February 28, 2002

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:

The Advisory Board on Radiation and Worker Health held its second meeting on February 13 and 14, 2002, in Washington, D.C. Nine of the ten currently appointed members were present as well as the designated Federal Official who serves as Executive Secretary. The sessions were open to the public in accordance with Federal Advisory Committee Act 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.

The primary focus of the meeting was the proposed rule-making in 42 CFR, Part 82 (Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000). In preparation for the meeting, the Board members individually reviewed the Draft Interim Rule as well as Draft Implementation Guidelines for Internal Dose Reconstruction and External Dose Reconstruction. At the Board sessions, formal presentations were provided by National Institute for Occupational Safety and Health staff members on these and related issues. In addition, comments were provided by some of the 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 82. These recommendations are summarized in Enclosure 1.

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

Sincerely,

[Signature]

Paul L. Ziener, Ph.D., C.H.P.
Chairman

Enclosures (2)

cc:
Members of the Advisory Board on Radiation and Worker Health
Enclosure 1

Recommendations and Comments from the Advisory Board or Radiation and Worker Health

The following comprise recommendations and comments from the Advisory Board in the context of response to the three major questions found in Section I of the Preamble to the proposed rule, 42 CFR, Part 82:

Interim proposed rule 42 CFR, Part 82, makes appropriate use of current science in reconstruction of radiation dose scenarios to the extent practicable. The Board recognizes that if the efficient and expeditious consideration of claims is to be made, absolute precision is not possible. The methods proposed are intended to result in dose estimates favorable to the claimants and are appropriate to the occupational illness compensation program envision by the Energy Employees Occupational Illness Compensation Program Act (EEOICPA).

The process for involving the claimant is fair and provides multiple opportunities for interaction with the involved agencies. Indeed, in cases where acceptably dependable personal exposure data do not exist, the National Institute for Occupational Safety and Health (NIOSH) will utilize other sources of information as the basis for dose reconstruction. This approach unavoidably introduces additional uncertainty into the calculation of dose. However, we view the proposed methods as being appropriate for the available information. There will be circumstances where NIOSH will not be able to estimate the dose with sufficient accuracy. Those circumstances need to be clarified in the implementation of the regulation and in the Board’s review of NIOSH’s dose reconstruction work. Groups whose exposure cannot be estimated with sufficient accuracy may be candidates for the Special Exposure Cohort.

In addition to the recommendations relating to the questions set forth in Section I of the Preamble, the Board has the following specific comments and recommendations:

1. The Advisory Board recommends that Section K of Part III, “background” concerning changes to scientific elements underlying the dose reconstruction process be moved to the main body of the Rule so as to formalize the updating process including the role of the Advisory Board. The rule does an admirable job of providing an objective process for conducting dose reconstruction. However, the assessment of the adequacy of the exposure information will involve professional judgment, and thus, some subjectivity. The Board plays an important role through its review of such decisions on dose reconstructions, and that role needs to be included in the main body of the Rule. Although this role is included in the Preamble “Background” (Section III, Subsection K) of 42 CFR, Part 82, making it part of the rule itself would formalize the change process, significantly strengthening assurance that review by the Advisory Board of proposed changes will occur.
2. The Advisory Board requests that the term “validated”, as used in Section 82.10 (j), be either defined or clarified.

3. The Advisory Board recommends that NIOSH clarify 82.10 (m), (n), and (o) in regards to the steps and timeline required for the claimants, or authorized representatives of the claimants, to provide information to NIOSH and to sign or submit form ‘OCAS-1’. NIOSH should ensure that the claimants, or authorized representatives of the claimants, have adequate time to obtain and submit additional information to NIOSH.

4. The Advisory Board recommends that Section 82.18, concerning the use of International Commission on Radiological Protection (ICRP) models, be clarified so as to clearly indicate that NIOSH intends to use current ICRP models.

5. The Advisory Board recommends that the last sentence in Section 82.28 (b), be clarified in regards to the coverage of the Privacy Act.
DRAFT AGENDA
Advisory Board on Radiation and Worker Health
Washington Court Hotel
525 New Jersey Avenue, N.W.
Washington, D.C. 20001
(202) 628-2100
February 13-14, 2002

February 13, 2002

8:30 a.m. - 9:00 a.m. Registration and Welcome Dr. Paul Ziemer, Chair
                 Mr. Larry Elliott, Executive Secretary
9:00 a.m. - 9:45 a.m. Program Report Mr. Larry Elliott, Executive Secretary
9:45 a.m. - 10:00 a.m. Break
10:00 a.m. - 11:00 a.m. Recap of Advisory Board Comments on Probability Of Causation Rule (42 CFR Part 81)
                 Mr. Larry Elliott, Executive Secretary
11:00 a.m. - 12:00 p.m. Status of Rule Promulgation Russ Henshaw, NIOSH
                 (42 CFR Part 81)
12:00 p.m. - 1:00 p.m. Lunch
1:00 p.m. - 2:30 P.M. Status of Rule on Dose Jim Neton, NIOSH
                 Reconstruction (42 CFR Part 82)
2:30 p.m. - 2:45 p.m. Break
2:45 p.m. - 3:45 p.m. Board Discussion
3:45 p.m. - 5:00 p.m. Public Comment Period
5:00 p.m. Adjourn

***Agenda items are subject to change as priorities dictate***
February 14, 2002

8:30 a.m. - 9:00 a.m.  Registration and Welcome  Dr. Paul Ziemer, Chair
                      Mr. Larry Elliott, Executive Secretary

9:00 a.m. - 9:15 a.m.  Administrative Housekeeping  Ms. Cori Homer, NIOSH

9:15 a.m. - 10:15 a.m. Special Exposure Cohort  Ted Katz, NIOSH
                       Petitioning Process

10:15 a.m. - 10:30 a.m. Break

10:30 a.m. - 11:30 a.m. Board Work Schedule  Mr. Larry Elliott, Executive Secretary
                         Ms. Cori Homer, NIOSH

11:30 a.m. - 11:45 a.m. Public Comment Period

11:45 a.m. - 1:00 p.m.  Lunch

1:00 p.m. - 2:00 p.m.  Board Working Session

2:00 p.m. - 3:00 p.m.  Board Discussion

3:00 p.m. - 4:00 p.m.  Public Comment Period

4:00 p.m.  Adjourn

**** Agenda items are subject to change as priorities dictate. ****