Government Accountability Project
1612 K Street, NW • Suite 400
Washington, DC 20006
202-408-0034 • fax: 202-408-9855
Email: gap1@erols.com • Website: www.whistleblower.org

January 17, 2002

VIA U.S. MAIL and E-MAIL

Larry Elliott
Director, Office of Compensation Analysis and Support
National Institute for Occupational Safety and Health
4676 Columbia Parkway
Cincinnati OH 45226

Dear Mr. Elliott:

The Government Accountability Project respectfully submits the attached comments to NIOSH's proposed rules "Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000" (42 CFR Part 82) and "Guidelines for Determining the Probability of Causation Under the Energy Employees Occupational Illness Compensation Program Act of 2000" (42 CFR Part 81). We send these additional comments on each of the aforementioned rules with the intention of supplementing and correcting the errors of our original comments. We are grateful for your decision to reopen the comment period and allowing us the opportunity to submit these additional comments.

The Energy Employees Occupational Illness Compensation Program Act (EEOICPA) is groundbreaking legislation. EEOICPA reverses the Department of Energy's history of denying compensation to the men and women who suffered injuries at a result of their exposures in our nation's atomic weapons facilities. We are dedicated to ensure that the administration and execution of the EEOICPA reflects its full congressional intent. It is our hope that these comments are helpful in your deliberations and we look forward to working with you in the future. If you have any questions or comments feel free to call Richard Miller at (413) 536-3858 or Frank Morales at (202) 408-0034 ext. 128.

Sincerely,

Louis Clark,
Executive Director

Government Accountability Project
1612 K Street, NW • Suite 400
Washington, DC 20006
202-408-0034 • fax: 202-408-9855
Email: gap1@erols.com • Website: www.whistleblower.org

01-23-02P02:00 RCVD

COMMENTS OF THE GOVERNMENT ACCOUNTABILITY PROJECT ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' PROPOSED RULES "METHODS FOR RADIATION DOSE RECONSTRUCTION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000" (42 CFR PART 82)

JANUARY 16, 2002

I. INTRODUCTION

A. Overview of the Government Accountability Project

The Government Accountability Project ("GAP") is a non-profit law firm and public interest organization that represents the interests of workers who have suffered retaliation for raising concerns about illegal or unethical conduct in 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 Energy Employees Occupational Illness Compensation Program Act of 2000 ("EEOICPA"). GAP's Washington, D.C. office is located at 1612 K. St, NW, Suite 400, Washington, D.C. 20006. We can also be reached via fax at (202) 408-9855 or e-mail at gap1@erols.com.

B. Statement of Purpose

The purpose of these comments is to address our concerns about the National Institution of Occupational Safety and Health ("NIOSH") proposed regulations "Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act

of 2000; Interim Final Rule With Request for Comments" (42 CFR Part 82). 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 Department of Energy ("DOE") and Department of Energy contractor facilities.

Section 3623 (d) of EEOICPA states that "the President shall, through any Federal agency (other than the Department of Energy)... establish by regulation methods for arriving at reasonable estimates of the radiation doses" for a cover employee with cancer who worked at a DOE or DOE contractor facility. Specifically, Section 3623 stipulates that the regulation should apply to employees who:

(1) were "not monitored for exposure to radiation at such facility;"
(2) were "monitored inadequately for exposure to radiation at such facility;" or
(3) "whose records of exposure to radiation at such a facility are missing or incomplete."

The President issued Executive Order 13179 "Providing Compensation to America's Nuclear Weapons Workers," which delegated the authority under Section 3623 (d) to the Department of Health and Human Services, which in return delegated their responsibility to NIOSH.

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 for dose reconstruction, however, NIOSH's should closely analyzed all of the data in its entirety, rather than monitoring each piece of data separately.

Section 82.2(a) states that "if found to be complete and adequate, individual worker monitoring data, such as dosimeter readings and 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 recorded employees. GAP believes that all data should be considered and weighted based on site or individually 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. at the Paducah site transuranics were not measured but uranium uptake was monitored). Additionally, understanding the process and source term is important to realistically assessing 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 the data is 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 radiation dose cannot be made. The EEOICPA states that NIOSH shall "establish by regulation methods for arriving at reasonable estimates of the radiation doses received by an individual...." GAP believes that the phrase "reasonable estimate" as used in the EEOICPA is of sufficient importance to require a clear definition within the regulations. This dovetails with the criteria for Special Exposure Cohort determinations, where NIOSH must determine when it is not feasible to estimate radiation dose with sufficient accuracy.

