Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health

Ninth Meeting of the Advisory Board on Radiation and Worker Health

December 12, 2002

Conference Call Meeting

National Institute for Occupational Safety and Health (NIOSH)
Advisory Board on Radiation Worker Health (ABRWH)
Record of the Teleconference held December 12, 2002

The Advisory Board on Radiation Worker Health (ABRWH) held a teleconference on December 12, 2002. The purpose of this meeting was to discuss the scope of work and technical evaluation plan for the procurement of technical consultation for the ABRWH for its review of dose reconstructions conducted in fulfillment of the Energy Employees Occupational Injury Compensation Program Act (EEOICPA). This procurement will aid the ABRWH in meeting its responsibility to review the scientific validity and quality of dose reconstructions completed by NIOSH and to assist the Board in advising the Secretary of Health and Human Services in making determinations for or against additions to the Special Exposure Cohort. Public comment was solicited during this call, but it was explained that questions regarding the scope of work and technical evaluation may not be answered due to specifications of the procurement process. When the final scope of work is published as a Request for Proposals (RFP), questions may be raised as specified in the RFP.

ABRWH Chair Dr. Paul Ziemer convened the teleconference at 1:15 p.m. Committee members present were:

Paul L. Ziemer
Larry J. Elliott, Executive Secretary
Henry A. Anderson
Roy L. DeHart (attended until 3:00 p.m.)
Richard L. Espinosa
Mike Gibson
Mark A. Griffon
James M. Melius
Wanda I. Munn
Leon Owens
Robert W. Presley
Genevieve S. Roessler

Member Antonio Andrade, Ph.D., did not attend.

Attendees Included:

Department of Health and Human Services (DHHS):
Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH): Larry Elliott, Cori Homer, James Neton, David Sundin, Elizabeth Homoki-Titus, David Naimon, Ted Katz, Twila Saitow

Department of Energy (DOE), Rocky Flats: Bob Eisline

Department of Labor (DOL): Rose Toufexis, Jeff Kotsch

Members of the public:
Jeff Clemm, SAIC, Inc.
Ray Green, Court Reporter
Sylvia Keating, Pace International Union
Arjun Makhijani, Institute for Energy and Environmental Research (IEER)
Richard Miller, Government Accountability Project (GAP)

John Morrow, Sanford Cohen and Associates
Marie Murray, Recorder
Herman Potter, Pace International Union
Bob Tabor, Fernald Atomic Trades and Labor Council, Harrison, OH

Opening Comments:
Dr. Ziemer reported that former member Sally Gadola had resigned to avoid a possible perception of conflict of interest. Ms. Gadola is employed by the Oak Ridge Associated Universities (ORAU), which had been awarded the contract to conduct the dose reconstructions associated with EEOICPA claims. The Board agreed that Ms. Godola's departure was a great loss for the Board.

Dr. Ziemer thanked Mr. Griffon and the Dose Reconstruction Workgroup for their development of several working documents with which to procure technical consultative support to the Board. The documents: Attachment C: Statement of Work; Attachments D and E: Example Tasks 1 and 2 (Basic and Advanced Reviews respectively); and, Attachment A: Technical Evaluation Criteria will be the main parts of the Request for Proposal (RFP) and incorporated into the subsequent contract. Attachment D and E provide basic and advanced, respectively, examples of the tasks the bidders will be asked to quote upon. Consensus on these documents is necessary to begin the procurement process. Thus, they were the focus of this teleconference meeting. For the process to advance in a timely manner, only minor changes to the SOW and the technical evaluation criteria would still be possible at the next (January 2003) meeting.

After an overview of Attachments A and C was provided by Mr. Griffon, the Board discussed each section. This review and discussion was not editorial in character (e.g., for typographical or grammatical errors, etc.), but on the substance of the documents. Editorial comments and minor corrections were not discussed on this call and were to be sent in to NIOSH/OCAS. The following summary highlights discussion on specific passages from the documents.

ATTACHMENT C: STATEMENT OF WORK

This is delineated by criteria for basic and advanced review, as well as a "blind" dose reconstruction review. (Note: ¶ indicates "paragraph")

C.1: Purpose of contract: No comment

C.2: Background and Need:

¶3, Munn: Sentence 2: It is unclear to what "'as least as likely as not'" relates; the employment, or the dose. The Act addresses employment. Edit to ensure this parallels the Act.

