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

# **Summary Minutes**

Fourteenth Meeting of the Advisory Board on Radiation and Worker Health March 28, 2003

Meeting held by telephone conference

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# **Executive Summary**

The Fourteenth meeting of the Advisory Board on Radiation and Worker Health (ABRWH, or the Board) was held by telephone conference on March 28, 2003. All ABRWH members were in attendance. Others in attendance included staff of various Federal agencies and members of the public. A list of those in attendance is included in the Summary Minutes of this fourteenth meeting.

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Public comments were solicited during the first thirty minutes of the telephone conference.

| Publ | ic input included the following:  |
|------|---|
|      | One commenter asked that Los Alamos be included in the Special Exposure Cohort (SEC).   |
|      | A number of comments addressed the possibility that the National Institute for Occupational Safety and Health (NIOSH) might limit the number of specified cancers for adding a class to the SEC. Commenters felt that NIOSH had no authority with which to limit the specified cancers.             |
|      | Concerns were raised regarding whether the proposed rule should use the singular "facility" or the plural "facilities," and what its use meant to workers who worked at multiple facilities.  |
|      | The lack of timeliness of the compensation program concerned some commenters. Claimants wondered how dose reconstruction could be done in a timely manner when site profiles are not completed, there are inadequate and/or missing records, and monitoring was faulty.                             |
|      | One commenter raised the issue of workers having to provide two witnesses to exposure incidents. It was asserted that this requirement would not be feasible, given that most of the incidents happened long ago, and that there are faulty records and a lack of living witnesses to these events. |
|      | There was a concern by one member of the public who asserted that the 10,000 claimants are not being informed of the ABRWH meetings and cannot appropriately voice their opinions.  |
|      | One commenter indicated that he had difficulties in obtaining health related data from the Department of Energy (DOE), through the Freedom of Information Act.  |
|      | Strong support was given to the idea of a special cohort mechanism for workers whose records proved inadequate for dose reconstruction.   |

Special Exposure Cohort Notice of Proposed Rulemaking Finalization of Board Recommendations Dr. Ziemer led a discussion on the Board's final recommendations for the proposed rulemaking. The reference document utilized for the discussion was the Federal Register/Vol. 68, No. 45/Friday, March 7, 2003/Proposed Rule. The ultimate recommendations were as follows:

### Pg. 11296, col. 3, para. 2:

Last sentence: This statement is confusing, and the Board recommended that NIOSH rewrite the sentence for clarification.

# Pg. 11303, IV, A, para. 3:

Second sentence should be revised to read: "If the employee had sufficient occupational radiation exposure outside of his work experience as a member of the Cohort . . ."

#### Pg. 11306, §83.5(c):

It was pointed out that there are two conflicting definitions of the word "facility" in the legislation. The word "facility" should be considered broadly (e.g., Los Alamos, Rocky Flats). As currently defined in the legislation, the word facility refers to specific buildings. NIOSH would have to expend considerable effort developing an inventory of defined "facilities" at each DOE site and would have difficulty considering the SEC classes for workers in operations that might have taken place in more than one building or facility at a DOE site. It was also suggested that NIOSH include an operational definition of "facility" in Subpart B—Definitions.

Dr. Melius moved to accept his and Dr. Andrade's recommendation to NIOSH with the intent that it be included in some form of an operational definition. Dr. Andrade seconded the motion. The motion received unanimous approval.

The text of the final recommendation is as follows: "There are two definitions of facility existing in the legislation under Subtitle B, Section 3621 and Section 3626, Designation of Additional Member of Special Exposure Cohort. For the purposes of this draft regulation, the Board recommends that "facility" should be considered broadly (e.g. Los Alamos, Rocky Flats). Then the "class" definition would be used to limit the class to those workers who worked in some specific operation(s) at the facility and whose dose could not be reconstructed with sufficient accuracy. If facility was defined to refer to specific buildings, etc., NIOSH would have to spend considerable effort developing an inventory of defined "facilities" at each DOE site and would have difficulty considering new SEC classes for workers in operations that might have taken place in more than one building or "facility" at a DOE site".

# *Pg.* 11307, §83.9(c)(2)(iii):

This paragraph was reworded as follows: "A report from a health physicist or other individual with expertise in dose reconstruction describing the limitations of DOE or AWE records or radiation exposure at the facility as relevant to the petition. This report should specify the basis for believing 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."

