# 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

#### VOLUME II

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at the Washington Court Hotel, Washington, D.C., on Thursday, February 14, 2002.

# AAACH LEE & ASSOCIATES

Certified Verbatim Reporters
P. O. Box 451196
Atlanta, Georgia 31145-9196
(404) 315-8305

### CONTENTS

# VOLUME II February 14, 2002

| PARTICIPANTS (by group, in alphabetical order)  | •   |   | •  | •   | . 3        |
|---|-----|---|----|-----|------------|
| REGISTRATION AND WELCOME Dr. Ziemer   | . • |   | •  | •   | . 5        |
| ADMINISTRATIVE HOUSEKEEPING Ms. Homer   |     |   | •  | •   | . 6        |
| BOARD WORK SCHEDULE Mr. Elliott, Ms. Homer  | . • |   |    | •   | . 8        |
| BOARD DISCUSSION/DEVELOPMENT OF COMMENTS ON DOSE RECONSTRUCTION RULE (42 CFR PART 82) |     |   |    |     | . 24       |
| Motion and Vote   |     |   |    |     |            |
| Motion and Vote   |     |   |    |     |            |
| Motion and Vote   |     |   |    |     |            |
|   |     |   |    |     |            |
|   | •   | • | •  | 57  | , 55<br>61 |
|   |     |   |    |     |            |
| Motion and Vote   |     |   |    |     |            |
|   |     |   |    |     | •          |
| Motion and Vote   |     |   |    |     |            |
| Motion and Vote   | •   | • |    | /4, | 112        |
| PUBLIC COMMENT PERIOD  Mr. Richard Miller   |     | • |    |     | . 84       |
|   |     |   |    |     |            |
| CONTINUATION OF BOARD DISCUSSION  |     |   |    |     |            |
| Motion and Vote   |     |   | •  | 90  | , 99       |
| Motion and Vote   |     |   | 1( | 00, | 106        |
| Motion and Vote   |     |   | 1( | )7, | 107        |
| Motion and Vote   |     | • | 1( | )8, | 108        |
| ADJOURN   |     | • |    |     | 120        |
| CERTIFICATE OF REPORTER   |     |   |    |     | 121        |

#### PARTICIPANTS

(By Group, in Alphabetical Order)

#### ADVISORY BOARD MEMBERS

#### CHAIR

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

#### EXECUTIVE SECRETARY

LARRY J. ELLIOTT

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

#### **MEMBERSHIP**

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

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

ROY LYNCH DeHART, M.D., M.P.H.

Director

The Vanderbilt Center for Occupational and Environmental Medicine

Professor of Medicine Nashville, Tennessee

RICHARD LEE ESPINOSA
Sheet Metal Workers Union Local #49
Johnson Controls
Los Alamos National Laboratory
Espanola, New Mexico

SALLY L. GADOLA, M.S., R.N., COHN-S Occupational Health Nurse Specialist Oak Ridge Associated Universities Occupational Health Oak Ridge, Tennessee

JAMES MALCOM MELIUS, M.D., Ph.D.
Director
New York State Laborors' Health and Safety Trust Fund
Albany, New York

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

ROBERT W. PRESLEY Special Projects Engineer BWXT Y-12 National Security Complex Clinton, Tennessee

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

#### STAFF/VENDORS

CORRINE HOMER, NIOSH
TED KATZ, NIOSH
MARIE MURRAY, Writer/Editor
KIM NEWSOM, Certified Court Reporter

#### AUDIENCE PARTICIPANTS

RICHARD MILLER

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#### PROCEEDINGS

9:00 a.m.

DR. ZIEMER: Good morning again, everyone. We'll resume deliberations of the Advisory Board on Radiation and Worker Health.

(Comment off the record)

DR. ZIEMER: For members of the public, again we remind you that if you wish to make public comment during the meeting today, there is a sign-up sheet in the foyer or the entryway. Please sign up.

Also, those members of the public who wish to have copies of the minutes of this meeting, there is a sheet for signing up to make such a request for those minutes.

On our agendas, as distributed and as published, we always have a footnote that says agenda items are subject to change as priorities dictate. And based on that footnote, I will exercise the Chair's prerogative to rearrange the schedule somewhat.

We have at the front end here some administrative housekeeping things that we want to take care of, and then it would seem appropriate to also handle the Board work

schedule items at that time. So we'll move the 10:30 item, Board work schedule. We'll move that up and do that immediately following the administrative housekeeping things. That will allow us, then, basically the rest of the morning to work on the development of the Board's comments relating to the dose reconstruction rule.

So without objection, we'll make that rearrangement of the morning agenda.

There will also be time for public comment.

And depending on how far we get this morning, we will then take a look at the afternoon agenda.

So let us begin with these housekeeping items, and Cori, if you will come at this time and take care of the administrative housekeeping matters, and then we'll -- Larry will join us with some additional materials.

#### MS. HOMER: Thank you.

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Good morning, ladies and gentlemen. I just wanted to update you on your salary and travel pay issues. I wanted to let you know that your salary should be direct deposited into your accounts tomorrow. I don't have in front of me the number of days you'll be paid for. If you

have any questions on that you can just give me a call. It will be less taxes. And if you have forwarded your voucher information to us, myself or Nichole, then it's either being worked on or it's been signed and is going to be reimbursed.

I do want to ask if any of you have any questions at all about how you're paid, how you're reimbursed, anything about your travel issues, per diem, how that's paid?

(No response)

MS. HOMER: I know some folks have asked about per diem for travel.

MS. MUNN: Cori, will we be getting some
sort of document in the mail --

UNIDENTIFIED: Use your mike, Wanda.

MS. MUNN: Will we be receiving some sort of written information about itemization of our per diem and travel funds?

MS. HOMER: That will come on your travel voucher. When that comes to you, for those of you who have seen one or have signed one, your voucher will come to you for signature and dating.

MS. MUNN: Okay.

MS. HOMER: And if you have any questions at

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that time, looking it over, you can call myself or Nichole on that. You will also be getting, as soon as I have it, your earnings and leave statement for salary, and that will tell you how much was deposited into your account. If you have not received that in your account, please call me as soon as you know. That way I can go back and check when it was paid, what day it was supposed to have been deposited, and we can get that taken care of as quickly as possible.

Also, for the time you spent reviewing the technical guidelines, if you could let Larry know how much time you spent.

And any other questions?

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DR. DEHART: And the time on the phone call?

MS. HOMER: Yes, the time on the phone call as well.

I guess that'll be it.

DR. ZIEMER: Okay. Larry, you have additional items?

MR. ELLIOTT: Yes. Let's do it the way we did last meeting. If you'll just jot me a note with the number of hours of prep time, then I sign off on that note and hand it over to Cori to take care of your salary for prep time for the

teleconference. And we know what the teleconference was; you'll get that covered. And then your preparation time for yesterday and today's meeting.

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I think there was one question, and I'm not sure everybody got an answer to. That was how do I know — this came up yesterday — how do I know when my salary gets deposited, and how do I know when my travel voucher or my travel expense gets deposited to my account? When you sign off on your travel voucher, make note of — and you should get a copy of this for your own records — but make note of what that dollar value is, and that's what will be actually added to your account for your travel. But your salary will not be X number of days times your salary; it'll be minus the tax. So that'll be a figure that we can't predict for you.

The other thing, under the Board work schedule, we -- as Dr. Ziemer used his prerogative to move this up, we need to talk about the -- we tentatively have March 25th and 26th set aside in your calendars for the next meeting. What work do we have for that meeting, and do we need to have that meeting? Should we

postpone that meeting? I think that's a topic of this agenda item at this point in time.

It's very unlikely that we would have the Special Exposure Cohort procedures ready for review in March, at that time frame. It's just too hard for me to predict right now. The only thing I would see that the Board could work on in March would be to come together to discuss or to decide how to conduct its review of dose reconstructions.

I would suggest to you that the review of dose reconstructions would probably not start, however, until early fall; late, late summer, early fall. I think it's important for us to build a completed case load of those for you to sample from. I don't think you want to start out looking at the first 100 or so, or first ten that come out of the gate. But I think you need to come to grips and decide, discuss and decide how you want to approach setting up a review of dose reconstructions.

I know there were several other things that were proposed yesterday for presentations to the Board, and we certainly are willing to accommodate those interests. But I would ask

that you consider our preparation for those kind of presentations at this point in time takes staff away from completing some of their necessary work that we have in order to try to achieve our goals. And we can certainly get to those things later on, but that would be just my suggestion for your consideration.

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So I'll turn it over to the Chair, and you should discuss how you want to proceed.

DR. ZIEMER: First of all, let me suggest something here, and then we can entertain other comments.

It's clear that the staff has an immediate job of getting the responses to the comments for the two rule-makings and getting the rule-making out the door. I think you were shooting for an April 1st to get that out your door and into the system. It would seem to me that it would be in the interest of the NIOSH staff if we did not have a meeting in March that would detract from their ability to get that immediate job done.

The pressing issues for this Board were the comments on Part 81 and 82, which we hope to complete today, so that I don't see a compelling reason to meet in March, but there may be a

| 1   | compelling reason not to meet in March.                    |
|-----|--|
| 2   | Personal views? Let's get other comments.                  |
| 3   | Yes, James.  |
| 4   | DR. MELIUS: What are you proposing, then,                  |
| 5   | as the next meeting, just roughly?                         |
| 6   | DR. ZIEMER: Then it would be an April time                 |
| 7   | frame. Did we collect the April you have the               |
| 8   | April possibilities there?                                 |
| 9   | MS. HOMER: Looks like in April the second                  |
| LO  | week. Dr. Anderson is only available on the                |
| L1  | 12th. Everybody else seems to be available all             |
| L2  | week. The third week looks good. That would be             |
| L3  | the 14th through the 20th.                                 |
| L 4 | DR. DEHART: I'm out that total week.                       |
| L 5 | DR. ANDERSON: Yeah, I've got a wedding at                  |
| L 6 | the end of the week not mine.                              |
| L 7 | DR. ROESSLER: Cori, I must not have put it                 |
| L 8 | on, but I'm out the week of I'm out April 9th              |
| L 9 | through 11th.  |
| 20  | MS. HOMER: 9th through 11th? Okay.                         |
| 21  | DR. ROESSLER: And then in addition, on my                  |
| 22  | agenda, I changed an EPA advisory committee                |
| 23  | meeting from March to April 23rd to $25^{ m th}$ . But you |
| 24  | can't get everybody, probably.                             |
| 25  | MS HOMER: Well how does the 22nd and 23rd                  |

| 1  | or 23rd and 24th sound?                             |
|----|---|
| 2  | DR. ANDERSON: That's the EIS conference at          |
| 3  | CDC that week. For me, anyway, and I would          |
| 4  | assume  |
| 5  | DR. ZIEMER: I'm out the 23rd. Actually              |
| 6  | I'll be in Los Alamos on the 23rd. Maybe we         |
| 7  | could meet out there.                               |
| 8  | MR. ESPINOSA: Sounds good to me.                    |
| 9  | DR. ZIEMER: Roy, did you say you were out           |
| 10 | the week of the 15th?                               |
| 11 | DR. DEHART: Actually, I'm out well,                 |
| 12 | certainly from the 13th through the 18th.           |
| 13 | Aerospace medical meeting.                          |
| 14 | DR. ZIEMER: Was the week of the 8th a               |
| 15 | possibility?  |
| 16 | DR. ROESSLER: Well, the 10th and 11 <sup>th</sup> , |
| 17 | that's the NCRP meeting.                            |
| 18 | DR. ZIEMER: That's right here, so if we met         |
| 19 | the 8th and the 9th, why you could just go right    |
| 20 | over there, right?                                  |
| 21 | DR. ROESSLER: Sure.                                 |
| 22 | DR. ANDERSON: Yeah, I have a conflict on            |
| 23 | I think, Jim, you're on the Rocky Flats             |
| 24 | DR. MELIUS: Yeah, we both -                         |
| 25 | DR. ZIEMER: Okay. Is the 11th and 12th of           |

| 1  | April out, also?  |
|----|---|
|    |   |
| 2  | UNIDENTIFIED: The 12th is okay, but not the                   |
| 3  | 11th.   |
| 4  | DR. ZIEMER: What about I'm out the 4th                        |
| 5  | and 5th, but what about the 1st through 3 <sup>rd</sup> ? Any |
| 6  | problems there?   |
| 7  | UNIDENTIFIED: For which month?                                |
| 8  | MR. ELLIOTT: That's too close.                                |
| 9  | DR. MELIUS: We've already committed all                       |
| 10 | of us have set aside those other two. To move it              |
| 11 | a week is hardly worth it.                                    |
| 12 | DR. ZIEMER: Oh, right, that doesn't help                      |
| 13 | much.   |
| 14 | DR. ANDERSON: May 2 or 3?                                     |
| 15 | MS. HOMER: First week of May looks open.                      |
| 16 | DR. ZIEMER: Any conflicts beginning April                     |
| 17 | 29 through May 3rd?   |
| 18 | (No responses)  |
| 19 | DR. ZIEMER: Hey, looks good, doesn't it?                      |
| 20 | DR. ANDERSON: I have a conflict Monday and                    |
| 21 | Tuesday, but  |
| 22 | DR. ZIEMER: That's the 29th and 30th.                         |
| 23 | DR. ANDERSON: Yeah. So 1, 2, or 3 is fine.                    |
| 24 | DR. ZIEMER: Anyone with a conflict May 1st                    |
| 25 | through 3rd?  |

1 (No response) 2 DR. ZIEMER: Shall we try for either 1st and 3 2nd, or 2nd and 3rd? UNIDENTIFIED: I'm sorry? 4 5 DR. ZIEMER: 1st and 2nd, or 2nd and 3rd, depending on availability of facilities and so 6 7 Does that sound --8 MS. HOMER: That's good. 9 DR. ZIEMER: Okay, let's all pencil that in. 10 Block off 1st through 3rd until we get it finalized. 11 12 Any reason we shouldn't just meet here again in D.C.? 13 14 (No response) 15 DR. ZIEMER: Sounds okay. MS. HOMER: I'll check on the availability 16 17 of the hotels. 18 DR. ZIEMER: Cherry blossoms still out then, or -- is that on your calendar? Too late. 19 20 Okay, we have tentative dates, then, blocked 21 off for that meeting. Now let me make sure, is 2.2 everybody agreeable that we should postpone till 2.3 then? Is there any that feel that there's 2.4 compelling reason to meet in March? I don't want 25 to preclude that.

