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Sent: Friday, August 23, 2002 8:34 AM

To: niocindocket@cdc.gov

Subject: comments on proposed procedures for designating additional members ....

attached are the comments of PACE international union on NIOSH"s proposed procedures for designating additional members of the special exposure cohort.

August 23, 2002

Sent Electronically to NIOCINDOCKET@CDC.GOV

NIOSH Docket Office
Robert A. Taft Laboratories
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To the Docket Officer:

These comments are submitted on behalf of the Paper, Allied-Industrial, Chemical and Energy Workers International Union (PACE) in response to the Proposed Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000 published in the ***Federal Register*** on June 25, 2002.

PACE represents 320,000 workers nationwide in oil, chemical, pulp, paper, auto parts and nuclear industries. We represent workers at eleven Department of Energy (DOE) sites in the DOE nuclear complex and workers at a number of current and former beryllium and other atomic weapons employers. Additionally, PACE represents tens of thousands of former workers potentially affected by this proposed rule. These procedures for designating additional members of the special exposure cohort (SEC) will govern whether our members and their families, and thousands of other workers, receive compensation for radiation induced cancers.

PACE believes NIOSH's proposed procedures are fundamentally flawed. PACE views these procedures as a "general statement of policy" which, according to caselaw interpreting the Administrative Procedure Act (APA), does not establish norms binding on claimants or NIOSH, but announces how NIOSH intends to exercise its discretion under EEOICPA in the future. We applaud NIOSH for seeking public input on these procedures, even though they could be promulgated without notice and comment. However, we urge NIOSH to change these procedures promptly and to make clear that the new procedures are a statement of NIOSH policy which may be applied flexibly in the future to ensure that workers exposed to radiation at DOE facilities who develop cancer have a meaningful opportunity to be added to the SEC. We would oppose NIOSH's publishing these procedures as a "rule" (interim or final) since to do so would 1 limit NIOSH's ability to revise or modify the procedures without a new round of notice and comment or to depart from the procedures when circumstances warrant.

The most significant flaw in NIOSH's proposed procedures, is that they cling to the notion that exposure assessment -- however illusory because of missing records -- should be the touchstone for all decisions about whether radiation may be related to an employee's cancer. In some cases, too few records exist to have any credible idea of an employee's radiation dose. In

such cases, making up estimates to substitute for missing exposure data or forcing employees to search in vain for missing records is not useful. Likewise, NIOSH IREP is not useful in evaluating the likelihood that radiation caused cancer when dose cannot meaningfully be reconstructed. NIOSH IREP is a series of dose-response estimates. Without adequate dose information, NIOSH IREP is useless in measuring response.

EEOICPA recognizes that in some cases dose reconstruction is a farce. NIOSH's procedures, unfortunately, do not. EEOICPA Section 3623 requires a determination of the likelihood that radiation caused cancer using radio-epidemiology tables. Section 3626, by contrast, requires no such thing. It was intended to provide an alternative means of obtaining compensation when radiation dose cannot reasonably be estimated. And radio-epidemiology tables are of no use. If NIOSH relies on a quantitative exercise to decide whether to add employees to the SEC, even in instances where radiation dose cannot be accurately estimated, it will undermine Congress' intent. It will place thousands of employees in a cruel Catch 22 -- NIOSH will decide whether workers are added to the SEC by reference to dose-response tables (NIOSH IREP) even though dose information for these workers is too uncertain to be estimated. It makes no sense, and deprives workers of a real chance for inclusion in the SEC, to insist on dose quantification when too little reliable information exists to estimate dose. Applying worker friendly assumptions or extrapolating from exposures of others who worked nearby does not cure this fundamental problem.

Instead, NIOSH's procedures should ensure that employees exposed to radiation at DOE sites, but for whom exposure records are either poor, incomplete, or nonexistent so that dose-reconstruction is pure folly, are not left without a meaningful avenue to obtain compensation. NIOSH's proposed rules do not provide such an avenue.

For individuals who are not included in the SEC, EEOICPA requires NIOSH to complete dose reconstruction. §3623(d). When NIOSH concludes that dose cannot reasonably be reconstructed, the employee's only chance of obtaining compensation is to be added to the SEC. Once NIOSH concludes that dose cannot be accurately reconstructed, 42 C.F.R. §82.12, neither further efforts at guessing the employee's radiation dose, nor reliance on NIOSH IREP are helpful in deciding whether such an employee's health was endangered by radiation exposures.

PACE believes that when NIOSH concludes that it cannot complete a dose reconstruction for an individual, under 42 C.F.R §82.12, it should automatically consider adding that employee to the SEC. No further petition by the employee should be required. Instead, NIOSH should request that the employee submit evidence as to why the employee's health was endangered by radiation exposures. Acceptable evidence, on which NIOSH should rely to include an employee in the SEC, should include the opinion of a physician or other health professional that radiation likely caused or contributed to an employee's cancer. This type of qualitative, expert evidence on causation is routinely relied upon by workers' compensation agencies and trial courts in deciding whether illness is work-related. There is no reason for NIOSH to apply a higher standard of proof to employees who seek to be included in the SEC. NIOSH and the Advisory Board can then evaluate whether the evidence submitted by the employee provides a reasonable **qualitative** basis for believing the employee's health was endangered by radiation exposures.