#### Pg. 11307, §83.9(c)(2)(iv):

This paragraph was reworded for clarity: "A scientific or technical report published or issued by a governmental agency or published in a peer review journal that identifies dosimetry and related information that are unavailable (due to either a lack of monitoring or the destruction or loss of records) for estimating the radiation doses of employees covered by the petition."

#### *Pg.* 11307-8,§83.9(c)(3):

This portion of the section deals with exposure incidents and describes the process for evaluating the information required for such incidents in the event that NIOSH is unable to obtain records or confirmation of the incident. The Board recommends that NIOSH consider where the placement of this part of the section should be within the rule, since it refers to information required after the petition has been evaluated by NIOSH. As presently located, this portion could be confusing to the petitioner.

#### Pg. 11308, §83.9(c)(3)(i-ii):

These paragraphs require either medical information or witness affidavits in the event that the exposure incident cannot be confirmed. For the requirement that two (2) employees who witnessed the accident submit affidavits, the Board recommends that the petitioner be counted as one of these two (2) witnesses, if the petitioner was an individual employee who witnessed the incident. The Board recommends NIOSH offer the option for other parties to submit confirmation of the incident in the absence of eye witnesses or records.

#### *Pg.* 11308, §83.11(b):

The Board is concerned that there is no further appeal process for petitions that do not satisfy the relevant requirements. Accordingly, the Board recommends that NIOSH explore possible appeal mechanisms within the DHHS for such cases.

# *Pg.* 11308, §83.13(b)(1)(iii):

The Board recommends this sentence be revised to read: "In general, access to personal dosimetry and area monitoring data is not a defining factor that must be available in order to estimate the maximum radiation dosage which could have been incurred by any member of the class."

#### *Pg.* 11309, §83.13(b)(1)(iv):

This clause was discussed at length, with some members of the Board recommending the following:

| More clarity is needed in regard to how NIOSH plans to make the determination to         |
|--|
| exclude certain cancers.   |
| If ever NIOSH has to invoke the rule on limiting specific cancers, those cases must be   |
| presented to the Board for added attention and advice.                                   |
| Clarification from the Department of Health and Human Services (DHHS) and Congress       |
| on the intent of the legislation in regard to the twenty-two specified cancers is needed |

The Board decided that the exact wording of the motion needed work. Dr. Ziemer offered to draft a motion and send it to Board members for additional discussion at the next conference call. Everyone agreed, and the Board moved the discussion to other sections of the proposed rulemaking.

#### Pg. 11309, §83.14:

No comments, suggestions, or changes were made.

#### Pg. 11309, §83.15:

No comments, suggestions, or changes were made.

#### Pg. 11310, §83.16:

The Board decided against recommending a deadline for the final decision on the designation of a class.

#### *Pg.* 11306, §83.5(c) Facility versus Facilities:

The Board addressed the issue of "facility," versus "facilities," and whether the plural or singular should be being utilized in the proposed rulemaking. The Board agreed that an allowance needed to be made for workers who worked the minimum of 250 days at different physical locations, whether the locations were in the same complex or in different parts of the country, and where dose reconstructions are not possible

Dr. Ziemer indicated that he would write a draft of the proposed recommendation and send it out to the Board for review.

# **Housekeeping and Miscellaneous**

- Dr. Ziemer indicated that he would present a final draft of the Board Recommendations on the Proposed Rulemaking and a draft of the cover letter for discussion at the next meeting.
- The next telephone conference is scheduled for May 1, 2003, from 3:00 p.m. to 5:00 p.m., EST.
- Although there was no additional time for a public comment period at this end of this meeting, the Board addressed the following concerns of the public:
  - Regarding the issue of members of the public obtaining information or knowing about meetings, and that many claimants do not have computer access, it was noted that the Board meetings are publicized through the Federal Register and posted on the NIOSH/OCAS web site.

→ Mr. Elliott directed the public to the address in the Federal Register to which additional public comment may be sent regarding the compensation process and the Board deliberations.

With no further business posed, the meeting was officially adjourned at 5:08 p.m.