Yes, Roy, please.

DR. DEHART: I was just curious. There are probably some topics that would not need presentation by the NIOSH group, but where others from outside could come in. We were hearing yesterday about a number of dose critical issues where when it was really -- the paper record was really checked, it was found not to be adequate. Could we hear those stories? That's the kind of information that perhaps wouldn't take so much time. But again, you see a lot of people sitting around here that might have to be here in any case, which would interfere with the staff, I don't know.

DR. MELIUS: Yeah, I think along those lines there's those topics.

I think it would be useful to hear a legislative history or background, particularly with relationship to Special Exposure Cohorts.

But I think there's other sections that would be helpful to hear from some of the Congressional staff. There's David Michaels, there's a lot of -- somebody can choose who, but sort of a panel to present to us the legislative background.

There's a number of topics related to the

IREP model and so forth that we had talked about

at the first meeting, that I think it would be

useful to get a panel together to give us

background on some of the issues related to that.

So I don't think it necessarily has to require the NIOSH staff to spend a lot of time preparing for us, and that will somewhat depend on where they are with the various regulations.

But I think getting some of that background together with information would be good, and would be a good use of a meeting so that down the road we're prepared for -- as these issues come up.

DR. ZIEMER: Let me ask both Roy and Jim, are you suggesting that there's an urgency to do that in March rather than, say, April? Certainly that could be part of the April thing. I think these folks are going to be pretty well tied up through March anyway, so maybe having that topic at the April meeting might still be appropriate to have.

DR. MELIUS: Yes, that's what I was saying.

DR. DEHART: That would be fine with me. I
just would like to see some of that information
presented soon.

DR. ZIEMER: Henry had a comment.

DR. ANDERSON: Yeah, I would agree. I would like to hear some of the other background, and maybe have some of the peer reviewers from the IREP come in and talk about their -- have more of a dialogue with them at some point in time.

And I think we also probably then need to do some planning on how are we going to organize to review -- I've just felt that we're very much in a reactive mode, and to wait only until we have something from NIOSH to present and review, we may want to think about what are some of the more proactive things that might be something that we would carry on between several meetings.

But April, in order to do that -- we could probably put that -- I just don't want to get us rushed again, because next will be coming the NIOSH responses to the rule package, and changes there that we may want to discuss as well. This might be a catch-up meeting for us to look at things that are good for us, but I don't feel strongly about not postponing. I just don't want to get caught down the line, that we spend all our time reacting on a rapid basis rather than kind of beginning to plan a process for the long

term.

DR. ZIEMER: Okay, good comment. Thank you. Others? Wanda.

MS. MUNN: I agree fairly strongly with what Henry had to say.

I think it may take us a little time to get our thoughts in order with respect to how we do want to approach these evaluations we're going to undertake. I think we ought to give the NIOSH staff all the space they need in March to do these ugly things they have to do to try to make their deadline. By the same token, I'm uncomfortable with putting our next meeting off too far. I think it may be to our detriment to have too much time between our meetings, even though regularity, obviously with a group like this, is going to be impossible.

But there are several items -- I shouldn't say several -- there's at least one item that I would like to discuss with the group at some juncture before we get too far down the road. It's already behind us and nothing that can be done about it, but there is some language in the law that establishes this entire procedure, which is -- there's not much of it, but what's there is

misleading, to say the least, and inaccurate is the kindest word one can say about it.

For a group like this to not comment on that, I think would be inappropriate, and at some juncture I'd like to discuss that with the Board. But -- and would like that not to be long after all of the disbursements have begun to take place.

DR. ZIEMER: Thank you. Wanda, let me ask. However, are you comfortable with the meeting date that we're talking about, or are you urging us to meet again in March? You said that you wanted to give them space, so I took that to mean you're okay with this proposed meeting date that we talked about.

MS. MUNN: I think we should just throw up our hands with respect to March.

DR. ZIEMER: Yes, okay.

MS. MUNN: It looks impossible to me.

DR. ZIEMER: Thank you.

MS. MUNN: And my preference would have been April, but that also looks impossible at this juncture.

DR. ZIEMER: Well, we're not too far out of
April, so --

3 Any other comments as --DR. ANDERSON: Do we want to look at some 4 5 other dates? By the time we get to May, I think we're then going to find that June is gone, 6 7 because everybody's going to fail. So if we're 8 going to plan for three or four meetings four to 9 six weeks apart, we may want to start to look at 10 some of those dates. DR. ZIEMER: Cori, can we distribute the 11 12 calendars, or do you want to just have us tell 13 you what our bad dates are again through May, 14 June, and on beyond? MS. HOMER: Yeah, you have May. 15 16 DR. ZIEMER: Okay. In the packet -- is it 17 in the packet? There is a tab in the packet 18 called 2002 year planner. So I think, Cori, if 19 this is what you want, have each person put their 20 name on that, and then X out your bad dates. 21 that how we want to do that? 2.2 MS. HOMER: Yes. 2.3 DR. MELIUS: That's how we did it last time. 2.4 MS. HOMER: We did it that way last time. 25 DR. ZIEMER: But how far did -- last time we

MS. MUNN: This is true, so May is fine.

Thank you.

DR. ZIEMER:

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only had through May, so --

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MS. HOMER: Some folks have given me June,

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but --

DR. ROESSLER: But that changes.

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UNIDENTIFIED:

It changes.

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MS. HOMER: Yes, it does.

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Why don't you update that, and DR. ZIEMER: let's -- how far can we go now? Can we take it on through at least August, and get those dates? And then turn those in yet today. Thank you.

Could we also then ask the staff, as you're able to begin identifying who might some of these presenters be -- again, I think there will be time, but we do have to allow those people time to schedule things, too. So having a little advance notice will be important there.

Jim.

DR. MELIUS: Could I make a suggestion that maybe we set up a -- I don't know if it's a subcommittee or group, just to work with the Chair, a couple of people to help choose some of the people, or we can work with the staff in terms of coming up with some names and people from the outside that we might want to come in for those meetings? That might make it easier,

rather than have the staff calling around and --

DR. ZIEMER: Let me -- Jim, would this work just as if you know of or have suggestions, just to turn those over to Larry, and let them try to put together something? Do you think you need -- do we need a subcommittee, or --

DR. MELIUS: That would be -- if they want,
prefer that way, that's fine, too.

MR. ELLIOTT: That would be great. Whatever your suggestions are, if you can give them to me. And certainly I've already talked with David Michaels. I think he would be pleased to accept an invitation to present on the legislative background to you. Josh Silverman and I spoke this morning, and I think DOE would welcome an invitation to talk about records. But others, I'm sure there are other people that you know of you would like to hear from.

DR. MELIUS: Can I just -- maybe if we can do that interactively, then, if you could then email out what you think will be the agenda and who the speakers would be. Then if someone says, well, I really think we ought to hear from someone with this viewpoint or this experience would be a good addition, or some point, then I

think at least we're not getting to the meeting and saying, well, next meeting we should have somebody else come in.

The other thing I would request maybe for setting up this meeting, so we don't get to May and be struggling with a July meeting, because by that time our calendars will all have changed also, is if Larry could work with the Chair. And I think somebody's just going to make a decision at some point that not everyone can be there, and maybe make it your -- we'll have someone to blame besides Larry.

DR. ZIEMER: I was hoping that wouldn't happen, but we'll do that. Sure, we'll do that.

DR. MELIUS: But also, again, if you'd let us know. There are times we can move meetings if we're not available, just -- the farther ahead we can do this, I think the better, that's all.

DR. ZIEMER: Right, it's sort of the first thing on the calendar is going to get the priority in many cases, so right.

DR. MELIUS: Exactly.

DR. ZIEMER: Right.

Okay, other comments?

Thank you, that's very helpful.

(No response)

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DR. ZIEMER: Let us now proceed to the discussion and development of the dose reconstruction rule comments.

We did ask for each of you to give some thought and maybe jot down some ideas. thought we might do to begin is to prepare a kind of inventory of the items that we want to address, just to identify them. We sort of did this at the end of the session yesterday. But I've asked Cori to help us by preparing an overhead; that is, she will prepare it as we make the inventory.

Is this agreeable, to try to identify the items that we wish to comment on? And then we can talk about actually developing the formal comments after we see what it is that's before us in terms of numbers of items and the subjects. Is that agreeable, to try to get an inventory here?

Now one of the reasons I'm suggesting we do this is because I've started an inventory. actually have a list of eight items that I put together, I think based on yesterday's comments. And so what I thought I would do is identify

these, and then we can either delete or add to them. But most of these -- and these aren't my ideas. These are ones that I think I heard yesterday from the Board.

For example, the first item would be to move the paragraph Item J Section 2 (sic), and you can say move Item J, Section 2, page 50981, to the body of the rule. This is the one dealing with the role of this Board. Actually, the whole paragraph, which is not only the role of the Board but the general idea of revising, perhaps the whole thing should move. So maybe to identify this, move Item J, sentence -- let's say Item J of the background section to the body of the rule. We can come back and talk about these, but let me get the list up here.

MS. HOMER: Move Item J from background to
where?

DR. ZIEMER: To the body of the rule. I'm not sure where that would go, actually, but --

DR. DEHART: It's page 50981.

DR. ZIEMER: Yeah, page 50981 is where that is. That's where this section is.

The second item is Section 82.10, paragraph (j), so 82.10(j), clarify the use of the term

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"validated."

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DR. ROESSLER: What page is that on?

MS. NEWSOM: 50988.

DR. ZIEMER: Third item, clarify the steps and time line for -- oh, I'm sorry, I should have given you the section first. That's all right, put it in the next -- that'll be Section 82.10(m), (n), (o). Clarify the steps and time line for claimant's action on form OCAS-1, claimant's actions on form OCAS-1.

Section 82.14(f)(1), clarify the use -- this is one I just picked up; we didn't talk about this. But the title of this uses the word "may," and the words used -- use the word "will." There seems to be a discrepancy, so I'm suggesting a clarification on the use of "may" and "will." It's -- let's get the page -- page 50989.

If you look at the title of Section 82 -
I'm sorry, I have the wrong one. It's 82.13.

I'm sorry, I gave you the wrong one, 82.13. I

gave you the wrong one there. Just cross out the

(f)(1); it's just 82.13. Look at the title, and

then the sentence right after the title. It

appears to me to be a conflict. We might decide

it isn't, but put it down here for the moment.

82.14(f)(1), and this is one that was not discussed yesterday. But I noticed last evening, and maybe I'll ask the question, and probably should direct it to Jim Neton. On the medical screening with X-rays, are there other medical screening procedures that use radiation that may not be X-rays that should be included? Were there any nuclear medicine procedures or other imaging modalities, or is it only medical X-rays?

DR. NETON: There are no other modalities that I'm aware of as far as nuclear medicine, screens or something like that, that were required, occupationally required, in what I would consider like a surveillance-type program.

DR. ZIEMER: Therefore only -- so, then, as far as I'm concerned this can drop out. I was just raising the question as to whether that was restrictive in a way that it was not intended, so I think it can drop out.

82.18, this is another one that we did not discuss, but I picked up last night. It requires the use of NCRP (sic) models. There's nothing said about the fact that they should be current models. Is there a need for clarification? So right now I've just said to clarify that.

1 **DR. NETON:** Do you mean ICRP models? 2 DR. ZIEMER: ICRP; did I say NC? I meant 3 ICRP models. The statement is that ICRP models will be used. Do we want to say current ICRP 4 5 models or something like that? So that was my point in raising that. 6 7 Next item is 82.28(b), clarify the restriction concerning the availability of the 8 9 names of claimants to researchers. Clarify the 10 restriction concerning the availability of the names of claimants to researchers. 11 12 Then the last item on my list is answer the 13 three questions. 14 Now I'm aware that there is at least one and 15 possibly two that I simply couldn't remember or 16 hadn't made a note on, and so -- but some of you 17 will remember your own items from yesterday to 18 add to this list. So let me now open it up. 19 I think, Jim, you may have had one that I 20 simply couldn't remember. 21 DR. MELIUS: No, I've forgotten it also. 2.2 DR. ZIEMER: Good, I feel good about that, 2.3 then. If you don't remember it --2.4 DR. MELIUS: I don't.

DR. ZIEMER: Well, if it comes to you --

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1 does anyone remember the great idea Jim had 2 yesterday? 3 MS. MURRAY: I'll check back in my notes from yesterday and see, because I underline 4 5 things that look like --DR. ZIEMER: Good, okay. Are there some 6 7 others? 8 (No response) 9 DR. ZIEMER: Did you have one that I missed 10 here? Okay, please, Bob. MR. PRESLEY: Bob Presley. Yesterday we 11 came out on 82.16 where it says evaluate and 12 validate, and I had marked word "validate" on 13 14 there. We had some discussion on that. I don't 15 think that's up there. 16 DR. ZIEMER: Item two, Bob. MR. PRESLEY: I'm sorry. 17 18 DR. ZIEMER: I think that was the one that 19 you had raised, clarify the use of the term 20 "validated" in Section 82 -- is that the right 21 section? Is there another --MR. PRESLEY: 82.16 is the one I marked it 2.2 2.3 on. 2.4 DR. ZIEMER: Oh, okay. So is there another

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one, then?

1 DR. ANDERSON: Yes. I think you've caught 2 it. 3 DR. ZIEMER: Yes, that is 82.16. DR. ANDERSON: And there was also on --4 DR. ZIEMER: Actually, it looks like it's 5 The 82.16 is simply in the sentence. 6 7 It's not that --8 MR. PRESLEY: That's right, I'm sorry. 9 DR. ZIEMER: It actually is 82.10, but the 10 sentence just ahead of that ends with the words 82.16, and it makes it look like that's the 11 reference. 12 13 So what I'm asking now, we have this list 14 before us. Are there any things on the list that 15 you think we should not comment on? Are there 16 some things that aren't on the list that we 17 should comment on? 18 MR. PRESLEY: Bob Presley again. I had 19 marked 82.12, that title, will it be possible to 20 conduct dose reconstruction for all claimants --21 for all claims? We had a discussion on that. 2.2 DR. MELIUS: Can I follow up on that? I'm 23 not sure if this fits as a comment directly on 2.4 that, or is an answer to one of the three

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questions.

