Miller, Diane M.

From: RickuDana@aol.com
Sent: Saturday, May 03, 2003 10:00 PM
To: NIOCINDocket@cdc.gov
Subject: GAP Comments on 42 CFR Part 83

Dear Sir or Madam:
]
Attached please find the Comments of Richard D. Miller, Policy Analyst on behalf of the Government Accountability Project (GAP), concerning the HHS Notice of Proposed Rulemaking for Designating Classes of Employees as Members of the Special Exposure Cohort under EEOICPA, published in the Federal Register March 7, 2003, Vol. 68, No. 45, pp 11294-11310.

The comments are attached in a Word file "NIOSHCommentsNPRMJ#2". They are 15 pages total.

Please contact me if you have any questions or if you have any problems receiving or opening the attached document.

Richard D. Miller
GAP
rickudana@aol.com
413-536-3858 (h)
413-536-9616 (fax)
413-531-5787 (cell)

Government Accountability Project
1612 K Street, NW, Suite 400, Washington, DC 20006,
202/408-0034
www.whistleblower.org

COMMENTS OF RICHARD D. MILLER, POLICY ANALYST GOVERNMENT ACCOUNTABILITY PROJECT (GAP) REGARDING THE HHS NOTICE OF PROPOSED RULEMAKING FOR DESIGNATING CLASSES OF EMPLOYEES AS MEMBERS OF THE SPECIAL EXPOSURE COHORT UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000 (EEOICPA) FEDERAL REGISTER VOL. 68, NO. 45, PP. 11294-11310 (MARCH 7, 2003)

Outlined below are the Government Accountability Project's (GAP's) comments on the HHS Notice of Proposed Rulemaking Procedure for Designating Classes of Employees as Members of the Special Exposure Cohort under EEOICPA, 68 ***FR*** 11294-11310, published on March 7, 2003 (hereinafter NPRM #2). GAP filed comments on the previous HHS Notice of Proposed Rulemaking related to Special Exposure Cohorts, 67 ***FR*** 42962-42973, published on June 25, 2002 (hereinafter NPRM#1). Contact: Richard Miller, Policy Analyst at 202/408-0034, x.128 for additional information.

GAP is a non-profit, public-interest group based in Washington, DC which operates programs to protect the rights of whistleblowers, advocates for worker health and safety, and provide oversight of the DOE nuclear weapons complex. In addition, GAP provides policy analysis and serves as an information dissemination hub for claimants, worker advocacy groups, unions and media outlets concerned about the implementation of EEOICPA. GAP has participated in all of the 14 NIOSH Advisory Board meetings held since its inception, including the Advisory Board conference calls and meetings held to discuss this rules and previous rules.

Due to the complexity of this rule, GAP had requested a 30 day extension of the initial 30 day comment period under this rulemaking. The Advisory Board requested a 15 day extension of the comment period. GAP thanks HHS for providing a 60 day comment period. GAP also made a written request for a public hearing on this rule. Members of the NIOSH Advisory Board and interested members of public also made requests on the formal record. No response was provided by NIOSH or HHS to these requests. We are disappointed by the lack of a response.

SECTION 83.1–WHAT IS THE PURPOSE OF THE PROCEDURES IN THIS PART?

NIOSH should add a provision to explain that there are two types of Special Exposure Cohort ("SEC") petitions: (1) a petition for claimants where NIOSH has not been able to complete a dose pursuant to 42 CFR Part 82.12 due to insufficient or inadequate data; and (2) a petition for individuals or classes of employees, whether or not any of the members of the class have been diagnosed with specified cancer, where it is not feasible to estimate dose with sufficient accuracy. The rule should state that petitioners do not necessarily have to file a claim with DOL to file a petition under option 2. However, if a member of an approved class does

develop a specified cancer, they would be eligible to file for benefits if they meet the DOL eligibility criteria.

SECTION 83.5–DEFINITIONS

There are three (3) sets of comments on the "definitions" section of the rule:

1) **Class of Employees**--In §83.5(c), the proposed rule defines a "class of employees" as "a group of employees who work or worked at the same DOE or AWE facility and for whom the availability of information and recorded data is comparable with respect to the informational needs of dose reconstructions conducted under 42 CFR Part 82." (Emphasis added)

(a) the definition of "class of employees" should be modified so that employees who work (or worked) at one or more DOE and/or AWE facility may be included in a "class of employees" if they are similarly situated with respect to employment (time and place) and insufficient radiation monitoring. Radiation technicians, "burn and turn" workers, and construction workers are groups that could conceivably fall into a class of employees who were employed in multiple facilities. NIOSH has an unquestionable legal right to interpret the term "facility" to allow more than one facility in defining a class of employees, pursuant to §3626. Section 3626 states, in part:

> *"...the members of a class of employees at a Department of Energy facility, or at an atomic weapons employer facility, may be treated as members of the Special Exposure Cohort for purposes of the compensation program..."* (Emphasis added)

Whenever the interpretation of a legislative enactment becomes an issue in a case, the courts will commonly resort to the *Rules of Statutory Construction* to determine the proper application of the statutory language to the facts at hand.

