

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 verbatim transcript of the Meeting of the
Advisory Board on Radiation and Worker Health held
via Teleconference on Thursday, May 1, 2003.

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

(By Group, in Alphabetical Order)

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(Continued)

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

(Continued)

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RENEE ROSS
DAVE SUNDIN

DEPARTMENT OF LABOR

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CONTRACTORS

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JANINE ANDERSON, K-25 Worker
CARMEN GONZALES, Survivor
EPIFANIA JACQUEZ, Survivor
RICHARD MILLER, Government Accountability Project
CHERYL MONTGOMERY, St. Louis, Missouri
BETTY JEAN SHINAS, Survivor
TIM TAKARO, University of Washington

P R O C E E D I N G S

3:04 p.m.

[Preceding the call to order, a roll call of the Board was taken. All Board members were present.]

DR. ZIEMER: Let the record show that all the Board members are present and accounted for, and we will proceed.

I assume you all have the agenda, which just has two items on it, the first of which will be a public comment period, and then the deliberations of the Board on the Special Exposure Cohort.

And again, let me ask that as individuals speak be sure to identify yourselves. I know that some of us, some Board members, are able to identify each other by the sound of their voices, but we do have the recorder, court reporter aboard who will be taking the transcripts and will need identities of all the speakers as we proceed.

So with that, let us turn first to the public comment period, and I will ask those members of the public who wish to speak identify themselves, and if appropriate their affiliation. We'd like to ask you, since we only have a brief 15-minute

1 period, I'd like to give priority to members of
2 the public who have not yet addressed the Board
3 in the past couple of conference calls. If
4 you've already addressed the Board on this issue
5 or pertaining to the Special Exposure Cohort,
6 your remarks are already on the public record and
7 the Board has heard those. And unless you have
8 additional or new information, we'd like to give
9 priority to any members of the public who haven't
10 had a chance yet to express their views or
11 comments either on the rulemaking or on anything
12 pertaining to the Special Exposure Cohort.

13 So with those comments, let me ask if there
14 are any members of the public on the conference
15 call who do wish to speak? Just please speak
16 right up and identify yourself.

17 **MS. JACQUEZ:** Epifania Jacquez, E-P-I-F-A-N-
18 I-A, J-A-C-Q-U-E-Z. I am a survivor.

19 **DR. ZIEMER:** Okay. Proceed.

20 **MS. JACQUEZ:** Thank you.

21 **DR. ZIEMER:** Proceed.

22 **MS. JACQUEZ:** Aren't you taking the names of
23 the people that want to comment? I'm just giving
24 you my name.

25 **DR. ZIEMER:** Oh, well -- yeah, we'll take the

1 names. That's fine. And then we'll come back to
2 you. We'll take them in the order that they give
3 us the information.

4 Who else will wish to speak?

5 **MS. SHINAS:** My name is Betty Jean Shinas, S-
6 H-I-N-A-S, and I have spoken in the past but I'd
7 like a few comments.

8 **DR. ZIEMER:** Okay.

9 **MR. MILLER:** Richard Miller, Government
10 Accountability Project.

11 **DR. ZIEMER:** Richard.

12 Any others?

13 **MS. GONZALES:** Carmen Gonzales. I have also
14 commented previously, but you don't have too many
15 today, I'm sure you have time to listen to mine.

16 **DR. ZIEMER:** We will if we don't have too
17 many.

18 Are there any others? That's four so far.

19 **MS. ANDERSON:** Janine Anderson. I'm a former
20 K-25 worker on disability.

21 **DR. ZIEMER:** And any others?

22 [No responses]

23 **DR. ZIEMER:** Now of these five, the first two
24 individuals, have you spoken to the Board before?

25 **UNIDENTIFIED:** I have.

1 UNIDENTIFIED: I have also.

2 UNIDENTIFIED: I have also.

3 DR. ZIEMER: Ms. Anderson, had you?

4 MS. ANDERSON: I have not.

5 DR. ZIEMER: If it's agreeable, then, let's
6 let Ms. Anderson go first, then we will go back
7 to the others.

8 MS. ANDERSON: If possible I'd like to wait
9 till the end.

10 DR. ZIEMER: Oh, you would?

11 MS. ANDERSON: I'm not prepared at this time.

12 DR. ZIEMER: Okay. Then let's hear from the
13 first individual, then.

14 MS. JACQUEZ: Okay. I guess that was me.
15 This is Epifania Jacquez.

16 And during our last conference call certain
17 subjects were raised, and one of them was the
18 special cohort. Our request was the Los Alamos
19 workers be included in this Special Exposure
20 Cohort. I'd like to know where the Board has
21 gone on this, if it has given any consideration
22 to this subject.

23 Also, I would like to -- I'm wondering if
24 there is going to be some process in motion to
25 speed up claims, because it's going very, very

1 slowly. And I was present in Los Alamos. They
2 celebrated 60 years of the National Lab. And
3 that was mentioned by our state governor, that he
4 wishes that all of you would get on your toes and
5 start perhaps expediting this whole thing.
6 Because the claims that have been received, the
7 claims that have been paid, are just -- it's
8 almost a joke. And so I think that this needs to
9 be addressed.

10 And I know this -- it's not a question-and-
11 answer session, but these things need to be
12 answered. And I know that your Board is right
13 there where they can address these issues.

14 And I guess the last one that I would like to
15 address is the fact that the 22 cancers that were
16 in the original Act need to be left in there,
17 because it is a law. And so I also want
18 (inaudible), the 22 cancers that (inaudible)
19 named in the law should be left in there because
20 that's what this whole thing is about.

21 So I'd like these issues addressed, or I'd
22 like some response from your Board.

23 **DR. ZIEMER:** Let me just indicate quickly --
24 and I don't want to take all of the public
25 comment time -- but on your first comment asking

1 what the Board has given consideration to since
2 the last telephone conference, and the answer is
3 the Board -- all the Board meetings are open to
4 the public, and the last conference call was the
5 last Board meeting. And so that meeting that you
6 were present at is the last consideration the
7 Board has had. This one today will follow up on
8 that. The Board does not meet privately between
9 these -- between its meetings, so this --

10 **MS. JACQUEZ:** Well, this is perfect, then,
11 because you can address it while I'm on. I'd
12 like these things addressed, please.

13 **DR. ZIEMER:** Yeah. So that is the answer to
14 that first question.

15 The speeding up of the claims is the
16 objective of having the contractor aboard, and
17 that has already occurred. I don't think we have
18 time today to go into all the data on the rates
19 at which those are being processed, but that is
20 occurring now.

21 **MS. JACQUEZ:** Could I have one last comment,
22 please, and I know that you have other people
23 waiting. But there was some legislation that was
24 passed, HR-1758 by Ted Strickland, democrat from
25 Ohio, that puts like 180-day table, timetable for

1 you to process these claims.

2 And again, if any of these things can be
3 addressed I would really appreciate it. And I'm
4 going to let somebody --

5 **DR. ZIEMER:** I don't believe that will be
6 addressed today. That is not on the agenda.

7 **MS. JACQUEZ:** Well, then I'd like to get some
8 kind of response for this. You might give it
9 some thought and let us know when we can hear
10 about this.

11 **DR. ZIEMER:** Thank you.

12 **MS. JACQUEZ:** Okay.

13 **DR. ZIEMER:** The second speaker? Who was
14 second?

15 **MS. GONZALES:** I'll just go ahead.

16 Good afternoon. My name is Carmen Gonzales.
17 I'm a surviving daughter of Manuel Almeida -- and
18 if you would please spell that correctly I'd
19 appreciate it, that's A-L-M-E-I-D-A -- who worked
20 in Los Alamos, my father did, for 34 years.

21 My purpose today is not to comment but to
22 request the Board to seriously consider and put
23 forth every effort to include Los Alamos in its
24 special cohort. I am also requesting the Board
25 to adhere to the list of 22 cancers that were

1 mandated by law in 2000.

2 And I'll be -- that's all I have to say
3 today, and thank you for your time.

4 **DR. ZIEMER:** Thank you.