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But I believe we should comment on the limits of -- I don't think that the regulations in what we've heard so far have clarified, at least for my mind, when NIOSH will not be able to do an accurate dose reconstruction.

Now some of this backs into the whole issue of Special Exposure Cohorts, because one of our tasks in the legislation is to advise the Secretary when they're not able to do an accurate dose reconstruction, if there are groups of people for whom they cannot do it. And so it's hard to -- it may be that the Special Exposure Cohort regulations, if they come out there, would specify this.

But I think we ought to comment that this is something that the Board needs to continue to monitor and work with NIOSH on. I'm just very uncomfortable with the implication that we're going to reconstruct every dose. Well, you can do that, but how accurate will it be, and so forth. And I think we should say that that's something the Board needs to continue to follow and work with NIOSH on.

DR. ZIEMER: Jim, let me ask this. Are you suggesting that this might be a sort of general

making? In other words, it seems conceivable that dealing with that in detail might be in the guidance document as opposed to the rule, but that perhaps you would wish to have the Board comment in a general sense as opposed to adding something to the rule, some detail that spells out how they're going to make this decision, or -

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DR. MELIUS: I think there are options.

Whether -- I can't come up with wording that could be put in the regulation right now. I think that's difficult, particularly until they've done the Special Exposure Cohort. You can define it by -- from the other side, from the Special Exposure Cohort side, easier than you can say when can you not do it in terms of a regulation.

I think it's more likely through the manuals, the procedures, and so forth that we would be able to advise them and get clarification on that. I spent some time last night going through those sections of the manuals that we were given, handbooks, and trying to see if there was adequate information in there, and I

was not. I don't believe there is at this point in time. It is something that is very hard to define. How do you define when you can't do something is difficult.

But I think it's such a critical point that we need to comment on it in a general way, leaving a number of options; that this is something that would be clarified either in regulation, in procedure, or as we work with NIOSH on reviewing the dose reconstructions that they do. And I would hope that that would be one focus of our reviews.

DR. ZIEMER: It appears to me, then, that that concept might be included as part of our comments to question one -

DR. MELIUS: (Nods head)

DR. ZIEMER: -- which is does the interim rule make appropriate use of current science for conducting dose reconstruction, and in that context to raise this issue. Would that be agreeable?

DR. MELIUS: And I also think it pertains -I think it's question two that talks about the
efficiency of the process --

DR. ZIEMER: Yes.

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DR. MELIUS: -- because there's also how much effort do you put into doing this. The more effort, the greater accuracy or whatever. But it may be out of proportion to what you gain.

DR. ZIEMER: So let me ask you to take it upon yourself to make sure, as we word both question one and two, that that idea gets incorporated in an appropriate way, then. Thank you.

Other items?

MS. MUNN: No, I just wanted to comment on what Jim had just said.

I found last night when I was trying to put together my comments with respect to the three items we felt we needed to comment on that precisely because of the kinds of things you mentioned, Jim, I found these things overlapping and not as easy to quantify in terms of response to number one, response to number two, and response to number three. So I --

DR. ZIEMER: They probably aren't mutually
exclusive, yes.

MS. MUNN: So I wound up with language that did accommodate several of the things that you were speaking of; whether in the way you want, I

1 don't know. But I think they probably fall in 2 the general --3 DR. ZIEMER: We'll hopefully make use of that in just a little bit, then. Okay. 4 5 Again, let me ask if there are other items, then, that we need to identify here, separate 6 7 items? 8 (No response) 9 DR. ZIEMER: Is there anything on the list 10 that you would wish just to delete or not address? 11 12 (No response) 13 DR. ZIEMER: Some of these may turn out to 14 be as simple as clarify the use of the word 15 "may." MS. MURRAY: Yeah, that one -- let's me see 16 17 -- number four, is that about the closing after 18 60 days? That was one you had brought up yesterday. 19 20 No, the closing after 60 days DR. ZIEMER: 21 has to do with the clarification of the steps and 2.2 time line, item three. It's the time line thing. 2.3 MS. MURRAY: Okay. 2.4 DR. ZIEMER: That was the 60-day issue. 25 MS. MURRAY: I'm still looking.

DR. ZIEMER: If something else turns up, we can always come back. I'm not saying this is restrictive at this point, but it sort of gives us a road map of where we have to go today to sort of finish our task.

Do I sense that there's general agreement that this scopes what we have to do?

(No response)

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DR. ZIEMER: Now as we look at this list, a number of these items are very straightforward and simply require a sentence or two. To move Item J, for example, and we can get wording that's similar to what we said last time. We don't need to spend a lot of time here, but we'll have one of us work up that wording.

Clarify the use of the term "validated," clarify steps and time line for claimants, clarify use of the word "may." I guess almost everything, one through six, is probably fairly straightforward, a single sentence or two, probably, which means we would focus most of our attention on the three questions.

It occurs to me, though, there was an additional question -- maybe Dr. Roessler doesn't wish to raise it, but Gen, didn't you have -- you

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were going to talk -- or you talked to me about the use of the term "precision and accuracy." Is that something you don't wish to raise, or do wish to raise?

DR. ROESSLER: I think I have to now.
(Laughter)

- DR. ROESSLER: I will raise it, since you
  brought it up. It's not --
- DR. ZIEMER: Well, I thought maybe you were
  just being shy.
- DR. ROESSLER: It's not in the rule -- well, it's not in the part we were looking at. It's on page 50978, in the second question that we are going to deal with. And it's the use of the -
- DR. ZIEMER: Part of the question itself, is
  it not?
- DR. ROESSLER: It's part of the question itself, and it's the word "precision." And I guess before I talked this morning to a number of people, I would have thought that based on Larry's comments that they are going to try and produce the most accurate results possible; that should be accuracy. But now I'm not sure what the word should be. I think perhaps as we deal with that question we should look at the wording

1 on it. 2 DR. ZIEMER: Okay, thank you. 3 Wanda. MS. MUNN: That was one of the things I 4 5 addressed in my generalized wording, and what I said was the Board recognizes that if efficient 6 7 and expeditious consideration of claims is to be 8 made, absolute precision is not possible. 9 that's, I think, a response to the question they 10 wanted answered, and incorporates the recognition that the further down the precise road you go, 11 12 the more time and money are being incorporated in 13 the process. 14 DR. ZIEMER: So perhaps the issue will 15 emerge in an appropriate way as we word the answer to the question. 16 Okay. 17 Now let me ask how many of you, on your own, prepared sets of wording such as Wanda has done? 18 19 Wanda, you have some words. Robert, you 20 have some. Gen has some. Three sets of wording, 21 okay. 2.2 Wanda, did you prepare words for all three 2.3 questions? 2.4 MS. MUNN: Yes, I did, but I did not number 25 them one, two, three. They're all sort of --

| 1  | DR. ZIEMER: 1A, 1B, 1C, I guess.                  |
|----|---|
| 2  | MS. MUNN: Well, as Jim pointed out, some of       |
| 3  | them  |
| 4  | DR. ZIEMER: Okay. But you've tried to             |
| 5  | address them all?                                 |
| 6  | MS. MUNN: Yes.                                    |
| 7  | DR. ZIEMER: Robert, how about you?                |
| 8  | MR. PRESLEY: Yes.                                 |
| 9  | DR. ZIEMER: Gen?                                  |
| 10 | DR. ROESSLER: I mostly have two comments on       |
| 11 | two, the second question.                         |
| 12 | DR. ZIEMER: And the first and the                 |
| 13 | second, or  |
| 14 | DR. ROESSLER: No, just                            |
| 15 | DR. ZIEMER: Oh, just comments on number           |
| 16 | two, okay. I thought you meant -                  |
| 17 | DR. ROESSLER: I couldn't think of really          |
| 18 | anything to do with the first, other than using   |
| 19 | part of what we did last time.                    |
| 20 | DR. ZIEMER: Okay. Now let me ask the group        |
| 21 | if you would like to work on these three          |
| 22 | questions as a committee of the whole, or we can  |
| 23 | have each individual get their words up for us as |
| 24 | straw men to look at, or do you prefer to break   |
| 25 | into smaller groups?                              |

1 DR. MELIUS: I think the committee as a 2 whole would be better. 3 DR. ZIEMER: Okay, we can do that. Now I'm trying to see what the most 4 5 expeditious way to do this would be. I have a -Okay, go ahead. Henry's got a suggestion. 6 7 DR. ANDERSON: I was going to say, since I raised the availability of names, do we want to 8 9 just leave it kind of generic like this? Or do 10 you want us to propose specific language, because there are some --11 12 DR. ZIEMER: No, I want some specific 13 language on each of these, and --14 DR. ANDERSON: Because I have some specific 15 correction or additional language that would 16 clarify six that I -17 DR. ZIEMER: Right, If we have that, then we'll do that. 18 19 Let me suggest the following, and we'll take 20 a -- we're going to take a break. But I'll ask 21 each of those who have prepared something, if we 2.2 can get it -- is it readable if we photocopied it 2.3 onto a transparency? 2.4 MS. MUNN: Just barely. 25 DR. ZIEMER: Just barely. Well, the

1 alternative would be to take a transparency 2 during the break and have you write on the 3 transparency. MS. MUNN: Oh, please, do take this and make 4 5 a transparency of it. DR. ZIEMER: Let me ask Cori -- is Cori 6 7 still here? Well, we'll take a break and find 8 out during the break, because maybe what we can 9 do is take that, do a blow-up of it and then a 10 transparency, and get it up before us so we can see the words. And if we can do that on the 11 others, either hand-write them onto a 12 13 transparency, or we'll photocopy them. And then 14 after the break then we can work on the words. 15 Is that agreeable? Okay, let's take a 16 15-minute break. 17 (Whereupon, a recess was taken from 18 9:53 to 10:25 a.m.) 19 20 DR. ZIEMER: I'd like to call us back to 21 order. 2.2 We're going to work here a little bit in 2.3 real time. Cori has already typed in some sentences which will be straw men for the general

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big three questions. We also have some words for

the sort of brief sentence ones that we talked about. And I think right now these are being numbered in the order that we had them on the overhead, the first one being the moving of Section J from the background or the preamble of the rule-making, moving that into the body of the rule-making. And those words are being put up there even as we speak.

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I might ask you to open your books to 50981, Section J, because as I proposed the wording on this it would basically be to move the whole section, which includes the sentence about the public petitioning for changes in the rule-making, as well as the Board's review of proposed changes in the rule-making.

The words here now would say that the Board recommends that Section J, concerning changes to scientific elements underlying the dose reconstruction process, be moved to the main body of the rule, and then it should say so as -- the main body of the rule so as to formalize the updating process -- you need to insert a "so" after the word "rule" at the beginning of the line that you're on there, Cori - so as to formalize the updating process.

It is actually Section K, how will NIOSH make changes in the scientific elements underlying. It should be Section K.

MS. HOMER: Instead of J?

DR. ZIEMER: Instead of J, be moved to the main body of the rule so as to formalize the updating process. And I guess all we really need to say there is the updating process, including the role of the Board, and that'll parallel, or the role of the Advisory Board. We don't have to go through all the details.

Should we say Advisory Board?

UNIDENTIFIED: Yes.

DR. ZIEMER: Okay.

Now, Cori, why don't you go ahead and start working on that second brief one that you have while we look at --

MS. HOMER: Marie's working on it.

DR. ZIEMER: Oh, okay. Okay.

Let's look at those words. We can just take these -- some of these I think will be fairly simple.

Is there any comment on that first one there, just that first sentence? Just the first sentence up there. That's the first

1 recommendation. Nothing to do with the three 2 questions. That's just the moving of that 3 section on updating from the preamble to the body of the rule. It basically codifies the role of 4 5 the Board in changes. (No response) 6 7 DR. ZIEMER: Can I have a motion that we 8 adopt this as a recommendation? 9 DR. DEHART: So moved. 10 DR. ZIEMER: Second? UNIDENTIFIED: (Inaudible) 11 DR. ZIEMER: Formal discussion on this? 12 13 (No response) 14 DR. ZIEMER: Word changes, pro or con? 15 (No response) 16 DR. ZIEMER: All in favor, say aye. 17 (Affirmative responses) 18 DR. ZIEMER: Opposed? 19 (No response) 20 Now I might add that -- I'm not DR. ZIEMER: 21 proposing that we're going to adopt all these as 2.2 we go. I think some of the simple ones we'll 2.3 just do, but I want to save particularly our 2.4 actions on the three questions and so on till 25 after the public comment period today, in

1 fairness to hear other views. Some of these are 2 more sort of minor things in how the rule is 3 written right now. We had the item on clarifying the use of the 4 5 term "validated." And Roy, did you -- who rewrote that? Did somebody rewrite that? 6 7 DR. DEHART: That was number three. 8 DR. ZIEMER: That was number three? 9 MS. MURRAY: Just about done. 10 DR. ZIEMER: Just about done? What was number two? 11 12 MS. HOMER: (inaudible) 13 DR. ZIEMER: I meant number two from our 14 early list. I had on my list that number two was 15 the use of the word "validated." 16 MR. PRESLEY: That's right, 82.10(j). DR. ZIEMER: Yes. 17 18 DR. DEHART: Do you have the overhead? DR. ZIEMER: 19 Yes. MS. HOMER: Number two, Section 82.10, 20 21 paragraph (j), clarify the use of the term 2.2 "validated" on page 50988. 2.3 DR. ANDERSON: It seems to that what we 2.4 might want to do is ask -- that might be a good 25 one for a definition, that if they were to define

| 1  | "validated" up front in their list of            |
|----|--|
| 2  | definitions, then that would tell us what they   |
| 3  | mean.  |
| 4  | DR. ZIEMER: So possibly something as             |
| 5  | follows: The Advisory Board requests that the    |
| 6  | term "validated" be either defined or clarified. |
| 7  | DR. ANDERSON: Yeah.                              |
| 8  | DR. ZIEMER: Let's say "validated" as used        |
| 9  | in Section 82.10(j).                             |
| 10 | Now let me ask if that captures the idea,        |
| 11 | because this may be all we need to do on that.   |
| 12 | Does someone wish to move adoption of that?      |
| 13 | MR. PRESLEY: So moved.                           |
| 14 | DR. ZIEMER: Second?                              |
| 15 | MS. MUNN: Second.                                |
| 16 | DR. ZIEMER: Any discussion?                      |
| 17 | (No response)                                    |
| 18 | DR. ZIEMER: All in favor, say aye.               |
| 19 | (Affirmative responses)                          |
| 20 | DR. ZIEMER: Any opposed say no.                  |
| 21 | (No response)                                    |
| 22 | DR. ZIEMER: Carried.                             |
| 23 | The third one had to do with the time line.      |
| 24 | Is that correct?                                 |
| 25 | MS. HOMER: Clarify steps and time line for       |

1 claimants.