In reviewing the question of whether the singular includes the plural, five different texts dealing with the rules of statutory construction all make the same point: the singular includes the plural (and none were found that contradict this principle). For example:

> "The singular includes the plural, and the plural, the singular..."
> "Most drafting texts advise drafters to use the singular when possible." See: Reed Dickerson, *The Fundamentals of Legal Drafting*, pp. 124-125.

Thus, unless the result of such an interpretation was to defeat clear legislative intent, the rules of statutory construction allow the singular to include the plural. In this case, legislative intent is enhanced, not defeated, by construing the term "facility" to include "facilities," because the object of the Special Exposure Cohorts is to define a class of employees where radiation doses cannot be estimated, and this may include groups of workers employed in similar jobs at multiple facilities with similar limitations on the quantity or quality of radiation exposure information.

The Department of Labor (DOL) allows the use of multiple facilities for members of the SECs in its EEOICPA regulations at 20 CFR 30.214. DOL's rules allow members of the class to accumulate days of employment at multiple gaseous diffusion plants in up to 3 different states to meet the 250 day threshold for members of that Special Exposure Cohort. There is no logical

reason for NIOSH to impose a cramped reading of the law.

Recommendation: The NIOSH rule at §83.5(c) should be amended to allow for employment in either "one or more DOE and/or AWE facilities" to be used in defining both a "class", and in accumulating days of potential radiation exposure to meet the 250 day employment threshold under §83.13).

(b) a "class" is also defined in the proposed rule by the requirement that "availability of information and recorded data is comparable with respect to the informational needs of dose reconstructions conducted under 42 CFR Part 82." It doesn't make sense to require specific "information and recorded data" be "available" for purposes of "class definition" The point of a Special Exposure Cohort is that the information and recorded data needed for a dose reconstruction is not available. This section must be redrafted to establish that the class is defined by what information is NOT available.

2) **Section 83.5 should define "facility" as a term.**

Employees from two categories of facilities covered under EEOICPA can file petitions: an Atomic Weapons Employer Facilities (as defined in EEOICPA §3621(5)) and a Department of Energy facility (as defined in EEOICPA §3621(12)).

The definition of "facility" in this rule should include all buildings, structures, premises, production processes, and the grounds upon which such buildings, structures, premises and production processes are or were located at an Atomic Weapons Employer facility or a Department of Energy facility.

The reason for making the definition of facility as broad and inclusive as possible is that it will reduce the number of classes to be established for a given group of workers. It makes more sense to group classes based on exposure histories within a DOE site or an AWE site. Common exposure histories can crossover from process-to-process, building-to-building and site-to-site. The law doesn't call for "facility cohorts," rather it calls for exposure cohorts. A narrowly defined facility (*e.g.*, a production line) would frustrate the establishment of exposure cohorts, or result in the unnecessary proliferation of exposure cohorts. Instead, the classes should be defined by whether there was insufficient data to estimate doses for employees who meet the employment duration threshold.

3) **Specified Cancer–**

Section 83.5(k), the list of Specified Cancers, should be amended to provide at the end of subsection 83.5(k)(6), the following phrase "or specified within Department of Labor policy or procedures". For example, DOL has included rectal cancer as a subset of colon cancer, and cancer of the tonsils as a subset of pharynx cancer. It has also treated cancer of the bone cartilage of the larynx as a subset of bone cancer. These policy determinations should be incorporated by reference.

SECTION 83.7--WHO CAN SUBMIT A PETITION ON BEHALF OF A CLASS OF EMPLOYEES?

NIOSH has developed a well considered approach to who can file a petition, and assures that petitioners are adequately authorized. One labor union (PACE) filed comments which

demanded that labor unions be the exclusive entity entitled to petition for an SEC on behalf of employees which they represent because the union is the "exclusive representative." This argument is bedrocked on a misreading of the National Labor Relations Act's (NLRA's) definition of "exclusive representative." The provision of the NLRA dealing with the ambit of responsibilities of an "exclusive representative" is limited to representation on rates of pay, wages, hours, and other conditions of employment. Section 9(a) of the National Labor Relations Act, 29 USC §159(a), states:

> **Exclusive Representatives**
> *"Representatives designated or selected for the purposes of collective bargaining by the majority of employees shall be the exclusive representatives of all the employees in such unit for purposes of collective bargaining in respects to rates of pay, wages, hours of employment, or other conditions of employment."*

The matter of an individual or group filing for federal worker compensation benefits is outside of the ambit for which unions are the "exclusive representative." Unions are clearly well positioned to file SEC petitions, but when it comes to worker compensation proceedings, unionized workers have the freedom of choice to elect to be represented by their own legal counsel, or by their union, or an advocacy group (such as injured workers unions), or a state appointed advocate. NIOSH shouldn't take away that freedom of choice.

If NIOSH were to adhere to narrow limits proposed by the PACE national union–namely only a labor union representing its own members at a unionized site can file an SEC petition--NIOSH will be needlessly enmeshed in making findings on whether one union improperly included workers in a class who belonged to different union. NIOSH could be forced to deny petitions where competing unions were claiming that they were the "exclusive" representative due to jurisdictional disputes (a not uncommon occurrence at DOE facilities). Moreover, where unions have failed to file SEC petitions, but a COSH group or an injured workers organization (*i.e.*, Coalition for a Healthy Environment in Oak Ridge) did file a petition with authorization from individuals encompassed within the proposed class, NIOSH would be required to dismiss this petition. What happens if some of the affected employees in the class are bargaining unit workers and others are non-bargaining unit employees? What happens if some members of the class are in one bargaining unit, and other members of the class are in another bargaining unit? Who should file? Must there be two petitions instead of one? This is more than a hypothetical. In the case of workers at Rocky Flats who fought the plutonium fires, there are three separate groups of unionized employees (firefighters, security guards and Steelworkers) plus salaried employees that were potentially exposed to high-fired oxides of plutonium. Limiting petitions to the basis of specific union membership is clearly impractical.

