

ADVISORY BOARD ON RADIATION AND WORKER HEALTH

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May 5, 2003

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

Dear Secretary Thompson:

On August 22, 2002, the Advisory Board on Radiation and Worker Health provided comments to you concerning 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*. In response to these comments, as well as comments by other organizations and members of the public, the proposed rule was extensively revised. On March 7, 2003, a new Notice of Proposed Rulemaking was issued for public comment, and the Advisory Board on Radiation and Worker Health is now submitting its comments on the proposed rule as revised.

First, I would like to convey the thanks of the Advisory Board for the responsiveness of the National Institute for Occupational Safety and Health (NIOSH) staff members who prepared the revision. The issues raised by the Board on the first Notice of Proposed Rulemaking were addressed well in the revision.

At its meeting on March 7, 2003, the Advisory Board reviewed the changes that were made in the originally proposed rule, heard comments from members of the general public on the proposed rule, and discussed at length certain provision in the proposed rule. Subsequently, the Advisory Board held three public conference calls (on March 14, March 28, and May 1, 2003) to deliberate further and hear additional public comment. As a result of these meeting and deliberations, the Advisory Board has developed the general and specific comments that are appended to this letter.

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The Advisory Board appreciates the willingness of DHHS and the NIOSH staff to consider these comments in the drafting of the final 42 CFR 83 rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul L. Ziemer". The signature is written in a cursive style with a large, sweeping flourish at the end.

Paul L. Ziemer, Ph.D., CHP

Chairman

Advisory Board on Radiation and Worker Health

Enclosure

Advisory Board on Radiation and Worker Health
May 5, 2003

Comments on 42 CFR Part 83, March 7, 2003: Procedure for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Notice of Proposed Rulemaking; Proposed Rule

1. Page 112296, Column 3, paragraph 2, last sentence: The statement “Hence, it may be appropriate...” is confusing and should be rewritten.
2. Page 11303, Column 1, paragraph 2, sentence 2: Add the word “occupational” after “sufficient” so as to read “If the employee had sufficient occupational radiation exposure outside of his work experience as a member of the Cohort...”
3. Page 11305, Column 2, first line: Replace “this” with “these” so as to read “...collect these data...”
4. Page 11306, Column 3, Section 83.5: Add the definition of “facility” (as found in the regulation); also, provide some clarification of the use of this term for the SEC case. There are actually two definitions of “facility” in the legislation (Subtitle B, Sections 3621 and 3626). The bill references work at a “facility” as necessary for individual eligibility but does not limit “exposure” to a single “facility” either in the dose reconstruction section or the SEC section.

For the purposes of this draft regulation, the Board recommends that “facility” should be considered broadly (e.g., Los Alamos, Rocky Flats). Then the “class” definition would be used to limit the class to those workers who worked in some specific operation(s) at the facility and whose dose could not be reconstructed with sufficient accuracy. If “facility” was defined to refer to specific buildings, etc., NIOSH would have to spend considerable effort developing an inventory of defined “facilities” at each DOE site and would have difficulty considering new SEC classes for workers in operations that might have taken place in more than one building or “facility” at a DOE site.

The Board also recommends that the regulation provide for the possibility of combining SEC facilities (physical locations) for purposes of meeting the 250-day requirement for eligibility as a member of a class.

5. Page 11307, Column 3, Section 83.9 (c)(2)(iii): Reword this section in order to provide more clarity as follows: “A report from a health physicist or other individual with expertise in dose reconstruction describing the limitations of DOE or AWE records on radiation exposures at the facility, as relevant to the petition. This report should specify the basis for believing the stated limitations might prevent the completion of dose reconstructions for members of the class under 42CFR Part 82 and related NIOSH technical implementation guidelines; or”

6. Page 11307, Column 3, Section 83.9 (c)(2)(iv): Reword this section in order to provide more clarity as follows: "A scientific or technical report published or issued by a governmental agency or published in a peer-reviewed journal that identifies dosimetry and related information and that is unavailable ..." Delete the last part of the sentence beginning with the phrase "and also finds..."
7. Page 11307, Column 3, Section 83.9 (3) through the top of page 11308: This portion of the section deals with exposure incidents and describes a process for evaluating the information required for such incidents in the event that "NIOSH is unable to obtain records or confirmation..." of the incident. The Board recommends that NIOSH consider where the placement of this part of the section should be within the rule, since it refers to information required after the petition has been evaluated by NIOSH. As presently located, this portion could be confusing to the petitioner.
8. Page 11308, Columns 2-3, Section 83.9 (3) (i) and (ii): These paragraphs require either medical information or witness affidavits in the event that the exposure incident cannot be confirmed. For the requirement that two employees who witnessed the incident submit affidavits, the Board recommends that the petitioner be counted as one of these two witnesses if the petitioner was an individual employee who witnessed the incident..

The Board is also concerned that a petitioner may have difficulty finding witnesses for an exposure incident that occurred many years ago. Witnesses may no longer be living or may be difficult to identify or locate. In such cases, the Board recommends that NIOSH offer the option for other parties to submit confirmation of the incident in the absence of available eye witnesses or records.

9. Page 11308, Column 1, Section 83.11 (b): The Board is concerned that there is no further appeal process for petitions that do not satisfy the relevant requirements. Accordingly, the Board recommends that NIOSH explore possible appeal mechanisms within the DHHS for such cases.
10. Page 11308, Column 3, Section 83.13 (b)(1) (iii): For clarity, it is suggested that the first sentence of this paragraph be reworded as follows: "In general, access to personal dosimetry and area monitoring data is not a defining factor that must be available to estimate the maximum radiation doses that could have been incurred by any member of the class."
11. 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 Advisory Board recommends that the Department of Health and Human Services remove the provision to limit the cancers eligible for compensation for a particular class being considered for special cohort status, and modify this paragraph accordingly.

12. Page 11309, Column 2, Section 83.13 (b)(2)(iii): The same issue concerning tissue-specific sites, as outlined in item 11 above, arises in this paragraph. Hence, the same comments by the Board apply here as well.
13. 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. Therefore, the Advisory Board recommends that guidelines addressing feasibility and sufficient accuracy be developed. These guidelines should be developed by NIOSH 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 process for their development. Appropriate changes in the dose reconstruction regulations should be made to address any potential conflict between this Rule and 42 CFR 82 that could leave some claimants ineligible for either individual dose reconstruction or special cohort status.