¶3 Elliott: This paragraph contains language taken from another contract; NIOSH will adjust the date and ensure that "proposed" is dropped from reference to the rule.

Attachment C.3: Contract Tasks lists three primary tasks: A) individual dose reconstruction review, B) NIOSH OCAS "Site Profile" and "Worker Profile Review", and C) Review of Special Exposure Cohort (SEC) Petitions. The text of the latter was intentionally broad, since the SEC regulation has not yet been finalized.

C.3.A Individual dose reconstruction reviews

¶1 Elliott: Change line 2 to "as needed to adjudicate the claim".

¶1 Ziemer: Add for quality control, whether case determination includes if NIOSH followed their own guidelines in doing the dose reconstruction. Agreed to change this to "was done in a manner consistent with NIOSH dose reconstruction regulations with CFR..." or, after "other cases", to add "...,and whether NIOSH followed its own guidelines in the dose reconstruction".

¶1 Change "contractor shall determine" to "contractor shall evaluate"

C.3.A.1 Basic Review

B-2: Naimon: Data for the dose estimate comes from many places, not just from the interview. Agreed: add "and if inconsistent, to evaluate if there is reasonable justification why the inconsistency is so" (e.g., the inconsistency could be due to a misinformed survivor's comments).

C.1 Munn: How could it be determined to what extent the benefit of the doubt was resolved in the claimant's favor? Are they being asked to quantify it? Agreed: delete "and to what extent"

C.3.A.2 Advanced Review

B.2 Review work history interview and documentation provided by claimant.

Ziemer: If the claim is successful, the customer satisfaction is probably a moot point; but it is unclear how satisfaction can be rated with an interview. Is that an appropriate role for an audit, or should it just be ascertained from the record that the interview was properly conducted?

Comments included:

- The question is what is to be validated? Is it the tool's effectiveness in gathering all necessary information or the interview itself? If the latter, an independent auditor should ask the same questions. Changing them may garner different information but will not validate the tool. How can *all* the potentially needed questions be known from the start? Reopening interviews could open Pandora's box.
- Griffon: The idea was to both audit the method itself (does the questionnaire get the right result?) and the specific process (did the interview capture the relevant information from the interviewee and report it accurately?).
- Issues impeding the re-interview relate to protecting confidentiality of the individuals (Privacy Act); the inference of an obligation/burden put back on the population; the requirement of an Office of Management and Budget (OMB) review and clearance to interact in this manner; and, assuring all legal requirements are met under such an approach.
- Melius/Gibson: This does place the burden back on the claimants or their survivors, many of whom do not understand the process or what is/is not important information to convey. A tool is needed to check if the appropriate information was followed up on, which requires a re-interview.
- The re-interview is not meant to re-adjudicate claims, but to ensure that the system in place works. Doing the audit of the process can be accomplished with the records at

hand for a given claim. It is preferable to do so without going back to the claimants or persons interviewed.

- The NIOSH process is straightforward. Standardized questionnaires are used, the claimant reviews both the draft interview report and the draft dose reconstruction, and signs the OCAS-1 form to signify agreement that all the information they had available was captured and addressed. All this information is in the administrative record and should be the initial basis for the audit of the process. There are many points along the process where a claimant can raise concerns about the development of their claim.
- The review is a critically important part of the process and it is not envisioned many such follow-up interviews would be necessary. People are frequently less comfortable in an oral interview setting, which may produce inaccuracies.
- Possible solutions:
  - Munn: Have the last question be whether the interviewee believes everything necessary was covered, or if they would like the interview to be conducted in some other way.
  - Anderson: To avoid irritating the claimants, pre-select cases and get their agreement at the first interview to doing a follow-up, or to tape the interviews for later use by the reviewer.
- Mr. Elliott stated that the policy is not to record or tape interviews. He advised deleting B.1's text from the point of transcript on, and the parenthetical statements in B.1 and B.2. Related sensitivities are that this imposes another burden on the claimants (not all claimants would be comfortable with recording their interview); the potential causing further anguish of survivors by finding on follow-up that the claimant had passed away; the need for an OMB clearance (which will take an undetermined period of time to receive); and, assuring that all legal requirements are met under such an approach. If the details can be worked out later, that can be effected through a separate Task Order, but waiting to develop such details would prevent issuing a RFP with a proposed requirement now.
  - Responses:
    - Dr. DeHart would be satisfied with that since time is of the essence.
    - Dr. Melius was not willing to advance the SOW without a clear Board method to review the appropriateness of the process, such as this interview audit. He would prefer waiting for a DHHS response to the present proposed language.
    - Mr. Owen: The Paducah union often finds that the worker is deceased, but the widow generally appreciates the follow-up. And, the longer the program is delayed, the more claimants will pass on and the more the program's credibility is eroded.
    - A literature review could explore if there is any gold standard for such interview processes to elicit the desired response. NIOSH can provide references to scientific literature on how survey instruments are used.
- Elliott: The technical consultant contractor could attend and review interviews while they are in progress, and provide an evaluation of those cases after adjudication.
  - Problem: This would not be representative of the normal interview, and there could be legal problems if the claimant becomes involved in litigation.

