Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Summary Minutes

Thirteenth Meeting of the
Advisory Board on Radiation and Worker Health
March 14, 2003

Meeting held by telephone conference

Advisory Board on Radiation Worker Health
National Institute for Occupational Safety and Health
Department of Health and Human Services

Summary Minutes of the Thirteenth Meeting
March 14, 2003

The Advisory Board on Radiation and Worker Health (ABRWH) convened a teleconference to discuss "Rule Making on Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort" (SEC, 42 CFR Part 83) under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), a rule-making by the National Institute for Occupational Safety and Health (NIOSH). The Advisory Board on Radiation Worker Health ABRWH is the Board charged to advise the Secretary of Health and Human Services on matters relating to the EEOICPA process.

These summary minutes and a verbatim transcript are available on the Internet at the NIOSH/Office of Compensation Analysis and Support (OCAS) web site located at www.cdc.gov/niosh/ocas.

Those present for the telephone conference included the following:

ABRWH members:

Paul L. Ziemer, Ph.D., Chair
Henry A. Anderson M.D.
Antonio Andrade, Ph.D.
Roy L. DeHart M.D., M.P.H.
Richard L. Espinosa
Michael H. Gibson
Mark A. Griffon
James M. Melius, M.D.
Wanda I. Munn
Leon Owens
Robert W. Presley
Genevieve S. Roessler, Ph.D.

Designated Federal Official: Larry J. Elliott, M.S.P.H., C.I.H., Executive Secretary

Federal Agency representatives:

Department of Health and Human Services:

- Office of General Counsel: David Naimon, Liz Homoki-Titus
- CDC Committee Management: Cathy Ramadei, Renee Ross
- NIOSH: Stu Hinnefeld, Cori Homer, Ted Katz, Jim Neton, Dave Sundin

Department of Labor

- Jeff Kotsch, Rose Toufexis

Members of the public:

* Terrie Barrie, wife of a sick worker
* Filimon Casados, LA POW
* Kevin Dougherty, Alaska District Council of Labor, Anchorage
* Gaylon Hanson, Idaho National Environmental and Engineering Laboratory (INEEL)
* Sylvia Kieding, PACE union
* Epifania Jatcuec, survivor
* Gerry Leyba, LA POW, Los Alamos National Laboratory (LANL)
* Mark Lewis, PACE,
* Richard Miller, Government Accountability Project
* Ted Silver, LA POW
* Bob Schofield, LA POW
* Bill Field, University Iowa College of Public Health
* Betty Jean Shinas
* Bob Tabor, Fernald Atomic Trades Labor Council
* Tim Takaro, University of Washington

ABRWH Chair Dr. Paul Ziemer convened the teleconference at 1:05 p.m.

Public Comment

Dr. Ziemer requested public comment before the Board's discussion began, so that they could be considered during the Board's deliberations.

In addition to the items summarized below, all the respondents indicated they had heard that NIOSH had stricken 21 of the 22 cancers specified as compensable under the EEOICPA, and could limit the cancers claimed whether or not they are one of the 22. This issue was one of concern to all who commented.

Ms. Barrie said Congress' intent for EEOICPA is plain: if a worker develops cancer, NIOSH will attempt a dose reconstruction; if they cannot do the latter, the worker can petition to become a member of the SEC. She asked that those interested in this rule be provided with more time to review all the related materials provided.

Ms. Shinas spoke on behalf of the claimants and her husband, a Department of Energy (DOE) worker, had died of esophageal cancer. She did not feel that the affected families were being compensated and stated that the burden of proof is on those families.

Mr. Leyba stated that NIOSH is creating a disease, rather than exposure cohort. The latter's point is to provide a remedy for those workers who were not properly monitored by DOE. He felt that NIOSH is not treating workers equitably or following Congress' instructions to address the 22 specified cancers. *Mr. Lewis* agreed.