The proposed rule at §83.7 has come up with the right formula for assuring that unions can file petitions, and that petitions by others are adequately authorized. NIOSH should not tamper with this section in this rulemaking.

SECTION 83.9 --WHAT INFORMATION MUST A PETITION INCLUDE?

Section 83.9(c)(iv) only authorizes report(s) published by a "scientific" government agency to meet the informational requirements regarding deficient information in this subsection

(emphasis added). The word "scientific" should be deleted in §83.9(c)(iv), in order to allow government agency reports from any agency or branch. For example, the U.S. General Accounting Office (GAO) is not a "scientific" agency, but it has done extensive auditing on the inadequacy of DOE dosimetry practices and provided this information to Congress. Likewise, Congress has published reports (such as Committee reports and hearing records) which describe inadequate radiation monitoring and/or destruction of dose records. Although these are not "scientific" agencies, their reports are credible and should not be rejected when evaluating an SEC petition. In fact "scientific" agencies, such as the Department of Energy (and its predecessors), have issued reports declaring their contractor's radiation measurement programs credible, only to be contradicted by subsequent reviews by non-scientific agencies or declassified documents. Recommendation: the word "scientific" should be removed as a limitation on the source of government agency assessments that can be used by petitioners; rather, any authentic government report should be allowable as a source of information.

Section 83.9(c)(iv) also contains a limitation that government agencies reports or peer review articles of deficient radiation dosimetry programs must "also find that such information might be essential to produce such estimates." It is over-burdensome for a petitioner to produce an article which finds that both radiation dosimetry is unavailable and also make a finding that such information might be essential to produce such estimates. Although such conclusions would be helpful, NIOSH has reduced the universe of information commonly available to petitioners, such as the DOE Tiger Team Reports, Occurrence Reports, Inspector General Reports, or Oversight and Investigation Team Reports. These reports typically identify deficiencies in radiation dosimetry, but may not make a formal finding that "such information might be essential to produce such [dose] estimates"; indeed, that kind of conclusion depends upon NIOSH using its professional judgment in consultation with the Advisory Board. We urge the deletion of the requirement in §83.9(c)(iv) that the report must explicitly "find that such information might be essential to produce such estimates."

Finally, GAP supports the reduced information requirements for submitting a SEC petition in this rule, compared with what had been proposed in NPRM #1.

SECTION 83.11–WHAT HAPPENS TO PETITIONS THAT DO NOT SATISFY ALL RELEVANT REQUIREMENTS UNDER §§ 83.7 THROUGH 83.9?

The rule should provide an independent administrative appeals process within HHS for petitioners after NIOSH makes a determination under §83.11(b) that the petition has failed to meet the requirements for evaluation. Absent an administrative review process, claimants will have no choice but to seek judicial review in federal court after NIOSH renders a final agency action. While we expect NIOSH will act in good faith, people are occasionally fallible. An independent review within HHS is a way to help conserve judicial resources and reduce the agency's burden on its legal department. The rule should specify with whom the request for an appeal must be filed, the address, the procedural requirements, and the regulations that will govern these appeals proceedings.

SECTION 83.13–HOW WILL NIOSH EVALUATE PETITIONS, OTHER THAN PETITIONS FOR CLAIMANTS COVERED UNDER §83.14?

1) **Definition and Application of the "Sufficient Accuracy" Test--**

Section 83.13(b)(1)(i) states that NIOSH will determine that "radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose that could have been incurred in plausible circumstances by any member of the class" (called a "worst case" or "capping the dose").

First, the rule should define what "sufficient information" means. (a) What is the minimum amount and type of information needed to "cap the dose"? (b) Is there a checklist or some other methods that can provide a basis for qualitative judgment when there is not "sufficient data" to "cap the dose"? For example, if workers moved between multiple process buildings, such as maintenance workers or security guards, and there is no valid personal monitoring data, how will NIOSH know whether or not it can cap the dose for this class of workers? (c) What methods will be allowed or disallowed in determining whether NIOSH fairly "capped the dose," (d) What test will be applied to determine whether NIOSH improperly underestimated maximum potential dose? Simply saying that NIOSH will decide these questions on a case-by-case basis is not adequate, and offers no clear basis for assuring that NIOSH will achieve consistency from case-to-case.

GAP recommends that NIOSH develop guidelines which use statistical methods to define "sufficient accuracy". For example, if the standard error is many times the size of the mean (or mode), there may be a basis for drawing conclusions about whether the estimate is sufficiently accurate (assuming that even the upper 95% confidence interval of the dose estimate would not be compensable). An example is the Bethlehem Steel site profile developed by NIOSH (posted at www.cdc.gov/niosh/ocas) where the mode is 2 MAC and the upper confidence interval is 1000 MAC. Is a distribution with such a larger error around the mode "sufficiently accurate"? Or is the range of error so large that the class properly belongs in an SEC?