End of Executive Summary

The Advisory Board on Radiation and Worker Health

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

Summary Minutes of the Fourteenth Meeting March 28, 2003

The fourteenth meeting of the Advisory Board on Radiation and Worker Health (ABRWH, or the Board) was held by telephone conference on March 28, 2003. These summary minutes and a verbatim transcript are available on the Internet on the NIOSH/OCAS web site located at <a href="https://www.cdc.gov/niosh/ocas">www.cdc.gov/niosh/ocas</a>. Those present for the telephone conference included the following:

ABRWH Members: Dr. Paul Ziemer, (Chair); Dr. Henry Anderson; Dr. Antonio Andrade; Dr. Roy DeHart; Mr. Richard Espinosa; Mr. Michael Gibson; Mr. Mark Griffon; Dr. James Melius; Ms. Wanda Munn; Mr. Leon Owens, Mr. Robert Presley; and Dr. Genevieve Roessler.

**<u>Designated Federal Official:</u>** Mr. Larry Elliott, (Executive Secretary)

#### **Federal Agency Attendees:**

# Department of Health and Human Services:

Ms. Cori Homer, Mr. Ted Katz, Mr. David Naimon, Dr. James Neton, Ms. Cathy Ramadei, Ms. Renee Ross, and Mr. David Sundin.

# Department of Labor:

Mr. Jeffrey Kotsch, and Mr. Peter Turcic.

Members of the Public: Ms. Teorie Arrib (Colorado); Mr. James Barnes (Rocketdyne Boeing); Mr. George Barrie (Rocky Flats, Colorado); Ms. Kay Drey (St. Louis, Missouri); Ms. Denise Brock (United Nuclear Weapons Workers of St. Louis, Missouri); Dr. Bill Feld (College of Public Health, University of Iowa); Mr. Bill Foley (Worker Health Protection Program, Paducah Kentucky); Ms. Carmen Gonzales (Survivor); Ms. Epifania Gonzales (Survivor); Ms. Sylvia Keating (PACE); Mr. Mark Lewis (Ohio); Dr. Daniel McKeel (Physician and Pathologist); Mr. Richard Miller (Government Accountability Project); Ms. Kim Newsom (Certified Court Reporter, Nancy Lee and Associates, Atlanta, GA); Mr. Ray (Ohio); Ms. Teresa Robinson (Writer/Editor, Cambridge Communications, Atlanta, GA); Mr. Phillip Schofield (Los Alamos; POW, Espanola, NM); Mr. Ken Silver (Los Alamos POW); Mr. Bill Tankersly (ORAU); Ms. Gloria Trujillo (Survivor).

### **Opening Remarks**

# Call to Order/Welcome

Dr. Paul Ziemer called the meeting to order at 2:10 p.m. and welcomed everyone to the ABRWH meeting via telephone conference call. Next, Dr. Ziemer asked participants to introduce themselves.

Following the introductions, he asked those members of the public who indicated that they wished to speak to begin their comments.

# **Public Comment Period**

<u>Ms. Carmen Gonzales</u> indicated that her father, who is now deceased, worked at Los Alamos for thirty-four years. She said that Los Alamos National Laboratory is a facility that has been known to have missing, incomplete, and inaccurate exposure records. In light of the alarming discrepancies discovered in workers' files, she believes that it is important that Los Alamos be included in the Special Exposure Cohort (SEC). Ms. Gonzales's also thought that the number of cancers being considered for the SEC should not be drastically altered.

<u>Mr. Ken Silver</u> addressed the issue of limiting the list of cancers for the SEC. He indicated that at the last Board meeting, one board member pointed out that the entire list of twenty-two cancers appeared in §83.5. However, there is also a clause in §83.13 that allows NIOSH the discretion to limit the list of specified cancers to as few as just one cancer. Mr. Silver stated that he has not found any justification in legislative history for the clause in §83.13 that authorizes NIOSH to limit the specified cancers for the SEC.

Mr. Richard Miller indicated that during the last Board meeting there was extended discussion regarding the definition of a "facility" and whether to use the singular "facility" or the plural "facilities" within the proposed rulemaking. It is important that the issue of "facility" versus "facilities" be carefully considered, because there exists a group of workers who regularly move from facility to facility to ensure regular employment. They may have difficulty accumulating the necessary 250 days of employment in a single facility, and yet may have been exposed to harmful substances in their multiple facilities. He pointed out that the DOL's regulations allow for a similar circumstance by allowing workers to accumulate days of employment at multiple gaseous diffusion plants in three states, in order to meet the 250 work days threshold for the SEC.