Ms. Jatcuec stated that the compensation process, which was intended to be claimant friendly, is not. She asked for another meeting in Santa Fe with NIOSH to discuss these issues face to face, and demanded that NIOSH throw out the current proposal as unfair, cruel, and evil.

Mr. Casados had recently been confirmed as having beryllium sensitivity. He wanted recognition by the representatives in Congress as well as in the state of New Mexico.

Mr. Schofield stated that there would likely not be adequate records to show what everyone was exposed to. Persons at Los Alamos could have been exposed to multiple elements and NIOSH will not know what isotopes/elements a person had been exposed to over their career.

Ms. Kieding noted that the PACE union conducts a Worker Health Protection Program for former and current workers at the three gaseous diffusion plants (GDP) cited by EEOICPA and at the Idaho National Environmental and Engineering Laboratory (INEEL). She expressed concern that the three GDPs are part of the SEC, but Idaho is not. She also hoped that the Rule's comment period would be extended to allow more input.

Mr. Takaro asked about NIOSH's basis for choosing particular cancers over others, thinking that they were based on the radioepidemiological tables, and asked if NIOSH had adopted other criteria for identifying radiogenic cancers.

Dr. Ziemer commented that, although there may be differences of opinion over the law's intent, both the Board and NIOSH are required to and will follow the law. Mr. Elliott stated that the administration and other agencies, rather than DHHS, have been part of the development of this rule. While at this point in the rule making, the agencies cannot discuss it, he could state categorically that the rule does not say that one particular cancer will be assigned. What it does imply is that this is an option for NIOSH to use if that makes the most sense for a given exposure scenario. That does not mean that this will be done in every case and the whole list will be used in the definition of the class.

Mr. Naimon added the rule is not illegal in any sense and does not change the Act's list of cancers. The rule making can not change the statute; only Congress and the President can do that.

Board Discussion

Dr. Ziemer pointed out that this rule is proposed, not final. NIOSH is required to take comments from the public, the Board and other agencies, as they were doing in this call. But they also are under time pressure because by law the SEC rule making must be complete before anything further can be done, including identifying any others who should be in an SEC other than those identified by Congress. The 30 day comment period reflects that reality. He closed the comment period at this point.

Several Board members expressed surprise and concern at the expressed perception by members of the public that this rule making would eliminate 21 of the 22 cancers established as compensable. That was untrue. In fact, the proposed rule gives the ABRWH options to define classes with cancers not so listed, although that did not guarantee that those would be compensable. Mr. Gibson noted the public point that, if NIOSH cannot determine the dose from

particular isotope, how would they know that there were not other isotopes that people were exposed to that could cause other cancers?

For those who did not have the changes suggested since the last meeting, NIOSH e-mailed or faxed them. They also were read aloud to allow the public to hear them, as well.

Review of 42 CFR Part 83

The review began with the first section of this document. Although informational and not part of the rule itself, clarifications were provided.

Introduction

Clarifications and changes suggested by Ms. Munn were:

- Section III, Summary of Public Comments, Item B, next to last paragraph: beginning with "The Health Physics Society further recommended:..." NIOSH was asked to clarify the syntax of the last sentence: "Hence, it may be appropriate to limit the finding ... with specific types of cancers."

- Section IV, Recommendations of the ABRWH, Item H. Recommendation for Section 83.10: the second sentence of paragraph 1 should be changed to read "The Board would review each petition "*for which*" (changed from "that") DHHS proposes to deny....." The Board **AGREED**

- Section IV, Recommendations of the ABRWH's, Item A, paragraph 3, Sentence 2, beginning with "If the employee had sufficient radiation exposure outside of his work experience as a member of the cohort..." This could be misinterpreted to include medical or environmental exposures outside the work environment. Insert *"occupational"* between "sufficient" and "radiation." **AGREED**

Changes suggested by Mr. Griffon:

- Section III, Summary of Public Comments, Item B, Accuracy of Dose Reconstruction; change the sentence beginning "Hence, for the purposes of a compensation program... at least as high as the highest dose that the cohort could have received," to read: "reasonably certain to be *no greater than* the highest dose than the cohort could have received." **AGREED**

Subparts A (Introduction) and B (Definitions) 83.5 produced no further comments.

