

**THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
CENTERS FOR DISEASE CONTROL AND PREVENTION  
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH**

convenes the

**ADVISORY BOARD ON  
RADIATION AND WORKER HEALTH**

The summary minutes of the meeting of the Advisory Board on Radiation and Worker Health held at The Westin Cincinnati, 21 East Fifth Street, Cincinnati, Ohio, on March 7, 2003.

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March 7, 2003

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## **SUMMARY REPORT LEGEND**

The following summary report was derived from the certified verbatim transcript, the March 7, 2003 version of the Rulemaking (in two formats, once of which was the published *Federal Register* version), and other handouts such as PowerPoint presentations. The legend in the verbatim transcript indicated the following, “In the following transcript a dash (--) indicates an unintentional or purposeful interruption of a sentence. An ellipsis (. . .) indicates halting speech or an unfinished sentence in dialogue or omission(s) of word(s) when reading written material. In the following transcript (sic) denotes an incorrect usage or pronunciation of a word which is transcribed in its original form as reported,” and also, “In the following transcript (inaudible) signifies speaker failure, usually failure to use a microphone.”

There were numerous occasions where one or more of these issues occurred. This summary has been written with an effort to complete the discussion of those speaking for ease of reading and a professional report; however, there may be times where reporting is inadvertently not written as the speaker intended. At points in the discussion where there was definite concern that the summary may not accurately capture the discussion, referral has been made to the location in the certified verbatim transcript (CVT), and the area in question has been highlighted in yellow in the summary for quick reference.

Although sometimes questions and/or comments were raised during a speaker’s presentation, all questions/comments are included under Discussion Points for each section for ease of reading.

Although the Public Comment Period for this meeting occurred between the two Board Discussion/Work Sessions at midday, the Public Comment Period appears in the document prior to the deliberations from the two Board Discussion/Work Sessions which have been combined to better capture the discussion regarding the new NPRM.

**P A R T I C I P A N T S**

(By Group, in Alphabetical Order)

**BOARD MEMBERS**

**CHAIR**

ZIEMER, Paul L., Ph.D.  
Professor Emeritus  
School of Health Sciences  
Purdue University  
Lafayette, Indiana

**EXECUTIVE SECRETARY**

ELLIOTT, Larry J.  
Director, Office of Compensation Analysis and Support  
National Institute for Occupational Safety and Health  
Centers for Disease Control and Prevention  
Cincinnati, Ohio

**MEMBERSHIP**

ANDERSON, Henry A., M.D.  
Chief Medical Officer  
Occupational and Environmental Health  
Wisconsin Division of Public Health  
Madison, Wisconsin

ANDRADE, Antonio, Ph.D.  
Group Leader  
Radiation Protection Services Group  
Los Alamos National Laboratory  
Los Alamos, New Mexico

DeHART, Roy Lynch, M.D., M.P.H.  
Director  
The Vanderbilt Center for Occupational and Environmental Medicine  
Professor of Medicine  
Nashville, Tennessee

ESPINOSA, Richard Lee  
Sheet Metal Workers Union Local #49  
Johnson Controls  
Los Alamos National Laboratory  
Española, New Mexico

GIBSON, Michael H.  
President  
Paper, Allied-Industrial, Chemical, and Energy Union  
Local 5-4200  
Miamisburg, Ohio

GRIFFON, Mark A.  
President  
Creative Pollution Solutions, Inc.  
Salem, New Hampshire

MELIUS, James Malcom, M.D., Ph.D.  
Director  
New York State Laborers' Health and Safety Trust Fund  
Albany, New York

MUNN, Wanda I.  
Senior Nuclear Engineer (Retired)  
Richland, Washington

OWENS, Charles L. (via telephone)  
President  
Paper, Allied-Industrial, Chemical, and Energy Union  
Local 5-550  
Paducah, Kentucky

PRESLEY, Robert W.  
Special Projects Engineer  
BWXT Y12 National Security Complex  
Clinton, Tennessee

ROESSLER, Genevieve S., Ph.D.  
Professor Emeritus  
University of Florida  
Elysian, Minnesota

AGENDA SPEAKERS

Mr. Ted Katz, Special Exposure Cohort  
Mr. Mark Griffon, Workgroup Chair

STAFF

HHS:

Martha DiMuzio  
Russ Henshaw  
Cori Homer  
Liz Homoki-Titus  
Ted Katz  
David Naimon  
Jim Neton  
David Sundin

DOL:

Jeffrey L. Kotsch  
Rose Toufexis

VENDORS

Steven Ray Green, Certified Merit Court Reporter  
Kristin Jones, Writer/Editor

PUBLIC PARTICIPANTS

Brock, Denise  
Cofelt, Evelyn  
Darnell, Peter  
DeHart, Julia  
Fowee, Steven R  
Hinnefeld, Stu  
McGowan, William J  
Miller, Richard  
Presley, Louise S  
Rolfes, Mark  
Rutherford, LaVon  
Tabor, Bob  
Taulbee, Tim

Tomes, Thomas  
Toohey, R E  
Ziemer, Marilyn

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**8:30 a.m.**  
**REGISTRATION AND WELCOME**

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**Call to Order**

***ZIEMER, Paul L., Ph.D.***  
***Professor Emeritus***  
***School of Health Sciences***  
***Purdue University***  
***Lafayette, Indiana***

Dr. Ziemer called the twelfth meeting of the Advisory Board for Radiation and Worker Health (also referred to as the Board) to order, noting that he was Chairman of the Board. He requested that the record show that all of the Board members were present with the exception of Leon Owens, who was in attendance via telephone.

Dr. Ziemer indicated that the primary focus of this meeting was to be on the Notice of Proposed Rulemaking (NPRM), 42 CFR Part 83, dealing with the Procedures for Designating Classes of Employees as members of the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). The reference document utilized for the discussion was the Federal Register/Vol. 68, No. 45/Friday, March 7, 2003/Proposed Rule.

**Preliminary Comments**

***ELLIOTT, Larry J.***  
***Director, Office of Compensation Analysis and Support***  
***National Institute for Occupational Safety and Health***  
***Centers for Disease Control and Prevention***  
***Cincinnati, Ohio***

Mr. Elliott reminded those present that NIOSH produced a NPRM last summer, and that the NPRM which meeting participants had before them was being published that day in the *Federal Register*, and that it would be open for public comment for 30 days hence. He explained that because of the public comments NIOSH received on that NPRM last summer, and the changes that NIOSH made in addressing those comments, NIOSH needed to publish a second NPRM rather than finalize that NPRM from last summer.

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**SPECIAL EXPOSURE COHORT:  
NOTICE OF PROPOSED RULE MAKING**

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***Mr. Ted Katz***  
***Agenda Speaker***  
***Special Exposure Cohort***

Mr. Katz reviewed the major elements of the rule and summarized relevant recommendations of the Board and comments of the public. He noted that there were two statutory criteria for considering additions to the Class, namely that: 1) It is not feasible to estimate with sufficient accuracy the radiation dose that the Class received; 2) There is a reasonable likelihood that such radiation dose may have endangered the health of the members of the Class.

