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

15th Meeting of the Advisory Board on Radiation and Worker Health

May 1, 2003

Meeting Minutes

This meeting was convened by teleconference. A transcript of the meeting is available from NIOSH by request or from the Web page: $\frac{www.cdc.gov\\niosh\\ocas}$





Attendance

Advisory Board on Radiation and Worker Health

All Board members were in attendance.

Ziemer, Paul L., Ph.D. (Chair) Elliott, Larry J., M.S., CIH (Executive Secretary)

Members:

Anderson, Henry A., M.D.
Andrade, Antonio, Ph.D.
DeHart, Roy Lynch, M.D., M.P.H.
Espinosa, Richard Lee
Gibson, Michael H.
Griffon, Mark A.
Melius, James Malcom, M.D., Ph.D.
Munn, Wanda I.
Owens, Charles L. (via telephone)
Presley, Robert W.
Roessler, Genevieve S., Ph.D.

Federal Attendees

Department of Health and Human Services:

Gaye, Annette Homer, Corrine Homoki-Titus, Liz Katz, Theodore Naimon, David Neton, James Ross, Renee Sundin, David

Department of Labor:

Kotsch, Jeff

Public Attendance

Approximately 10 members of the public attended the teleconference.

Public Comment

Public comments were provided by the following members of the public:

Epifania Jacquez Carmen Gonzales Richard Miller Betty Jean Shinas

Comments addressed the following matters:

- A desire to have Los Alamos added to the Special Exposure Cohort;
- A desire to see quicker claims adjudication for employees of Los Alamos;
- Opposition to a provision of the proposed rule allowing cancer-specific designations of classes of employees;
- The use of worst-case assumptions as an efficiency measure in dose reconstructions;
- Methods of using worst-case assumptions in dose reconstructions;
- Dose reconstruction methods for claimants who are members of the Special Exposure Cohort; and
- Renewal of the Board's charter.

Discussion on Special Exposure Cohort Proposed Rule

Cancer-specific Class Designations

The Board discussed concerns regarding the provisions of the proposed rule addressing cancer-specific class designations (see sections 83.12(b)(1)(iv), 83.12(b)(2)(iii), and 83.12(c)(4)). These provisions would provide NIOSH the option to define a proposed class for addition to the Special Exposure Cohort that would be limited to employees who incur a cancer from a set of one or more types of cancers that would be specified by NIOSH. Board members discussed their individual views on public satisfaction, fairness, congressional intent, and scientific and practical considerations pertaining to these provisions. Also, prior to the meeting, Dr. Ziemer and Dr. Melius each had distributed alternative draft comments relating to these provisions for the Board's consideration.

The Board decided to recommend that the rule not provide for cancer-specific class designations, such that the membership of classes that HHS may add to the Special Exposure Cohort would not be defined with respect to cancer types. Eleven members voted in favor of the motion and 1 member abstained. The approved text of the recommendation was the following:

"Page 11309, Column 1, Section 83.13(b)(1)(iv): This paragraph refers to cases where NIOSH finds that, while it is not feasible to estimate radiation doses, it may be possible to determine that doses are limited to certain specific sites, thus excluding certain other tissue-specific cancer sites from

being considered as part of an SEC class. While the Advisory Board understands that it may be scientifically and theoretically possible for such a situation to exist, the Board is also concerned about meeting the legislative intent of Congress on this matter and in providing some level of equity between the definition of new SEC classes and those already defined in the legislation. Accordingly, the Board recommends that HHS remove sections 83.12 (b)(1)(iv), 83.12 (b)(2)(iii), and 83.12 (c)(4)."

Sufficient Accuracy

The Board discussed provisions of the proposed rule using the term "sufficient accuracy" (see sections 83.13(b)(1), 83.13 (b)(1)(iv) and Section 83.13 (b)(3). Board members discussed their individual views on the need for NIOSH to clarify the concept of sufficient accuracy and to develop guidelines to implement related determinations under the proposed rule. Also, prior to the meeting, Dr. Ziemer and Dr. Melius each had distributed alternative draft comments relating to this provision for the Board's consideration. Dr. Ziemer had also distributed questions and responses related to this provision exchanged by e-mail between a member of the public (Mr. Richard Miller) and a member of the NIOSH staff (Mr. Ted Katz).

The Board decided to recommend that NIOSH develop guidelines after a final rule is promulgated. All 12 members of the Board voted in favor of the motion. The approved text of the recommendation was the following:

"Page 11309, Column 1, Section 83.13 (b)(1)(iv) and Section 83.13 (b)(3): Both of these sections include the concept of "not feasible to estimate doses with sufficient accuracy." The idea of "sufficient accuracy" is not completely clear or obvious. It would be helpful if NIOSH could provide additional clarification of this concept. Accordingly, the Board recommends that NIOSH develop guidelines addressing feasibility and sufficient accuracy. These guidelines should be developed within a reasonable time period after the promulgation of the regulation and should be submitted to the Board for review. Appropriate changes should be made in the regulation to indicate the planned development of these guidelines and the process for their development. Appropriate changes in the dose reconstruction regulations should be made to address any potential conflict between the two sets of regulations that could leave some claimants ineligible for either individual dose reconstruction or special exposure cohort status."

Conclusion

The Board members agreed that the Board had completed its review of the proposed rule.

Adjournment

The meeting adjourned without further discussion of substantive matters.

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

Paul L. Ziemer, Ph.D., Chairperson

8/29/03 Date