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DR. ZIEMER: Right. And Henry, did you have the words on that?

DR. ANDERSON: No.

DR. ZIEMER: Who did the time line words?
Did anybody?

(No response)

DR. ZIEMER: Okay, we'll come back to that
one, then.

What we had as number four was the use of the word "may" versus "will." If you'll turn to Section 82.13, and I'd like to ask Ted -- is Ted here? Yes, Ted, you explained that to me, I think, in a satisfactory way. We may be able to drop it. I'd like you to clarify that to the Advisory Board.

MR. KATZ: Sure, thanks.

So the title says, what sources of information may be used for dose reconstruction? And we want that to be inclusive of possibilities, but not binding NIOSH to using all sources under that title in each instance.

And then the following sentence, which Dr.

Ziemer noted sounds contradictory, it says NIOSH
will use the following sources of information for

1 dose reconstructions, but it has the caveat "as 2 necessary," so it in fact isn't binding NIOSH to 3 use all of those sources for each instance. So they're actually, I think, they're 4 5 consistent and appropriately organized. DR. ZIEMER: So I was comfortable with that 6 7 explanation, and felt we probably could drop 8 But I wanted, since we had it on the 9 floor, to see if there are those who wish to keep 10 it, or are you satisfied with what you just heard 11 as the explanation? 12 (No response) 13 DR. ZIEMER: Are there any that object to 14 just dropping that one? 15 (No response) 16 DR. ZIEMER: Without objection, it will drop 17 from our inventory of comments. 18 Thank you, Ted. We'll allow for those editorial corrections. 19 20 The intent was clear. Let's see. 21 Pardon me? 2.2 MR. PRESLEY: Bob Presley. We said we were 23 going to drop five. Is that correct? 2.4 DR. ZIEMER: I think the number that I had 25 it here on my list was four. Was it four? Was

four on our inventory list, the use of "may" and "will." Okay. We're just dropping that one.

I have number five as being the reference to the ICRP models. Might I suggest that on that one, rather than us trying to specify what ICRP models are to be used -- right now, as it appears in here, there would be no restrictions on what ICRP models are used, including the ICRP 2. And I think that's not the intent. The intent is to use current models, but it doesn't say that, either.

So perhaps the best thing that we could do right now is to ask NIOSH to clarify in some way the intent and meaning of the phrase "ICRP models," so as to -- without us trying to say what those models are. I know that the intent is to use current models, but current models may change. And how rapidly does NIOSH need to change when a new model comes out is also an issue.

I don't think we can solve that today, but perhaps the way to address this is simply to ask NIOSH to clarify their intent on the phrase "use ICRP models."

DR. ANDERSON: Could we put a modifier in

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1 front and say most appropriate, which would --2 DR. ZIEMER: Well, perhaps without us trying 3 to do the wording for them, simply ask the staff to clarify that. 4 5 Would that -- let me ask either Larry or Jim, is this something that you could clarify the 6 7 wording? We would simply ask that that be 8 clarified in the final document. DR. NETON: Yes, I think we could do that. 9 10 DR. ZIEMER: So that the recommendation --11 let's see where we are here. Okay, we'll just 12 pause a minute, because they're inputting some 13 other words for a later comment. 14 DR. MELIUS: I wrote up number three and 15 gave it to them, so --16 DR. ZIEMER: Okay, thank you. Number three 17 on the inventory list, yes. 18 DR. ZIEMER: Okay. Henry has suggested that 19 the words that just show up there under number 20 one be added to our original number one that we 21 adopted on the issue of moving Section K into the 2.2 body. Is that correct, Henry? This is simply 2.3 some words of amplification on the 2.4 recommendation. 25 (Reading) The rule does an admirable job of

1 providing an objective process for conducting 2 dose reconstruction. However, the assessment of 3 the adequacy of the exposure information will involve professional judgment; thus some 4 subjectivity. The Board plays an important role 5 through its review of such decisions on dose 6 7 reconstructions, and that role needs to be included in the rule. 8 9 DR. ANDERSON: I just thought we needed to 10 have a strong justification. Otherwise it sounds 11 very self-serving. DR. ZIEMER: So Henry, you are making this 12 13 as a motion to add this to what we adopted for 14 the number one comment? DR. ANDERSON: Yes. 1.5 16 DR. ZIEMER: Is there a second? DR. ROESSLER: Second. 17 18 DR. ZIEMER: Any discussion? 19 (No response) DR. ZIEMER: All in favor of this addition 20 21 to number one, say aye. 2.2 (Affirmative responses) 2.3 DR. ZIEMER: Any opposed, say no. 2.4 (No response) 25 DR. ZIEMER: Thank you.

1 Now the one that's going up there now is 2 number three, I believe, the time line issue. 3 Is this the one, Jim, that you prepared? DR. MELIUS: Yes. 4 5 DR. ZIEMER: So what's being typed there would be preceded by a pound sign three from our 6 7 inventory list. 8 (Reading) The Board recommends that NIOSH 9 clarify 82(m), (n), (o) in regards to the time 10 line for the claimants or representative of the claimants to provide information to NIOSH as to -11 12 13 DR. MELIUS: And to sign or submit. 14 DR. ZIEMER: And to sign or -- yeah, rather 15 than as. And to sign or submit form OCAS-1. 16 So while that's being typed before you, turn 17 to page 50988, right-hand column, and there are the Sections (m), (n) and (o). 18 19 So the words that Jim has proposed here now: 20 (Reading) The Board recommends that NIOSH 21 clarify 82.10(m), (n), (o) in regards to the time 2.2 line for the claimants or representative of the 2.3 claimants -- should that be representatives? 2.4 UNIDENTIFIED: Claimants or their 25 representatives --

1 DR. ZIEMER: -- of the claimants -- that 2 could be editorial -- to provide information to 3 NIOSH and to sign or submit form OCAS-1. NIOSH should ensure that the claimants or 4 5 representatives of the claimants have adequate time to obtain and submit additional information 6 7 to NIOSH. 8 That's the proposed wording. Was that a 9 motion, Jim, to -10 DR. MELIUS: Yes. DR. ZIEMER: -- to include that? 11 Is there a second? 12 13 MR. ESPINOSA: Second. 14 DR. ZIEMER: And seconded. 15 Let me ask -- you haven't said anything 16 other than clarify. Is there an issue on the 60-17 day, or do you think this will -- the 18 clarification that you're asking for will address the 60-day issue? 19 20 DR. MELIUS: (inaudible) the 60 days. 21 Remember, the 60 days is (inaudible) how you 2.2 interpret -2.3 MS. NEWSOM: Would you use your mike, 2.4 please?

DR. MELIUS: Sorry. It's as much how you

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1 interpret (m), (n), and (o), and Ted and I 2 disagree on some of those paragraphs, but I think 3 it's just a matter of clarification. DR. ZIEMER: So this would at least point 4 out that there's some degree of ambiguity there 5 that needs to be looked at. 6 7 Further discussion? 8 (No response) 9 DR. ZIEMER: Are you ready to act on motion 10 to adopt this recommendation? Yes, Wanda. 11 MS. MUNN: One minor comment. When we were 12 13 talking about it originally, we said we wanted 14 clarification of the steps and time line. 15 want to include --16 DR. ZIEMER: Yes, I have that same wording 17 in my notes. 18 Jim and the seconder, do you object to adding the word "steps?" 19 20 DR. MELIUS: No. 21 DR. ZIEMER: The steps and time line in line 2.2 one? 2.3 DR. MELIUS: I probably said it yesterday 2.4 and forgot, but --2.5 DR. ZIEMER: That's the one you forgot, yes.

| 1  | Steps and time line. And an editorial change,   |
|----|---|
| 2  | let's say again the Advisory Board at the       |
| 3  | beginning of the sentence.                      |
| 4  | Without objection, this is the motion, then.    |
| 5  | DR. MELIUS: Could I if we're                    |
| 6  | editorializing, actually the wording, I think,  |
| 7  | used in the regulation is "authorized           |
| 8  | representative of the claimant," is the         |
| 9  | DR. ZIEMER: So noted. A friendly editorial      |
| 10 | amendment, without objection, will be included. |
| 11 | Are we prepared now to act on this              |
| 12 | recommendation?                                 |
| 13 | All those in favor will say aye.                |
| 14 | (Affirmative responses)                         |
| 15 | DR. ZIEMER: All opposed.                        |
| 16 | (No response)                                   |
| 17 | DR. ZIEMER: Eyes above the nose, as they        |
| 18 | say. That didn't work, did it?                  |
| 19 | MR. ELLIOTT: I laughed.                         |
| 20 | DR. ZIEMER: I was just seeing if                |
| 21 | everybody's awake.                              |
| 22 | DR. MELIUS: And by the next meeting, your       |
| 23 | staff better start laughing when you laugh,     |
| 24 | right?  |
| 25 | (Laughter)                                      |

1 DR. MELIUS: Speak to them, Larry. 2 MR. ELLIOTT: Point well taken. 3 DR. ANDERSON: Cori, did you get my number six? 4 That's a good question. 5 MS. HOMER: MS. MURRAY: Uh-oh, is that this one 6 7 (indicating)? 8 (Laughter) 9 DR. ZIEMER: We have punts on one, two, 10 three. Number four was dropped. Number five was the ICRP model one. Where is number five? 11 MS. HOMER: (inaudible) 12 DR. ZIEMER: Okay, thank you. We'll pause 13 14 for a moment. 15 Okay, we're back to number five on the 16 inventory list, which was Section 82.18. In 17 referring to ICRP models, the Advisory Board --I'll give you some words here -- In referring to 18 ICRP models in Section 82.18 -- start the 19 20 sentence over. 21 In referring to ICRP models in Section 82.18 22 -- actually, I already don't like this sentence 2.3 because I know what's going to happen. This is 2.4 going to end up as a dangling participle. 25

(Laughter)

1 DR. ZIEMER: And I want to advise everyone 2 that dangling participles are one thing that I 3 hate. I jump on my graduate students for them all the time, and I can assure you that almost 4 5 any sentence beginning with I-N-G, including the documents we reviewed yesterday, are full of 6 7 dangling participles, which someone needs to deal 8 with. So this sentence is going to be changed 9 before I even get it out. We're going to go back 10 to the Advisory Board -- we're going to get rid of the dangling participle before it dangles. 11 12 MS. MURRAY: You can cut and paste later, 13 Cori. 14 DR. ZIEMER: Sorry.

The Advisory Board recommends that Section 82.18 concerning the use of ICRP models be clarified so as to clearly indicate the models that NIOSH intends to use.

Now let me ask somebody to move this formally, and we'll get it on the floor here.

DR. ROESSLER: So moved.

DR. ZIEMER: Seconded?

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MR. PRESLEY: (inaudible)

DR. ZIEMER: And seconded.

The intent here is -- let me editorialize --

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the intent here is not to ask them to list the models in the document, but rather to indicate how they decide what models to use. And I think the intent is to use current models, but if we ask them to put the word "current" in, then that locks them into changing every time, immediately when a new model comes out. And there has to be some process by which the use of even new models as they come out is handled.

So perhaps we simply ask them to clarify, and I think Jim and Larry have indicated that the might come up with some appropriate words to make sure that everybody understands it's the current models within reason, so to speak. And does this wording cover what we want to say here?

And I think Wanda, do you have you hand up?

MS. MUNN: Yes, I do. In the second line, could we -- don't type anything yet, Cori -- could we say indicate which models NIOSH intends to use and the rationale for that choice?

DR. ZIEMER: I like that. I'll take that as a friendly amendment if the mover and seconder will assume that to be a friendly amendment.

MS. HOMER: To indicate which?

MS. MUNN: Which, take out "the," and you

1 can take out "that." Which models NIOSH intends 2 to use, comma --3 DR. ZIEMER: Yes? DR. ROESSLER: I thought of suggesting that, 4 5 too, but then to me "which" is very specific. me it would mean that they'd have to tell us. 6 7 That's what I -MR. PRESLEY: DR. ROESSLER: I think it was better to 8 9 leave it -- I know what Wanda's saying, but I'm 10 afraid the "which" can be interpreted to mean 11 that they have to tell us the numbers or the exact models. 12 13 DR. ZIEMER: That's not the intent here 14 either, is it, Wanda? 15 MS. MUNN: No, it isn't. 16 DR. ZIEMER: So that friendly amendment 17 turned out not to be so friendly, then. 18 MS. MUNN: That's true. It just screwed up 19 the whole thing. 20 DR. ZIEMER: It's rapidly turning to an 21 adversarial amendment. 2.2 DR. ROESSLER: What words did --2.3 MS. MUNN: We don't want that. 2.4 DR. ROESSLER: What words did you use when

you had the dangling participle? I think there

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1 were some other words in that section that might 2 have worked better. DR. ZIEMER: Well, I don't want to return to 3 that. 4 DR. ROESSLER: No, I'm not saying to use the 5 I-N-G word, but on your paper there you had 6 7 something written after that that might work. DR. ZIEMER: Well, I originally on my notes 8 9 had that we want them to specify that the most 10 current models are to be used, but I don't think 11 we want to specify here the exact wording of this. I think the intent here would be to ask 12 13 them to word it in such a way that it's clear 14 that they are using current models, and have a 15 framework for incorporating new models as they 16 come into play. MS. MURRAY: Could you just say current 17 18 models? 19 DR. DEHART: Aren't the people who are going 20 to answer that here, hearing our comments? 21 MR. ELLIOTT: This is sufficient. 2.2 DR. ZIEMER: Yeah, if this is sufficient, it was simply to ask them to clarify. And part of 2.3 2.4 their clarification may be we're not going to 25 tell you the model numbers, but we're going to

tell you more the intent and the process.

