COVER

TO: NIOSH DOCKET OFFICER
NIOSH DOCKET OFFICE
ROBERT A. TAFT LABORATORIES
M/S C34
4676 COLUMBIA PARKWAY
CINCINNATI, OHIO 45226

FROM: FERNALD ATOMIC TRADES & LABOR COUNCIL
7400 WILLEY Rd.
HAMILTON, OHIO 45013
OR
FAT&LC
P.O. BOX 126
ROSS, OH. 45061

Recd 8/26/02
KED
forwarded cc: → Dave Sundin

FERNALD ATOMIC TRADES & LABOR COUNCIL
COMMENTS ON HHS's PROPOSED RULE
"PROCEDURES FOR DESIGNATING CLASSES OF EMPLOYEES
AS MEMBERS OF THE SPECIAL EXPOSURE COHORT
UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS
COMPENSATION PROGRAM ACT of 2000" 42CFR PART 83

WE FULLY ENDORSE & SUPPORT GAP'S POINT-BY-POINT COMMENTS ON THE HHS's PROPOSED RULE. SEE ATTACHMENT

IN ADDITION WE HAVE SOME PARTICULAR ADDITIONAL COMMENTS.

- TO QUALIFY FOR THE SPECIAL EXPOSURE COHORT BY PETITION APPEARS TO BE MORE ASTRINGENT THAN THE ORIGINAL IDENTIFIED COHORTS — WE FIND THE EQUALITY IN THE PROCESS NOT TO BE EQUITABLE,

- NIOSH SHOULD CONSIDER BOTH PREVIOUS AND SUBSEQUENT DOSES FOR INDIVIDUAL MEMBERS OF THE "CLASS" TO DETERMINE IF THEY QUALIFY FOR THE S.E.C.

- WE BELIEVE THE IREP MODEL IS NOT TOTALLY APPLICABLE TO DOE. CONTRACTOR WORKERS — WE HAVE NIOSH TO CONTINUE TO REVIEW IREP IN LIGHT OF OTHER EPIDEMIOLOGICAL STUDIES.

- THE DEFINITION OF "ENDANGERED HEALTH" IS ILLOGICAL AND DOES NOT CONSIDER THE POSSIBILITY THAT THERE WILL NOT BE ANY DOSE DATA AT ALL — THERE IS NOTHING ILLUDED TO IN THE DEFINITION THAT WOULD CONSIDER THE POSSIBILITY OF THE COMPLETE ABSENCE OF DOSE DATA.

- WE BELIEVE THAT THE INFORMATIONAL BURDEN ON PETITIONERS IS TOO HIGH. PETITIONERS, PARTICULARLY, SURVIVORS WILL NOT HAVE THE ACCESS AND KNOWLEDGE TO ACCUMULATE THE DOCUMENTATION NECESSARY.

RESPECTFULLY SUBMITTED,

Gene Branham — GENE BRANHAM
PRESIDENT, FAT&LC

Robert C. Tabor — ROBERT C. TABOR
LABOR/MGNT LIAISON FAT&LC
AUTHOR OF COMMENTS

**GAP'S POINT-BY-POINT COMMENTS ON HHS'S PROPOSED RULE "Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000" 42 CFR Part 83**

