

**Miller, Diane M.**

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**From:** kenneth.crase@srs.gov  
**Sent:** Tuesday, December 04, 2001 4:09 PM  
**To:** niocindocket@cdc.gov  
**Cc:** karent.brown@srs.gov  
**Subject:** Comments on 42 CFR 81 and 82

I have attached comments on the two federal rules HHS has promulgated for use in the EEOICPA of 2000. These email comments will likely be included in a formal organizational comment letter to NIOSH, but are being sent informally for your agencies use in compiling and utilizing comments that may prove useful to the effort to consistently evaluate claims of radiation association with illnesses of radiation workers.

In general, I applaud the extent of effort NIOSH has already gone to in order to establish programs to do a difficult task. It is my hope these comments will be of some benefit to your effort.

Ken Crase

**Comments on Draft 42 CFR 81, Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Notice of Proposed Rulemaking**

1. The IREP software planned for use in calculating Probability of Causation has only been available for independent evaluation a few weeks, and may yet have additional modifications. Insufficient review time prior to the comments deadline will not allow independent review of the scientific merit and correctness of the software and techniques employed.
2. Preliminary test runs (primarily for leukemia) appear to give higher Probability of Causation than the same test runs did for the 1985 NCI tables, and yet there has been no significant change in the leukemia experience data in the interim. Some of the change can be attributed to use of more recent ICRP recommendations for dosimetric methodologies. A scientific workshop may provide the most efficient scientific feedback mechanism to evaluate and validate the efficacy of the IREP software, and is recommended prior to issuance of the Final Rule.

**Comments on Draft 42 CFR 82, Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Interim Final Rule With Request for Comments**

1. Organizations that monitor workers at Department of Energy (DOE) sites are currently required (by 10 CFR 835) to utilize recommendations of the International Commission on Radiological Protection (ICRP) in Reports 26 & 30, but not the later recommendations planned for use in 42 CFR 82 (Reports 60 and above). Use of different scientific models will result in some differences in dose for some cases of intakes of radionuclides. Other differences may occur as a result of actions NIOSH may take to estimate doses not recorded as part of the dose of record for an individual. The Interim Final Rule should address how such differences will be communicated to claimants, to minimize the degree of confusion and concern claimants may have over differences in dose from their previously communicated dose of record.
2. While the Interim Final Rule and the activities NIOSH has initiated this year give every indication that a thorough effort will be utilized to reconstruct doses in a consistent manner, the level of technical detail provided in Sections 10, 13, 14, 15, 16, 17, and 18 is insufficient to allow an independent evaluation of the still emerging techniques. The Final Rule should provide enough technical detail to enable an independent review of techniques to be used for reconstructing doses under the Act.

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