5 Richard Miller?

6 **MR. MILLER:** Thank you, Dr. Ziemer. I have
7 three brief points to make.

8 The first was at the last Board call there
9 was a question raised about legislative intent.
10 And maybe the Board has already received this
11 information, but I will state it in any event,
12 that this question of whether it should be 22
13 cancers and whether the list is fixed or variable
14 was addressed in the Congressional record on
15 October 12th of 2000.

16 In a floor statement by Senator Bingaman, who
17 was one of the people in the conference who put
18 this legislation together --

19 **DR. ZIEMER:** And Richard, let me interrupt
20 that that has in fact been distributed to the
21 Board.

22 **MR. MILLER:** Oh, okay. Thank you, Dr.
23 Ziemer.

24 And so I think it makes pretty clear what
25 legislative intent was, so I hope that's not a

1 question for debate going forward. I would also
2 add that I think that message was conveyed to
3 NIOSH staff when they did briefings both on the
4 House and Senate side, it was a pretty clear
5 message delivered by those who were in the room
6 when the deal was done. Not that it carries as
7 much weight as something in writing on the
8 record, but it should be considered.

9 Secondly, I understand -- at least I heard
10 this morning -- that correspondence may have been
11 forwarded that I think I copied you on, Dr.
12 Ziemer, between myself and Ted Katz regarding
13 this question about whether or not it is possible
14 that people who have greater than a 50 percent
15 probability of causation and have a worst-case
16 dose estimate will necessarily be compensated.
17 And although the record clearly reflects Ted
18 Katz's comments at the March 7th meeting that
19 indeed people, if they did have a worst-case
20 estimate and their probability of causation was
21 above 50 percent and there was no other data
22 available to do anything other than a worst-case
23 estimate, that that would be used for
24 adjudicating claims.

25 And that provided some comfort until I looked

1 at both the rule and the preamble to the rule
2 under Part 82, where I think at least the Board
3 may want to consider the ambiguities in Part 82.
4 And there are two parts of Part 82 that are
5 relevant. The first part is that it clearly
6 states that worst-case dose estimates will be
7 used under 82.10, subpart (k), when the
8 probability of causation is less than 50 percent.
9 But the preamble states that it would only be
10 with great difficulty to use a worst-case dose
11 estimate in the event that the probability of
12 causation exceeded 50 percent. And this all
13 becomes very relevant, it seems, if SEC petitions
14 are now going to be denied based upon the ability
15 to perform a worst-case dose estimate.

16 And so maybe it is all okay, and maybe as we
17 have been assured verbally that is the case. But
18 the rule itself does not provide explicit clarity
19 in that area, and probably could stand some
20 improvement.

21 **DR. ZIEMER:** And let me comment, I had
22 received your comments and thought it would be
23 useful to let the full Board hear those comments
24 as well as Ted's reply, because I was the only
25 one that I knew of at that point that had the

1 benefit of those comments. So I did distribute
2 those a couple of days ago to the Board.

3 **MR. MILLER:** Good, good. I'm glad.

4 **DR. ZIEMER:** Or actually I sent -- I asked
5 NIOSH to, I -- no, I think I sent them out.

6 **MR. MILLER:** Whatever, it's fine. I have no
7 objection. But I do want to make sure that that
8 issue --

9 **DR. ZIEMER:** So basically the question you're
10 raising now, I think the Board has some written
11 stuff on it from you.

12 **MR. MILLER:** Okay. Fine.

13 The third issue has to do with a question
14 that came up at the March 7th Board meeting, and
15 I bring this up because it was now in the
16 transcript which finally was posted in which the
17 question is whether the dose, when you do a
18 worst-case dose estimate, is it going to be a
19 point estimate or a constant value which you
20 would input to IREP, or will it be -- will the
21 worst-case be some part of a distribution? And
22 if it's part of a distribution, what we've
23 discovered is that if you -- whether you use a
24 triangular mode distribution as in the Bethlehem
25 Steel case or use a normal distribution,

1 obviously if you put something at the tail end it
2 gets a lot less weight. And so I just wanted to
3 note that the Health Physics Society had
4 recommended that a constant value be used.

5 Hello?

6 **DR. ZIEMER:** Yeah, go ahead.

7 **MR. MILLER:** The constant value --

8 **DR. ZIEMER:** The line is so good this time
9 that you're not sure it's still there, right?

10 **MR. MILLER:** Exactly right. I'm amazed. But
11 let's leave the static out, though.

12 So I would just raise for the Board the
13 question of whether or not to recommend the point
14 estimate or constant value which the Health
15 Physics Society recommended, or whether it would
16 be better to provide a distribution; and if so,
17 why would a distribution which provides less
18 weight to a worst-case estimate be applied if
19 you're trying to give the claimant the benefit of
20 the doubt?

21 And finally, I guess the only other question
22 I would have is that the Board probably has not
23 discussed, and maybe doesn't have time today, is
24 what do you do in cases where you have a non-SEC
25 cancer, but you have someone who is in an SEC?

1 What do you do with the dose that you can't
2 estimate that they received as a member of the
3 SEC when you're trying to estimate their dose
4 reconstruction for a non-SEC cancer? And so you
5 may have some dose within and some dose without
6 the SEC. And it wasn't clear how to assign dose,
7 and NIOSH's rule didn't really recommend any
8 methods for assigning dose. And so I just
9 thought I would put that on the table as an
10 unresolved issued from the rulemaking.

11 **DR. ZIEMER:** Okay, thank you, Richard.

12 Let's see --

13 **MS. NEWSOM:** There was Betty Jean Shinas.

14 **DR. ZIEMER:** Betty Jean, yes, please. Go
15 ahead.

16 **MS. SHINAS:** The only comment I had, and I
17 may have misunderstood or misread something, that
18 the Advisory Board, that the term would be coming
19 to a close. Is that correct? And if so, what is
20 -- what's in motion to get that going again?

21 **MR. ELLIOTT:** Let me respond to that.

22 **DR. ZIEMER:** Yes, let the --

23 **MR. ELLIOTT:** This is Larry Elliott.

24 **DR. ZIEMER:** Larry Elliott, the Federal
25 officer --

1 **MS. SHINAS:** And I'd like to just close, just
2 a few more words on that, as I feel that I am
3 thankful that we are being heard, but I think
4 this is about the only place that we've been able
5 to really comment. And I know the comments are
6 short, but at least it has been given us an
7 opportunity to do this as a family.

8 **DR. ZIEMER:** Right. Thank you.
9 Larry Elliott.

10 **MR. ELLIOTT:** Sure.

11 To respond to your question about the Board,
12 the charter does expire this August. And we are
13 in fact proceeding to renew that charter, and
14 will have it in place before the expiration date
15 so that the Board can continue its business as
16 required by statute and the delegated authority
17 through the Department.

18 Let me also say that -- so I hope that
19 answers your question. The Board is not going to
20 go away. Its charter expires, but we have full
21 interest and attempt underway to renew that
22 charter.

23 With regard to providing comments, we
24 continually continue to encourage everyone to
25 provide written comments to the docket. This

1 forum of public comment during the Board meeting
2 is only one approach for the public to have their
3 voices heard. The real opportunity for the
4 public to comment on the proposed rule, however,
5 is by providing written comments as proscribed by
6 the rule.

7 Thank you.

8 **MS. SHINAS:** Thank you.

9 **DR. ZIEMER:** Thank you.

10 And then we have -- did that complete your
11 comment, Betty Jean?

12 **MS. SHINAS:** Yes, it did. I had just read
13 that, and it was a concern with me.

14 **DR. ZIEMER:** Thank you.

15 And then I think we have Ms. Anderson yet.

16 **MS. ANDERSON:** Yes, my questions have already
17 been answered, thank you.

18 **DR. ZIEMER:** They have? Okay, thank you very
19 much.

20 Actually, it is now time for us to move to
21 the Board deliberations. Members of the public
22 are still welcome to listen in on this. We are
23 not asking you to participate in the
24 deliberations since these are deliberations of
25 the Board, but you're certainly -- the

1 discussions are public, and you are welcome to
2 continue to listen in.