Mr. Katz summarized provisions of the first NPRM concerning feasibility and noted that the Board had recommended the rule provide clearer criteria. He noted that the Board also suggested that NIOSH develop operational guidelines outlining criteria, including time limits, to address the issue of feasibility.

Mr. Katz also summarized a variety of public comments concerning feasibility.

Mr. Katz identified two new provisions, consistent with comments received:

- ☐ It is “Feasible . . . if we have access to sufficient information to estimate the maximum radiation dose that could have been incurred in plausible circumstances by any member of the class.” He noted that in circumstances when information is limited to this extent, an enormous amount of benefit of the doubt would go to the claimants.
- ☐ “In some circumstances, feasibility could be cancer site-specific and hence cancer-specific.” Mr. Katz explained that since dose reconstructions are tissue-specific, they do not estimate doses generally. They estimate doses to the tissue related to the cancer that has been incurred. Hence, in certain circumstances, it is possible that feasibility will hinge on the particular cancer site. To illustrate, Mr. Katz shared the following two examples:

*Example 1:* If NIOSH could estimate all radiation doses for an individual except for doses associated with exposure to radon daughters, then the organ that is exposed to radiation from radon would be the lung. For practical purposes, other tissues, other organs, would not be exposed to the radiation from radon. NIOSH could cap the dose associated with radon for those individuals with cancers other than lung cancer. In that case, NIOSH could establish a Class that included anyone who had, or incurred in the future, lung cancer and who was exposed to radon at the site. For all other individuals, NIOSH could complete a dose reconstruction.

*Example 2:* In circumstances involving partial body irradiation, such as when there is shielding; as when workers use a glove box, then only certain cancer sites would be at

issue for dose reconstruction. With the glove box, the skin would be exposed as would the bones in the hand, and that possibly could relate to three cancers: skin cancer, bone cancer, and leukemia. However, dose reconstruction could be completed for individuals who incur lung cancer, for example, because the exposure of concern is not an exposure to the lungs.

Mr. Katz stated that the Board wanted the rule to provide as much guidance as possible to the public regarding feasibility. The hierarchy of information outlined in 42 CFR Part 82 provides some of that guidance. It explains that if there are no personnel monitoring data, they go to the next step, and so on. NIOSH also made a couple of statements in the NPRM that are intended to be helpful, including the following:

- ❑ “In general, [one] must be able to specify the types and quantities of radioisotopes to which the workers were potentially exposed. Or, [one] must know the design and performance information for *radiation generating* equipment, such as particle accelerators.” (Mr. Katz noted that without such basic information, it would be unlikely NIOSH could complete a dose reconstruction, even calculating the maximum dose); and
- ❑ “In general, data from personal dosimetry and area monitoring are not essential.” (Mr. Katz explained that it was important for the public to understand that there is a hierarchy of information that can be used for a dose reconstruction, and that while NIOSH prefers good personnel monitoring data, dose reconstructions can be completed, that are fair to claimants, which are based on more general information).

NIOSH committed to additional guidance in the Preamble of the NPRM, specifically ~~in~~ that NIOSH will publicize summaries of circumstances in which doses cannot be estimated, as these arise through the dose reconstruction program. Mr. Katz said that these will be illustrative cases to help the public understand where the limits are and what circumstances result in being unable to estimate doses. He stressed that NIOSH was committed to working with the Board to do whatever they could to expand guidance for the public on this topic.

Concerning feasibility with respect to time limits, Mr. Katz indicated that NIOSH would consider establishing a time limit or guidelines for completing dose reconstructions once the dose reconstruction program reaches its full operating capacity.

Mr. Katz then discussed the next major element of the NPRM, health endangerment. He summarized relevant provisions of the first NPRM regarding health endangerment and noted that the Board recommended that NIOSH consider other suitable criteria.

Mr. Katz also summarized some of the public comments concerning health endangerment and explained the relationship between the feasibility of dose reconstruction and limitations concerning the evaluation of health endangerment.

Mr. Katz summarized the current proposal for determining health endangerment HHS made the following changes: 1) Eliminated the use of cancer risk models, 2) Limited determination to an employment duration requirement for exposed employees, 3) Retained the 250-day employment criterion as the default requirement; and 4) Allowed HHS to specify "presence" as sufficient employment duration for discrete incidents in which doses were likely to have been exceptionally high.

Mr. Katz also summarized a variety of public comments on petition requirements. In response to public comments regarding petition requirements, HHS proposed the following changes to the petition requirements in the first NPRM:

- Expanded the scope of eligible petitioners (Mr. Katz indicated that now, any individual or entity who is authorized in writing by the workers or survivors, could serve as a petitioner.
- Made the use of petition form(s) voluntary.
- Eliminated the requirements to obtain verification of record deficiencies from DOE or an AWE.
- Eliminated the requirement to address health endangerment in the petition justification.
- Simplified the petition justification concerning feasibility to a set of specific, discrete options.

Another major issue is timeliness. Mr. Katz indicated that the public expressed concern about expediting consideration of petitions for which NIOSH has already found that dose reconstruction is not feasible. In response, HHS proposed measures that would minimize the time required to consider petitions for a class with an employee whose dose reconstruction they cannot complete (see §83.14). Mr. Katz said that the basic strategy was that NIOSH would evaluate the petition based on the information it had already collected from attempting to complete that dose reconstruction.

If the information at hand only allowed NIOSH to define a class of a limited scope, but NIOSH had some indication that feasibility issues could extend beyond that scope, NIOSH would evaluate that issue separately without delaying the advance of the petition evaluation to the Board. The evaluation would cover that claimant who has cancer and all similarly situated employees. Mr. Katz also noted that HHS intends to convene the Board as frequently as necessary and possible to minimize the delays with respect to the Board's role in advising the Secretary on Cohort decisions.

Mr. Katz indicated that the Board and public had commented on the roles of the Board and the Secretary. One suggestion was to limit or eliminate the Secretary's discretion to apply non-specified procedures. Mr. Katz pointed out that at the end of the earlier NPRM, the Secretary had the right to invoke such procedures. He also indicated that the Board recommended limiting the Board's role in reviewing NIOSH decisions to deny evaluations of petitions that do not meet the petition requirements. A public comment, on the other hand, recommended retaining the

Board's role. Mr. Katz indicated that HHS eliminated the Secretary's discretion to apply the non-specified procedures, and eliminated the Board's review of petitions that NIOSH decides do not meet the minimum requirements.

