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From: frank morales [frankmorales@yahoo.com]
Sent: Monday, November 05, 2001 6:18 PM
To: NIOCINDOCKET@CDC.GOV
Subject: Comments of the Government Accountability Project on the NIOSH Proposed Rule (42 CFR Part 82)

GAP's NIOSH Comments.doc

Dear Mr. Elliot,

The Government Accountability Project respectfully submits these attached comments on NIOSH's proposed rule "Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000" (42 CFR Part 81). We are thankful for this opportunity to comment and hope that you will find our comments useful in the promulgation and review of your final rule.

We will send you a hard through the mail, in addition to this electronic copy. If you have any questions or concerns feel free to contact us.

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Sincerely,

Louis Clark
Executive Director

COMMENTS OF
THE GOVERNMENT ACCOUNTABILITY PROJECT

ON

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' PROPOSED RULES

"GUIDELINES FOR DETERMINING THE PROBABILITY OF CAUSATION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000"
(42 CFR PART 81)

AND

"METHODS FOR RADIATION DOSE RECONSTRUCTION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000"
(42 CFR PART 82)

OCTOBER 5, 2001

I. INTRODUCTION

A. Overview of the Government Accountability Project-- The Government Accountability Project (GAP) is a non-profit law firm and public interest organization which represents the interests of workers who have suffered retaliation for raising concerns about the workplace. We advocate on behalf of groups of workers interested in the enforcement of safety and health standards and specific acts of individual whistleblowing. GAP has a nearly thirty-year history defending workers who raise health and safety concerns, either to an enforcement agency or as part of filing a claim for compensation. GAP has developed a program to track, educate and advocate on issues related to the implementation of the EEOICPA. GAP has offices in Washington, D.C. and Seattle, WA.

B. Statement of Purpose-- The purpose of these comments is to address our concerns about the National Institution of Occupational Safety and Health's (NIOSH) proposed regulations on select provisions of the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). The EEOICPA is an essential first step to ensuring that the men and women who dedicated their lives to the defense of our nation during the Cold War are adequately and equitably compensated for the injuries they suffered during their employment in DOE facilities.

Section 3623 (c) of the EEOICPA requires the promulgation of guidelines for the purpose of determining whether a cancer sustained in the performance of day "was at least as likely as not related to employment." Specifically, the EEOICPA states that such guidelines must: (1) "be based on the radiation dose received by the employee... at such facility and the upper 99 percent confidence interval of the probability of causation in the radioepidemiological tables published under section 7(b) of the Orphan Drug Act," (2) incorporate specific methods of dose reconstruction for employees who were not monitored, monitored inadequately, or whose records are incomplete, and (3) "take into consideration the type of cancer, past health related activities (such as smoking), information on the risk of developing radiation-related cancer from the workplace exposure, and other relevant factors." Our comments focus solely on NIOSH proposed 42 CFR Part 82 concerning the method of dose reconstruction.

II. THE PROPOSED RULE "METHODS FOR RADIATION DOSE RECONSTRUCTION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000" (42 CFR PART 82)

A. Section 82.2 What are the basics of dose reconstruction?

Section 82.2 of the proposed rule states that "the basic principle of dose reconstruction is to characterize the radiation environments to which workers were exposed and to then place each worker in time and space within this exposure environment." GAP supports NIOSH's approach and believes this is a reasonable method, however, NIOSH's should be closely analyzed all of its data in conjunction with the assessment of personal monitoring records, rather than analyzing each piece of data separately.

Section 82.2(a) states that "if found to be complete and adequate individual worker monitoring bioassay sample results, are given the highest priority in assessing exposure. NIOSH will interpret this monitoring data using additional data characterizing the workplace radiation exposures." There is clear evidence from various studies of workplace monitoring as well as congressional testimony that workers were inadequately monitored. The EEOICPA expresses this concern by incorporating into Section 3623(d) requirements for the consideration of inadequately monitored or record employees. GAP believes that all data should be considered and weighted based on site or individual specific cases, rather than creating a hierarchical method of data consideration.

