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Sent: Friday, August 23, 2002 6:08 PM
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Subject: Comments of PACE Local 5-4200

Please include these comment in the record. The attached document is in "word" format.

If you have any questions, please call 937-865-4658

August 22, 2002

PACE Local 5-4200 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

These comments are submitted on behalf of the PACE Local 5-4200 members by Vice President and H&S Chairman, Mr. Eric Parker. For over 40 over years we have represented the hourly workforce at the Department of Energy's Mound Facility in Miamisburg, Ohio. We the workers believe we are uniquely qualified to express the shortcomings in the proposed regulation.

NIOSH has admitted many of the questions concerning the proposed procedures cannot be resolved until it gains some experience with petitions. Some of these questions are paramount to the successful implementation of this program and compensating eligible claimants. Defining issues such as estimating potential dose, using IREP for the determination of "endangerment", defining classes, and estimating and applying potential SEC doses when reconstructing dose for non-SEC cancers. Until these issues are resolved and vetted with the Advisory Board, it would be premature to issue a Final Rule. For that reason we recommend an Interim Final Rule with a commitment in the Preamble to issue a final rule in 8 months. Interim Final will allow petitions to be processed, and approved, but will not prejudice those which would benefit from a denial should the Final Rule resolve a matter in the petitioner's favor.

Preamble

1. In the preamble, it states that "if NIOSH can successfully reconstruct the radiation doses of members of the class, under the requirements of 42 CFR Part 82, then the dose of the class members can be estimated with 'sufficient accuracy' for DOL to adjudicate claims." "Successful" dose reconstruction needs to be defined by NIOSH so that claimants, contractors, the Advisory Board, and the Congress are able to identify a successful claim. Also, NIOSH uses indeterminate language to define "reasonable" estimate in 42 CFR Part 82.

2. NIOSH will evaluate each petition on "case-by-case basis" however, there are specific criteria established for these evaluations. The presumption should be in favor of the petitioner whenever there is uncertainty in applying established criteria. Dose reconstruction, at best, uses many assumptions that could lead to a grossly underestimated dose. Some real examples are: date of intake is usually assumed be the midpoint between two bioassay samples, the solubility class of the isotope is usually assumed to be 50%Y/50%W or 33%W/33%M/33%Y, the particulate size is usually assumed. If any of this information is unknown the worst case scenario should be applied, i.e., use day after previous bioassay sample as date of intake, use "yearly" for the solubility of the isotopic class, etc. The justification for using anything other than worst case should documented and explained.

Section 83.2(a)

1. As proposed, the proposed rule sets forth a subjective standard for a NIOSH "determination that it cannot complete a dose reconstruction for the claimant." This doesn't match the higher standard set in section 3626(b)(1) of the EEOICPA, which states: "it is not feasible to estimate with sufficient accuracy the radiation dose the class received." It is unreasonable for NIOSH to deny SEC petitions if it cannot define how and why it's determined that it can "complete a dose reconstruction." As worded, NIOSH dose reconstructions may be inaccurate, unreliable and miss significant unmonitored doses. The NIOSH rule should spell out the criterion that establishes when NIOSH must determine that "insufficient information exists for completing a dose reconstruction. These guidelines should include the variable uncertainties mentioned above under comments on Preamble 2, technological shortfalls in radiological monitoring for some radioisotopes, history of the sites radiological protection program, i.e., documented programmatic failures, etc.

83.5(b)

The proposed rule does not explain with sufficient accuracy how NIOSH will define the terms "feasibility", "sufficient accuracy" and "endangered health" for the purposes of the rule The EEOICPA states that the SEC will apply to employees for who "it is not feasible to estimate the radiation dose that the class received." Congress gave NIOSH guidance through two examples—both of which are based on duration of employment in a potential radiation exposure environment. 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 and those with little potential for exposure. 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. Also, NIOSH should develop additional procedures for workers who may have been endangered in short-term and/or acute exposure scenarios.

"NIOSH-IREP" is not mentioned in any statutory provision for determining whether claimants should be included in SEC. This has been included in this rule without legislative direction or guidance. Guidelines need to establish criteria to determine it is not "feasible" to estimate radiation dose" i.e., time, cost and difficulty in finding meaningful and reliable data. For example, NIOSH's could use the 180-day limit as criteria to conclude that it is not "feasible" to estimate that radiation dose.