**Discussion Points:**

- ❖ Dr. Melius said that, if he recalled correctly, a claimant whose dose reconstruction could not be completed would still have to submit a petition, and that then justification would really be the NIOSH finding that it was not feasible to reconstruct the dose. Mr. Katz responded that this was accurate, and that this is addressed in the NPRM. He pointed out that the claimant would be notified and encouraged to petition and that all the claimant is required to do is affirm that they wish to petition because the NIOSH finding is the entire justification for the petition.
- ❖ Dr. Melius requested that Mr. Katz comment on an administrative review of a petition that has been turned down. Mr. Katz responded that NIOSH asked for public comment regarding whether people thought they should have an administrative review of NIOSH decisions if these were not going to go to the Board. He explained that the process has changed somewhat in other ways, too, because if a petition does not meet requirements, NIOSH will specifically identify to the petitioner why it does not meet the requirements and provide the petitioner with guidance for what would be required to make that petition meet the requirements. The petitioner would then have 30 days then to address those specific components.
- ❖ Dr. DeHart asked Mr. Katz to expand on the elimination of cancer risk models for the determination of health endangerment. Mr. Katz responded that the purpose of originally including the cancer risk models was to establish a dose level benchmark and then determine whether doses could have exceeded it. If doses exceeded the benchmark, that would satisfy the requirement that the health of the class may have been endangered. However, under the current proposal, if NIOSH cannot put an upper limit on the dose that someone might have received, then any benchmark becomes irrelevant because whatever the benchmark, the dose could have exceeded.
- ❖ With regard to benchmarking, Dr. Ziemer said it seemed somewhat semantic to him that if they did benchmark in the sense discussed before, and found that every member of the class was very high and there was a number, under the change they would be saying that it was a dose reconstruction that fit in the other category. In that circumstance, they would end up compensating every individual in any event, as a group, and they simply would not call it a "Special Exposure Cohort." Mr. Katz responded that this was not quite what was meant. He explained that NIOSH would complete the dose reconstruction if they could cap the dose, but if NIOSH can cap the dose, it does not mean that everyone who incurs that dose would be compensated. It means NIOSH would complete the dose reconstruction based on that maximum dose, and whether someone were to be compensated would depend on the specific cancer incurred.

- ❖ Mr. Griffon said he was trying to grapple with the notion of tissue-specific cancer sites, noting that one of the examples given in the Preamble (Page 15) was that radon progeny or uranium, would only concentrate and significantly irradiate certain organs and tissues. He wondered how the term "significantly" was defined, or whether this was left open to case-by-case analysis. Mr. Katz responded that it would certainly come before them case-by-case because the Board would see each of these petitions and the NIOSH evaluation for each.
- ❖ Mr. Griffon, Dr. Andrade, Mr. Katz, and Dr. Neton discussed the issue of whether one can estimate a maximum dose for certain tissues and organs when one cannot for other organs, using the examples of radon progeny and plutonium.
- ❖ Dr. Melius expressed concern that the Board was going to spend a lot of time trying to decide where to make the cutoff, which organ systems would be covered in these situations, which cancers of other organ systems would not be covered. While he did not necessarily disagree with the simple examples that had been presented, he was not sure how practical or common those would be.
- ❖ Dr. Melius asked whether the new NPRM had addressed the question of what would be done for individuals who are in the Cohort but have a type of cancer that is not eligible for compensation under the provisions of EEOICPA covering members of the Cohort.
- ❖ ~~Dr.~~ Mr. Katz responded that these issues were addressed in the Preamble. He explained that, where an individual has doses outside of the window of exposure for the Cohort, coupled with the fact that the individual has a cancer that is not compensable as a member of the Cohort, NIOSH has to complete a dose reconstruction. Discussed in the Preamble is that there is not an answer currently regarding what to do in a dose reconstruction with that window for which you cannot estimate doses
- ❖ Mr. Griffon requested clarification on the definition of "sufficient accuracy," wondering if it was when one could calculate a maximum dose to be used in the determination of probability of causation. Mr. Katz responded that if one could calculate a maximum dose to the Class, then a dose reconstruction could still be completed with sufficient accuracy. Dr. Neton clarified that it would not necessarily be the maximum dose. If they could develop a distribution, the maximum credible dose would be used in the analysis.
- ❖ Mr. Espinosa and Dr. Melius expressed concern regarding the amount of time allowed for review of the NPRM, and for the public comment timeframe. He believed that the public comment period should be extended to 60 days. Mr. Espinoza also wondered whether there was a stakeholders meeting planned regarding the NPRM. Mr. Elliott responded that the comment period would be 30 days, which was a Department decision. He

explained that there were no town hall meetings scheduled to deliver this NPRM like there were for the last NPRM.

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## **DOSE RECONSTRUCTION REVIEW PROCESS WORKGROUP**

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***GRIFFON, Mark A.***

***Chair, Dose Reconstruction Review Process Workgroup***

***President, Creative Pollution Solutions, Inc.***

***Salem, New Hampshire***

Mr. Griffon indicated that during the previous Board meeting, the Dose Reconstruction Review Process Workgroup (also referred to as the Workgroup in this presentation), as a newly-established working group, was tasked with the following dose reconstruction review process activities: 1) Develop draft procedures for the review process; 2) Develop procedures for case selection; and 3) Develop individual task orders to be released after the task order contract is awarded.

Mr. Griffon noted that during the previous Board meeting, Dr. Ziemer distributed a first cut of a draft for the basic review which delineated how the contractor and the Board would move through the process for the basic review of a individual dose reconstruction. They now have draft procedures currently in place for basic review and advanced review case reviews which include: the Report Form, the Executive Summary Form, and the Board Summary Report Form.

He explained that the Executive Summary would be a summary of the case review. This report will not have as many details, and will probably be distributed to the entire Board for consideration. The Board Summary Report is what the Workgroup envisioned as the Board's report to HHS, which would be a summary of an aggregate number of cases, including information regarding findings or concerns in aggregate from the cases that have been reviewed during the agreed upon timeframe (e.g., during a particular quarter, during half a year).

Mr. Griffon indicated that during the Workgroup's ORAU site visit, they were first briefed by NIOSH regarding the database structure of the NIOSH-OCAS Claims Tracking System (NOCTS) and the Administrative Record for each case file. The Workgroup then engaged in a preliminary review of cases, for which decisions have been made, against the draft procedures. They reviewed the Administrative Record for each case file, taking into consideration the various components in order to gain insight into the types of records actually captured. The components include a Dose Reconstruction Folder, a Correspondence Folder, a Department of Energy (DOE) Correspondence Folder, and a Department of Labor (DOL) Correspondence File. All records used for the individual dose reconstruction case are captured within those folders. Given that most other forms are in PDF format, while the data is there, should a reviewer wish to use said data, they would have to re-enter the raw data to conduct their own assessment. Mr. Griffon said that NIOSH did indicate a willingness to create Excel files for certain items to reduce re-keying efforts.

Another issue considered by the Workgroup pertained to how to schedule the case reviews and the coordination of the Board and the contractor or contractors. In the past, there have been discussions of designating Board members (which could be a rotating basis) who would meet with the contractors on groups of cases prior to presentations back to the full Board. The contractor would engage in the bulk of the legwork, but the designated Board members would then have an opportunity to work with the contractor prior to presenting to the full Board.