Second, NIOSH should define in the rule what the term "plausible circumstances" means. And what it doesn't mean. Simply saying that this term will be applied on a case-by-case basis is not adequate. Substituting one vague term ("sufficient accuracy") in the statute with another vague term ("plausible circumstances") in the rule, does not meet the minimal requirements of a rule giving effect to a statute and offers no clear basis for assuring NIOSH will achieve consistency from case-to-case.

Third, we are concerned that claimants could fall into a regulatory void between NIOSH's proposed Special Exposure Cohort rule and NIOSH's existing dose reconstruction rule (42 CFR 82). Under the proposed rule, SEC petitions would be dismissed if there is enough data "to estimate maximum potential dose", e.g. a "worst case". However, these claims could also be dismissed under the dose reconstruction rule (42 CFR 82.10(k)(3)) because "worst case" estimates are only allowable at as part of an "efficiency" mechanism if the dose falls below the 50% probability of causation. 42 CFR 82.10(k)(3) states:

> *"Worst case assumptions will be employed under condition 2 [which allows completing a dose reconstruction with worst case estimates] to limit further research and analysis only for claims which it is evident that further research and analysis will not produce a compensable level of radiation dose [a dose producing a*

> *P of C >50% or greater], because using worst case assumptions it can be determined that the employee could not have incurred a compensable level of radiation dose. (Emphasis added)*

What happens to claimants where the "worst case" estimates exceed 50% probability of causation? Do they fall into a void?

According to the record of a discussion between NIOSH's Ted Katz and Advisory Board Member Mark Griffon at the March 7, 2003 Advisory Board meeting, staff believes that maximum dose estimates would be used in determining claims under 42 CFR Part 82:

> **Mr. Griffon:** And just to clarify that....if you can calculate a maximum dose, then those maximum doses will be used in their determination of–
>
> **Mr. Katz:** Yes.
>
> **Mr. Griffon:** --probability of causation?
>
> **Mr. Katz:** Then they {the claimant} would have dose reconstructions based on those maximum doses versus something more accurate and lower. (See: transcript, pp. 45-46)

The contents of the rule at 42 CFR 82.10(k) and the representations of Mr. Katz do not align. Furthermore, the Preamble to the dose reconstruction rule at 67 ***FR*** 22325 suggests that using a worst case estimate will be "difficult" and "the ability of NIOSH to complete dose reconstruction depends on extent and quality of information available to substitute for monitoring data." It states:

> *"Simplifying assumptions (e.g., worst case) become more difficult to apply, however, when the potential level of radiation for individual ranges greatly, particularly when they range from low levels to potentially compensable levels... In these circumstances, the ability of NIOSH to complete dose reconstruction depends on extent and quality of information available to substitute for monitoring data..."*

As noted above, the Preamble is equivocal, at best, and there is no other explicit support in 42 CFR 82 for the argument that when data is limited, the worst case estimate would always be even where the P of C >50%.

If NIOSH wants to introduce the use of "worst case" dose estimates to limit who can be placed in new Special Exposure Cohorts, it should do so in an even-handed way. Indeed, it would be contradictory (and unfair) for NIOSH to take the position that claimants cannot be compensated if data only permits a worst-case dose estimate which ends up above the 50 % probability of causation threshold.

NIOSH should--coincident with the current SEC rulemaking--amend its dose reconstruction rule to provide absolute clarity that worst case estimates will be used to "complete" a dose reconstruction (if it wants to retain the "worst case" threshold for determining an SEC).

Fourth, NIOSH must spell out how it will use a "maximum potential dose" in a compensation case. The Health Physics Society, in their comments on the SEC Rule, recommends that "[a] "maximum realistic" dose estimate should be estimated and used as a point estimate of dose for the remainder of the probability of causation determination." (HPS Comments, pp.10, Section B3). Assuming that the "maximum realistic dose" is the same as the "maximum potential" dose or a "worst case" estimate, will NIOSH include this maximum potential dose as a point estimate? Or is NIOSH going to use a "worst case" estimate as part of a dose distribution where the maximum is at the upper tail end of a distribution where it will receive lesser weight in a P of C determination. (A triangular mode distribution was compared with a single point estimate to confirm this conclusion using NIOSH-IREP). Clearly, using the worst case as a point estimate would generate a more claimant friendly outcome than including it in the tail of a distribution.

At the March 7 Advisory Board meeting, NIOSH's health physics director (Jim Neton) indicated that the maximum potential dose would not be used as a point estimate, rather it would be used as part of a distribution:

> **Dr. Neton:** I'd like to maybe clarify what Ted said. Not necessarily the maximum dose, if we could develop some sort of distribution, but the maximum credible dose would be used in the analysis. It would not always be the maximum dose.
> **Mr. Katz:** But it could be.
>
> **Dr. Neton:** It could be, sure.
>
> **Mr. Katz:** Yes, which is–
>
> **Dr. Neton:** But if one generated distribution, a theoretical distribution of doses, that would be the sampling that would be done to that dose reconstruction. (Tr. p. 46)

NIOSH should clarify the rule to provide the "worst case" as a point estimate (*e.g.*, input the dose as a "constant value" in IREP). NIOSH needs to justify why it would not use the maximum potential dose as a point estimate.

