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Sent: Thursday, November 01, 2001 10:55 AM
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Subject: Comments on 42 CFR Part 82

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NIOSH Docket Officer, attached are Defense Threat Reduction Agency/Department of Defense comments collected thus far on the proposed EEIOCPA Rules published in the Federal Register on 5 October 2001, pgs 50978ff. <<EEOICPA.doc>>

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Defense Threat Reduction Agency (DTRA)/Department of Defense (DoD) Comments on Proposed Rules Being Issued under 42 CFR Part 82, Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000

A. General Comments:

It appears NIOSH has developed the dose reconstruction program for the EEOICPA on the premise of only supporting compensation decisions. In section III. E. of the rule, the discussion about balancing efficiency and accuracy makes it clear that reconstructed doses likely would not be suitable for future epidemiological study, given the need to have a dataset of consistently constructed and accurate doses with ranges of uncertainty. If the rule were intended to provide doses to serve both purposes, then the principles for efficiency would have to be abandoned to assure consistency. The rule should clarify NIOSH's purpose in building a dataset of doses and the attendant limitations if compensation is the prevailing purpose.

In section III. F. in the discussion of differences between veterans' and NIOSH's dose reconstruction programs, complexity is mentioned as a distinguishing difference along with worker experiences. While we agree that work experience in a long term occupational setting is a significant difference, complexity is not. Certainly, a veteran with participation over 10 nuclear test operations, each involving different provisional radiation safety organizations and evolving dosimetry monitoring science and practices presents both a challenging, diverse, and complex situation. Complexity is not a distinguishing factor between the programs.

In section III. F., NIOSH discusses the degree of intended interaction with claimants during the information-gathering phase to be a principal difference in comparison to the veterans' program. We believe that differences, if any, are small and that fact should be reflected in the rulemaking. After receiving the dose reconstruction, a veteran may have iterative contacts with both DTRA and VA to resolve questions, issues, and differences of opinion. Unlike the NIOSH process, there is no prescribed limit to the number of iterations or appeals.

The essential difference between the veterans' and NIOSH programs is knowing the probability of causation (PC) threshold value needed for compensation before the dose reconstruction is completed. NIOSH's program ties the PC and dose reconstruction process together. Although this tie-in is required in order to promote efficiency for dose reconstruction, it will run the risk of increasing ill public opinion about NIOSH's efforts. Knowing the PC value required for compensation will create the impression that the organization performing the dose reconstruction will be influenced to construct a low-sided dose to deny claimants compensation. The veterans' program has frequently received this criticism from its claimants even though dose reconstructions are completed by DTRA and then provided to the Department of Veterans Affairs (VA) for application of the PC method. We stress that each process is performed independently of the other and by two federal agencies that do not interact on the processes. NIOSH should segregate the processes to

ensure the public will not lose confidence in the objectivity of the NIOSH program from its inception.

B. Specific Comments:

Paragraph III. B: There needs to be some description of specific factors that the Board will use in conducting a verification of a dose reconstruction sample. For example, will the Board be focused on methodology itself, its proper application, completeness of historical documents and related research, or currency of scientific knowledge, or all of the above factors? This part of the NIOSH process is crucial to gaining and maintaining public confidence. There should be more detail and attention given to the verification process in the description of the NIOSH program.

Paragraph 82.12: There should be examples given of circumstances for which doses cannot be reconstructed. The minimum factors necessary for reconstructing a dose should be determined and made evident for the NIOSH program.

Paragraph 82.2(a): There needs to be some discussion of how to evaluate the adequacy of dosimetric data, concentrating for example on film badge emulsion damage, TLD glow curve anomalies, imprecise bioassay results at low levels of detection, and possible falsification, inadvertent mistranscription, or calculational errors involving dosimetric raw data.

Paragraph 82.5(e)(1): It would be helpful to also detail who is not in the covered population, i.e. DoD atmospheric nuclear test workers, both military and civilian, DoD workers in other specified radiation occupations, medical caregivers involved in diagnostic radiation procedures. Otherwise, workers other than in the described population for the NIOSH will apply needlessly for EEIOCPA benefits because it was not clear to potential claimants that they do not fall under the programs. One exclusion is noted in the paragraph for the Naval Reactors program. A more extensive list of excluded program would minimize the number of extraneous claims being filed and sent to NIOSH for research.

Paragraph 82.10: We do not understand why exposures from medical procedures are being covered under the NIOSH program. This proposed practice sets a precedent that radiation exposures from routine, publicly accepted medical practices are compensable. If medical procedure exposures are being quantified for the purposes of taking into account confounding or contributing factors in assessing the connection between the occupational exposure only and claimed disease, then a clarifying statement to that effect should be added.

Paragraph 82.10(h) and 82.15: There need to be criteria added for judging the adequacy and completeness of the data and records. Having these criteria specified will enhance the claimant's confidence that a thorough search and analysis of the data and records were performed to support the dose reconstruction. Also, the criteria should detail how differences noted within document sources and data discrepancies are resolved as well as between personal recollections and accounts by other workers, and available documents and data records. There should be stepwise process for claimant to resolve differences in what the

claimant perceives the records and data to mean and how they are used in the dose reconstruction.

Paragraph 82.10(k)(1): The dose reconstruction process needs to be segregated and isolated from the PC application process. Otherwise, the claimant will be left with the belief that doses are purposely reconstructed to be under the value needed for a claim award so as to minimize the Government's chances of having to pay a claim.

Paragraph 82.10(m) and 82.25: Measures should be described for handling a claimant who will not sign off on the dose reconstruction. Like the veterans' program, NIOSH should elaborate on procedures for evaluating a dose reconstruction performed by a qualified expert party engaged by the claimant to counter the Government prepared dose reconstruction. Further, the procedures should include a mechanism for resolving or reconciling significant differences in the two reconstructions and defining the final end point in the process.

Paragraph 82.14: The implication is the sources of information are bounded by the listing in this paragraph. For example, there could be information pertinent to dose reconstruction beyond the list in this paragraph. There should be a general provision for allowing other available information and historical documents relevant to exposure circumstances to be taken into account.

Paragraph 82.18: There should be provisions for allowing or disallowing or for deciding the relevancy of the results from a recently taken bioassay sample in the dose reconstruction process. As for the veterans' program, it should be pointed out that, even if air sampling data are non-existent, an air concentration for internal dose deposition could possibly be derived. Knowing the source term and isotopic content of the source term, an external dose can be reconstructed from the contribution of the derived air concentration and then normalized to results of available external dosimetry. In turn, the derived air concentration, after the normalization, can be used to reconstruct the internal dose component. This process, used for the veterans' program, should also be included in the NIOSH program.

Paragraph 82.26: There should be clarification to the claimant that signing off on the NIOSH prepared dose reconstruction does not imply agreement, only that all known and available sources of information between the claimant and Government were collected. There should be provisions for the situation when the claimant refuses to sign off on the reconstruction no matter what the conditions are.

Paragraph 82.27: There needs to be a detailed description of the review process, including what body or organization conducts the review, the professional background of individuals concerned with the review, and the expected outcomes of the review.