Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health

Seventh Meeting of the Advisory Board on Radiation and Worker Health

August 22, 2002

Conference Call Meeting

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
Office of Compensation Analysis and Support

Records of the Telephone Conference of the
Advisory Board on Radiation Worker Health
August 22, 2002

A telephone conference of the Advisory Board on Radiation Worker Health (ABRWH) was convened by the National Institute for Occupational Safety and Health's (NIOSH) Office of Compensation Analysis and Support (OCAS) on August 22, 2002. A notice of the teleconference had been published in the *Federal Register* to allow for public input to the discussions. Under discussion in this conference were the Board's final recommendations to the Secretary of the Department of Health and Human Services (DHHS) on the Proposed Rule 42 CFR Part 83, "Procedures for Designating Classes of Employees as Members of the SEC," as well as a letter to the Secretary about: 1) the Memorandum of Understanding (MOU) between NIOSH and the Department of Energy (DOE) that governs the Rule's process and 2) about retention of documents. A copy of the final letters and documents are attached to this report. ABRWH Chair Dr. Paul Ziemer called the meeting to order at 1:18 p.m.

Members participating were:

Paul Ziemer, Chair	Roy DeHart	James Melius
Larry Elliott, Executive Secretary	Richard Espinosa	Wanda Munn
Henry Anderson	Sally Gadola	Bob Presley
Antonio Andrade	Mark Griffon	

Member Dr. Genevieve Roessler was not in attendance, but had e-mailed her comments on the document, which were generally supportive. Mr. Mike Gibson and Mr. Leon Owens, new ABRWH members approved by the White House but not yet seated, also participated in the call.

NIOSH staff on line were: Larry Elliott, Cori Homer, Ted Katz, David Naimon, Liz Homoki-Titus

Mark Reinhold of the Department of Labor also was on the teleconference.

Members of the public or others attending the call were:
Vina Colley, Portsmouth Gaseous Diffusion Plant (GDP)
Ken Crase, Savannah River Site
Joy Gest, Hanford Site
Richard Miller, Government Accountability Project (GAP)
Frank Morales, Government Accountability Project (GAP)
Bob Tabor, Fernald Site

Jerry Tudor, Oak Ridge Site

Letter to the Secretary
Dr. Ziemer read the draft August 22, 2002, letter to Secretary Thompson about the MOU and retention of records. Mr. Elliott reported that the citation of the relevant October 28, 1991 DOE memo will be inserted to this letter and the memo attached. The letter cited the Board's open public meetings, discussions about the importance of having complete exposure and other available site records provided in a timely manner to facilitate NIOSH's work. It asked that DOE be urgently requested to continue the retention of such records by each DOE office and present/former DOE contractors. Minor edits were provided in discussion.

In ***public comment,*** *Ms. Joy Gest* reported receiving two letters from NIOSH indicating that they have requested her records from DOE. She wanted to know if DOE was holding up the process. Mr. Elliott explained that NIOSH's ongoing notification to claimants about their claim status requires multiple letters. Ms. Gest commented that the slowness of the process made it appear as if the "right hand doesn't know what the left hand is doing." Dr. Ziemer responded that this conference and the letter to the Secretary were designed to improve the timely response of DOE and to remind new contractors about the mandated records retention.

Ms. Gest asked how many claims had been processed to date by NIOSH staff. Mr. Elliott reported that the difficulty of the compensation program and its associated legal process requires great care and deliberation, but the process is expected to greatly speed up when the contractor is in place. They will be staffed/equipped to handle at least 8000 claims per year. Of the ~6700 claims filed to date, NIOSH has sent ~7 files to DOL for a recommended decision, and was to send more this week.

Ms. Vina Colley reported Portsmouth workers were upset with this process, as well as suspicious that efforts were underway to get them to "sign away their rights." She asked for a public meeting to be held at Portsmouth and that all DOE sites be included in the Special Exposure Cohorts (SEC), since all workers were exposed to various types of chemicals as well as radioactive materials.