There is no reason NIOSH should search for quantitative evidence of causation when, by definition, the dose for employees seeking to be added to the SEC cannot accurately be quantified. Any effort to rely on NIOSH IREP to decide whether exposures "endangered an employee's health" when the estimate of the employee's radiation dose is nothing more than hypothetical assumptions, smoke and mirrors, and other guesstimates simply denies employees for whom DOE lacks exposure information a reasonable opportunity to obtain compensation for their cancers. Congress intended no such artificial limitations.

Similarly, when a class of employees petitions to be added to the SEC, NIOSH should determine whether the radiation exposures of the class can be accurately estimated. For some job locations or job classifications, too little monitoring data will be available for a reasonable assessment of radiation dose. For others, specific instances of high exposure may have gone unrecorded. When NIOSH receives reliable descriptions of radiation exposures from a group of exposed employees, and it cannot locate comprehensive exposure records for the group, NIOSH should conclude that it cannot accurately estimate the dose for the class of employees. NIOSH should not impose, as proposed §83.9 would, on individual members of the group the obligation to seek, and be refused access to, radiation exposure records. Neither private contractors nor DOE are required to provide these records to workers. Likewise, NIOSH should not, as proposed §83.9 would, require a petitioner to retain a health physicist documenting the limitations of exposure records. This places an enormous, unwarranted burden on the petitioner. Many employees requesting to be included in the SEC are seriously ill or dying; for those who have already died, their survivors may not know where to seek records.

Since NIOSH has superior access to exposure records, when NIOSH receives a petition it should investigate by requesting exposure records from DOE or its contractor. This request should be subject to a time limit; in other words if DOE or its contractor fail to provide records within a reasonable amount of time, NIOSH should assume that no adequate records exist to reconstruct dose. Petitions should not wait indefinitely for exposure records that may never be produced. If a group of employees chooses to retain a health physicist or other professional to explain why DOE records do not reliably explain the radiation dose employees receive, NIOSH should give substantial consideration to such evidence. But, NIOSH should not require employees to spend thousands of dollars on expert witnesses as a condition of filing a petition.

In addition to an explanation of why NIOSH cannot accurately measure the radiation dose of a group of employees, NIOSH should require only that a petition also include qualitative, expert evidence as to why the radiation dose of the group may have endangered their health. NIOSH should accept, as a reasonable basis for concluding that radiation endangered worker health, the opinion of a physician or other health professional. This type of qualitative, expert evidence on causation is routinely relied upon by workers' compensation agencies and trial courts in deciding whether illness is work-related. There is no reason for NIOSH to apply a higher standard of proof to employees who seek to be included in the SEC. NIOSH and the Advisory Board can then evaluate whether the evidence submitted by a group of employees provides a reasonable **qualitative** basis for believing the group's health was endangered by radiation exposures. NIOSH should not try to guess what radiation dose the group received or

where that dose would place the group on the NIOSH IREP tables. NIOSH must abandon its effort to estimate dose and effect when it has no reliable basis for doing so.

At gaseous diffusion plants, Congress presumes that an employee with more than 250 days of employment in a job that was or should have been monitored had a radiation dose high enough to cause certain cancers. NIOSH should apply a similar presumption to other facilities, like Hanford and Idaho Falls, where radiation exposures are known to be high and exposure monitoring incomplete and misleading. Failure to apply a presumption similar to that applicable to the gaseous diffusion plants means that other radiation exposed employees must meet a higher standard of proof than others in the DOE nuclear weapons complex.

NIOSH's flawed effort to concoct hypothetical radiation dose estimates, when reliable evidence on which to base dose reconstruction is absent, just so it can use NIOSH IREP to determine whether cancers are work-related runs throughout various provisions of the proposed procedures. Below we describe several provisions where this flaw is most acute. However, this list is not exhaustive since, in PACE's view, the premise of NIOSH's proposed procedures should be completely revised.

The definition of *"endanger the health"* included in NIOSH's proposed procedures is flawed. Under EEOICPA §3623, NIOSH must determine whether a cancer is "at least as likely as not" caused by radiation. NIOSH uses NIOSH IREP to make such determinations. Under §3626, NIOSH is to determine whether there is a reasonable likelihood that radiation may have endangered an employee's health. The standard in section 3626 is intentionally different from the standard in section 3623, because in cases under 3626 it is not possible to estimate dose with any accuracy. Unfortunately, NIOSH's proposed procedures attempt to equate the two standards and try to force petitions under §3626 into the standards of §3623. This flawed interpretation of the statute should be changed. In cases where dose cannot be estimated NIOSH's reliance on quantitative methods to determine whether radiation is linked to cancer is inconsistent with Congress' recognition that alternate, **qualitative** methods may be necessary when quantification is not possible.

