Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health

Second Meeting of the
Advisory Board on Radiation and Worker Health

February 5, 2002

Meeting Held via Conference Call

National Institute for Occupational Safety and Health
Advisory Board on Radiation and Worker Health
Summary of the Minutes from the February 5, 2002, Teleconference

The National Institute for Occupational Safety and Health (NIOSH) convened a telephone meeting of the Advisory Board on Radiation and Worker Health (ABRWH) on February 5, 2002. Participants included the Board members; Department of Health an Human Services, Department of Labor, and National Institute for Occupational Safety and Health (NIOSH) staff, as well as members of the public.

The purpose of this meeting was to discuss and vote on the Board's draft comments on the proposed NIOSH rule making for 42 CFR, Part 81, Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). The members also suggested expanding its membership to allow additional representation by nuclear industry workers.

Public comment was provided by Mr. Richard Miller, of the Government Accountability Project, and Mr. Ken Crase, of the Savannah River Site.

The members discussed **ABRWH Chair's letter**, specifically addressing altering the suggested membership expansion to specify two more, but the original "additional representation" was found to be satisfactory. However, to avoid perception that the Board was unanimous in feeling that its representation of workers is unbalanced, language was added referencing "any perceived or real imbalance amongst the various sectors represented" by the Board. Upon a **vote**, a **motion passed** to approve that change and to **approve the letter as amended**.

With minor amendments, the Board unanimously **voted to advance its drafted recommendations to the Department of Health and Human Services (DHHS) Secretary**. The amendments were to replace the text "sound science" with "application of the existing science"; to reverse the order of recommendations #2 and #3; and to add "by the Board" to review of any changes to the rule subsequent to comments received.

The Chair stated that the letter and attachment would be prepared on the Board's letterhead and sent forward with a copy of the January meeting agenda.

The next meeting would be held on February 13-14 in Washington, D.C., at the Washington Court Hotel. Travel information, two technical implementation guidelines (on external and internal dose reconstruction) to be reviewed prior to the meeting, and the meeting briefing books will be sent beforehand. The meeting agenda will focus on the dose reconstruction rule (42 CFR, Part 82) and on the implementation guidelines for the internal and external dose. The issues related to the Special Exposure Cohort (SEC) will be discussed at a later meeting.

National Institute for Occupational Safety and Health
Advisory Board on Radiation and Worker Health
Minutes of the February 5, 2002, Teleconference

The National Institute for Occupational Safety and Health (NIOSH) convened a public teleconference meeting of the Advisory Board on Radiation and Worker Health (ABRWH) on February 5, 2002. The meeting was called to order by its Chair, Dr. Paul Ziemer, at 1:00 p.m., eastern standard time. Verbatim transcripts are being taken and will be made available on the NIOSH/OCAS website (www.cdc.gov/niosh/ocas) when complete.

The purpose of this meeting was to allow discussion and a vote on draft comments on the proposed NIOSH rule making of 42 CFR, Part 81. The initial draft was developed at the January, 2002, meeting by an ad hoc ABRWH working group. The resulting recommendations and a draft cover letter from the Chair to the DHHS Secretary had been circulated to the members for their discussion and vote, and were available for the public's review on the NIOSH Website (www.cdc.gov/niosh/ocas).

Attendance:

Members present were:
Dr. Paul Ziemer, Chair
Mr. Larry J. Elliott, Executive Secretary
Dr. Henry A. Anderson
Dr. Antonio Andrade
Dr. Roy L. Dehart
Mr. Richard Lee Espinosa
Ms. Sally L. Gadola
Dr. James M. Melius
Ms. Wanda I. Munn
Mr. Robert W. Presley
Dr. Genevieve S. Roessler

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

Department of Health and Human Services (DHHS):
- Office of General Council: Mary Armstrong, Liz Homoki-Titus, and Alice Kelley.
- NIOSH: Ted Katz and Corrine Homer.

Department of Labor: Jeffrey L. Kotsch

Members of the public present were:

James Barnes, Boeing
Karen Brown, Westinghouse Savannah River
Karen Butler, Westinghouse Savannah River
Ken Crase, Westinghouse Savannah River
Mark Griffon, CPS/PACE
Richard Miller, GAP
Jerry Tudor, Worker/Oak Ridge

Certified Court Reporter: Ms. Kim Newsom, Nancy Lee and Associates

Writer/Editor: Ms. Marie Murray

Opening Comments:
Dr. Ziemer referenced the documents under discussion: a draft letter written by him to Secretary Thompson describing the Board's initial meeting and discussions, including a recommendation on its composition, and an attachment of specific comments on 42 CFR, Part 81. Mr. Elliott read both into the record and to launch discussion.

