Attached are the DOE Office of Environment, Safety and Health comments on subject interim final rule; hard copy will follow.

(See attached file: 42cfr82comments-email.wpd)
National Institute of Occupational Safety and Health
Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, Ohio 45226

Dear NIOSH Docket Officer:

This is in response to the October 5, 2001, Federal Register notification of the interim final rule with a request for comments. Enclosed are the Department of Energy, Office of Environment, Safety and Health, comments on interim final rule, Title 42 of the Code of Federal Regulations, Part 82, Methods for Radiation Dose Reconstruction under the Energy Employee Occupational Illness Compensation Program Act of 2000.

Sincerely,

Steven V. Cary
Acting Assistant Secretary
Office of Environment, Safety and Health

Enclosure
III. Background
E. How is Dose Reconstruction Conducted

1. The National Institute of Occupational Safety and Health (NIOSH) dose reconstruction methodology codifies an approach to dose reconstruction that differs from the current system of radiation protection used in the United States. The draft NIOSH approach uses International Commission on Radiological Protection recommendations that have not been adopted in the United States, it proposes to estimate doses that cannot be measured by current available technology, and it uses models for estimating the incidence of radiation induced cancers that have not yet been incorporated into the currently accepted system for control of radiation exposure.

While we support use of the latest scientific base for estimating the radiation dose and the resulting “probability of causation,” we feel that the approach to dose reconstruction and probability of causation, as specified in 42 CFR parts 81 and 82, unintentionally creates the impression that the current system may not adequately protect radiological workers in the United States.

Rather than stating that the approach is well grounded in the best available science, the language needs to state more clearly that a very conservative approach is being taken in assessing the potential doses. This conservative approach will minimize the possibility that a claimant will be wrongfully denied compensation. The program is set up such that any claimant whose cancer had a reasonable potential to have been caused by occupational exposure to radiation will be compensated.

2. The rule needs to determine if any occupational radiation exposures occurred while not employed by DOE, a DOE contractor, or an atomic weapons employee (AWE). This change is needed to properly determine the probability that radiation caused a cancer and then to determine the assigned share of that probability. For example, the dose received by an “atomic veteran” while in the service may be too low, by itself, to earn compensation. When added to subsequent DOE dose, it may qualify for compensation. Likewise, large exposures from nongovernment activities need to be accounted for appropriately in determining the assigned share. The rule should clearly describe how dose incurred while not a covered employee will be treated.
3. The rule needs specifically to address the situation where an individual has a dose of record for the organ/tissue of interest from DOE that is higher than that calculated by NIOSH using newer models. This is especially critical for situations where the DOE dose of record would qualify for compensation and the NIOSH calculated dose would not. It is recommended that the DOE dose of record be used in these situations.

Specific Comments

III. B, paragraph 3: Provide a citation for the agreement under which it was determined that the Department of Health and Human Services (HHS) would inform covered employees of the results of dose reconstructions on behalf of DOE. This same comment applies to section 82.3(b).

III. D, paragraph 2: Specific technical details of how complex dose reconstructions issues will be determined, and assumptions made, should be provided.

III. G: The use of new biokinetic models for mathematically describing the uptake, transport, and retention of radionuclides in the body is discussed. This part should also discuss the approach for mathematically describing the uptake, transport, and retention of radionuclides in specific organs/tissues/parts of body for which there is no accepted modeling (i.e., nervous system, salivary glands etc.).

IX, table: DOE contractors and AWEs should be added to the number of respondents as well as the number of hours they will require to provide NIOSH with the information needed to reconstruct doses.

42 CFR 82.2 and 82.3: The language in these sections is somewhat conflicting and makes it appear that there are no instances in which a dose reconstruction will not be performed, even if monitoring data, as described in paragraph (a) of section 82.2, is adequate. These sections should be combined and the situation described in 30 CFR 30.115(b) should be explained so it is clear that the requirement for dose reconstruction by HHS may be waived when “there is clear evidence showing a sufficient level of radiation exposure to qualify a claimant for benefits.” This would be the case when the claimant’s “dose of record” provided by DOE is at a level that would result in an award. Also, some of the language that appears in section III. F. might be helpful here.

42 CFR 82-10: Many claimants will be survivors of a covered employee. Section 82.10 should explain that several paragraphs of this section might not apply to survivors who are filing claims. For example, paragraph (c) of section 82.10 details the extensive interview NIOSH plans to use to obtain all types of information but does not explain if such information is expected of survivors who are filing claims.
42 CFR 82.10, table 1: The radiation weighting factor for high energy neutrons is 20. Current radiation protection standards in the United States use a value of 10. In the introductory text, it states that HHS will take an approach similar to that of the Defense Threat Reduction Agency (DTRA). The DTRA does not use the newer neutron weighting factor of 20. They would need additional review to validate the acceptability of using the newer value. The HHS approach differs from the DTRA, and it should be consistent.

42 CFR 82.10(l): Add to this section that the draft of the dose reconstruction report will also be sent to DOE for review and for any additional information that would enhance the dose estimation.

42 CFR 82.16: A NIOSH publication is referenced (National Technical Information Service (NTIS)-PB 95189601). This publication is not available from the NIOSH publication website and must be purchased from NTIS. DOE recommends that NIOSH make this publication available on their website.

42 CFR 82.19: The uncertainty associated with each estimate of annual dose for each organ will be larger than the uncertainty of the dose for a longer period of time. This section, and others that mention annual doses, should allow for the use of doses estimated for the total time from first exposure to date of diagnosis when determining the total uncertainty.