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So maybe we're all right as we -- did the mover and seconder agree that this is what they really were intending to move and second? Yes?

MR. PRESLEY: That's fine.

DR. ZIEMER: We finally got their motion out of them.

Ted, now a comment.

MR. KATZ: Is it all right, Dr. Ziemer, if I just make a comment?

I'm a little bit concerned about this language, because the public might read this -- despite the fact that we know what you're driving at here, the public might read this as the Board saying, in effect, we want you to specify the models. And that could be a problem, then, in terms of producing a final rule, and maybe that rule being challenged if someone in the public then says, well, NIOSH didn't do what its Advisory Board said.

DR. ZIEMER: Thank you. It's certainly not our intent to do that, so we may need to think of some words to modify this to make it clear that we simply want to -- we want to indicate -- want them to indicate how they will decide what models

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to use, I guess is the issue, right?

Jim, can you help us with some words here?

DR. MELIUS: Well, I don't have wording, but I think what we want to do -- we have in our first recommendation a process for how they would change to a new model.

DR. ZIEMER: Yes.

DR. MELIUS: It would come back to the Board and go through that process. So I think we want to just indicate for this current -- at the current time, presently, what models they will be using. I think we want some language just to indicate that they should be scientifically -- reflect current state of the science in this area.

DR. ZIEMER: So you're suggesting that this might even go so far as to say so as to clearly indicate that they intend to use current models at the time that the rule is adopted?

DR. MELIUS: Yeah.

**DR. ZIEMER:** Because there is a provision for changing the models.

DR. MELIUS: Right. And I don't think -- are there any models that are just very recently adopted, that there'd be some concern or question

1 about? DR. ZIEMER: Ted, can you answer that? 2 3 MR. KATZ: We don't think so. I think that'll be all right. 4 5 UNIDENTIFIED: That's what you're using (inaudible). 6 7 DR. ANDERSON: Is there any risk that in the 8 future ICRP won't be the ultimate source of 9 models, and that there might well be a -10 DR. ZIEMER: Well, that --DR. ANDERSON: I mean, this ties them into -11 12 - it's you're going to use ICRP. 13 DR. ZIEMER: Well, they're currently tied 14 into that here anyway, and that's pretty 15 problematical. I don't know that we should try 16 to deal with that. 17 DR. MELIUS: Yeah, but again, the process --18 DR. ZIEMER: Right. -- would allow that to be 19 DR. MELIUS: 20 (inaudible) -21 DR. ZIEMER: Right. I think it's a good 2.2 suggestion. 2.3 Why don't you just give us a motion to amend 2.4 here, and what words would you put in there to

indicate that NIOSH -- to clearly indicate that

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| 1          | NIOSH intends to use current models at the time  |
|------------|--|
| 2          | of the adoption of the rule-making, or something |
| 3          | like that?                                       |
| 4          | DR. MELIUS: Yeah, I think just to clearly        |
| 5          |  |
|            | indicate that NIOSH intends to use current ICRP  |
| 6          | models.  |
| 7          | DR. ZIEMER: Do we need to say at the time        |
| 8          | of the adoption of the rule-making, or           |
| 9          | DR. MELIUS: Okay.                                |
| 10         | DR. ZIEMER: No?                                  |
| 11         | DR. MELIUS: I don't think so, but we've          |
| 12         | I don't have any objections to that.             |
| 13         | DR. ZIEMER: Let's just formalize this.           |
| 14         | This is a motion to amend.                       |
| 15         | Is there a second?                               |
| 16         | DR. DEHART: Second.                              |
| 17         | DR. ZIEMER: Any discussion?                      |
| 18         | (No response)                                    |
| 19         | DR. ZIEMER: All in favor to amend, say aye.      |
| 20         | (Affirmative responses)                          |
| 21         | DR. ZIEMER: Any opposed?                         |
| 22         | (No response)                                    |
| 23         | DR. ZIEMER: Now the motion before us is          |
| 24         | number five, as written. Okay, let's vote.       |
| 25         |  |
| <b>Z</b> J | All in favor, say aye.                           |

1 (Affirmative responses)
2 DR. ZIEMER: Any opposed?

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(No response)

**DR. ZIEMER:** The motion carries. Number five is adopted.

Let's see, four was dropped. Can we move -where you have number one there, where you say
add, can you do a cut and paste now and stick
that up with the original part of number one so
we can see that?

Now you can move that number one up to where the original one was. Pound sign one, right.

Pound sign one at the beginning. We're sort of distinguishing between the three questions in the inventory numbers here. And then you can drop the word "add" there at the end, then.

This has already been adopted. We just wanted to get it all together. Did we pass the second -- yeah, I thought we did. But I think there was -- somebody wanted to make a comment.

Ted, did you want to make a comment on this?

MR. KATZ: I would, thank you. You may want to consider the statement in there, all methods proposed -- this is in the second paragraph -- will result in significant bias in favor of the

1 claimant. And -2 DR. ZIEMER: Wait, hold on. We're not there 3 yet, Ted. MR. KATZ: Okav. 4 5 DR. ZIEMER: That's a separate item. That's a separate item. 6 7 Sorry. MR. KATZ: 8 DR. ZIEMER: Did you have a comment on just 9 that first paragraph? Okay, that's fine. 10 One, two, three; four was dropped; five we've done. Six is the Privacy Act issue and the 11 researchers. And Henry, is this your --12 DR. ANDERSON: 13 Yeah. 14 DR. ZIEMER: Okay. Henry is making a motion 15 that we say except as provided under -- this 16 would say the Advisory Board recommends that Section 82.28(b) be revised so as to state that; 17 and then the words would be, quote, "except as 18 19 provided for under the Privacy Act, researchers will not receive names," et cetera. 20 So that's your motion? 21 2.2 DR. ANDERSON: Yes. 2.3 DR. ZIEMER: Is there a second? 2.4 MR. ESPINOSA: Second.

DR. ZIEMER: Now wasn't there already a

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| 1  | Privacy Act statement in there?                   |
|----|---|
| 2  | DR. ANDERSON: It starts in there, yes.            |
| 3  | DR. ZIEMER: So are you suggesting that            |
| 4  | paragraph (b) be replaced by these words, or how  |
| 5  | would the   |
| 6  | DR. ANDERSON: No, it's the end. It's the          |
| 7  | second it's the last sentence. You could          |
| 8  | delete  |
| 9  | DR. ZIEMER: Okay. It repeats the Privacy          |
| 10 | Act issue, or what?                               |
| 11 | DR. ANDERSON: Yes, right. And my                  |
| 12 | understanding was that NIOSH wanted to make it    |
| 13 | clear that except for the Privacy Act,            |
| 14 | categorically no names would be released.         |
| 15 | DR. ZIEMER: Okay. So basically this               |
| 16 | motion, if adopted, does not restrict the         |
| 17 | releasing of names, but only says it will only be |
| 18 | done within the provisions of the Privacy Act.    |
| 19 | DR. ANDERSON: Yes.                                |
| 20 | DR. ZIEMER: Rather than the complete              |
| 21 | exclusion.  |
| 22 | DR. ANDERSON: Yeah.                               |
| 23 | DR. ZIEMER: I think that was the intent,          |
| 24 | right? Okay.                                      |
| 25 | DR. MELIUS: Can I offer just a friendly           |

1 amendment to clarify that? That we recommend 2 that the last sentence of Section -3 DR. ANDERSON: Yes. DR. MELIUS: -- 82.28 be --4 5 DR. ZIEMER: Thank you. That, without objection, will be added. 6 7 MS. HOMER: That this will be added to the 8 last sentence? 9 DR. ANDERSON: Yes. 10 DR. ZIEMER: Section -- put it after the (b), I think, Cori, Section 82.28(b) --11 DR. MELIUS: The last sentence. 12 13 DR. ZIEMER: -- last sentence be revised so 14 as to state. Okay. 15 This now is the motion before us. Any other 16 discussion? 17 Wanda, thank you. 18 MS. MUNN: I guess I have some concern that 19 there are other identifying demographic items 20 which would identify individuals other than just 21 their names. For example, anybody who knows my 2.2 Social Security number can find out who I am. 2.3 And so I would suggest that possibly the 2.4 insertion of "or other clearly identifiable data" 25

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DR. ZIEMER: Before we take that as a formal motion, let me ask you a question. Does the Privacy Act itself cover that kind of issue so that this broad statement takes care of that?

Jim, and then Larry.

DR. MELIUS: I think the preceding sentence actually addresses Wanda's concerns. The problem is that it wasn't clear that the last sentence was -- that names were specifically covered, but other information, as I read that sentence, would be; other identifying information would be covered. So I think the preceding sentence takes care of your concern.

MR. ELLIOTT: The Privacy Act does address confidential information.

DR. ZIEMER: Including --

MR. ELLIOTT: Not only name, Social Security number, any personal identifiable information like job title. If that's the only job title in that plant, we could not use that. So it addresses all of that.

DR. ZIEMER: Thank you.

Further comments or -- yes, Henry.

DR. ANDERSON: Yeah, my druthers would be to have deleted that sentence, because I think it's

all covered in the first part. And I would agree, I think one could interpret this to mean that everything else would be fair game, although I think legally you would be bound by the -- if you said it was confidential, or identify -- personal -- we could say researchers will not receive names of claimants or covered employees or other identifying information. I don't know.

MR. ELLIOTT: If I could offer a suggestion and a comment here. We understand what your concern is with this language. If you simply just ask us to clarify the intent of that passage, we can do so, and we have to do so with guidance from general counsel and the Privacy Act officer, okay?

DR. ANDERSON: Yeah.

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MR. ELLIOTT: Now this is kind of a tricky entry here, and I need to get clearance and guidance from both of those sources of support. So don't lock me into not adding a sentence you want to see added, because it could go counter to what -

DR. ZIEMER: Yeah. So what you're saying is that it may be that legally this is not the right sentence anyway to put in there, or there may be

| 1  | a better way of doing it. And the way to get   |
|----|--|
| 2  | around that, then, would simply be to ask      |
| 3  | DR. ANDERSON: The last sentence be             |
| 4  | clarified.                                     |
| 5  | DR. ZIEMER: that this be clarified.            |
| 6  | DR. ANDERSON: As to the intent of it.          |
| 7  | MR. ELLIOTT: That's what you want.             |
| 8  | DR. ANDERSON: Yeah.                            |
| 9  | DR. ZIEMER: Do the mover and seconder wish     |
| 10 | to withdraw that motion and make a substitute  |
| 11 | motion?  |
| 12 | DR. ANDERSON: Yes, I'll withdraw.              |
| 13 | DR. ZIEMER: The motion has been withdrawn.     |
| 14 | Do you wish to give us a substitute motion,    |
| 15 | such as the Advisory Board recommends that     |
| 16 | Section 82.28(b), last sentence, be clarified? |
| 17 | DR. ANDERSON: Yes.                             |
| 18 | MS. HOMER: Be clarified, period?               |
| 19 | DR. ZIEMER: Be clarified so as to what? Or     |
| 20 | clarified in regards to yes?                   |
| 21 | DR. MELIUS: In regards to the coverage of      |
| 22 | the Privacy Act for that information?          |
| 23 | MR. ELLIOTT: That's fine.                      |
| 24 | DR. ANDERSON: Yeah, that's good.               |
| 25 | DR. ZIEMER: Okay, who's moving that?           |

| 1  | Henry, that's your new motion, right?           |
|----|---|
| 2  | DR. ANDERSON: I will, yes.                      |
| 3  | DR. ZIEMER: Thank you. Who seconded             |
| 4  | Henry's new motion?                             |
| 5  | MR. ESPINOSA: Second.                           |
| 6  | DR. ZIEMER: Okay. In just a moment you'll       |
| 7  | get to see what your motion is.                 |
| 8  | DR. ANDERSON: That got it. That's it.           |
| 9  | DR. ZIEMER: Thank you.                          |
| 10 | Any discussion on this?                         |
| 11 | (No response)                                   |
| 12 | DR. ZIEMER: All in favor, say aye.              |
| 13 | (Affirmative responses)                         |
| 14 | DR. ZIEMER: Any opposed?                        |
| 15 | (No response)                                   |
| 16 | DR. ZIEMER: Motion carries. Thank you.          |
| 17 | Now have we covered all the inventory items?    |
| 18 | DR. ANDERSON: I think so.                       |
| 19 | DR. ZIEMER: With the exclusion of the three     |
| 20 | broad questions? Okay.                          |
| 21 | Now I'd like to have us get the words of the    |
| 22 | the proposed words of the three broad           |
| 23 | questions before us. I think the word "interim" |
| 24 | there, does that start number one?              |
|    |   |

MS. HOMER: Yes, it does. Well, it starts

what Ms. Wunn -- Ms. Munn submitted to me. Excuse me.

DR. ZIEMER: It's almost easier to say
Wanda, isn't it?

MS. HOMER: Wanda.

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DR. ZIEMER: Yes, Wanda, please. Could you repeat what you just said?

MS. MUNN: Those two paragraphs were intended to cover all three of the issues that were placed before us.

DR. ZIEMER: Right, thank you for clarifying that.

In a sense, Wanda has integrated her comments to cover the three paragraphs. We need to determine whether or not we should simply say that we're commenting on all three with sort of a set of statements, or whether we will in fact at some point break them back down into three pieces. But we're looking at, I think, three paragraphs -- for the moment, let's put a one there, if we might, just -- so we have one, which right now is in two paragraphs; and then the number two there is the next part.

So that's what we would have before us as a sort of starting points as general comments on

the three questions.

MS. MUNN: Actually, I believe we have
number three also, don't we? I think that's --

DR. ZIEMER: Is there a --

MS. MUNN: Someone wrote --

DR. ZIEMER: Well, that number three is -oh, yes. Okay, right. Okay. Now we have -right now we do have those three general sets of
comments.

Now just for procedural matters let me just ask someone to move those three, and we'll just have them before us, and then we'll discuss them.

DR. DEHART: I move.

DR. ZIEMER: And we're not going to -- as I said, I'm going to specify that we not vote on these. We may not vote on them till after lunch, even. But I want to get them out here, discuss them.

I also want to have opportunity for public comment not only on these items, but just other comments that might be -- again, reminding members of the public if you do wish to comment and haven't done so, please get your name on the comment roster. We're actually scheduled for public comment, I think, in 15 minutes.