Dr. Ziemer requested that a faxed comment and attachments from the Government Accountability Project be made part of the official record: a letter directed to him from Richard Miller dated January 29th, 2002, a January 25, 2002, news release by the Department of Veterans Affairs (DVA) on radiation exposures, and a May 15, 2000, statement by Senator Paul Wellstone on the compensation plan for Department of Energy (DOE) workers. The Board members had received copies of these.

Public Comment:
Mr. Richard Miller of the GAP, thanked the Board for its recommendation of additional members to represent nuclear industry workers. He asked if the recommendation's statement, that simple exposure to radiation does not necessarily lead to disease, translated to an expressed opinion on the linear no-threshold debate. Dr. Ziemer said no; rather, it reflects the legislation's (the Energy Employees Occupational Injury Compensation Program Act -- EEOICPA) intent that compensation not be based simply on the fact that a person was at a location. It requires a dose reconstruction to determine the Probability of Causation (POC). Dr. Andrade added that NIOSH's methodologies include analyses in which the linear no-threshold theory is used with a conservative approach that favors the worker.

Mr. Ken Crase, of the Savannah River Site, asked about the Board's discussions of using the POC tables and other data for analysis. Dr. Ziemer responded that the law itself specifies the approach to be used, making the question moot.

Discussion of the ABRWH Letter:
Dr. Dehart **moved that the ABRWH approve the letter and its attachment**, and was seconded by Ms. Munn. Dr. Ziemer observed that the Executive Memorandum and the mandate to the Board does not specifically invite comments on its own membership. But, since they also do not bar that and it seemed useful to the members, the suggestion was advanced. Mr. Elliott reported that the substance of this comment had been communicated to DHHS and to the White House as well.

In discussion, **Mr. Espinosa moved to amend the recommendation in the letter to specify the number of worker representatives as two.** Dr. Melius seconded the motion and suggested a friendly amendment to change "representative" to an unspecified number of "representative(s)."

Mr. Espinosa agreed to that friendly amendment and withdrew his motion. There was some agreement that the original language finding benefit from "...additional representation from the nuclear production workers sector" was felt to be adequate to Mr. Espinosa's intent.

However, Ms. Munn expressed again her feeling that the Board's representation is not unbalanced. To diminish any perceived imbalance amongst the various sectors, she moved to restructure the sentence to read "... as a means of diminishing any perceived imbalance amongst the various sectors represented by the Board membership, the Board recommends that additional representation..." and leaving the rest of the sentence the same. In a compromise, **Ms. Munn reworded her motion to read "... any perceived or real imbalance amongst the various sectors represented by the Board membership, the Board suggests that additional representation from the nuclear production workers sector would be a clear advantage and benefit to the Board in carrying out its mandate."** Mr. Presley agreed as the seconder. Upon a **vote**, all were in favor, none opposed, and none abstained. **The motion passed.**

Dr. Anderson called the question on the **original motion to approve the letter as amended**. Upon a **vote**, all were in favor, none were opposed, and there were no abstentions. **The motion passed.**

Discussion of the Attached Recommendations:
Dr. Ziemer noted that the title would be corrected to read Advisory Board on Radiation and Worker "Health." Dr. Anderson **moved to amend the recommendation to replace "sound" science with "application of the existing science."** The motion was seconded, and with no discussion, the Board voted unanimously to **pass the motion**, with no abstentions. Dr. Dehart suggested that the order be changed to reverse recommendation 2 and 3, so as to parallel the order published in the Federal Register. Without objection, the Board agreed to this editorial change.

Ms. Munn asked if the last text ensures the ABRWH's review of the planned changes. To clarify that, Dr. Ziemer suggested adding the phrase "by the Board" under recommendation #3 (formerly recommendation #2). Without objection, the Board agreed to this editorial change. Upon a **vote, the attachment was unanimously approved** with those two minor changes, with no abstentions.

Dr. Ziemer stated that these would now be prepared on the Board's letterhead and sent forward with the second attachment (a copy of the agenda).