Mr. Richard Miller suggested that the DOE Secretary be copied on this letter, since the recommendation may be beyond the DHHS Secretary's purview, and asked if the sufficiency of NIOSH staffing was addressed. Mr. Elliott responded that NIOSH will send it according to the agencies' protocol for correspondence between agencies. The letter also will be posted on the NIOSH Website. Dr. Ziemer reported the NIOSH staffing was discussed at the ABRWH meeting the previous week. It is also included on the agenda for next meeting, along with evaluating the status of the dose reconstruction contractor.

Dr. Ziemer called for a **vote to approve the letter to the Secretary regarding the NIOSH/DOE MOU and DOE's retention of personnel records** with the two minor changes in wording suggested. The motion was **unanimously approved** by the Board with no members abstaining.

Recommendations on Rule 42 CFR, Part 83
The Board's comments on the proposed rulemaking of 42 CFR, Part 83 were sent via a cover letter along with two attachments containing both general and specific comments. The cover letter, which was read by Dr. Ziemer, included the dates the Board reviewed and discussed the Rule, and noted that they heard a number of presentations and public comments. Dr. Anderson had to leave the call early, but supported the contents of the letter and the two attachments, and voted in favor of sending them.

In one change to the letter, the Board agreed to modify its recommendation to clarify that since the Rule's provisions were not ready for examination, paragraph 1 should state that the Board "examined the issues relevant to . . ." the Rule during the May 2-3 meeting.

Attachment #1
Several changes and clarifications were suggested to Attachment #1, the Board's general comments on the Rule:

Inclusion of non-SEC listed cancers. Clarify, regarding compensation for non-SEC listed cancers, that the proposed regulation should "ensure that <u>these</u> do not preclude . . ."

"Health endangerment" definition. The definition of "health endangerment" had been extensively discussed at the last meeting and no consensus was yet apparent. Dr. Ziemer strongly preferred sending a consensus recommendation to the Secretary. Although the Federal Advisory Committee Act requires consensus advice of committees chartered under it, the Board's operational guidelines only require a majority opinion to be reached by eligible members to allow a vote to go forward. However, advice from individuals is also accepted, and Mr. Elliott expected that a statement of such concerns by "some members" would also capture the Secretary's attention.

In this discussion, there was some agreement that the ABRWH should "recommend that NIOSH consider suitable criteria" (e.g., a facility with poor/no monitoring and holding the potential for external or internal dose) or "consider this issue," to express the concern but leave it sufficiently open-ended to allow time to work on the issue. There was clearly a majority of the Board concerned about the definition of health endangerment, although the solution to it differed among members.

Dr. DeHart **moved that the Board suggest that the proposed rule for determining if a potential SEC class meets the health endangerment criteria is not adequate. If not adequately justified, this could lead to arbitrary decisions. The Board recommended that NIOSH consider other suitable criteria**. Mr. Presley seconded the motion.

The **vote on the issue of the "health endangerment" definition** showed eight in favor and one opposed. The **vote passed.**

Dose Reconstruction Guidelines

Dr. Ziemer read the Board's draft recommendation that, in the Rule's preamble, NIOSH clarify the criteria that determine whether completion of a dose reconstruction with sufficient accuracy is not possible, and clarify the criteria to be used to evaluate an application. Also recommended, to ensure the consistency/fairness of the process, was NIOSH's development of operational guidelines to determine the adequacy of the data to complete a dose reconstruction, also to be reviewed by the Board. Several clarifying edits and a substantive change (to include time limits in the guidelines) were offered.

Interim Final Rule
Dr. Ziemer read the proposed Board recommendation that NIOSH issue this as an Interim Final Rule. This would allow adjustments as needed and provide time for resolution of issues not yet fully worked out by the Board and NIOSH. However, the text specified that "if this would prevent the Secretary from certifying classes, then the Board would ask that this option not be considered." The last phrase resolved several of the the members' primary concern. However, since there was lingering unease that perhaps not all the implications of the difference between an interim and final rule were known, Dr. DeHart moved to state that the **"Board recommends that DHHS consider issuing this regulation as an interim final rule..."** Mr. Presley seconded the motion, and upon a vote, the motion **unanimously passed.**

Mr. Griffon raised the question of assigning the dose of an SEC category to another reconstructable dose, and was satisfied that this was addressed under Section 1 of Attachment #2, under non-SEC listed cancers.