**August 20, 2002**

| COMMENT # | SECTION # | RULE OR PREAMBLE SECTION | COMMENT OR QUESTION | RECOMMENDED CHANGES |
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| 1 | Preamble Sec. II. C | Background: Purpose of Proposed Procedures | There are many areas in the proposed rule that have yet to be spelled out. By their own admission, NIOSH cannot resolve many of the questions concerning the proposed procedures until it gains some experience with petitions, such as: (1) estimating potential dose, (2) using IREP for the determination of "endangerment", (3) defining classes, and (4) estimating and applying potential SEC doses when reconstructing dose for non-SEC cancers (see item #20 below). Rather than issuing a "Final Rule," HHS issue should an "Interim Final Rule," which would allow decisions on petitions to proceed without impairing petitioners' rights as the rule becomes further refined. Issuing a "work in progress" as a "Final Rule" is bad policy. It will undermine public confidence, and result in negative public reaction. There are alternative choices available to HHS. | NIOSH should issue an "Interim Final Rule" with commitment to issue a "Final Rule" rule within 6-12 months of publication of Interim Rule. This will avoid delays while giving HHS more time to resolve significant issues and further consult with Advisory Board. This is a legally permissible route. The Administrative Procedure Act, Title 5 Section 553 ("Rulemaking"), does not dictate what form a rule must take subsequent to a notice of proposed rulemaking. |
| 2 | Preamble Sec. III., Subtitle C | Summary of Proposed Rule: Procedures for Adding Classes of Employees to the Cohort states: "If the proposed class includes one or more members who have already submitted claims and for whom NIOSH was unable to complete a dose reconstruction due to insufficient information, the informational requirements of the petition are minimal." (emphasis added). | These underlined terms are ambiguous, subjective and not amenable to adjudication. | NIOSH should establish, through rule or procedure, criteria (i.e. a checklist or metrics), establishing a "bright line" test for when doses cannot be "completed" due to "insufficient information." Perhaps after NIOSH has done a few petitions it will be able to propose such a bright line test, but this underscores the case for an Interim Rule. |

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| 3 | Preamble Sec. II. E | The preamble to the rule states that "if NIOSH can successfully reconstruct the radiation doses of members of the class under the requirements of 42 CFR Part 82 (emphasis added), then the dose of the class members can be estimated with 'sufficient accuracy' for DOL to adjudicate claims." | The Rule fails to set forth the criteria for what determines a "successful" vs. an "unsuccessful" dose reconstruction. The concern is that NIOSH and its contractors will have broad latitude to declare what constitutes a "successful" effort, based on subjective judgments. Radiological hazards, which are masked by the lack of underlying data, could be assumed away in a dose reconstruction, thus depriving claimants of a chance to successfully petition for the SEC. There must be some line between the two, and this should be defined on something other than a case-by-case determination. There has to be criteria less subjective than "NIOSH-will-know-it-when-they-see-it." | NIOSH must define what it means by a "successful" and an "unsuccessful" dose reconstruction so that claimants, contractors, the Advisory Board, and the Congress will also know one when they see it. NIOSH has used very ambiguous language to define the term "reasonable" estimate in 42 CFR Part 82. |
| 4 | Preamble Sec. II. E | NIOSH states that simplifying assumptions will not always be easy to apply, especially when potential levels of radiation exposure for an individual ranges between low doses and those that qualify for compensation. NIOSH will evaluate each petition on "case-by-case basis and not by using rigid criteria." | There should be an automatic presumption in favor of the petitioner whenever there is uncertainty in applying simplifying assumptions. For example, if the solubility of the isotope is unknown, NIOSH could choose "Y" class or a mixture of 50% "W" class and 50% "Y" class. The worst case (in terms of dose effect) should be applied. The basis for assuming anything other than the worst case (e.g., "Y" class) should be spelled out and justified. | NIOSH's rule or procedures manual must spell out a policy that the petitioner will always receive the benefit of the doubt when using simplifying assumptions to calculate a potential dose. NIOSH must spell out in its report on a petition which simplifying assumptions it selected, which it could have selected, and reasoning must be provided whenever the benefit of the doubt is not given to the petitioners. |

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| 5 | Preamble Sec. II. E | NIOSH's proposed rule states that even where dose reconstructions are not feasible, "the process of determining that dose reconstructions are not feasible should provide information to determine imprecisely the potential level of radiation to which the class could have been exposed." | This is a counterintuitive approach to ascertain endangerment. When NIOSH determines that there is not enough data to reconstruct a dose to ascertain individual causation determinations, its rule assumes that there will nonetheless be sufficient "potential" dose data to establish "endangerment" using IREP. NIOSH has not demonstrated this counterintuitive assumption to be true in all cases. There will be situations where NIOSH will not be able to determine the potential level of radiation to which the class was exposed and the rule does not state what NIOSH will do in these situations. The rule's silence implies that NIOSH has only one choice. When it cannot estimate a potential dose, it will conclude that the class was not endangered. This would be an unreasonable and illogical conclusion. Additionally, it would be an unlawful execution of the SEC provision, which is to provide compensation to those claimants who "may have been endangered" and for whom "sufficient" dose data does not exist. NIOSH should, if it sticks with the proposed "endangerment" algorithm, create alternative methods when it cannot estimate "potential" dose. | NIOSH must state what it will do when it cannot estimate potential doses. GAP recommends that when NIOSH cannot estimate potential doses, NIOSH assign a dose that exceeds the threshold for the most radio-sensitive cancer to meet the endangerment test. The NIOSH Rule will violate the EEOICPA if it allows SEC petitions to be denied for lack of information to estimate a "potential dose". Without a fall back to determine endangerment in the absence of data, the Courts and Congress will readily see this proposed rule as circular and self-defeating reasoning. |