Fifth, NPRM #1 set the threshold for "sufficient accuracy" at the level at which a dose could be "completed." When "completing" a dose estimate, NIOSH is making a "reasonable estimate of dose received." In NPRM #1, when a reasonable estimate cannot be developed, NIOSH concludes it cannot estimate dose with "sufficient accuracy."

In NPRM#2, NIOSH appears to have raised the bar for evaluating whether doses can be estimated with "sufficient accuracy" to only those cases (or classes) for whom NIOSH cannot "cap the dose." NIOSH has not explained why it chose to raise the bar on eligibility for SECs.

NIOSH personnel have stated that they can "cap any dose," which effectively pre-judges any SEC petition. Indeed, NIOSH's decision to raise the bar may have precluded virtually anyone from ever qualifying for the SEC. Is this the intent of NIOSH? If so, NIOSH should explain its view, so that claimants will understand the futility of petitioning for a Special Exposure Cohort.

2) **Limiting the List of 22 Specified Cancers**--In §83.12(b)(1)(iv), NIOSH says that when it finds it is not feasible to estimate dose with sufficient accuracy, NIOSH will then "determine" whether such finding "is limited to radiation doses incurred at certain tissue-specific cancer sites." Likewise, in §83.13(b)(2)(iii), NIOSH proposes to identify tissue specific cancers for which it was not feasible to estimate dose with sufficient accuracy. Further, in §83.13(c)(4), NIOSH may, in its report to the petitioner and Board, limit specified cancers to "a set of one or more types of cancers specified by NIOSH."

NIOSH's proposal to limit the number of specified cancers in a given Special Exposure Cohort contradicts Congressional intent. Authority to limit cancers should be deleted from §83.13 of the rule.

NIOSH has no legal authority to reduce or limit the 22 specified cancers designated by EEOICPA for any members of any Special Exposure Cohort, including both those designated by Congress or those designated by the Secretary of HHS pursuant to EEOICPA §3626.

The legislative history for EEOICPA delineates Congressional intent that a "fixed list" of specified cancers would serve as the basis for compensation for members of a Special Exposure Cohort, and not a variable list drawn up on a case-by-case basis at the discretion of the agency. The *Congressional Record* (Page 10377) for October 12, 2000 states (attached):

> *"There are a few groups of workers that we know, today, belong in this category. They are specifically mentioned in the definition of Special Exposure Cohort. For other workers to be placed in this special category, the decision that it was infeasible to reconstruct their dose would have to be made both by the President (or his designee) and by an independent external advisory committee of radiation, health, and workplace safety experts. We allow groups of workers to petition to be considered by the advisory committee for inclusion in this group.* ***Once a group of workers was placed in the category [i.e., the Special Exposure Cohort], it would be eligible for compensation for a fixed list of radiation-related cancers."*** (Emphasis added.)

By saying it can identify which organs are at risk and which organs are not at risk in an SEC, NIOSH has contradicted its published declaration that it is infeasible to quantify cancer risk when there is insufficient data to "cap the dose."

NIOSH states in the Preamble to the §83.13 of the proposed rule at 68 ***FR*** 11297:

> *Lacking a factual basis for establishing such a cap or upper bound to the possible level of radiation exposure, NIOSH cannot quantitatively evaluate health endangerment.*

By authorizing a process to determine which organs will be significantly affected (*e.g.*, "endangered"), the rule is at odds with this section of the Preamble. The proposed rule is also at odds with a previous recommendation of the NIOSH Advisory Board to remove risk

quantification from the SEC rule precisely because it is impossible to assign risk where a maximum potential dose cannot even be estimated. It is scientifically unsound to set up a process where the HHS has already conceded that "NIOSH cannot quantitatively evaluate health endangerment" for those classes of workers where it lacks sufficient data to estimate a maximum potential dose.

Moreover, in limiting the list of cancers, the rule establishes "disease cohorts" rather than "exposure cohorts" without any Congressional authority. Congress resolved the question of scientific uncertainty with respect to covered cancers in favor of claimants precisely because risk cannot be quantified when exposures are not known, and it is the ethical policy to follow when the government puts workers at risk but failed to monitor them. NIOSH should not be second guessing or otherwise undermining this sound Congressional policy decision.

Given NIOSH's apparently heavy reliance upon the recommendations of the Health Physics Society (HPS) staff for limiting the list of specified cancers for given classes, a critique of this position is necessary.

First, HPS staff challenged the fundamental policy decision to create Special Exposure Cohorts when EEOICPA was enacted in 2000. They lobbied Congress and the Administration against SECs. This is documented in the HPS newsletter. Today, HPS is seeking to overturn through rulemaking what they could not achieve in the legislative process. This is revealed, in part, in the HPS staff comments, where they want to first establish the principle in the NIOSH SEC rule that cancer types should defined on a case-by case basis for each SEC, and then they want use this as the basis to re-examine whether all 22 cancers should apply to the statutory SECs at the GDPs and Amchitka. (Of course, the latter objective cannot be controlled by NIOSH.). HPS staff has been told, but has failed to accept, that Congress placed GDP workers in the SECs, in part, to remedy the fact that these workers were placed in harm's way by DOE and its contractors, lied to about it by management, and not tested or adequately protected from exposure to transuranics for over 40 years. These unethical actions were never criticized by the Health Physics Society. No one to our knowledge had their health physics accreditation removed because of professional malfeasance, despite the abundant evidence of such misconduct by health physicists and others in the DOE complex.