3 **MS. HOMER:** Dr. Ziemer?

4 **DR. ZIEMER:** Yes.

5 **MS. HOMER:** This is Cori.

6 **DR. ZIEMER:** Yes, Cori.

7 **MS. HOMER:** I would like to --

8 **DR. ZIEMER:** Do we need to get a roll call of
9 others?

10 **MS. HOMER:** If we could get a roll call of
11 the federal employees for the record.

12 **DR. ZIEMER:** Okay, either a roll call or ask
13 them to identify themselves.

14 **MS. HOMER:** Yes, please identify yourself for
15 the court reporter.

16 **MR. NAIMON:** This is David Naimon, and Liz
17 Homoki-Titus.

18 **MS. HOMER:** Thank you.

19 **MR. KOTSCH:** Jeff Kotsch with the Department
20 of Labor.

21 **DR. ZIEMER:** I'll ask the reporter, if you
22 need to hear names spelled just so indicate.

23 **MS. NEWSOM:** All right, thank you.

24 **MR. NETON:** This is Jim Neton from NIOSH.

25 **MR. SUNDIN:** Dave Sundin, NIOSH.

1 **MS. HOMER:** And I guess Cori Homer, NIOSH.

2 **MR. KATZ:** I'm sorry, Ted Katz, NIOSH.

3 **MS. ROSS:** Renee Ross, Committee Management,
4 MASO.

5 **MS. GAY:** Annette Gay, Birth Defects, CDC.

6 **DR. ZIEMER:** Any others?

7 [No responses]

8 **DR. ZIEMER:** Okay, thank you very much.

9 **MR. TAKARO:** (Inaudible) other people on the
10 line. This is Tim Takaro at the University of
11 Washington (inaudible).

12 **DR. ZIEMER:** Okay. Any others that want to
13 identify themselves?

14 [No responses]

15 **DR. ZIEMER:** Okay, then we will proceed.

16 The focus of our attention today -- I want to
17 make a few preliminary remarks, and then we'll
18 get very specific. Our preliminary focus today
19 will be to finalize the comments and views of the
20 Board pertaining to Section 83.13.

21 Now in that connection there are two
22 particular sections that I see us as focusing on,
23 all of which are part or two particular portions
24 of the SEC that are subsets of Section 83.13.
25 Now I'm working fully out of the *Federal Register*

1 copy today, if that's agreeable with everyone.
2 So Board members, you want to have your *Federal*
3 *Register* copy handy there so that if we give page
4 numbers that will be helpful to you.

5 Now I'm getting some echo. Something change
6 here? Okay, is that better?

7 **UNIDENTIFIED:** Yes.

8 **DR. ZIEMER:** Okay. In Section 83.13 there's
9 two particular subsections that I expect we will
10 focus on.

11 One of those is subsection (b)(1), which is
12 in the third column of page 11308, and this is
13 the issue relating to estimating doses with
14 sufficient accuracy. That was an issue that we
15 discussed at our last meeting, and remains an
16 issue which we have not yet come to closure on.

17 Then on page 11309 in column one, section --
18 this would be paragraph (b)(1)(iv), Roman numeral
19 (iv) near the top of the page, which -- and then
20 that one, coupled with item (b)(2), Roman numeral
21 (iii) near the middle of the page, both of these
22 deal with the issue of specified cancer types and
23 the definition of an SEC class that involves
24 tissue-specific cancer sites. So that's
25 basically this issue of less than the 22 cancers,

1 or to put it another way, one or more cancer
2 sites as being part of the class definition.

3 It seems to me those are the two main issues
4 we need to focus on today. In that connection,
5 you should have a couple of written items.

6 First, I want to make sure everyone on the
7 Board received what would be labeled the draft
8 comments on 42 CFR 83. I believe these are --
9 this is a compilation of everything that we had
10 done to date, as well as some new items. It is
11 stamped in the upper right as "draft" with a date
12 of 4/24/03 on it. It should have been
13 distributed, I believe, within the last couple of
14 days by either Cori or by Nichole, and it has 13
15 numbered items on it.

16 Does everyone have that draft, or if you
17 don't speak up.

18 **MS. MUNN:** This is Wanda. Did that come by
19 mail?

20 **DR. ZIEMER:** Should have been by e-mail.

21 **UNIDENTIFIED:** Came by e-mail. Mine came in
22 at 1:28 p.m. today.

23 **MS. MUNN:** Oh. I haven't been online today.
24 I'd better check it.

25 **MS. NEWSOM:** Cori?

1 **MS. HOMER:** Yes?

2 **MS. NEWSOM:** This is Kim. Would you mind e-
3 mailing that to me, please?

4 **MS. HOMER:** Absolutely.

5 **MS. NEWSOM:** Thanks.

6 **DR. ZIEMER:** Now while that's occurring, let
7 me point out to you that on that document the
8 first ten items are items that we have already, I
9 would say, come to closure on and agreed to.
10 It's items 11, 12, and 13 which pertain to the
11 topics that I just mentioned here -- that is, the
12 issue of specified cancer types and the issue of
13 sufficient accuracy.

14 Now the other document that you should have
15 was distributed a couple of days ago. These are
16 some comments that were developed by Jim Melius.
17 This was, I believe, a little over three pages
18 long. It has a title on it called "SEC
19 Comments," and it specifically deals with this
20 Section 83.13. It includes actually two
21 recommendations. There's a lot of narrative, but
22 there are actually two recommended actions, in a
23 sense, both of which are underlined as action
24 paragraphs. One of those is on the third page of
25 Jim's document, and that's the issue of

1 sufficient accuracy; and then on the fourth page
2 of Jim's document is a recommendation relating to
3 the limit on the provisions for limiting cancers
4 eligible for compensation in the Special Exposure
5 Cohort. So that is a document, as well, that I
6 think we need to have before us as we proceed.

7 And let me tell you that there's some
8 differences in these two. The document that I
9 distributed with the original set of comments was
10 -- the three points, 11 through 13, were sort of
11 summaries of where I thought we had sort of
12 agreed at the last meeting in terms of at least
13 identifying some issues, although we had not
14 fully come to closure on it.

15 Jim's documents relates to those, or Jim's
16 comments and recommendations relate to those.
17 They have a somewhat different specificity in the
18 case of the specified cancers. Jim's
19 recommendation is one of simply removing the
20 provision to limit. The words that I had used in
21 mine had to do with requiring that NIOSH
22 reconfirm or establish Congressional intent with
23 regard to that issue. So there's kind of
24 variations on the same thing, and we can discuss
25 a direction that the Board may or may not wish to

1 go on that issue.

2 Similarly, on sufficient accuracy, Jim's has
3 a little more specificity in that the comment I
4 had, which is comment 13, was to ask for
5 clarification. Jim's has a little more
6 specificity in asking that some actual guidelines
7 be developed as NIOSH proceeds. So those are
8 sort of -- I just used that to kind of lay out
9 what's before us.

10 I want to make sure everybody has the
11 documents. Is there anyone that didn't get the
12 Jim Melius discussion?

13 [No responses]

14 **DR. ZIEMER:** Apparently everybody got that.
15 Okay.

16 Now let me also, as we get underway here, ask
17 the Board members -- and you can just comment on
18 this briefly if you wish -- do you agree that
19 those are the items we would like to come to
20 closure on today, and are there any other items
21 that you think have been left hanging that are
22 not -- that we didn't already cover?

23 [No responses]

24 **DR. ZIEMER:** Pro or con. I want to make sure
25 that we feel like we've captured all of the

1 salient points in the proposed rulemaking that we
2 want to comment on, and what I'm saying is I
3 think these are the last two. Am I right, there?
4 Anyone think there are other issues we need to
5 comment on?

6 [No responses]

7 **DR. ZIEMER:** Yeah or nay?

8 **MS. MUNN:** Sounds good to me. This is Wanda.
9 I think these are the two we need to be
10 addressing.

