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From: john abbotts [abbotts@u.washington.edu]
Sent: Tuesday, May 06, 2003 11:50 AM
To: niocindocket@cdc.gov
Cc: timothy takaro
Subject: comments on proposed procedures for Special Exposure Cohort,



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Dear NIOSH officials:

Please accept the attached comments (Word file) on the subject proposed rulemaking, RIN 0920-AA07. As the comments indicate, contributors are Tim Takaro and myself.

We understand that the deadline for comments is today.

We hope the attached comments may be useful. As the cover letter in the attached file indicates, please feel free to contact Dr. Takaro at 206-616-7458 on any matter related to these comments.

John Abbotts

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This message from:

John Abbotts

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May 6, 2003

NIOSH Docket Office
Robert A. Taft Laboratories
MS-C34
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Cincinnati, OH 45226
email to: niocindocket@cdc.gov

Re: Comments on Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000; Proposed Rulemaking
RIN 0920-AA07
Comments invited by 68 FR 11294, March 7, 2003
Deadline extended to May 6, 2003

Dear NIOSH Docket Officials:

We appreciate the opportunity to comment on the subject proposed rulemaking. We also appreciate the Institute's practice of making applicable documents available through its web pages, which facilitates the opportunity for public comment. Please accept the attached written comments; contributors to these comments are John Abbotts, Ph.D. and Tim K. Takaro, MD, MPH. The commenters are faculty (T.K.T.) and staff affiliated with the University of Washington, whose research has been supported in part by the U.S. Department of Energy. However, responsibility for these comments lies with the contributors as individuals. The views expressed have not been endorsed by the University, the State of Washington, nor the Department of Energy. Please feel free to contact me at 206-616-7458 on any matter related to these comments.

Sincerely,

Tim K. Takaro, M.D., MPH
University of Washington
4225 Roosevelt Way NE
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Seattle, Washington 98105

Comments on Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000 (Compensation Act); Proposed Rulemaking
Comments invited by 68 FR 11294, March 7, 2003

We appreciate the opportunity to comment on this Proposed Rulemaking. The Department of Health and Human Services (HHS) deserves credit for proposing procedures to expand the Special Exposure Cohort for compensation, and for presenting its proposed rules in a question and answer format, which facilitates understanding of the rules. We recognize that the Department was given the responsibility to administer the Compensation Act, but the Act's limitations in establishing the Special Exposure Cohort seemed to create an inconsistent system for awarding compensation.

Our comments cover the following themes, which we develop below in more detail:

1. It appears that the Compensation Act established a two-tier system for compensating Energy Employees.
2. The procedures HHS establishes for adding classes of workers to the Special Exposure Cohort should be consistent with the characteristics of those worker classes designated legislatively by the Compensation Act.
3. Scientific data in the form of available epidemiology studies and information from the U.S. Department of Energy (DOE) Former Workers Program should be sufficient to allow at least rough comparisons of cancer risks between workers at a given DOE/contractor site and workers in the designated Special Exposure Cohort classes.
4. The latest proposed rules seem to convert a two-tier compensation system into a three-tier system, by potentially reducing compensable cancers among new SEC populations.
5. HHS, in coordination with the Department of Labor, should keep Congress informed as problems develop in administering the Compensation Act.

1. It appears that the Compensation Act established a two-tier system for compensating Energy Employees.

Under the Compensation Act, employees meet requirements for the Special Exposure Cohort (SEC) if they were exposed to ionizing radiation during designated times at specified gaseous diffusion plants, or as part of duties related to specified nuclear tests at Amchitka Island. Once an employee is designated a member of the SEC, then compensation can be expected for specified cancers, if contracted after beginning employment with DOE or a DOE contractor. Similar to the situation for U.S. Atomic Veterans, members of SECs are not required to meet the strict radiation dose and causation components of the Compensation Act.

The SEC provision seems to establish a two-tier system for compensation. For energy employees not classified as part of the Special Exposure Cohort, requirements appear more demanding: employee dose must be determined or reconstructed, probability of causation must be evaluated, and the estimated probability must meet or exceed 50 percent for a given cancer before compensation can be granted. It seems likely under this two-tier system that compensation will be granted with significantly greater frequency for workers designated as members of the Special Exposure Cohort. We recognize that HHS is constrained by the provisions of the law, but if this situation develops, a likely outcome will be pressure on the Department to expand the Special

Exposure Cohort. The current proposed rulemaking would establish procedures under which HHS would incorporate additional worker classes into the SEC.

2. The procedures HHS establishes for adding classes of workers to the Special Exposure Cohort should be consistent with the characteristics of those worker classes designated legislatively by the Compensation Act.

If the compensation system is to be viewed as equitable, then the procedures for adding classes to the SEC should incorporate criteria no more stringent than those applicable to the SEC classes already designated by the Compensation Act. That is, proposed procedures should be verified by determining whether the designated worker classes at gaseous diffusion plants and Amchitka would qualify for the Special Exposure Cohort, if the proposed procedures were to be applied to those populations. If those worker classes would not qualify, then such a finding would suggest that the proposed procedures were too restrictive, and the barriers for qualification were too high. Such a situation would only exacerbate the two-tier compensation system by locking additional classes of workers out of the SEC designation.