The policy algorithm for SECs in EEOICPA is rooted in the Recommendation #2 of the Final Report of the President's Advisory Committee on Human Radiation Experiments. This Recommendation states that when the government put individuals in harm's way without their knowledge and consent, and harm can be attributable to those actions, then compensation should be paid. This ethics-based remedy may not suit HPS's broader political agenda, but it is the product of extensive deliberation by an expert committee. This algorithm was subsequently adopted by DOE Secretary Richardson, DOE Assistant Secretary Michaels and a bi-partisan group of House and Senate members in the enactment of EEOICPA.

Second, at 68 ***FR*** 11296, the rule tracks the HPS position that for certain emitters, there is adequate information about "where the radioactive compounds concentrate and significantly irradiate certain organs and tissues" that could allow NIOSH to estimate which cancers could be

excluded from a class where the dose cannot be "capped". The proposed rule does not define the term "significantly," leaving completely open to speculation what risk level is actually indicated. NIOSH concedes, properly, that some amount of radiation that is inhaled or ingested will find its way into every organ in some quantity (March 7, 2003 hearing transcript). Thus, every organ will incur some unquantified risk from radiation dose, but the amount is unknown, because NIOSH concedes that in these instances the dose cannot even be capped.

The rule doesn't explain whether HPS's recommendations will be adopted when it comes to defining threshold exposure levels where certain tissues would be deemed "significantly" irradiated. HPS opines that 10 rem is the threshold level beneath which no adverse health effects occur. HPS's March 2001 position paper states: "there should be no compensation for persons whose lifetimes doses are less than approximately 0.1 Sv (10 rem)." The scientific validity of the HPS contention that a threshold compensation model should be adopted at the 10 rem level is completely at odds with the premises underlying NIOSH IREP. Indeed, the NIOSH-IREP model compensates certain cancers below 5 rem exposure (*e.g.*, leukemia). If the HPS recommended threshold is adopted, NIOSH will be presented with highly visible inconsistencies in its application of the NIOSH-IREP model on the one hand, and risk estimations used to include or exclude certain cancers from SECs on the other hand.

Moreover, the record of the Advisory Board reveals that neither NIOSH staff, nor the Advisory Board, has been able to identify a single theoretical example where dose cannot be capped and yet it can identify the "significantly" affected organ(s). Indeed, in every case where affected organs could be identified, NIOSH (or the Board) also found that a worst case estimate could also be developed.

In sum, limiting the list of specified cancers is unworkable and at odds with NIOSH's previous finding that where a dose cannot be capped, health endangerment cannot be determined. Congress did not want to limit the list of 22 cancers precisely because of this reason.

3) **Is it "feasible" to estimate dose?--** The proposed rule takes the position that dose reconstruction is feasible "if HHS has access to sufficient information to estimate the maximum radiation dose that could have been incurred in plausible circumstances by any member of the class." This standard is inconsistent with clearly expressed Congressional intent. The pertinent discussion in the legislative history (October 12, 2000 *Congressional Record*, S10377) states:

> "There are several reasons why reconstructing a dose might be infeasib[le]. First, relevant records of dose may be lacking, or might not exist altogether. Second, there might be a way to reconstruct the dose, but it would be prohibitively expensive to do so. Finally, it might take so long to reconstruct a dose for a group of workers that they will be all dead before we have an answer that can be used to determine their eligibility."

This passage evidences a much broader test of feasibility than the one proposed in the rule. Congress consciously used the word feasible in EEOICPA §3626 because it was motivated by a concern that the dose reconstruction process could become so complicated that the essential aim of the statute (i.e., timely compensation) would be frustrated. The standard proposed in the

rule will result in dose reconstructions being attempted in many of the circumstances that Congress sought to exclude when crafting the statute. Thus, GAP urges that the rule incorporate the legislative history cited in the previous paragraph. Thus, the SEC rule must define "feasibility" to include length of time to reconstruct dose from date claim is received from the DOL (we recommend 180 days) and prohibitive cost (cost to estimate dose exceeds benefits to be paid to claimant(s)).

4) **May have endangered the health of the members of the class**--In §83.13(b)(3), the proposed rule, NIOSH establishes endangerment by two basic tests:

a) employment information that indicated the potential for radiation exposure
b) 250 days of employment, or less in the event of discrete exposure event(s).

This basic framework is a major improvement compared with the approach used in NPRM#1 for determining "endangerment". However, added refinements are needed.

Employment information– What employment information is needed to establish potential for radiation exposure?

Duration of employment – NIOSH sets forth duration of employment as exposure to "discrete events" (such as criticality), or in the absence of a "discrete event", having been employed for 250 work days within the employment parameters set forth for the class.

First, the rule itself (and not just the Preamble) should provide added flexibility in abbreviating the 250 days requirement when appropriate. Thus we recommend that the rule explicitly state in §83.13(b)(3)(ii):

"NIOSH will use the 250 day employment criterion only when it lacks sufficient basis to establish a lower minimum duration."