Section 82.2(c) states that "if neither adequate worker nor workplace monitoring data are available, the dose reconstruction may rely substantially on process description information to analytically develop an exposure model." GAP believes that it is also important to consider process information and source term information as outlined in Section 82.2(a) and (b). There are cases where monitoring is adequate for some internal exposures or external exposures but not for both (i.e. the Paducah transuranics question). Additionally, understanding the process and source term is important in order to realistically assess the data. For example, increasing and then decreasing Pu results are assumed to be a chronic exposure, when in reality they represent an acute exposure to Pu-238 oxide. The determination that the exposure is more likely acute comes from Radiation Work Restriction documentation and incident/occurrence reports, as well as knowledge of the actual composition of the source term. This could be completely misinterpreted if that data was not reviewed along with the bioassay data for the individual.

Additionally, NIOSH does not specify when or how it decides that a reasonable estimate of dose can not be made. The EEOIPCA states that NIOSH shall "establish by regulation methods for arriving at reasonable estimates of the radiation doses received by an individual ...." GAP believes that this phrase as used in the EEOICPA is of sufficient importance to require a clear definition within the regulations.

B. Section 82.3 What are the requirements for dose reconstruction under the EEOICPA?

The proposed rule lists the three groups of individuals requiring dose reconstruction as stated in Section 3623(d) of the EEOICPA. Although the EEOICPA lists only these three groups of employees, GAP believes that it is important to remain open to employees which do not necessarily fit within these specific groups. The rule should broadly define the statutory provisions to potentially include all individuals who are filing for compensation for a radiation related cancer.

C. Section 82.5 Definitions of Terms Used in this Rule.

The definition of "uncertainty distribution" is unclear. Specifically, the type of distribution is not specified, nor a statement as to how NIOSH will determine the distribution around the central estimate (see comment to Section 82.19 below).

D. Section 82.10 and 82.12 of the Dose Reconstruction Process

Sections 82.10 through 82.12 state the general procedure for dose reconstruction, as well as determining what claims will receive dose reconstruction. GAP has several concerns about this section which can be divided into two general themes, information and denial of dose reconstruction.

1. Information

GAP believes that it is important to look at all source of employment information and radiation exposure date (source term, other employees exposure data, process information, bioassay analysis methods and modifications, etc.) for a given facility to get the best understanding of what actually occurred 10 to 60 years earlier. Information regarding radiation incidents, occurrences, and other unusual situations should also be included in the claims packet. NIOSH should include information regarding work restrictions, which would include programmatic information on how work was restricted and what the restriction meant at a given facility, as well as, data on individuals work restrictions. NIOSH should also include exposures to medical staff from the medical screening process.

Section 82.10 also states that NIOSH "may compile data and information from NIOSH records that contribute to the dose reconstruction." GAP believes NIOSH must use all available data not just what DOE provides or what they feel is sufficient. Other sections of the regulation seem to suggest a broader vision of what data will be included (see 82.10 (e)) creating a significant ambiguity in what to expect for the compilation of data.

Section 82.10(h) requires "certification from DOE that record searches have been completed" for a claim to go forward. DOE field people have their pre-conceived ideas of what data NIOSH will need and not need to do their job. It is critical that NIOSH and/or their contractors understand initially what data is available, and not rely solely on DOE field office guidance. NIOSH has great experience in this area, but also needs to have some kind of direct check or review of this process. Furthermore, NIOSH should include stronger in this section to encourage DOE to cooperate. Such language may state that "NIOSH will request that DOE provide all applicable records or access to all records potentially related to radiation dose reconstruction in a timely and efficient manner. If DOE fails to provide adequate documentation the dose reconstruction process will proceed based on the assumption that the employee's evidence, including testimony, is correct."

Additionally, the provision in 82.10(e) that the evidence be "reasonably, supported by substantial evidence and not refuted by other evidence" unfairly favors the evidence of the DOE and DOE's contractors against the evidence of the claimant. The rule should state that when the evidence is contradictory, but of equal weight, the benefit of the doubt should go to the claimant. The clause "not refuted by other evidence" should be stricken as all together.

2. Denial of Dose Reconstruction

Both Sections 82.12 and 82.10 provide, in one way or another, that if the evidence is non-existent or insufficient (based on worst case assumptions) NIOSH can deny dose reconstruction and/or send information to DOL denying claim. Although GAP understands NIOSH's desire to expedite the process and filter out cases that are clearly ineligible, there are nonetheless several problems with these provisions. First, DOL's initial screening procedure has already filtered out frivolous claims. It is unnecessary for NIOSH's rule to provide for such extensive and ambiguous denial authority. Second, the NIOSH rule does not clarify when exactly there is a lack of "adequate information" or what "extremely unlikely to produce a compensable level of

radiation dose" means. It is unfair that NIOSH is able to validate these denials based on such flexible standards, while approvals have to adhere to such rigorous scientific review. Third, these provision are inconsistent with Sections 82.16 and 82.17 remedying the lack of information for claims. NIOSH does not state how these sections relate to one another and what claims will be eligible for remedy while other claims are denied.