Closing Comments:
Mr. Elliott noted that the next meeting would beheld on February 13-14, 2002, in Washington, D.C., at the Washington Court Hotel. The members will be sent their travel information by Federal Express, along with two technical implementation guidelines, on external and internal dose reconstruction, to be reviewed prior to the meeting. Another Federal Express will transmit the meeting briefing books. The meeting agenda focuses on the dose reconstruction rule (42

CFR, Part 82) and on the implementation guidelines for the internal and external dose. The issues related to the Special Exposure Cohort (SEC) will be discussed at a later meeting (tentatively scheduled for March 25-26, 2002), by which time the policy SEC guidelines should have been reviewed by DHHS.

With no further discussion, Mr. Presley moved to adjourn and was seconded by Dr. Dehart, and the meeting adjourned at 2:02 p.m.

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

Paul L. Ziemer, Ph.D., Chair

May 5, 2002
Date

Attachment #1
ABRWH Letter to the DHHS Secretary

Dear Secretary Thompson:

The Advisory Board on Radiation and Worker Health held its first meeting on January 22 and 23, 2002, in Washington, D.C. All of the currently appointed members were present as well as the designated Federal Official who serves as the Executive Secretary. 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. A copy of the meeting Agenda is enclosed for your information.

In preparation for the meeting, the Board members individually reviewed proposed NIOSH rule making for 42 CFR 81 (Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000) and 42 CFR 82 (Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000). The members also reviewed written comments by subject matter experts and by members of the public for these two rules. At the Board sessions, formal presentations were made by NIOSH staff members on these and related issues. Also, comments were provided by some members of the public who were in attendance.

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 recommendations concerning the proposed Guidelines for Determining Probability of Causation as set forth in 42 CFR Part 81. These recommendations are summarized in Attachment 1.

In addition to dealing with the specific items mandated by the Executive Order, the Advisory Board wishes to comment on its current composition and makeup. We note that since the Public Law under which the Advisory Board was established provides for up to 20 members, and since the current number of members appointed is 10, there may be additional future appointments made to the Board. As a means of providing improved balance among the various sectors represented by the Board membership, the Board suggests that additional representation from the nuclear production workers sector would be a clear advantage and benefit to the Board in carrying out its mandate.

Please let me know if additional information or clarification is needed concerning the recommendations contained herein.

Sincerely,
Paul L. Ziemer, Ph.D., C.H.P., Chairman

Attachment #2
(Attachment #1 to the ABRWH Letter to the DHHS Secretary):
ABRWH Recommendations and Comments

The following comprise recommendations and comments from the Board in the context of responses to the three major questions found in Section I of the Preamble to the proposed rule, 42 CFR, Part 81:

1. The Board agrees that the National Institute for Occupational Safety and Health (NIOSH) guidelines and procedures for probability of causation determinations have been developed using the best and most current scientific information relating radiation exposures to cancer risks. The use of current recommendations from independent expert bodies lends strength to the approach proposed by NIOSH. The NIOSH approach also implements the spirit of concern for nuclear workers that was inherent in the legislation underlying this compensation program. In this context, the NIOSH guidelines and procedures provide an appropriate application of sound science to the compensation process.

2. The Board also agrees that the proposed NIOSH procedures appropriately allow for the incorporation of new scientific information into the compensation procedures as this new information becomes available. However, given the limited time that the Board has had to review the details of the probability of causation procedures and the potential impact of changes in the NIOSH Interactive RadioEpidemiologic Program (IREP) on compensation decisions, the Board recommends that the regulations be amended to formalize the role of the Board in reviewing any substantial changes in these procedures – that is, the NIOSH IREP. This change should include publication of planned changes in the *Federal Register,* an appropriate opportunity for public comment, and then reviewed by this Board before finalization. Although these actions are included in the Preamble Background, Section III, Subsection I, Paragraph 3 of
42 CFR, Part 81, making them part of the rule itself would formalize the updating process, significantly strengthening assurance that review of revisions will occur.

3. The Board has also noted the differences between the approach being used in this compensation program and that of the Atomic Veterans Act. There are significant differences in the categories of compensation covered by the two acts. In some cases, the Atomic Veterans Act required primarily that the claimants were present in a specific area, had one of the specified cancers, and were therefore compensated. This proposed rule is an effort to address much more complicated situations and to face the reality that simple exposure to radiation does not automatically presume the development of disease. The Board recognizes the excellent efforts of NIOSH staff and their subject matter experts in bringing the best known current science to an appropriate method for translating experience gained in the veterans exposure calculations to this civilian nuclear worker proposal.