



ADVISORY BOARD ON RADIATION AND WORKER HEALTH
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August 22, 2002

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The Honorable Tommy G. Thompson
Secretary, Department of Health and Human Services
200 Independence Avenue
HHH Building, Room 603G
Washington, D.C. 20201

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 issues relevant to the provisions of the Department of Health and Human Services (DHHS) 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 National Institute for Occupational (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, Department 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

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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,

A handwritten signature in black ink, appearing to read "Paul L. Ziemer". The signature is fluid and cursive, with a prominent loop at the end.

**Paul L. Ziemer, Ph.D., CHP
Chairman
Advisory Board on Radiation and Worker Health**

Enclosures (2)

**cc:
Members, Advisory Board on
Radiation and Worker Health**

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 Special Exposure Cohort (SEC) class but who developed a non-SEC listed cancer. The Board recommends that the National Institute for Occupational Safety and Health (NIOSH) carefully review the proposed regulations to ensure that these 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 claimant's dose history is included in a SEC class.

Health Endangerment

The Board members suggest that the proposed rule for determining whether a potential SEC class meets the criterion of "health endangerment" is not adequate. In particular, the proposed method for estimating whether the cohort met the criterion for "health endangerment" is not adequately justified and could lead to arbitrary and unfair decisions. The Board recommends that NIOSH consider other suitable criteria.

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 inclusion in any SEC designation. The Board also recommends that NIOSH develop operational guidelines outlining the criteria, to include time limits, 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

The Board recommends that DHHS consider issuing 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.

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 recommend 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 thorough dose reconstruction performed and have had a claim denied AND 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 use the procedures for designating SEC classes as a route for appealing a decision. This does not preclude appeals as provided for in Department of Labor rules.”

Section 83.5

In item (c), in addition to the parameters specified, it is important to add an additional 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 Atomic Weapons Employers (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 published scientific research report indicating that such historical records are not available for that facility.

Section 83.10

The wording of items (b)(2), (b)(3), and (b)(4), infers the Advisory Board is directly involved at an early stage in processes which should be DHHS (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 adjudicatory 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 DHHS. 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, DHHS 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.