Mr. Miller also addressed the idea of NIOSH limiting the list of cancers. He indicated that nothing in legislative history that would authorize NIOSH to limit the list of covered cancers.

<u>Ms. Denise Brock</u> stated that she felt that Congress's intent was clear when they chose the twenty-two cancers for the SEC. Therefore, she is perplexed how the list might be made more organ-specific. Ms. Brock also wondered how dose reconstruction could be done in a timely manner when site profiles are still not complete, when there is loss or destruction of records, or when workers were exposed to substances for which they were never even monitored.

Ms. Brock also pointed out that it may not be not feasible for workers to provide two witnesses to exposure incidents.

<u>Ms. Epifania Jaquez</u> said that she was a survivor and that she was calling on behalf of her father. She stated that the claimants are not being notified of changes in the proposed rule. In the beginning, the program centered around twenty-two specified cancers. She said that this proposed SEC rule is not acceptable, and that the claimants demand that this rule be obliterated.

<u>Ms. Betty Shinas</u> is also a survivor. She strongly supported the idea of abiding by the spirit of the law that was passed two and a half years ago. She stressed that she supports not changing the rule in regard to limiting the specified cancers.

<u>Ms. Gloria Trujillo</u> stated that she is also a survivor and expressed strong disagreement with NIOSH's intention to change the qualifying factors for the SEC. She feels this change would be very unfair to all claimants, including survivor claimants.

<u>Dr. Daniel McKeel</u> is a physician and a pathologist who has been advising Ms. Brock and the group in St. Louis, for the Mallinckrodt chemical workers. He expressed an interest in the issue of disallowing certain cancer types. He stated that the scientific basis for disallowing various kinds of cancers as possibly being caused by radiation exposure is scientifically unsound. Secondly, he has had extraordinary difficulty getting from the DOE, through the Freedom of Information Act, any useable medical data on Mallinckrodt workers, including requests about their death certificate information. He stated that he would be glad to assist the Board in any way that he could with these matters.

<u>George Barrie</u> thanked the DHHS for listening to the Board and the public, and for agreeing to extend the comment period. He suggested that more cancers and diseases should be covered beyond the twenty-two legislated cancers. He asked that NIOSH please not limit any class to any specific cancer.

# Special Exposure Cohort Notice of Proposed Rulemaking Finalization of Board Recommendations

Dr. Ziemer moved the Board to a discussion of their recommendations for the proposed rulemaking. He pointed out that if the discussion was completed before 5:00 p.m., additional time for public comment would be allowed. In the meantime, he invited everyone to listen to the deliberations. He directed the Board's attention to the discussion reference document, the Federal Register/Vol. 68, No. 45/Friday, March 7, 2003/Proposed Rule and to Part IV, Department of Health and Human Services, 42 CFR Part 83: Procedure for Designating Classes of Employees as Members of the SEC Under the EEOICPA of 2000; Notice of Proposed Rulemaking; Proposed Rule. Some Board members did not have a copy of the Federal Register, but did have with them the earlier typewritten draft version of the proposed rulemaking. Dr. Ziemer indicated that he would try to refer to both documents during the discussion. He pointed out that the Board ended the last meeting at §83.12 and that they would begin this discussion with §83.13.

#### *Pg.* 11308, §83.13(b)(1)(iii):

The board recommended this sentence be revised to read: "In general, access to personal dosimetry and area monitoring data is not a defining factor that must be available in order to estimate the maximum radiation dosage which could have been incurred by any member of the class." There were no objections to the revisions.

# Pg. 11309, §83.13(b)(1)(iv):

This clause currently reads: "If NIOSH determines that it is not feasible to estimate radiation doses with sufficient accuracy, NIOSH will also determine whether such finding is limited to radiation doses incurred at certain tissue-specific cancer sites, and hence limited to specific types of cancers (whether or not such cancer[s] is a specified cancer under §83.5[k])."

Dr. Ziemer reminded the Board about the comments heard from members of the public on this issue and indicated that he also had discussed this issue with NIOSH staff. The thinking behind this clause of the rulemaking regards whether one is able to demonstrate that particular organs have not been exposed in certain cases where the radiation exposure is unknown.