11 **DR. ZIEMER:** Okay. Then I suggest that we
12 begin with the issue of sufficient accuracy since
13 that's the first paragraph to deal with under
14 83.13. It's the right-hand column of page 308.

15 **DR. ANDRADE:** Paul?

16 **DR. ZIEMER:** Yes.

17 **DR. ANDRADE:** This is Tony Andrade.

18 **DR. ZIEMER:** Tony.

19 **DR. ANDRADE:** I'd like to suggest that we
20 start with 83.13, Section (b)(1), little Roman
21 (iv), regarding the --

22 **DR. ZIEMER:** Oh, on the cancer types?

23 **DR. ANDRADE:** -- the cancer tissues, cancer
24 types and tissues.

25 **DR. ZIEMER:** I'm fine with doing that. Is

1 there a particular reason you want to go in that
2 order?

3 **DR. ANDRADE:** Well, I think that we have now
4 had three conference calls, and basically we end
5 up at a stumbling block with respect to this
6 particular issue.

7 And after doing much soul-searching about
8 kind of limitation, I've come to the conclusion
9 that reaching sufficient -- I hate to use the
10 word "sufficient" because it starts to tie us up
11 with the other topic, but let's put it this way:
12 You used the word "equity," some level of equity
13 between the definition of a new SEC class that is
14 limited in this -- in the way it's described in
15 that paragraph with the SEC that's already
16 defined in legislation.

17 Well, frankly, I don't think we're ever going
18 to get there, because the way Congress described
19 or defined SEC, the SEC which included three
20 gaseous diffusion plants and some veterans that
21 were associated with weapons testing, they did us
22 all an injustice by a bunch of lawyers getting
23 together and deciding that an entire facility
24 should be designated as Special Exposure Cohort.

25 I'd really like to know, for example, what

1 percentage of those entire facilities' work force
2 that were there for the requisite amount of time
3 are going to ever really present with cancer.
4 Ten to one, it's going to be 30 percent or less,
5 the specified cancers. So they put us off to a
6 bad start. So that forces us into a very
7 difficult situation insofar as determining
8 equity.

9 I would say, and I'd like to put this forward
10 for the rest of the Board to comment, the
11 following:

12 I believe that the only way that we're going
13 to ever satisfy ourselves, the public, and
14 Congressional intent, which I believe to be
15 simply stated in three words -- be fair, and be
16 claimant friendly -- is to simply include all 22
17 cancers that were listed in the original
18 legislation, and do away with any type of
19 limitation as a way to define or to specify a
20 group. In other words, get rid of any relation,
21 any -- get rid of small paragraph small Roman
22 (iv), and anything in the preamble that alludes
23 to limiting the number of cancers to anything
24 less than the 22.

25 **DR. ZIEMER:** Okay. Tony, are you asking for

1 comment on this at this point, or am I to
2 understand this to be a formal motion on your
3 part?

4 **DR. ANDRADE:** I'm asking for comment at this
5 particular point in time.

6 **DR. ZIEMER:** Okay, thank you.

7 Let me ask how other Board members wish to
8 respond to that comment and view.

9 **DR. MELIUS:** This is Jim Melius.

10 That was basically what I was proposing, with
11 the -- I guess with the added change that should
12 it work out that in the future we feel that this
13 is inappropriate in some way in our actual
14 experience in designating cohorts that we can
15 always make later recommendations, whether it be
16 to Congress or to NIOSH, to work out ways of
17 addressing this.

18 I mean, I think there are reasons other than
19 the reasons Tony just gave, but then we all may
20 have obviously different reasons or weigh
21 different reasons differently. But I think that
22 it really is the best way to go forward at this
23 time given the equity issue, given the amount of
24 public concern, and given just some of the
25 potential difficulties of trying to make these

1 decisions.

2 **DR. ZIEMER:** Thank you, Jim.

3 This is Ziemer again.

4 Jim, if I might also comment on the way you
5 had worded it, I think your last sentence there
6 dealing with the or suggesting that we might
7 later on change this in some way, seems to me
8 that once we go in this direction I don't think
9 there's much chance of turning back. It would be
10 like changing the criteria for probability of
11 causation, very difficult to go back the other
12 way, don't you believe? Or are you suggesting
13 that if experience showed that it would be
14 possible that you would restrict the cancers
15 again, having not done so initially?

16 **DR. MELIUS:** Presuming this meets
17 Congressional intent and sort of these legal
18 issues that are out there, assuming it addresses
19 that, I think we'd have to examine the experience
20 down the road and then make the determination.
21 Are we encountering situations where it is not
22 (inaudible; ongoing beeping) the Board doesn't
23 feel it's appropriate to be including all the
24 cancers in the cohort, then we would have a way
25 of redressing that (inaudible). Would it be

1 hard? Yes. But it's obviously hard to do it the
2 other -- do it the way that's being proposed now.

3

4 So I guess I was just trying to indicate
5 there that I don't think we should necessarily
6 close off that possibility, but I just -- my
7 personal view is that it -- I think it's unlikely
8 we would go back, but we could.

9 **DR. ANDRADE:** This is Tony Andrade again.

10 Jim, again, one of the reasons that I am
11 proposing this for discussion at this point is
12 that if you read the Congressional record and you
13 try to pull out the intent, you really do come to
14 that conclusion that they want us to be fair, but
15 they also want us to be claimant friendly. And
16 so I really think that (inaudible) way of being
17 able to accomplish that in some equitable sense
18 is to define for life, from here on out, that all
19 22 cancers shall be considered.

20 **DR. ZIEMER:** Other comments? I got cut off
21 there briefly. I'm back on the line again. Jim
22 was talking when I lost it, but I'm back on.

23 Jim, did you say anything important?

24 [Laughter]

25 **DR. MELIUS:** I doubt it.

1 **DR. ZIEMER:** I guess, Tony, you were
2 responding to something Jim had said?

3 **DR. ANDRADE:** Right, right.

4 **DR. ZIEMER:** Did we lose any other Board
5 members, or was it only --

6 **DR. DeHART:** Yes, I think so. Everybody's
7 coming in now.

8 **DR. ZIEMER:** Coming back in?

9 **DR. DeHART:** This is Roy.

10 **DR. ZIEMER:** Let me interpret --

11 **MR. ELLIOTT:** This is Larry Elliott.

12 **DR. ZIEMER:** Cori, I wonder if we need to
13 take a roll call again?

14 **MS. HOMER:** Another roll? Okay, very well.

15 **DR. ZIEMER:** Let's take a roll call --

16 **MR. ELLIOTT:** Cori, while you're doing that
17 I'm going to ask --

18 **DR. ZIEMER:** -- (inaudible) losing people
19 here.

20 **MR. ELLIOTT:** Cori, while you're doing the
21 roll I'll have Nichole call the phone people and
22 make sure that we didn't lose a series of ports.

23 **MS. HOMER:** Okay, very well. Thanks.

24 Okay, Paul Ziemer?

25 **DR. ZIEMER:** Yes.

1 MS. HOMER: Henry Anderson?
2 DR. ANDERSON: Yes.
3 MS. HOMER: Tony?
4 DR. ANDRADE: Here.
5 MS. HOMER: Roy?
6 DR. DeHART: Yes.
7 MS. HOMER: Rich?
8 MR. ESPINOSA: Here.
9 MS. HOMER: We know Larry's here.
10 Mike Gibson?
11 MR. GIBSON: Yeah, I'm here.
12 MS. HOMER: Mark?
13 MR. GRIFFON: Yeah.
14 MS. HOMER: Jim Melius.
15 DR. MELIUS: I'm here.
16 MS. HOMER: Okay. Wanda Munn?
17 MS. MUNN: Here.
18 MS. HOMER: Leon?
19 MR. OWENS: Here.
20 MS. HOMER: Bob?
21 MR. PRESLEY: Here.
22 MS. HOMER: Gen?
23 DR. ROESSLER: Here.
24 MS. HOMER: Okay.
25 DR. ZIEMER: Okay, good.

1 **MS. HOMER:** Should I go through the list of
2 public?