1 So we have a little time for some 2 preliminary discussion here. DR. DEHART: Are you wanting a motion? 3 DR. ZIEMER: Yes. 4 5 DR. DEHART: I would propose the motion. DR. ZIEMER: 6 Okay. 7 MS. MUNN: Second. 8 DR. ZIEMER: Motion to adopt these four 9 paragraphs. Is there a second? 10 MS. MUNN: Second. DR. ZIEMER: Okay. Now discussion. 11 And for 12 convenience, you might want to just talk about 13 them a paragraph at a time, although realizing there's a sense in which there's some integration 14 15 here it may not be fully possible. Comments? Roy, please. 16 DR. DEHART: I don't know whether it's 17 18 appropriate to try to incorporate a single answer to the three questions, but I like the concept of 19 20 doing that. And in fact, item number three 21 listed there is appropriately covered by the 2.2 second paragraph. 2.3 MS. NEWSOM: Dr. Ziemer, might I suggest you 2.4 read those into the record?

DR. ZIEMER: Okay, read them into the

record. Let me ask the officer of the Board, the Federal officer, to read them into the record.

New title.

MR. ELLIOTT: Okay.

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DR. ZIEMER: I was trying to think of that official title, but I knew you were a Fed and I knew you were some kind of an officer, so --

MR. ELLIOTT: You can call me whatever you
wish to call me.

(Reading) Number one, interim proposed rule 42 CFR Part 82 makes appropriate use of current science in reconstruction of radiation dose scenarios to the extent practicable. The Board recognizes that if the efficient and expeditious consideration of claims is to be made, absolute precision is not possible. All methods proposed will result in significant bias in favor of the claimant, and in that regard are consistently conservative.

The process for involving the claimant is fair and provides multiple opportunities for interaction with the involved agencies. Indeed, in cases where acceptably dependable exposure data do not exist, the claimant or claimant family may be the only source available to

provide information that could form the basis for dose reconstruction. This circumstance automatically injects a high but unavoidable level of uncertainty into the calculation.

However, we view the proposed methods for addressing these cases to be as equitable as reasonably achievable at this time.

Number two, the interim rule outlining methods for radiation dose reconstruction uses a number of innovative, scientifically sound, and implementable techniques which make the dose reconstruction process efficient without the loss of proper decision-making information.

Number three, the Board agrees that the interim rule implements an appropriate process to involve the claimant, from the formal claims application to interview to feedback on the specific dose reconstruction.

DR. ZIEMER: Thank you. So this is the motion before us.

It occurs to me that we have the makings of a new acronym here, AERA, As Equitable as Reasonably Achievable. Why not.

(Laughter)

DR. ZIEMER: Okay, let's have discussion.

1 Is implementable not a word? Why is that under -3

MS. HOMER: It doesn't recognize it.

DR. ZIEMER: It doesn't recognize it as a word. Okay.

DR. ROESSLER: It doesn't recognize NIOSH, either. So what?

(Laughter)

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DR. ZIEMER: Jim, did you have a comment?

DR. MELIUS: Yeah. I object and don't believe that the third sentence of the first paragraph is accurate. I don't believe that all methods result in significant bias in favor of the claimant and et cetera. I think there may be some that are -- I guess I don't like the term "bias," but depending on how it's defined, but I think there are some parts of the methods that are conservative, but certainly not all of them So I would actually propose striking that I don't believe it's necessary to sentence. answer certainly the first question.

I also object to the -- it really it starts with the third sentence of the second paragraph, which is also the last sentence. I don't believe that using a claimant or claimant family as a

source of information automatically injects a high level of uncertainty. An easy example of that would be that the claimant or claimant's family points out that John Doe worked with Bob Smith, and that that then leads NIOSH to look at John -- look at Mr. Smith's exposure records and use them to reconstruct a dose estimate for John Doe. So I think there's a lot of circumstances there where that would not automatically have a high level of uncertainty. And again, I don't think that that section is necessary here.

DR. ROESSLER: I'd like to agree with Jim on the first point in particular. And I think one

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DR. ROESSLER: I'd like to agree with Jim on the first point in particular. And I think one way to get rid of what I think are two objections. The "all methods" -- this is in the third sentence in the first paragraph there -- that "all methods" part and the significant bias. I really don't like the word "bias" in here, because it has a scientific meaning and it has a kind of a general meaning. So I think his suggestion to just delete the paragraph might work. Or if not, we can change some of the words -- sentence, that last sentence.

DR. ZIEMER: Let me ask the Board at this
time, do you wish the Chair to entertain specific

2 sort of a general discussion on all these points 3 and then do changes all at once? 4 DR. DEHART: Prefer a general discussion. First, and just leave the words 5 DR. ZIEMER: for the moment, and then ask for formal motions 6 7 for amendments? Okay. 8 Is that agreeable, and we'll come back and -9 DR. MELIUS: Yeah. 10 11 DR. ZIEMER: Okay, sort of get general 12 comments first, and then we can entertain 13 changes. 14 MR. PRESLEY: Bob Presley. 15 DR. ZIEMER: Bob. 16 MR. PRESLEY: In the first sentence up 17 there, would you want to say scientific 18 technologies in reconstruction? It's just 19 wordsmithing, but it puts the words "science" and 20 "technology" there. That's just a thought. 21 DR. ZIEMER: Thank you. Keep that thought. 2.2 I believe the reason that was used is because 2.3 that's the terminology used in the question. 2.4 specific question is does the interim rule make appropriate use of current science, and I believe 25

motions to change this, or do you prefer to have

that was why the word is used. That does not preclude us from saying current science and technology or something, but I believe that's the reason.

Okay, other comments?

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DR. MELIUS: This is more in terms of an additional subject that should be discussed, though it would fit to some extent in the second paragraph that's up there under number one.

And again, going to the second sentence, indeed, where cases where acceptably dependable exposure data do not exist, I would like to add some section there, as I mentioned before, where we -- I have concerns about the ability of the method to, or I guess the lack of clarification on the part of NIOSH in these current regulations and procedures, on how they will deal with the situation where there is limited information available and their ability to accurately reconstruct the dose. And then again, this gets into the issue of the Special Exposure Cohorts.

And I would be in favor of sort of working from that point there, the start of that second sentence, to talk about some of the uncertainties and difficulties in that area. I think without

1 necessarily focusing on the claimant or the 2 claimant family as being the source of some of 3 these issues, but rather that it's a general issue that the Board and NIOSH have to wrestle 4 5 with in terms of doing these dose reconstructions, and that there's a limited 6 7 ability to do that. 8 At some point NIOSH will not be able to do 9 that, and we're presuming that the Special 10 11

Exposure Cohort provisions will step in at that point, but we really haven't seen that yet.

DR. ZIEMER: Thank you for those comments. And Jim, perhaps we might consider adding a couple of sentences that might be developed over lunch that could -- rather than try to do that right here as we sit. It's a good idea, and maybe get a straw man couple of sentences, which if you would be willing to think about that.

DR. MELIUS: If it can fit on a small napkin, we'll --

Right, thank you. DR. ZIEMER: We'll limit the size of the napkins.

Wanda.

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MS. MUNN: The author would like to suggest a potential change for that third sentence of the

1 first paragraph that was objected to. Would it 2 be acceptable to say the methods proposed tend to 3 favor the claimant, and in that regard are consistently conservative? Would that be 5 acceptable? DR. ZIEMER: You're asking the group in 6 7 general? MS. MUNN: Yes. 9 DR. ZIEMER: And again, without doing 10 revisions at the moment, get that thought down, and then we can come back. And maybe others want 12 to think about that for a little bit, as well. 13 14 15 16

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DR. ANDERSON: Yeah, instead of the consistently conservative, I'd probably use are consistent with an occupational illness compensation program, or the concept, something like that. Because that's in the question, and I think the idea here is the intent of the law. This is consistent with that.

DR. ZIEMER: Okay. Keep that, Henry. that ready.

Other comments on any of the paragraphs? Yes, Gen.

DR. ROESSLER: I'm not clear what we're doing. Are we looking at number one as being the answer on all three? Or are we considering all three steps now with number two and number three specifically answering questions two and three?

DR. ZIEMER: Well, I think as was indicated earlier, there's a sense in which perhaps the first two paragraphs sort of answer all three, so right now it's not fully separated out. And it may be, depending on how we modify and so on, that we will just have a set of comments that aren't necessarily one, two, and three, but we say that in response to the three questions we have the following comments, and we don't necessarily say they're one to one. That's a possibility.

I think Wanda, who's the original composer of the first two paragraphs, has indicated that she has integrated her comments in a sense that they sort of overlap, as I understood it.

Wanda, is that not correct?

MS. MUNN: (Nods head)

DR. ZIEMER: Let's not look at these at the moment as being in one-to-one correspondence with the three questions in the NIOSH document.

Are there other comments at this point?
(No response)

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DR. ZIEMER: If there are not, I'm going to declare a recess on our deliberations on this, without objection. We are not tabling it, but are simply -- will come back. We want to have opportunity for public comment on this or other matters before the lunch hour, have an opportunity for you to give further thought to these words during the lunch hour. And then my proposal would be that we come back, either with specific modifications or actions, right after lunch.

We have no sign-ups. Let me just ask if there are any comments from the public.

Yes, please. Richard, if you would use the front mike, and it will be easier for everyone.

MR. MILLER: Hi, it's Richard Miller.

I just have one question. As I was reading your discussion, what is the plan for -- in these rules and as the committee looks at them, if you have a situation where DOE has calculated a dose, lo and behold, and the estimate that they come up with that may be in the employee's record winds up being higher based on the methods that the DOE used than the methods that are applied through the NIOSH dose reconstruction process, will you

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use the NIOSH outcome or the DOE outcome in that circumstance?

DR. ZIEMER: I think we'll have to have the staff answer that. But before they do, let's also recognize that the DOE number will be a point number. I think the NIOSH number's going to be a distribution with a mean and several standard deviations. And I guess your question would be what if that 95 percent number is still, say, less than the DOE number?

MR. MILLER: Right, if you wind up --

DR. ZIEMER: Point number?

MR. MILLER: Right, if you wind up -- if 99 (sic) percent is what's used as the upper confidence limit, and you wind up with a delta between that and what DOE came up with as their estimate.

DR. ZIEMER: Yes. And here's Jim to -- Jim
Neton to answer that.

DR. NETON: It's our intent that we would use our estimate, not the Department of Energy estimate, given the fact -- and I think you're alluding to a scenario where we would actually not use this efficiency process, and we would drop out and have to do a complete dose

reconstruction on the individual rather than do these conservative estimates at the two ends. And if we got to that point, we would use our estimate, which would be not a point estimate as the Department of Energy uses, but it would be an estimate with an uncertainty distribution about it.

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Also, it is unlikely that there will be a one-to-one correspondence, because the Department of Energy typically only from the internal dose perspective calculates effective dose equivalent. They don't normally calculate -- well, they will calculate the dose to the highest exposed organ. For instance, many of the organs that we're calculating doses for are not estimated doses in the Department of Energy system.

Also, when the IREP program runs, it uses equivalent dose, not effective dose. And then the radiation weighting factors that are applied are applied as distributions within the IREP program, which adds another level of uncertainty to the estimate, thereby essentially increasing the claimant's chance or probability of compensation.

So there's a number of differences that

exist.

MR. MILLER: Oh, I think that's right, Jim.

I just was posing the hypothetical, because you could easily wind up with an annual dose. As you -- and you're correct, the IREP model inserts a dose for each year throughout the latency period up to the point of the cancer.

DR. NETON: Right.

MR. MILLER: And so you're introducing a distribution for each year on a, I guess, a committed basis, but not an effective dose basis.

DR. NETON: Right. And there are no annual internal doses calculated in the Department of Energy system. They are assigned in that year, but they're calculated over a 50-year time period.

MR. MILLER: That's today. But prior to 1990 -- and correct me if I'm wrong -- the Department of Energy never calculated committed dose. And it only was a result both of ICRP -- the new ICRP that came out and the DOE's Price-Anderson regulations that were promulgated that required the calculation of committed effective dose.

DR. NETON: That's correct.

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MR. MILLER: But that's only post-1990, and so I guess how would you deal with that if it was pre-1990?

DR. NETON: Pre-1990 annual doses were not calculated either for an internal perspective. There were maximum permissible organ burdens or maximum permissible body burden levels that can be related to annual dose or a dose to the organ. But in my experience, most sites did not calculate an annual dose to an internal organ and record it in their records. It's unlikely that you'll find --

MR. MILLER: Well, we wind up with it with those where you have relatively short biological half-lives. Say you have a biological half life of -- I'm quite familiar with some cases where there'd, say, be 30 days or so, and so you actually could and would have what is effectively an annual dose. I'm just trying to figure out, what do you if there's a conflict between what DOE comes up with as a data set, and what you're saying is there's no possibility of comparison between the two?

DR. NETON: Right. Even if there were a situation where DOE would have a higher annual

1 dose than we were putting into our IREP input, 2 it's not intuitively obvious to me that the 3 person would be better served using the distribution that we applied to the dose that had 4 a lower central tendency estimate than the point 5 estimate that the Department of Energy provided. 6 7 You understand what I'm saying? 8 MR. MILLER: Oh, I certainly understand it. 9 I'm just asking about what happens if you --10 DR. NETON: Again, the short answer is we 11 would use our approach and not the Department of Energy's. 12 13 MR. MILLER: That's the answer. Okay, thank 14 you. 15 I probably should have said DR. NETON: 16 that. 17 DR. ZIEMER: Thank you. 18 Are there any other members of the public that wish to comment? 19 20 (No response) 21 DR. ZIEMER: Jim, on the board. 2.2 DR. MELIUS: I have a procedural issue. 23 have done my wording, and I can give it to Cori 2.4 I don't know if you want to try to break now.

for lunch now and come back, or do we want to --

1 DR. ZIEMER: I think we -- I wasn't sure 2 what we would have in the way of public comment, 3 so we had allowed on the calendar or on the 4 agenda 30 minutes. Obviously we have time, and we can proceed. I'm quite willing that we 5 proceed. I think others are interested in 6 7 pushing ahead. 8 While that wording -- is this wording for a 9 modification here? 10 DR. MELIUS: Yeah, and actually fits -DR. ZIEMER: Before she inserts that, would 11 12 you move to amend, then? 13 DR. MELIUS: Yeah, I would move to amend. 14 DR. ZIEMER: And can you read your amendment 15 Before we insert it, I want to get it on to us? 16 the floor and --DR. MELIUS: Okay. This would be inserted 17 18 right up here -19 MS. MURRAY: You need to be at a microphone, 20 I'm sorry. 21 DR. MELIUS: Oh, okay. And this will need 2.2 some further wordsmithing. 2.3 (Reading) Indeed, in cases where acceptably 2.4 dependable personal exposure data do not exist,

NIOSH will utilize other sources of information

as the basis for dose reconstruction. This approach unavoidably injects additional uncertainty into the calculation of dose. However, we view the proposed methods as being appropriate for the available information.