# Discussion Points:

- ❖ Given that there are different processes for different isotopes, Mr. Gibson asked how NIOSH could really be sure that a particular isotope would limit itself to one specific organ or one specific part of the body. He cited an example where workers inhale tritium-contaminated metal particles and the tritium irradiates the lung tissue rather than following the usual the biokinetic model based on skin absorption. He wondered how anyone could really know that the tritium will limit itself to the lungs. Dr. Ziemer responded that dose reconstructors would have to determine whether the tritium stayed with the metal in the body. The list of twenty-two cancers would still apply, unless it could be shown that there was no way the tritium could have detached itself.
- Dr. Ziemer brought up an opposing example, where a class of workers engaged in X-ray diffraction work. The X-rays from the X-ray diffraction units are of such low energy, that one cannot physically irradiate any of the deep organs. The skin and the lens of the eye can be irradiated, but not the deep organs. What is proper for this class of workers? Does one consider only the skin cancers but not spleen cancer? What if only the extremities were exposed? Not all exposures deliver a dose to all organs.
- Dr. Ziemer also reminded the Board that the laws of nature had to be taken into consideration. For example, there is a limit to how much uranium a person can ingest, a limit to how much mass can be put into the lungs. Therefore, an upper limit for a lung dose can be set. This case would certainly be compensable for lung cancer, but would it be compensable for other cancers? Dr. Melius pointed out that the case would not be considered for the SEC because a maximum dose estimate would be available.
- Dr. Melius asked how NIOSH would handle cases where there is little information about sources of exposure or where and how people worked at these sites. If there is little information on sources of exposures and people's work histories, then how can there be enough information to limit organ systems involved? He felt that enough information must be available, before NIOSH could decide it was going to limit the organ systems affected.
- Mr. Griffon directed the Board's attention to the proposed rulemaking, Supplementary Information, Section III--Summary of Public Comments, Item B: Accuracy of Dose Reconstruction, Paragraph 8 (page 11296). This section states: "The Health Physics Society further recommended that determinations of the feasibility of estimating doses with sufficient accuracy be limited to relevant cancers. This comment reflects the fact that the feasibility of a dose reconstruction can be specific to certain cancer sites in the

body and hence to the type of cancer an employee incurs. Hence, it may be appropriate to limit the finding that it is not feasible to estimate radiation doses with sufficient accuracy to certain tissue-specific cancer sites relevant to individuals with specific types of cancers." Mr. Griffon asked for clarification on what the HHS meant by "significantly irradiate." As Dr. Neton mentioned in an earlier meeting, if a person obtains an exposure to the lung from uranium, the predominate organ might be the lung, but other organs will obtain some dose. Mr. Griffon asked: "At what level is the cut off of 'significance?" Is this cut off based on the Interactive Radio-Epidemiological Program (IREP) probability of causation (POC) model or is the HPS using some other metric to determine "significance?" Others agreed that more clarification on this point was needed.

- Mr. Griffon asked Dr. Ziemer how the IREP model would handle an individual case, such as Dr. Ziemer's example X-ray diffraction case, if one knows of the individual exposure. Would all of the organs at least be considered to have some potential exposure probability? Dr. Ziemer responded that he believed the energy would be plugged in and then the doses calculated to the individual organs, much like what is done for a beta emitter.
- Mr. Elliott noted that this was not a final rule, and that this was not the time for the Department or NIOSH staff to interpret the pending rule or debate the meaning of the rule with the members of the public or the Board. He stressed that they did not want to engage in any type of communication that any individual or group may perceive as misrepresenting the Department's offering of interpretation of the rule. Therefore, they would limit themselves to directing the Board to pertinent parts of the proposed rulemaking or statute where they thought clarity might be provided. He then explained that each dose reconstruction considered, and the feasibility of that dose reconstruction, can depend on the type of radiation exposure and the type of cancer the employee contracted. The statute requires a determination that the dose reconstruction is not feasible for the DHHS to add a class to the SEC. This notice of proposed rulemaking proposes that the proposed class not include persons for whom a dose reconstruction can be done.
- ❖ Dr. Neton added that when NIOSH approaches a dose reconstruction, the outlined process in 42 CFR 82 is applied. The dose reconstruction is attempted so that an unambiguous decision regarding compensability can be made. If a maximum dose assumption suggests an unreasonable exposure, given the circumstances of the work environment, the dose reconstruction could still be completed by applying the efficiency process. Not all organs are radiated uniformly. In certain types of cancers and in certain organs, broad maximizing assumptions can be made to complete the dose reconstruction. Mr. Elliott interjected that the language in the proposed rulemaking states that NIOSH "may, where appropriate." Because of the ability to do dose reconstructions for certain cancers, NIOSH may define a class. However, NIOSH also must do dose reconstructions when feasible.
- Dr. Roessler asked whether the Board would deliberate after the public comment period ended. Dr. Ziemer indicated that the public comment period was for the benefit of the agency while it is going through the rulemaking process. The Board would not deliberate on the rulemaking after the public comment period had ended.

