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

Summary Minutes

Eleventh Meeting of the
Advisory Board on Radiation and Worker Health
February 5-6, 2003

Meeting Held at the DoubleTree Guest Suites
Charleston, South Carolina

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Executive Summary

The Eleventh Meeting of the Advisory Board of Radiation Worker Health (ABRWH, or the Board) was held at the DoubleTree Guest Suites in Charleston, South Carolina on February 5-6, 2003. All but one member was in attendance, with one joining later in the day. Others in attendance included staff of various federal agencies as well as members of the public. A list of those in attendance is included in the Summary Minutes of this Eleventh Meeting. The Summary of the Closed Session of Meeting 10 was approved with no changes.

Wednesday, February 5, 2003

OCAS Program Status Report

Ms. Martha DiMuzio reported on NIOSH's Office of Compensation Analysis and Support (OCAS) Program through the end of January 2003. To date, approximately 10,472 cases have been transferred (~150-200/week) from the Department of Labor (DOL). The majority of the claims are from Department of Energy (DOE) workers, with approximately 16% from Atomic Weapons Employer (AWE) workers.

In January 2003, Oak Ridge Associated Universities (ORAU) assumed responsibility for carrying out dose reconstructions. Ms. DiMuzio shared response statistics, as of December 31, 2002, for seven larger sites and indicated that if a claim response takes over 150 days, the DOE will be contacted for a status report. To date, approximately 726 telephone interviews with claimants have been conducted. Currently, 144 dose reconstructions are underway

On January 24, 2003, 35 physicians were appointed to the DOE Physician Panel. OCAS is working to fill an additional 22 positions, and 6 new health physicists and 5 public health advisors will be joining the program soon. Dr. James Neton and Dr. Richard Toohey updated the Board on the status of claimant correspondence and how ORAU would incorporate its correspondence into OCAS's process. Dr. Toohey distributed the latest personnel chart for ORAU and indicated that ORAU's webpage may be accessed live at www.oraucoc.org.

Update on IREP Latency Adjustment Functions for Leukemia and Thyroid

Mr. Russell Henshaw updated the Board on recent changes to the proposed leukemia and thyroid cancer latency adjustment models, and distributed tables of *Comparison of Probability of Causation Results at the 99th Percentile* for both leukemia and thyroid cancer. Using hypothetical claimant inputs, the tables compared three latency adjustment models: the model currently in use, a model developed in October 2002, and a newer model which NIOSH intends to adopt. Also presented were changes in the NIOSH-IREP *User's Guide* and in the NIOSH-IREP software, that have been made since April, 2002.
Mr. Henshaw also presented a list of proposed research needs for NIOSH-IREP.

IREP and Scientific Issues Workgroup Report

Dr. James Melius presented the Workgroup's ideas regarding reasons for possible review of IREP, proposed a list of possible research topics, which looked very similar to Mr. Henshaw's list of topics, and proposed a topic review process. ***A motion to utilize the Workgroup's recommended topic review process was seconded and unanimously passed.*** The Board then organized the workgroup's possible research topics into priority areas.

Savannah River Site Health Effects Subcommittee (SRSHES) Activities

Dr. Sergio Bustos, Chair of the SRSHES, explained the purpose, membership, and past and present activities of the SRSHES. He distributed and explained a map of the Savannah River Site (SRS), reminding the Board that SRS occupies 310 square miles in the boundary between Georgia and South Carolina.

Board Discussion/Working Session

Contract Procurement Office Issues

Mr. Elliott asked the Board whether it wanted to switch contract procurement over to the DOL. Both Mr. Elliott and Mr. Pete Turcic of DOL described to the Board how each agency might handle contract procurement. Advantages and disadvantages were discussed. The Board deferred decision on this issue until later in the meeting.

Workgroup and Subcommittee Issues

The Board discussed how to best organize itself to handle dose reconstruction review. The advantages and disadvantages of subcommittees and workgroups were discussed. Processes involving both types of groups were discussed. No decision was made regarding which type would be used for the dose reconstruction review process.

Dose Reconstruction Workgroup Update

Mr. Griffon indicated that a decision needed to be made on how dose reconstruction cases would be reviewed. Mr. Griffon presented possible steps for the process. Members agreed that the Board should select the cases for review and that a stratified sampling of the cases would be necessary. It was also decided that the sample of the overall caseload should not be greater than 2.5%. The Board agreed that some type of checklist might be used to review all cases and that a fatal error process needed to be developed.

Public Comment Period

Public comment was solicited on both the first and second day of the deliberations. There were no comments on the second day. Public input on the first day included the following:

- ❑ Issues related to NIOSH-IREP dose measures regarding internal and external exposures to the thyroid and how iodine intake was measured.
- ❑ Quality of the telephone interview reports was questioned.
- ❑ Concerns were expressed over the time it is going to take to process claims.
- ❑ Concerns were raised regarding the smoking adjustment.
- ❑ The Board was asked what would happen if adjudicated claims were found to contain errors.

Thursday, February 6, 2003

Board Discussion/Working Session

Review and Approval of Draft Minutes, Meeting 10

A motion to approve the executive summary and the minutes of the tenth meeting (with discussed edits) was seconded and unanimously passed.