Second, the 250 day employment requirement should allow for workers to accumulate this time at multiple facilities, if their employment at one site totals less than 250 days, and the class includes employment at more than one facility.

Third, the rule should allow clarify that "discrete events" covered under §83.13(b)(3)(i) could include short duration operations where radiation controls were largely non-existent. For example, would a "discrete event" include AWE vendors where production operations (rolling of uranium or thorium) from start to finish took several weeks or months, but didn't take 250 work days, and for which maximum potential exposures were unquantifiable? The 250 day limit would be unfair to impose in this instance, because there were not 250 days in the discrete event.

Would those fighting a plutonium fire or conducting related rescue operations count as a "discrete event," even though the class of individuals involved in fighting the fire may not have received the same dose as a person would have received in a criticality event, but nonetheless received an unknowable potential uptake of high fired oxides of plutonium (which cannot be monitored through bioassay)? This potential class was discussed by Dr. Robert Bistline at the

July 1, 2002 NIOSH Advisory Board meeting in Denver (pp. 203-212). Unless the workers were deemed to have been included in a "discrete event", they would be disqualified as a class under the 250 day employment rule, because the employment in firefighting and cleanup operations took less than 250 work days.

The rule should be modified, as recommended above, to provide additional flexibility in setting forth shorter durations of employment (outside of criticality or equivalent events).

SECTION 83.16–HOW WILL THE SECRETARY DECIDE THE OUTCOME OF A PETITION?

1) **Secretarial Decision Criteria** – Where the Secretary receives a NIOSH recommendation in favor of granting a petition, and such recommendation is supported by the Advisory Board, does the Secretary have the discretion to reverse such a finding in the absence of substantial evidence to the contrary? What weight will HHS give to recommendations from the Advisory Board, if these recommendations differ from the NIOSH recommendation? Can the Secretary remand the NIOSH determination for further deliberations without making a finding?

2) **Timelines for Initial Secretarial Decision** – The rule should stipulate that the Secretary shall review recommended decisions from NIOSH and the Advisory Board and issue a final written determination not more than 21 days after receipt of such materials from NIOSH and the Advisory Board. Inasmuch as all of the evaluations and reviews have been undertaken by NIOSH staff, its contractors and the Advisory Board, the Secretary's review appears to be more of a formality, unless there is an appeal taken.

3) **Delegation of Authority Will Increase Efficiency**--We restate our views that authority for decision making on SEC petitions should be delegated by the Secretary to the Director of NIOSH. The Preamble states that "the Secretary may delegate authority for making final SEC determinations to the Director of NIOSH, if upon experience, the Secretary finds this is likely to improve the effectiveness and efficiency of the program." This action would eliminate a time consuming step in the process and increase the efficiency and effectiveness of the program.

4) **Type of Appeals, Hearings** – The proposed rule does not indicate which Office or branch of HHS will hear appeals of adverse determinations by the Secretary (or his/her designee). Will the same individuals who rendered an adverse determination on an SEC petition be the same individuals who evaluate the appeals of their initial finding? Or will there be an independent review within HHS? We recommend that an independent review be provided. What rules of procedure will be used? Will such appeals allow for oral presentations by petitioners? Will hearings allow for presentations by experts in support of a petition? Will the entire administrative record involved in the NIOSH SEC evaluation be made available to petitioners for use during the appeals process?

5) **Notification** – GAP applauds the addition of notification in the *Federal Register* immediately after the Secretary makes a determination to add a class to the SEC and forwards such recommendation to Congress for its 180 day review.

OTHER RECOMMENDATIONS

NIOSH requested comment on how to address several issues related to an employee's

dose history that is partially but not completely covered in a SEC class. See: 68 ***FR*** 11302-03.

1) **Assigning Dose**–(a) For claimants who have both radiation exposures that can be estimated and radiation doses that cannot be capped (but not included in an SEC due to employment for less than 250 days), how should NIOSH assign the dose that cannot be estimated? Options for the amount that would be "assigned" are not discussed in the Preamble. EEOICPA §3626 provides guidance on assigning dose in this case. Where it is not feasible to estimate dose with sufficient accuracy, the claimant, by default should be added to the SEC. (The endangerment question is presumably mooted by the employment history.)

For individual claimants who received an unknowable dose as an SEC member, and also received dose that can be estimated outside of the SEC, how will dose be assigned if the claimant has a cancer which is not on the list of 22 "specified cancers"? Options were not described in the Preamble. One option would be to assign dose to the organ with cancer where dose reconstruction indicates that the P of C was at least 25% (at the 99% confidence interval). The amount to be assigned from employment within the SEC should add dose to allow a P of C determination >50% for that organ. Given the uncertainties at hand, the challenge is to assure potentially valid claims are not arbitrarily denied where it is not feasible to estimate a dose for an organ that is known to have had some potential for meaningful amounts of radiation dose. This may require further discussion in a workshop setting.

2) **Time lines**-- NIOSH should establish a time frame for completing SEC petitions and sending them to the Secretary within 180 days. If it cannot meet this time line, NIOSH should provide written notice to Congressional Committees and the House and Senate Members who have petitioners in their district or state with an estimate of when such petitions will be completed.