3 **DR. ZIEMER:** Well, that would be fine.

4 **MS. HOMER:** Okay. Cheryl Montgomery?

5 **MS. MONTGOMERY:** Here.

6 **DR. ZIEMER:** But they're not required to stay
7 on.

8 **MS. HOMER:** Oh, okay. Well, I guess we can
9 go ahead and proceed with discussion.

10 **DR. ZIEMER:** Right. We're required to have a
11 quorum of Board members.

12 **MS. HOMER:** Yeah, exactly.

13 **DR. ZIEMER:** But public members can stay on
14 or not as they wish.

15 Okay, further discussion on this item?

16 **DR. ANDRADE:** Paul, very briefly, what I
17 mentioned, I guess when people started getting
18 cut off, was the fact that in responding to Jim
19 about perhaps leaving the door open on this, I
20 said if we really want to meet Congressional
21 intent -- and again, I take that to be, quote,
22 "fair and claimant friendly" -- then I think that
23 once and for all we should allow all 22 cancers
24 to be considered in any Special Exposure Cohort
25 petition.

1 **DR. ZIEMER:** Okay. Other comments?

2 **DR. DeHART:** This is Roy.

3 I really never understood why we were
4 limiting the cancer. I couldn't understand it as
5 we went through the proposal to begin with.

6 And secondly, I have to agree with Tony, that
7 the intent is so strongly stated in the original
8 legislation that I think that we might very well
9 find that we're directed to go back to the 22
10 cancers.

11 So I think from the beginning we ought to
12 hold to it, and hold to it for the duration.

13 **DR. ZIEMER:** And Roy -- Ziemer here again --
14 I was trying to point out in the comment that I
15 inserted in there on comment 11 that in fact,
16 scientifically and theoretically I believe it's
17 entirely possible that you could have an unknown
18 exposure situation where you could, in fact, say
19 that certain tissues could not have gotten
20 exposed. You might not know anything about
21 doses, but you might know enough to be able to
22 eliminate those.

23 But the real issue comes down to
24 Congressional intent and the equity issue, it
25 seems to me.

1 **DR. DeHART:** Yes.

2 **MR. GRIFFON:** But Paul -- this is Mark
3 Griffon -- just one response, short response on
4 your comment.

5 You mentioned you may have reasons for
6 limiting it to certain tissues for certain
7 unknown exposures. I think the key there is that
8 you are dealing with unknown exposures, so it
9 seems a little contradictory to say that you can
10 --

11 **DR. ZIEMER:** Well, you notice I put it in
12 terms of theoretically. I think I could
13 (inaudible) a case where you could not figure out
14 dose, but you could -- but based on some
15 information -- I mean, we know about certain
16 things about different facilities. Even though
17 we may not know the dose, we know of some things.

18
19 But be that as it may, it's one thing to talk
20 theoretically and say yes, but scientifically it
21 could be possible. But there's kind of two sides
22 to this. One is what's possible scientifically,
23 and this other issue, which seems to be to some
24 extent overriding, is Congressional intent and
25 fairness.

1 Who else has comments?

2 [No responses]

3 **DR. ZIEMER:** And I guess I'll add to that.
4 In fact, it's not clear in practice that they
5 would ever find such a situation, even though it
6 would be allowed for in the regulation.

7 **MR. GRIFFON:** I guess that's sort of where I
8 was going.

9 This is Mark Griffon again, I'm sorry.

10 I didn't want to accept that we're dismissing
11 science here. I think that even in the preamble
12 to this proposed rulemaking, page 11297 under the
13 Health Endangerment section, NIOSH says talks
14 about (inaudible) a factual basis for
15 establishing the possible level of radiation
16 exposure (inaudible) quantitatively evaluate
17 health endangerment. I think they're separating
18 health endangerment there from -- as opposed to
19 an organ, but I think they're very closely
20 related.

21 So my point is that if you can't establish an
22 upper bound you can't really specify which
23 tissues. You don't know enough about exposure to
24 specify which cancers, the tissues might be
25 affected.

1 **DR. ZIEMER:** Okay. How about other comments,
2 anyone?

3 **DR. ROESSLER:** This is Gen.

4 I just want to go on the record as saying
5 that I think this proposal goes against common
6 sense from the scientific point of view, but yet
7 Tony was very persuasive in what he said. It
8 seems that we really have the goal or the
9 responsibility of meeting the Congressional
10 intent, and from that point of view we
11 possibility have no other choice.

12 **DR. ZIEMER:** Other comments?

13 **MR. GIBSON:** This is Mike Gibson.

14 I'd just like to say that given the site that
15 -- given the fact that some of these sites were
16 not even told that they were working with
17 radioactive material, given the fact of DOE's
18 poor recordkeeping and et cetera, I don't think
19 we can ever actually determine if a person was
20 correctly monitored for the correct isotope. So
21 they may be put in a special cohort because of
22 being exposed to a certain isotope, but in fact
23 there could be other isotopes in the mix that
24 were never, never -- employees were never
25 monitored for that could catch one of the other

1 types of cancer.

2 DR. ZIEMER: Thank you. So you're arguing in
3 favor of including all the cancers, then?

4 MR. GIBSON: Absolutely, yes.

5 DR. ZIEMER: Other comments? Pro or con.

6 MR. PRESLEY: Paul, this is Bob Presley.

7 DR. ZIEMER: Bob.

8 MR. PRESLEY: I agree with Tony 100
9 (inaudible).

10 DR. ZIEMER: Okay.

11 Any others?

12 DR. ANDRADE: In that case, Paul, I think I'd
13 like to perhaps put forth a position to be voted
14 on in the form of a motion, and that is simply
15 that Section 83.13, subsection (b), subsection
16 (1), small Roman (iv), be removed, or that we
17 advise the Secretary that it is the sense of the
18 Board that this section be removed; and that all
19 other text, whether it be in the preamble or in
20 the rule itself, that relates to limiting cancer
21 types also be removed.

22 DR. ZIEMER: Okay. The motion has been made.
23 Is there a second?

24 MR. GIBSON: I'll second that. This is Mike
25 Gibson.

1 **DR. ZIEMER:** Mike Gibson has seconded the
2 motion.

3 Is there any discussion, pro or con?

4 [No responses]

5 **DR. ZIEMER:** Is there anyone who wishes to
6 speak against the motion?

7 [No responses]

8 **DR. ZIEMER:** I hear none. Let me, before we
9 vote -- based on comments so far it appears that
10 there may be strong support for the motion.

11 Let me suggest that if the motion carries --
12 and I want you to look at item 11 on the draft
13 comments that refers to this section -- and let
14 me ask you if you were to take everything down to
15 the second to last line where it says
16 "accordingly," and if you were to cross out all
17 the words following "accordingly" and insert the
18 Jim Melius statement that says, so it would say
19 "Accordingly, the Advisory Board recommends that
20 DHHS remove the provision to limit cancer
21 eligible for compensation for a particular class
22 being conducted for Special Exposure Cohort
23 status," and insert that in place of the
24 statement that asks NIOSH to determine this, and
25 then that would be followed by an identification

1 of the particular section to be removed or
2 altered.

3 **DR. ROESSLER:** Paul, this is Gen.

4 Then in Melius's suggested substitution there
5 we would not put in the part that says that later
6 experience with the program shows and continuing
7 on, that would not be a part of it?

8 **DR. ZIEMER:** What I'm going to suggest is
9 that we act on this without that at the moment,
10 and then if someone wishes to modify it by adding
11 that, so that we can deal with this main issue
12 and then ask whether you want to allow the later
13 possibility -- the possibility of a later change.
14 Would that be agreeable? I don't want to get two
15 issues mixed up on a fairly critical vote here.

16 **DR. ANDRADE:** That, I think, splitting that
17 off would certainly meet the intent of -- the
18 full intent of the --

19 **DR. ZIEMER:** Of your motion?

20 **DR. ANDRADE:** Of my motion.

21 **DR. ZIEMER:** What I'm suggesting, your motion
22 would still hold. I'm suggesting how it might be
23 worded in the transmittal.