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| 6 | Proposed Rule, Sec. 83.2(a) | Section 83.2 states: (a) A current cancer claimant can petition on behalf of a class of employees to be added to the Cohort upon determination by NIOSH that it cannot complete a dose reconstruction for the claimant. | Section 83.2(a), as proposed, sets forth a subjective standard for deciding whether or not it will determine that dose can be reconstructed. A "determination by NIOSH that it cannot complete a dose reconstruction for the claimant" is inconsistent with the EEOICPA Section 3626(b), which sets a higher standard: "it is not feasible to estimate with sufficient accuracy the radiation dose the class received." It is not acceptable to deny SEC petitions if NIOSH can assert, without defining its terms, that it can "complete a dose reconstruction. The way this is worded, NIOSH can "complete" dose reconstructions, which are inaccurate, unreliable and miss significant amounts of unmonitored dose. | The NIOSH rule or policy manual should define the criteria--perhaps a checklist and/or metrics--when NIOSH will establish that insufficient information prevents it from completing a dose reconstruction. A checklist should include uncertainty on the various source terms, energy level, solubility, lack of a biokinetic model, lack of reliable monitoring technology, failure to use proper monitoring procedures, unmonitored dose, conflicting data, missing records, doctored records, adequacy of workplace radiation protection, etc. |

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| 7 | Rule Section 83.5(b) | Definition of "feasibility" | The rule does not explain how NIOSH will define the term "feasibility" for the purpose of the rule, although the EEOICPA states that the SEC will apply to employees for who "it is not feasible to estimate with sufficient accuracy the radiation dose that the class received." (Emphasis added). The term "feasible" is of equal importance to "sufficient accuracy" and "endangered the health" to warrant an explanation and definition. | NIOSH rule should set forth a checklist of items that should be used in determining "feasibility", including time to recover data, cost to establish data, difficulty in finding data, etc. For example, NIOSH's letter responding to a claimant dated April 25, 2002, gives an estimate of 90 to 180 days to complete dose reconstruction. NIOSH could use the 180-day limit as criteria to conclude that it is not "feasible" to estimate that radiation dose. |
| 8 | Rule Section 83.5(b) | Section 83.5 Definition of "endangered the health" for purposes of these procedures means that "there is a reasonable likelihood that the radiation dose may have caused a specified cancer" determined according to these procedures using NIOSH IREP. | NIOSH's definition proposes circular reasoning: If the radiation dose is assumed to be an unknown (and not knowable), then how can you determine whether health was endangered using potential radiation dose estimates to define the degree of endangerment? If there is not a good enough dose for estimating likelihood of causation, how is it possible that there is a good enough dose for deciding whether someone was endangered? | NIOSH should use the approach Congress applied to SEC's at the gaseous diffusion plants (250 days and the individuals in class were monitored for radiation or should have been monitored) or, in cases were potential dose cannot be estimated, NIOSH should assign a dose that exceeds the threshold for the most radio-sensitive cancer to meet the endangerment test. Additional criteria will have to be developed for acute exposures of a shorter duration (e.g., fought fire with pyrophoric radioactive materials) that can serve as a proxy for endangerment. |