Dose Reconstruction Review Process

The Board decided to establish a Workgroup to develop a Dose Reconstruction Review Process. The Dose Reconstruction Workgroup was charged with developing the procedures for identifying available dose reconstruction cases; developing the dose reconstruction case selection process; and developing the procedures for the selection of dose reconstruction cases. In parallel, the workgroup was tasked to develop task orders and task order process and procedures for the reviewer contractor soon to be hired. If time permits, the workgroup will also develop procedures for the review of dose reconstruction cases.

Basic Review Report

The Board discussed what a basic review report might look like. Items to be included in the report include adequacy and consistency of site and personnel data; adequacy of interview; adequacy of dose reconstruction and probability of causation determination. The report should identify strengths and weaknesses and eventually be part of a possible annual report that will be sent to the Secretary of the Department of Health and Human Services (DHHS).

Procurement Administration Decision

Dr. Ziemer asked the Board if anyone wished to make a motion to move the procurement administration to the DOL. Hearing no motion, Dr. Ziemer declared that the procurement would stay with CDC/NIOSH.

Statement of Work Amendments

The Dose Reconstruction Workgroup submitted a rewrite of Attachment A, Section E, Pages 9-10, Conflict of Interest. The section was revised to be more inclusive of prospective bidders.
A motion to approve the rewrite of Attachment A, Section E, Conflict of Interest was seconded and unanimously passed.

Federal Register Changes Workgroup

A Workgroup was appointed and charged with drafting discussion points concerning changes in the federal register regarding the Special Exposure Cohort (SEC) rulemaking. The group plans to meet via telephone or e-mail sometime before the next Board meeting to prepare points to discuss at the full Board meeting in March.

ABRWH Schedule and Future Agenda Items

The ABRWH's next two meetings are scheduled for March 7, 2003, in Cincinnati, Ohio; and May 19-20, 2003, in Oak Ridge, Tennessee. The Dose Reconstruction Workgroup plans to meet on March 6, 2003, and will present a progress report to the full Board in March. The back-up meeting date for the next ABRWH meeting is planned for March 18, 2003, with the Dose Reconstruction Workgroup meeting on March 17, 2003, in Cincinnati, Ohio.

Housekeeping and Miscellaneous

- ❏ Mr. Presley has forwarded concerns to the DOL regarding a DOL pamphlet that was causing confusion with regard to whether certain claims were to be handled through Workers Compensation or through the Sick Workers' Bill.
- ❏ Ms. Homer verified which action items on the list had been covered by this ABRWH meeting.
- ❏ Mr. Presley offered to set up an ABRWH tour of parts of the Oak Ridge facility for the May 19-20 meeting.

Public Comment Period

No members of the public signed up to address the Board during this second public comment period.

With no further business posed, the meeting was officially adjourned at 1:51 p.m.

End of Executive Summary

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

Summary Minutes of the Eleventh Meeting
February 5-6, 2003

The Eleventh Meeting of the Advisory Board on Radiation and Worker Health (ABRWH, or the Board) was held at the DoubleTree Guest Suites in Charleston, South Carolina on February 5-6, 2003. The meeting was called by the Centers for Disease Control and Prevention's (CDC's) National Institute for Occupational Safety and Health (NIOSH), the agency charged with administering the ABRWH. These summary minutes, as well as a verbatim transcript certified by a court reporter, are available on the Internet on the NIOSH/Office of Compensation Analysis and Support (OCAS) Website located at (www.cdc.gov/niosh/ocas). Those present included the following:

ABRWH Members: Dr. Paul Ziemer, Chair; Dr. Henry Anderson; Dr. Antonio Andrade; Dr. Roy DeHart; Mr. Richard Espinosa; Mr. Michael Gibson; Mr. Mark Griffon; Dr. James Melius; Ms. Wanda Munn; Mr. Robert Presley; and Dr. Genevieve Roessler.

Designated Federal Official: Mr. Larry Elliott, Executive Secretary

Federal Agency Attendees:

Department of Health and Human Services:
Ms. Martha DiMuozi, Mr. Russell Henshaw, Ms. Cori Homer, Ms. Liz Homoki-Titus, Mr. Ted Katz, Mr. David Naimon, and Dr. James Neton

Department of Labor:
Mr. Jeffrey Kotsch and Mr. Peter Turcic

Guests and Members of the Public: Ms. Rose Marie Andrade (Los Alamos, NM); Dr. Hans Behling (S. Cohen & Associates, Edenton, NC); Ms. Kathleen Behling (S. Cohen & Associates, Edenton, NC); Ms. Denise Brock (United Nuclear Weapons Workers of St. Louis, MO); Dr. Sergio E. Bustos (SRSHES, Augusta, GA); Mr. Todd V. Crawford (SRSHES, New Ellenton, SC); Ms. Julia DeHart (Nashville, TN); Donald Elisburg (CPWR); James Griffin (MJW Corporation, Olean, NY); Mr. Charles Jernigan (August Old Trades Medical Screening Program, Augusta, GA); Mr. W. Jeffrey Kleem (Science Applications International Corporation); Mr. Richard Miller (Government Accountability Project); Ms. Louise Presley (Clinton, TN); Dr. Knut Ringen (CPRW, Seattle, WA); Mr. Richard G. Tabor (Fernald Atomic Trades and Labor Council); Ms. Teresa Robinson (Writer/Editor, Cambridge Communications, Atlanta, GA); Mr. D. Michael Schaeffer (DTRA); Dr. Richard Toohey (Oak Ridge Associated Universities); Ms. Debbie G. Williams, CVR (Certified Court Reporter, Cumming, GA); Ms. Marilyn Ziemer (Lafayette, IN).