3. Scientific data in the form of available epidemiology studies and information from the DOE Former Workers Program should be sufficient to allow at least rough comparisons of cancer risks between workers at a given DOE/contractor site and workers in the designated Special Exposure Cohort classes.

As indicated above, additional worker classes should be able to qualify for the Special Exposure Cohort if the recognized risks to those workers are comparable with risks to the SEC worker classes designated legislatively. Data from available epidemiology studies and medical surveillance results from the DOE Former Workers program should be sufficient to allow at least rough comparisons of cancer risk among workers at other sites. We recognize that the Former Workers program cannot be viewed as a controlled epidemiology study, since there is self-selection among workers who believe that their health may have been damaged by exposure as energy employees. However, the Former Worker data do provide an indication of potential pathology that should allow a rough comparison across DOE sites. In addition, studies sponsored and/or conducted by HHS/NIOSH could develop more definitive epidemiological data for making such comparisons between the legislatively designated SEC classes and cohorts at other sites across the DOE complex. Such studies would help "level the playing field" since few DOE sites have had the scrutiny on worker exposure enjoyed by the gaseous diffusion plants in the mid-1990s. The investigations performed by DOE Office of Environment, Safety and Health at these sites formed the basis for SEC designation. Were other sites scrutinized to this degree it is likely that such information would strengthen the arguments for SEC status.

In its current notice inviting comment, the Department noted the difficulties of making epidemiological comparisons across sites, including limits of data already available, and different population sizes at different sites. We acknowledge such difficulties, but we encourage the Department to use epidemiological data as available for rough comparisons. Again, the standard for fairness of proposed rules for determining "health endangerment" should be to use the legislatively established SEC categories as a test: If those worker classes would not qualify, then such a finding would suggest that the proposed procedures were too restrictive, and the barriers for qualification were too high. In addition, the Department should recognize that epidemiological findings are likely to evolve, particularly with studies at DOE sites sponsored and/or conducted by HHS/NIOSH. The Department should be receptive to evaluating future

epidemiological results and comparing them with the results among the SEC populations already established.

4. The latest proposed rules seem to convert a two-tier compensation system into a three-tier system, by potentially reducing compensable cancers among new SEC populations. As noted above, the expected greater difficulty for employees outside of SEC categories in gaining compensation will challenge perceived fairness of the system. The proposed rules seem to establish a "third tier" in the system. As one concern, there may be significant obstacles to obtaining new SEC designations. That is, there are multiple points at which a petition to add a class to the SEC may be rejected: by NIOSH, by the Advisory Board, or by the Secretary of HHS. It seems that the practical effect will be to make addition of new SEC classes comparatively more difficult than it was to establish the legislatively designated classes.

In addition, even if new classes are added to the SEC, the proposed rules would give HHS authority to reduce the number of compensable cancers from the list designated by the Compensation Act [under Proposed Section 83.13, as explained at 68 FR 11296]. This would seem to represent an Executive Branch amendment of the Compensation Act, especially since the Act connected the list of compensable cancers with the Special Exposure Cohort. We urge HHS to address whether it has the authority to implement such an amendment, and in any event whether limiting the types and numbers of cancers compensable for the SEC is consistent with Congressional intent in approving the Compensation Act. Finally, changing the list of cancers at this time, before additional studies are available contributes to the real (or perceived) lack of fairness in dealing with former workers from different sites.

5. HHS, in coordination with the Department of Labor, should keep Congress informed as problems develop in administering the Compensation Act. We recognize that Congress maintains responsibility for improving the Compensation Act through amendment, and HHS and DOL were given the responsibility for administering the Act. But the Departments also should take responsibility for informing Congress as problems with administering the Act develop. If our analysis above is correct, workers applying under the SEC category should experience a higher success rate in receiving compensation than workers applying in the non-SEC category. Similarly, if the bar is set too high for adding worker classes to the SEC, then the three-tier compensation system will be solidified. Consequently, HHS should coordinate with the Department of Labor in reporting program results to Congress. The Department of Labor should maintain records on the frequency of compensation for workers applying under the legislated SEC, "petition" SEC, and non-SEC categories, and alert the Congress of any differences between those categories. Similarly, HHS should report to Congress not only its recommendations for or against addition of specific worker classes to the SEC category, but as well on the overall success rate of workers or classes who petition for SEC inclusion.

In overall summary, we recognize that the Department of Health and Human Services, in coordination with the Department of Labor, has been given the responsibility for administering the provisions of the Compensation Act. As HHS noted in an earlier Federal Register notice on this rulemaking, the Department takes responsibility for making determinations "as fairly, transparently, and consistently as possible" [67 FR 42966, June 25, 2002]. Unfortunately, the

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manner in which the Act established the Special Exposure Cohort seems neither fair, transparent, nor consistent, a situation that calls for administrative and legislative corrective action.