24 **DR. ANDRADE:** That's fine, Paul.

25 **DR. ZIEMER:** Unless anyone sees any major

1 change -- and what I've done in suggesting this
2 is allow the little narrative statement that says
3 that we recognize the scientific and theoretical
4 possibility that this could occur. And if you
5 don't like that statement, I need to know that.

6 **DR. ANDRADE:** I think that that's fine.

7 **DR. ROESSLER:** I like leaving it in.

8 **DR. ZIEMER:** Although that in itself is not
9 part of your motion, but I was trying to look at
10 how we would actually present it. And we could
11 present it just as exactly the way you stated it
12 without this other stuff, if people were
13 uncomfortable.

14 **UNIDENTIFIED:** I think it helps other people
15 understand the discussions we've gone through.

16 **DR. ZIEMER:** Okay. Are you ready to vote on
17 this motion?

18 [No responses]

19 **DR. ZIEMER:** Okay, I'm going to take a roll
20 call vote.

21 Cori, if you will begin the roll call, and I
22 will vote last.

23 **MS. HOMER:** All right.

24 Henry Anderson?

25 **DR. ANDERSON:** Yes.

1 MS. HOMER: Antonio Andrade?
2 DR. ANDRADE: Yes.
3 MS. HOMER: Roy DeHart?
4 DR. DeHART: Yes.
5 MS. HOMER: Richard Espinosa?
6 MR. ESPINOSA: Yes.
7 MS. HOMER: Mike Gibson?
8 MR. GIBSON: Yes.
9 MS. HOMER: Mark Griffon?
10 MR. GRIFFON: Yes.
11 MS. HOMER: James Melius?
12 DR. MELIUS: Yes.
13 MS. HOMER: Wanda Munn?
14 MS. MUNN: I abstain.
15 MS. HOMER: Okay. Leon Owens?
16 MR. OWENS: Yes.
17 MS. HOMER: Bob Presley?
18 MR. PRESLEY: Yes.
19 MS. HOMER: And Genevieve Roessler?
20 DR. ROESSLER: Yes.
21 MS. HOMER: Okay.
22 DR. ZIEMER: Okay, the motion carries.
23 MS. HOMER: Okay. Ziemer, would that be a
24 yes?
25 DR. ZIEMER: Pardon me?

1 **MS. HOMER:** Would that be a yes from you?

2 **DR. ZIEMER:** Oh, yeah. I will vote to
3 support the motion.

4 **MS. HOMER:** Okay.

5 **DR. ZIEMER:** Now the Chair will also now
6 entertain, if anyone wishes to make a motion to
7 add to this, Section -- the statement suggested
8 by Dr. Melius, "If later experience with the
9 program shows that including all eligible cancer
10 types is problematic for a significant number of
11 Special Exposure Cohort classes, then the Board
12 is prepared to recommend steps to address this
13 issue."

14 **DR. MELIUS:** This is Jim Melius.

15 I actually personally don't feel that that
16 sentence is then necessary since we've already
17 talked about this, that it's theoretically
18 possible and so forth. I think that really
19 covers the same concept, and I think it's implied
20 that we can change our minds later. Whoever
21 wants to, a new board or whatever, can change
22 their minds and make other recommendations. So I
23 --

24 **DR. ZIEMER:** So you're not suggesting we --

25 **DR. MELIUS:** I don't believe it's necessary.

1 **DR. ZIEMER:** Anyone else? Anyone want to add
2 that?

3 [No responses]

4 **DR. ZIEMER:** It appears not.

5 Am I correct, now, that the main sections in
6 addition to the preamble this will deal with are
7 those that I had previously identified, which
8 would be (b)(1) Roman numeral (iv), and (b)(2)
9 Roman numeral (iii), both of which are -- there
10 may be some others, but --

11 **UNIDENTIFIED:** Yes, those are the two main
12 ones, Paul.

13 **DR. ZIEMER:** There are some other places
14 where specified cancer comes up also, so -- but a
15 general statement, if it's agreeable in terms of
16 just editing, I can add that into the comment.

17 **DR. ANDRADE:** This is Tony, Paul.

18 Yeah, I believe that would be good, because
19 there is substantial text in the preamble that
20 needs to be removed as well.

21 **DR. ZIEMER:** Okay. Well, of course, then the
22 -- I think in -- the final rulemaking actually is
23 going to have discussion on issues that are made,
24 and depending on the outcome of the final
25 rulemaking there would possibly still be a

1 discussion of this issue and how NIOSH ultimately
2 handled it. So I don't anticipate we would ask
3 NIOSH not to discuss this issue in the preamble,
4 and they will ultimately deal with how -- they
5 will ultimately discuss with -- how they finally
6 handle it. Right?

7 **UNIDENTIFIED:** That is correct.

8 **DR. ZIEMER:** Yeah. So I don't think we need
9 to get into asking them to revise the preamble.
10 It's going to be different anyway in the final
11 copy, because they have to deal with all the
12 comments that have -- this preamble dealt with a
13 lot of comments from the earlier document, so
14 those will all change anyway.

15 Okay, then I think we're ready to deal with
16 the issue of sufficient accuracy.

17 I'm looking at -- and actually, again we have
18 two possible things, two possible wordings, one
19 of which is simply more or less a simple
20 statement asking NIOSH to clarify the meaning of
21 that. This is -- on the draft I distributed it's
22 item 13. But those sections include the concept
23 of not feasible to estimate doses with sufficient
24 accuracy, the idea of sufficient accuracy not
25 completely clear or obvious. It would be helpful

1 for NIOSH to provide additional clarification,
2 whereas the Melius proposal is a little more --
3 has a little more specificity and asks for
4 guidelines, that guidelines be developed. And as
5 I see it, the guidelines could be developed later
6 on.

7 I don't, Jim -- and you can clarify -- I
8 don't think that you were asking that the
9 guidelines be in the rule.

10 **DR. MELIUS:** No, no. That the rule could
11 reference or the preamble to the rule, however,
12 could reference the development of guidelines,
13 and that the guidelines would be reviewed by the
14 Board. This is not dissimilar to how we've
15 handled the IREP changes in the dose
16 reconstruction rules changes. The same, really
17 the same --

18 **DR. ZIEMER:** Yeah. But so there's actually
19 -- in a sense there's two kinds of options, and I
20 think there's probably a third. But one option
21 is just to point out the issue and ask NIOSH to
22 address it; the second option is to pin it down a
23 little closer and ask for the development of
24 specific guidelines; another option would be that
25 if people weren't concerned about this we don't

1 address it at all; and a fourth option would be
2 to do something other than those three things.

3 And again, let me open it in general for
4 Board discussion, and we can get some feeling for
5 what direction you wish to go on this.

6 **DR. MELIUS:** Let me just -- Jim Melius.

7 Let me just speak to -- the reason I like to
8 follow the pattern we did with the prior rules in
9 terms of developing guidelines is I just think
10 they provide more consistency to the process.
11 And I think as opposed to purely a case-by-case
12 approach, which is what NIOSH has talked about,
13 all the guidelines does is make you sort of
14 categorize your cases a little bit better, and
15 think about making sure that you're consistent in
16 the application of -- as you review different
17 claimants that you're treating them fairly and
18 equitably in that process, and guidelines just
19 assist that.

20 And then as you develop experience with
21 particular situations, they allow you to catalog
22 that experience and organize them in a way that
23 helps you to, I think, handle the claims, I
24 think, both more efficiently but also more
25 fairly.

1 And I think since it's called for in the
2 original legislation, I think it's helpful that
3 there be some record of what -- of how sufficient
4 accuracy is being considered, and some record of
5 how the feasibility of doing a dose
6 reconstruction or not being able to do a dose
7 reconstruction is considered. I sort of suspect
8 that NIOSH would end up doing this gradually
9 anyway. I just think this adds a little bit more
10 focus on that.