Ms. Munn moved to accept Attachment #1 as amended and Mr. Presley seconded the motion. With no opposition or abstentions, the **vote unanimously passed.**

Attachment #2
Dr. Andrade, who had to leave the conference early, voiced his support of this attachment as long as it was not modified beyond minor editorial changes. Since only Section 83.9 had been altered (everything else remained unchanged since the last meeting and had been distributed publicly), that Section was addressed first.

Sec 83.9:
- In the last sentence addressing the applicant's submission of a "government or other research report," add "published scientific research report" after "other." Applicants' requirements to submit to NIOSH are that: 1) the individual tried to get their dose record and could not; 2) provides a report from a health physicist or dose reconstruction expert that they were involved in the specific situation; or 3) submits a research paper report about the adequacy of available dose information.

Other changes agreed to included:
- *83.1,* correct spelling in last line.
- *83.2 (b):* change the sequence of the first sentence to "... dose reconstruction performed and who have had a claim denied."

■ Clarify that a cancer claimant who dose reconstruction is completed but whose claim does not qualify them for compensation "cannot reapply as a member of a special cohort or use the procedures for designating such classes as a route for appealing a decision." (Underline indicates new text).

However, concern was expressed about both this and the original wording. If the dose reconstruction is denied and it is later found that a dose reconstruction could not be done for the applicant's particular work experience, they should be able to apply for a special class. Since the Board had no wish to prevent an appeal based on insufficient accuracy, alternative language was suggested to prohibit using "... the procedures for designating a special cohort class specifically as a route for appealing a decision," but again it was questioned how this would be determined

It was agreed that the intent was clear that the Board wished the DHHS attorneys to craft appropriate language, such as by adding "this does not preclude them from filing an appeal under (cite Section)" to be clear that this route still remains.

With Dr. Melius' second, Ms. Munn **moved to adopt the text: "A cancer claimant whose dose reconstruction is completed but whose claim does not qualify them for compensation cannot use the procedures for designating a special cohort class specifically as a route for appealing a decision. This does not preclude them from filing an appeal as provided for elsewhere by the DOL rules."**

Upon a vote, the motion was **unanimously approved.**

■ *83.5*, correct typo "addition"to "additional."
■ *83.10*, first sentence to read "the wording of all those items infers" rather than "appears", which "are appropriately DHHS or NIOSH functions."
■ *83.13*: Remove the parentheses in sentence one and make it a separate sentence.

Mr. Presley **moved to approve Attachment #2** with the above changes. Dr. DeHart seconded the motion, which was **unanimously approved** with no abstentions.

Dr. Ziemer agreed to e-mail a marked up copy of these document to Ms. Homer, to be attached to the final reports. With no further comment and the Chair's thanks, the meeting adjourned at 3:08 p.m

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

/s/

Paul L. Ziemer, Ph.D.

October 31, 2002

Date

DRAFT

Report Attachment #1: Letter to the DHHS Secretary

August 20, 2002

The Honorable Tommy G. Thompson
Secretary, Department of Health and Human Services
Washington, D.C.

Dear Secretary Thompson:

Since my last communication to you on February 22, 2002, The Advisory Board on Radiation and Worker Health has held three additional meetings. The sessions were open to the public in accordance with FACA requirements and were attended by a variety of individuals representing themselves or interest groups. Copies of the meeting Agendas are attached for your information.

During the Advisory Board meeting in Cincinnati on August 14 and 15, two of the issues under consideration relating to past records were deemed to be of sufficient substance to require your attention. The Board continues to be seriously concerned about the critical need to have complete personnel exposure records and other related site records available in a timely manner. The dose reconstruction processes being conducted by NIOSH, as required by law, cannot function fairly and quickly in the absence of those data. As the bulk of the required information is accessible almost exclusively through the Department of Energy, the Board recommends that:

- A Memorandum of Understanding between DHHS and DOE be pursued as expeditiously as possible to assure NIOSH is provided timely and appropriate DOE exposure records required by Section 3623(e) of EEIOCPA.