With regard to case selection, given that the plan is to review cases only after final decision, the Workgroup engaged in discussions about how many cases would be available and when, and they compared this against the calendar and the timing of when the contract is likely to be awarded. In addition, they further discussed Case Selection Criteria.

The final activity will be to develop individual task orders. The Workgroup will probably focus on the initial task orders that they perceive as most urgent, which include the Basic Review Task Order, the Advanced Review Task Order and the Procedures Review Task Order. They believe this can be done in parallel so that they can have the final drafts of these task orders in final form by the time the contract is awarded.

The anticipated timeline was delineated as follows:

<b>Task Order Contractor Timeline</b>	
<b>Description</b>	<b>Date</b>
5-member technical evaluation panel identified/ incorporated into the procurement	2/18/03
Task Order RFP published in <i>Commerce Business Daily</i>	3/18/03
RFP released for bid	4/21/03
Final proposals due	End of May
Bidder Meeting	To be determined
Workgroup completes draft task orders	To be determined
Technical review and past performance review	To be determined
Contract award	To be determined
Task orders awarded	To be determined

**Discussion Points:**

- ❖ Dr. DeHart noted that the entire Board would have an opportunity to review these cases as they come through the contractor, working with the contractor. There will be two to three reviewers for each cycle, which they envision occurring on a monthly basis. Time must be set aside in August/September for training so that each member can observe how the data files exist, how they can access the files, and what the files mean.
- ❖ Dr. Melius inquired as to how many contracts would be awarded, and the determination criteria for making the awards. Mr. Elliott responded that multiple awards could be made based upon who bids and how the Technical Evaluation Panel qualifies them. If there are two equally technical, capable contractors, multiple awards can be made under this procurement. The Board will need to give their advice regarding the number of contractors desired at the time of the Best and Final Offer (BAFO).
- ❖ Dr. Melius expressed concern regarding the timeline, particularly given OMB regulations which may need to be considered. He reminded the group that there is an option for only part of the document to be public, so they could focus on the interview section without violating procurement rules. Mr. Elliott indicated that he would check into the requirements.
- ❖ Mr. Presley recommended that the full Board make a site visit to ORAU as soon as possible to become familiar with the procedures, so that they are ready at the time the contract is awarded.
- ❖ Dr. Melius noted that one of the next steps for the Workgroup would be to consider options for reviewing the interviews. Mr. Griffon responded that they will have to flesh this out, indicating that he would try to schedule a conference call with the Workgroup prior to the Oak Ridge meeting.

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### **PUBLIC COMMENT PERIOD**

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*Members of the public presented comments on the following topics:*

**Mrs. Evelyn Cofelt**  
**Claimant, St. Louis, Missouri**

Mrs. Cofelt presented a statement, read by her daughter Denise Brock, relating information about the work experiences and health issues of her late husband, Christopher Davis, who had worked at Mallinckrodt Chemical Co.

**Ms. Denise Brock**  
**United Nuclear Weapons Workers of St. Louis, Missouri**

Ms. Brock summarized her efforts to address concerns raised by many potential claimants, and she indicated that she has a number of specific questions about the proposed rulemaking on the SEC, interpretation of the term “facility” as used in the rule,

**Discussion Points:**

- ❖ Ms. Brock wondered what effect having multiple job titles would have on the 250-day requirement. Mr. Katz responded that it would depend on how a class is defined. The Class could be defined to cover any number of jobs over multiple locations at the facility.
- ❖ Ms. Brock understood that a witnesses was needed in reference to the SEC (only in the case of an alleged exposure incident for which NIOSH has no records or information from DOE or other sources), but she wondered if that same was true for dose reconstruction. Dr. Neton responded that in the dose reconstruction process, NIOSH would try to ascertain the names of workers who were present at an alleged incident. If they were still alive and able to be interviewed, NIOSH would pursue that..
- ❖ With regard to a Hematite facility in Missouri, Ms. Brock said she understood that the years of coverage are only through 1968 and that they are no longer under a DOE contract. She wondered what they needed to do to expand coverage beyond 1968. Dr. Neton explained that “coverage” meant that while the DOE may have established that a facility was under contract for a certain period of time, for example 1958 through 1964, that represents the eligibility window for a person to be eligible to file a claim. However, the dose reconstruction would actually be performed through that period up until the date of diagnosis.
- ❖ Dr. Melius requested clarity on the NIOSH policy for expediting interviews for people who are ill or may become incapacitated. Mr. Elliott responded that it is the intent of NIOSH to capture the story of the individuals, and if their death is imminent and NIOSH is made aware of that, they do attempt in all cases to capture that person’s interview as quickly as possible.
- ❖ Mr. Espinosa asked Ms. Brock to speak to the issues raised in the 150 telephone calls she had received. Ms. Brock answered that most were acknowledging receipt of her letter and indicating that they have difficulty understanding the NPRM as well.

- ❖ Dr. Ziemer inquired as to whether NIOSH has considered crafting a simplified brochure, once the NPRM is in place, that would describe the NPRM in laymen's terms so that the burden was not on individuals such as Ms. Brock. Mr. Elliott responded that NIOSH anticipated this and that they have an effort underway.

***Richard Miller***  
***The Government Accountability Project***

Mr. Miller provided a number of comments concerning extending of the public comment period for the proposed rulemaking, clarification of the 250 day requirement for eligibility for the SEC, limitations on the specified cancers in an SEC, methods for estimating upper bound maximum doses, and the appeals process for unsuccessful petitioners.

**Discussion Points:**

- ❖ Regarding Mr. Miller's concern about whether NIOSH would apply a distribution when estimating the maximum potential dose, Dr. Neton responded that the issue of whether they would use a distribution or a maximum value really depended upon the data that are available to evaluate the case. If dose reconstructionists had some monitoring information at all that would allow them to generate a distribution with some best estimate of the exposure, they would assign a distribution. Lacking that information, though, they would be required to calculate some upper bound maximum dose that would not likely have a distribution. So, it really is a case-specific scenario based on the amount of data available.

***Bob Tabor***  
***Fernald Atomic Trades and Labor Council***

Mr. Tabor raised concerns about limiting the specific cancers in a class of the SEC.

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**BOARD DISCUSSION/WORK SESSION**  
**SPECIAL EXPOSURE COHORT - NPRM**

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**Overview**

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Although the group considered beginning by reviewing the Preamble, a decision was made that Mr. Katz would first walk the group through the new NPRM section-by-section, reviewing exactly what was changed and explaining why, and referring to the Preamble as necessary. Two

versions of the NPRM were circulating during this meeting: 1) The unpublished version numbered pages 1 to 91; and 2) The *Federal Register* version (Federal Register/Vol. 68, No. 45/Friday, March 7, 2003/Proposed Rule) numbered pages 11294 to 11310. These deliberations began with Subpart A: Introduction on page 66 of the unpublished version, and page 11306 of the published version. To delineate where in the NPRM deliberations were taking place, the page number, sections, and any subsections are denoted based on the official published version of the NPRM. Discussion points raised during this meeting in each section are signified by the iconic symbol □.