***Subpart* C**: Procedures for Adding Classes of Employees to the Cohort

Sections

83.1: No comment
83.2: No comment

83.5, *Definition, Item C; Class of Employees:* Mr. Espinosa had questioned at the last meeting if multiple facilities could be included, so the class could cross facilities. As now written, this is

limited to employees "at the same DOE/AWE facility;" that is, a single facility. Mr. Katz reported that the statute limits NIOSH to prescribing a class of employees to a single facility. DHHS is talking to the Department of Labor (DOL) to clarify what will be defined as a "facility," since the EEOICPA does not specify. The Board's discussion included the following:

- This is critical and needs to be clearly defined in the rule as well in the introduction. It poses strong implications to several possible claim scenarios. For example, 1) big sites such as the INEEL have several large sub-sites, or facilities, dealing with different operations and radioisotopes; 2) persons were transferred (or, as in the building trades, worked) between "facilities" that dealt with different isotopes; and 3) one building could house work on different types of operations/radioisotopes, which should be defined distinctively.
- EEOICPA defines "facility" as "... any building, structure, or premise, including the land upon which such building, structure or premise is located." But this is still broad, and could identify individuals who worked in particular part of a site (whether outdoors or inside) as opposed to another part that was never exposed to radioactivity.
- The dictionary definition of "premise" is "a tract of land with the buildings thereon; a building or part of buildings."
- Dr. Andrade stated that the definition of facility should be based on/tied to the operation and the radioisotopes involved.

The question was posed, since many workers on site could have worked with different isotopes over time, consecutively, does that preclude someone from being under one or more SECs, or are all doses under one SEC? Such a person's multiple facilities and opportunities would have to be defined under the SEC. But each would relate to a separate class, and not be combined to achieve the 250 days of exposure required (e.g., 125 days in one facility and 125 days in another; or with a dose that could not be calculated for one portion of the 250 day criterion).

Mr. Katz said that, where a dose reconstruction can be done, those days in that window of time in that location would not be added into the class. But their experience outside of that window would be irrelevant as far as their membership in the cohort is concerned, since the cohort only applies to periods in which a dose reconstruction cannot be done. And, if a person was placed in a cohort but did not have a compensable cancer, they would still come to NIOSH for a dose reconstruction because they cannot be compensated for other than those 22 cancers. All their other doses would be calculated, but the question of what to do with the unknown dose that put them in this SEC cohort was still open.

Dr Ziemer asked the Board if NIOSH should be charged to define "facility?" Responses were:

- This definition is important. If overly restrictive, it could affect how the rule is implemented. This could be seen very broadly, using "class" as way to define the group that may work at a certain part of that facility or at smaller facilities on site. The Act's definition could be an entire site; individual definitions of "facility" may be needed.
- The DOL regulation (30.214 Sec B) states that the 250 work day requirement of the existing SEC may be aggregated for days of service at the GDP plants, so the DOL has already interpreted that the SEC exposure periods could be combined. However, Mr. Naimon pointed out that the DOL's SEC definition differs from the one under discussion.

Finally, it was **agreed** that NIOSH should frame the question for discussion in another conference call to be held in two weeks. This could indicate the parameters to be incorporated into the definition; or they could provide a sample in keeping with the definition in the law. Drs. Melius and Andrade offered to also craft something for the next meeting. Dr. Andrade felt that aggregating the days to qualify for an SEC should be allowed.

It was also **agreed** that, if a dose reconstruction can be performed, but not for another class of workers that lacks sufficient data, the process should be flexible enough to consider them. There were no other comments except to note that all 22 cancers are still present in 83.5, Sec K, Specified Cancer.

