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From:

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Sent:

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To:

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Cc: Subject: Andrea Jones; Cheryl Trottier Comments on 42 CFR Part 82



In response to the October 5, 2001, Federal Register Notice requesting comments on the Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Interim Final Rule with Request for Comments, several comments are provided as an attachment to this message. These comments also will be mailed to the NIOSH Docket Office located in Cincinnati, OH.

It is my hope that these comments will be of assistance to you and your staff. If additional information is desired, please contact me at (301) 415-8715 or via e-mail at evh@nrc.gov.

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42 CFR Part 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. Page 50979, column 3, para 1; Delete first full sentence. Why should NIOSH notify claimants on behalf of DOE? Claimants should have a single, coordinated point of contact for correspondence regarding their claim for worker compensation. Currently, the Office of Worker Advocacy (EH-8), NIOSH (OCSA), a Physicians Panel (HHS) and DOL's Office of Workers' Compensation Programs all appear to have roles in the EEOICPA program.
- 2. Page 50979, column 3, Section D How Are Radiation Doses Reconstructed?; Delete sentences 2 and 3. The Act does not require all claimants to receive dose reconstruction. Rather, dose reconstruction is directed for those claimants who (1) were not monitored, (2) were monitored inadequately, or (3) if the claimants exposure records are missing or incomplete. Is it NIOSH's contention that none of the 600,000 former workers were adequately or completely monitored? In later sections of the FRN, NIOSH proposes alternative methods to a full dose reconstruction in order to provide timely compensation to claimants that qualify and deny claims when it is unlikely occupational exposure to radiation induced cancer. For reasons to be stated, this approach is unadvisable. Rather, limit dose reconstruction to those instances cited above and not for all claimants.
- 3. Page 50980, column 2, section F, para 2; Comment. Efficiency in establishing a reconstructed dose may not be prudent. For those claimants that NIOSH determines would not benefit because it is unlikely to produce a compensable level of radiation dose, rejection of a claim undoubtedly will be appealed. Claims will not be awarded on point estimates of the probability of causation. Rather, a majority of claims will be awarded to individuals with large uncertainties in dose reconstruction and uncertainty correlations between radiation exposure and carcinogenesis for certain cancer types. Consequently, NIOSH should consider the impact of full dose reconstruction for all requesting claimants.
- 4. Page 50980, column 3, section G, para 1; Comment. Coordination with other Federal agencies regarding the biokinetic models used for calculating internal dose is recommended. Recommendations by the International Commission on Radiological Protection are not binding on any country. In fact, many for the exposure recommendations and models proposed since 1990 have not been adopted by most Federal agencies to include DOE. Consequently, all internal estimates of exposure to radionuclides will need to be re-evaluated if ICRP 66+ methodologies are employed. In most cases, the committed effective dose equivalents calculated by NIOSH using ICRP 66+ methodologies will yield lower doses, some by 1 or 2 orders of magnitude due to changes in absorption and dose coefficients (e.g., Sr, U, Th). How will NIOSH respond to a denied claimant who wants information from his official dosimetric records used rather than NIOSH reconstructed values?
- 5. Page 50981, column 3, para 1; Replace "used by DOL" with "used by HHS appointed physicians panels"
- 6. Page 50982, column 1, para 3; Comment. The reconstruction of a claimant's exposure will become an official document. As such, a claimant under the Freedom of Information Act may request copies for the purpose of future litigation against the Federal Government and its current and former contractors. Consequently, NIOSH is obligated to conduct a thorough dose reconstruction, regardless of whether or not an award will be made.

- 7. Page 50982, column 1, para 4; Comment. NIOSH is not responsible for assessing probability of causation. Rather, this responsibility belongs to the HHS appointed physicians panels. It would be presumptive for NIOSH not to prepare a full dose reconstruction for use by the panel because they believe the claimants cumulative occupational exposure isn't great enough to exceed 50%. Also, see comment 3 above.
- 8. Page 50984, column 1, para 1. What is the basis for estimating several thousand dollars for each dose reconstruction? This may be significantly underestimated. At \$100/hour, this may be less than twenty hours of staff time for each estimate (assuming no other expenses). Upwards of twenty hours of staff time could be required to pull occupational exposure records and verify the claimants occupational work history alone. Dose reconstruction costs associated with Veterans Affairs claims would not be valid because of the multiple/continuous exposure of workers to radiation during the course of their employment with the DOE or its contractor(s).
- 9. Page 50984, column 3, para 1. At what point will NIOSH review the Department of Labor form EE-3, Employment History for Claim Under Energy Employees Occupational Illness Compensation Program Act? The claimant is required to provide their identify and a complete employment history to include dates of employment, location of employment, position titles and descriptions of work performed, information regarding dosimetry badges worn, etc.
- 10. Page 50984, column 3, para 4. The estimated burden table does not include the follow-up interview with each claimant to explain the results of the dose reconstruction. Similarly, the number of respondents is grossly underestimated. DOL expects 43,130 claims per year from former workers and 28,760 claims per year from survivors. Of the 600,000 former workers, as many as 200,000 will develop cancer; 150,000 of these cancers will be fatal (based upon normal cancer incidence without occupational exposure to radiation). Hypothetically, each of these workers or their survivors could submit a claim and under NIOSH's proposed rule, they are committing the Institute to conducting dose reconstructions on each of these cases. Hence, the total respondent burden may be underestimated by a factor of 10 and the cost to NIOSH may easily exceed several \$100's million for dose reconstruction.
- 11. Page 82987, §82.10(a); delete "including exposures from medical screening x rays that were required as a condition of employment." Rationale Routine medical screening with x-rays should not be included in the dose reconstruction. Medical exposures are usually intended to provide a direct benefit to the exposed individual. If the practice is justified and the protection optimized, the dose in the patient will be as low as is compatible with the medical purposes (ICRP 60, Para 180). If medical exposures are included in the dose reconstruction, the impact of all medical exposures to radiation, diagnostic and therapeutic, should be evaluated as well since these exposures also can induce cancer, but should be non-compensatory under the Act.
- 12. Page 82988, §82.10(j), last sentence: Revise to read "The equivalent dose(s) will be calculated using radiation weighting factors recommended by the International Commission on Radiological Protection." If NIOSH specifies ICRP 60, this precludes using any revisions subsequent to Report 60 without going through a new rulemaking. By deleting Table 1 and revising the sentence, as suggested, NIOSH retains the flexibility to use future ICRP recommendations without having to undergo extensive regulatory change.
- 13. Page 82988, §82.10(k); delete all. For reasons outlined previously, full dose