Wednesday, February 5, 2003

Opening Remarks

Call to Order/Welcome

Dr. Paul Ziemer called the meeting to order at 8:35 a.m., welcoming the attendees. He reminded everyone to register their attendance each day at the registration table located in the back of the room, and instructed members of the public to sign up if they wished to address the Board during the public comment periods.

Announcements

Mr. Larry Elliott, Executive Secretary, explained that the *Notice of Proposed Rulemaking on Additions to the Special Exposure Cohort* was not complete. Therefore, that discussion did not appear on the agenda.

Approval of Summary of Closed Session, Meeting 10

Dr. Ziemer deferred approval of the full draft of the tenth meeting minutes until the next morning because the Board had not had a chance to review them. He then asked the Board to enter in a formal motion to approve the *Summary of the Closed Session* of the January 8, 2003 meeting.

Motion

Dr. Antonio Andrade moved to approve the January 8, 2002 *Summary of the Closed Session* minutes as written. **Mr. Robert Presley** seconded. The motion received unanimous approval.

Program Status Report

Ms. Martha DiMuzio
Program Analyst , NIOSH/OCAS

Ms. DiMuzio presented the Office of Compensation Analysis and Support (OCAS) Program Report for February 2003, as Mr. David Sundin was unable to attend. Ms. DiMuzio provided statistics for the number of cases received for dose reconstruction as of January 31, 2003. She indicated that the National Institute for Occupational Safety and Health (NIOSH) has moved to a new SQL system used by both NIOSH and ORAU, and numbers in her presentation might not be exact. As of January 2003, OCAS has received approximately 10,472 cases from the Department of Labor (DOL) for dose reconstruction, receiving, on average, 150 to 200 cases per week. The majority of the claims are from Department of Energy (DOE) sites. Approximately 16% are from Atomic Weapons Employer (AWE) workers.

In January 2003, Oak Ridge Associated Universities (ORAU) took over responsibility for conducting dose reconstructions. Ms. DiMuzio shared DOE response statistics as of December 31, 2002 for the seven larger sites (Idaho, Nevada, Oak Ridge, Ohio Field, Richland, Rocky Flats, Savannah River [SRS]) which represented 81% of the total information requests that OCAS has made to the DOE. If a claim response takes over 150 days, the DOE is contacted for a status report. Response numbers are not indicative of the quality of the data received from the sites. In many cases, sites that have taken the longest to respond have provided OCAS with the most complete claimant information.

To date, approximately 726 telephone interviews with claimants have been conducted and more than 389 interview reports have been sent to claimants for review and comment. Currently, 144 dose reconstructions are underway. Over the past month, OCAS staff have focused on reviewing the initial 62 dose reconstructions received from ORAU to ensure compliance and to establish procedures. ORAU is currently updating those 62 dose reconstructions to incorporate NIOSH comments and continues to work on an additional 82. OCAS has completed 18 draft dose reconstruction reports. Of the 18 cases, 14 have been transmitted back to DOL for completion of administrative records and for final adjudication. On January 24, 2003, letters were sent to 35 physicians appointing them to the DOE Physician Panel. OCAS also has been working to fill an additional 22 positions. Six new health physicists and five public health advisors will be joining the program soon.

Discussion Points:

- ❑ Ms. DiMuzio indicated that OCAS is not tracking website hits.
- ❑ Dr. Melius asked why Idaho and SRS took so long to respond to requests for information, and whether these were initial responses. Dr. Jim Neton replied that OCAS has recently received approximately 100 additional completed responses from SRS, but not all of them have been entered into the new system. Both sites had to add personnel for the increased workload. He reiterated that the information received from sites that took longer to respond were good quality responses, and often better than those who responded more quickly. He indicated that all responses, initial, secondary, and other, will be tracked and that all information will go into the claimant's file.
- ❑ Mr. Elliott pointed out that the numbers in the program would soon become more fluid and that cases would be handled on a first-come-first-served basis, with the older claims being handled first.
- ❑ Dr. Melius asked about the status of the Memorandum of Understanding (MOU) with DOE. Mr. Elliott replied that the MOU is now being reviewed by NIOSH's general counsel.
- ❑ Dr. Melius suggested posting the timeline for pending claims on the website for accountability purposes.

Status of Claimant Correspondence

Dr. Jim Neton ***Dr. Richard Toohey***
NIOSH/OCAS ***Oak Ridge Associated Universities (ORAU)***

Dr. Neton indicated that during the current claims process, OCAS sends the following communications to claimants:

Communication	Purpose
Acknowledgment Letter	Informs claimant that OCAS has received claim and has issued a request to the DOL for exposure information. In the current process, file transferred to ORAU for receipt of DOE information.
Telephone Interview Letter	Asks claimant to schedule a telephone interview. The package includes a summary of the line of inquiry allowing claimant to gather their information and prepare responses.
Telephone Interview Summary Report	Gives claimant an opportunity to either correct or provide supplemental information.
Draft Dose Reconstruction and OCAS-1 form	Informs claimant that dose reconstruction has been assigned and completed. Provides claimant with opportunity to provide feedback on the dose reconstruction. (If claimant agrees dose reconstruction adequately addresses concerns, the claimant signs the OCAS-1 form and returns it to OCAS).
Final Dose Reconstruction	Once OCAS receives the signed OCAS-1 form, the final dose reconstruction is issued and copies are forwarded to the DOL and the claimant.