– If the claim is denied, the follow-up will surely entail bias. However, while this can be accounted for (e.g., if 20 awarded cases are happy and 20 denied claims are not), to make it fair, this would have to be done before the adjudication.

- Mr. Griffon stated that the workgroup had originally had a task to review the method and procedures, but then rolled those in the individual cases. Had that not been done, the comparison with the literature would be possible.

Conclusion: Reexamine this issue in January. To properly address the concerns of both the agency and the Board, it was agreed to table this until the January meeting. More information and direction from the Department should be available by that meeting.

2.A.3 Munn: If these data are not readily available, it would be a huge job to identify all relevant data sources, especially those outside the official record. Agreed: change "determine" to "evaluate if a reasonable effort was made to identify relevant sources..." There is a similar question in B.3. A rule of thumb for these eventualities should be generated at some point in future.

C.3.B NIOSH OCAS Site and Worker Profiles and Review. The site profile incorporates all dosimetry data taken from all DOE sites in NIOSH's database, and the worker profile includes all data and analysis on co-workers' exposures, that could be potentially useful to claimants without data. These will be reviewed by the independent contractor. Both C.3.B and C.3.C are broad, as noted earlier. This is a 'marker' to alert the contractor that they might have to do tasks such as these.

¶2 Line 1: Change "The contractor shall investigate..." which infers onsite study, to "review", as in the next sentence. This is not intended to be comprehensive, as a site profile will be. This is the same issue as in 2.A.3 above.

¶2 Delete " / Contractor"; this refers only to NIOSH.

¶2 The intent of the last sentence is that these interviews could be conducted at a hotel, not on a DOE site.

¶2 Munn: as with 2.A.3, above, the term "site 'experts'" will have to have some criteria assigned to it. The intent is to indicate people familiar with the site, but a minimum benchmark will be needed.

¶4 All ten sites are expected to involve visits for interviews, but that is not realistic in the first year. Ten comprises 33% of the major DOE sites, all of which are huge.

-- Neton: Change the number of sites to 5. Just because the site profile is not complete does not automatically mean a dose reconstruction cannot be done.

– Elliott: Use phrases like "as needed, as deemed appropriate," etc. Or, strike these two sentences completely, since Attachments D&E address that.

– Agreement: leave this for a decision at the January meeting.

C. Review of SEC petitions. This was left broad since there is no established policy as yet, and inserted to allow for technical assistance to the Board. This can be in the SOW despite the absence of the rule, but in view of the latter, NIOSH will strike the text in #2 to simply say the contractor "will review SEC petitions." Again, this was inserted to be a marker for the contractor's bid estimation.

***C.4 Work Assignments*:** No comments. This text and that of C.5 is boilerplate from past NIOSH work, slightly modified for this application.

C.5 Report Preparation

5.1 Ziemer: at the end of C.5.1, have the report sent simultaneously to the NIOSH Project Officer and the Chair of the Board. Agreed.

Closing Comments on Attachment C:.