- Mr. Elliott explained that at the March 7, 2003 ABRWH meeting, the Board recommended that the comment period for the second notice of proposed rulemaking for the SEC be extended to fifteen days, for a total of forty-five days of public comment. The Board also indicated that it wanted to ensure that both the Board and the public had adequate time to review and comment on this proposal, especially in light of the significant changes that the first public comment period produced. The DHHS agreed with the Board's recommendation and decided to provide an additional thirty days of comment, making the public comment period sixty days in length. The deadline for the end of the public comment period is now set for Tuesday, May 6, 2003. At that time, the public comment period will close and the next step will be for NIOSH to review, evaluate, consider, and address those comments for promulgating a final rule. Therefore, the Board must complete its business by May 6, 2003.
- Dr. Ziemer indicated that he had begun to draft the Board's comments to the DHHS, and would continue to add to that draft as the Board deliberated on the proposed rulemaking. He reminded the Board that their comments to DHHS could be in the form of general comments or specific recommendations.
- ❖ Dr. Melius indicated that his discomfort level was very high with two issues: 1) How well NIOSH had delineated the issue of sufficient accuracy of dose reconstructions and the parameters placed on those dose reconstructions; and 2) Lack of delineation on the issue of specific cancer sites. In practical application, he sees no limits on how NIOSH may choose to apply this, or how the Board can get involved in trying to make judgments in reviewing NIOSH's application and making recommendations on which cancers should be included. He did not think that the rule in these two sections, as currently drafted, was workable.
- A general discussion ensued as to how the Board might make recommendations to NIOSH regarding its role in limiting cancers. The main points iterated by some Board members concerning this issue were:
  - If it is impossible to estimate a maximum dose, then how can a limit be placed on exposed organs?
  - → One requirement of a SEC is that a dose reconstruction cannot be accomplished, and if a dose reconstruction cannot be accomplished, then how can a SEC's cancers be limited?
  - → Does NIOSH have the legal authority to make an interpretation based on what was presented to the legislation? The comfort level would be greater if NIOSH had Congressional approval to keep §83.13. The concern is that limiting the number of cancers below 22 is not the spirit and intent of the law.
  - Ms. Munn did not perceive this section as limiting, and did not understand the concern regarding limiting the number of cancers. She expressed her reservations about the political ramifications and the scheduling problems involved in requesting a Congressional review of this portion of the law. Her personal assessment was that they would push back any claims currently on-going that might fall into this SEC. Dr. Melius and others felt strongly that they should at least seek further clarification.

- ❖ Ultimately, the Board reached an impasse on the subject of limiting cancers, and the following recommendations to NIOSH were proposed by some members of the Board:
  - → More clarity is needed in regard to how NIOSH will make the determination to include/exclude certain cancers.
  - If ever NIOSH has to invoke the rule on limiting specific cancers, those cases must be presented to the Board for added attention and advice. If a case comes before the Board that limits effects to less than all of the cancers on the list, NIOSH must provide specific justification for such limitations.
  - Some Board members requested clarification from DHHS and Congress on the intent of their legislation in regards to the list and limitation of the twenty-two specified cancers.

#### Motion

Dr. Melius moved that NIOSH clarify the appropriateness of the procedure for limiting specific cancers with regard to legislation and what the intent of Congress was for that legislation. The group decided that the exact wording of the motion needed work. Dr. Ziemer offered to compose a proper motion, based on the discussion, and send it out to Board members for additional discussion at a future conference call. Everyone agreed, and the Board moved the discussion to other sections of the proposed rulemaking.