ORAU is attempting to integrate into this process. Dr. Richard Toohey highlighted the ORAU claimant correspondence process as follows:

Communication	Purpose
ORAU Introduction Letter	Briefly describes the roles and responsibilities of the ORAU team, making it clear that ORAU is a support contractor to NIOSH, which retains responsibility for the claims process. Four teams will cover the claimants; includes information about ORAU and its principles and partners (tri-fold brochure); includes a brief corporate history; assigns a claims manager (health physicist) and a claims specialist (support staff) who will be the claimant's main point of contact (POC); includes the toll-free number to ORAU; includes Telephone Interview Letter (From OCAS process).
Telephone Interview Summary Report	From OCAS process
Status Report	Informs the claimant that claim is moving into the process of dose reconstruction. Claimant will receive information on the health physicist assigned to do their dose reconstruction. At this point, claimant has opportunity to object to the health physicist. If no objections, then the actual dose reconstruction will proceed.

After the dose construction is completed, ORAU will send the dose reconstruction to NIOSH for review and approval. Then the claimant is sent the Draft Dose Reconstruction and OCAS-1 form and the Final Dose Reconstruction (from OCAS process). Dr. Toohey distributed the latest chart, which lists the ORAU personnel to date. He also indicated that the ORAU webpage was live at www.oraucoc.org. Currently, the website displays biographical sketches of several ORAU health physicists, and more will follow.

Discussion Points:

- ❑ Dr. Ziemer wondered what the parameters were on requesting a different dose reconstructor. Dr. Toohey responded that requests would be considered on an individual basis, and that ORAU anticipated that most requests will center around conflicts of interest. All valid and reasonable requests will be considered.
- ❑ A discussion ensued regarding the anticipated number of calls to the toll-free line and whether ORAU had adequate staff to handle those calls. Dr. Toohey and others explained that the claim specialist's job is to interact with the claimant and retrieve data. Also, both NIOSH and ORAU will be assigning staff to each claimant. All POCs will be able to access the NIOSH-OCAS Claims Tracking System (NOCTS).
- ❑ Concerns were raised regarding the adequacies of the telephone interview program and report. Dr. Neton pointed out that changes were being made in the computer system to allow the telephone interviewer more response space on the computer form. Claimants are given the opportunity to make changes to and provide feedback on that report. Dr. Toohey clarified that there were two opportunities for claimant recourse: first, when the claimant receives the Draft Dose Reconstruction Report, and second, after claimant receives the final dose reconstruction. Once the DOL receives the final dose reconstruction and the full administrative record, the DOL will render a decision. At that point, the claimant may contest that decision.
- ❑ Mr. Elliott noted that in the next few weeks, assignments for dose reconstruction will occur. A number of Computer Assisted Telephone Interviews (CATI) have been completed. He stressed that it was important to integrate the ORAU communications into the process soon. He explained that the process for the initial 62 claims would be different from the rest of the claims because of the integration of the ORAU process. The first 62 were test dose reconstructions to ensure proper procedures were in place.
- ❑ Some Board members expressed an interest in seeing samples of the letters that were going to be used by ORAU. E-mailing them or posting them on the web-site was suggested. Dr. Toohey indicated that they would be distributed to the Board members in some fashion.
- ❑ Mr. Griffon asked if there was a list of ORAU procedures available. Dr. Toohey responded that ORAU supplies a list of documents, including procedures, with their monthly report to NIOSH. He stated that he could provide a draft external dose reconstruction procedure, but that the internal dose reconstruction procedure had not been approved.
- ❑ Mr. Gibson expressed concern regarding the shallow pool of internal dosimetrists and wondered whether enough of them would remain at the sites to do their current work. Dr. Toohey explained that most of the health physicists were recruited from closing sites, and the majority are part-time staff who are acting as independent consultants to ORAU. Dr. Andrade pointed out that normally, those responding to requests for facility information are usually document specialists and not necessarily health physicists, so they would not be competing with this pool of health physicists.
- ❑ Mr. Elliott stated that NIOSH is very aware of the obligation to protect information vital to national security. He indicated that NIOSH has conducted five secure interviews, and secure interviews are always available for claimants who feel they need them.

IREP Update

Mr. Russell Henshaw
NIOSH/OCAS

Mr. Henshaw noted that NIOSH was concerned that the NIOSH-Interactive RadioEpidemiological Program (NIOSH-IREP) assigned no risk, no probability of causation, for radiation exposures that occurred within two years of diagnosis for leukemia and within three years of diagnosis for thyroid cancer. The feeling at NIOSH was that science did not support such a severe and absolute adjustment function for these two cancer models. SENES Oak Ridge, Inc. (SENES) was tasked to develop new adjustment models that factored in nonzero risk for short latency periods. Those models were presented to the Board in October. Upon evaluation of the new models, NIOSH found that, even though they did not factor in probability at short exposure periods, they actually reduced probability of causation at some times since exposure. NIOSH was uncomfortable with this unanticipated effect.