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| 9 | Rule Section 83.5(b) | Section 83.5 Definition of "endangered health" for purposes of these procedures means that "there is a reasonable likelihood that the radiation dose may have caused a specified cancer" determined according to these procedures using NIOSH IREP. | The "may have been endangered" standard for the Gaseous Diffusion Plant workers in a Special Exposure Cohort is, in most circumstances, far more defensible. It eliminates inequity between the statutory SECs and most potential NIOSH SECs. In some circumstances, NIOSH's proposed rule will require potential radiation doses of 40 rad (for populations age 40 who develop a cancer 15 years later). This is a very high threshold for endangerment, when cancers such as leukemia are compensable at much lower exposures. NIOSH responds that Congress did not direct them to use the GDP (or any other time duration) criteria. Congress gave NIOSH guidance through its two examples (Amchitka is duration specific, as are GDPs). Congress did not tell NIOSH not to use time duration. Congress wanted to assure that the endangerment test was rational enough to include "at risk" workers and eliminate those who had very short tenure (Pepsi delivery persons) and those with little potential for exposure (office workers removed from buildings with radiation related jobs). | The test for the statutory term "there is a reasonable likelihood that such radiation dose may have endangered the health of the members of the class" should be changed in the Rule to provide for employment duration-based tests, such as the test as used for the SEC at the Gaseous Diffusion Plants. However, when there are short duration high-risk work environments, NIOSH will need to develop alternative procedures for determining whether such workers may have been endangered. As a legal matter, NIOSH IREP is not suggested in any statutory provision for determining whether claimants should be included in an SEC. This is wholly an invention created in this rule with no legislative history. |

Comments of the Government Accountability Project on the Department of Health and Human Services Proposed Rule "Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000" 42 CFR Part 83.

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| 10 | Rule: Section 83.5, 83.12 | NIOSH is relying upon the use of the NIOSH-IREP Model to calculate the SEC test for "may have been endangered" based on potential dose estimates. | IREP requires individual characteristics for probability of causation calculations, but many of these inputs will not be available for entire classes of workers. Section 83.12((b)(ii) states that NIOSH will use "reasonable values that confer the benefit of the doubt to the class". Absent better guidance, it is questionable whether identical inputs would be used in two identical circumstances. Many IREP calculations are age sensitive. Data will be scarce on age at exposure; will NIOSH use 20? 30? 40? Since ages within the class will vary, how can an "average" ever give the whole class the benefit of the doubt? Will NIOSH always assume the gender or race most favorable to the class when gender or race is unknown? Cancer risks vary with latency; what latency assumptions will be used? Biokinetic models do not exist for many isotopes and chemical forms; how will NIOSH select the most radiosensitive location? Why not use leukemia as the most radiosensitive cancer in all external radiation cases? IREP allows for multiple primary cancers; will the probability of causation be adjusted for exposures to multiple isotopes? | NIOSH does not appear to have "road tested" its proposed approach to calculating endangerment using IREP to know what the range is of potential radiation doses for setting a threshold of "endangerment." The NIOSH rule or policy manual must be far more prescriptive in spelling out how it will address the range of variables. Since cancer effects have been observed at 10 rem and below, it would be prudent to assure that this endangerment threshold doesn't produce a contrary outcome. |
| 11 | Section 83.7 | This section states that "Petitioners must be one of the following: (a) One or more DOE, DOE contractor or subcontractor, or AWE employees or their survivors; and/or (b) A labor union representing or formerly having represent DOE, DOE contractor or subcontractor, or AWE employees who would be included in the proposed class of employees." The preamble states that other potential representatives were excluded because "HHS found it reasonable to require that such experts work on behalf and with the class, who are the interested parties." | Worker advocacy organizations, if formally authorized in writing by a member or members of a potential class, should be able to submit petitions. Organizations such as Los Alamos POWS, CHE (Oak Ridge), FACTS of Tonawanda are uniquely qualified to submit petitions and are often composed of non-union workers, and/or workers whose unions are not engaged in this issue. To eliminate the ability of organized groups of workers from submitting petitions because they are not labor unions is unfair. | The rule should be expanded to include other types of petitioners in addition to DOE contractor or AWE workers or their unions. NIOSH should add established worker advocacy groups, including injured worker organizations and worker support groups to apply on behalf of workers if they represent potentially compensable workers, and have received written authorization to submit a petition on behalf of at least two members of a potential class. Also the rule should provide that attorneys working on behalf of an individual or class of workers may submit a petition on their behalf. |