11 And also, I think it's fairer for the
12 claimants because they would then understand that
13 their claims are being treated the same as
14 similar claims; there's some rule or some
15 guidance document to go back to that sort of
16 fills in. It becomes more than just a case-by-
17 case or the judgment of an individual dose
18 reconstructor and the people reviewing that
19 particular case.

20 **DR. ZIEMER:** Now let me ask if any of the
21 Board members require any additional
22 characterization or clarification of the issue
23 itself. Does everybody understand how this
24 arose?

25 And this also relates to comments that -- the

1 comments that Ted Katz was making and that Dr.
2 Miller was making on this whole issue of
3 sufficient accuracy. This deals with that worst-
4 case business, where if there's a worst-case
5 estimate and the probability of causation is
6 greater than -- less than 50 percent, then in a
7 sense if you've shown that there's no way that
8 the person could have met the 50 percent
9 probability of causation criteria, in a sense
10 you've completed a sort of dose reconstruction
11 and you're done.

12 But if they're over 50 percent they don't
13 automatically meet the criteria of a dose
14 reconstruction, because you at that point have
15 only used worst-case estimate and haven't really
16 done enough research, and additional
17 information's called for. They might end up in a
18 Special Exposure Cohort, but they also might not.
19 And that was kind of the issue at that point.

20 But does anyone wish to make any specific
21 motions or ask for additional clarification, or
22 just comments, pro or con?

23 **DR. ANDRADE:** Paul, this is Tony.

24 By way of comment, I believe that Jim and Ted
25 and others probably have a fairly clear

1 understanding of what they mean by sufficient
2 accuracy, and I'm sure that it's consistent among
3 the health physicists there at NIOSH.

4 Nevertheless, the way it came through in the
5 proposed legislation or proposed rulemaking, it
6 did suffer from lack of clarity. So what I guess
7 I'd like to see is follow-through on your item
8 number 13, that includes as the last sentence
9 that it would be helpful if NIOSH could provide
10 additional clarification of this concept either
11 through the development of guidelines, further
12 definition of the term, or through specific
13 examples.

14 Now I'm sure they'll be able to come through
15 on this.

16 **DR. ZIEMER:** Okay, other comments?

17 **DR. MELIUS:** This is Jim Melius.

18 I would, speaking up, but I could very well
19 see guidelines that would rely on specific
20 examples as the way that they would sort of
21 communicate the guidelines. So I don't think
22 that's inconsistent.

23 **DR. ANDRADE:** No, I don't think that's
24 inconsistent either.

25 **DR. ZIEMER:** Tony, does your -- what you kind

1 of recommended there would be to start out with
2 the paragraph 13, and then kind of move into
3 Jim's words about developing specific guidelines
4 within a reasonable period of time and so on, or
5 were you not wanting to be that specific on it?

6 **DR. ANDRADE:** I didn't want to be too
7 terribly specific and tie their hands, but I
8 think what Jim is saying is a perfect example.
9 It could be guidelines that use specific
10 examples. And so I want to leave the concept
11 open enough for the real technical people to take
12 a stab at being a little bit more clear about the
13 definition.

14 **DR. ZIEMER:** Other comments?

15 [No responses]

16 **DR. ZIEMER:** Let me ask a general question.
17 Is there general concurrence amongst Board
18 members that you would like us to ask for more
19 specificity on this issue of sufficient accuracy?
20 Or do you think it's okay as it is?

21 **MR. GRIFFON:** This is Mark Griffon.

22 **DR. ZIEMER:** Mark.

23 **MR. GRIFFON:** Yeah, I think -- I'm not sure
24 if we can -- I agree with Jim Melius's asking for
25 guidelines and actually having an opportunity for

1 the Board to review those guidelines.

2 I think the reason for that, I would like
3 more specificity and possibly in the rulemaking,
4 but I think we've had two cracks at it here in
5 two proposed rulemakings, and I'm not sure that
6 there's that much more clarity. So I think this
7 might take a little longer, and might be better
8 suited to guidelines --

9 **DR. ZIEMER:** As opposed to a rule?

10 **MR. GRIFFON:** Yes. So I think -- but I
11 think, in this proposed rulemaking, I think we
12 should recommend that NIOSH should develop
13 guidelines and have input from the Board helping
14 those guidelines.

15 **DR. ZIEMER:** Okay. Other comments?

16 [No responses]

17 **DR. ZIEMER:** Does anyone wish to make any
18 specific motions?

19 [No responses]

20 **DR. ZIEMER:** Nobody wants to make any
21 specific motions?

22 **DR. MELIUS:** I'm trying to combine the two
23 here -- this is Jim Melius, Paul -- so that we
24 can --

25 **DR. ZIEMER:** I was going to suggest something

1 similar, Jim, as it were, just take where I said
2 it would be helpful if NIOSH could provide
3 additional clarification of this concept,
4 accordingly the Advisory Board recommends --

5 **DR. MELIUS:** And then use --

6 **DR. ZIEMER:** -- then move into your
7 statement. In fact, let me suggest this, and
8 then somebody can move it.

9 If you look at the Melius underlined
10 paragraph on page 3 -- Jim, I think the words
11 "DHHS reexamine the proposed approach to dose
12 reconstruction and special exposure cohort
13 designation," I don't know that we need all that.
14 Just say "The Advisory Board recommends that
15 guidelines addressing feasibility and sufficient
16 accuracy be developed."

17 **DR. MELIUS:** That's fine.

18 **DR. ZIEMER:** And then "These guidelines
19 should be developed within a reasonable time
20 period," which is pretty flexible, "after
21 promotion [sic] of the regulation and should be
22 submitted to the Board for review. Appropriate
23 changes should be made in the regulation to
24 indicate the planned development of these
25 guidelines and the process for their

1 development."

2 Is this too much, now? "Appropriate changes
3 in the dose reconstruction regulations should be
4 made to address," and where it says "the
5 potential conflict," there's kind of an
6 assumption there that there is -- there's an
7 assumption that I'm uncomfortable with that there
8 is a potential conflict. Just could generalize
9 it, and say "any potential conflict between this
10 rule and 42 CFR 82."

11 **DR. MELIUS:** That's fine with me.

12 **DR. ZIEMER:** That could leave some claimants
13 ineligible for either individual dose
14 reconstruction or Special Exposure Cohort status.

15 Do you want to make such a motion?

16 **DR. MELIUS:** This is Jim Melius.

17 I so move.

18 **DR. ZIEMER:** Is there a second?

19 **DR. DeHART:** This is Roy.

20 I'll second.

21 **DR. ZIEMER:** So what we have now is the
22 statement kicks off with item 13, but it drops
23 the last part of the sentence on 13 that says
24 "either through definition of the term or through
25 specific examples," and just moves into "It would

1 be helpful if NIOSH could provide additional
2 clarification of this concept," and then it would
3 stop there.

4 And then it would say "Therefore," and we'd
5 continue with the Melius statement, but we'd
6 delete from his first sentence "DHHS reexamine
7 the proposed approach to dose reconstruction and
8 special exposure cohort designation and that."
9 Right there's where you would delete, and then
10 you would continue with "guidelines addressing
11 feasibility and sufficient accuracy be
12 developed."

13 And then skipping down to the last sentence
14 would say, "Appropriate changes in the dose
15 reconstruction regulations should be made to
16 address any potential conflict between this rule
17 and 42 CFR 82 that could leave some claimants
18 ineligible for either individual dose
19 reconstruction or special exposure cohort
20 status."

21 This that your motion, Jim?

22

23 **DR. MELIUS:** Yes, it is. Very good.

24 **UNIDENTIFIED:** Well stated.

25 **DR. ZIEMER:** Now let me ask if the Board, in

1 connection with that, wants to retain any of the
2 other narrative that appeared in the Melius
3 document, or is this sufficient?

4 I think the narrative was largely there to
5 help to Board think about this, as opposed to
6 being part of what you wanted to put in the
7 recommendation.

8 Is that correct, Jim?

9 **DR. MELIUS:** Correct.

10 **DR. DeHART:** My second is as stated earlier.