SENES was asked to revisit these cancer adjustments, specifying that any developed model should not have the effect of reducing probability of causation at any time since exposure when compared to the current models, and yet still factor in some nonzero risk, as appropriate, at all times since exposure. In December, SENES developed the new models. Mr. Henshaw presented tables of *Comparison of Probability of Causation Results at the 99th Percentile* for both leukemia and thyroid cancer. Using hypothetical claimant inputs, the tables compared three latency adjustment models: the model currently in use, the model presented to the Board in October 2002, and a newer model which NIOSH intends to adopt.

Regarding other NIOSH-IREP issues, Mr. Henshaw indicated that a new *NIOSH-IREP User's Guide* had been distributed and that copies had been FedExed to the Board. The new guide was redesigned specifically for the DOL for use by their claims examiners. The guide includes changes to software since April 2002; a revised and expanded glossary; file-naming conventions for input files; expanded coverage of claims needing extra calculations; and new screenshots (log-on screen, summary report, "Multiple Primary Cancers" online calculator, input file template). The new *User's Guide* will be placed on the website.

Since April 2002, several improvements have been made to the NIOSH-IREP software. Changes include: new opening screen allowing choice of manual data entry or use of input file; default simulation sample size increased to 2000; random seed number generator; multiple primary cancer calculator; online direct links to cancer model tables in NIOSH-IREP Technical Documentation (work in progress).

Regarding scientific issues and IREP research needs, Mr. Henshaw noted that the current version of IREP was created under time constraints imposed by EEOICPA and was never intended to be a stationary product. It has been recognized from the beginning that more research would be needed and that changes should be made whenever appropriate. The changes in the leukemia and thyroid latency models are the beginning, but there are other issues that are just as or even more important. Mr. Henshaw compiled a list of research topics for the Board to consider. This list, which is not all-inclusive, is as follows: Evaluation of DOE workforce data; review of risk transfer from the Japanese cohort; review of time-dependent factors, such as age at exposure and time since exposure; update of cancer incidence background rates; review of "minimum latency" adjustments, of various smoking/lung cancer issues, of race/ethnicity adjustment for skin cancers, of DDREF and other dosimetry issues; re-evaluation of chronic lymphocytic leukemia (CLL); and review of interactions with other workplace exposures.

Discussion Points:

- ❑ Dr. Ziemer asked how the National Cancer Institute (NCI) planned to utilize the new model. Mr. Henshaw responded that at first NCI was planning to adopt the old model, but now they are leaning toward adopting the new model.
- ❑ Mr. Henshaw noted that latency is the most difficult aspect of modeling, especially in regard to leukemia and that it is NIOSH's mission to be claimant-friendly where science fails.
- ❑ Dr. Melius asked what the status was of NCI finishing IREP. Mr. Henshaw responded that another draft of the working report had been sent for internal peer review by NCI in early December, 2002. Mr. Elliott added that the changes that NIOSH has sponsored have triggered a revision of NCI's working document. Those revisions must be cleared through the Department of Health and Human Services (DHHS).
- ❑ Dr. Melius inquired about the National Academy of Sciences (NAS) review report. Mr. Elliott responded that the NAS review was completed and addressed all the National Academy of Science's comments. The NIOSH-IREP is standalone and has been approved by DHHS for use. Regulations allow for substantial modifications through a formal process.
- ❑ Dr. Ziemer asked the Board if they wished to show support for the current fixes in the NIOSH-IREP leukemia and thyroid cancer latency models. Board members agreed to the fixes, but cautioned that any support should be qualified with some statement to the effect that science does not necessarily support either model, and that this is a claimant-friendly approach. Dr. Neton indicated that the documentation includes a discussion about cancer models, their adoption to IREP, and the science supporting them. He stated that modifications could be made to the leukemia and thyroid cancer model discussions regarding the claimant-friendly approach in adopting the new models.
- ❑ Dr. Roessler asked for a status update on BIER-VII and whether it would cover some of the above research issues. Dr. Ziemer noted that BIER-VII was not yet published. The release would be dependent upon the National Academy of Science's (NAS) review process.

IREP & Scientific Issues Workgroup Report

Dr. James Melius
IREP & Scientific Issues Workgroup

Dr. Melius indicated that the IREP and Scientific Issues Workgroup was charged with setting up a review process for IREP and other scientific issues that might be raised during the overall claims and dose reconstruction processes. Reasons for possible review include: limitations of IREP or other science-based models used for dose reconstruction; limitations usually related to applicability of model for DOE workers; limitations related to assumptions used for model; possible need to review science to improve IREP or other models for use in this application; and review may be triggered by alternate approaches used in other programs using IREP or perceived problems with application.