83.6: Overview of Procedures: No comment.

83.7: Who Can Submit a Petition: No comment.

83.8: How a Petition Is Considered. The Board requested that section on ABRWH comments in the Introduction include praise for NIOSH for making the changes requested, as done in this section. **AGREED**

83.9 Information the Petition Must Include.

Item C.2.iii: Mr. Griffon suggested the following to clarify this section: "A report from a health physicist or other individual with expertise in dose reconstruction *describing* (rather than "documenting") the limitations of DOE or Atomic Weapons Employer (AWE) records on radiation exposures at the facility, as relevant to the petition. This report should specify the basis for *believing* (rather than "finding") the stated limitations might prevent the completion of dose reconstructions for members of the class under 42 CFR Part 82 and related NIOSH technical implementation guidelines; or ...."

Mr. Griffon **moved to recommend this new language to NIOSH to replace the previous text.** Dr. Andrade seconded the motion. Dr. Ziemer noted that this was a conditional approval, since further refinement is possible on the next conference call. The motion was **unanimously passed.**

Item C.2.i: Dr. DeHart had suggested during the last Board meeting to amend the existing paragraph, inserting *"scientific or technical"* in front of "report, published by a "*governmental* (delete 'scientific') agency;" and deleting the last phrase beginning with "and also find" and inserting "dosimetry and related information that *is otherwise* unavailable." Dr. Ziemer suggested a friendly amendment to change the phrase "scientific or technical report published *"or issued"* by a governmental agency." Then, since "otherwise" implied that this report has the information needed to do the dose reconstruction, when it is in fact not available anywhere, the term "otherwise" was dropped. A final grammatical edit was to make "is" unavailable to "are" unavailable. **AGREED**

83.9, Petition Information; Section C.2, introductory paragraph: Mr. Griffon suggested inserting after "petitioner's basis for believing...", "*DOE or AWE records may be inadequate*", in order to remain consistent with the paragraph just approved by the Board. However, he agreed to reconsider this, since the broader current wording is not limited to those agencies' lack of information.

Paragraph 3: Dr. Melius suggested moving to 83.11, or to a separate section, the text on the process for evaluating the information required for such exposure incidents in the event that "NIOSH is unable to obtain records or confirmation..." This refers to information required after the petition has been evaluated by NIOSH. Upon Dr. Ziemer's comment that this could be interpreted that NIOSH reconsider even having it in the document, Dr. Melius amended that to "... that NIOSH consider changing the placement of this section within the regulation..." **AGREED**

Public comment

(Chairman Ziemer permitted a member of the Public, who had just entered the conference call, to provide comments at this point.) Mr. Hanson, who is the Health and Safety representative at the INEEL, expressed two areas of concern. One was that the INEEL Chemical Processing Plant had the same exposures as the GDP at Paducah, whose workers are in the present SEC. The other was to request that special consideration be given to any worker at the INEEL's SL-1 facility who may have filed a claim, since they may have received a high short-term dose during an explosion there.

Continued Document Review

The Board then continued its review of Dr. Melius' suggested changes to the rule document.

83.9, Petition Information; *Witness Affidavits:* Dr. Melius suggested text to clarify that if the employee claimant witnessed the incident, that s/he would count as one of the two witnesses whose affidavits are needed to confirm the exposure not otherwise documented. Dr. Andrade **moved to adopt and to recommend to the Secretary this text as provided.** Dr. Melius seconded the motion, which Dr. Ziemer again, noted, could be changed if necessary in the next call.

In discussion, it was clarified that the "employee" could work for a contractor or sub-contractor. Ms. Munn expressed her own lingering concerns over the concept of requiring only one corroborating statement, although she understood that in some instances even that would be difficult to get. Flexibility is needed on the number to corroborate, considering the 50-year time period involved. Mr. Gibson and Mr. Presley also pointed out that the buddy system often had only two people working together; the three-man rule did not begin until the 1990s. The Board **unanimously approved** the motion.