3) **Technical Assistance**--GAP urges NIOSH to provide small technical assistance grants to assist in the development of SEC petitions. Grants would be used to hire health physicists or other qualified professionals to assist in the development of a technically sound petition. NIOSH should also hold several training workshops to address the information requirements of a petition.

4) **Harmonizing the SEC Rule with the Dose Reconstruction Rule** –
HHS should have proposed necessary changes to its dose reconstruction rule at 42 CFR Part 82 in conjunction with this rulemaking proceeding, rather than dealing with the two rules in a piecemeal fashion. NIOSH should refrain from finalizing any adverse SEC determination until it implements revisions to its dose reconstruction rule due to need to align thresholds for eligibility in both rules.

5) **Administrative Record** – GAP requests that the March 7, 14, 28 and May 1 transcripts of the Advisory Board be incorporated in the Administrative Record for this rulemaking.

Attachment: Excerpt from October 12, 2000 Congressional Record dealing with Special Exposure Cohorts by Jeff Bingaman (a lead sponsor with Senator Fred Thompson)

EXCERPT FROM FLOOR STATEMENT OF SENATOR JEFF BINGAMAN

October 12, 2000 **CONGRESSIONAL RECORD—SENATE** **S10377**

For radiation, the situation is more complex. Radiation is proven to cause cancer in high doses. But when you look at a cancer tumor, you can't tell for sure whether it was caused by an alpha particle of radiation from the workplace, a molecule of a carcinogen in something you ate, or even a stray cosmic ray from outer space. But scientists can make a good estimate of the types of radiation doses that make it more likely than not that your cancer was caused by a workplace exposure.

The original legislative proposal passed by the Senate put the Department of Health and Human Services, HHS, in charge of making the causal connection between specific workplace exposures to radiation and cancer. Within the HHS, it was envisioned that the National Institute for Occupational Safety and Health, or NIOSH, take the lead for the tasks assigned by this legislation.

This assignment followed a decision made in DOE during the Bush Administration, and ratified by the National Defense Authorization Act for Fiscal Year 1993, to give NIOSH the lead in identifying levels of exposure at DOE sites that present employees with significant health risks. While in the final legislative text, the President was assigned these responsibilities, I think it is clearly the intent of the Senate proponents that he delegate these authorities as laid out in the original Senate amendment.

HHS was also given a Congressional mandate, in the Orphan Drug Act, to develop and publish radioepidemiological tables that estimate "the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of those doses." I would like to ask unanimous consent that a more detailed discussion of how the Senate proponents envision these guidelines being used be included as an exhibit at the end of my remarks. (See Exhibit 2.)

Under guidelines that would be developed and used under this legislation, if your radiation dose was high enough to make it at least as likely as not that your cancer was DOE-work-related, you would be eligible for compensation for lost wages and medical benefits.

The HHS-based method will work for the many of the workers at DOE sites. But it won't work for a significant minority who were exposed to radiation, but for whom it would be infeasible to reconstruct their dose.

There are several reasons why reconstructing a dose might be this infeasibility might exist. First, relevant records of dose may be lacking, or might not exist altogether. Second, there might be a way to reconstruct the dose, but it would be prohibitively expensive to do so. Finally, it might take so long to reconstruct a dose for a group of workers that they will all be dead before we have an answer that can be used to determine their eligibility. One of the workers who testified at my Los Alamos hearing might be an example of a worker who could fall into the cracks of a system that operated solely on dose histories. He was a supervisor at what was called the "hot dump" at Los Alamos. All sorts of radioactive materials were taken there to be disposed of. It is hard to reconstruct who handled what. And digging up the dump to see what was there would not only be very expensive, it would expose new workers to radiation risks that could be large.

There are a few groups of workers that we know, today, belong in this category. They are specifically mentioned in the definition of Special Exposure Cohort. For other workers to be placed in this special category, the decision that it was infeasible to reconstruct their dose would have to be made both by the President (or his designee) and by an independent external advisory committee of radiation, health, and workplace safety experts. We allow groups of workers to petition to be considered by the advisory committee for inclusion in this group. Once a group of workers was placed in the category, it would be eligible for compensation for a fixed list of radiation related cancers.

The program in this amendment provides for a lump-sum payment, combined with ongoing medical coverage under language identical to that used to provide medical coverage under the Federal Employee's Compensation Act, or FECA, in section 8103 of title 5, United States Code. Since Congress has consciously mirrored FECA for one important part of this new program, I hope that the Administration, in implementing our legislation, looks to FECA as a precedent for establishing other parameters for this program.

The legislation before us also invites the Administration to submit further legislative proposals to help implement this new program. In my view, it was not a good policy call for Congress to enact this program without more direction on the details of how it should operate, as was the case in the original legislative proposal passed by the Senate. I believe that the flexibility that the Congress has provided to the Executive Branch should be used to the fullest extent by the President to put the necessary implementing framework in place by Executive Order. If there are changes needed to the law that we have passed, they should be sent up by the President forthwith. But I do not have much confidence that Congress will be able to enact additional legislation on this program before the deadline date of July 31, 2001.

We have a duty to take care of sick workers from the nuclear weapons complex today. It is a doable task, and a good use of our national wealth at a time of budget surpluses. I congratulate my colleagues on having achieved a successful result from our initial ipartisan amendment.