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| **12** | Section 83.8 | This section states "the petitioner(s) must send a completed 'SEC Petition Form' to NIOSH/OCAS...." | The form was not published with the rule. Comments cannot be provided. | NIOSH should provide the form for public comment and review by the public and the Advisory Board on Radiation and Worker Health to assess the informational requirements, clarity, and ensure the form is not unduly burdensome. |
| **13** | Section 83.9(a) | This section applies to a claimant who has attempted and failed a dose reconstruction. The petitioner need only transmit a copy of a report produced by NIOSH under 42 CFR 82.12 notifying the petitioner's that NIOSH attempted and could not complete a dose reconstruction for the individuals due to insufficient records or information. | The process under 83.9(a) is excessively time consuming and the rule should seek to eliminate delays. From the point the claim is filed with the DOL, NIOSH attempts dose reconstruction, fails, DOL denies claim, the petitioner files for SEC status, a positive determination goes to the ABRWH, and Secretary sends it to Congress for mandatory 180-day review, it appears that several years will pass. Moreover, except for Congressional review, there are no time limits at any phase of this process. The Secretary for HHS should delegate final decision making to the Director of NIOSH under Section 83.14, with a mandatory 20-day turnaround after receipt of NIOSH staff and ABRWH recommendation. | Time limits need to be specified to accelerate the process. Three recommendations follow: (1) Streamline decision-making through the delegation of authority to approve/deny petitions to the Director of NIOSH (the Secretary can delegate this authority to NIOSH); (2) A 20-day timeline should be set from receipt of a recommendation from NIOSH staff and ABRWH for issuance of a final determination and transmittal to Congress; (3) Set forth a maximum 180-day period for reconstructing radiation doses as an outer limit, after which NIOSH should determine that it is not "feasible" to estimate dose. (Delay is a very real. The Secretary's office has added months of delay in issuing a draft SEC rule, and delayed issuance of the report to Congress on atomic energy weapons employer sites that was due back on June 28, 2002, pursuant to Section 3151(b) of the FY 2002 Defense Authorization Act.) |

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| **14** | Section 83.9(b) | This section applies to all individuals or groups who do not or could not petition under section 83.9(a). In summary, these workers must submit a petition to the Secretary of Health and Human Services with 1) a proposed class definition identifying: (i) facility, (ii) job titles, (iii) period of employment, and if relevant, (iv) exposure incidents; 2) the basis for health endangerment: either (i) health effects or health care or (ii)(A) identification of potential exposures and (B) shortcoming of radiation protection; and 3) the basis for infeasibility of dose reconstruction: either (i) demonstrated lack of records or (ii) expert report. | Under 83.9(b)(3), petitioners must describe the basis of their belief that the available data is insufficient to estimate the radiation doses with sufficient accuracy. First, NIOSH is imposing an added informational burden for claimants under 83.9(b) that is not required under 83.9(a). It is apparent that the informational requirement is solely to achieve NIOSH's goal of discouraging petitions under 83.9(b). Second, the informational requirement of 83.9(b) imposes an impossible informational requirement for most AWE petitioners. Pursuant to a DOE memorandum dated February 27, 2002 to the DOL, DOE stated that for certain AWE facilities, DOE has no records to verify employment. Doe would not likely have access to exposure records at these AWEs. Third, DOE does not construe EECOIPA 3623(e) to require them to request records from the AWEs. Also, AWE's are not covered under the Freedom of Information Act; such a request for information will be futile. Claimants will not even get an answer that "the records do not exist". Fourth, petitioners for a class will not be able to get class member records from DOE due to Privacy Act restrictions. Fifth, health physicists, absent access to comprehensive data, will not be able to offer an informed opinion on whether the "documented limitations would prevent the completion of dose reconstructions for individual members of the class." | The requirements of section 83.9(b)(1) and (2) provide sufficient information for NIOSH to determine whether to evaluate the petition. NIOSH will always have the discretion to deny a petition for evaluation or request additional information for the petitioner. The informational requirements of section 83.9(b)(3) should be optional because they significantly increase the burden on the claimant and in many cases will be a futile endeavor. If a record request is required there must be a limit on the time DOE has to respond to a petitioner. |