Section 83.12 also relies on this flawed concept by clinging to quantification even when inadequate exposure information is available to quantify dose. No useful purpose is served by trying to construct a minimum level of radiation dose that might have caused one of many cancers if dose cannot be reconstructed. Again, NIOSH must abandon the notion that it can construct a hypothetical dose or look to NIOSH IREP to determine whether an employee or group of employees will develop cancer in cases where dose cannot accurately be reconstructed.

NIOSH should impose time limits on its evaluation of a petition. Under the proposed procedures, petitions to be added to the SEC cannot be considered until after NIOSH concludes dose reconstruction is not possible and DOL denies a claim. Only then may an employee petition to be added to the SEC – at which time NIOSH will undertake another lengthy analysis of exposure, report its findings to the Advisory Board after notice in the Federal Register, possibly review the application again, resubmit it to the Advisory Board, forward it to the Secretary for a decision possibly inconsistent with the recommendations of the Advisory Board, and if the

proposed decision is in favor of the employee, wait another 180 days for Congressional review.

This endless review, discussion, and more review will take years. Exposed employees do not have that luxury. Many are seriously ill or dying. For those who have died, their survivors may have waited decades for compensation. NIOSH lacks the resources necessary timely to consider petitions under these procedures and to complete the thousands of dose-reconstructions for filed claims. It is inherently unfair for NIOSH to propose an endless maze of analyses which will trap employees in a time-consuming process that may take several years to complete.

PACE suggests several ways to impose time constraints on the process. First, NIOSH should establish time limits for its own evaluation of an application. If NIOSH fails to meet these deadlines, the petition should move forward to the next step in the process with a favorable recommendation. Employees right to receive compensation should not be suspended indefinitely in the search for exposure data which may not exist or awaiting additional resources NIOSH is unlikely to receive. Second, NIOSH should assume no adequate records exist to reconstruct dose where they are not provided to NIOSH by DOE or its contractor within a specified period of time. Third, NIOSH should not publish ***Federal Register*** notices every time it acts favorably on an application and it moves forward in the process. For example, the ***Federal Register*** notice announcing an Advisory Board meeting can note which petitions will be considered. NIOSH should also send a letter informing the petitioner that the Advisory Board will consider the petition at its next meeting and including information on the time and place of the meeting. By contrast, it is important that NIOSH publish notice when a petition has been approved, so others similarly situated are aware of that fact. PACE believes publicity around favorable actions on petitions is important, but few workers are aware of or read the ***Federal Register.*** Within HHS, ***Federal Register*** notices require several levels of bureaucratic review; each internal review causes further delays in actually approving a petition. Therefore, while PACE strongly supports publicizing NIOSH's actions, less time consuming methods should be found to do so.

Other sections of the proposed procedures pose problems as well. No reason exists why NIOSH should insist (§83.8) that a petition be filed on a specific form. Any correspondence or other communication which contains the information required of a petitioner should qualify.

The report of the Advisory Board should not be described as a consensus report. Consensus implies that all parties agree. (§83.13) The Board should be free to adopt majority/minority reports where its members do not agree.

The procedures should be amended so the Secretary of HHS is not able to disregard a recommendation from the Board to add employees to the SEC. (§83.14). The Secretary should be required to comply with a majority recommendation of the Advisory Board to add employees to the SEC. The procedures should bar NIOSH from considering "other factors" as a basis for denying a petition. (§83.14(e)). Finally, the provision allowing NIOSH to cancel or modify a decision to add employees to the SEC must be changed to make clear that changes will not be made retroactively. No employee who receives compensation should be required to repay compensation if NIOSH later modifies a class of employees included in the SEC. Such modifications should apply prospectively.

Finally, PACE believes NIOSH should consider adding a training and grant program to its proposal. Community groups, labor unions and other organizations who work with exposed employees and their families have little funding to become expert in the procedures for obtaining inclusion in the SEC, training affected employees and their families in the process, providing technical assistance to them, or otherwise assisting in the dose reconstruction process. Training grants would allow local unions to participate more fully and knowledgeably in the petition process. This is imperative. Exposed employees have long been misled about their exposures and health status. A significant purpose of EEOICPA is to correct those false impressions. Workers need to participate in the dose reconstruction process, understand what records are available, which are missing, and what other information they can supply to improve the dose reconstruction process. They cannot do so without adequate funding to groups with the capacity to train them to participate in the dose reconstruction and petition process. NIOSH should develop a funding mechanism, patterned after NIEHS Hazardous Waste training program, to accomplish these goals.

PACE appreciates the opportunity to comment and urges NIOSH to modify the proposed procedures in the manner describes in these comments.

Very truly yours,

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