### **Subpart A—Introduction**

#### Pg. 11306, §83.0

Mr. Katz indicated that in §83.0, minor clarifications were made, and legal citations were added. He said that there was nothing substantive changed from what the group had reviewed previously.

- No further questions, comments, or changes were offered by the participants of this meeting regarding this section.

#### Pg. 11306, §83.1

Mr. Katz indicated that in §83.1, NIOSH added an explanation clarifying that the SEC rule is not intended as an alternative compensation avenue for cancer claims that have received dose reconstructions and have been denied under the non-Cohort procedures, and indicate that there is a DOL procedure under 20 CFR Part 30 for a claimant to contest a finding of a NIOSH dose reconstruction. This was done in response to the Board's recommendation that NIOSH make this clarification.

- No further questions, comments, or changes were offered by the participants of this meeting regarding this section.

#### Pg. 11306, §83.2

Mr. Katz indicated that minor clarifications were made to §83.2, and that NIOSH dropped a section. He explained that in the original NPRM, there was a §83.2 entitled, "How would cancer claimants be affected by the procedures in this part?" This was non-procedural and was redundant of other explanation in the rule, so it was removed.

- Dr. Melius said that while he had no problem with the deletion of 83.2 from the old NPRM, it was helpful to have some sort of explanatory information for people in terms of what their options are et cetera. While he did not think that this information necessarily had to be in the regulation, he did believe it was important to include in outreach materials (e.g., web site and so forth).

**Subpart B—Definitions**

Pgs. 11306-11307, §83.5

In §83.5, Mr. Katz indicated that NIOSH revised the definition of (c) *Class of employees* to delete the requirement that the employees of a class be similarly exposed to radiation. He explained that all that was important was that NIOSH could not reconstruct their doses, but that they do not have to be similarly exposed to be within the class. NIOSH deleted the definitions for *endangered the health*, *IREP*, and *probability of causation*. These are no longer needed given the way the NPRM is now constructed. NIOSH also revised the definition of (k) *Specified cancer* to be consistent with the definition under the DOL regulation that was finalized in December 2002. A definition was added for (l) *survivor* under EEOICPA given that this term is used in the NPRM.

- Dr. Andrade commented that under the definition of (c) *Class of employees* “facility” should be changed to “facilities” in this section. Mr. Katz pointed out that this language came from the legislation wherein the legislation specifically discusses classes at a *facility* using the singular form of “facility.”
- The issue of including the term *health endangerment* was raised. Mr. Katz responded that the term was used in the 1<sup>st</sup> NPRM because they were using IREP to establish a health endangerment benchmark. Given that this benchmarking approach is not included in the 2<sup>nd</sup> NPRM, the definition for *health endangerment* is excluded as well.

**Subpart C—Procedures for Adding Classes**

Pg. 11307, §83.6

Mr. Katz indicated that in §83.6, HHS made only minor clarifications.

- No further questions, comments, or changes were offered by the participants of this meeting regarding this section.

Pg. 11307, §83.7

In §83.7, Mr. Katz indicated that HHS made two changes: 1) It clarified that the eligibility of one or more employees or survivors of a petition on behalf of a class is limited to members of the proposed class or their survivors. In other words, employees and survivors cannot petition on behalf of a proposed class in which they are not included (e.g., on behalf of another class); and 2) It added a third group of eligible petitions comprised of one or more individuals or entities authorized by employees or survivors of the proposed class. Mr. Katz indicated that this was responsive to the request from non-union advocacy groups to have the authority to petition as well on behalf of a class. HHS allowed for as broad a possible interpretation as possible.

- No further questions, comments, or changes were offered by the participants of this meeting regarding this section.

Pg. 11307, §83.8

Regarding §83.8, how a petition is submitted, HHS made one change, which was to eliminate the requirement for the use of a petition form. It received comments saying that they should not require people to use the petition form, so NIOSH has made use of the form voluntary. He explained that petitioners will have to address the informational requirements of the petition either way, but they will not be required to use the form NIOSH is providing.

- ❑ Dr. Ziemer asked whether the OMB-cleared petition form would become part of the rule by reference. Mr. Katz responded that the form would not become part of the rule by reference—use of the form is voluntary. However, instructions will be included which will be useful for petitioners regardless of whether they use the petition form.
- ❑ Dr. DeHart thought it would be important for the Board to see the form as soon as it was OMB-cleared. Mr. Katz clarified that the form would cover all of the questions that are delineated in §83.9. It also provides explanation to help the petitioner understand what is being requested.

Pg. 11307-11308, §83.9

Mr. Katz indicated that there were several changes made to §83.9, including: 1) The requirement for submitting a report to NIOSH was eliminated for those people for whom dose reconstructions were attempted but could not be completed. They now only need to indicate the basis of the petition; 2) The requirement was eliminated for the petitioners to provide information specifically related to the determination of health endangerment; 3) New maximally objective requirements have been established for the petitioners to justify their concern that it might not be feasible for NIOSH to estimate their radiation doses with sufficient accuracy; 4) A requirement was deleted concerning the feasibility of dose reconstruction (the requirement for petitioners to seek verification from DOE or an AWE with respect to their information on what data is available; and 5) If a petition is based on an exposure incident versus normal operations, NIOSH included the option of requiring the petitioner to provide evidence of the incident in cases when NIOSH cannot confirm the occurrence of the incident through any other sources. NIOSH does not think this situation will be common.

- ❑ Dr. Anderson noted that as part of the applications, a proposed case or class definition would ultimately be decided by HHS. He pointed out that if someone filed and then as part of the definition was excluded, it would mean that they created a class, but there would be no one in it because it would not apply to the person making application. He wondered if it would still go forward as a class. Mr. Katz acknowledged that this type of situation was possible, and said that ~~it~~ the petition would still go forward. He explained that the point of a petition is to initiate the consideration of a class that should be considered. A petitioner might be determined to be in a separate class for whom ~~they~~ NIOSH can complete dose reconstructions. Hence, NIOSH may add a class to the Cohort that does not include the original petitioner. That petitioner would still have had his/her

proposed class considered, but the result of that consideration could be two distinct classes, one that is added and one that is not.