NIOSH should create a standardized process which all claims go through initially and if upon completion of the initial review it is extremely likely that the claim will succeed or fail dose reconstruction, only then NIOSH should have the authority to approve or deny the claim. If the evidence remains uncertain, then NIOSH should conduct further research. The initial review should consist of the completion of a standardized form, listing all the sources of relevant information (specified in section 82.14), whether that information exists, and what that information says. The reviewer should fill out the form, contacting DOE and the claimant, gathering the information and listing the information on the form. This form could be completed in a short period of time, no more than 60 days. If the claim is initially denied, it would have to be denied within this 60-day period, subject to and based upon the completion of the form. The benefit of this form is two-fold: first, it standardizes the procedure for the initial denial or approval of dose reconstruction, and second it allows for time constraints on the process.

3. Additional considerations

Under Section 82.10(i), NIOSH will assess the effect of non-uniformity and geometry for external exposures. This could be a formidable task and needs further clarification.

Under Section 82.10(j), NOSH should use the word "assigned" or "ascribed" rather than the word "imputed."

Imposing time limitations on dose reconstruction is difficult because of the complex nature of does reconstruction. If NIOSH created a two-step dose reconstruction process there could be two time limitations allowing for some flexibility and some reassurance for claimants. The initial time limitation of 60 days for the initial review and a longer period of no more than 180 days or a year.

E. Section 82.14 What types of information could be used in dose reconstruction?

Section 82.14 lists all the relevant information to be used in dose reconstruction. Although we addressed some concerns about information in the previous sections, it is important to include the following pieces of information:

1. Blood results;
2. Reports documenting unusual circumstances and associated related data;
3. Information regarding *in vivo* detection limits;
4. Information regarding locations of air sampling heads for both workplace and BZA samplers;

5. Information regarding particle sizes;
6. Airflow patterns in relation to locations (3D) of the sampling heads;
7. Information regarding facility specific interpretation of air monitoring data (i.e. sample flow rate, filter type, filter size, collection efficiency, dustiness of environment, frequency of filter change, filter analysis method(s), etc.); and
8. Information regarding physical forms (e.g., solid, particulate, solution, vapors, etc.)

Additionally, there has been much debate on what historical detection limits might have been for the early bioassay programs and how to determine such detection limits (examples: no background recorded, no negative values recorded, no count times, no chemical recovery data recorded, thus you can not calculate the detection limits) (see Section 82.14(d)(3)). There are examples of procedures suggesting longer count times than were actually used. Resolving this inconsistency can be a very complicated process and may result in necessitating the "selection" of a "conservative" estimate of the detection limit.

F. Section 82.16 How will NIOSH add to monitoring data to remedy limitations of individual monitoring and missing dose?

Section 82.16 states that "for monitoring periods where external dosimetry data are missing from the records, NIOSH will estimate a claimant's dose based on interpolation...." The determination of what constitutes a "missing" dose is a difficult and needs further explanation. Also NIOSH should consider why the data is missing and if the individual was involved in any kind of accident or special work which may have resulted in greater dose than would be assigned if "normal tasks" were assumed.

NIOSH should also make sure that sample collection practices are examined and that actual practices, not just those described in procedural documents, are considered while interpreting the data. NIOSH should verify this data because employees reports at all DOE sites state that "according to procedures we were supposed to do it one way but what really happened was different." (See DOE Portsmouth, K-25 and Paducah investigation reports)

The use of the words "missed dose," as used in Section 82.16(b) has many connotations and should avoided . Also, for internal doses, in many cases, the minimum detectable dose cannot be simply added for the monitoring periods to determine an upper limit for an extended period. The minimum detectable dose should be based on the actual data available. For example a radionuclide exposure measured using urinalysis may have a MDD of 3 rem per quarter but that does not necessarily mean that there would be an annual MDD of 12 rem.

G. Section 82.17 What types of information could be used to supplement or substitute for individual monitoring data?

The words "and radioactivity" or "and radioactive contamination" should be inserted between "radiation" and "survey" to read: "general area radiation and radioactive contamination survey results, air sampling data; or,... ."