Another paragraph:

(Reading) There will be many circumstances where NIOSH will not be able to estimate the dose with sufficient accuracy. These circumstances need to be clarified in the implementation of the regulation and in the Board's review of NIOSH's dose reconstruction work. Groups whose exposure cannot be estimated with sufficient accuracy will be candidates for Special Exposure Cohorts.

DR. ZIEMER: Is there a second to the
motion?

DR. DEHART: Second.

DR. ZIEMER: Okay, it's seconded.

Now before we act on the motion, I'd like to ask that it be inserted with the redline insert so we keep the old words there for the group to see. And then we'll have an opportunity to discuss it without losing the current words.

Because if the amendment were to be defeated, we don't want to have lost what we had. So we're

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going to do a redline insert.

While that's being typed in, let's look ahead here at the agenda. The afternoon agenda calls for a Board working session and discussion of our comments, which is what we're doing now. The only other thing on the afternoon agenda is the public comment period.

If in fact we're able to come to closure here -- in fact, let me ask the Board, do you wish to continue working even if we go past 12:00 in order to come to closure on these items?

DR. ROESSLER: Yes.

DR. DEHART: Yes.

DR. ANDERSON: Yes.

DR. ROESSLER: It's Valentine's Day.

DR. ZIEMER: It's Valentine's Day, okay. Then we will push ahead.

Let me ask if there are any members of the public who had planned to make additional comments this afternoon. We don't want to preclude anyone if you were saving up something for this afternoon.

(No response)

DR. ZIEMER: It appears not. So we will then, without objection, push ahead and try to

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finish, at which time we will have completed our duties for this meeting, and we'll go to our various Valentine's parties, which for some of us will be in the airport, I'm sure.

MS. GADOLA: While you're working on that, I had a question for Wanda. On the first sentence when she -- at the end you have to the extent practicable. And I'm not sure -- well, I think I do know what you meant by practicable, but I was sort of wondering if other people might misrepresent that.

DR. ZIEMER: Are you talking about the current wording, or what Wanda was proposing?

MS. GADOLA: The one that Wanda was proposing. The first sentence in number one where it says that it makes appropriate use of current science in reconstruction of radiation dose scenarios to the extent practicable. My concern was that some of the public might take that as meaning, well, we only did as much as we were easily able to do.

And I don't think that was your intent, Wanda.

MS. MUNN: I thought the second sentence clarified that, Sally.

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DR. ZIEMER: Sally, were you suggesting that that phrase "to the extent practicable" simply be deleted, or --

MS. GADOLA: I was thinking maybe instead of practicable, you would say possible or allowable. To us it might mean exactly the same thing, but I was just wondering for those in the public that might be viewing this a little bit differently, and they might be criticizing that while saying, well, you could have done a better job if you had looked a little harder.

DR. ZIEMER: Yeah, and I suppose one of the issues on the use of the word "practicable" is often -- carries with it the balance between what is possible -- I mean, given enough time and money a lot of things are possible. But if you have to spend \$5 million to reconstruct a dose, that is not -- it may be possible but not practical.

MS. MUNN: Which is why I worded this -

DR. ZIEMER: So it is the issue of what those words mean. I think the word "possible" is not the right one. What was the other one you used, Sally?

MS. GADOLA: Allowable.

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DR. ZIEMER: Allowable. Why don't we ponder that for a bit, and we can come back to that.

Are you also doing the strike-out on this -- of the words that won't apply if the new thing's adopted?

DR. MELIUS: Actually, everything below the red down to number two will be struck out, I think.

MS. HOMER: The red is the new stuff.

DR. ZIEMER: Yes. I'm asking what is going to be stricken.

DR. MELIUS: Everything after the red down
to number two.

DR. ZIEMER: Okay. So if you delete that, it'll still stay there with a line through it. Yeah, right.

DR. MELIUS: Yeah, it's just a little hard
to keep the original without --

DR. ZIEMER: Right. Let me ask the court recorder if -- you did get the original insert words, I believe, correct? Do we need to reread what this would say in the context, or are we okay with what you have? There are some words that are going to be struck, but -- we'll get the final thing there. If we need to reread it,

we'll do so.

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MS. NEWSOM: Yeah, I think reread it before you take a vote on it.

DR. ZIEMER: Thank you.

Now let me ask Jim, is this everything that you were including in your motion?

DR. MELIUS: Correct.

DR. ZIEMER: It would be to insert the red and strike out the items indicated.

DR. MELIUS: Right. I just want to clarify,
I have utilized some of the wording from what was
originally up there, so it's a little bit -- it
is confusing, but --

DR. ZIEMER: Okay, so let's ask Larry to read this as the second paragraph now. Read this for the official record, that paragraph.

MR. ELLIOTT: (Reading) The process for involving the claimant is fair and provides multiple opportunities for interaction with the involved agencies. Indeed, in the cases where acceptably dependable personal exposure data do not exist, NIOSH will utilize other sources of information as the basis for dose reconstruction. This approach unavoidably injects additional uncertainty into the calculation of dose.

However, we view the proper methods as being appropriate for the available information.

There will be many circumstances where NIOSH will not be able to estimate the dose with sufficient accuracy. Those circumstances need to be clarified in the implementation of the regulation and in the Board's review of NIOSH's dose reconstruction work. Groups whose exposure cannot be estimated with sufficient accuracy will be candidates for Special Exposure Cohorts.

DR. ZIEMER: Might I ask, Jim, where it says we may view the proper methods, was it your intent to say proper or proposed methods?

DR. MELIUS: Proposed.

DR. ZIEMER: It's -- the word was "proposed," right. So that is not a change, it's simply an editorial -- I think that proposes what you had originally said.

DR. MELIUS: Yes.

DR. ZIEMER: The proper methods are always appropriate, but proposed methods may not be.

DR. MELIUS: And can I just -- one other clarification, that last red sentence, "with sufficient accuracy may be candidates," not "will be candidates."

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DR. ZIEMER: Well, "may be" will capture it, I think, right? We don't know if they should or not, but they may be. So consider that an editorial change.

This now is the motion before us. Wanda, comment.

MS. MUNN: As the maker of the original motion, I am pleased to accept this revision as appropriate.

DR. ZIEMER: Thank you.

We are handling it as an amendment, rather than a friendly amendment since it's rather extensive.

Other comments? Larry.

MR. ELLIOTT: As Ted rightfully whispers into my ear, there's only one Special Exposure Cohort, so that should be singular, not plural.

DR. ZIEMER: May be candidates for the Special Exposure Cohort. Consider that an editorial change, as opposed to an amendment.

Other comments? Henry.

DR. ANDERSON: Do you want to just address paragraph two? I have a suggested change for the third sentence in paragraph one, I think.

DR. ZIEMER: Right now the motion before us

| 1  | is this item in red, plus the strikeout. We'll |
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| 2  | deal with that.                                |
| 3  | Any other comments on this change or           |
| 4  | modification of paragraph two?                 |
| 5  | (No response)                                  |
| 6  | DR. ZIEMER: If not, let's vote on the          |
| 7  | amendment to modify paragraph two as shown.    |
| 8  | All in favor, say aye.                         |
| 9  | (Affirmative responses)                        |
| 10 | DR. ZIEMER: Any opposed?                       |
| 11 | (No response)                                  |
| 12 | DR. ZIEMER: The motion carries.                |
| 13 | Now we're back to the original motion, as      |
| 14 | amended, which is the items one and two and    |
| 15 | three.   |
| 16 | Henry, you have something on paragraph one.    |
| 17 | DR. ANDERSON: (Inaudible)                      |
| 18 | DR. ZIEMER: This would be Henry, would         |
| 19 | you read for us                                |
| 20 | DR. ANDERSON: I'll read it. What I have -      |
| 21 | MS. MURRAY: At a microphone.                   |
| 22 | UNIDENTIFIED: Use the mike.                    |
| 23 | DR. ZIEMER: You can use the podium mike.       |
| 24 | DR. ANDERSON: What I propose                   |
| 25 | DR. ZIEMER: This will be inserted as the       |

second to last sentence in the first paragraph.

DR. ANDERSON: Yes. It would say the methods proposed are intended to result in dose estimates favorable to the claimant, and are appropriate to the occupational illness compensation program envisioned by the EEOICPA --which is the legislation.

DR. ZIEMER: Okay, that's a motion to amend. Is there a second to that?

MR. ESPINOSA: Second.

DR. ZIEMER: Seconded. So we'll do a
redline strikeout of those words here.

(Comments off the record)

DR. ZIEMER: A comment from Ted Katz.

MR. KATZ: This is again largely editorial, but down below in the second paragraph we have right now -- and this is courtesy, in part, from Josh, Department of Energy -- but we say there will be many circumstances where NIOSH will not be able to estimate the dose with sufficient accuracy. Those circumstances -- you can break that into two sentences, for one; and I would just add, you may want to consider also, instead of prejudging whether there's many or some, you might just want to say there will be

1 circumstances, rather than quantifying them. 2 DR. ZIEMER: Thank you, Ted. Actually, as I look at this, that is a run-on sentence, 3 editorially. I don't see any dangling 4 5 participles, but it is a run-on sentence. without objection, we should insert a period 6 7 after "accuracy" and then start a new sentence, 8 "Those circumstances." 9 The point on whether there will be many, I 10 suppose is problematical. Is there any objection to leaving out the word "many?" Any objection? 11 12 (No response) 13 DR. ZIEMER: Without objection, that 14 editorial, there will be circumstances where 15 NIOSH will not be able to estimate the dose with 16 sufficient accuracy. 17 Gen. 18 DR. ROESSLER: Should the word be "may" instead of "will?" We don't know for sure there 19 20 will. 21 DR. ZIEMER: Well, and certainly "may" is 2.2 inclusive of both the zero and every other --23 without objection, that's an editorial change. 2.4 DR. MELIUS: I object.

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DR. ZIEMER: There will be?

1 DR. MELIUS: I think there will be. It's 2 hard for me to imagine where there will not be, 3 given all our discussions here. DR. ZIEMER: So you'd rather leave it in as 4 5 The legislation provides for 6 DR. MELIUS: 7 There already is a Special Exposure Cohort 8 where that's, I think -9 DR. ZIEMER: Thank you. 10 DR. MELIUS: -- what Congress presumed. 11 DR. ZIEMER: Okay, so there is objection to 12 that. So the only way we'll change that is by 13 motion. Are you making a motion? 14 DR. ROESSLER: (Shakes head) 15 DR. ZIEMER: No. Okay. Where there's a 16 will, there's a way. There will be 17 circumstances. Okay. 18 Now is there any strikeout -- this was --19 DR. ANDERSON: Yes, the last sentence. 20 DR. ZIEMER: Last sentence gets stricken. 21 So that the proposed amendment is to insert what 2.2 I said was the second to last sentence, now will 2.3 become the new last sentence, since we will 2.4 strike out the previous last sentence. And the 25 new paragraph one reads as follows.

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MR. ELLIOTT: I'm getting better at this,
aren't I?

(Reading) Number one, interim proposed rule
42 CFR Part 82 makes appropriate use of current
science in reconstruction of radiation dose
scenarios to the extent practicable. The Board
recognizes that if the efficient and expeditious
considerations of claims is to be made, absolute
precision is not possible. The methods proposed
are intended to result in dose estimates
favorable to the claimants and are appropriate to
the occupational illness compensation program
envisioned by EEOICPA.

DR. ZIEMER: That motion is before us.

Any comments? Wanda.

MS. MUNN: My only comment is with respect to the original use of the word "conservative." I think one of the things that is sometimes confusing to readers other than technical readers is what does conservative mean. And in these cases, I believe both the intent and the application of these methods was to be conservative, to give the claimant the benefit of the doubt.

So I'm wondering if it's possible to insert

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that so that the sentence would read the methods proposed are intended to result in dose estimates favorable to the claimants, comma, are conservative, comma, and are appropriate to the -- does that confuse the issue?

DR. ANDERSON: Yeah, your point is exactly why I did it. Conservative could be cautious, or it could be as you said. That's why I put it in, favorable to the claimant. It's maybe not concise language, but the idea was conservative, as you said, can be interpreted to be -- can either be high or low.

DR. ZIEMER: Normally probably would be interpreted as being the lower one. But maybe a way to get around this and meet Wanda's comment would be to say that the -- get the sentence here -- dose estimates -- result in conservative dose estimates, parenthesis, favorable to the claimants, parenthesis.

DR. ANDERSON: Sure.

MS. MUNN: Yes.

DR. ZIEMER: That's one way. I'm not proposing that; don't insert it. It's just one way to do it. Roy.

NANCY LEE & ASSOCIATES

DR. DEHART: (Inaudible)

| 1  | DR. ZIEMER: Use the mike there, Roy.              |
|----|---|
| 2  | DR. DEHART: To get rid of the parenthetical       |
| 3  | phrase, why not say results in dose estimates     |
| 4  | that are consistently conservative and favorable  |
| 5  | to the claimant?                                  |
| 6  | DR. ZIEMER: Henry, does that is that a            |
| 7  | friendly amendment?                               |
| 8  | DR. ANDERSON: I do have somewhat of a             |
| 9  | problem. Consistently conservative, again,        |
| 10 | suggests to me low. And it's favorable then to    |
| 11 | their health, but not necessarily to their        |
| 12 | DR. ZIEMER: So you're speaking you'd              |
| 13 | rather not have the word "conservative" in there. |
| 14 | DR. ANDERSON: I just think the                    |
| 15 | "conservative" I understand what you're           |
| 16 | getting at, but I just think that's problematic.  |
| 17 | DR. ZIEMER: Wanda.                                |
| 18 | MS. MUNN: And that's exactly why I used it        |
| 19 | the way I did in the original sentence, that it's |
| 20 | intended to favor the claimant, and in that       |
| 21 | regard is consistently conservative. I wanted to  |
| 22 | tie the word "conservative" to the "favorable to  |
| 23 | the claimant."                                    |
| 24 | DR. ZIEMER: Other comments? Gen.                  |
| 25 | DR. ROESSLER: I tend to go along with             |

Henry. I think introducing the word "conservative" at all, even trying to kind of explain it, is confusing. I think we've really captured it here by just saying estimates favorable to the claimants, as long as that's grammatically correct.