# Pg. 11303, IV, A, para. 3:

The second sentence should be revised to read: "If the employee had sufficient occupational radiation exposure outside of his work experience as a member of the Cohort . . ."

# Pg. 11309, §83.14:

No comments, suggestions, or changes were made.

# Pg. 11309, §83.15:

No comments, suggestions, or changes were made.

#### Pg. 11310, §83.16:

It was decided that the Board should not recommend a deadline for the final decision on the designation of a class. They left this section with the assurance that this would be done in a timely fashion, following the agency's normal process, noting that the DHHS already had a timeline for providing information to petitioners, etcetera.

#### Pg. 11306, §83.5(c):

There was some concern over the definition of a "facility" in this proposed rulemaking. Drs. Melius and Andrade had written and distributed to the Board a paper called *Facility Definition Issue*, which pointed out that there were two conflicting uses of the term "facility" in the legislation. The one definition of the Atomic Weapons Facility (AWE) facility talks about "facility" in a broad sense. The other definition talks about a "DOE facility" in a much more "building-specific" sense. The legislation neither discusses the exposure at a particular facility nor restricts the exposure to any particular facility. It does discuss an employee having an

exposure, but does not limit that exposure to the facility at which the employee worked. Still, in terms of the SEC, it makes sense to think of the word "facility" in the broader sense.

Drs. Melius and Andrade proposed the following recommendation to NIOSH for the purposes of the proposed rulemaking: The word "facility" should be considered broadly (e.g., Los Alamos, Rocky Flats). The class definition should be utilized to limit the class to those workers who worked in some specific operation at the facility and whose dose could not be reconstructed with sufficient accuracy. As currently utilized, the word "facility" refers to specific buildings. NIOSH would have to expend considerable effort developing an inventory of defined "facilities" at each DOE site and would have difficulty considering the SEC classes for workers in operations that might have taken place in more than one building or facility at a DOE site. Drs. Melius and Andrade also suggested that NIOSH include an operational definitions in Subpart B—Definitions.

#### Motion

Dr. Melius moved to accept his and Dr. Andrade's recommendation to NIOSH with the intent that it be included in some form of an operational definition. Dr. Andrade seconded the motion. Ms. Munn proposed a friendly amendment, suggesting that rather than repeat the two definitions, the revised definition section should begin with a preceding sentence that reads: "There are two definitions of 'facility' existing in the legislation, namely Subtitle B §36.21 and §36.36, Designation of Additional Member Special Exposure Cohort" and then move to the recommended final paragraph suggested by Drs. Melius and Andrade. The motion received unanimous approval.

The Board then addressed the issue of "facility," versus "facilities," and whether the plural or singular should be being used in the proposed rulemaking.

#### Discussion Points:

- ❖ Dr. Andrade proposed that there be no limit placed on classes in the SEC with respect to crossing facility boundaries.
- Mr. Owens pointed out that the sites in Paducah, Kentucky; Portsmouth, Ohio; Oak Ridge, Tennessee; and Amchitka Island, Alaska have been designated as part of the SEC. He believes that the expectation from other sites throughout the country is that they will also be treated in a like manner when they petition for SEC inclusion. The legislation plainly allows these other sites to petition to be included in the SEC. Mr. Owens suggested the Board consider that in current legislation, it does not matter whether an employee is a clerical or process worker. It does not matter if they are hourly or salaried. What matters is that they qualify under the SEC for compensation. Dr. Ziemer responded by explaining that requirements of selection for the SEC included that the workers were exposed to radiation at the facility, and that there not be enough information available with which to accomplish a dose reconstruction. Mr. Owens agreed, but wanted to ensure that the Board was cognizant of the public's expectations. He urged the Board to

consider those expectations, thereby ensuring that the compensation process remained transparent, which in turn would strengthen the Board's credibility.