- Dr. Melius inquired as to who could represent that class in terms of whether there should be an appeal. Mr. Katz responded that the petitioner would not be excluded from the process. If they do not like the outcome, they can appeal.
- Dr. Melius wondered what the process would be if there was another part of the outcome that somebody else might object to who was not a party to the original petition. He was concerned that someone might not be represented. For example, if they were going to do organ-specific cancer, but all people who had kidney cancer were turned down. Mr. Katz responded that regardless of whether a petitioner is adversely affected, the petitioner can appeal the final decision of the Secretary.
- Dr. Andrade commented that the other side of this issue was that multiple petitions could be filed by different people or groups of people, and what HHS could do is combine petitions if they are similar in nature.
- Dr. DeHart requested clarification regarding a situation in which NIOSH has evaluated a claimant's dose and is unable to complete a dose reconstruction, and whether that claimant would be entered into a petition automatically, or if he or she must file a petition specifically. Mr. Katz responded that the claimant must submit a petition. He said that when NIOSH cannot complete a dose reconstruction, they will directly encourage the individual to submit the petition, and provide them with the form to submit the petition.
- Dr. Anderson wondered if NIOSH would be able to identify, up front, that someone was part of a class so that they did not go through all of the process of attempting to reconstruct, only to find out after the fact that they could not do so. Mr. Katz responded that he did not think those would come to NIOSH for dose reconstruction. DOL would identify them as part of that class. Class will be defined sufficiently so that even people who do not know they are part of the Cohort will be treated as a member of the Cohort by DOL. In addition, NIOSH plans to do as much as they can to get the word out to the claimant population that they have added a class to the Cohort.
- Dr. Melius noted that there appeared to be some reorganization of the way the information is presented about short-term over incidents of exposure, suggesting that the Board members should take a look at that to determine whether it was clear.
- Referring to page 11307, §83.9, (2)(iii) and (iv), Mr. Griffon expressed concern that they might be setting the expectations too high for information to come from petitioners, for example, at the end of 11307, §83.9, (2)(iii) regarding a health physicist or other individual with expertise in dose reconstruction documenting the limitations of existing records on radiation exposure at the facility as relevant to the petition. Specifying the basis for finding these documented limitations might prevent the completion of dose reconstructions for members of the class. The same is true for 11307, §83.9, (2) (iv). There may not be that many peer-reviewed journal articles that are specific for a subgroup of workers at a certain facility. Mr. Katz responded that (iv) was not in the previous version of the NPRM. It was added at the behest of the Board. He explained that it is an either/or requirement. The DOE would come in under this, and they do not have to be published in a peer-reviewed journal.
- Dr. Ziemer thought the intent was that it was a scientific or technical report from a government agency, so the wording will need to be clarified.

- Dr. Melius thought that perhaps page 11307-11308, §83.9, (3) (i) (ii) should be included in 11308, §83.11. To him, this seemed informational and should be fleshed out in terms of what constitutes confirmation of the incident. Dr. Andrade agreed, but thought it was a matter of a simple addition to §83.11 that says that further information contained in this particular section may be requested during the period of time that NIOSH assists with the development of a petition. Dr. Anderson added that rather than requiring the person as a part of the petition to go out and find support, they could say that if someone alleges an incident, they may ultimately have to provide other information as part of the validation. Mr. Katz agreed, pointing out that they were merely letting people know that NIOSH may come back to them for further verification at some point. Ultimately, it was agreed that when NIOSH drafts the final version of the NPRM, they should clarify §83.9, (3) (i) (ii) and determine the best position for this section.
- Mr. Griffon, Dr. DeHart, Dr. Andrade, and Ms. Munn discussed a variety of approaches for clarifying the wording of §83.9 (2) (iii).
- Dr. Melius thought the Board should recommend that in §83.9 (2) (ii), the petitioner should be included as one of the two employees who can submit an affidavit regarding witnessing an incident. This may be particularly important where there are no exposed persons surviving. Dr. Ziemer pointed out that the case where there were no witnesses or only one is not really addressed in this section. He also thought the issue of hearsay evidence should be addressed. Dr. Anderson pointed out the petitioner could be a union. Two changes were suggested by individual Board members for §83.9 (2):
  - The wording in §83.9 (2) (ii) should be changed to read “two witnesses, one of whom could be the petitioner if the petitioner actually witnessed the exposure” and
  - A §83.9 (2) (iii) should be added to deal with the lack of a second witness and lack of any witnesses.

Pg. 11308, §83.10

Mr. Katz indicated that §83.10 was a new section which was not included in the previous version of the NPRM. He explained that it was intended to clarify the distinction between the role of petitioners in providing sufficient justification for a petition and the role of HHS in determining whether to add a class to the Cohort. Some members of the public are under the impression that meeting the informational requirements for a petition means that the class will be added to the Cohort; however, this is not the case. Satisfying the requirements means that the petition will receive a full evaluation by NIOSH, the Board, and HHS. This is an addition which serves as a clarification in response to confusion they heard from the public on this matter.

- No further questions, comments, or changes were offered by the participants of this meeting regarding this section.

Pg. 11308, §83.11

Mr. Katz indicated that there were a number of changes to this section: 1) §83.11 and §83.12 were split out of the original §83.10. They wanted to separate the procedures for dealing with inadequate petitions from the procedures for notifying interested parties of petitions that qualified for evaluation. There is a notification component. They wanted to break that out because it was cumbersome the way it was; 2) They no longer require the Board to consider and recommend the disposition of petitions that NIOSH finds do not meet the basic requirements; and 3) NIOSH will provide guidance and assistance to petitioners in addressing the deficiencies of their petitions.

- This section was flagged to ensure that the issue of an inadequate number of witnesses was addressed.
- Regarding §83.11 (b), Dr. Ziemer, Dr. Melius, and Ms. Munn discussed whether a recommendation should be made that there should be a review process delineated here (e.g., perhaps there should be some mechanism for petitioners whose petitions fail to meet the requirement for evaluation to have that decision be reviewed).

Pg. 11308, §83.12

In §83.12, Mr. Katz indicated that NIOSH simplified the provisions concerning NIOSH/Board interactions on the development of evaluation plans. The Board's involvement in evaluating petitions inherently provides for the Board to review the NIOSH evaluation and provide NIOSH with related recommendations if more research is needed et cetera.

- Recognizing that this is going to go on over time, Dr. Anderson wondered what would occur should a petition come in which does not meet the criteria, and which is denied, but then a similar petition is presented at a later date by someone else. Mr. Katz responded that it would depend on whether the new petitioner brought forth new information. However, it would be treated the same as the previously denied petition. It would still be reviewed; it would not be summarily dismissed due to precedent. Dr. Andrade noted that this issue was covered under Pg. 11308, §83.11(c).
- Dr. Anderson pointed out that there still needed to be an integrating function of “putting two-and-two together” if a subsequent petitioner filed an incident not knowing that the first person existed. Rather than going back to the petitioner to tell them they need to find someone to verify, the two should be matched together.
- Dr. Melius asked for clarification regarding whether the requirement for confirmation by affidavit had to be from two others aside from the petitioner. Mr. Katz responded that they are not specifying who the two are, but clarified that it would be read as two individuals in addition to the petitioner. Dr. Ziemer added that it was not fully clear whether two or three affidavits were required, and that this should be clarified.
- Mr. Gibson wondered if only survivors were available to serve as witness, whether that could preclude someone from becoming a member of an SEC. Mr. Katz responded that it could preclude them from making the case that the incident occurred if there are no records and only survivors are asserting that the incident occurred. Dr. Ziemer added that it was similar to how to handle what the courts might call “hearsay.” It is removed from

the direct evidence, although sometimes that can be established as being credible depending on the situation.