reconstruction should be undertaken for all claimants referred to NIOSH by DOL. The reconstructed dose will be an official document that should be as complete as possible because it may be used in future litigation. Failure to complete a full dose reconstruction may be grounds for appeal by a previously denied claimant.

- 14. Page 50989, §82.11; Revise section to comply with the Act. The Act does not require all claimants to receive dose reconstruction. Rather, dose reconstruction is directed for those claimants who (1) were not monitored, (2) were monitored inadequately, or (3) if the claimants exposure records are missing or incomplete.
- 15. Page 50989, §82.13(a); Delete. As previously stated (comment 11), routine medical screening with x-rays should not be included in the dose reconstruction. Medical exposures are usually intended to provide a direct benefit to the exposed individual. If medical exposures are included in the dose reconstruction, the impact of all medical exposures to radiation, diagnostic and therapeutic, should be evaluated as well since these exposures also can induce cancer, but should be non-compensatory under the Act.
- 16. Page 50989, §82.14(e); For many claimants, residential exposure to radon may be greater than occupational exposures. How will these exposures be reflected in the claimant's evaluation and later assessment of probability of causation?
- 17. Page 50989, §82.15(a); How does NIOSH propose to resolve differences in completeness, adequacy, and/or accuracy of exposure information from the comparisons listed? Will one source of information be weighted over another?
- 18. Page 50990, §82.16(a), last sentence; Revise to read: "For monitoring periods where external dosimetry data are missing from the records, NIOSH will estimate a claimants dose based on monitoring data on other workers engaged in similar tasks in the same work area. If this information is not available, a claimant's dose will be based on interpolation using available monitoring results from other time periods close to the period in question. Rationale: 10 CFR Part 835.402 Individual monitoring -- (a) For the purpose of monitoring individual exposures to external radiation, personnel dosimeters shall be provided to and used by: (1) Radiological workers who, under typical conditions, are likely to receive one or more of the following: (i) An effective dose equivalent to the whole body of 0.1 rem (0.001 sievert) or more in a year. Hence, those individuals who would not typically receive 100 mrem per year or more, would not be individually monitored at a DOE facility. Hence, the next best estimate of radiation exposure, if any, would be from other workers, engaged in similar tasks in the same work area at the same period of time.
- 19. General comment. NIOSH proposes to use the latest recommendations and models of the ICRP. However, the DOE dosimetry program is not implementing these recommendations. For example, tissue weighting factors are based upon ICRP 26 (1977), not ICRP 60. Similarly, 10 CFR 835 dictates the radiation weighting factors that must be used to calculate internal and external dose equivalent, and these factors are not consistent with ICRP 60. If DOE were to change their regulations to incorporate the newer values, rulemaking to revise Part 835 would be required. This activity could take years. NIOSH must consider the impact of using dose conversion or weighting factors that have not been adopted by other Federal agencies. NIOSH generated doses will not agree with Department records. In some cases, the NIOSH doses may be lower than official Department records. What is the possibility these differences could lead to litigation if claims are denied? Additionally, it would be prudent if NIOSH did not codify

those weighting factors it wishes to use. If ICRP's recommended values ever change, NIOSH will not be able to use the new values without undertaking a new round of rulemaking and consideration of public comment on the future changes. Finally, NIOSH should consider degree of uncertainty would be associated with a hypothetical worker would received up to but no more that 100 to 500 mrem per year at a "typical" DOE facility for an average career span. Next, NIOSH should calculate the probability of causation for this exposure history and its attending uncertainties of a series of radiogenic and nonradiogenic cancers for male and female claimants. Are there situations in which workers could demonstrate at the 99% confidence level a probability of causation of 50%? What implications does this assessment have on Federal Guidance for Members of the Public?