The issue of reviewing the interview process will be a problem, preventing the SOW from being entered into the procurement process. However, NIOSH can work with Mr. Griffon to make the edits/changes discussed and to identify the issues remaining. Mr. Elliott will seek guidance from DHHS and the Office of General Counsel on how to proceed with regard to the interest to re-interview and record interviews.

ATTACHMENT A

A ***Personnel***: No comment

B ***Management Approach:*** No comment

C ***Technical Approach:*** No comment

D ***Past Performance.*** This Section D and Section E are designed to help evaluate the contractor's expertise and approach to this work, so as to provide a level playing field for all the proposers. Dr. Neton reported that this was boilerplate NIOSH language. Some changes in department procedures will require some minor (not substantive) changes that will be in the text provided at the January meeting. Agreed; re-review in January.

E ***Conflict of Interest:*** Will discuss at future meeting.

¶¶2&3 The evaluation criteria involved areas of disagreement in the workgroup. Scrutiny will be focused on work with DOE, and atomic weapons employer (AWE), or contractors of either, in the past 5 years. This criterion includes key personnel who the contractor may engage to supplement their staff expertise. It also includes persons who had served as expert witnesses at any time in the past, on behalf of DOE, AWE, or contractors of either. The 5-year term was set arbitrarily, to address any perceptions of conflict of interest.

Aspects discussed on this issue were:

- Roessler: The 5-year term may eliminate the most technically up to date contractors for no valid reason. This should be either dropped or shortened. Previous statements developed by the workgroup left it up to the contractor to provide a conflict of interest form that could be evaluated.
- Since NIOSH is engaging the services of both the contractor and the reviewing panel, being as prescriptive as possible seemed advisable to avoid any perception of conflict of interest.

- The general feeling of the Board was that five years is too long; most contracts cite 1 year. Two years would more than enough and probably still may eliminate most of those best qualified to do the work. Consultants may have multiple contracts, some with a minor DOE component. Those with DOE as the major source of funding are the ones bearing scrutiny, not 1-2 short projects. This should be listed as an evaluation consideration; then, the Board would want to discuss rationale of why or why not that person was chosen.
- Gibson: People justifiably do not trust DOE so it is important to have someone completely divorced from DOE to do the evaluation.
- If a perception of mistrust is the consideration, this should go much farther back than 5 years, to work done when the exposures occurred, in addition to the key personnel and contractors involved in the epidemiologic dose estimate studies.
- Mr. Elliott pointed out that NIOSH, not ORAU, will be evaluated, and the evaluation panel will have one Board member to participate in the selection process. The technical review panel works with confidential information and the names are not made public. But the Board representative can reassure the ABRWH members that this issue is addressed.
- Dr. Ziemer suggested a minimum of 2 years without DOE work and looking back at work done over the last five years.
- Melius: The perception of conflict could relate to the type and extent of the contractor's past work for DOE (e.g., doing lab or quality control work versus work in radiation protection or dose reconstruction). As a compromise, he suggested "a minimum of 2 years not working with DOE, and evaluation of a history of longer than 5 years, balancing the conflict of interest with expertise and other criteria".
- Although there was some feeling that two years may be more restrictive than necessary, there was agreement on the compromise language for this criterion of <u>"at a minimum not working with DOE for the past 2 years, and evaluated on the degree/extent of work performed for DOE or a DOE contractor. If necessary, the bidder should include justification for key personnel if there is conflict of interest."</u>

¶*4* *Issue of those involved in litigation.* If a case was adjudicated for DOE, the contractor should not be involved in the panel at all; if they did so for an individual, they would just not address that particular case if it arose.

Aspects discussed on this issue were:

- Dr. DeHart felt there should be parity between the two situations, but had had to leave the teleconference before the SEC text review began.
- Munn: There is no way of knowing how many people this would affect, and she disliked automatically eliminating anyone credentialed who testified on the science.
- ORAU allegedly has 90 people on staff that meet this criterion, and ORAU accepted these criteria. The contractor should be at least as stringent.
- Due to the deep distrust of DOE in the field, even the perception of any bias relative to the claimants must be removed. This criterion mostly pertains to perception. Most scientists are honest, but testifying for DOE clouds the issue.
- There was <u>agreement to retain the current language,</u> but Dr. DeHart may raise it again in January.

Attachment E: Example Task 2

Footnote 1: Since information has been considered but not included as relevant since more data already supported the claim, add "that should have been considered."

