to address the comments on the two rules and finalize both rule-making by April, 2002. Since the pressing issues for the Board were to comment on Parts 81 and 82, a task that should be completed on this day, the members agreed to meet next on May 1-2 or 2-3. At the same time, however, the desire was also expressed to not have overly lengthy time gaps between meetings.

Topics suggested for the next meeting included:

- Information that could be addressed by experts other than the NIOSH staff, such as those topics mentioned the previous day in connection with DOE records found to be deficient.
- A legislative background/history, particularly as relates to the SEC.
- Background on IREP model issues discussed at the first meeting.
- Comment on the statute's language describing the ABRWH's review procedure, which was felt by some to be at least misleading, if not inaccurate, and to require Board comments.

The members agreed to provide names of suggested presenters to Mr. Elliott. Dr. David Michaels' interest in presenting a legislative background and DOE's perspective on its records was noted. NIOSH agreed to distribute the names of the suggested presenters to the members. It was also suggested that consideration be given to identifying what items can be proactively pursued between the meetings, in order to plan a process for the long term. It will take time to decide how the Board wishes to approach the dose reconstruction evaluations that will need to be done.

Discussion of Dose Reconstruction Rule 42 CFR 82:
Dr. Ziemer summarized the items identified by the Board on which it wished to comment regarding the dose reconstruction rule:

1. Move the text on page 50981 (ABRWH role) to the body of the rule.
2. Clarify the use of the term "validated" on page 50988, Sec 82.10, J.

3. Clarify in 8210 M,N, the steps/time line for claimants' action on Form OCAS-1.
4. Clarify use of "may" and "will" on page 50985, Section 82.13.
5. The use of ICRP models does not specify "current" models. (Sec. 82.18)
6. Clarify the restriction regarding the availability of claimants' names to researchers in Sec. 82.28B.
7. Answer the three questions posed in the *Federal Register*.

Further comments included:

- In the response to Questions 1 and 2, note that the ABRWH will continue to monitor and work with NIOSH in reviewing the dose reconstructions done, to determine when the Secretary should be advised that an accurate dose reconstruction cannot be done and an addition to the SEC should be made.
- Examine the use of the term "precision" as opposed to "accuracy" with regard to claimants' time for action (page 50978).

Rule Components; Motions:
After a short break, the Board voted on several related motions:

1. "The Board recommends that Section K of Part III, "background" concerning changes to scientific elements underlying the dose reconstruction process be moved to the main body of the rule so as to formalize the updating process including the role of the Advisory Board. The rule does an admirable job of providing an objective process for conducting dose reconstruction. However, the assessment of the adequacy of the exposure information will involve professional judgment, and thus, some subjectivity. The Board plays an important role through its review of such decisions on dose reconstructions and that role needs to be included in the Rule." Dr. Anderson moved to accept that text. Dr. Roessler seconded the motion, and all were in favor. **The motion passed unanimously.**

2. "The Board requests that the term 'validated', as used in Section 82.10 (j), be either defined or clarified." Dr. Presley so moved and was seconded by Ms. Munn. **The motion passed unanimously.**

3. "The Advisory Board recommends that NIOSH clarify 82.10 m, n, o, in regard to the steps and time line for the claimants, or authorized representatives of the claimants, to provide information to NIOSH and to sign or submit form OCAS-1. NIOSH should ensure that the claimants, or authorized representatives of the claimants, have adequate time to obtain and submit additional information to NIOSH." Dr. Melius so moved and Mr. Espinosa seconded the motion. **The motion passed unanimously**.

4. Page 50985, Section 82.13: Clarify use of "may use" and "will use, as necessary." Mr. Katz explained the intent of the language, which the Board agreed is consistent as written. By consent of the Board, that comment was dropped from the list of action items.

5. The Advisory Board recommends that Section 82.18, concerning the use of ICRP models, be clarified so as to clearly indicate that NIOSH intends to use current ICRP models. The intent

was not to list models in this document, but to indicate what should be used to reflect the current state of the science. Dr. Melius so moved and Dr. DeHart seconded the motion. **The motion passed unanimously.**

6. The Advisory Board recommends that Section 82.28 b, last sentence, be clarified in regard to the coverage of the Privacy Act. Originally, Dr. Anderson had moved, and was seconded by Mr. Espinosa, that the original text be revised so as to state that, "Except as provided for under the Privacy Act, researchers will not receive names..." However, Mr. Elliott noted that a change in this regard would have to be determined by the Office of General Counsel and the Privacy Act Officer. Dr. Anderson altered his motion to the language above, was again seconded by Mr. Espinosa, and **the motion passed unanimously.**

Discussion of Rule Questions:
The following advice to the Secretary on the three questions posed was considered:

1. The Interim proposed Rule 42 CFR, Part 82, makes appropriate to use of current science in reconstruction of radiation dose scenarios to the extent practicable. The Board recognizes that if the efficient and expeditious consideration of claims is to be made, absolute precision is not possible. All methods proposed will result in significant bias in favor of the claimant, and, in that regard, are consistently conservative.