Section 83.5

The 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 using NIOSH IREP. If the radiation dose cannot be established with reasonable certainty, how can it be determined whether health was endangered? As noted above, NIOSH should adopt the approach Congress applied to SEC's at the gaseous diffusion plants, i.e., 250 days and the individuals in the class were, or should have been, monitored for radiation or in cases where potential dose cannot be estimated. Also, additional criteria should be developed for short acute exposures that would serve to meet the "endangerment" criteria.

The SEC petition form was not published with the rule. NIOSH should provide and allow the public and the Advisory Board on Radiation and Worker Health time to review and comment on the informational requirements, clarity, and ensure the form is not unduly burdensome.

Section 83.9(a)

The process under 83.9(a) is excessively time consuming and the rule should seek to eliminate delays. In fact, it appears that 2-3 years could pass between initial filing or a DOL cancer claim and granting of an SEC petition claim, because of the time it takes to file with the DOL, NIOSH attempts and fails dose reconstruction, DOL denies claim, petitioner files for SEC status, NIOSH staff reviews and evaluates, a positive determination goes to ABRWH, and Secretary sends it to Congress for mandatory 180-day review. Time limits need to be specified to accelerate the process. The review by the Secretary of HHS could be eliminated to reduce time delays. ABRWH meetings will need to be held at more frequent intervals to accelerate this process as well.

83.9(b)(1)

Many petitioners have worked on a "need to know basis." This fact alone will make it very difficult, if not impossible to gather documentation necessary for proof. For survivors this would be an insurmountable task. Also, some radioisotopes are considered "shortfall" isotopes, which means there is/was not an approved acceptable method for radiological monitoring, i.e., High fired oxides of plutonium, Stable tritiated particulates, etc. NIOSH needs to address the fact there are multiple potential radiation types. Also, these varying radioisotopes have different biokinetic models with different target organs that could produce multiple primary cancers. NIOSH needs to address how it will ascertain endangerment when there is not enough information to formulate a potential dose. Moreover, to what degree will NIOSH offer benefit of the doubt to the claimant? NIOSH has no proposed methods for determining endangerment when inadequate information is available to estimate a potential dose. In this case, it should assign a potential dose to overcome the endangerment threshold (if duration of employment is not used instead).

Also, health physics is an area of expertise that laymen petitioners (labor unions and workers) have very little, if any knowledge base. NIOSH should provide Technical Assistance Grants to organizations (or set up university based providers who are not tied to the DOE) with health physics or radiation dose reconstruction expertise who can assist petitioners 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.

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.

Section 83.15

Congress acts 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." Then the section talks about "within 200 days after transmittal of the report to Congress, the Secretary will transmit to DOL" the designation. The twenty-day lag time needs to be explained or eliminated.

NIOSH need to explain how it will address the situation that arises when an individual(s) who meet the exposure and time periods for inclusion in a SEC, but who have a non-SEC cancer. NIOSH should assure that claimants can obtain dose reconstruction for their 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 who then subsequently files for a non-SEC cancer in another time period. "Potential" dose estimates for SEC time periods should be added to the dose estimates for the non-SEC time periods. The policy also needs to address the opposite situation, i.e., where there is not enough potential dose to establish a class in the SEC but when added to dose estimates received outside of the SEC time periods, they would exceed the threshold for endangerment.

NIOSH should continue to use the *Federal Register,* in addition to other ways to better communicate with groups of potential SEC members, i.e., press releases, etc. NIOSH should also publish in the Federal Register and on the NIOSH web site when petitions, which are approved, have been transmitted to Congress for review. This would serve as a tracking mechanism for claimants and the public follow the progress through each stage.

Section 83.16

The 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 this section. Further, the Secretary should notify the petitioners and issue a press release in the area where the facility was located, in addition to placing a notice in the Federal Register.

In closing, in the interest of the EEOICPA and potential claimants, HHS should issue an "Interim Final Rule" with the commitment to issue a final rule within 6 to 12 months rather than issuing a "Final Rule." This would allow decisions on petitions to proceed without impairing petitioners' rights as the rule becomes further defied and refined. This will avoid delays in claims and negative public opinion while giving HHS the time needed to resolve these and other significant issues and further consult with ABRWH.

Questions should be directed to Mr. Eric Parker, Vice President and Health and Safety Chairman of PACE Local 5-4200 at 937-865-4658.