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 that do not necessarily fit within these three 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 sources of employment information and radiation exposure data (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. NIOSH should also include information regarding radiation incidents, occurrences, and other unusual situations in the claims packet. NIOSH should include information regarding overall 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 individual work restrictions. NIOSH should also include exposures to medical staff from the medical screening process.

Section 82.10 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 broad vision of what data will be included (see 82.10 (e)) creating significant ambiguity as to what a claimant should expect during 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 has pre-conceived ideas of what data NIOSH will need and not need to do their job. It is critical that NIOSH and/or its 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 DOE's data gathering process. NIOSH should include stronger language in this section to encourage DOE to cooperate. Such language should 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 during the dose reconstruction process, the process will stop, and individual will be notified that it is not feasible to estimate radiation dose and NIOSH will provide for their placement in a Special Exposure Cohort."

Additionally, the provision in 82.10 (e) that the information provided by the claimant be "reasonable, 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 all together.

2. Denial of Dose Reconstruction

Section 82.12 provides that if the evidence is non-existent or insufficient (based on worst-case assumptions), NIOSH may determine that dose reconstruction is not possible, resulting in the denial of the claim. Although GAP understands NIOSH's desire to expedite the process and filter out cases that are clearly ineligible, it is unclear from the rule what constitutes "adequate information." Additionally, in absence of a rule on the Special Exposure Cohorts (SEC), it is

unclear how a finding of insufficient data will affect a petition for membership in a SEC. These two issues are tied closely together.

NIOSH should create a standardized process that all claims go through initially consisting of the completion of a uniform checklist, listing all the sources of relevant information (specified in section 82.14), whether that information exists, and what that information says. The reviewer should complete the checklist, including obtaining data from DOE, the DOE contractor/vendor, the claimant, and others sources (DNFSB, AEC Health and Safety Laboratory Reports, NIOSH Reports, court filings, etc). This checklist will provide an administrative record for claims in the event of a subsequent challenge. In the event that NIOSH determines that it is not feasible to reconstruct a claimant's dosage, we agree under Section 82.12 that NIOSH should provide this notification to claimants. However NIOSH should go a step further, and provide claimant with the forms necessary to petition for Special Exposure Cohort status.

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."

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 that NIOSH consider the following pieces of information:

1. Blood results;
2. Reports documenting unusual circumstances and 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 cannot 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.

We recommend that NIOSH obtain the library of the AEC Health and Safety Laboratory Reports, including the papers on methods used as various sites presented as symposia, to understand monitoring methods, and to serve as a data source for dose reconstruction work.

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 dosimeter 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 ambiguous 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 a greater dose than would be assigned if NIOSH assumes the individual engaged solely in "normal tasks."

NIOSH should also examine sample collection practices and ensure 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 be defined. 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)?

In determining the effect of internal dose in relationship to the primary cancer site, NIOSH should consider all of the relevant data. It would be inappropriate to use isolated pieces of data to determine a given dose and later justify that determination. Where bioassay data is unavailable, NIOSH should not simply rely on air monitoring data when completing dose

reconstruction. Data regarding source term, process knowledge, external contamination levels, and other relevant data, should be considered when available. Additionally, NIOSH should allow individual specific models– rather than just relying on ICRP data.

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 intakes. Early data sometimes over or underestimated exposures to allow for a best fit to the data with simplified assumptions. While the concept of uncertainty is important and the uncertainty of these assessments should be characterized, the uncertainty should 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 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 of error around the mean and how wide of an uncertainty measure will NIOSH accept?

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

GAP believes that the answers 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 answered by regulation, which is 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 real significance. In the end, NIOSH should consider the total dose to a specified tissue for some relevant time period. The importance of acute and chronic exposures is only meaningful in terms of modeling the data, not in terms of reporting the actual reality, which is an unknown.

Additionally, the language of Section 82.26(b)(2) creates the impression that separate estimates for each radiation type, exposure pathway and exposure period are required. In many cases the data NIOSH receives will be reported in Sv. 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. This is true particularly if you are applying a single DDREF. As we note in other comments, the DDREF should be set at 1.

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 due to lack of data, NIOSH should file for Special Exposure Cohort status on the claimant's behalf. Such a rule will come at minimal expense to NIOSH and will remedy the denial in the most equitable fashion.