- With regard to §83.12 (c) and (d), Dr. Roessler requested an example of when (d) would be acted upon rather than (c). Mr. Katz responded that it would depend on the coincidence of timing that they would want to get to work on these petitions as quickly as possible, and the timing of the next Board meeting NIOSH would initiate work without waiting on the Board.

Pg. 11308-11309, §83.13

Mr. Katz indicated that the changes made in §83.13 included: 1) Pg. 11309, §83.13 (3): NIOSH made the determination of health endangerment contingent on finding that it is not feasible to conduct dose reconstructions. 2) Pg. 11309, §83.13(b)(1): They clarified the criterion for finding that dose reconstructions are feasible, provided other guidance; 3) They included provisions to allow for a determination that it is not feasible to estimate radiation dose that is specific to one or a limited set of cancer sites; 4) They have omitted the use of IREP. They are not using cancer risk models as provided in 1<sup>st</sup> NPRM; 5) 11308-113109, §83.13 (2) (i-iii) and (3) (i-ii): Health endangerment includes a change to defining class solely by duration of exposure or presence at an exposure incident.

- Ms. Munn pointed out that her first impression of 11308, §83.13 (1) (iii) was that the wording was very dismissive of dosimetry and area monitoring data. Mr. Katz responded that it was specifically not necessary to estimate the maximum radiation doses that could have been incurred, which is different from saying not necessary to do a focused dose reconstruction. Dr. Ziemer suggested rewording in some way to remove the connotation of concern to Miss Munn that it sounds dismissive of the data. Ms. Munn agreed to craft a revision to be presented during the teleconference the next Friday.
- Dr. Melius suggested that there were three major issues on which they needed to spend some time: 1) 11308, §83.13 (1) (iii): Not feasible to, with sufficient accuracy, dose reconstruction, for which they have been provided with a very vague definition and very little guidance in the draft regulation; 2) 11308-11309, §83.13 (1) (iv): The organ-specific determination that is going to be made, which is new and is described very briefly and without any guidelines; and 3) 11308-113109, §83.13 (2) (i-iii) and (3) (i-ii): The health endangerment where there has been a major change from the approach used before to a way of defining class by duration of work or duration of exposure at an exposure incident. Dr. Melius's concern was that the wording in these areas of §83.13 could lead to arbitrary and inconsistent decisions because the wording does not provide enough framework or guidance on whether a dose can be determined with "sufficient accuracy." Other suggestions/comments regarding the three issues raised by Dr. Melius:
  - Mr. Griffon noted that the definition of "sufficiently accurate" differed somewhat in this section from in the Preamble.
  - Dr. Andrade thought the problem was an issue with the definition of "sufficiency." However, he also pointed out that this would likely have to be handled on a case-by-case basis, and that if they belabored the issue or tried to

include exact definitions of what constitutes *sufficiency*, the result would be a 1000-page document.

- Dr. Neton suggested inserting the key word “plausible” should be added to read “plausible dose.” Conversely, there could be implausible doses that do not pass the reasonableness test that one could assign for dose reconstruction to other organs. For example, in the case of uranium inhalation, it is implausible to come up with an upper limit when there is no data at all. It may be known that the person was exposed to uranium, which concentrates in the lungs and can lead to lung cancer. Though a dose reconstruction could not be done for the lung, one could come up with implausible exposure scenarios wherein a person would have to inhale five pounds of uranium, which would choke the person. One could still calculate a dose and demonstrate that the dose reconstruction was done, and that the probability of causation was very small for certain remaining organs. One could not assume that people inhaled five pounds of uranium and say that other organs should be considered for the SEC. This provision would be used on a limited basis when they knew there were certain scenarios that did not pass some reasonableness test. Dr. Melius felt that this section needed to be worded far more clearly.

Pg. 11309, §83.14

Mr. Katz indicated that this is a new section added to deal with petitions arising when NIOSH cannot complete a dose reconstruction out of that situation.

- Dr. Melius said he found this section confusing.
- No further questions, comments, or changes were offered by the participants of this meeting regarding this section.

Pg. 11309-11310, §83.15

Mr. Katz noted that there were three changes made to this section, namely: 1) Pg. 11309, §83.15 (c) NIOSH clarified that the Board may obtain and consider additional information not addressed in the petition or the initial NIOSH evaluation report, 2) They eliminated the use of the term "evidence;" and 3) They eliminated the term "consensus" which was used to characterize the recommendations of the Board, but which was confusing to the public.

- Ms. Munn requested clarification on the issue of petitioners appearing before the Board with regard to privacy. Mr. Elliott responded that if the petitioner is a claimant who wants to talk about his or her own claim, they can do so at their own volition. However, if the petitioner wants to talk about others who are in the system, the Board cannot respond with discussion of information covered by the Privacy Act. If information is submitted that is Privacy Act-related, the petition will be summarized to the Board in a fashion that will not reveal the confidential information.
- Dr. Melius noted that there needed to be a procedure in place for how information goes back to the petitioner and how the Board’s recommendations should go to the Secretary.

Dr. Ziemer said there was certainly nothing to preclude the Board from individually transmitting a decision to a petitioner, although he stressed that the Board's recommendation is not the decision; it is a piece of information the Secretary uses in making the final decision.

- Dr. Anderson raised the procedural issue of timelines to invite the petitioner to comment, for NIOSH evaluation of findings, et cetera, and whether that needed to be included in the NPRM itself. Mr. Elliott responded that this was a procedure they needed to put in place, and that they needed to develop a meeting cycle that is practical, appropriate, and not so rushed. If they could achieve the required 30-day *Federal Register Notice* timeline in advance of a meeting, this would be beneficial. However, he did not believe this needed to be part of the NPRM.

Pg. 11310, §83.16

Mr. Katz indicated that there were a number of changes in §83.16, including: 1) Pg. 11310, §83.16 (a): They clarified that the Secretary will take into consideration the NIOSH evaluation, the Board report, and information presented to the Board in its deliberations. This came out of a recommendation that the Board made to NIOSH; 2) Pg. 11310, §83.16 (a): They revised the reporting provisions to report all decisions to the Secretary at this time, including affirmative decisions to add classes. This was in response to a public comment suggesting that they add this; 3) They eliminated the Secretary's discretion to employ procedures and consider factors not specified in the rule.

- Dr. Andrade referred to §83.11 which indicates that after 30 days of review, NIOSH will notify the petitioners of its decision to evaluate the petition or its final decision that the petition has failed to meet the requirements. However, in 83.16 it appears that either the Secretary is the one who bears this burden on the notification and/or there is no final decision because a petitioner can actually submit, in writing, information that they believe that factual or procedural errors have occurred in the evaluation of their petition. Not clear to Dr. Andrade was how the petitioner was going to know whether factual or procedural errors occurred. He asked for a claimant-friendly explanation for that. He also noted that toward the bottom of §83.16 no date or time period is given during which the Secretary has to respond to the claimant or to the petitioner, as is done for NIOSH in §83.11. Mr. Katz responded that §83.11 and §83.16 are separate. In §83.11, if they decide the petition does not go forward, it is never evaluated, and never goes to the Secretary. The Secretary makes no decisions on the petition in this case. Dr. Ziemer noted that since these two sections led to some confusion, perhaps some of the wording needed to be revised. Dr. Andrade suggested adding a deadline to §83.16 (c)
- Dr. Melius noted that some of the sub-headings were somewhat confusing throughout the document.