   The process for involving the claimant is fair and provides multiple opportunities for interactions with the involved agencies. Indeed, in cases where acceptable dependable exposure data do not exist, the claimant or claimant family may be the only source available to provide information that could form the basis for dose reconstruction. This circumstance automatically injects a high, but unavoidable, level of uncertainty into the calculation; however, we view the proposed methods for addressing these cases to be as equitable as reasonably achievable at this time.
2. The interim rule outlining methods for radiation dose reconstruction... uses a number of innovative, scientifically sound, and implementable techniques which made the dose reconstruction process efficient without the loss of proper decision making information.
3. The Board agrees that the interim rule implements an appropriate process to involve the claimant from the formal claims application, the interview, to feedback on the specific dose reconstruction.

The discussion that produced this advice considered and altered the following statements:

- #1, ¶1, last sentence: change to: "the methods proposed tend to favor the claimant and ... are consistently conservative"; or "... are consistent with the Occupational Workers Compensation Program." There was general agreement to such a change.
- #1, ¶ 2: add discussion of uncertainties/difficulties without defining the claimant or family as the issue. Dr. Melius moved to replace, and Dr. DeHart seconded the motion, the section of text extending from "dependable exposure data do not exist..." to the end of the paragraph, with: "NIOSH will utilize other sources as the basis for dose reconstruction. This approach unavoidably interjects uncertainty into the calculation of dose. However, we view the proposed methods as appropriate for the available information. There will be circumstances when NIOSH will not be able to estimate the dose with sufficient accuracy. Those circumstances need to be clarified in the implementation of the regulation and in the Boards review of NIOSH's dose reconstruction work. Groups whose exposures cannot be estimated with sufficient accuracy may

be candidates for the SEC." Motion carried.

- #1, ¶1: replace "practicable" with "possible" or "allowable" to avoid misunderstanding of practicable as all NIOSH was willing to do. After further discussion, it was agreed to keep the original wording.
- The meaning of the word "conservative" was discussed. Since it can be misconstrued to mean an assumption of a low rather than high exposure, it was deleted by general consensus.
- Since these discussions now made #2 redundant, it was deleted by general consensus.
- Similarly, #3 was now redundant to ¶2, sentence 1, and was deleted by general consensus.

Therefore, Dr. DeHart moved to adopt the following response to the three questions posed, as the Board's recommendation to the Secretary:

> "Interim proposed rule 42 CFR, Part 82, makes appropriate use of current science in reconstruction of radiation dose scenarios to the extent practicable. The Board recognizes that if the efficient and expeditious consideration of claims is to be made, absolute precision is not possible. The methods proposed are intended to result in dose estimates favorable to the claimants and are appropriate to the occupational illness compensation program envisioned by EEOICPA."
>
> "The process for involving the claimant is fair and provides multiple opportunities for interaction with the involved agencies. Indeed, in cases where acceptably dependable personal exposure data do not exist, NIOSH will utilize other sources of information as the basis for dose reconstruction. This approach unavoidably injects additional uncertainty into the calculation of dose. However, we view the proposed methods as being appropriate for the available information. There will be circumstances where NIOSH will not be able to estimate the dose with sufficient accuracy. Those circumstances need to be clarified in the implementation of the regulation and in the Board's review of NIOSH's dose reconstruction work. Groups whose exposure cannot be estimated with sufficient accuracy may be candidates for the Special Exposure Cohort."

The motion to adopt was approved unanimously.

A summary of the comments officially approved will be sent in a letter to the Secretary with the meeting agenda attached. Dr. Anderson suggested additional note in the letter that dose reconstruction is a work in progress, and that the Board looks forward to working with NIOSH as this rule is implemented. He agreed to write suggested language for Dr. Ziemer. Mr. Elliott said that the text will be e-mailed to the committee members, including to Dr. Andrade.

Dr. Ziemer asked NIOSH to investigate whether the members of FACA committees, as opposed to federal agencies, can work both individually and as a group in an formulating predecisional drafts. Mr. Elliott agreed to inquire about this with the Office of General Counsel and Committee Management, and to advise the members. He reminded the members that the comment period for of the dose reconstruction rule closes March 1, 2002. The Board's comments will be added to that as soon as received.

Public Comment:

Mr. Richard Miller asked, if DOE has calculated a dose higher than the IREP's, which would be used for

the claimant? Dr. Ziemer responded that the DOE number will be a point number, while the IREP number will be a distribution with a standard deviation. Dr. Neton added that NIOSH will use their estimate, not DOE's, if a complete dose reconstruction is done. DOE did not calculate an annual internal dose before 1990. In addition, the IREP program uses equivalent dose, and the weighting factors use a distribution which addresses uncertainty, along with the claimant's chances of compensation.

Closing Comments:
Mr. Espinosa asked if more hotel rooms could be reserved for future meetings to accommodate (non-Board) attenders from out of town. Mr. Elliott responded that NIOSH could help them find hotels and rooms, but cannot reserve those rooms on their behalf. Finally, Dr. Ziemer asked the members to inform Mr. Elliott of any topics, presenters, etc., desired for the next meeting agenda.

Then, with no further comment, the meeting adjourned at 12:28 p.m.

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

Paul L. Ziemer, Ph.D., Chair

6/2/02
Date