- DOE be urgently requested to reissue its directive on retention of personnel records (DOE Number ?????) to each of their offices, contractors, and former contractors to ensure that all necessary data are appropriately retained and accessible.

If there are questions, or if further explanations of the Board's concerns are desired, please advise accordingly.

Sincerely,

Paul L. Ziemer, Ph.D., CHP
Chairman

DRAFT

Report Attachment #2: Transmission Letter Re. SEC Rule

August 20, 2002

The Honorable Tommy G. Thompson
Secretary, Department of Health and Human Services
Washington, D.C.

Dear Secretary Thompson:

During meetings held May 2-3, 2002, July 1-2, 2002 and August 14-15, 2002, The Advisory Board on Radiation and Worker Health examined the provisions of the Department of Health and Human Services proposed rule 42 CFR Part 83 entitled ***Procedures for Designating Classes of employees as Members of the Special Cohort Under the Energy Employees Occupational Illness Compensation program Act of 2000***.

At the Board sessions, formal presentations were provided by NIOSH staff members concerning the Special Exposure Cohort issues. In addition, presentations were made by outside experts, including individuals from the Department of Veterans Affairs. Members of the public also provided valuable input on this matter.

Under the provisions of the President's Executive Order of December 7, 2000, the Advisory Board has very specific responsibilities on advising the Secretary of Health and Human Services. In accordance with those responsibilities, I am pleased to provide the Advisory Board's comments and recommendations concerning the proposed procedures set forth in 42 CFR Part 83. These comments and recommendations are summarized in Attachments 1 and 2. Attachment 1 provides general comments on certain aspects of the proposed rule. Attachment 2 provides more specific comments on particular sections of the proposed rule.

Please let me know if additional information or clarification is needed.

Sincerely

Paul L. Ziemer, Ph.D., CHP
Chairman

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Report Attachment #3; Rule Comment Attachments

Attachment 1.
General Comments

Non-SEC Listed Cancers

The Board noted that there were a number of unresolved issues concerning how to handle claimants who were part of a SEC class but who developed a non-SEC listed cancer. The Board recommends that NIOSH carefully review the proposed regulations to ensure that they do not preclude appropriate handling of these cases. The Board also recommends that NIOSH develop appropriate procedures to address situations where part but not all of a claimants dose history is included in a SEC class.

Health endangerment

Some of the Board members felt that the proposed rule for determining whether a potential SEC class meets the criterion of "health endangerment" was not adequate. In particular, the proposed method for estimating whether the cohort met the criterion for "health endangerment" was not adequately justified and could lead to arbitrary and unfair decisions. These members recommended that NIOSH consider criteria similar to those used for the current SEC classes based on duration of work in a facility in a situation where the monitoring of radiation exposures was required or should been required (after first determining that the information was not adequate for individual dose reconstruction).

Dose Reconstruction Guidelines

The Board recommends that NIOSH clarify the criteria for determining that it was not possible to complete an individual dose reconstruction with sufficient accuracy. These criteria should be more completely outlined in the preamble to the final rule in order to assist potential SEC class applicants to understand the criteria that will be used for evaluating an applicant for SEC class designation. The Board also recommends that NIOSH develop operational guidelines outlining the criteria for determining that the available data are not adequate for conducting individual dose reconstruction. These guidelines should be reviewed by the Board. The Board believes that these guidelines are necessary for ensuring consistency and fairness in these important determinations.

Interim Final Rule

Some of the Board members recommended that NIOSH issue these regulations as an interim final rule rather than a final rule. The former would allow later modifications to the rule without necessarily going through the full rule making process. Given that some elements of this rule (e.g., health endangerment criteria, how to handle SEC class members with non-SEC listed

cancers, etc.) have not been fully worked out and will need further development by NIOSH and review by the Board, this may be a prudent approach. If issuing this rule as an interim final rule would inhibit the Secretary of DHHS from certifying new SEC classes, then the Board would recommend that this option not be considered.