Item B. When the interview issue is resolved, adjust this text as well.

The agenda for the next meeting (January 7-8) will include:

January 7/Day one:

- A critique of the interview process
- Vote on the document
- Program status report
- Update on dose reconstruction
- Review of the latest version of these documents with wording resulting from this call.

January 8/Day two:

- Administrative Housekeeping and Board Work Schedule
- Close session for development, review, and discussion of the proposed independent Government cost estimate for a contract.

- If closure is reached on the scope of work on day 1 (Tuesday), then tentatively on Wednesday morning, a review may be done with NIOSH staff of the dose reconstructions completed by NIOSH and adjudicated to date (there are currently DOL decisions on ~7 of the 13 completed). At the start of the meeting, what can/cannot be publicly discussed from the administrative record will be presented. In small workgroups, the information used for the finalized claims will be reviewed with a staff member present to assist as needed. Since this will be a public meeting, the entire administrative record for each case will need to be redacted. NIOSH OCAS will determine if and how such a review might be accomplished.
- On January 8, there will be a closed session to develop the independent government cost estimates for the work discussed on this call.
- NIOSH was requested to:
  - Have the Office of General Counsel present the legal issues of the evaluation contract pertaining to the interviews.
  - Review NIOSH's current plans for internal evaluation of the interview process, by NIOSH and by the contractor, to inform the Board's recommendation on this issue.

Since the redrafted SEC rule, which includes the comments from the Board, public input and the town hall meeting comments, has been substantially changed from the rule proposed last summer, it will not be ready for review and discussion in the January meeting. Another Notice of Proposed Rule Making will have to be issued.

Public Comment:
John Mauro, of Sanford Cohen & Associates, asked if the RFP announcement was scheduled and would it include anticipated work hours. Mr. Elliott replied that the RFP will specify a "not to exceed" amount of work hours and those interested should call OCAS or get on the list to receive the announcement of the RFP at the NIOSH/OCAS Website.

Arjun Makhijani, Institute for Energy and Environmental Research, offered several comments.

- He found the Attachment C.3.A criterion of "performed fairly ... consistent with other cases" to be ambiguous about the standard for judging performance, since some DOE work has been sloppy. A better thought-through statement is needed.
- Regarding the workers whose applications are denied, he felt that historically, workers have generally been proven more right than the establishment in stating effects. Their technical credibility should be given greater weight than that given to establishment views or measurements, particularly since some DOE data are fraudulent. Their testimony should not be dismissed nor should they be considered hysterical or afraid of radiation. The distrust of DOE was well earned by its actions. This approach should be part of the criteria to select the independent reviewer.
- The dose reconstruction should include assessment of whether the DOE data are fraudulent. Without that, neither the dose reconstruction process nor its audit will

be very credible. A more straightforward process of putting people in the SEC should consider that as well.

Richard Miller, of the Government Accountability Project, noted that the specifications for the technical review personnel do not include previous experience in conducting dose reconstructions. If more than one contractor is not selected, a blind review is not possible.

Dr. Neton defined Mr. Miller's method as a double blind review (i.e., done by two reviewers). This process of blind review starts from scratch and re-conducts the dose reconstruction from the data used without any knowledge of the adjudication. NIOSH could not provide any interpretation of this language until the SOW is fully developed, but suggestions were welcomed.

Mr. Miller offered two forms of advice: 1) specify two auditors for a double blind review, given the huge scope of an audit and the desirability of making it as "bullet proof" as possible. And 2) the auditor should be someone with actual dose reconstruction experience, and experience in dealing with contradictory and fraud records as well as with uncertainty analysis and bounding techniques. These are all central to what needs to be looked at in this process. He had circulated an e-mail with suggested text.

Jeff Clemm, of SAIC, Inc., asked if the Section E text on conflict of interest refers to the prime contractor or the affiliation/team member. Again, there could be no response until the RFP is released. And, given the Rule 83 as proposed, a dose reconstruction that cannot be done should be reviewed by the Board and its contractors.

With no further comment, the conference adjourned at 4:07 p.m.

♦♦♦

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

Paul L. Ziemer, Ph.D., Chair

1/16/03
Date