Fernald Atomic Trades & Labor Council

AFL - CIO Metal Trades Affiliated

P.O. Box 126, Ross, Ohio 45061

Comments of the Fernald Atomic Trades & Labor Council (FAT&LC) 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 (42 CFR Part 83) Federal Register Vol. 68, No. 45, pp. 11294-11310 (March 7, 2003)

Outlined below are FAT&LC's comments on the March 7, 2003 NIOSH Notice of Proposed Rulemaking Procedure for Designating Classes of Employees as Members of the Special Exposure Cohort under EEOICPA, 68 *FR* 11294-11310, March 7, 2003 (hereinafter NPRM #2). FAT&LC also filed comments on the previous HHS Notice of Proposed Rulemaking related to Special Exposure Cohorts, 67 *FR* 42962-42973, (published on June 25, 2002).

FAT&LC represents approximately 575 hourly employees of the prime contractor and certain subcontractors at the Department of Energy's Fernald, OH site. FAT&LC has represented production, maintenance, environmental restoration and support service workers at the Fernald site since 1952. Fernald produced uranium metal, processed thorium and uranium compounds, and conducted uranium rolling and machining operations for the AEC and DOE. Recycled uranium was used at Fernald which was contaminated with transuranics. FAT&LC believe this dose will be impossible to estimate and thus many workers may be candidates for a Special Exposure Cohort.

FAT&LC has 13 affiliated unions from industrial and craft based unions, including the International Chemical Workers Union Council, International Association of Machinists, Operating Engineers, Carpenters, Masons, Painters, International Brotherhood of Electrical Workers, Ironworkers, Pipefitters, Oilers, Sheetmetal Workers, Teamsters and Service Employees (SEIU).

Questions on these comments should be directed to Gene Branham or Robert Tabor, 513-648-5079.

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

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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 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.

Thus, unless the result of such an interpretation were 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.

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 of days of employment at multiple gaseous diffusion plants in up to 3 different states to meet the 250 workday 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 unclear why the rule imposes a requirement for specific "information and recorded data" be "available" for purposes of "class definition" when 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.

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 commentor on this rule suggested that only the union representing employees at a site would have the right to file a petition. At Fernald that could mean that there would have to be 13 different petitions, one for each of the on-site production and maintenance unions in the Fernald Atomic Trades & Labor Council. In addition, the 14 unions that make up the Greater Cincinnati Building and Construction Trades Council might have to file another 14 petitions for their members. We could forsee 27 petitions for a single time period at Fernald. The proposal made by a consultant who prepared PACE's comments to limit the petitioners to the "exclusive representative" is simply unworkable.

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 or 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 judgement 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."

FAT&LC supports the reduced information requirements for submitting a SEC petition in this rule, compared with what had been proposed

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 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.

Second, 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 that there is not "sufficient data" "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.

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 for "to estimate maximum potential dose." However, these claims could also be dismissed under the dose reconstruction rule because "worst case" estimates are only allowable at 42 CFR 82.10(k) as part of an "efficiency" mechanism if the dose falls below the 50 percent probability of causation. What is not clear is what happens to claimants where the worst case estimates exceed 50 percent 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, 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 policy to use "worst case" estimates, when data is limited and the probability of causation ("P of C") is > 50%, has not been spelled out in clear language within the dose reconstruction rule. Rather than providing clear authority, 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 worst case estimate could be used when 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 <u>above</u> the 50 percent probability of causation threshold.

<u>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).</u>

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 "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 <u>not</u> 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.

(*See*: March 7, 2003 Transcript, pp.46)

We agree with using the "worst case" as a point estimate (*e.g.*, IREP provide for a "constant value"). NIOSH needs to justify why it would not use the maximum potential dose as a point estimate and make its methodology clear in the rule.

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.

If statements by senior NIOSH personnel can be credited that they can "cap <u>any</u> dose," NIOSH's decision to raise the bar may have intentionally precluded virtually anyone from ever qualifying for the SEC. Is this the intent of NIOSH? If not, what NIOSH should do is provide some examples in the Preamble of the kinds of cases where it believe it will not be able to estimate dose with sufficient accuracy under the new thresholds set forth in NPRM #2. If there are no conceivable cases, NIOSH should state this as well, 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."

<u>First, NIOSH's proposal to limit the number of specified cancers in a given Special</u>

Exposure Cohort directly contradicts Congressional intent.

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)

NIOSH should delete the provisions authorizing it to select organ specific cancers in §§83.13(b)(2), 83.13(b)(3) and 83.13(c)(4).

Second, by determining that certain cancers are not at risk in a given SEC class, NIOSH contradict its own finding in the *Federal Register* notice for this rule 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"), NIOSH has positioned itself at odds with its clearly stated declaration (above) that "NIOSH cannot quantitatively evaluate health endangerment" for those classes of workers where it admittedly lacks sufficient data to even come up with a maximum potential dose.

Furthermore, by authorizing risk estimation to determine which specified cancers should be included or excluded in a class, the proposed rule positions itself at odds with the previous recommendations of the NIOSH Advisory Board and public–which NIOSH had properly accepted-- 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. This double standard on

the use of risk estimation should be soundly rejected.

Congress resolved the question of scientific uncertainty in favor of claimants precisely because risk cannot be quantified when exposures are not known and it is the right thing to do for those put at risk. NIOSH should not be second guessing or otherwise undermining this sound policy decision.

At 68 *FR* 11296 NIOSH takes the position that 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 NIOSH will adopt the Health Physics Society's (HPS) recommendations 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 underlaying 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.

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. The final rule should specify parameters related to time and cost to serve as a means of considering the issues of excessive length of time and prohibitive cost in dose reconstruction. This should include time limits on dose reconstruction.

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

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) **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 in 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.

2) **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 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?

3) **Notification** – FAT&LC applauds the addition of a 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 issues

1) **Time lines**--We believe NIOSH should establish a time frame of 180 days to complete a dose reconstruction, after which NIOSH should establish that "it is not feasible to estimate dose with sufficient accuracy."

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.

2) **Technical Assistance**--NIOSH should 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.

3) **Coordination Between SEC and Dose Reconstruction Rule** – NIOSH 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.

Gene Branham

Gene Branham, President

Fernald Atomic Trades & Labor Council