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Attachment 2.
Specific Comments

Section 83.1

The proposed rule states that "HHS will consider adding new classes of employees only in response to petitions by or on behalf of such classes of employees…." This wording gives the impression that the burden for adding new classes lies completely on the individual employees. The Board believes that it would be beneficial if the rule made it clear that NIOSH intends to be proactive in identifying and assisting employees who may be in such categories to develop the appropriate petitions. Accordingly, we reco7mmend that a new statement be added to Section 83.1 that could read as follows:

> "Because NIOSH itself may be in a better position to identify classes of employees that may comprise special cohorts (based on its own findings from collections of individual dose reconstruction efforts or from new findings that result from site profiles), NIOSH intends to be diligent in identifying and assisting employees who may be in such categories to develop the appropriate petitions."

The Advisory Board is also concerned that some individuals may misunderstand the purpose and role of the Special Exposure Cohort. Although the language of the Rule clearly states that it applies to individuals for whom doses cannot be estimated by the completion of a dose reconstruction, it seems likely that some individuals may simply regard this as a route for appealing a decision where a claim did not qualify for compensation. Thus, the Board is suggesting that an additional statement be added in this section that states explicitly that the purpose of the Rule is not to serve as an appeal for those whose dose reconstructions did not lead to compensation.

Section 83.2

A statement addressing our concerns about individuals who have had a claim denied AND who have had a thorough dose reconstruction performed, might appear as item "b" in Section 83.2 (requiring that the current item b become item c). This could read as follows.

> "A cancer claimant whose dose reconstruction was completed but whose claim did not qualify for compensation cannot reapply for or use the procedures for designating classes of employees as members of the special cohort as a route for appealing a decision."

Section 83.5

In item (c), in addition to the parameters specified, it is important to add an addition parameter, namely that of a common time period for the work. The addition of the phrase "during similar time periods" after "at the same DOE or AWE facility" would remedy this matter.

Section 83.9

The Board recommends that NIOSH change the requirements for petitioning for SEC class consideration to modify the proposed requirement that "DOE or the AWE responded indicating the records do not exist" in response to a request for records relevant to the class petition. Obtaining such a response is not possible for most AWE facilities and may be difficult for some work at many DOE facilities. Rather, the applicant should be required to have made a "good faith effort" to obtain such records. Even this may be difficult for AWE facilities. The Board also recommends adding a third element to this section indicating that the applicant may submit a government or other research report indicating that such historical records are not available for that facility.

Section 83.10

In items (b) (2), (b)(3), and (b)(4), it appears the Advisory Board is directly involved at an early stage in processes which should be HHS (or NIOSH) staff functions. This can be remedied by deleting the last sentence of item (b)(2), deleting the last sentence of item (b)(3), and deleting the last phrase of item (b) (4). Additionally, in item (c) sentence 1, insert the phrase "together with its evaluation plans" after the word "evaluation" so as to read:

> "NIOSH will present petitions selected for evaluation, together with its evaluation plans, to the Board for review."

Section 83.13

The Board is concerned that the language in this Section makes it appear that the Board's role is ad judicatory in nature, and the review of petitions by the Board may be regarded as a formal hearing (see, for example, the language in paragraph 83.13 (b) concerning the presentation of "evidence"). We understand that the language of the Public Law does specify certain responsibilities for the Board in terms of evaluating petitions for Special Exposure Cohort status. At the same time, the Board's role is advisory to the Secretary of HHS. Thus, we would recommend language that makes it clear that, while petitioners will be invited to meetings where they can present pertinent information to the Board, the Board's report is simply one piece of information that the Secretary will consider in making a final decision on the petition.

Section 83.15

We assume that the intent of this Section is to provide the Secretary of HHS with flexibility in considering other factors (perhaps procedures or information not even thought of at the time of the rule-making) in reaching a final decision. However, insofar as this statement opens the door for any number of arbitrary issues to be introduced into the process, the Board is concerned that the statement may be too open-ended. As a minimum, perhaps it could be specified that the "other procedures" must not be in conflict with the procedures established in the Rule.