H. Section 82.18 How will NIOSH calculate internal dose to the primary cancer site(s)?

Again, in determining the effect of internal dose in relationship to the primary cancer site NIOSH should considered all of the relevant data. It would be inappropriate to use isolated bits of data to determine a given dose and later justify that determination. Where bioassay data are unavailable, NIOSH should not simply rely on air monitoring data when completing dose reconstruction. Data regarding source term, process knowledge, external contamination levels, etc., should be considered when available. Additionally, NIOSH should allow individual specific models if available data supports – rather than just relying on ICRP data.

The phrase in Section 82.18(b) stating that "when NIOSH cannot establish exposure conditions with sufficient specificity, the dose calculation will assume exposure condition that maximize the dose to the organ under consideration" is ambiguous and could create potentially unfair results. At what point does NIOSH decide that the dose determination cannot be completed? At what point are the estimates too uncertain to complete a "reasonable estimate?"

Methods of interpreting data will be based on numerous assumptions, including protracted and acute exposures, therefore exposures calculated for a given year are unlikely to represent reality. Additionally, only having bioassay results every six months can make it very difficult to determine annual doses. NIOSH should ascertain the exposure for the purpose of PC determination to some date that is not necessarily 50 years old. This can be done without estimating annual doses. The error associated with any given year's calculated dose will be typically significantly higher than that associated with the overall assessment, and could be the basis for significant disagreement in dose determinations. The resulting arguments will not serve anyone and this extraneous and non-meaningful requirement should be eliminated.

I. Section 82.19 How will NIOSH address uncertainty about dose levels?

Annual uncertainty is not a useful concept for these historical internal dose assessments. Often assumptions of chronic exposures are used to characterize a series of acute intake. Relatively small exposures in a given year may not be directly accounted for and early data is sometimes over or underestimated to allow for a best fit to the data with simplifying assumptions. While the concept of uncertainty is certainly important and the uncertainty of these assessments should be characterized, it should be characterized over the period of interest. Typically the period of interest should be at least 5 years but may be more than 20, 30 or 50 years in some cases.

This section must outline how the uncertainty in dose will be determined and define "reasonable certainty" as outlined in the statute. This section should answer three fundamental questions namely:

1. Which uncertainties will NIOSH will account for (i.e. uncertainties concerning particle size, solubility, chemical yields, calibration error, biokentic models, laboratory methods, failure to follow proper bioassay protocols, and failure to monitor for specific isotopes)?

2. What is the acceptable standard error around the mean and how wide of an uncertainty measure will NIOSH accept?

3. At what point is dose no longer reasonable because the error is so large relative to the mean?

GAP believes that the answer to these questions are fundamental to the effectiveness of the program and we do not want to leave it to a private contractor to determine the range of uncertainty. These questions should be answer by regulation, a politically accountable mechanism.

J. Section 82.26 How will NIOSH report dose reconstruction results?

Section 82.26(b)(2) states that a dose reconstruction report will include "separate dose estimates for acute and chronic exposures..." As noted above, because of the need for simplifying assumptions to assess historical bioassay data, the importance of providing separate realistic dose estimates for acute and chronic exposures is negated and has little meaning in reality. In the end, NIOSH should consider the total dose to a specified tissue for some relevant time period of time. The importance of acute and chronic exposures is only meaningful in terms of modeling the data, not in terms of reporting the actual truth, which is an unknown.

Additionally, the language of Section 82.26(b)(2) creates the impression that separate estimates for each radiation type, and exposure pathway and exposure period are required. This distinction is somewhat arbitrary. There is no reason as to why the dose from alphas plus x-rays cannot be combined or why it would be necessary to report these separately, especially in the case of internal dose.

Under Section 82.26(b)(3) it is unclear as to how the words "as necessary" will be interpreted in association with determining when an uncertainty distribution must be performed for a given dose estimate. This phrase needs additional clarification.

K. Additional Considerations

NIOSH's rule should provide for review of a certain percentage of cases by the Advisory Board on Radiation and Worker Health.

In the event that a claim is denied dose reconstruction process due to lack of data, NOISH should file the claim for Special Exposure Cohort status as a default rule. Such a rule will come at minimal expense to NIOSH and will remedy the denial in the most equitable fashion.