11 **DR. ZIEMER:** Okay. So what you're saying is
12 then we would not need to include all of the
13 narrative that's in the document.

14 **DR. MELIUS:** Correct.

15 **DR. ZIEMER:** Okay. Now let me -- we have a
16 motion on the floor before us.

17 I want to see now if there are any comments,
18 pro or con. Anyone wish to speak in support of
19 this motion or in opposition to the motion? And
20 please feel free to do either. You won't hurt my
21 feelings. I know you won't hurt Jim's feelings.

22 **UNIDENTIFIED:** We don't mind hurting Jim's
23 feelings.

24 [Laughter]

25 **DR. ANDRADE:** This is Tony.

1 I support the motion. I think that tying
2 this back to former legislation and ensuring that
3 there's consistency is important, and the way it
4 is stated -- I can't think of a better way to
5 state it than the way y'all worked it out. So
6 I'm in support of that.

7 **DR. ZIEMER:** Others, pro or con?

8 **DR. ANDERSON:** This is Andy.

9 I'm in support of it.

10 **DR. ZIEMER:** Okay. If anyone has got any
11 major heartache with this one then get it out,
12 because that might be helpful. Maybe we're
13 overlooking something, so don't hesitate if
14 you're uncomfortable or antsy about it.

15 **MR. PRESLEY:** Bob Presley.

16 I like it.

17 **DR. ZIEMER:** You're okay by it. Okay.

18 **MS. MUNN:** This is Wanda.

19 It isn't that I necessarily dislike where we
20 are here. I guess at this juncture I'm having a
21 little concern with what I perceive to be, and
22 perhaps inaccurately perceive to be, a movement
23 away from knowledge that we have based on the
24 best science available, and acceptance of the
25 responsibility that we have given our overseeing

1 agencies to perform their duties properly.

2 I recognize the desire that's been expressed
3 here repeatedly. The term "specificity" must
4 have been used 15 times already. I recognize the
5 desire for that, and I'm certainly not opposing
6 the language that's been presented. I just have
7 some very severe heartfelt reservations about
8 some of the directions that I see the Board
9 making with respect to how the Agency is going to
10 address these things, and what "fair" means.

11 That having been said, I have no objection to
12 the wording as stated.

13 **DR. ZIEMER:** And Wanda, let me add that it
14 seems to me that as a practical matter, in fact
15 some guidelines are going to be developed anyway
16 along these lines, perhaps explicitly or maybe
17 implicitly. But, I mean, there has to be some
18 methodology that's developed as we go forward.

19 And I think in a sense it seems to me we're
20 simply asking for a better understanding of how
21 those decisions are made in these cases where you
22 have these worst-case estimates made on the one
23 hand for the efficiency issues in the dose
24 reconstruction, and as opposed to the issues of
25 the special cohort which is a somewhat different

1 situation.

2 **MS. MUNN:** Yes.

3 **DR. ZIEMER:** Okay. Other comments?

4 [No responses]

5 **DR. ZIEMER:** Let me ask if the Board is ready
6 to vote on this item.

7 [No responses]

8 **DR. ZIEMER:** Anyone not ready to vote?

9 [No responses]

10 **DR. ZIEMER:** Okay. Then we're going to vote
11 on this motion, and all in favor will say "aye"
12 when the roll is called.

13 And Cori, you're ready to call the roll?

14 **MS. HOMER:** Okay.

15 Henry Anderson?

16 **DR. ANDERSON:** Aye.

17 **MS. HOMER:** Antonio Andrade?

18 **DR. ANDRADE:** Yes.

19 **MS. HOMER:** Roy DeHart?

20 **DR. DeHART:** Aye.

21 **MS. HOMER:** Richard Espinosa?

22 **MR. ESPINOSA:** Aye.

23 **MS. HOMER:** Mike Gibson?

24 **MR. GIBSON:** Aye.

25 **MS. HOMER:** Mark Griffon?

1 **MR. GRIFFON:** Aye.
2 **MS. HOMER:** Jim Melius?
3 **DR. MELIUS:** Yes.
4 **MS. HOMER:** Wanda Munn?
5 **MS. MUNN:** Okay.
6 **MS. HOMER:** Leon Owens?
7 **MR. OWENS:** Aye.
8 **MS. HOMER:** Robert Presley?
9 [No responses]
10 **MS. HOMER:** Bob?
11 **DR. ZIEMER:** Did we lose Robert?
12 **MS. HOMER:** Uh-oh.
13 **MR. PRESLEY:** Yeah. Can you hear me?
14 **MS. HOMER:** Yes.
15 **MR. PRESLEY:** Aye.
16 **MS. HOMER:** Okay. And Genevieve Roessler?
17 **DR. ROESSLER:** Yes.
18 **MS. HOMER:** Dr. Ziemer?
19 **DR. ZIEMER:** Yes, and the Chair will vote
20 aye.
21 **MS. HOMER:** Okay.
22 **DR. ZIEMER:** So the motion carries, and we
23 will incorporate that combination statement into
24 the last item on the list of comments.
25 Now one more time, let me ask the Board

1 members, are there additional comments that you
2 believe should be included in the comments sent
3 to the Secretary of HEW -- HHS, not HEW. HHS.

4 [No responses]

5 **DR. ZIEMER:** It appears not.

6 I also have provided you with the draft cover
7 letter. That will be revised to reflect the fact
8 that there were three conference calls rather
9 than two on this subject, in the second to last
10 paragraph, so I will update that.

11 The cover letter itself, we don't need to
12 vote on. But if you have any grammatical things
13 or something like that that you want to pass on
14 to me before it goes to final form, why, you can
15 do that individually.

16 Okay. Now it's my judgment that we have
17 completed action on all the comments we want to
18 comment on for the proposed rulemaking. Is
19 everybody of the same understanding? Any that
20 think there are additional things that we need to
21 address at this point?

22 [No responses]

23 **DR. ZIEMER:** Apparently not.

24 I will ask Cori if you have any housekeeping
25 issues relating to our upcoming meeting.

1 **MS. HOMER:** No. I think I've asked everybody
2 for their travel arrangements.

3 I do have a question for you, if you could
4 just go ahead and forward whatever comments in
5 the final to me.

6 **DR. ZIEMER:** I will do that. And our
7 comments are due in to the Secretary by what
8 date, again?

9 **MR. ELLIOTT:** May the 6th.

10 **DR. ZIEMER:** May 6th, okay. Very good.

11 Now, let's see. Cori, just for the record,
12 give us the dates of our next meeting again in
13 Oak Ridge.

14 **MS. HOMER:** Okay. Our next meeting is
15 scheduled for May 19th and 20th.

16 **DR. ZIEMER:** That will be --

17 **MS. HOMER:** In Oak Ridge at the Garden Plaza
18 Hotel.

19 **DR. ZIEMER:** Okay, thank you very much.

20 **MR. PRESLEY:** Cori, are the meetings going to
21 be at the Garden Club?

22 **MS. HOMER:** Yes, they are.

23 **MR. PRESLEY:** Wonderful.

24 **MS. HOMER:** Yes.

25 **DR. ZIEMER:** Okay. I think that then

1 completes our meeting, and I will declare us
2 adjourned.

3 Thank you, everyone, very much.

4 [Whereupon, the meeting was adjourned at
5 approximately 4:21 p.m.]

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C E R T I F I C A T E

STATE OF GEORGIA)
)
 COUNTY OF DEKALB)

I, KIM S. NEWSOM, being a Certified Court Reporter in and for the State of Georgia, do hereby certify that the foregoing transcript, consisting of 65 pages, was reduced to typewriting by me personally or under my direct supervision, and is a true, complete, and correct transcript of the aforesaid proceedings reported by me.

I further certify that I am not related to, employed by, counsel to, or attorney for any parties, attorneys, or counsel involved herein; nor am I financially interested in this matter.

This transcript is not deemed to be certified unless this certificate page is dated and signed by me.

WITNESS MY HAND AND OFFICIAL SEAL this 7th day of May, 2003.

KIM S. NEWSOM, CCR-CVR
 CCR No. B-1642

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