The group compiled a list of possible research topics based on past discussion, communications, and public comments that the Workgroup felt were of importance. Dr. Melius pointed out that the Workgroup list looked quite similar to NIOSH's research needs list, even though the two groups did not collaborate on this issue. The list includes the following:

- Smoking adjustment for lung cancer
- Age at exposure/survivor population

- Incorporation of occupational studies
- CLL and other leukemias
- Incorporation of background cancer risks
- Grouping of rare types of cancer; DDREF adjustments
- Latency for thyroid cancer and leukemia

The workgroup proposed the following process regarding these topics: Prioritize the topics; NIOSH prepares a background briefing (report) on each of these topics that might include recommended changes or policy issues; Peer review consultation on background briefing (could include agencies like NCI and other outside scientists); Presentation of report and review to Board by NIOSH and consultants (as necessary); Board would make recommendations based on report, review, and presentation; If change in IREP or other dose reconstruction is needed, NIOSH would proceed with Federal Register notice, etc.; and Board reviews changes, comments, and makes final recommendations.

Discussion Points:

- ❑ Mr. Elliott reminded the Board that the regulation which speaks to modification of IREP, Section 81.12b, allows the Board and other sources to recommend revisions to the NIOSH-IREP for NIOSH consideration. Section 81.12c requires that before NIOSH implements any revisions to the NIOSH-IREP that would substantially affect estimates of probability of causation, NIOSH must obtain a review of the Board and address any Board recommendations arising from such review. Section 81.12d requires NIOSH to notify the public, through the relevant Board meeting notice, of any substantial change. Fixes are different and require no such process.
- ❑ Dr. Andrade and others felt that prioritization of the topics needed to be done first. He also liked the proposed process and felt it increased transparency. Mr. Elliott stressed that some of the suggested topics would take more time to accomplish than others, and asked that timeline be considered when prioritizing.

Motion

Dr. Ziemer interpreted the IREP and Scientific Workgroup's report as a motion that the Board utilize the workgroup's recommended topic review process. There were no objections from the Board, and a vote was taken. The motion received unanimous approval.

The Board then grouped the possible research topics into the following order:

Priority One Topics

- ❑ Incorporation of occupational studies
- ❑ Smoking adjustment for lung cancer/incorporation of background cancer risks
- ❑ Grouping of rare and miscellaneous cancers (including prostate cancer)

Priority Two Topics

- ❑ Age at exposure/survivor population
- ❑ Interaction with other workplace exposures.

Regarding all topics, the Board should consider consistency with other compensation programs. This list is not all inclusive and may be amended from time to time.

Savannah River Site Health Effects Subcommittee Activities

Dr. Sergio Bustos, Chair
Savannah River Site Health Effects Subcommittee (SRSHES)

Dr. Bustos indicated that the SRSHES was established to identify the needs of exposed and potentially exposed populations around the SRS; make recommendations to the CDC; and advise NCEH, NIOSH, and Agency for Toxic Substances and Disease Registry (ATSDR). The Subcommittee also evaluates the adequacy of the agencies' health research and public health activities at SRS. SRSHES membership, which currently stands at 18, includes knowledgeable persons selected by federal agencies who bring experience and/or scientific and technical expertise to the group, as well as representatives of concerned or affected communities. The vision of the SRSHES is to study the potential health effects of releases of radioactive and hazardous materials from SRS on offsite populations and SRS workers. Since 1995, the Subcommittee has: considered presentations, summaries and proposals by agencies; recommended changes in the peer review protocols used by agencies; advised RAC on Phase I procedures of the dose reconstruction procedures; developed a brochure describing purpose and functions of SRSHES; instituted a toll-free phone line; provided input to the Advisory Committee for Energy-Related Epidemiological Research (ACERER); and participated in Phases I and II of the Dose Reconstruction Project.

The SRSHES is currently assisting in developing scenarios for radionuclide screening analysis, which includes defining types and locations of those families who may have been exposed to harmful substances. Dr. Bustos reminded the Board that SRS occupies 310 square miles in the boundary between Georgia and South Carolina, and small creeks and rivers inside the SRS drain into the Savannah River.

Discussion Points:

During the discussion, Dr. Bustos provided the Board with the following information:

- ❑ There is sufficient evidence for investigating whether effects are multiplicative or cumulative.
- ❑ No anomalies were found during dose reconstruction except that inventory was kept better at some points than at other points. This anomaly was corrected by interviews with the past workers who provided missing information.
- ❑ Mr. Elliott pointed out that one of the SRSHES's greatest accomplishments was to effect change across the three agencies, ATSDR, NCEH and NIOSH, regarding how the peer review process was handled on individual research projects.

Board Discussion/Working Session

Contract Procurement Agency Issues

Dr. Ziemer directed the Board's attention to the Request for Contract developed by the Board's Dose Reconstruction Workgroup. He asked Mr. Elliott for an update on the procurement process.

Mr. Elliott indicated that the document labeled Draft 01/31/03 was the document that NIOSH understood the Board had reached a consensus on at their January meeting. Also, at previous meetings, some concerns were expressed regarding NIOSH acting as the contracting office for procurement of the Board's dose reconstruction auditor. After discussions at NIOSH, it was decided that the DOL might, under existing regulations, alternatively serve as the contracting office for this purpose. Mr. Elliott asked the Board whether they would prefer NIOSH or the DOL to act as the contracting agency.

Mr. Pete Turcic presented the DOL's perspective on how they would handle the contract's award and administration, a process similar to NIOSH's process. No matter which agency was chosen, either would be working in an administrative capacity only, and neither felt there that there were any conflict of interest issues. If the change is made, a MOU might be in order between involved parties. The Board discussed choosing one agency over the other, and ultimately deferred the decision until after salient points of the dose reconstruction review process could be considered.