# Motion

The Board agreed that an allowance needed to be made for workers who worked the minimum of 250 days at different physical locations, whether the locations were in the same complex or in different parts of the country, and where dose constructions were not possible. These are workers who, although they may have accumulated 250 work days, might not qualify under the employment parameters established for any particular class. Two scenarios would be: 1) A class of workers who worked in multiple facilities; and 2) An individual worker who could be part of two classes. Dr. Ziemer indicated that he would write a draft of the proposed recommendation and send it out to the Board for review.

| Regarding the two recommendations that the Board is formulating, Mr. Katz noted that          |
|---|
| the recommendation regarding defining the classes as potentially including multiple           |
| facilities was very clear. In terms of aggregating the days if one is in multiple classes, he |
| offered clarity that this was really a recommendation for DOL given that the DOL              |
| determines compensation. Labor does that for the individuals in gaseous diffusion plants      |
| Mr. Katz wondered if they were trying to recommend that NIOSH create a new aggregate          |
| class. The classes are going to be defined, and must be defined generically, by job           |
| categories, time period, etcetera as it has been explained in the regulations.                |
| Dr. Melius suggested that they recommend that NIOSH figure out how to determine this          |
| issue.  |

Dr. Ziemer then reviewed the Board's recommendations for the proposed rulemaking that were made during the twelfth meeting.

# Pg. 11296, col. 3, para. 2:

Last sentence: This statement is confusing, and the Board recommended that NIOSH rewrite the sentence for clarification.

#### *Pg.* 11307, §83.9(c)(2)(iii):

This paragraph was reworded as follows: "... a report from a health physicist or other individual with expertise in dose reconstruction describing the limitations of DOE or AWE records or radiation exposure at the facility as relevant to the petition. This report should specify the basis for believing 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."

#### *Pg.* 11307, §83.9(c)(2)(iv):

This paragraph was reworded for clarity: ". . . a scientific or technical report published or issued by a governmental agency or published in a peer review journal that identifies dosimetry and related information that are unavailable (due to either a lack of monitoring or the destruction or loss of records) for estimating the radiation doses of employees covered by the petition."

# *Pg. 11307-8,§83.9(c)(3):*

This portion of the section deals with exposure incidents and describes the process for evaluating the information required for such incidents in the event that NIOSH is unable to obtain records or confirmation of the incident. The Board recommends that NIOSH consider where the placement of this part of the section should be within the rule, since it refers to information required after the petition has been evaluated by NIOSH. As presently located, this portion could be confusing to the petitioner.

### Pg. 11308, $\S 83.9(c)(3)(i-ii)$ :

These paragraphs require either medical information or witness affidavits in the event that the exposure incident cannot be confirmed. For the requirement that two (2) employees who witnessed the accident submit affidavits, the Board recommends that the petitioner be counted as one of these two (2) witnesses, if the petitioner was an individual employee who witnessed the incident. The Board is also concerned that a petitioner may have difficulty finding witnesses for an exposure incident that occurred many years ago. In such cases, the Board recommends NIOSH offer the option for other parties to submit confirmation of the incident in the absence of eye witnesses or records.

# Pg. 11308, §83.11(b):

The Board is concerned that there is no further appeal process for petitions that do not satisfy the relevant requirements. Accordingly, the Board recommends that NIOSH explore possible appeal mechanisms within the DHHS for such cases.

# **Housekeeping and Miscellaneous**

- Dr. Ziemer indicated that he would present a final draft of the Board Recommendations on the Proposed Rulemaking and a draft of the cover letter for discussion at the next meeting. The next telephone conference was scheduled for May 1, 2003, from 3:00 p.m. to 5:00 p.m., Eastern Standard Time. Although there was no time for a final public comment period, the Board addressed several concerns of the public: One claimant asked how the Board intended to notify 10,000 claimants about their conference calls. Dr. Ziemer stated that the calls are publicized through the Federal Register and posted on the NIOSH/OCAS web site. The claimant pointed out that many claimants do not have access to computers and are not being informed of the Board meetings.
  - Mr. Elliott directed the public to the address in the Federal Register to which additional public comment could be sent regarding the compensation process and Board deliberations.

- The public was informed that the public comment periods usually occurs at the beginning of each Board meeting.
- The transcript from the March 7, 2003, Board meeting should be posted to the web site next week, or at least before the next conference call.

With no further business posed, the meeting was officially adjourned at 5:08 p.m.

I hereby confirm that these Summary Minutes are accurate to the best of my knowledge:

Paul L. Ziemer, Ph.D., Chair

End of Summary Minutes