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| **15** | Section 83.9(b) | See Above | Petitioners will have a very difficult time meeting all the levels of proof necessary under 83.9(b)(1) when they worked on a "need to know" basis and, for survivors, may not know enough detailed information about the conditions of the workplace. Moreover, health physics is a highly specialized area of expertise not available to most potential petitioners, yet this knowledge base is required to establish a credible petition. | NIOSH should provide Technical Assistance Grants to organizations (or set up university based providers) with health physics or radiation dose reconstruction expertise who can assist claimants in demonstrating the shortcomings of radiation protection when preparing petitions for special exposure cohorts. DOE and DOE contractors should not be funded by NIOSH to provide this service, although DOE and its contractors are free to assist petitioners. |
| **16** | Section 83.9 (b)(1)(i), (b)(2), and 83.12 (c)(2)(i) | Section 83.9(b) requires "the facility at which the class worked" and "a description of the petitioner's basis for believing the class was exposed to levels of radiation at the facility..." | This definition precludes treating workers who worked at multiple facilities as a single class. This particularly affects construction workers who moved from site to site. At Oak Ridge, for example, there was a common pool of construction workers that served Y-12, X-10 and K-25. By definition, these are multi-site employees. Likewise security guards and production workers floated between Y-12, K-25 and X-10. | NIOSH's rule needs to expand the definition of a class to include multiple facilities when workers moved from DOE site to DOE site. NIOSH needs to modify this rule to allow multi-facility petitions, which incorporates information as workers moved from site to site. This is a reasonable interpretation of the EEOICPA, even though the Act did not expressly authorize multi-facility petitions. |

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| **17** | Section 83.12 (b)(1) | NIOSH evaluates a petition to determine is there is a "reasonable likelihood that such radiation dose may have endangered the health of members of the class." To make this determination NIOSH will determine if there is a reasonable likelihood that a potential radiation dose may have caused a specified cancer (i.e. the minimum level of radiation dose which NIOSH-IREP will produce a probability of causation of 50% at the upper 99 percent credibility limit for the most radiogenic specified cancer or cancer that could have resulted from the type of radiation exposure). | NIOSH says that its estimate of potential dose will depend on the information that NIOSH collects on the types and levels of radiation exposures that potential members of the class may have incurred. The assumption that the information will be available or to any degree sufficient is presumptuous at best, and generally counterintuitive when the basic premise is that there is not enough information to reconstruct dose. NIOSH has no proposed methods for determining endangerment when such information is not available. Moreover, NIOSH has to spell out the degree to which it will provide benefit of the doubt to the claimant. What will NIOSH do when there is no credible source term information for a class? Or solubility information? What will it do when there are multiple potential radiation types? How will NIOSH account for different biokinetic models with different target organs that could produce multiple primary cancers? | NIOSH's rule or procedures manual needs to state how it will ascertain endangerment when there is not enough information to formulate a potential dose. See comment and recommendation #5. |
| **18** | Section 83.13 | This section describes how the Advisory Board on Radiation and Worker Health (ABRWH) will evaluate a petition. | All petitions evaluated by NIOSH should be submitted to ABRWH regardless of the outcome. A positive decision by NIOSH should not preclude the Board's review, because NIOSH and the petitioners may disagree on the class definition even though the petition was granted in part. | All petitions evaluated by NIOSH should be submitted to ABRWH regardless of the outcome. |