Workgroup Versus Subcommittee: Organizational Issues

A discussion ensued regarding the differences between a workgroup and a subcommittee. Agency staff explained that a workgroup is a short-term group charged with specific tasks. Once those tasks are completed, the workgroup is dissolved. A Subcommittee handles longer, ongoing tasks that need to be performed on a more regular basis. A Subcommittee must be formally established, and the same rules that apply to the Advisory Board would apply to a Subcommittee. In regard to the Board, a Subcommittee would not necessarily be doing the reviews of individual dose reconstructions, but instead would oversee the flow of work, deciding the numbers of the different categories of dose reconstructions that will be reviewed by the Board, and assigning tasks of the review process to Board members and consultants.

It was pointed out that a Subcommittee does not have to be a majority of the Board members and that outside consultants may participate on the Subcommittee. Neither a Subcommittee nor a workgroup may act on behalf of the Board. Any decisions or work done by Subcommittees or workgroups must be brought to the full review of the Board.

The Board asked for clarification on the dose reconstruction process so that they could think about group organization relative to that timeline. Ms. DiMuzio presented a handout on how the entire task order contract award processing worked at NIOSH. If the procurement is complete, the task order process could take 2 months to go from the Board to the contractor. The main procurement, under optimal conditions, takes 3 to 4 months. Ultimately, the entire process could take up to six months.

Mr. Elliott asked whether there would need to be two executive sessions on any individual task order, one to prepare the task order and the IGE, and another to examine the contractor's proposal, deliberate on the proposals, and estimate and provide any negotiation points back to the contracting officer. It was decided that an IGE must be developed during a full Board meeting in

a closed session. Ms. DiMuzio indicated that if the Board receives a proposal back from the contractor and approves the estimate, there would be no need for a second executive session.

Dose Reconstruction Workgroup Update

Mr. Griffon explained the Dose Reconstruction Workgroup's review process model. He called the Board's attention to the workgroup's slides from July presentation and indicated decisions needed to be made on how dose reconstruction cases would be reviewed. The Board discussed the completed dose reconstruction case selection process, including the projection of possible numbers of cases and the types of cases that might be available at any given time. The Board agreed with the workgroup that the Board should select the cases for review. A stratified sampling of the cases is necessary, considering at least the following parameters: site, exposure type, cancer type, time period (50s, 60s, etc.). The sample of the overall caseload should not be greater than 2.5%. Discussion included the idea of an audit report form or a checklist with which the Board or workgroup might review all cases. It was pointed out that although the contractor will provide the expertise required to do case reviews, ultimately, oversight of these reviews is the Board's responsibility. A fatal error process also needs to be developed.

Public Comment Period

Dr. Hans Behling
S. Cohen and Associates
Dr. Behling raised a question about whether the IREP thyroid cancer model addresses the effects of internal and external exposure to the thyroid. In response, Dr. Neton indicated that internal and external exposures are treated independently and that NIOSH-IREP used the standard default ICRP values for uptake of iodine.

Ms. Denise Brock
United Nuclear Weapons Workers of St. Louis, Missouri
Ms. Brock raised a number of issues on behalf of all the Missouri claimants. Ms. Brock has gathered a tremendous amount of information regarding the Mallinckrodt Downtown Destrehan facility, where her father worked for 16 years before his death. She raised questions about the review process, about a DOL standard letter to claimants stating that reconstrucetion may take months or years, and about the adjustment in the risk models for smoking.

Mr. Richard Miller
Government Accountability Project
Mr. Miller inquired as to what the Board would do if they looked at a case and found questionable assumptions that might affect an individual's case or several cases Mr. Elliott responded that regulations allow dose reconstructions that have been completed to be revisited. If credible evidence of errors is provided by a review, those errors will be addressed.

Regarding the idea of DOL becoming the contracting authority for the Board, Mr. Miller commented on the advantages or disadvantages of one agency over the other.

With no further comments, the Board officially recessed at 5:05 p.m., until the following morning.

Thursday, February 6, 2003

Board Discussion/Working Session

Dr. Paul Ziemer called the meeting to order at 8:35 a.m.

Review and Approval of Draft Minutes, Meeting 10

The Board reviewed the minutes of their tenth meeting, held on January 7-8, 2003, and approved the following changes:

- ❑ **Executive Summary, Page 7, Board Housekeeping, Sentence #1**: Corrected to read: "Board housekeeping included an added agenda item (update on implementation of the conflict of interest policies) at the February meeting in Charleston, SC; a likely need for a conference call on February 19 or 20, for 2-3 hours **to discuss the expected SEC rulemaking if it is issued on the week of January 20** for a 30-day comment period that ends February 21."

- ❑ **Main Minutes, Page 21, Board Housekeeping, Paragraph 2, Sentence #1**: Corrected to read: "Dr Ziemer noted that the SEC rulemaking **may** be issued on the week of January 20, and the 30-day comment period ends February 21."

Motion

Mr. Presley moved to approve the executive summary and the minutes of the tenth meeting with noted changes. Dr. Andrade seconded. The motion received unanimous approval.

