

Miller, Diane M.

From: mike schaeffer ;
Sent: Wednesday, December 05, 2001 7:21 PM
To: NIOCINDOCKET@CDC.GOV
Cc: dennis.schaeffer@dtra.mil
Subject: Comments on 42 CFR part 81 from Deapartment of Defense



PCcomment.doc

Attached is a corrected copy of the comments provide by Department of Defense on 12/4/01. Please substitute the attached corrected copy for the for the comments provided earlier. Pls confirm timely receipt.

Physicist
Program

D. Michael Schaeffer
Program Manager/Senior Health
Nuclear Test Personnel Review

Technology Development Directorate
Defense Threat Reduction Agency
6801 Telegraph Road
Alexandria, VA 22310-3398
(703) 325-2407
fax (703) 325-2954

COMMENTS PROVIDED BY DEPARTMENT OF DEFENSE ON THE PROPOSED
RULEMAKING UNDER 42 CFR PART 81 - GUIDELINES FOR DETERMINING THE
PROBABILITY OF CAUSATION UNDER THE EEOICPA ACT OF 2000

1. The National Institute of Occupational Safety and Health (NIOSH) plans to implement a modified version of the Interactive Radio-Epidemiological Program (IREP) to calculate PC. The IREP acts as a "black box", where details of the program, the assumptions it makes, and the biases it uses are hidden from the user. This lack of detail prevents proper evaluation of the PC. The NIOSH-IREP software should be revised to output the bases for a calculated PC and the associated data.

2. NIOSH intends to modify IREP to account for different relative biological effectiveness distributions according to neutron doses of various energies. It is not evident how energy correction will occur based solely on exposure records and without an understanding of the source.

3. The proposed rule makes a note several times throughout the register that non-radiogenic cancers are to be included in the proposed guidelines. As a National Research Council (2000) report notes (commenting on the National Cancer Institute Working Group's efforts to update the 1985 Radioepidemiological Tables), for cancers lacking documentation of a specific dose-response pattern, compensation may be awarded under dubious conditions of causation while a scientifically stronger case with narrower confidence would fail to award.

4. The inclusion of dose from medical radiographs that are performed as a condition of employment in PC calculations should not be performed. The American College of Radiology has stated that radio-epidemiological tables should not be applied to cases involving medical irradiation. Additionally, if radiograph procedures were prescribed to diagnose or screen for a disease, they represent a positive benefit-risk judgement for the patient.

5. The proposed rulemaking requires the Department of Labor to include benign neoplasms and carcinoma *in situ* to be malignant for the purposes of calculating a PC. These conditions can be attributed to many more causes than are covered by IREP.

6. The proposed rulemaking states that changes to the NIOSH-IREP can be made in the future at NIOSH's discretion. The rule should state that revisions to the NIOSH-IREP should be put

out for public comment. The revision should be based on peer-reviewed studies that have the support of the scientific community.

7. The proposed rulemaking states that determination of whether a cancer was "at least as likely as not" (probability of causation (PC) of 0.5) caused by a radiation dose is based on an upper 99 percent "confidence interval". This scheme in effect means that the doses qualifying a person for a claim could in some cases be up to an order of magnitude less than the doses corresponding to the actual PC value of 0.5. The rule needs to recognize that the actual compensation decision threshold based on this confidence interval is much in the claimant's favor. A graphical depiction of the actual scheme used to make a claims decision should be provided in the final rule.

8. The rulemaking proposes to use uncertainty analysis for PC estimates, taking into account the uncertainties in the distribution of PC at 0.5 and in the individual measurements of dose. The rulemaking does not describe the methodology for how these sources of uncertainty interact or are taken into account in the process of computing the PC. The rulemaking should include a discussion of the methodology used to combine the sources of uncertainty and how they influence the PC estimate. The IREP software does not provide a detailed understanding of how the various sources uncertainties are handled.