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| 19 | Section 83.15 | This section describes the role of Congress in acting upon the final decision of the Secretary to add a class of employees to the Cohort. The section provides that the Secretary's designation of a class "will take effect 180 days after the date on which the report of the Secretary is submitted to Congress" and that "within 200 days after transmittal of the report to Congress, the Secretary will transmit to DOL" the designation. | What is the purpose of the extra 20-day period after Congress's 180-day review has been exhausted? Why isn't the Secretary's designation transmitted to DOL immediately after 180-day review is concluded? | Designation of SEC should be transmitted to DOL on the first business day after the 180-calendar day Congressional review period expires. |
| 20 | Comment of NIOSH official, Ted Katz at July 23, 2002, NIOSH Hearing on SEC Rule in Amherst New York, transcript at pp.14-15 | Mr. Katz stated: "And the last point I just want to make is that the decisions to add a class to the cohort are really, in a sense, grave decisions, and we view them as grave decisions. They have important consequences because if you add a class to the cohort, members of that class then can only be compensated for the 22 cancers that are specified cancers as allowed by EEOICPA, allowed by the law; and if you have a different cancer you cannot be compensated under this program -- for example, if you have prostate cancer or skin cancer. So when we make decisions to add a class to the cohort it's a grave decision. It's an important decision. It has real implications for some members of that class, in all likelihood, because some members of a class are likely to have skin cancer or prostate cancer." | NIOSH's policy statement, which was not proposed in its rule, blocks anyone in an SEC class from seeking a dose reconstruction for non-SEC cancers. This policy is unsupported in EEOICPA. Classes are defined by time and exposure. People with a non-SEC cancer who are covered in an SEC class should be able to file for a non-SEC cancer if they received other radiation exposures at a DOE/AWE facility. For example, those who worked at a DOE site within an SEC class (e.g., all who worked 1960-1970) and also received radiation dose outside of an SEC class which can be estimated (e.g., 1971-1981) should be able to file a claim for a non-SEC cancer. NIOSH will need to assign a dose estimate (e.g., the potential radiation dose used in determining "endangerment") for the 1960-1970 time period to tally a composite dose estimate for 1960-1981. This may require an amendment to the dose reconstruction rule or procedures manual. Further, NIOSH should consider the circumstance where petitioners for a proposed SEC would not have enough potential dose to meet the threshold for "endangerment," but when combined with non-SEC exposures, some would qualify for inclusion in an SEC. | NIOSH must fill in this gap before it issues an Interim or Final Rule. NIOSH need to explain how it will address individuals who meet the exposure and time periods for inclusion in a SEC, but who have a non-SEC cancer. NIOSH will need to assure that claimants can obtain dose reconstruction when there are radiation exposures that are not covered in the time frame of a special cohort. NIOSH needs to establish radiation dose estimates for the time periods someone was employed in a SEC and files for a non-SEC cancer in another time period. GAP recommends that the "potential" dose estimated for the SEC time period (if calculable) be added to the dose estimates for the non-SEC time periods. Likewise, the policy needs to consider the opposite circumstance where there is not enough potential dose to include the class in the SEC (e.g., P of C is 40%) but for certain subgroups, when added to exposures incurred outside of the Special Cohort time periods, they would exceed the threshold for endangerment (>50%). NIOSH's policy as elucidated on the record at the July 23rd meeting in Amherst, New York must be revised and subject to notice and comment. |

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| 21 | Rule Section 83.13, 83.14, 83.15 | *Federal Register* notices are required when petitions are sent to Advisory Board, when petitions are denied, and when petitions are approved after Congressional review. | GAP supports notifications in the *Federal Register*. NIOSH should use the *Federal Register* in addition to other ways (press releases) to communicate with widely dispersed groups of potential SEC members. We request one additional notification in the *Federal Register*: When petitions, which are approved, have been transmitted to Congress for review. We also believe Petitions should be tracked on the NIOSH Web page, so that its progress through each stage can be followed by claimants, the public and press. | Add one additional *Federal Register* notification requested: when a petition that has been approved by Secretary of HHS (or designee) is sent to Congress for 180-day review. |
| 22 | Rule: Section 83.16 | Secretary can cancel or modify a final decision to reduce scope of a class. Secretary must notify public via Federal Register. | If claims have been paid by DOL for members of an SEC that has been approved by the Secretary of HHS after Congressional review, and the Secretary subsequently reduces the size of the class under Section 83.16 such that some claimants would be disqualified who have already been paid as members of the SEC, will these claimants have to repay their benefits? | Rule should preclude any requirement for claimants who have been awarded benefits to have to repay them if the Secretary reduces the size of the class under Section 83.16. Further, the Secretary should notify the petitioners and issue a press release in the area where the facility was located, in addition to the placing a notice in the Federal Register. We strongly support the use of Federal Register notice. |