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Sent: Wednesday, April 30, 2003 7:23 AM
To: NIOCINDOCKET@CDC.GOV
Subject: Comments on NIOSH SEC Rule



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**Comments from PACE Local 5-4200, Miamisburg, Ohio
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)**

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Designating Classes of Employees as Members of the Special Exposure Cohort under EEOICPA.**

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PACE Local 5-4200 is pleased to offer its comments the NIOSH Notice of Proposed Rulemaking Procedure for Designating Classes of Employees as Members of the Special Exposure Cohort under EEOICPA, published on March 7, 2003 (68 *FR* 11294-11310, hereinafter NPRM #2). PACE Local 5-4200 filed comments on August 23, 2002 with respect to the previous HHS Notice of Proposed Rulemaking related to Special Exposure Cohorts (67 *FR* 42962-42973, published on June 25, 2002). Eric Parker can be reached at 937-865-3389.

PACE Local 5-4200 has represented hourly workers for over 40 years at the US Department of Energy's Mound site located in Miamisburg, Ohio. PACE Local 5-4200 (and its predecessor Oil, Chemical and Atomic Workers) represented production, maintenance, environmental restoration and support service workers in support of the many missions and subsequent decontamination/decommissioning at the site, including Polonium-210 operations, Plutonium 238 Heat Source Project, the Reactor Waste Decontamination Project, the Reactor Fuels Program, the Uranium-234 Program, and the Neutron and Alpha Source Program, tritium operations, operations involving insoluble high-fired oxides of plutonium and stabilized metal tritites (Class YY), the Radium-Actinium Separation Program, the Ionium (Th-230) Program, the Protactinium-231 Program, the Thorium-232 Refining and Redrumming Program, the Cotter Concentrate Program and non-nuclear components and explosives testing programs.

DOE contracted for an internal dose reconstruction at the Mound facility for workers with at least 20 rem internal dose prior to 1989. Phase II results (MJW, June, 2002) identified significant uptakes. These results have not been widely communicated, unfortunately, and nearly 60% of those with a dose >20 rem have not been notified by DOE.

Number of Assessments < 20 rem:	751
Number of Assessments = 20 rem:	2
Number of Assessments > 20 but < 30 rem:	226
Number of Assessments > 30 but < 50 rem:	181
Number of Assessments > 50 but < 100 rem:	215
Number of Assessments > 100 but < 250 rem:	122

Number of Assessments > 250 rem:	<u>25</u>
Total	1522

The MJW report notes a lack of data to reliably reconstruct dose for a wide array of less commonly used nuclides. "The nuclides used to varying degrees consisted of actinium-227, protactinium-231, radium-226 and 228, thorium-228, 230 and 232 and uranium-233, 234, 235 and 238. As detailed in the Phase I Final Report, the bioassay information for these relatively minor players in the Mound facility operations was not well documented and often was non-existent." (Phase II Report, pp 3). Further, it will be difficult, if not impossible, to estimate exposures to workers who were exposed in the 1990s to high fired oxides of plutonium, actinium-227 and stable metal tritites and for which bio-assays were not conducted, or for which samples results were not deemed valid (See: Levell v Monsanto). Subsequent bioassay resampling of Ac-227, for example, resulted in minimum detectable levels so high, that it would have failed to detect most uptakes that were <100 rem.

PACE Local 5-4200 believes that the absence of dose data will make it impossible to estimate dose for certain groups of workers, and thus there may be several classes of workers who are viable candidates for the Special Exposure Cohort at the DOE's Mound facility.

Section 83.5—Definitions

Section 83.5 should define "facility" as a term.

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?

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 of government. 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.

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.”

PACE Local 5-4200 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

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.”

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” 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.

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?

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 above the 50 percent probability of causation threshold.

In sum, 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. 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. Clearly, using the worst case as a constant value would generate a more claimant friendly outcome than including it in the tail of a distribution.

Fifth, 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. Why did NIOSH raise the bar compared with NPRM #1? Will this have the effect to limiting the number of classes added to the SEC, and was this intentional?

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 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 explains 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).

By saying it can identify which organs are at risk and which organs are not at risk in an SEC, NIOSH has contradicted its own finding 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 "endangered" from radiation exposure in a SEC, 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.

The proposed rule also positions itself at odds with the previous recommendations 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. This double standard on the use of risk estimation should be 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.

The rule doesn't explain whether NIOSH will adopt the Health Physics Society's (HPS) recommendations for deciding which 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.

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 infeasible. 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 or doses cannot be estimated.

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 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?

3) **Notification** – PACE Local 5-4200 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 petitioners 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. In addition, NIOSH should also hold several training workshops to address the informational 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.