Pg. 11310, §83.17

Mr. Katz indicated that in §83.17, they reduced from 20 to 5 days the time allowed for HHS to report to DOL the results of any Congressional action, or lack thereof, concerning the Secretary's decision. This was in response to a public comment.

- No further questions, comments, or changes were offered by the participants of this meeting regarding this section.

Pg. 11310, §83.18

Mr. Katz pointed out that changes made to this section included: 1) Pg. 11310, §83.18 (b) (3) and (b) (4): NIOSH added provisions to the section to specify that the Board would advise the Secretary in these cases and that members of the class would be provided an opportunity to contest such decisions.

- Dr. Melius requested clarification on whether this modification happens before it goes to Congress or simultaneous with it going to Congress. Mr. Katz responded that this was not a decision to add a class to the Cohort. This is for a class that has already been added to the Cohort, with the hypothetical situation here that might find a cache of records that allows NIOSH to reconstruct doses for a class of workers for whom, previously, doses could not have been reconstructed.

11302-11305, Preamble

- Referring to *A. Dose Reconstruction for Members of the Cohort*, Dr. Anderson said she was not clear what the line on 11303 meant which reads, "NIOSH will discuss with the Board this option to assign doses." Mr. Katz responded that this was the question Dr. Melius raised about what to do with people in the Cohort with cancers not compensable under EEOICPA provisions regarding compensation for members of the Cohort. He said that this was not an issue for the NPRM; it is an issue for dose reconstruction, which is why it is not addressed in the NPRM.

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**FORMAL MOTIONS**

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Dr. Ziemer reminded everyone that there had been concerns expressed regarding the 30-day comment period for the current version of the NPRM. He requested that Mr. Elliott check into the possibility of extending the comment period. While they wish to be expeditious in finalizing the NPRM, they also want to ensure accuracy.

**Motion 1**

Dr. Melius moved to make a formal recommendation to NIOSH to extend the 30-day comment period. Mr. Owens seconded the motion. Dr. Ziemer made a friendly amendment that they couch the recommendation in terms of recognizing comments from the general public that indicated that the extension would be helpful in getting the NPRM right.

**Discussion Points:**

- ❖ Dr. Andrade inquired as to whether the motion would need to be specific at this time, or if they could act on the motion and vote at a later date.
- ❖ Dr. Melius wanted to make the recommendation strong, and he did not perceive that waiting to learn the Secretary's pleasure regarding the issue would be beneficial. He thought the request had to be made soon, given that notification needed to be made to the public.
- ❖ Dr. DeHart did not think a week's delay would have an impact, and in view of Mr. Elliott's comments, there may be some political advantage perhaps with a delay, so he moved to table this motion to the next Friday.

**Motion 2**

Dr. DeHart moved to table the first motion until the next Friday, March 14, 2003. Dr. Andrade seconded this motion. Dr. Ziemer called for a vote to table Motion 1. The motion to table failed.

**Further Discussion Points on the original motion (Motion 1):**

- ❖ Mr. Espinosa suggested that it would help the Board to convene a stakeholders meeting of some sort to entertain public comment, rather than simply reviewing e-mails et cetera.
- ❖ Dr. Anderson commented that they had really not had an opportunity to hear public comments, and he thought it would be potentially helpful to hear more from the public.
- ❖ Ms. Munn said the public comment that she heard most frequently from every site was, "Will you please get on with what you're doing?" For that reason, she opposed any extensions of time that they did not feel absolutely necessary for whatever reason. Hence, she spoke against the motion to request additional public comment time.
- ❖ Dr. Gibson said that during this meeting, he heard almost 100% from the public that they want an extension because of the potentially significant changes in certain areas that need to be fleshed out.

**Motion 1: Amended**

Dr. Melius moved to make a formal recommendation to NIOSH to extend the 30-day comment period. Mr. Owens seconded the motion. Dr. Ziemer made a friendly amendment that they

couch the recommendation in terms of recognizing comments from the general public that indicated that the extension would be helpful in getting the NPRM right. Dr. Andrade made a friendly amendment to limit the additional time period to 15 days, for a total public comment period of 45 days. Dr. Ziemer called for a vote. The motion carried unanimously.

There was no further discussion regarding this issue.

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### CLOSING REMARKS

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Dr. Ziemer said he thought they had pretty well framed out the issues that they needed to discuss the next time the Board convened, and that perhaps they would be fairly near closure at the next meeting. It was suggested that participants review the previous NPRM and the docket that contains all of the comments, which can be found on the website.

The following upcoming meetings are scheduled:

- A telephone conference call is scheduled for March 14, 2003, 1:00 to 4:00 p.m. Eastern Standard Time.
- A telephone conference call is scheduled for April 4, 2003, 1:00 to 4:00 p.m. Eastern Standard Time.
- A face-to-face meeting is scheduled for May 19<sup>th</sup> and 20<sup>th</sup> in Oak Ridge, Tennessee.

#### Discussion Points:

- ❖ Ms. Munn inquired as to whether they anticipated addressing the Preamble during their next discussion. Dr. Ziemer responded that the Preamble is not really part of the NPRM. However, if there are errors or changes that should be made in that, he thought they should try to identify those.
- ❖ Mr. Presley asked whether they wanted to set a date for the Board to meet in Cincinnati for training. Dr. Ziemer pointed out that this would have to be after the Oak Ridge meeting in May, and that they may encounter some Privacy Act issues, so they will have to look into whether the meeting will be announced and open to the public.
- ❖ Mr. Elliott stressed that it was important for all Board members to experience what the Workgroup had at ORAU. His suggestion was to identify two Working Groups so that no quorum and no public forum would be required given that they will not be conducting business.
- ❖ Dr. Anderson suggested that the two groups come on separate days so that they were not too disruptive. Mr. Elliott indicated that he would have Cori Homer poll everyone for possible dates, and Dr. Ziemer identified the following Working Groups:

**Group 1:** Dr. Andrade, Chair; Dr. Melius, Ms. Munn, Mr. Owens

**Group 2:** Dr. Anderson, Chair; Dr. DeHart; Mr. Gibson

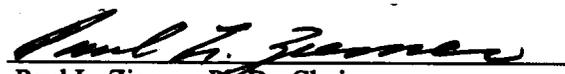
*With no further business posed, Dr. Ziemer officially adjourned the twelfth meeting of the ABRWH at 5:00 P.M.*

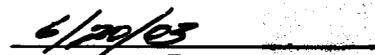
*End of Summary Minutes*



**CERTIFICATION**

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

  
Paul L. Ziemer, Ph.D., Chair

  
Date