Dose Reconstruction Review Process

The Board decided to establish a workgroup to develop a Dose Reconstruction Review Process. Following an in-depth discussion regarding possible workgroups tasks, Dr. Ziemer appointed a Dose Reconstruction Workgroup comprised of the following Board members: Mark Griffon (Workgroup Chair), Roy DeHart, Robert Presley, Genevieve Roessler, and Richard Espinosa. Alternate members include: Jim Melius, Mike Gibson, Tony Andrade, Wanda Munn, and Henry Anderson.

The Dose Reconstruction Workgroup was charged with the following tasks: 1) Develop the procedures for identification of available dose reconstruction cases; 2) Develop the dose reconstruction case selection process; and 3) Develop the procedures for the selection of dose reconstruction cases. In parallel, the Dose Reconstruction Workgroup was tasked to: Develop the task orders and task order processes and procedures for the dose reconstruction reviewer contractor soon to be hired. Time permitting, the Dose Reconstruction Workgroup also will: Develop the procedures for the review of dose reconstruction cases.

Basic Review Report

The Board then discussed what a basic review report might look like. Following their deliberations regarding this issue, the Board decided that the proposed report might be or include the following:

1) Adequacy and consistency of the site and personnel data; 2) Adequacy of the interview; 3) Adequacy of the dose reconstruction and the probability of causation determination; 4) Individual

reports and group reports, compiled into a composite annual report that identifies strengths and weaknesses; and 5) Annual report sent to the Secretary of DHHS. The Report was passed on to the workgroup for further development.

Procurement Administration Decision

Dr. Ziemer asked the Board if anyone wished to make a motion to move the procurement administration to the DOL. Hearing no motion, Dr. Ziemer declared that the procurement would proceed through the CDC/NIOSH, and instructed Mr. Elliott to proceed with the procurement.

Statement of Work Amendments

Dr. Ziemer asked the Dose Reconstruction Workgroup if they recommended any changes to the Request for Contract document. The Workgroup asked that the Board consider the changes in the newly drafted Workgroup Request of Contract document labeled "Draft - 02/06/03." Mr. Griffon explained revisions to Attachment A, Section E, Page 9-10, Conflict of Interest. This section was completely redrafted and the language was amended to be more inclusive of prospective bidders. The amendments were discussed in detail.

Motion

Mr. Griffon moved to accept the amendments made to Attachment A. Dr. Roessler seconded. The motion received unanimous approval.

Federal Register Changes Workgroup

A second workgroup was established and charged with drafting discussion points concerning changes in the Federal Register regarding the Special Exposure Cohort rulemaking. Jim Melius, Mike Gibson, and Paul Ziemer volunteered for this task. The group plans to meet via telephone or e-mail sometime before the March 7, 2003 ABRWH meeting to prepare points to discuss at the full Board meeting. Ted Katz also plans to attend the meeting and will assist the group by providing a crosswalk analysis of changes made in the federal register language regarding the SEC.

ABRWH Schedule and Future Agenda Items

The ABRWH's next meeting will be held on March 7, 2003, in Cincinnati, Ohio. Proposed agenda items include:

- ❑ If published, review the Special Exposure Cohort rulemaking under the guidance of the Federal Register Workgroup.
- ❑ Review the Dose Reconstruction Workgroup's progress regarding procedures and processes of case selection and task orders.
- ❑ Discuss IREP and other scientific issues. Suggested priority topics include:

Priority One Topics	Priority Two Topics
Incorporation of occupational studies	Age at exposure/survivor population
Smoking adjustments for lung cancer/incorporation of background cancer risks	Interaction with other work place exposures

Priority One Topics	Priority Two Topics
Grouping of rare and miscellaneous cancers (including prostate cancer)	

The Dose Reconstruction Workgroup plans to meet on March 6, 2003, in Cincinnati, Ohio, and will present a progress report to the full ABRWH meeting on March 7, 2003. The Workgroup requested that a staff representative of NIOSH also attend the meeting. The back-up meeting date for the next ABRWH meeting is planned for March 18, 2003, with the Dose Reconstruction Workgroup meeting on March 17, 2003, in Cincinnati, Ohio. The following ABRWH meeting is planned for May 19-20, 2003, in Oak Ridge, Tennessee.

Housekeeping and Miscellaneous

Mr. Presley reported that he has forwarded concerns to the DOL regarding a DOL pamphlet which was causing confusion with regard to whether certain claims were to be handled through Workers Compensation or through the Sick Workers' Bill. DOL will be addressing those concerns.

Ms. Homer reviewed the current action item list, verifying which items were covered during this meeting. She asked Board members to check the roster to make sure their contact information was correct. Ms. Homer also asked members to record time spent (other than meeting time), noting they should be specific when identifying meeting preparation time and workgroup time, and forward for approval.

Mr. Presley offered to set up an Advisory Board tour of parts of the Oak Ridge facility for the May 19-20 meeting, in Oak Ridge, Tennessee. Approximately twenty people indicated that they would be interested in the tour. Mr. Presley will make the necessary arrangements.

Public Comment Period

No members of the public signed up to address the Board during the public comment period.

Dr. Ziemer thanked the Board for their hard work. With no further business posed, the meeting was officially adjourned at 1:51 p.m.

End of Summary Minutes

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

Paul L. Ziemer, Ph.D., Chair

6/20/03
Date