New item, or "iii": When the evidence suggests that an event occurred years ago, but a survivor petitioner cannot find witnesses (due to death or difficulty to identify or locate), Dr. Melius suggested recommending that NIOSH "... offer the option for other parties to submit confirmation of the incident in the absence of available witnesses or records. For example, affidavits from the widows of three employees who may have been involved in exposure incidents would be acceptable if those widows recall similar reports from their spouses about the exposure incident at the time that it occurred."

Mr. Espinosa **moved to accept the recommendation as stated** and Mr. Owens seconded the motion. Dr. Roessler raised gender concerns in a friendly amendment, and the Board agreed to replace "widows" with "eligible survivors." Subsequently, Dr. Melius suggested the motion be limited to the first three sentences, since he had offered the example just for the Board's consideration. Mr. Espinosa and Mr. Owens agreed. The motion was now:

> "The Board is also concerned that a petitioner may have difficulty finding witnesses for an exposure incident that occurred many years ago. Witnesses may no longer be living or may be difficult to identify or locate. In such a case, the Board recommends that NIOSH offer the option for other parties to submit confirmation of the incident in the absence of available witnesses or records."

The Board **unanimously accepted** the motion.

83.10: No comments.

83.11 (b): There was a question at the last meeting about whether a claimant could appeal a NIOSH final decision that s/he has not met the requirements for evaluation, and if so to whom. This question also pertained to the preamble.

The opinions expressed in discussion were:

- In the present process, the petitioner petitions; NIOSH notifies them of the deficiency and assists the petitioner to meet the requirements. It is then resubmitted and reviewed within 30 days. If it is decided that it still does not meet the requirements, it is turned down again. The Board had previously agreed that two applications are adequate.
- Dr. Melius felt that the petitioner should have the right of appeal to DHHS if they feel they have been treated unfairly by NIOSH. However, section (c) notes that if

there is new information, NIOSH may reconsider the petition and the petitioner can return.

Mr. Espinosa also advocated for an appeal process, having particular concern about petitioning survivors' potential trouble in getting new information to allow them to file an appeal. Others noted that the appeal also relates on the adequacy of the petition to even be considered (i.e., it is an unevaluated petition); and that currently, the same "umpire (NIOSH) delivers the two strikes". The question is whether there should there be another avenue of appeal if the petitioner has no access to other information.

Since the Board cannot mandate how the agency conducts its appeals and is not an adjudicatory entity; and since this is a complex issue of some public concern, some members felt that another forum in which to address such complaints was needed. On the other hand, the more other entities that are involved, the less likely they are to have the expertise of NIOSH or this Board in making these kinds of judgements. The provision of new information was felt by some to be fair enough. At some point, "no is no". The process must be practical and careful not to raise unreasonable expectations.

Due to time constraints, Dr. Ziemer **tabled** this issue to the next conference call. It was agreed to reconvene on April 4 from 1-4 p.m. EST. The date was based in part on the 30-day limit on the comment period. DHHS had not yet decided on the Board's request to extend the latter by 15 days, so an April 7 postmark was still required for comments to be accepted. Only Dr. Roessler reported an inability to attend that call. A subsequent conference call may be held on April 28th from 2-5 p.m. EST. The discussion on April 4 will begin from Section 83.11. The Board members were asked to send their recommendations to Ms. Homer to distribute in enough time for all the Board members' review beforehand.

Additional public comment was deferred to the next call. Mr. Field asked if comments could be submitted as part of public record without waiting for the next call, and Dr. Ziemer said yes. They should be sent to him at the NIOSH address on their Website. He then thanked all for their time, and the teleconference adjourned at 4:05 p.m.

I hereby certify that to the best of my knowledge, the foregoing minutes are accurate.

Paul L. Ziemer, Chair, ABRWH

7/4/03
Date