DR. ZIEMER: Other comments? Do you --

DR. ANDERSON: Just a question, and I don't remember, is "conservative" used anywhere in the proposed rule?

MR. ELLIOTT: I do not believe we've used the term "conservative" in the proposed rule. But you did see it used in the draft implementation guidelines, which I have a big issue with, and you won't see it in the next version that you have presented.

DR. ZIEMER: That may answer the question.

DR. ANDERSON: That answers the question.

DR. ZIEMER: Are you ready to vote?

Okay, all who favor amending the document in paragraph one as shown, by the addition of the redlined paragraph and the deletion of the -- or sentence, rather, and deletion of the indicated sentence, say aye.

(Affirmative responses)

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DR. ZIEMER: Opposed?

(No response)

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DR. ZIEMER: Okay.

Now we're back to the document as amended. We've looked at paragraph one, paragraph two. Let's see, and then we have a paragraph which has a number two, which is paragraph three. That's all right, leave it as it is for the moment.

The interim rule outlining methods and so on, anything on this paragraph? Gen.

DR. ROESSLER: That was my wording before Wanda tried to capture everything in the first part. And right at the moment, unless somebody thinks it adds something, I think it's redundant. And so I think it should be deleted.

DR. ZIEMER: The motion then would be to delete this third paragraph, which carries the number two. Is there a second?

MS. MUNN: Second.

DR. ZIEMER: Do we need to -- well, let's just line that out, just so we have it there before us, so we'll do a strikeout on that for the moment. This is a proposed motion by Gen Roessler to strike that paragraph, second by Wanda.

| 1  | Discussion?                                      |
|----|--|
| 2  | (No response)                                    |
| 3  | DR. ZIEMER: Those who favor deleting this        |
| 4  | paragraph, say aye.                              |
| 5  | (Affirmative responses)                          |
| 6  | DR. ZIEMER: Opposed?                             |
| 7  | (No response)                                    |
| 8  | DR. ZIEMER: Okay, it's deleted.                  |
| 9  | Third fourth paragraph, carrying number          |
| 10 | three.   |
| 11 | DR. MELIUS: Can you go back? I can't             |
| 12 | remember what's the first sentence of the second |
| 13 | paragraph. I think again number three is         |
| 14 | redundant, I think, with the first sentence of   |
| 15 | the second paragraph.                            |
| 16 | DR. ZIEMER: Therefore you are proposing          |
| 17 | DR. MELIUS: I move that we drop that number      |
| 18 | three.   |
| 19 | DR. ZIEMER: Motion to drop that paragraph.       |
| 20 | DR. DEHART: Second.                              |
| 21 | DR. ZIEMER: Seconded. We'll do a strikeout       |
| 22 | here, and ask for comments on that proposed      |
| 23 | amendment.                                       |
| 24 | (No response)                                    |
| 25 | DR. ZIEMER: Ready to vote?                       |

1 Those who favor dropping this paragraph, 2 which is also a sentence, say aye. 3 (Affirmative responses) DR. ZIEMER: 4 Opposed? 5 (No response) 6 DR. ZIEMER: And that drops off the map. 7 Now let's back the screen down so we can see 8 what's left on that document. No, no, the other 9 way, please. I just want to get those first two 10 paragraphs before us -- there. 11 So what you have on the screen now, which is 12 the two paragraphs, right now constitutes the 13 Board's response to the three questions. Now I 14 ask if we have answered the three questions to 1.5 your satisfaction? That's a question to the Board, not to the staff, to the Board. 16 17 (No response) 18 DR. ZIEMER: Is there anything you wish to 19 add or delete? 20 (No response) 21 2.2 23

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DR. ZIEMER: I'm going to give you about five minutes to think about that, because we're going to have a comfort break here since we're not having lunch. Okay, let's take a stretch before we do a final vote. Five official

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minutes; let's see if we get everybody back here by then.

(Whereupon, a recess was taken from 12:04 to 12:15 p.m.)

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- DR. ZIEMER: I believe we're ready to vote now on these two paragraphs as amended. It was originally four paragraphs, now down to two, as amended. Let me ask once again, are there any other comments or -- yes, questions. Gen Roessler.
- DR. ROESSLER: Are we wordsmithing before or after the vote, because in the first sentence we discussed a possible change of the words.
- DR. ZIEMER: Well, I think if there are word changes, let's get them right now before us. If they're editorial, minor, let's just go ahead and do it.
- DR. ROESSLER: Well, I think it's more than editorial. I think we discussed in the first sentence the words "to the extent practicable," and I don't have a suggestion for different words, but I don't like the word "practicable." And I thought we were going to come back to this part and discuss it again.

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DR. ZIEMER: I think it's appropriate now.

If we want to change that, let's do it now. I

don't know what the change would be if it's not

"practicable." Is it "reasonable," "reasonably
achievable"?

DR. MELIUS: I would just suggest dropping "to the extent practicable." I think appropriate captures that idea, because part of whether something's appropriate or not is whether it's practical and efficient and so forth. So I just don't think we need --

DR. ZIEMER: So that would be one way of handling this, would simply be to drop the phrase "to the extent practicable." That's not a formal motion yet, or was it a formal motion? Well, let's hear some comments.

Wanda, because this is your sentence.

MS. MUNN: I guess I still -- I understand the issues that folks have with "practicable." But by the same token I think it's a necessary prerequisite for the second sentence, because what we're trying to make very clear is that good, fast, and cheap, you can have any two out of three. That's really what we're saying here. And if you don't say "practicable" before you

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talk about efficient and expeditious, then you're not getting the sense of what I thought we were trying to capture.

DR. ZIEMER: Okay, thank you.

Other comments? So Wanda is urging us to keep it, and Jim, I don't know if you were urging -- you were suggesting as an alternative to drop it. Do you object to not dropping it?

DR. MELIUS: No, it doesn't bother me.

DR. ZIEMER: Gen? Gen's okay with it.
Okay.

MS. GADOLA: Since I first --

DR. ZIEMER: The motion still before us is the original as -- okay, wait a minute. Sally, yes.

MS. GADOLA: Since I first brought that up, I felt uncomfortable because I was afraid that the public would misinterpret that. And even -- I still have a little bit of doubt there, I do think that the rest of the information that we've now added clarifies that word, so I feel more at ease with it than I did before.

DR. ZIEMER: Okay, thank you.

Okay, I take it that we're ready to vote, then, this point, it appears. So we will be

voting now on adopting these two paragraphs, as you see there -- that is, with the new words in red and the deleted words stricken.

All in favor, say aye.

(Affirmative responses)

DR. ZIEMER: And those opposed, say no.

(No response)

DR. ZIEMER: And the motion carries.

We now have adopted all of the items I think that we had before us. Is there anything that's been omitted?

(No response)

DR. ZIEMER: Then I would ask, if the Board is agreeable, I will take these -- again, they will be formatted into letter form. I may rearrange the order, and may have some sentences that say in response to the three questions the Board has the following comments, something of that sort, without changing the items that have been officially approved.

Is it agreeable that the Chair would have the prerogative of formatting this into letter form, somewhat like we did before? But it would probably all be in one letter, or else a letter with an appendix or an attachment, and a meeting

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agenda, again as we did before.

(No response)

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DR. ZIEMER: Without objection, we'll
proceed on that basis. We'll make copies
available to everyone. Oh, wait --

DR. ANDERSON: I was just thinking, I think leaving this as an attachment that goes part of the record is important. I wonder if in the covering letter we might want to mention something about that this kind of a work in -- the dose reconstruction as opposed to the other is more of a work in progress, and that we look forward to working closely with NIOSH as this is implemented and our revisions are considered, or things like that.

DR. ZIEMER: I'd be glad --

DR. ANDERSON: So it really is -- the proof
is going to be in the pudding, once it's --

DR. ZIEMER: Okay, I'd be glad to do that.

And Henry, before you leave, just write that down on a piece of paper, save me from writing it down. No, I certainly -- I don't mean to be facetious. I just want to be sure to capture your words on that, and any others that have some thoughts that you want to include.

1 Also, I'm wondering if it's possible -- and 2 I'll just ask Cori, and I think at this point you can go ahead and tell the machine to get rid of 3 4 that strikeout stuff. Is it possible to get a 5 printout of these for anyone that wants to take 6 with, or not? Maybe not. Maybe the thing to do, 7 you can e-mail these to us, can you not? MR. ELLIOTT: We'll e-mail the text that 8 9 you've approved. DR. ZIEMER: Right, not --10 11 MR. ELLIOTT: So all the Board has --12 DR. ZIEMER: I just want to make sure 13 everybody has that. You'll be able to get that 14 in the next day or two, probably. 1.5 MR. ELLIOTT: Yeah. DR. ZIEMER: Okay, that'll be good. 16 17 everybody okay on that? 18 DR. MELIUS: Yeah, I would just -- could you 19 also share this, what we've written and the 20 process and so forth, with Tony, who couldn't be 21 here? 2.2 MR. ELLIOTT: Yes. 23 DR. MELIUS: Just so he's --24 MR. ELLIOTT: Absolutely. Everything that 2.5 we've assembled as a product from the last two

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days of meeting will be shared with Tony.

DR. MELIUS: Sort of get it to him, and I don't -- if there was additional comments or questions he has, I think we should just try to -- you know.

DR. ZIEMER: Now everybody's okay on that
process, then?

(No responses)

DR. ZIEMER: One final thing I'd like to request if the staff is able to do this, and maybe to have general counsel or somebody that's available to you, I would like to see if we can find out precisely what the FACA rules are for advisory committees, as opposed to Federal agencies, on this issue of predecisional drafts, the extent to which we can work individually and exchange information.

Not that we're going to, because our work is done; but if we have situations like we had last time, I'd like to find out exactly -- because I've heard several versions from different members of the public on exactly what the requirements are, and the comments I've gotten are completely 180 degrees apart. I don't know what the legal requirement is on that.

1 Obviously we're going to try to make 2 everything as public as possible. But there's a sense in which you come to a screeching halt if 3 4 you can't work sort of off-line at times. MR. ELLIOTT: We certainly will get a 5 6 counsel's quidance and committee management's 7 quidance on that, and we'll send it to you. DR. ZIEMER: And we want to do whatever's 8 9 both fair to the Board and to the public. MR. ELLIOTT: Understood. 10 11 DR. ZIEMER: Just to find out what is the 12 requirement. 13 Are there any other items that need to come 14 before us? 1.5 DR. DEHART: I don't know whether you care to mention it or not, but this was with unanimous 16 17 consent. 18 DR. ZIEMER: The record will show that these 19 things were adopted with unanimous consent, 20 recognizing that one of our members is absent. 21 Tony is not here today. 22 MR. ELLIOTT: And just for everyone's reminder, the public comment period remains open 23 24 for dose reconstruction rule 82 CFR -- 42 CFR 82

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until March 1st. Once your letter has been sent

1 forward to the Secretary, it also will be added 2 that day to the docket on this rule. Public comment can be received until March 1st. 3 4 DR. ZIEMER: Thank you. 5 Any other items that need to come before us? 6 Any other comments for the good of the order? 7 (No response) 8 DR. ZIEMER: Any other public comments? 9 (No response) 10 DR. ZIEMER: If not, we stand adjourned. MR. ESPINOSA: Paul, just --11 12 DR. ZIEMER: Hold on, hold on just a moment, 13 because --14 MR. ESPINOSA: Because of the public 1.5 interest in this and people coming from out of town and out of state, is there any way that the 16 17 Board can reserve more rooms? MS. HOMER: Well, the difficulty with 18 19 putting more rooms on a block is that we just 20 don't know for sure who's going to be on there. 21 MR. ESPINOSA: Is there any way or any 2.2 manner that --23 DR. ZIEMER: Use your mike, please. 24 MR. ESPINOSA: Is there any way or any 2.5 manner that people that are interested in this

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can get in contact with NIOSH, CDC?

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MS. HOMER: They can contact me. difficulty is in setting up the contract. I'd have to let them know at the time I'm arranging the contract how many people will be attending. All I can do is quarantee an estimated amount based on the Board's attendance and staff attendance. So if I know ahead of time, I can tell them.

MR. ELLIOTT: We certainly would appreciate hearing from folks who want to attend the meeting, but we cannot provide them space. We can help them -- we can identify other hotels that they might be able to get space in. But it helps us to have advance notice of who wishes to attend the meeting, and we'll try to assist them in what ways we can.

DR. ZIEMER: Thanks.

DR. ANDERSON: Just one last --

DR. ZIEMER: Henry.

DR. ANDERSON: What is our process -- I think we had some ideas about the next meeting and what we'd like to see. And how are we going to -- what's our process to get things on the agenda for the next meeting and subsequent

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meeting?

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DR. ZIEMER: Right. We agreed that if you had suggested individuals or groups that you wanted to hear from, we would let Larry know what those are, either by individual or by agency or topic. Larry and I would work up an agenda which we'll share with the group in a draft form to see if -- and this is for the April meeting, now, we're talking about and --

**UNIDENTIFIED:** May.

DR. ZIEMER: Yeah, the April meeting, which will be held in May. And I think that's what we've agreed on. Is that --

MR. ELLIOTT: Yeah.

DR. ZIEMER: Okay. Thank you, everyone. We'll see you next time. Be sure to give Larry your time sheets, as it were, and calendars to Cori.

(Whereupon, the meeting was adjourned at 12:29 p.m.)

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## <u>C E R T I F I C A T E</u>

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
120 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.

WITNESS MY HAND AND OFFICIAL SEAL this  $7^{\text{th}}$  day of March, 2002.

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

(SEAL)